

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### Evaluation of efficacy and safety of *Psilocybe cubensis* on depression and PTSD symptoms of veterans; a randomized, double-blind, placebo-controlled trial

#### Protocol summary

##### Study aim

pharmacologic evaluation of the alkaloids extracted from *psilocybe cubensis* on symptoms of Post-traumatic stress disorder (PTSD)

##### Design

Purification of the alkaloids will be performed through a common method designed for alkaloids specifically. A chromatographic method (HPLC) will be used to detect the amount of psilocybin. Then, we formulate solid capsule dosage forms with 20 milligrams of psilocybin in a capsule. A randomized, double-blind, placebo-controlled clinical trial with treatment (the alkaloids) group and 68 sample size. 1) The treatment group will receive alkaloids and the common antidepressants (SSRIs or SNRIs), while 2) the placebo group will take fried bread and SSRIs for 6 weeks.

##### Settings and conduct

The study was conducted in the outpatient at 505 hospital. Demographic characteristics of patients are registered at the start of the study. Evaluations include HAMD, PCL-V, and BAI scores are recorded on days 0, 28, and 42

##### Participants/Inclusion and exclusion criteria

veterans with a diagnosis of Post-traumatic stress disorder (PTSD)

##### Intervention groups

1) Control group: will receive a single dose of placebo capsules, with the exact size, color, and appearance were filled with fried bread at the first of the study 2) treatment group: will receive a single dose of 20 milligrams of alkaloids extracted from the psilocybe mushroom at the first of the study

##### Main outcome variables

depressed mood; Feelings of guilt; Suicide; Insomnia (early, middle, and late insomnia ); Work and interests; Psychomotor retardation; Psychomotor agitation; Anxiety, psychotic; Anxiety, somatic

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20170311033004N4**

Registration date: **2022-06-28, 1401/04/07**

Registration timing: **prospective**

Last update: **2022-06-28, 1401/04/07**

Update count: **0**

##### Registration date

2022-06-28, 1401/04/07

##### Registrant information

##### Name

Ali Razmi

##### Name of organization / entity

Academic Center for Education, Culture and Research

##### Country

Iran (Islamic Republic of)

##### Phone

+98 26 3476 4015

##### Email address

arazmi@alumnus.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-07-23, 1401/05/01

##### Expected recruitment end date

2022-12-21, 1401/09/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

Evaluation of efficacy and safety of Psilocybe cubensis on depression and PTSD symptoms of veterans; a randomized, double-blind, placebo-controlled trial

### Public title

Evaluation of efficacy and safety of Psilocybe mushroom on depression and post-traumatic stress disorder symptoms in veterans

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

patients with PTSD diagnosis moderate to severe depression male aged 45-75 years without any previous diagnosis of other mental disorders such as without any previous diagnosis of diabetes or CV disorders without diagnosis of the other mental disorders taking antidepressants SSRIs or SNRIs not hospitalized

#### Exclusion criteria:

they have a diagnosis of psychosis suicide attempting taking antidepressants except for SSRIs and SNRIs or electroconvulsive therapy follow up interrupting sensitivity to the mushroom emerging adverse effects including fever, GI and heart diseases hospitalization

### Age

From **45 years** old to **75 years** old

### Gender

Male

### Phase

2

### Groups that have been masked

- Participant
- Care provider

### Sample size

Target sample size: **68**

### Randomization (investigator's opinion)

Randomized

### Randomization description

Randomization will be performed through block randomization (block of four). In Excel, we would arrange the Treatment and Control values systematically and then add a column with a block number. The third column would be our random numbers. Here is what it would look like. Then, we sort the numbers, by block and by random number within block.

### Blinding (investigator's opinion)

Double blinded

### Blinding description

Blinding and randomization will be carried out by an independent person unrelated to the study, while the investigator will administrate capsules and will assess the patients. Capsules will be packed and numbered serially using numbers generated by random number tables. They are the same in appearance, size, and color.

### Placebo

Used

### Assignment

Parallel

### Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

دانشگاه علوم پزشکی ارتش جمهوری اسلامی ایران

##### Street address

Chamran highway

##### City

Tehran

##### Province

Tehran

##### Postal code

1411718541

#### Approval date

2022-06-19, 1401/03/29

#### Ethics committee reference number

IR.AJAUMS.REC.1401.024

## Health conditions studied

### 1

#### Description of health condition studied

Posttraumatic stress disorder (PTSD)

#### ICD-10 code

F43.1

#### ICD-10 code description

Post-traumatic stress disorder (PTSD)

## Primary outcomes

### 1

#### Description

Anhedonia, depressed mood, change in appetite, sleep, BAI score, and suicidal ideations

#### Timepoint

Days 0, 28 and 42

#### Method of measurement

BAI, HDRS and PCL-V questionnaires

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Psilocybe cubensis alkaloids: The alkaloids purified through routine methods for alkaloids purifications. Then a semi-automatic capsule filler was used to fill the the capsules, prepared in an opaque

plastic container. Patients received powder capsules (equivalent 20 mg alkaloids), standardized to reference.

### Category

Treatment - Drugs

## 2

### Description

Control group: Control group: Placebo capsules, with the exact size, color, and appearance, were filled with fried bread.

### Category

Treatment - Drugs

## Recruitment centers

## 1

### Recruitment center

#### Name of recruitment center

AJA 505 hospital

#### Full name of responsible person

Mohammad Reza Ghasemzadeh

#### Street address

Artesh highway, Oshan Blvd

#### City

Tehran

#### Province

Tehran

#### Postal code

1956944141

#### Phone

+98 21 2248 1806

#### Email

m.rezaghasezadeh@yahoo.com

#### Web page address

<https://bima505.ajaums.ac.ir/>

## Sponsors / Funding sources

## 1

### Sponsor

#### Name of organization / entity

Iranian academic center for education culture and research

#### Full name of responsible person

Ali Razmi

#### Street address

Enghelab street, facing University of Tehran, central office

#### City

Tehran

#### Province

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#### Postal code

436414155

#### Phone

+98 21 6648 8515

#### Fax

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#### Email

[secretariat@acecr.ac.ir](mailto:secretariat@acecr.ac.ir)

#### Web page address

<http://acecr.ac.ir>

### Grant name

### Grant code / Reference number

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

Yes

### Title of funding source

Iranian academic center for education culture and research

### 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

Other

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Iranian academic center for education culture and research

#### Full name of responsible person

Ali Razmi

#### Position

Assistant preofessor

#### Latest degree

Ph.D.

#### Other areas of specialty/work

Medical Pharmacy

#### Street address

Institute of medicinal plants, Alborz science and technology park, Kamalshahr

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#### Province

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3365166571

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#### Email

[arazmi@alumnus.tums.ac.ir](mailto:arazmi@alumnus.tums.ac.ir)

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Iranian academic center for education culture and research

#### Full name of responsible person

Ali Razmi

**Position**

Assistant professor

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Medical Pharmacy

**Street address**

Kamalshahr, Jahad daneshgahi research complex

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**Web page address****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**

No - There is not 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**

demographic data and questionnaire final scores will be shared.

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

after publication

**To whom data/document is available**

Researchers from all the medical universities

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

The data can be used results in review articles.

**From where data/document is obtainable**

The data is available by calling Dr Ali Razmi; assistant professor at ACECR. email: arazmi@alumnus.tums.ac.ir  
Tel: 00989123945632

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

The request should be sent to the email.

**Comments****Person responsible for updating data****Contact****Name of organization / entity**

Iranian academic center for education culture and research

**Full name of responsible person**

Ali Razmi

**Position**

Assistant professor

**Latest degree**

Ph.D.

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