Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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
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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
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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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Person responsible for updating data

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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