

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

The Effectiveness of Transdiagnostic Intervention and Mindfulness Based Schema Therapy on Cancer Psychological Distress and Outcomes, Illness's Transdiagnostic Cognitive Processes and Cortisol Level in Patients with Breast Cancer

Protocol summary

Study aim

Examine the Effectiveness of Transdiagnostic Intervention and Mindfulness Based Schema Therapy on Cancer Psychological Distress and Outcomes, Illness's Transdiagnostic Cognitive Processes and Cortisol Level in Patients with Breast Cancer

Design

This study with practical goal is Quasi-Experimental Design with pretest, post test and follow up period that will be performed on 2 intervention and control groups with random assignment. targeted sampling will be based on entrance criteria from Mashhad hospitals. study situations will be explained for participants and letter of satisfaction will be taken with consideration of human sciences ethical and with emphasis on confidential data. the necessary information for cooperation (including attending to sessions, doing tasks, blood sampling) will be explained with the right to cancel in any step of the study. Study includes 60 participants in waiting list control group (2 session will be presented for them) and 2 intervention groups that will receive transdiagnostic intervention or mindfulness based schema therapy.

Settings and conduct

interventions will be applied in Mashhad hospitals. interventions will apply in 10 sessions 90 minutes via internet digital space with therapeutic protocols of references.

Participants/Inclusion and exclusion criteria

not using psychiatric drugs, age between 30 to 60, education at least elementary school, going under cancer therapy (except chemotherapy)

Intervention groups

Study includes a waiting list control group (2 session will be presented for them) and 2 intervention groups and will receive transdiagnostic intervention or mindfulness based schema therapy

Main outcome variables

Cancer Psychological Distress and Outcomes, Illness's Transdiagnostic Cognitive Processes and Cortisol Level

General information

Reason for update

because of problems and limitations in sampling process such as not participating in breast cancer patients and COVID-19 crisis and it's picks duration limitations in Mashhad city, the entering criteria changed to accepting not married and under diploma graduated patients and group therapy interventions was also performed through internet and digital space.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210128050165N1**
Registration date: **2021-06-26, 1400/04/05**
Registration timing: **prospective**

Last update: **2022-01-31, 1400/11/11**

Update count: **1**

Registration date

2021-06-26, 1400/04/05

Registrant information

Name

Fatemeh Ghayour Kazemi

Name of organization / entity

Azad University of Birjand and Mashhad Medicine University

Country

Iran (Islamic Republic of)

Phone

+98 51 3606 1093

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Recruitment status**Recruitment complete****Funding source****Expected recruitment start date**

2021-06-26, 1400/04/05

Expected recruitment end date

2021-08-22, 1400/05/31

Actual recruitment start date

2021-07-21, 1400/04/30

Actual recruitment end date

2021-09-23, 1400/07/01

Trial completion date

2022-01-20, 1400/10/30

Scientific title

The Effectiveness of Transdiagnostic Intervention and Mindfulness Based Schema Therapy on Cancer Psychological Distress and Outcomes, Illness's Transdiagnostic Cognitive Processes and Cortisol Level in Patients with Breast Cancer

Public title

The Effectiveness of Transdiagnostic Intervention and Mindfulness Based Schema Therapy on Patients with Breast Cancer

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

not using psychiatric drugs age between 30 to 60 education at least end of elementary school going under cancer therapy (except chemotherapy)

Exclusion criteria:

using psychiatric drugs or psychotherapies in the last 6 months absence in group therapy more than 2 sessions graduate from psychology major or related to that experienced trauma pressures or crisis in the grouptherapy for instance mourn

AgeFrom **30 years** old to **60 years** old**Gender**

Female

Phase

3

Groups that have been masked

- Participant
- Data analyser

Sample sizeTarget sample size: **60**Actual sample size reached: **41****Randomization (investigator's opinion)**

Randomized

Randomization description

In the first stage based on entrance criteria, the intended sample will be identified from Mashhad hospitals and in the second stage, 60 patients from them will be choose randomly from the number codes assigned to them. number codes will be assigned to each person and randomly will be taken out from drawing without replacement and the sequence will be noted for each

participant. In the second stage, number codes will be assigned to one of the three groups and randomly will be taken out from drawing without replacement and control or intervention groups will be drawn. In the third stage, each person will be assigned to each group randomly and this process will continue to the last person. It's necessary to be noted that dividing to the 3 groups will be done separately for each person and at last it will also be determined randomly that each one of the groups will receive which intervention or will be control group. One of the groups of intervention or control with using random numbers table sampling and assigning number code to each person (2 intervention groups and 1 control group). simple randomization way will be done (divide to 3 groups in sequence and concealment and assigning interventions with random concealment allocation).

Blinding (investigator's opinion)

Single blinded

Blinding description

participants in groups won't be informed about the other groups and the type and difference of other interventions with their own and they won't have communication with each other out of sessions. Execution of the questionnaires will be performed in pretest, post test and follow up by research's assistants who won't be informed about the type of groups and difference between interventions participants will receive or have received. data analysis will be done by someone else who won't know about the types of groups.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Sciences

Street address

Daneshgah Ave

City

Mashhad

Province

Razavi Khorasan

Postal code

13944-91388

Approval date

2021-04-24, 1400/02/04

Ethics committee reference number

IR.MUMS.REC.1400.026

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

Cancer Psychological Outcomes

Timepoint

pretest, post test, follow up

Method of measurement

Impact Of Breast Cancer questionnaire, Cancer Survivors Resilience Scale, Breast Cancer Self-Efficacy Scale

2

Description

Psychological Distress

Timepoint

pretest, post test, follow up

Method of measurement

Psychological Impact of Cancer, Spiritual Distress Scale, Depression, Anxiety and Stress Scale-21

3

Description

Illness's Transdiagnostic Cognitive Processes

Timepoint

pretest, post test, follow up

Method of measurement

Acceptance and Action Questionnaire, Posttraumatic Avoidance Scale, Chronic illness-related cognitive fusion questionnaire, Rumination in response to illness scale

4

Description

cortisol

Timepoint

pretest, post test

Method of measurement

blood sampling

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 2 groups, one will receive Transdiagnostic therapy and the other will receive Mindfulness based Schema therapy via internet. the period of each group therapy will be 10 session in group therapy format and 90 minutes. standard therapy sessions' protocols for mindfulness based schema therapy are from book with the same name (Vreeswijk, Broersen, J. Schurink, 2014) and Unified transdiagnostic therapy for emotional disorders (Barlow and others, 2016) and related scientific articles. the goal of Transdiagnostic therapy is for emotion processing and emotional experiences regulation and mindfulness based schema therapy is to becoming aware of schemas and mentalities, other attention domains such as monitoring emotions, body sensations and schema related coping mechanisms.

Category

Treatment - Other

2

Description

Control group: 1 group that is list waiting and later will receive 2 education sessions about life style behaviors.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

all Mashhad hospitals (specially Omid hospital)

Full name of responsible person

Soudabe Shahid Sales

Street address

Alandasht intersection, Koohsangi Ave, Omid hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

Full name of responsible person

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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
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

2

Sponsor
Name of organization / entity
Islamic Azad University of Birjand
Full name of responsible person
Majid Ali Abadi
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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
Islamic Azad University of Birjand
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact
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Azad University of Birjand, Mashhad Medicine University
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Person responsible for updating data

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Latest degree

Ph.D.

Other areas of specialty/work

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Fax**Email**

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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

Undecided - It is not yet known if there will be 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

Demographic information and variables' measuring data will be shared in thesis and science journals' articles.

When the data will become available and for how long

start from six months after collecting data

To whom data/document is available

researchers from universities and science journals

Under which criteria data/document could be used

using data is acceptable in other science interventions for references

From where data/document is obtainable

science journals articles, Azad University of Birjand

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

sending emails to authors of article and thesis or sending request to Azad University of Birjand

Comments