

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of cognitive group therapy and its combination with self-management program in reducing of depression, anxiety, aggression and pain of women with chronic pain

Protocol summary

Summary

Objective: The aim of this study was to compare effectiveness of cognitive group therapy and its combination with self-management program in reducing depression, anxiety, aggression and pain in women with chronic pain. **Design:** Statistical population consisted of all women with chronic pain musculoskeletal pain, recruited through Emam Reza Treatment Center Clinics, Quaem Treatment Clinic Center and the Clinical Psychology and Counseling Center at the Ferdowsi University of Mashhad. Thirty women with chronic pains were selected via judgmental sampling. **Setting and conduct:** It was used DASS-21, Aggression questionnaire and Multidimensional Pain Inventory for collecting data. 30 women with chronic pains were selected and they were assigned randomly in to two experimental groups and one control group. The treatment consisted of cognitive group therapy and cognitive pain self-management that consisted of eight 120-min weekly group sessions in each session. The intervention was performed on the Clinical Psychology and Counseling Center at the Ferdowsi University of Mashhad (Iran). **Participants:** Eligibility criteria were age between 18-50 years, suffered from chronic non specific pain and had pain for at least three months. Exclusion criteria comprised of unwillingness to participants, severe somatic illness requiring specific treatment and manifest psychiatric disorder. **Intervention:** The treatments consisted of cognitive group therapy and its combination with self-management program. Primary outcome variables are depression, anxiety, aggression and pain.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015111924265N2**

Registration date: **2016-07-13, 1395/04/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-07-13, 1395/04/23

Registrant information

Name

Faezeh Salayani

Name of organization / entity

Ferdowsi University of Mashhad

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-10-23, 1393/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of cognitive group therapy and its combination with self-management program in reducing

of depression, anxiety, aggression and pain of women with chronic pain

Public title
Comparison of cognitive therapy and cognitive pain self-management program in depression, anxiety, aggression and pain of women with chronic pain

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: ages 18-50 years, suffered from chronic non specific pain, had pain for at least three months, ability to complete self-assessment questionnaires, provision of written, signed informed consent; Exclusion criteria: unwillingness to participants, severe somatic illness requiring specific treatment, manifest psychiatric disorder such as psychosis, failed inclusion criteria, use of stimulants, drugs, alcohol at the time of the study.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Participants were selected via judgmental sampling and they were randomly assigned randomly into three groups of 10 as two experimental and one control groups. The way of randomization was done by Simple Random Sampling. A sample is called simple random sample if each unit of the population has an equal chance of being selected for the sample. Lottery method was used for the selection of a simple random sample.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ferdowsi University of Mashhad

Street address

faculty of psychology, Ferdowsi University of Mashhad,

Azadi Sq, Mashhad
City
Mashhad
Postal code
Approval date
2014-06-10, 1393/03/20
Ethics committee reference number
567

Health conditions studied

1

Description of health condition studied

chronic pain

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes

1

Description

depression

Timepoint

before intervention and two months later

Method of measurement

DASS-21 Questionnaire

2

Description

Anxiety

Timepoint

before intervention and two months later

Method of measurement

DASS-21 Questionnaire

3

Description

Aggression

Timepoint

before intervention and two months later

Method of measurement

Aggression Questionnaire (AQ)

4

Description

Pain

Timepoint

before intervention and two months later

Method of measurement

Multidimensional Pain Inventory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Cognitive group therapy treatment sessions comprised of eight 120 min group session. Protocol consisted of cognitive therapy protocol based on Michel Free. Session-by-session outlines are presented: Session 1: Introduction and ground rules, teach ABC model; Session 2: Identifying of automatic thoughts and logical errors ; Session 3: Welcome and reflections from last session, identifying negative schema content using the vertical arrow method; Session 4: Welcome and reflections from last session, making a master list of negative beliefs and cognitive maps; Session 5: Welcome and reflections from last session, beliefs that have changed, utility analysis, investigatory Analysis; Session 6: Welcome and reflections from last session, making counters, hierarchy construction ; Session 7: Welcome and reflections from last session, changing negative beliefs; Session 8: Welcome and reflections from last session, self punishment, using imagery, review of the program, get feedback about the treatment plan

Category

Behavior

2

Description

Intervention group 2: combination of cognitive therapy with self-management program. Treatment session was comprised of eight 120 min group session . Protocol consisted of cognitive therapy protocol based on Michel Free and the chronic disease self-management program (CDSMP) protocol that originally developed by Lorig et al. Session-by-session outlines are presented: Session 1: Introduction and ground rules, teach ABC model; Session 2: Identifying of automatic thoughts and logical errors, boom and bust over\under activity and exercise, breathing, being more active, goal setting and planning for action; Session 3: Welcome and reflections from last session, identifying negative schema content using the vertical arrow method, give an overview of good nutrition and a rationale for eating better, goal setting and planning for action; Session 4: Welcome and reflections from last session, making a master list of negative beliefs and cognitive maps, using Mind to Manage Symptoms and Distraction, goal setting and planning for action; Session 5: Welcome and reflections from last session , beliefs that have changed, utility analysis, investigatory Analysis, muscle Relaxation, goal setting and planning for action; Session 6: Welcome and reflections from last session, making counters, hierarchy construction; problem-Solving skill, communication Skills, goal setting and planning for action; Session 7: Welcome and reflections from last session, changing negative beliefs; depression management, guided Imagery, goal setting and planning for action; Session 8: Welcome and reflections from last session, self punishment, using imagery, review of the program, get feedback about the

treatment plan

Category

Behavior

3

Description

control group: Control group did not receive any treatment and after the initial eight-week delay, all those in the control group condition received the intervention.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Treatment Center Clinics

Full name of responsible person

Dr Sima Eftekharzadeh

Street address

Emam Reza treatment Center Clinic, Emam Reza Square, Ebne Sina Avenue, Mashhad, Iran

City

Mashhad

2

Recruitment center

Name of recruitment center

Quaem Treatment clinic center

Full name of responsible person

Dr hossein mashhadi nejad

Street address

Quaem Treatment clinic center, Ahmad Abad Ave, Ali Shariati Sq(Taghi Abad Sq), Mashhad

City

Mashhad

3

Recruitment center

Name of recruitment center

Clinical Psychology and counseling Center at school of psychology

Full name of responsible person

Dr.Seeyed Mohsen Asgari Nekah

Street address

Clinical Psychology and counseling Center, Ferdowsi University of Mashhad, Mashhad

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Ferdowsi University of

Mashhad
Full name of responsible person
 Bahrami Ahmad
Street address
 Vice president for research, Ferdowsi University of
 Mashhad , Azadi, Sq, Mashhad, Iran
City
 Mashhad
Grant name
Grant code / Reference number
Is the source of funding the same sponsor
organization/entity?
 Yes
Title of funding source
 Vice chancellor for research Ferdowsi University of
 Mashhad
Proportion provided by this source
 100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty