Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of Unified Protocol transdiagnostic treatment on psychological distress, emotion regulation, intolerance of uncertainty, and posttraumatic growth in women with breast cancer.

Protocol summary

Study aim
The Effectiveness of the Unified Protocol for Transdiagnostic Treatment on Psychological Distress, Emotion Regulation, Intolerance of Uncertainty, and Posttraumatic Growth in Women with Breast Cancer.

Design
Randomized clinical trial with a control group, parallel design, single-blind (data analyst), conducted on 50 patients (25 per group). Matched randomization was performed using the website www.randomizer.org.

Settings and conduct
This clinical trial involves 50 women with breast cancer in Kashan hospitals. Participants are assigned to intervention (8 sessions of UP) or control groups via matched randomization and assessed in three stages. The data analyst is blinded to group allocation.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Female gender; age 18-55 years; definitive diagnosis of breast cancer with history of at least one treatment course (chemotherapy, radiotherapy, or mastectomy); moderate score on psychological distress scale (DASS-21); literacy.
Exclusion Criteria: Absence from more than two sessions; acute psychiatric symptoms (such as suicidal ideation or psychosis); concurrent receipt of other psychological interventions; changes in psychiatric medication dosage.

Intervention groups
Intervention Group: Group treatment based on the Unified Protocol (UP) over 8 ninety-minute sessions.
Control Group: Receiving medical Treatment As Usual (TAU) without psychological intervention.

Main outcome variables
Reduction of psychological distress; Increase in post-traumatic growth.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20251118068037N1**
Registration date: **2026-01-03, 1404/10/13**
Registration timing: **prospective**

Last update: **2026-01-03, 1404/10/13**
Update count: **0**
Registration date
2026-01-03, 1404/10/13

Registrant information

Name
Mohamad javad Ghafoori
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2026-02-14, 1404/11/25
Expected recruitment end date
2026-04-05, 1405/01/16
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Unified Protocol transdiagnostic treatment on psychological distress, emotion regulation, intolerance of uncertainty, and posttraumatic growth in women with breast cancer.

Public title
"Examining the Effectiveness of a Group-Based Psychological Intervention in Reducing Psychological Distress and Stress, Improving Emotion Regulation, and Enhancing Coping with Illness-Related Uncertainty in Women with Breast Cancer"

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Female gender Age range of 18–55 years A definitive diagnosis of breast cancer confirmed by an oncologist Obtaining a moderate score on the Depression Anxiety Stress Scales (DASS-21) according to the questionnaire guidelines (scores of 14–20 for Depression, 10–14 for Anxiety, and 19–25 for Stress) Literacy (reading and writing skills) and the ability to comprehend the concepts presented in the therapy sessions Willingness to participate voluntarily in the study and signing the informed consent form Ability to attend regular group therapy sessions during the 8-week intervention period History of receiving at least one course of chemotherapy, radiotherapy, or mastectomy

Exclusion criteria:
Emergence of acute psychiatric symptoms such as suicidal ideation, psychotic disorders, or severe emotional instability that render the continuation of group therapy impossible Receiving concurrent psychological interventions (such as other individual or group therapies) during the study period Initiation of new psychiatric medications or significant changes in the dosage of current medications during the treatment period

Age
From **18 years** old to **55 years** old

Gender
Female

Phase
3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization Method: Matched Randomization. Randomization Unit: Individual. Stratification Layers: Participants are matched into pairs based on disease stage and initial severity of psychological distress. Randomization Tool and Sequence Generation: After forming matched pairs, one member is randomly assigned to the intervention group and the other to the control group using the website www.randomizer.org for each pair. Allocation Concealment: The use of this online tool ensures unbiased allocation and proper allocation concealment.

Blinding (investigator's opinion)
Single blinded

Blinding description
Due to the nature of the intervention, which is group psychotherapy, blinding of the participants and the principal investigator (who also acts as the therapist) is not feasible; participants are aware of receiving or not receiving the treatment, and the therapist must deliver the protocol. However, to adhere to scientific standards and minimize bias, the study is designed as single-blind. In this regard, the Data Analyst, who is responsible for examining the results and testing the hypotheses, is kept completely blinded to the group allocation. The raw data are coded (e.g., Group A and Group B) and provided to the analyst without labeling them as intervention or control, ensuring that the final analysis is conducted without prejudice.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics Committee, Faculty of Medicine and Dentistry, Kashan University of Medical Sciences

Street address
Pezeshk Blvd., Qotb Ravandi Blvd., Kashan

City
Kashan

Province
Isfehan

Postal code
8715973474

Approval date
2025-12-21, 1404/09/30

Ethics committee reference number
IR.KAUMS.MEDNT.REC.1404.174

Health conditions studied

1

Description of health condition studied
Breast cancer

ICD-10 code
C50-C50

ICD-10 code description
Malignant neoplasm of breast

Primary outcomes

1

Description

Primary Outcome 1: The total score obtained by participants on the Psychological Distress Scale (DASS-21) at the post-test and follow-up stages.Primary Outcome 2: The total score obtained by participants on the Posttraumatic Growth Inventory (PTGI) at the post-test and follow-up stages.Secondary Outcome 1: The total score obtained by participants on the Difficulties in Emotion Regulation Scale (DERS) at the post-test and follow-up stages.Secondary Outcome 2: The total score obtained by participants on the Intolerance of Uncertainty Scale (IUS) at the post-test and follow-up stages.

Timepoint

The measurement time points for all primary and secondary outcome variables in this study are identical and will be conducted at three stages as follows:Before the start of the first therapeutic intervention session (Baseline / Pre-test)Immediately after the completion of the final (eighth) therapy session (Post-test)Two months after the completion of the therapeutic intervention (Follow-up)

Method of measurement

Primary Outcome 1 (Psychological Distress): Measurement will be conducted using the 21-item version of the Depression, Anxiety and Stress Scale.Primary Outcome 2 (Posttraumatic Growth): Measurement will be conducted using the Posttraumatic Growth Inventory, designed by Tedeschi and Calhoun (1996).Secondary Outcome 1 (Emotion Regulation): Measurement will be conducted using the Difficulties in Emotion Regulation Scale, developed by Gratz and Roemer (2004).Secondary Outcome 2 (Intolerance of Uncertainty): Measurement will be conducted using the Intolerance of Uncertainty Scale, developed by Freeston et al. (1994).

Secondary outcomes

1

Description

Secondary OutcomesSecondary Outcome 1: The total score obtained by participants on the Difficulties in Emotion Regulation Scale (DERS) at the post-test and follow-up stages.Secondary Outcome 2: The total score obtained by participants on the Intolerance of Uncertainty Scale (IUS) at the post-test and follow-up stages.

Timepoint

The measurement time points for all primary and secondary outcome variables in this study are identical and will be conducted at three stages as follows:Before the start of the first therapeutic intervention session (Baseline / Pre-test)Immediately after the completion of the final (eighth) therapy session (Post-test)Two months after the completion of the therapeutic intervention (Follow-up)

Method of measurement

Secondary Outcome 1 (Emotion Regulation): Measurement will be conducted using the Difficulties in Emotion Regulation Scale, developed by Gratz and Roemer (2004).Secondary Outcome 2 (Intolerance of Uncertainty): Measurement will be conducted using the Intolerance of Uncertainty Scale, developed by Freeston et al. (1994).

Intervention groups

1

Description

Intervention group: Intervention group: Participants in this group will receive group therapy based on the “Unified Protocol for Transdiagnostic Treatment of Emotional Disorders” (UP), following the manual by David Barlow et al. The intervention consists of 8 weekly sessions (each lasting 90 minutes). The session content includes: Session 1: Motivation for change and treatment engagement (analyzing pros and cons, goal setting).Session 2: Understanding emotions and introduction to Emotion-Driven Behaviors (EDBs).Session 3: Emotional awareness training (non-judgmental observation of experiences and present-moment attention).Session 4: Cognitive reappraisal and enhancing cognitive flexibility. Session 5: Identifying and modifying emotional avoidance patterns and EDBs. Session 6: Increasing tolerance of physical sensations (interoceptive exposure).Session 7: Exposure to emotional situations and feelings (creating hierarchies and conducting exposure).Session 8: Maintaining treatment gains and relapse prevention.

Category

Rehabilitation

2

Description

Control group: Control group: Participants in this group will not receive any psychological intervention during the study period and are placed on a waiting list. They will only receive standard medical Treatment as Usual (TAU) related to their condition. Depending on the specialist physician’s prescription, these treatments include chemotherapy, radiotherapy, or surgery (mastectomy).

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Yasrebi Super Specialty Hospital

Full name of responsible person

Mohammad Javad Ghafoori

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Ayatollah Yasrebi Super Specialty Hospital, Parastar Blvd., Ghotb-e Ravandi Blvd., Kashan

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2

Recruitment center
Name of recruitment center
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Full name of responsible person
Mohammad Javad Ghafoori
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Shahid Beheshti Hospital, 5th km of Ghotb-e Ravandi Blvd., Kashan, Iran
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Web page address
https://beheshti.kaums.ac.ir/

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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Email
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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
Kashan University of Medical Sciences
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
Kashan University of Medical Sciences
Full name of responsible person
Mohammad Javad Ghafoori
Position
Master of Science Student in Clinical Psychology
Latest degree
Bachelor
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Person responsible for scientific inquiries

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
De-identified Individual Participant Data (IPD) will be shareable. These data include the main outcome variables of the study (scores from questionnaires on psychological distress, emotion regulation, intolerance of uncertainty, and posttraumatic growth) and baseline demographic variables.
When the data will become available and for how long
Access starts 6 months after the publication of the results
To whom data/document is available
Data will be available only to researchers working in academic and scientific institutions who intend to conduct secondary analysis or meta-analysis.
Under which criteria data/document could be used
Applicants must provide their research proposal. Data use is permitted solely for the scientific purposes stated in the applicant’s proposal. Citation of the original article resulting from this research is mandatory in the publication of results.
From where data/document is obtainable
Applicants can send their request to the corresponding author’s email address ([javadghafooriii@gmail.com]). They can also correspond with the Vice Chancellor for Research and Technology at Kashan University of Medical Sciences.
What processes are involved for a request to access data/document
The applicant sends a written request along with the research proposal to the corresponding author’s email. The request will be reviewed by the research team, and upon scientific and ethical approval, the data will be sent to the applicant as an encrypted file within 1 month.
Comments