# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

09 Nov 2026

## The impact of expressive writing versus acceptance and commitment therapy on inflammatory biomarkers, cognitive functioning, and psychological well-being in high-school students with moderate-to-severe stress or anxiety

## Protocol summary

**Study aim**
The comparative efficacy of expressive writing and acceptance and commitment therapy in the reduction of stress biomarkers and the improvement of psychological and cognitive health in adolescents

**Design**
A clinical trial designed with two parallel intervention groups, and randomized on 48 samples. The randomization method was conducted using the random block method with four blocks and the online tool Sealed Envelope

**Settings and conduct**
The study will include students attending a specified school (Sarv-e-Danesh, located in Shahriar, Tehran) who exhibit moderate to high stress or anxiety levels, as indicated by the DASS-42. The participants are randomly assigned to either the EW or ACT intervention group using the block randomization method. The experimental group will utilize expressive writing as a means of managing anxiety and stress over the course of six weeks, while the control group will engage in acceptance and commitment therapy during the same period. Prior to and following the conclusion of the treatment period, the blood levels of NLR, CRP, and cortisol will be quantified, and the scores from the DASS-42 and the PASAT will be ascertained. Subsequently, the changes observed in the two groups will be compared.

**Participants/Inclusion and exclusion criteria**
Students aged 15 to 20 who exhibit a DASS-42 stress score exceeding 18 or an anxiety score exceeding 9

**Intervention groups**
The experimental group will utilize expressive writing as a means of managing anxiety and stress over the course of six weeks, while the control group will engage in acceptance and commitment therapy during the same period

**Main outcome variables**
Stress biomarkers in the blood, including cortisol, C-reactive protein (CRP), and the neutrophil-to-lymphocyte ratio (NLR)

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20240910063001N2**
Registration date: **2024-10-05, 1403/07/14**
Registration timing: **prospective**

Last update: **2024-10-05, 1403/07/14**
Update count: **0**

**Registration date**
2024-10-05, 1403/07/14

**Registrant information**

**Name**
Hasan Moltazemi

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2024-10-22, 1403/08/01

**Expected recruitment end date**

2025-03-19, 1403/12/29

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
The impact of expressive writing versus acceptance and commitment therapy on inflammatory biomarkers, cognitive functioning, and psychological well-being in high-school students with moderate-to-severe stress or anxiety

**Public title**
Expressive writing and acceptance and commitment therapy for stress and anxiety

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Be between the ages of 15 and 20 A stress score of more than 18 or an anxiety score of more than 9 in the psychological interview based on the Depression, Anxiety and Stress Scale-42 Informed consent of the patient and legal guardian for participation

**Exclusion criteria:**
History of significant psychiatric, neurological, or endocrine disorders Prior engagement in psychotherapy Current pharmacological treatment with psychotropic medications or steroids Lack of compliance, defined as failure to participate in more than two follow-up sessions

**Age**
From **15 years** old to **20 years** old

**Gender**
Both

**Phase**
N/A

**Groups that have been masked**
*No information*

**Sample size**
Target sample size: **48**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
The participants will be divided into two groups, ACT and EW, using the random block method. Block randomization will be conducted using the website https://www.sealedenvelope.com. Each block will consist of four members, and the resulting combination will be as follows: [ABAB], [ABBA], [AABB], [BBAA], [BABA], [BAAB], where code "A" corresponds to the EW group and code "B" corresponds to the ACT group. The aforementioned website randomly selects 12 quadruple blocks, thus including 48 patients in the study. To ensure the allocation is concealed, a code is devised for each participant based on the generated blocks. These codes will be provided to the researcher at the time of admission by the study coordinator.

**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 Baqiyatallah University of Medical Sciences

**Street address**
Baqiyatallah University of Medical Sciences, Mollasadra Street, Tehran

**City**
Tehran

**Province**
Tehran

**Postal code**
1435915371

**Approval date**
2024-09-16, 1403/06/26

**Ethics committee reference number**
IR.BMSU.BAQ.REC.1403.117

## Health conditions studied

### 1

**Description of health condition studied**
Stress, not elsewhere classified

**ICD-10 code**
Z73.3

**ICD-10 code description**
Physical and mental strain NOS

### 2

**Description of health condition studied**
Anxiety disorder, unspecified

**ICD-10 code**
F41.9

**ICD-10 code description**
Anxiety NOS

## Primary outcomes

### 1

**Description**
Serum cortisol

**Timepoint**
Before the start of the intervention and one week after its end (week 7)

**Method of measurement**
Laboratory test

**2**

**Description**
Serum C-reactive protein
**Timepoint**
Before the start of the intervention and one week after its end (week 7)
**Method of measurement**
Laboratory test

**3**

**Description**
Neutrophil-to-lymphocyte ratio
**Timepoint**
Before the start of the intervention and one week after its end (week 7)
**Method of measurement**
Laboratory test

## Secondary outcomes

**1**

**Description**
Working memory and processing speed
**Timepoint**
Before the start of the intervention and one week after its end (week 7)
**Method of measurement**
Paced Auditory Serial Addition Test

**2**

**Description**
Stress
**Timepoint**
Before the start of the intervention and one week after its end (week 7)
**Method of measurement**
Depression, Anxiety, Stress Scale-42

**3**

**Description**
Anxiety
**Timepoint**
Before the start of the intervention and one week after its end (week 7)
**Method of measurement**
Depression, Anxiety, Stress Scale-42

## Intervention groups

**1**

**Description**
Intervention group (EW): a course of expressive writing therapy, comprising three consecutive days of therapy per week, with each session lasting 15 minutes, over a period of six weeks. The therapy was conducted under the guidance of a psychology expert, with follow-up sessions conducted via telephone
**Category**
Behavior

**2**

**Description**
Control group (ACT): a course of acceptance and commitment therapy in the form of six one-hour group sessions over six weeks based on the headings of the educational protocol of acceptance and commitment therapy
**Category**
Behavior

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Neuroscience Research Center, Baqiyatallah University of Medical Sciences
**Full name of responsible person**
Hedayat Sahraei
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Institute of Systems Biology and Personalized Medicine, Baqiyatallah University of Medical Sciences, Mollasadra Street, Tehran
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## Sponsors / Funding sources

**1**

**Sponsor**
**Name of organization / entity**
Bagheiat-allah University of Medical Sciences
**Full name of responsible person**
Abbas Ali Imani Fooladi
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**Phone**

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**Email**

R.bmsu@yahoo.com

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Bagheiat-allah University of Medical Sciences

**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**

Bagheiat-allah University of Medical Sciences

**Full name of responsible person**

Shima Shahyad

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Psychology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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## 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 can be shared after participants are de-identified

**When the data will become available and for how long**

Six months after the results have been published

**To whom data/document is available**

Academic and scientific institutions

**Under which criteria data/document could be used**

Systematic review studies and meta-analysis

**From where data/document is obtainable**

Shima Shahyad

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

Send an email to the corresponding author

**Comments**