

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Jun 2026

Comparison of the effectiveness of mindfulness-based cognitive therapy (MBCT) and acceptance and commitment therapy (ACT) on psychological indicators (perceived stress and perception of disease) and adherence to treatment and the level of liver enzymes in non-alcoholic fatty liver patients (by controlling the amount of exercise)

Protocol summary

Study aim

The effectiveness of mindfulness-based cognitive therapy and acceptance and commitment therapy on perceived stress and perception of disease in non-alcoholic fatty liver disease

Design

The statistical population consisted of 30 people who referred to the clinic and diagnosed non-alcoholic liver disease by liver and gastroenterologist who were volunteered to participate in the intervention and randomly divided into three experimental groups, one and two, and a control group will be employed

Settings and conduct

In this study there are two intervention groups and one control group. All three groups receive medical interventions, but the two experimental groups also receive psychological interventions (mindfulness-based cognitive therapy and acceptance and commitment therapy).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having liver enzymes twice as likely as usual, increased volume of liver on ultrasound standards, not receiving other psychological treatments, detection of fatty liver by gastroenterologist and liver. Exclusion criteria: Having alcohol addiction or hormone-mediated substances Being treated with steroids Treated with antipsychotics or lithium intake.

Intervention groups

Intervention group (1): This group participates in mindfulness-based cognitive therapy for 10 sessions, which is a total of 20 hours. Intervention group (2): This group participates in acceptance and commitment therapy for 10 sessions, which is a total of 20 hours. Control group: psychological intervention will not be

implemented.

Main outcome variables

Having liver enzymes twice as normal, Motivational beliefs in patients with non-alcoholic fatty liver, Effectiveness of third-generation cognitive-behavioral interventions on psychological and biological indices of fatty liver in patients undergoing experimental semi-

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181215041973N1**

Registration date: **2019-01-31, 1397/11/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-01-31, 1397/11/11**

Update count: **0**

Registration date

2019-01-31, 1397/11/11

Registrant information

Name

Ali Hosein zاده ghasem abbad

Name of organization / entity

The university of payam noor

Country

Iran (Islamic Republic of)

Phone

+98 34 3424 2191

Email address

arefmobin74@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-06-29, 1397/04/08

Expected recruitment end date

2019-03-11, 1397/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of mindfulness-based cognitive therapy (MBCT) and acceptance and commitment therapy (ACT) on psychological indicators (perceived stress and perception of disease) and adherence to treatment and the level of liver enzymes in non-alcoholic fatty liver patients (by controlling the amount of exercise)

Public title

The effect of two psychological interventions, mindfulness-based cognitive therapy and acceptance and commitment therapy in people with non-alcoholic fatty liver

Purpose

Education/Guidance

Inclusion/Exclusion criteria

Inclusion criteria:

Having liver enzymes twice as likely as usual Increased volume of liver on ultrasound standards Not receiving other psychological treatments Diagnosis of fatty liver disease by gastroenterologists and liver

Exclusion criteria:

Having alcohol addiction or hormone-mediated substances Being treated with steroids Treated with antipsychotics or lithium intake

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **30**

Actual sample size reached: **15**

Randomization (investigator's opinion)

N/A

Randomization description

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

The Ethics Committee of Payam Noor University of the whole country

Street address

Olive Blvd. Township Sunshine Alley No. 5

City

Rafsanjan

Province

Kerman

Postal code

7719757356

Approval date

2018-12-29, 1397/10/08

Ethics committee reference number

IR.PNU.REC.1397.047

Health conditions studied

1

Description of health condition studied

Non alcoholic fatty liver

ICD-10 code

K 76.0

ICD-10 code description

Non alcoholic fatty liver disease

Primary outcomes

1

Description

Treatment for patients with non-alcoholic fatty liver

Timepoint

Pre test, post test. Follow-up two half months

Method of measurement

Follow-up Morris's Revised Treatment Questionnaire and Kuhn's Perceived Stress Scale

Secondary outcomes

1

Description

Perceived Stress

Timepoint

Pre-test, post-test, follow up two half months

Method of measurement

Revised Morischi Questionnaire

Intervention groups

1

Description

Intervention group 1: This group participates in mindfulness-based cognitive therapy for 10 sessions, which is a total of 20 hours.

Category

Treatment - Other

2

Description

Intervention group 2: This group participates in acceptance and commitment therapy for 10 sessions, which is a total of 20 hours.

Category

Treatment - Other

3

Description

Control group: psychological intervention will not be implemented.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mehrad Tehran Gastroenterology Clinic

Full name of responsible person

Ali Hosseinzadeh Ghasem Abad

Street address

Professor Motahari Street - Miremad Street - Corner of 6th Alley

City

Tehran

Province

Tehran

Postal code

1587963111

Phone

+98 21 8874 7401

Email

info@mehradgeneralhospital.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Payam Noor University of the whole country

Full name of responsible person

Ali Hosseinzadeh Ghasem Abad

Street address

Central organization of Payame Noor University,

Artesh Blvd

City

Tehran

Province

Tehran

Postal code

1455643183

Phone

+98 21 2244 2060

Email

info@pnu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Payam Noor University of the whole country

Proportion provided by this source

20

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

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Payam Noor university of Tehran

Full name of responsible person

Ali Hosseinzadeh Ghasem Abad

Position

Ph.D Student, Psychology of Health

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Alley No. 5, Aftab Town, Zayton Blvd

City

Rafsanjan

Province

Kerman

Postal code

7719757356

Phone

+98 34 3424 2191

Email

arefmobin74@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Payam Noor University of Tehran

Full name of responsible person

Mohammad Oruki

Position

Associate Professor of Psychology

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

Street address

Center of South Tehran, Payam Noor university,
Nejatollahi Street

City

Tehran

Province

Tehran

Postal code

1598686613

Phone

+98 21 8422 4000

Email

m.oraki@pnu.ac.ir

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

Payam Noor university of Tehran

Full name of responsible person

Ali Hosseinzadeh Ghasem Abad

Position

Ph.D. student of psychology of health

Latest degree

Master

Other areas of specialty/work

Psychology

Street address

Alley No. 5, Aftab Town, Zayton Blvd

City

Rafsanjan

Province

Kerman

Postal code

7719757356

Phone

+98 34 3424 2191

Email

arefmobin74@yahoo.com

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