Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the Effectiveness of Compassion-Focused Therapy and Mindefulness - Based Cognitive Therapy on Resilience, Emotion Regulation, Rumination, and Worry in Mothers of Children with Cancer

Protocol summary

Study aim

Comparing the Effectiveness of Compassion-Focused Therapy and Mindefulness-Based Cognitive Therapy on Resilience, Emotion Regulation, Rumination, and Worry in Mothers of Children with Cancer

Design

A clinical trial with a control group and two parallel intervention groups was conducted on 45 mothers of children with cancer, randomly assigned.

Settings and conduct

Mothers with children with cancer were selected according to the research criteria, 45 of whom were then randomly assigned (drawing lots) to 15 people in (two intervention groups and one control group) and no blinding was performed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range between 25 and 50 years, mothers with a child with cancer. Exclusion criteria: Having a terminal physical illness such as cancer, having any significant psychological illness (such as personality disorder, major depression).

Intervention groups

The first intervention group, compassion-focused therapy, techniques aimed at reducing negative emotions, is the protocol from Gilbert's research, which will be implemented in 8 90-minute sessions, one session per week for three months. The second intervention group, cognitive therapy based on the psychological health of individuals and helps increase optimism. The protocol is by Segal, which will be implemented in 8 90-minute group counseling sessions, one session per week for three months. Control group: no intervention will be carried out on this research population.

Main outcome variables

Resilience, emotion regulation, rumination, maternal worry

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20250506065619N1**
Registration date: **2025-05-31, 1404/03/10**
Registration timing: **prospective**

Last update: **2025-05-31, 1404/03/10**
Update count: **0**

Registration date

2025-05-31, 1404/03/10

Registrant information

Name

Mahya Motiee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-05, 1404/03/15

Expected recruitment end date

2025-08-06, 1404/05/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparing the Effectiveness of Compassion-Focused Therapy and Mindefulness - Based Cognitive Therapy on Resilience, Emotion Regulation, Rumination, and Worry in Mothers of Children with Cancer

Public title
Comparing compassion-focused therapy intervention with mindfulness-based cognitive therapy

Purpose
Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:
Possession of at least a diploma Complete an informed consent agreement regarding participation in the research. She has not taken any psychiatric medication in the past three months. Age range between 25 and 50 years The mother has a child with cancer.

Exclusion criteria:
Having any significant psychological illness (such as personality disorder, major depression, obsessive-compulsive disorder, bipolar disorder, etc.) Suffering from incurable physical illnesses such as cancer and the like

Age
From **25 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **45**

Randomization (investigator's opinion)
Randomized

Randomization description
The sampling method was simple random sampling and participants were randomly assigned to compassion-focused therapy (15 people), mindfulness-based cognitive therapy (15 people), and control (15 people) groups. We use the simple random allocation rule, which is one of the methods of limited randomization, and divide the subjects into 3 intervention control groups. Participants will be assigned to the control group (no intervention), compassion-focused therapy, and mindfulness-based cognitive therapy with the help of a random number table. For concealment, the method of sealed opaque envelopes with a random sequence is used.

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 Islamic Azad University of Sari

Street address
Islamic Azad University of Sari Branch, Sea Road, Caspian Square

City
Sari

Province
Mazandaran

Postal code
4816119318

Approval date
2025-02-16, 1403/11/28

Ethics committee reference number
IR.IAU.SARI.REC.1403.382

Health conditions studied

1

Description of health condition studied
Worried

ICD-10 code
R45.1

ICD-10 code description
Restlessness and agitation

Primary outcomes

1

Description
Resilience

Timepoint
Before intervention - One week after intervention - Three months after intervention

Method of measurement
The Connor and Davidson Resilience Questionnaire has 25 items that are scored on a Likert scale ranging from zero (completely false) to five (always true).

2

Description
Emotional regulation

Timepoint
Before intervention - One week after intervention - Three months after intervention

Method of measurement
The Emotion Regulation Questionnaire was designed and developed by Gross and John (2003) to measure emotion regulation. The Emotion Regulation Questionnaire has 10 questions and 2 components including emotional suppression and emotional reappraisal, and it measures emotion regulation based on a seven-point Likert scale with questions such as (When I want to feel more negative emotion, I change my thinking about that

situation).

3

Description

Rumination

Timepoint

Before intervention - One week after intervention - Three months after intervention

Method of measurement

Hoeksma, in 1991, developed a self-test questionnaire that assessed four different styles of responding to negative people. The response styles questionnaire consists of two scales: the Intoxicating Responses Scale and the Sensory Distracting Responses Scale. The Intoxicating Responses Scale consists of 22 items, each of which respondents are asked to rate on a scale of never (1), sometimes (2), most of the time (3), and always (4).

4

Description

Worry

Timepoint

Before intervention - One week after intervention - Three months after intervention

Method of measurement

The Pennsylvania Worry Questionnaire (1990) is a 16-item scale developed by Meyer et al. (1990) and Molina and Brooke (1994) to measure a person's general tendency to worry. The 16 questions in the questionnaire were selected after factor analysis of 161 questions related to worry.

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group, compassion-focused therapy, is based on Gilbert's research. Each session includes a title and general content of the session, a description of the session, and assignments. This protocol will be implemented by a psychologist specializing in this field in 8 90-minute sessions, one session per week for three months. The first session is to establish initial group communication, review the structure of the sessions, familiarize yourself with the general principles and differentiate compassion from self-pity. The second session is to train mindfulness along with body scan and breathing exercises, familiarize yourself with brain systems based on compassion, and train empathy, train you to understand and appreciate how people feel and how to follow things with an empathetic attitude. The third session is to familiarize yourself with the characteristics of people who have compassion for others, cultivate a sense of warmth and kindness towards yourself, and develop an understanding that others also have flaws and problems. The fourth session, encouraging the subjects to self-recognize and examine their personality as a compassionate or non-compassionate person, according to the educational topics of identifying and applying compassionate mind-building exercises, the value of self-compassion, empathy and sympathy towards oneself and others, and teaching the physiotherapist metaphor) and teaching forgiveness. The fifth session, familiarizing and applying compassionate mind-building exercises, teaching accepting problems, accepting upcoming changes, and tolerating difficult and challenging situations, considering the variability of life and the fact that people face different challenges. The sixth session, practical practice of creating compassionate images, teaching styles and methods of expressing compassion and applying these methods in everyday life and for spouses, children, parents, friends, teachers, and acquaintances, teaching the development of valuable and transcendent emotions, the seventh session, teaching writing compassionate letters for oneself and others, teaching the method of recording and taking daily notes of real situations based on compassion and the individual's performance in that situation. Session 8: Training and practicing skills Review and practice of skills presented in previous sessions to help subjects cope with different life situations in different ways, and finally summarize and provide solutions for maintaining and applying this therapeutic method in daily life.

Category

Behavior

2

Description

The second intervention group, mindfulness-based cognitive therapy, is to prepare a treatment plan and package from the mindfulness-based cognitive therapy treatment guide, based on Segal et al. Mindfulness will be implemented in 8 90-minute group counseling sessions, once a week for three months by a psychologist specializing in this field. The first session, setting a general policy by considering the aspect of confidentiality and personal life of individuals, inviting individuals to introduce themselves to each other, practicing eating raisins in a mindful manner, introducing the concept of automatic guidance, introducing this coping strategy to use when the current situation provokes disturbing emotions, practicing body check, homework, discussing and setting weekly meetings, distributing tapes and handouts from the first session. The second session, reviewing last week's homework, practicing body check, reviewing the exercise, practicing alternative thoughts and feelings, and teaching defocusing mental thoughts and assumptions by passing the hypothesis label over them, recording pleasant events, sitting meditation for 1 to 10 minutes, setting homework. Third session, practice seeing or hearing, introduction to the sitting meditation practice and the logic of its implementation, 30 to 40 minutes in the meditation state, strengthening the field of being-in-mind, review of the assignment, 3-minute breathing space practice and review, homework assignment.

Fourth session, five-minute practice seeing or hearing, 40 minutes meditation, mindfulness of breathing, body, sound and thoughts review, mindfulness meditation practice, homework assignment. Fifth session, before any change, we must accept ourselves as we are and this requires allowing and granting permission for the presence of unpleasant emotions in consciousness, 40 minutes of sitting meditation review, review practice, review and review of the previous session's practice, homework assignment. Sixth session, training in paying attention to the mind and that thoughts are not facts, negative moods and thoughts limit our connection with experience; Understanding that thoughts are just thoughts, 40-minute seated meditation, mindfulness of breathing, body, sounds, and thoughts, review, homework review practice, preparing for the end of the course. Session 7, 40 minutes of seated meditation, awareness of breathing, body, sounds, and then thoughts, review exercises, activity planning, identifying and making a list of enjoyable and mastery-inducing activities, homework review, practice observing the connection between activity and mood. Session 8, review of previous material and summarization and post-test.

Category

Behavior

3

Description

Control group: This group will not receive any intervention in the study.

Category

Behavior

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Mahak Institute

Full name of responsible person

Mahya Motiee

Street address

Mahak Blvd, Professor Parvaneh Vosough St, Shahid Mozhdi Blvd,Azgol intersection,, the beginning of the Army Highway,Aghdasiyeh Square

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Islamic Azad 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

Islamic Azad University

Full name of responsible person

Mahya Motiee

Position

PhD student

Latest degree

Master

Other areas of specialty/work

Psychology

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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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available