

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the Effectiveness of Acceptance and Commitment Therapy (ACT) and Schema Therapy on Referral thinking, Psychological flexibility, Quality of life and Nausea and Vomiting due to Chemotherapy in Women with Breast Cancer

Protocol summary

Study aim

Comparison of the Effectiveness of Acceptance and Commitment Therapy (ACT) and Schema Therapy on Referral thinking, Psychological flexibility, Quality of life and Nausea and Vomiting due to Chemotherapy in Women with Breast Cancer

Design

1. Experimental group 1: pre-test then ACT intervention and then post-test 2. Experimental group 2: pre-test then schema therapy intervention, and then post-test

Settings and conduct

By referring to "Rasool Akram" Hospital in Tehran, 54 women will be selected through available sampling from among the women who are eligible to enter the study. They will be invited to participate in the study. Then, by simple random sampling method, volunteers will be divided into three groups, two intervention groups "one" and "two" and one control group, and the study will enter its therapeutic intervention phase.

Participants/Inclusion and exclusion criteria

Entrance criteria: 1. The person's satisfaction and willingness to participate in the study 2. Getting breast cancer 3. Performing the chemotherapy process 4. having minimum literacy up to 8th education grade 5. Not suffering from severe psychiatric disorders. Exit criteria 1. The time interval from the definitive diagnosis of the disease is less than two months 2. History of other malignancies 3. Having two consecutive absences from meetings 4. Unwillingness to cooperate 5. Use of complementary therapies

Intervention groups

1. Acceptance and Commitment Therapy (ACT) 2. Schema Therapy

Main outcome variables

Referral thinking, Psychological flexibility, Quality of life and Nausea and Vomiting due to Chemotherapy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190921044831N3**

Registration date: **2024-01-17, 1402/10/27**

Registration timing: **prospective**

Last update: **2024-01-17, 1402/10/27**

Update count: **0**

Registration date

2024-01-17, 1402/10/27

Registrant information

Name

Farima Minaee

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 51 3893 4320

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-01-21, 1402/11/01

Expected recruitment end date

2024-08-22, 1403/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effectiveness of Acceptance and Commitment Therapy (ACT) and Schema Therapy on Referral thinking, Psychological flexibility, Quality of life and Nausea and Vomiting due to Chemotherapy in Women with Breast Cancer

Public title

Comparison of the Effectiveness of Acceptance and Commitment Therapy (ACT) and Schema Therapy on Referral thinking, Psychological flexibility, Quality of life and Nausea and Vomiting due to Chemotherapy in Women with Breast Cancer

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

The person's satisfaction and willingness to participate in the study. Having breast cancer Carrying out the chemotherapy process Having at least 8th grade education Not suffering from severe mental disorders

Exclusion criteria:

The time interval from the definitive diagnosis of the disease is less than two months History of other malignancies Having two consecutive absences from meetings Unwillingness to cooperate Use of complementary therapies

Age

From **20 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Fifty-four women will be selected through available sampling among the women who are eligible to enter the study, and after a clear explanation of the objectives of the study and completion of an informed and voluntary written consent form, they will be invited to participate in the study. Then, by simple random sampling method, volunteers will be divided into three groups, two intervention groups "one and two" and one control group, and the study will enter its therapeutic intervention phase.

Blinding (investigator's opinion)

Single blinded

Blinding description

The participants do not know about the therapeutic intervention in other groups, and their choice to be in each of the three groups is completely random. The time of meetings is planned so that people in different groups do not meet each other.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Medical ethics committee of Islamic Azad University of Karaj

Street address

Karaj, the end of Rajaee Shahr, the intersection of Mozen and Esteghlal Blvd., Amirul Mominin University Complex (AS)

City

karaj

Province

Alborz

Postal code

3149968111

Approval date

2023-12-28, 1402/10/07

Ethics committee reference number

IR.IAU.K.REC.1402.130

Health conditions studied

1

Description of health condition studied

Breast Cancer

ICD-10 code

C43.5, C44

ICD-10 code description

Malignant neoplasm of breastIncl.:connective tissue of breastExcl.:skin of breast

Primary outcomes

1

Description

Referral thinking: Negative referential thinking is a type of thinking about negative experiences that has three characteristics: repetitiveness, spontaneity, and difficulty in interrupting thoughts.

Timepoint

10 sessions

Method of measurement

Ehring's Referential Thinking Questionnaire

2

Description

Psychological flexibility: The ability to abstract and

change cognitive strategies is based on changes in environmental feedback, which requires planning, organized search, and the ability to use environmental feedback to change cognitive patterns.

Timepoint

10 sessions

Method of measurement

Psychological Flexibility Scale: This questionnaire is a 24-question short self-report tool that measures the type of flexibility that is necessary in a person's success to challenge and replace inefficient thoughts with more efficient ones.

3**Description**

Quality of life is the perception of each person about his health condition and the level of satisfaction with these conditions. The World Health Organization defines quality of life as a person's understanding of his place in life in the context of the culture and values system in which he lives, which is related to his goals, expectations, standards and concerns.

Timepoint

10 sessions

Method of measurement

WHOQO-BREF questionnaire

4**Description**

Chemotherapy-induced nausea and vomiting

Timepoint

10 sessions

Method of measurement

Score from questionnaire and nausea and vomiting index form (INV-2) (Rhodes et al., 1986)

Secondary outcomes

empty

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

Intervention group: Acceptance and Commitment Therapy: ACT

Category

Treatment - Other

2**Description**

Intervention group: Schema therapy

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Tehran Rasool Akram hospital

Full name of responsible person

Shahrabano Sepehr Yeganeh

Street address

Tehran-Starkhan-Niyaish St.-Corner of Mansouri St.

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1445613131

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Email

Rasoolhospital@iums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Karaj University of Medical Sciences

Full name of responsible person

Afshin Zargar

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Karaj, the end of Rajae Shahr, the intersection of Mozen and Esteghlal Blvd., Amirul Mominin University Complex

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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Karaj University of Medical Sciences

Proportion provided by this source

1

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

Karaj University of Medical Sciences

Full name of responsible person

Shahrzad Sepehr Yeganeh

Position

PHD student

Latest degree

Master

Other areas of specialty/work

Psychology

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Latest degree

Master

Other areas of specialty/work

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Person responsible for updating data

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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

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Participant data contains their demographic information without mentioning personal information. The study protocol includes the method of sampling, assigning interventions to groups, and how to implement them. The analysis of details is based on the quantitative statistical analysis of people's scores according to the questionnaires used. The informed consent form is designed based on the rules of conducting clinical trial studies, and its report is published in the form of an original scientific article.

When the data will become available and for how long

Access starts one year after the article is published

To whom data/document is available

Researchers working in reputable scientific and research institutions

Under which criteria data/document could be used

In case of receiving reliable information about conducting a related study and under the condition of referencing and maintaining trustworthiness in the information, in order to help reach a consensus of different results related to the subject.

From where data/document is obtainable

Correspondent author of the manuscript

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

The person informs the author of the article about his

request via email, and after checking the information about the applicant and consulting with other authors, the information is provided with special conditions.

Comments