Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

A comparative study of the effectiveness of online cognitive behavioral therapy and mindfulness cognitive behavioral therapy on the psychological symptoms of celiac patients with the control group.

Protocol summary

Study aim
Comparing the effectiveness of online cognitive behavioral therapy and mindfulness cognitive behavioral therapy on the psychological symptoms of celiac patients in the control group.

Design
A clinical trial with a control group, with parallel groups including two intervention groups and one group without treatment, without blinding, randomized, on 45 patients, random number generator software was used for randomization.

Settings and conduct
The recent clinical trial was conducted at a university medical center, open-label with the available sampling method. The study objectives were explained to the participants, who will be screened for inclusion criteria. Those meeting the criteria will be randomly assigned to one of three groups, each consisting of 15 people. The first group will receive 8 sessions of cognitive behavioral therapy, the second group will receive 4 sessions of cognitive behavioral therapy based on mindfulness, and the third group will not receive any treatment. Scales will be completed before and after the treatment.

Participants/Inclusion and exclusion criteria
Having celiac disease diagnosed by a gastroenterologist, Age between 18 and 60 years, At least having a diploma degree, Ability to use smartphones, Not having neurological disorders.

Intervention groups
Cognitive behavioral therapy will be administered in the form of weekly 45-minute sessions. The cognitive behavioral therapy will be based on mindfulness and consist of 4 sessions, each lasting 75 minutes, with one weekly session of eight weeks

Main outcome variables
Severity of depressive symptoms, Severity of anxiety symptoms, The amount of quality of life, The amount of self-compassion

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20220316054306N4**
Registration date: **2024-08-26, 1403/06/05**
Registration timing: **prospective**

Last update: **2024-08-26, 1403/06/05**
Update count: **0**

Registration date
2024-08-26, 1403/06/05

Registrant information
Name
Shahab Lotfinia
Name of organization / entity
Country
Iran (Islamic Republic of)
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lotfiniashahab@sbmu.ac.ir

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-09-10, 1403/06/20
Expected recruitment end date
2024-11-30, 1403/09/10
Actual recruitment start date
empty
Actual recruitment end date
empty

Trial completion date
empty

Scientific title
A comparative study of the effectiveness of online cognitive behavioral therapy and mindfulness cognitive behavioral therapy on the psychological symptoms of celiac patients with the control group.

Public title
Investigating the effectiveness of cognitive behavioral therapy on the psychological symptoms of celiac patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Having celiac disease diagnosed by a gastroenterologist Age between 18 and 60 years At least having diploma degree Ability to use smartphones Not having neurological disorders
Exclusion criteria:
Age
From **18 years** old to **60 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
A code will be assigned to the people entering the study, and then each code will be randomly assigned to a group using the random list generator tool.
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
Ethic committee of Shahid Beheshti University of Medical Science
Street address
Bldg No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran
City
Tehranتهران
Province
Tehran
Postal code
1983963113
Approval date
2024-02-20, 1402/12/01
Ethics committee reference number
IR.SBMU.MSP.REC.1402.632

Health conditions studied

1

Description of health condition studied
Celiac disease
ICD-10 code
K90.0
ICD-10 code description
Celiac disease

Primary outcomes

1

Description
Severity of depressive symptoms
Timepoint
Before and after intervention
Method of measurement
Based on the score obtained in the Hospital Anxiety and Depression Scale

2

Description
Severity of anxiety symptoms
Timepoint
Before and after intervention
Method of measurement
Based on the score obtained in the Hospital Anxiety and Depression Scale

3

Description
The amount of quality of life
Timepoint
Before and after intervention
Method of measurement
Based on the score obtained in the World Health Organization Quality of Life Scale

4

Description
The amount of self-compassion
Timepoint
Before and after intervention
Method of measurement
Based on the score obtained in the Self Compassion

scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Cognitive behavioral therapy will be administered in the form of weekly 45-minute sessions over the course of eight weeks. During the first session, we will explore the rationale behind the treatment, negative automatic thoughts, and emotional inhibitions. Sessions 2 to 6 will focus on addressing dysfunctional thoughts and attitudes related to celiac disease. The final two sessions will involve the implementation of cognitive behavioral therapy techniques, such as creating flashcards to reinforce positive thoughts, and developing a plan to prevent relapse

Category
Treatment - Other

2

Description
Intervention group: The cognitive behavioral therapy will be based on mindfulness and will consist of 4 sessions, each lasting 75 minutes, with one session per week. In the first session, the therapist will introduce the treatment process and teach clients muscle relaxation and physical awareness. The second session will focus on teaching breathing mindfulness and discussing any obstacles to mindfulness with the clients. The third session will involve teaching and practicing physical examination while reviewing homework. The final session will include practicing silence and immobility exercises, as well as evaluating the progress of the treatment.

Category
Treatment - Other

3

Description
Control group: Waiting list. Patients in this group do not receive any therapy.

Category
Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Taleghani Hospital

Full name of responsible person
Shahab lotfinia

Street address
Ayatollah Taleghani Hospital, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

City
Tehranلیست انتظار. بیماران این گروه هیچ گونه درمانی دریافت نمی کنند.

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1985711151

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taleghanihospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Afshin Zarghi

Street address
No.2 Shahid Beheshti University of Medical science, Arabi Ave, Daneshjoo Blvd, Velenjak, Tehran, Iran

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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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Shahab Lotfinia

Position

PhD Student

Latest degree

Master

Other areas of specialty/work

Psychology

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Person responsible for scientific inquiries

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Position

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Latest degree

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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