Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Effectiveness Analysis of Web-Based Cognitive Behavioral Therapy on Cognitive Processing and Regulation in Depression and Anxiety

Protocol summary

Study aim

To study the effectiveness of web-based cognitive behavioral intervention on reducing depression and anxiety in students; to evaluate the cognitive-emotional network's role in enhancing cognitive processing and regulation (including thought suppression, cognitive avoidance, cognitive insight, and negative metacognition); to assess self-stigma's role in effectiveness; to check effect durability at 1- and 3-month follow-ups

Design

Quasi-experimental trial with pre-test/post-test design; simple random allocation of eligible students; no blinding; sample size 40 (30 main, 10 reserves for dropout)

Settings and conduct

Study conducted online at Maragheh University; MOODGYM intervention with weekly 15-minute phone/online sessions for progress tracking; no blinding

Participants/Inclusion and exclusion criteria

Maragheh University students; CES-D score 7-40 and K10 score 9-29; age 18-30; internet access and web program ability; B1 English proficiency (min. 10/15 on Test of English Proficiency); informed consent; no concurrent therapy or psychotropic drugs; excluded for severe disorders, unwillingness, or incomplete participation

Intervention groups

Intervention group receives web-based cognitive behavioral therapy via MOODGYM for 5 weeks with weekly 15-minute phone/online sessions for progress monitoring; control group receives no intervention and acts as a comparison group

Main outcome variables

Outcome variables include depression scores (Beck Depression Inventory and CES-D), anxiety scores (Beck Anxiety Inventory and K10), cognitive processing indicators (thought suppression and cognitive avoidance), cognitive regulation indicators (cognitive insight and negative metacognitions), and follow-up assessments at 1- and 3-month intervals.

General information

Reason for update

Acronym

IOTMDA

IRCT registration information

IRCT registration number: **IRCT20250521065839N1**
Registration date: **2025-10-22, 1404/07/30**
Registration timing: **retrospective**

Last update: **2025-10-22, 1404/07/30**
Update count: **0**

Registration date

2025-10-22, 1404/07/30

Registrant information

Name

Alireza Abdi

Name of organization / entity

The University of Maragheh

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-06-14, 1404/03/24

Expected recruitment end date

2025-07-15, 1404/04/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effectiveness Analysis of Web-Based Cognitive Behavioral Therapy on Cognitive Processing and Regulation in Depression and Anxiety

Public title

Impact of Online Therapy with MOODGYM on Depression and Anxiety

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Score between 9 and 29 on the K10 Score between 7 and 40 on the CES-D Not receiving concurrent psychological treatments Not using psychotropic medications Willingness and signed informed consent form Proficiency in English at B1 level or higher Be a student at the University of Maragheh Have access to the internet and the ability to use web-based programs

Exclusion criteria:

Diagnosis of severe psychiatric disorders such as schizophrenia or bipolar disorder Use of psychotropic medications that may affect intervention outcomes

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

This study used simple randomization The unit of randomization was individuals Gender balancing was applied with 2 males assigned to the intervention group and 2 males to the control group The randomization tool was a random number table The random sequence was generated by dividing 30 participants into two groups of 15 using a random number table Allocation concealment will be implemented using group coding

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

This quasi-experimental study employed a pre-test/post-test control group design. Participants were randomly allocated with gender balancing (two males per group). The intervention group received the web-based MoodGYM program, while the control group was placed on a waiting list. Initial screening was conducted to identify eligible participants before recruitment began.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees Certificate

Street address

University of Tabriz, East Azerbaijan Province, Tabriz, 29 Bahman Boulevard

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5166616471

Approval date

2025-07-23, 1404/05/01

Ethics committee reference number

IR.TABRIZU.REC.1404.073

Health conditions studied

1

Description of health condition studied

Depression

ICD-10 code

F32.1

ICD-10 code description

Major depressive disorder, single episode, moderate

2

Description of health condition studied

Anxiety

ICD-10 code

F41.1

ICD-10 code description

Generalized anxiety disorder

Primary outcomes

1

Description

Severity of depression symptoms

Timepoint

Measurement at baseline (before intervention), at the end of week 6 (post-intervention), and at 1-month and 3-month follow-ups

Method of measurement

Center for Epidemiologic Studies Depression Scale

2

Description
Severity of anxiety symptoms
Timepoint
Measurement at baseline (before intervention), at the end of week 6 (post-intervention), and at 1-month and 3-month follow-ups
Method of measurement
Beck Anxiety Inventory

Secondary outcomes

1

Description
Thought suppression level
Timepoint
Measurement at baseline (before intervention), at the end of week 6 (post-intervention), and at 1-month and 3-month follow-ups
Method of measurement
Wegner Thought Suppression Inventory

2

Description
Cognitive avoidance level
Timepoint
Measurement at baseline (before intervention), at the end of week 6 (post-intervention), and at 1-month and 3-month follow-ups
Method of measurement
Cognitive Avoidance Questionnaire

3

Description
cognitive insight
Timepoint
Measurement at baseline (before intervention), at the end of week 6 (post-intervention), and at 1-month and 3-month follow-ups
Method of measurement
Beck Cognitive Insight Scale

4

Description
negative metacognitions
Timepoint
Measurement at baseline (before intervention), at the end of week 6 (post-intervention), and at 1-month and 3-month follow-ups
Method of measurement
Metacognitions Questionnaire

5

Description
Level of emotion regulation strategies
Timepoint
Measurement at baseline (before intervention), at the end of week 6 (post-intervention), and at 1-month and 3-month follow-ups
Method of measurement
Emotion Regulation Questionnaire

6

Description
Level of perceived social stigma due to depression
Timepoint
Measurement at baseline (before intervention), at the end of week 6 (post-intervention), and at 1-month and 3-month follow-ups
Method of measurement
Depression Stigma Scale (SSDS)

Intervention groups

1

Description
Intervention group: Intervention group: Participants receive a 5-week Internet-based Cognitive Behavioral Therapy (ICBT) intervention using the MoodGYM program, consisting of one module per week. Additionally, they participate in weekly 10-15 minute telephone follow-up sessions conducted by a trained facilitator to monitor progress and provide support.
Category
Behavior

2

Description
Control group: Control group: Participants are placed on a waitlist and receive no intervention during the 5-week study period. They will be offered access to the ICBT intervention with MoodGYM after the study completion.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
University of Maragheh
Full name of responsible person
Alireza Abdi
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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?

Yes

Title of funding source

University of Maragheh

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

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Full name of responsible person

Alireza Abdi

Position

Research Student

Latest degree

Bachelor

Other areas of specialty/work

Psychology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Individual participant data (IPD) will not be shared to protect participant confidentiality and comply with ethical guidelines set by the University of Tabriz Biomedical Ethics Committee, from which the ethical approval was obtained. Aggregated, de-identified data will be available instead.

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

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Study Protocol: Detailed document outlining the study design, methodology, and procedures for the web-based cognitive-behavioral therapy trial.

When the data will become available and for how long

Access will begin approximately 1 month after study completion and receipt of the trial registration code (expected post-September 2025), with a possible extension to 3 months, and will last for 5 years.

To whom data/document is available

Access is granted to academic researchers affiliated with recognized academic institutions.

Under which criteria data/document could be used

Data is intended for academic research purposes only, requiring a written request detailing the research objectives, submitted to the University of Tabriz Biomedical Ethics Committee for approval.

From where data/document is obtainable

Requests should be submitted to the University of Tabriz Biomedical Ethics Committee. Contact details to be confirmed with the university (tentative email: tabrizubioethics@gmail.com, subject to verification).

What processes are involved for a request to access data/document

Requests will be reviewed within 30 days by the University of Tabriz Biomedical Ethics Committee, with approval notification sent via email, followed by data access within 15 days of approval.

Comments

The study population was not specified in the title to align with the approved protocol by the University of Tabriz Biomedical Ethics Committee.