Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The Effec of Compassion-Focused Therapy on Cognitive Emotion Regulation and Pain Perception in Patients With Chronic Pain

Protocol summary

Study aim

Determine the effectiveness of Compassion-Focused Therapy (CFT) on Cognitive Emotion Regulation (CER) and Pain Perception in female patients with Chronic Pain.

Design

Clinical trial of two control and intervention groups, randomized by lottery method (draws), with a sample size of 40 subjects

Settings and conduct

The population consists of all female patients with chronic pain in 2022. This is a randomized controlled trial using a pre-test-post-test design with a control group receiving the usual care of a standard study. The intervention will be done in Akhtar Hospital in Tehran.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female patients aged 40 to 65 years; Definitive diagnosis of chronic pain for at least 6 months by an anesthesiologist (Pain Fellowship); Healthy individuals and chronic pain patients with normal ranges for diabetes, blood pressure, and thyroid (fasting blood sugar less than or equal to110 mg/dL, high blood pressure less than or equal to 140 on 90 mmHg, normal thyroid according to the laboratory kit); Not having rheumatology diseases or being under control; The presence of problems with Cognitive Emotion Regulation and Pain Perception based on clinical interview and Cognitive Emotion Regulation Questionnaire and McGill Pain Questionnaire; Minimum literacy; Absence of vision and hearing problems; Exclusion criteria: History of attending the Compassion-Focused Therapy training programs; Drug and alcohol addiction; Mental retardation disorder; Cancer patients; Psychotic disorder patients.

Intervention groups

Intervention group: The intervention group (20 subjects), will individually undergo eight 60-minute sessions of Gilbert Compassion-Focused Therapy. Control group: The control group (20 subjects) will not receive any intervention and they will be on the waiting list.

Main outcome variables

Pain Perception; Cognitive Emotion Regulation; Self-Compassion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220706055393N1**
Registration date: **2022-09-10, 1401/06/19**
Registration timing: **prospective**

Last update: **2022-09-10, 1401/06/19**
Update count: **0**

Registration date

2022-09-10, 1401/06/19

Registrant information

Name

Kimiya Hashemi kashi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-09-18, 1401/06/27

Expected recruitment end date

2022-10-19, 1401/07/27

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
The Effec of Compassion-Focused Therapy on Cognitive Emotion Regulation and Pain Perception in Patients With Chronic Pain

Public title
The Effect of Compassion Therapy on Chronic Pain

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Female patients aged 40 to 65 years Definitive diagnosis of chronic pain for at least 6 months by an anesthesiologist (Pain Fellowship) Healthy individuals and chronic pain patients with normal ranges for diabetes, blood pressure, and thyroid (fasting blood sugar less than or equal to 110 mg/dL, high blood pressure less than or equal to 140 on 90 mmHg, normal thyroid according to the laboratory kit) Not having rheumatology diseases or being under control The presence of problems with Cognitive Emotion Regulation and Pain Perception based on clinical interview and Cognitive Emotion Regulation Questionnaire (CERQ) and McGill Pain Questionnaire (MPQ) Minimum literacy Absence of vision and hearing problems

Exclusion criteria:
History of attending the Compassion-Focused Therapy (CFT) training programs Drug and alcohol addiction Mental retardation disorder Cancer patients Psychotic disorder patients

Age
From **40 years** old to **65 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, the study population includes all female patients aged 40 to 65 with chronic pain who have referred to the Pain Clinic of Akhtar Hospital. The samples were selected using the convenience sampling method after the preliminary interview and based on the inclusion and exclusion criteria of study, and then were divided into two control and intervention groups by Simple Randomization and lottery method. In the simple randomization by lottery, first the names of 40 selected patients are written on sheets and then placed inside the vase; then the names of 20 people are drawn out of the vase. The names of 20 people removed from the vase are chosen as the first group and the names remaining in the vase are chosen as the second group. In the following, lots were drawn between the first group and the second group, and according to the lottery, the name of the group that was removed from the vase was placed in the intervention group and the name of the group inside the vase was placed in the control group. Finally, we will have two intervention (including 20 people) and control (including 20 people) groups using simple randomization by lottery.

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 Semnan Branch

Street address
University Town, Semnan

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Province
Semnan

Postal code
3513137111

Approval date
2022-06-22, 1401/04/01

Ethics committee reference number
IR.IAU.SEMNAN.REC.1401.021

Health conditions studied

1

Description of health condition studied
Chronic Pain

ICD-10 code
G89.4

ICD-10 code description
Chronic pain syndrome

Primary outcomes

1

Description
Pain Perception

Timepoint
Pain perception in patients with chronic pain is measured once before the intervention and once after the intervention (at the end of the eighth session). In the control group, they are measured once at the same time

as the sample group and once two months later.

Method of measurement

Pain perception is measured by McGill Pain Questionnaire (MPQ)

2

Description

Cognitive Emotion Regulation

Timepoint

Cognitive Emotion Regulation in patients with chronic pain is measured once before the intervention and once after the intervention (at the end of the eighth session). In the control group, they are measured once at the same time as the sample group and once two months later.

Method of measurement

Cognitive emotion regulation is measured by the Cognitive Emotion Regulation Questionnaire (CERQ)

3

Description

Self-Compassion

Timepoint

Self-Compassion, in patients with chronic pain, is measured once before the intervention and once after the intervention (at the end of the eighth session). In the control group, they are measured once at the same time as the sample group and once two months later.

Method of measurement

Self-Compassion is measured by the Self-Compassion Scale-Long Form Questionnaire (SCS-LF)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Following the selection of 40 subjects and assigning them to the two control and intervention groups by lottery method (draws), the intervention group will undergo Compassion-Focused Therapy (CFT). Moreover, both control and intervention groups completed demographic, McGill Pain Questionnaire (MPQ), Self-Compassion Scale-Long Form Questionnaire (SCS-LF), and Cognitive Emotion Regulation Questionnaires (CERQ), once before the intervention and once after the intervention. In this group, each subject will individually undergo eight 60-minute sessions of CFT, once a week; here is a brief description of the sessions. The first session: Familiarity with the general principles of Compassion-Focused Therapy (CFT), assessment and evaluation of shame, self-criticism, self-compassion, and soothing breathing rhythm training. The second session: Introducing the three emotion regulation systems and how they affect the person, the conflicts between the old brain and the new brain, and explaining the difference between the threat-focused mind and the compassionate mind. Training mindfulness, and introducing mindfulness exercises: breathing exercises, eating and touching raisins. The third session: Familiarity with the characteristics of compassionate people, compassion towards others, cultivating a feeling of warmth and kindness towards oneself, training the compassion expressing styles and methods using expressions (I feel safe, I am kind to myself), cultivating and understanding the fact that others also have flaws and problems (cultivating a sense of human commonality) versus self-destructive feelings and shame, training compassionate mental imagery. The fourth session: Focusing on the compassionate self, discussing the characteristics of the self-compassionate individuals, exercising the Gestalt empty chair (internal dialogue between the three thoughts of the self-critic, the compassionate self, and the self-criticized), performing a mental imagery exercise on the compassionate self, and accepting mistakes to enhance changes. The fifth session: Compassion skills training: compassionate attention, compassionate reasoning, compassionate behavior, compassionate imagery, compassionate feeling, compassionate sensory experience in compassion for self and others. Examining a person's compassionate or traumatic behavior in real-life threatening situations, training how to mentally visualize a compassionate safe place. The sixth session: Training love and affection meditation and cultivating compassion towards others, training forgiveness, focusing on self-compassion towards others. The seventh session: Training acceptance of issues and facing different challenges and changes ahead, training in writing compassionate letters for yourself and others, training the method of "recording and keeping a diary of compassion-based real situations and the person's performance in that situation". The eighth session: Fear of self-compassion, identifying and addressing thoughts hindering the development of self-compassion, reviewing and practicing the skills presented in the previous sessions to help the participant deal with different situations in their life in different ways, solutions to maintain and apply this therapy method in everyday life, and in the end, re-filling demographic, McGill Pain Questionnaire (MPQ), Self-Compassion Scale-Long Form Questionnaire (SCS-LF), and Cognitive Emotion Regulation Questionnaires (CERQ) by subjects.

Category

N/A

2

Description

Control group: A sample of 40 subjects is selected and then assigned into two groups of control and intervention by lottery method (draws). The control group will receive no intervention.

Category

N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Akhtar Hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
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Web page address
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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
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Kimiya Hashemi Kashi
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Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no further information.

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available