Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Clinical trial of effectiveness of acceptance and commitment therapy for patients with chronic low back pain

Protocol summary

Summary

The aim of this study is a clinical trial to investigate the Processes of change in psychological flexibility in an interdisciplinary group-based treatment for chronic backache based on Acceptance and Commitment Therapy (ACT) by using per and post-test. Participants are 28th of patients who attended treatment at pain clinic of Razi hospital in Rasht. Participants are clinically have chronic backache under the assessment of a specialist and the observation inclusion and exclusion criteria for the study will be checked. Participants completed an assessment instrument before treatment which was included MPQ(McGill Pain questionnaire) for collecting the data. The inclusion criteria of this study were informed consent for participating in group treatment, no drug consumer, no psychiatric disorders ,no absence more than one session will make the participants leave the study.. This study will be set up during 8 sessions of 90 minutes and the intervention will be according to manual of kevin.Evowles john T sorell included training of skills like mind fullness exercises and chronic pain acceptance. Effectiveness of treatment will be assessing by McGill Pain questionnaire.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201206039934N1**
Registration date: **2017-05-01, 1396/02/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-01, 1396/02/11

Registrant information

Name

Robabeh Soleimani Talemi

Name of organization / entity

Guilan University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

University Of Medical Sciences Guilan,Vice chancellor for research

Expected recruitment start date

2017-04-09, 1396/01/20

Expected recruitment end date

2017-06-21, 1396/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of effectiveness of acceptance and commitment therapy for patients with chronic low back pain

Public title

Clinical trial of effectiveness of acceptance and commitment therapy for patients with chronic low back pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: no drug consumer; no psychiatric disorders; completed high school; participants have no

absence more than one session. Exclusion criteria: psychiatric disorders; drugs or alcohol consumption; smoking cigarette.

Age
From **30 years** old to **50 years** old

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **28**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Block Randomization: In this study after obtaining informed consent from qualified individuals, these people will be divided randomly into two groups. This means that patients who entered the study will be randomly assigned number. This number identifies a person in one group will arrive.

Secondary Ids

1

Registry name
-

Secondary trial Id
-

Registration date
empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Guilan University of Medical Sciences

Street address
Ethics committee of Guilan University of Medical Sciences,Shahid Beheshti Blvd,Opposite to the Sepah bank, Above Iran Radiator Representation. Building Of Assistance Research and Technology, Rasht, Iran

City
Rasht

Postal code
4193893345

Approval date
2017-01-14, 1395/10/25

Ethics committee reference number
IR.GUMS.REC.1395.308

Health conditions studied

1

Description of health condition studied
Low back pain

ICD-10 code
M54.5

ICD-10 code description
Low back pain

Primary outcomes

1

Description
Low back pain

Timepoint
before the treatment and two week after the treatment and three month after the treatment

Method of measurement
McGill Pain questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention Group: changes in individual function and reduction of chronic pain and commitment to the actions which helps them to reach the clarified values .Session 1: Introduction and the Treatment Agenda(-Providing the opportunity for patients to become familiar with each other and the treatment aims.;-Determine the change agenda through the use of a “creative hopelessness”;Exercise.;-Homework.).Session 2: Behavior Change and Mindfulness (-Potential Values and an Issue of Choice.;-Introduce the behavioral model and the concept of behavior change.;-Mindfulness Practice; Homework.).Session 3: Values (-“Acceptance”.;-Values.-Mindfulness.;–Homework). Session 4: Values Clarification and Goals(-Values Clarification;-Barriers.;-Goal Setting and Introducing Committed Action.;-Mindfulness.;-Homework.). Session 5: Defusion (- Homework Review and Pacing.;-Defusing the threats of language.; -Mindfulness.; -Homework).Session 6 – Committed Action (-Treatment review.;-Committed action.;-Mindfulness and Observing Self-Exercises.;-Homework).Session 7 – Willingness(- Primary and secondary suffering;-Commitment and barriers to willingness.; -Walking Mindfulness. ; -Homework). Session 8: Wrap-up & Conclusions (- Values clarification).

Category
Other

2

Description
Contro Group: After completing the research and data collection in brief interventions will have a plan in 4 sessions.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Razi university Center Specialty and Subspecialty of Psychiatry Clinic of Rasht
Full name of responsible person
Dr Robabeh Soleimani
Street address
Razi university Center Specialty and Subspecialty of Psychiatry Clinic of Rasht, Sardarjangal Avenue, Razi Hospital,Rasht, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
University Of Medical Sceinces Guilan,Vice chancellor for research
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
University Of Medical Sceinces Guilan,Vice chancellor for research
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

Contact
Name of organization / entity
Guilan University Of Medical Sciences
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Dr Robabeh Soleimani
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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