Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Psychological interventions for migraine: A Randomized Controlled Trial Comparing the Efficacy of Intensive Short-Term Dynamic Psychotherapy, Modified Schema Therapy, and Acceptance and Commitment Therapy on Rumination, Experiential Avoidance, Pain severity and Quality of Life in Migraine Patients.

Protocol summary

Study aim

Main Objective Is Comparison of the effectiveness of modified intensive and short-term dynamic group psychotherapy, schema therapy and acceptance and commitment therapy on rumination, experiential avoidance, pain severity and quality of life of patients with migraine

Design

The clinical trial had a control group, with parallel groups, randomized,On 60 people

Settings and conduct

This research is a clinical trial study with a pre-test, post-test and one-month follow-up design. The statistical population includes patients with migraine headaches referring to clinics in Hamedan. Among them, 60 eligible patients will be randomly assigned to four groups. The experimental groups will receive their respective treatment protocols, while the control group will be placed on a waiting list. Data will be analyzed using one-way and two-way repeated measures analysis of variance.

Participants/Inclusion and exclusion criteria

The inclusion criteria for the study included individuals' willingness to participate in the study; no history of drug or alcohol use; no history of severe mental disorders such as hallucinations and delusions; and finally, individuals had not received any type of psychological treatment in the past 6 months.

Intervention groups

Three Psychotherapy group: Intensive and modified short-term dynamic therapy Schema therapy group Acceptance and commitment therapy group With a Control group

Main outcome variables

Rumination, which involves passive and repetitive thoughts that focus on the causes and consequences of symptoms; experiential avoidance, which is an attempt to avoid painful or actual experiences; pain intensity, which is an unpleasant sensory experience that arises in the face of actual or potential physical harm; and quality of life, which is an individual's perception of their position in life in terms of the culture and value system in which they live.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251024067743N1**
Registration date: **2025-11-12, 1404/08/21**
Registration timing: **prospective**

Last update: **2025-11-12, 1404/08/21**
Update count: **0**

Registration date

2025-11-12, 1404/08/21

Registrant information

Name

Mohammad Sina Hanifi

Name of organization / entity

The University of Lorestan

Country

Iran (Islamic Republic of)

Phone

+98 81 3826 5219

Email address

msinah92@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2025-11-22, 1404/09/01
Expected recruitment end date
2026-01-25, 1404/11/05
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Psychological interventions for migraine: A Randomized Controlled Trial Comparing the Efficacy of Intensive Short-Term Dynamic Psychotherapy, Modified Schema Therapy, and Acceptance and Commitment Therapy on Rumination, Experiential Avoidance, Pain severity and Quality of Life in Migraine Patients.

Public title
Comparing the effects of several psychotherapy models on migraine
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All patients with migraine disorder No history of drug use No history of alcohol consumption No history of severe mental disorders such as hallucinations and delusions. Participants must not have received any type of psychological treatment in the past 6 months
Exclusion criteria:
Have an education lower than a high school diploma Be over fifty years of age or under eighteen years of age Living outside the city of Hamedan
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
The sample size is 60 people based on the type of research, which is randomly selected through a lottery and assigned to four groups of 15 people, taking into account dropout. According to experts, the ideal number of members in the treatment groups is up to 12 people (Berg, Landreth, & Fall, 2013), but considering the possibility of dropout, dealing with outliers, and trying to have larger groups to establish homogeneity of variance, each group is 15 people. The sampling method is as follows: by referring to the Psychiatry and Psychology Clinic in Hamedan, a list of all people eligible to participate in the research is prepared with the guidance of the technical manager or the clinic receptionist; after reviewing and having the entry criteria, the first 15 people are assigned to the short-term dynamic therapy group, the second 15 people to the schema therapy group, the third 15 people to the acceptance and commitment therapy group, and the last 15 people to the control group.
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 Lorestan University of Medical Sciences
Street address
No. 7, 12 Metri Sangshir Ave
City
HAMEDAN
Province
Hamadan
Postal code
6515774764
Approval date
2025-10-14, 1404/07/22
Ethics committee reference number
IR.LUMS.REC.1404.302

Health conditions studied

1

Description of health condition studied
migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
The Nolen-Hooksman Rumination Questionnaire score of patients with migraines is reduced.
Timepoint

Before the intervention, after the intervention, and one month after the intervention.

Method of measurement

Nolen-Hooksman Questionnaire

2

Description

The score of Band et al.'s Experiential Avoidance Questionnaire related to experiential avoidance in patients with migraines should be reduced.

Timepoint

Before the intervention, after the intervention, and one month after the intervention.

Method of measurement

Band et al. Experiential Avoidance Questionnaire

3

Description

The McGill Pain Questionnaire score in relation to pain intensity in patients with migraines should be reduced.

Timepoint

Before the intervention, after the intervention, and one month after the intervention.

Method of measurement

McGill pain questionnaire

4

Description

The score of the International Standard Quality of Life Questionnaire SF36 increases in patients with migraine.

Timepoint

Before the intervention, after the intervention, and one month after the intervention.

Method of measurement

Quality of life questionnaire International Standard Quality of Life SF36

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: A group that has been affected by short-term intensive dynamic psychotherapy. Intervention group: The group that has been affected by short-term intensive dynamic psychotherapy. Modified short-term psychodynamic psychotherapy is a therapeutic approach that is based on investigating and discovering the underlying causes of mental disorders and creating lasting changes in the patient's thought and behavioral patterns. This treatment method is usually carried out for a limited period of time (several months to a year) and the patient plays an active role in this process. In this study, a 15-session protocol based on the Duvanlu short-term intensive dynamic psychotherapy protocol will be used.

Category

Treatment - Other

2

Description

Intervention group: A group affected by acceptance and commitment therapy.Acceptance and Commitment Therapy is a branch of clinical behavior analysis. It is an empirically based psychological intervention that uses acceptance and mindfulness strategies along with commitment and behavior change strategies to increase psychological flexibility (Hayes et al., 2006). This study will use the 8-session Acceptance and Commitment Therapy protocol (Wells & Sorrell, 2002).

Category

Treatment - Other

3

Description

Intervention group: A group affected by schema therapy. Schema therapy was developed by Jeffrey Young for use in the treatment of personality disorders and chronic disorders. The goal of schema therapy is to help patients meet their basic emotional needs through the treatment of schemas, by reducing the intensity of emotional memories including the schema and the intensity of physical sensations, and by changing the cognitive patterns associated with the schema (Young, 2006; Klasko, Wishar, 2006). In this study, a 10-session protocol based on group schema therapy (Young et al., 2003) will be used.

Category

Treatment - Other

4

Description

Control group: Group not affected by any treatment

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Farzane

Full name of responsible person

Farzane Izadi

Street address

Aramgah SQ

City

HAMEDAN

Province

Hamadan

Postal code

6519963199

Phone

+98 918 815 3169

Email

msinah92@gmail.com

2

Recruitment center
Name of recruitment center
Sepidar
Full name of responsible person
Mohamad Torkaman
Street address
Aramgah SQ
City
HAMEDAN
Province
Hamadan
Postal code
6519963198
Phone
+98 918 713 1947
Email
msinah92@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
The Lorestan University
Full name of responsible person
Dr Fazlollah Mirdarikvand
Street address
Goldasht 1
City
KHORAMABAD
Province
Lorestan
Postal code
6814857893
Phone
+98 916 663 4432
Email
mir.f@lu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
The Lorestan 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
The Lorestan University
Full name of responsible person
Mohamad Sina Hanifi
Position
Phd Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
NO 7 12 Metri Sangshir
City
HAMEDAN
Province
Hamadan
Postal code
6516774764
Phone
+98 81 3826 5219
Email
msinah92@gmail.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
The Lorestan University
Full name of responsible person
Mohamad Sina Hanifi
Position
Phd Student
Latest degree
Master
Other areas of specialty/work
Psychology
Street address
NO 7 12 Metri Sangshir
City
HAMEDAN
Province
Hamadan
Postal code
6515774764
Phone
+98 81 3826 5219
Email
msinah92@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
The Lorestan University
Full name of responsible person
Mohamad Sina Hanifi
Position
Phd Student

Latest degree
Master
Other areas of specialty/work
Psychology
Street address
NO 7 12 Metri Sangshir
City
HAMEDAN
Province
Hamadan
Postal code
6516774764
Phone
+98 81 3826 5219
Email
msinah92@gmail.com

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
All data is potentially shareable after de-identifying individuals.
When the data will become available and for how long
Access period starts 6 months after results are published.
To whom data/document is available
It will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
In order to observe and conduct similar research
From where data/document is obtainable
To Mohammad Sina Hanifi's email address: MSINAH92@GMAIL.COM
What processes are involved for a request to access data/document
Send a message to the above email six months after the results are published and I will respond to you within two business days.
Comments