Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 2026

Comparison of the effectiveness of group acceptance and commitment therapy and group schema therapy on perceived stress, pain perception, pain catastrophizing, depression and symptoms severity of women with fibromyalgia

Protocol summary

Study aim
Comparison of the effectiveness of group acceptance and commitment therapy on perceived stress, pain perception, pain catastrophizing, depression and symptoms severity of women with fibromyalgia

Design
The present study is a single-blind clinical trial with parallel groups. The research sample consisted of 60 women with fibromyalgia who will be selected in accessible form and randomly assigned into two experimental groups (each with 20 subjects) and one control group (20 subjects). After the replacement,questionnaires will be provided to subjects and pre-test will be performed. After completing the treatments, the subjects will be exposed again to the post-test.

Settings and conduct
This study will be done at the doctor's office of rheumatology specialist and data collection will be done through questionnaires.

Participants/Inclusion and exclusion criteria
Diagnosis of fibromyalgia by rheumatology specialist, Conscious willingness and willingness to participate in the research project, Age range 25-55, Education higher than diploma, No psychological treatment during the last 6 months; Having mental disorders or other chronic physical illness during the treatment process, Missing more than 2 sessions

Intervention groups
This study has two groups of tests and one control group. In the first test group, group acceptance and commitment therapy will be performed in 8 sessions and at intervals of once a week. In the second experiment group, the group schema therapy will be performed for 10 weeks and once a week. In the control group, placebo treatment will be performed.

Main outcome variables
Perceived stress; Pain perception; Pain catastrophizing; Depression; Symptoms severity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20181201041810N1**
Registration date: **2019-03-12, 1397/12/21**
Registration timing: **registered_while_recruiting**

Last update: **2019-03-12, 1397/12/21**
Update count: **0**

Registration date
2019-03-12, 1397/12/21

Registrant information

Name
Parisa Soleymani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 45 3327 1340

Email address
p.soleymani@iauardabil.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-03-06, 1397/12/15

Expected recruitment end date
2019-05-05, 1398/02/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effectiveness of group acceptance and commitment therapy and group schema therapy on perceived stress, pain perception, pain catastrophizing, depression and symptoms severity of women with fibromyalgia

Public title
Comparison of the effectiveness of acceptance and commitment therapy and schema therapy in women with fibromyalgia
Purpose
Education/Guidance
Inclusion/Exclusion criteria
Inclusion criteria:
Diagnosis of fibromyalgia by rheumatology specialist Conscious willingness and willingness to participate in the research project Age range 25-55 Education higher than diploma No psychological treatment over the past 6 months
Exclusion criteria:
Having mental disorders or other chronic physical illness during the treatment process Missing more than 2 sessions
Age
From **25 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The method of randomization will be simple. The randomization unit will be the person and the randomization tool will be a random number table.
Blinding (investigator's opinion)
Single blinded
Blinding description
Participants will not be aware of their assignment to the control group and placebo treatment will be performed on the control group
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Ardabil University of Medical Sciences
Street address
University Ave
City
Ardabil
Province
Ardabil
Postal code
5618985991
Approval date
2018-12-23, 1397/10/02
Ethics committee reference number
IR.ARUMS.REC.1397.168

Health conditions studied

1

Description of health condition studied
Fibromyalgia
ICD-10 code
M79.7
ICD-10 code description
Fibromyalgia

Primary outcomes

1

Description
Perceived stress
Timepoint
Before the beginning of intervention and after the end of intervention(after 2 months)
Method of measurement
Perceived Stress Scale

2

Description
Pain perception
Timepoint
Before the beginning of intervention and after the end of intervention(after 2 months)
Method of measurement
Short – form Mc Gill Pain Questionaire

3

Description
Pain Catastrophizing

Timepoint
Before the beginning of intervention and after the end of intervention(after 2 months)
Method of measurement
Pain Catastrophizing Scale

4

Description
Depression
Timepoint
Before the beginning of intervention and after the end of intervention(after 2 months)
Method of measurement
Beck Depression Inventory-II

5

Description
Symptoms severity
Timepoint
Before the beginning of intervention and after the end of intervention(after 2 months)
Method of measurement
Riviesed Fibromyalgia Impact Questionnaire

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: group acceptance and commitment therapy that will be performed in 8 sessions and once a week. Along with routine drug therapy
Category
Behavior

2

Description
Intervention group: group schema therapy that will be performed in 8 sessions and once a week. Along with routine drug therapy
Category
Behavior

3

Description
Control group: Plasebo with routine drug therapy
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Office of rheumatologists
Full name of responsible person
Ahad Azami
Street address
Shahriar Physicians Bldg., tava Alley., Sarcheshmeh Sq
City
Ardabil
Province
Ardabil
Postal code
5613665487
Phone
+98 45 3324 1622
Email
Ahadazami@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Aref Jalili
Street address
Islamic Azad University of Ardabil Complex., Basij Sq.,
City
Ardabil
Province
Ardabil
Postal code
5615731567
Phone
+98 45 3372 7799
Email
info@iauardabil.ac.ir
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
Parisa Soleymani
Position
Student
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No. 12., Motahhari3 Alley., Motahhari Ave
City
Ardabil
Province
Ardabil
Postal code
5613917381
Phone
+98 45 3327 1340
Email
p62.soleymani@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Reza Kazemi
Position
Assistant professor
Latest degree
Specialist
Other areas of specialty/work
Psychiatrics
Street address
No. 35, Shams Alley.,Sarcheshmeh Sq
City
Ardabil
Province
Ardabil
Postal code
5613666447
Phone
+98 45 3324 0374
Email
dr_reza.kazemi@yahoo.com

Person responsible for updating data

Contact
Name of organization / entity
Islamic Azad University
Full name of responsible person
Parisa Soleymani
Position
Student
Latest degree
Ph.D.
Other areas of specialty/work
Psychology
Street address
No. 12., Motahhari3 Alley., Motahhari Ave
City
Ardabil
Province
Ardabil
Postal code
5613917381
Phone
+98 45 3327 1340
Email
p62.soleymani@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Title and more details about the data/document
Information on the main outcome variable
When the data will become available and for how long
6 months after printing results
To whom data/document is available
Researchers
Under which criteria data/document could be used
With references to resources
From where data/document is obtainable
Parisa Soleymani Reza Kazemi
What processes are involved for a request to access data/document
Send email to people incharge of providing data
Comments