

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jul 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 Koomesh 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

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Opposite Sokan Park

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**Person responsible for scientific inquiries**

**Contact**

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**Full name of responsible person**

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**Person responsible for updating data**

**Contact**

**Name of organization / entity**

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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