Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the Effectiveness of Emotional Awareness and Expression Therapy (EAET) with Acceptance and Commitment Therapy (ACT) and Usual Care in Pain Severity, Pain Interference, and Quality of Life among Students with Chronic Pain

Protocol summary

Study aim

The primary objective of this study is to compare the effectiveness of Emotional Awareness and Expression Therapy (EAET) and Acceptance and Commitment Therapy (ACT) with usual care in reducing pain severity and pain interference and improving quality of life among students with chronic musculoskeletal pain.

Design

A randomized controlled clinical trial with a three-group parallel design, including pre-test, post-test, and 3-month follow-up; simple computer-based randomization; blinded outcome assessors; 15 participants per group, 45 participants in total; analysis using repeated-measures analysis of variance and hierarchical regression in SPSS and AMOS at a significance level of 0.05.

Settings and conduct

دانشجویان دارای سابقه درد مزمن اسکلتی‌عضلانی از طرح پایش سلامت دانشگاه‌های تهران از طریق ایمیل دعوت می‌شوند. پس از بررسی شرایط و تکمیل ارزیابی پایه، شرکت‌کنندگان به‌صورت تصادفی توسط درمانگران آموزش‌دیده در ACT و EAET تخصیص می‌یابند. مرکز مشاوره دانشگاه تهران اجرا می‌شوند و گروه کنترل درمان معمول دریافت می‌کند. ارزیابی‌ها در پیش‌آزمون، پس‌آزمون و پیگیری ۳ ماهه انجام شده و ارزیاب‌ها از تخصیص گروهی بی‌اطلاع خواهند بود.

Participants/Inclusion and exclusion criteria

Students with chronic musculoskeletal pain for at least 3 months; informed consent; no use of medications affecting psychological functioning or pain; excessive absence; initiation of a new treatment; voluntary withdrawal; development of a new medical condition; incomplete data.

Intervention groups

Participants will be randomly allocated to three groups: EAET based on the Lumley protocol, delivered in 90-minute group sessions; ACT based on the Hayes protocol, delivered in 90-minute group sessions; and a usual-care control group.

Main outcome variables

Pain severity; pain interference; quality of life; alexithymia; psychological flexibility

General information

Reason for update

Acronym

EAET vs ACT

IRCT registration information

IRCT registration number: **IRCT20250801066714N1**
Registration date: **2026-08-29, 1405/06/07**
Registration timing: **prospective**

Last update: **2026-08-29, 1405/06/07**
Update count: **0**

Registration date

2026-08-29, 1405/06/07

Registrant information

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Name of organization / entity
The university of Tehran
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Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-09-23, 1405/07/01

Expected recruitment end date
2026-12-22, 1405/10/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effectiveness of Emotional Awareness and Expression Therapy (EAET) with Acceptance and Commitment Therapy (ACT) and Usual Care in Pain Severity, Pain Interference, and Quality of Life among Students with Chronic Pain

Public title
Effectiveness of Emotional Awareness and Expression Therapy and Acceptance and Commitment Therapy in Students with Chronic Pain
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Students enrolled in public universities in Tehran Chronic musculoskeletal pain lasting at least 3 months Significant pain interference in quality of life Providing informed consent No use of medications that severely alter psychological or pain function
Exclusion criteria:
Excessive absence from treatment sessions Starting new pain treatment or psychotropic medications during the study Voluntary withdrawal Development of new medical conditions making continuation inappropriate Providing incomplete data
Age
From **18 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be performed at the individual level using simple randomization. After eligibility criteria are assessed and the baseline assessment is completed, each participant will be assigned a unique identification code. A computer-generated random sequence will then be used to allocate participants with equal probability to one of three groups: the Emotional Awareness and Expression Therapy (EAET) group, the Acceptance and Commitment Therapy (ACT) group, or the usual-care control group. The generation of the random sequence and group allocation will be performed by an individual independent of the principal investigator and therapists. The person responsible for randomization will not be involved in the assessment process, intervention delivery, or data collection. The unit of randomization is the individual, and neither cluster nor stratified randomization will be used. To reduce the risk of selection bias, group allocation will remain concealed from the assessors and the investigator responsible for assessment until completion of the baseline assessment. The participant's allocation will be disclosed after enrollment in the study and completion of the baseline assessment.
Blinding (investigator's opinion)
Single blinded
Blinding description
Due to the nature of the group-based psychological interventions, blinding of participants and therapists to treatment allocation will not be possible. Participants will be informed of their assigned intervention after allocation, and therapists will be aware of group assignment because of the distinct content and procedures of the interventions. However, outcome assessors and the data analyst will be blinded to participants' group allocation. Pre- and post-intervention assessments will be conducted by assessors who are not involved in treatment allocation or intervention delivery and who will not have access to participants' treatment-group information. To maintain assessor blinding, each participant will be identified by a unique study code, and information regarding treatment allocation will be stored separately from assessment data. Outcome assessors will have access only to coded assessment data and will not be provided with information regarding treatment assignment. Statistical analyses will be conducted using coded data by an analyst who is unaware of treatment allocation. Outcome assessors and the data analyst will be instructed not to ask about or seek information regarding participants' treatment assignments. The principal investigator and therapists will not be blinded to treatment allocation. If an adverse event or other clinical circumstance requires disclosure of a participant's treatment assignment, unblinding will be documented and managed in accordance with the study's ethical procedures.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Tehran
Street address
Faculty of Foreign Languages and Literatures, North

Kargar St., between 15th and 16th St

City

Tehran

Province

Tehran

Postal code

1439813164

Approval date

2026-03-01, 1404/12/10

Ethics committee reference number

IR.UT.PSYEDU.REC.1405.058

Health conditions studied

1

Description of health condition studied

Chronic musculoskeletal pains

ICD-10 code

M54.5

ICD-10 code description

Chronic musculoskeletal pains

Primary outcomes

1

Description

Pain Severity: Change in pain severity score on the Pain Severity subscale of the West Haven-Yale Multidimensional Pain Inventory; the score is measured on a 7-point Likert scale ranging from 0 to 6, with higher scores indicating greater pain severity.

Timepoint

Pre-test, before the beginning of the intervention; post-test, immediately after completion of the intervention at week 8; follow-up, 3 months after completion of the intervention.

Method of measurement

The Pain Severity subscale of the West Haven-Yale Multidimensional Pain Inventory, consisting of 3 items rated on a 7-point Likert scale ranging from 0 to 6; higher scores indicate greater pain severity.

2

Description

Pain Interference: Change in pain interference score on the Pain Interference subscale of the West Haven-Yale Multidimensional Pain Inventory; the score is measured on a 7-point Likert scale ranging from 0 to 6, with higher scores indicating greater interference of pain with daily functioning.

Timepoint

Pre-test, before the beginning of the intervention; post-test, immediately after completion of the intervention at week 8; follow-up, 3 months after completion of the intervention.

Method of measurement

The Pain Interference subscale of the West Haven-Yale Multidimensional Pain Inventory, consisting of 9 items rated on a 7-point Likert scale ranging from 0 to 6; higher scores indicate greater interference of pain with daily functioning.

3

Description

Quality of Life: Change in quality of life score measured by the World Health Organization Quality of Life Questionnaire; scores are rated on a 5-point Likert scale, with higher scores indicating better quality of life.

Timepoint

Pre-test, before the beginning of the intervention; post-test, immediately after completion of the intervention at week 8; follow-up, 3 months after completion of the intervention.

Method of measurement

The World Health Organization Quality of Life Questionnaire, consisting of 26 items covering four domains: physical health, psychological health, social relationships, and environment, is rated on a 5-point Likert scale.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention Group 1: Emotional Awareness and Expression Therapy (EAET); number of sessions: 8 sessions; duration of each session: 90 minutes; frequency: twice weekly; total intervention duration: 4 weeks; delivery format: group-based, with 15 participants per group; treatment protocol: the Lumley et al. protocol for Emotional Awareness and Expression Therapy; intervention description: the treatment focuses on identifying and increasing awareness of emotions, understanding the relationship between emotions, pain, and physical symptoms, processing and expressing emotions related to difficult experiences, and reducing emotional avoidance, using psychoeducation, emotional exercises, and emotion-expression techniques; therapists: therapists trained in Emotional Awareness and Expression Therapy and supervised by the study supervisor.

Category

Treatment - Other

2

Description

Intervention Group 2: Acceptance and Commitment Therapy (ACT); number of sessions: 8 sessions; duration of each session: 90 minutes; frequency: twice weekly; total intervention duration: 4 weeks; delivery format: group-based, with 15 participants per group; treatment protocol: the protocol developed by Hayes et al.; intervention description: the treatment focuses on acceptance of unpleasant experiences, increasing psychological flexibility, cognitive defusion, connection

with personal values, and commitment to value-based actions, and includes mindfulness exercises, therapeutic metaphors, experiential exercises, and identification of personal values; therapists: therapists trained in Acceptance and Commitment Therapy and supervised by the study supervisor.

Category

Treatment - Other

3

Description

Control Group: Usual care; number of sessions: no structured psychological sessions; intervention duration: 4 weeks; delivery format: participants will continue their usual medical or psychological care received outside the study and will not receive a structured psychological intervention from the research team. This group will be assessed at pre-test, post-test, and 3-month follow-up.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Tehran university

Full name of responsible person
Seyed Hasan taghavi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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?
No

Title of funding source
personal

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 University of Tehran

Full name of responsible person
Seyed Hasan Taghavi

Position
Consultant

Latest degree
Master

Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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