

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effectiveness of Integrated Schema Therapy and Mindfulness, Emotion Efficacy Therapy and Caregiver base Mindfulness Therapy on Entrapment, Guilt, Burden, Compassion Fatigue and Sense of Competence in Caregiving Patients with Dementia

Protocol summary

Entrapment, Guilt, Burden, Compassion Fatigue and Sense of Competence

Study aim

1. Comparison of the Effectiveness of Integrated Schema Therapy and Mindfulness, Emotion Efficacy Therapy and Caregiver base Mindfulness Therapy on Entrapment, Guilt, Burden, Compassion Fatigue and Sense of Competence in Caregiving Patients with Dementia

Design

A randomized, one way blinded, sham controlled clinical trial with a parallel group design of 72 participants. Excel software is used for randomization.

Settings and conduct

The method of conducting the present study will be slightly quasi-experimental. Before entering each of the stages and starting the research, first the necessary permits for conducting the research, such as referral letters to medical centers for dementia caregivers and patients, and the code of ethics will be obtained. Officials of medical centers will collect data.

Participants/Inclusion and exclusion criteria

Possible diagnosis of moderate or severe cognitive impairment in patients; Having at least one restriction on activities of daily living, or at least two dependencies on instrumental activities; Age 30 years and older; Caring for a relative with dementia for at least 6 months, at least four hours a day; Failure to receive psychiatric and psychological therapies; Average to moderate to high levels of depression, anxiety and stress

Intervention groups

Participants will be randomly assigned to three experimental groups and a control group, with a mindfulness and schema therapy package (8 sessions of 90 minutes), emotional efficiency (80 sessions of 90 minutes), and a caring mindfulness therapy (8 sessions of 90 minutes) for treatment groups will be executed.

Main outcome variables

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220127053841N1**

Registration date: **2022-04-18, 1401/01/29**

Registration timing: **prospective**

Last update: **2022-04-18, 1401/01/29**

Update count: **0**

Registration date

2022-04-18, 1401/01/29

Registrant information

Name

Nahid Ramezani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 31 3629 1196

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-05, 1401/02/15

Expected recruitment end date

2022-06-05, 1401/03/15

Actual recruitment start date

empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Integrated Schema Therapy and Mindfulness, Emotion Efficacy Therapy and Caregiver base Mindfulness Therapy on Entrapment, Guilt, Burden, Compassion Fatigue and Sense of Competence in Caregiving Patients with Dementia

Public title
Effect of Integrated Schema Therapy and Mindfulness on Improving Psychological Symptoms in Caregiving Patients with Dementia

Purpose
Education/Guidance

Inclusion/Exclusion criteria
Inclusion criteria:
Possible diagnosis of patients (recipients of care) with the diagnosis of a specialist doctor, or a short mental state test, which indicates moderate or severe cognitive impairment of patients At least one restriction on the activities of daily living, or at least two dependencies on the instrumental activities of the patients's daily life Being 30 years old and older Taking care of a relative with dementia for at least 6 months, at least four hours a day Not being under psychiatric and psychological treatments Achieving a moderate to high level of depression, anxiety and stress in the DOS questionnaire (25-40)
Exclusion criteria:
Having two sessions of absence in the intervention process Having cognitive, physical, sensory or language barriers that may prevent participation in the study Receiving psychological treatment Having previous experience in the therapies used in the research Age less than 30 years

Age
From **30 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Data analyser

Sample size
Target sample size: **72**

Randomization (investigator's opinion)
Randomized

Randomization description
The purpose of random allocation is that the clinician can not predict the treatment of the disease. Random allocation of the type of treatment or allocation random heart is the study of a clinical trial. The samples will be identified by random blocking method and using random number table, Random Allocation Software software. Block: This method is used to prevent significant imbalances in the number of participants assigned to

each group. Block randomization ensures that no significant imbalances occur between groups during randomization. At certain points, the number of participants in each group is equal. For this method, the size of each block must first be specified (for example, a block of four), then write a list of blocks and assign numbers to them (AABB (1) -ABAB (2) -ABBA (3) -BBAA (4) -BABA (5) - BAAB (6)), then select random numbers between one to 6 (for example 1, 4, 5, etc.) and finally specify the treatment allocation list based on previous random numbers (... AABB-BBAA-BABA-), Will be intervened in four groups including three groups and one control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants, or in other words, people who have been invited to participate in the study and after obtaining informed consent have been classified into intervention groups, may not know the main purpose of the study, these people only know that in a study They participate, which will lead to the improvement of their psychological problems, and they are only unaware of the allocation of groups. The statistical analyst does not know the content of the treatment sessions, but the hypotheses, goals, and study questions.

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, Isfahan Branch (Khorasgan)

Street address

No. 5, Banafshe Alley, Arasteh Alley(35), Nazar Gharbi St.

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Approval date

2022-02-22, 1400/12/03

Ethics committee reference number

IR.IAU.KHUISF.REC.1400.337

Health conditions studied

1

Description of health condition studied

Dementia

ICD-10 code

F03

ICD-10 code description

Unspecified dementia

Primary outcomes

1

Description

Entrapment is a special type of thinking and feeling that refers to trapping or trapping a person in a situation that he wants to avoid. Entrapment as a forced cessation of human activity and the inability of the individual to escape from the situation.

Timepoint

At the beginning of the study, after the intervention and three months after the intervention

Method of measurement

Gilbert and Allen Entrapment(Failure)Questionnaire

2

Description

Guilt score in the questionnaire of Losada et al., Which includes guilt about doing wrong by the care recipient,guilt about not rising to the occasion as caregivers, guilt about self-care, guilt about neglecting other relatives,and guilt about having negative feelings towards other people

Timepoint

At the beginning of the study, after the intervention and three months after the intervention

Method of measurement

The CaregiverGuilt Questionnaire of Losada et al(2010)

3

Description

The burden of care includes personal, social, emotional and economic pressures

Timepoint

At the beginning of the study, after the intervention and three months after the intervention

Method of measurement

Caregiver's burden questionnaire

4

Description

Compassion fatigue ("compassionate" "a state of fatigue and dysfunction (biological, psychological, and social) that results from prolonged exposure to the stress of compassion"; Caregivers are exposed to the suffering of their patients or are too emotional

Timepoint

At the beginning of the study, after the intervention and three months after the intervention

Method of measurement

Vocational life quality Stam

5

Description

A sense of competence expresses caregivers' feelings about their ability to care for a patient

Timepoint

At the beginning of the study, after the intervention and three months after the intervention

Method of measurement

Sense of competence questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: Intervention (package therapy) mindfulness and schema therapy (van Vreeswijk,M.,Broersen,J.,&Schurink (2014) This program has 8 training sessions and two follow-up sessions Messages once a week for one and a half hours. Session 1:Schemas, mindsets and mindfulness training- Introduction-Explanation-Practice-Homework Session 2: Conscious attention to the environment-Breathing-Sounds-Physical feelings-Thoughts-Emotions-Released consciousness-Homework Session 3: Conscious attention to breathing- Painful Memories - Walking - Three-Minute Breathing Space - Homework Session 4:Conscious Attention to Schema Coping (Coping with Problems) - Conscious Attention to Schemas - Familiarity with Schemas - Confectionery -Conscious Attention - Homework Session 5:Permission and Acceptance of everything that exists (reaction in the form of great mentalities Healthy year and happy child-Interactive conscious attention interaction with loved ones) - Conscious three-minute conscious attention to the schema-Accepting the conscious attention of oneself and others-Homework Session 6:Plans- Reality or fantasy Conscious attention to walking-Leaving the schemes to themselves-Homework Session 7:Taking care of yourself through a healthy adult and happy child-Conscious attention to healthy adults and happy children-Preparing for the future-Needs of healthy adults and happy children-Conscious attention to schemas حكم as pure thoughts-Homework Session 8 :Future - Schemas and mentalities in the future - Conscious attention to yourself as a child and adult - Stunt combined with awareness of schema and mentality in individual interactions Two follow-up sessions: 1 - one month after treatment and 2 - two months later - time Shorter - Emphasis on maintaining and improving previously acquired skills

Category

Lifestyle

2

Description

Intervention group 2: Intervention (treatment package) Emotional efficiency (McKay and West (2016)) This program has 8 training sessions and two follow-up sessions Messages once a week for one and a half hours. Session 1: Observation and acceptance: Awareness of excitement Session 2: Conscious mind acceptance: Wave riding on excitement Session 3: Value-Based Action - Part One Session 4: Value-Based Action - Part II Session 5: Conscious Mind Coping: Loneliness and self-relaxation Session 6: Conscious mind confrontation: مق Controversial thoughts and fundamental acceptance Session 7: Conscious mind confrontation: Return attention and rest time Session 8: Fixation, unwind and summarizing

Category

Lifestyle

3

Description

Intervention group 3: intervention (treatment package) mindfulness of the caregiver of Rezek(2015) This program has 8 training sessions and two follow-up sessions. Meetings last once a week for an hour and a half. Session 1: Introduction to mindfulness for caregivers - Explain the course and how the mind and body interact against stress -Training body postures in mindfulness exercises (sitting and lying down) Session 2: Breathing practice training (5 minutes) for caregivers Mindfulness training training Conscious care for caregivers Introductory mind training training for caregivers Session 3: Breathing training training (relaxing moments in less than 2 minutes) -Shower training training Conscious mind-training-Focusing training training (30 minutes) -Homework Session 4: Breathing practice training (5 minutes) for caregivers - Mountain meditation practice training for caregivers - Mindfulness training training for special caregivers thoughts - Homework Session 5: Breathing training training (relaxation moments in less than 2 minutes) - Training to choose to change the focus of caregivers as a solution to deal with unpleasant thoughts and emotions - Homework Session 6: Breathing training training (5 minutes) for caregivers - Training training for body posture training for caregivers - Training training for self-care for caregivers - Training training for setting boundaries along with the volume of work for caregivers - Homework: Special caregivers' body posture - Special caregivers' self-care exercise - Boundaries exercise along with the volume of caregivers' workload Session 7: Breathing training training (relaxing moments in less than 2 minutes) - Training training Mindful walking-Conscious training training Mindfulness training for caregivers, Homework Session 8: Breathing training training (5 minutes) for caregivers - Limiting exercises along with the volume of work for caregivers - Teaching strategies to deal with resistance to exercise - Homework

Category

Lifestyle

4

Description

Control group: A group that is not subject to any

intervention. They only complete the questionnaires before and after reading. If they wish, they can intervene after the end of the study.

Category

Lifestyle

Recruitment centers

1

Recruitment center

Name of recruitment center

private clinic

Full name of responsible person

Majid Barekataan

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first floor, Sarv Building, in front of Tejarat Bank, between Nikbakht and Sheikh Mofid Streets, Sheikh Sadough North Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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?

No

Title of funding source

Islamic Azad University Isfahan (Khorasgan) Branch.

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

Name of organization / entity

Islamic Azad University

Full name of responsible person

Nahid Ramezani

Position

Student

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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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

Participant data file only in general and without mentioning the name and address of the participants (number-gender-age-education). The study protocol can also be published as a table. The statistical analysis map can be published in the form of tables and statistical results. The informed consent can be published in full. The results of applied research can be published. Statistical methods and statistical analysis can be published. The obtained data can be published in the form of tables. All of the above can be provided to participants in accordance with the instructions of the journals and in case of no damage.

When the data will become available and for how long

The start of the access period is with the opinion and agreement of the relevant journals.

To whom data/document is available

It will be accessible to all people who have access to authoritative sources for publishing articles such as reputable journals and the results of this research can be used for them.

Under which criteria data/document could be used

All cases of using the documents will be possible with the permission of the university of study and professors related to the research and in compliance with the existing rules and regulations.

From where data/document is obtainable

Reputable journals in which research-related articles are published. The e-mails of the supervisors, advisors and

students implementing the project and their university website will be provided to the applicants using the results in accordance with the rules and regulations and maintaining the confidentiality of the participants.

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

Applicable requests will be answered as soon as possible if the rules related to research documents are observed.

Comments

All of the above can be done within the framework of the rules and regulations of research and publication in relevant journals and universities. If a case is not within the scope of these laws, it will not be published. A special case is to maintain the confidentiality of participants' information and not to harm them.