Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 zadeh 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