Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effects of the supplement supper food (NBS) on depression, anxiety, stress and weight in women with depression and overweight (or obesity) compared to control group

Protocol summary

Study aim
Promote clinical services to people with comorbidities, overweight/obesity, and depression

Design
A double-blind, randomized controlled clinical trial with parallel groups on 50 adult patients with overweight/obesity and depression. We use Excel software rand function for randomization.

Settings and conduct
The study site is a private weight loss clinic. Individuals 18 years of age and older who have been diagnosed with depression based on DSM 5 criteria will complete the DASS-21 Questionnaire, and Appetite Questionnaire, then standard body weight will be measured at the first visit after obtaining informed consent. They are then randomly divided into two groups receiving NBS or placebo superfood supplements. Assignment to groups is hidden from the researchers and patients by coding the NBS and placebo supplement groups.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age 18 to 50 years, overweight or obesity, diagnosis of depression based on DSM-5 criteria, signing of the consent form Not inclusion criteria: People taking antidepressants. also, severe depression, psychotic depression or suicidal ideation, taking glucocorticoids and steroidal anti-inflammatory drugs, people who take medicine to reduce appetite or weight, people with diabetes who are taking medication or insulin, people with heart disease or hypercholesterolemia who take drugs (stein, fibrates, diuretics), contraceptive hormones, pregnancy and lactation, menopause, severe mental disorders, bipolar and schizophrenia and ..., hypothyroidism

Intervention groups
Intervention group: 5 g daily dietary supplement of wheat germ powder (produced by Super Food NBS) Control group: 5 g of wheat germ placebo powder daily (produced by Super Food NBS)

Main outcome variables
body weight, depression score, appetite

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140203016465N7**
Registration date: **2021-01-29, 1399/11/10**
Registration timing: **retrospective**

Last update: **2021-01-29, 1399/11/10**
Update count: **0**

Registration date
2021-01-29, 1399/11/10

Registrant information

Name
Seyed-Ali Mostafavi

Name of organization / entity
Psychiatry Research Center/ Tehran University of Medical Sciences

Country
Iran (Islamic Republic of)

Phone
+98 21 5542 2002

Email address
mostafavi_a@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-04-08, 1399/01/20

Expected recruitment end date
2021-01-09, 1399/10/20

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating the effects of the supplement supper food (NBS) on depression, anxiety, stress and weight in women with depression and overweight (or obesity) compared to control group

Public title
The effect of superfood (NBS) on depression, anxiety, stress and weight
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18 to 50 years overweight or obesity diagnosis of depression based on DSM-5 criteria signing of the consent form
Exclusion criteria:
People taking antidepressants. Also severe depression, psychotic depression or suicidal ideation Taking glucocorticoids and steroidal anti-inflammatory drugs People who take medicine to reduce appetite or weight People with diabetes who are taking medication or insulin People with heart disease or hypercholesterolemia who take drugs (stein, fibrates, diuretics) Contraceptive hormones Pregnancy and lactation Menopause Severe mental disorders, bipolar and schizophrenia and ... Hypothyroidism
Age
From **18 years** old to **50 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: Simple randomization using a computer randomization method, in this method we randomly place each client in the intervention or control group Randomization unit: individual Randomization tool and randomization sequence: determined by excel software and RAND Function How to hide allocation concealment: The type of treatment allocated in the two groups is completely unpredictable. Assignment to groups is also hidden from the researcher and patients by coding the NBS supplement and placebo groups.
Blinding (investigator's opinion)
Triple blinded
Blinding description
This clinical trial is planned so that the participant does not know which of the two groups of placebo or the main supplement belongs by coding the supplement and placebo. Also, the clinician, researcher, outcome evaluator, and data analyst do not have any information about the individuals in the placebo and main supplement groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tehran University of Medical Sciences
Street address
No. 1, Ghods Street, Keshavarz Avenue, Tehran. Iran
City
Tehran
Province
Tehran
Postal code
1417653911
Approval date
2019-12-12, 1398/09/21
Ethics committee reference number
IR.TUMS.VCR.REC.1398.703

Health conditions studied

1

Description of health condition studied
Mild Depression
ICD-10 code
F32.0
ICD-10 code description
Major depressive disorder, single episode, mild

2

Description of health condition studied
moderate depression
ICD-10 code
F32.1
ICD-10 code description
Major depressive disorder, single episode, moderate

3

Description of health condition studied
obesity
ICD-10 code
E66.0
ICD-10 code description
Obesity due to excess calories

Primary outcomes

1

Description
Depression score in depression anxiety stress scale-21 (DASS-21) questionnaire
Timepoint
Baseline, week 4, and week 8
Method of measurement
depression anxiety stress scale-21 (DASS-21) questionnaire

2

Description
weight
Timepoint
Baseline, week 4, and week 8
Method of measurement
Standard scales

Secondary outcomes

1

Description
anxiety scored by depression anxiety stress scale (DASS-21)
Timepoint
at baseline, week 4, and week 8
Method of measurement
Depression anxiety stress scale (DASS-21)

2

Description
Stress score by depression anxiety stress scale (DASS-21)
Timepoint
at baseline, week 4, and week 8
Method of measurement
Depression anxiety stress scale (DASS-21)

Intervention groups

1

Description
Intervention group: daily, 5 grams of wheat germ powder supplement (produced by Super Food NBS)
Category
Other

2

Description
Control group: 5 grams placebo of wheat germ powder (produced by Super Food NBS)
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Weight loss clinic
Full name of responsible person
Seyed-Ali Mostafavi
Street address
No. 1, Second Floor, Majd Street, East Sarv Boulevard, Kaj Square, Saadat Abad, Tehran, Iran
City
Tehran
Province
Tehran
Postal code
1333795914
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mostafavi_a@sina.tums.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Dr. Sahraeian
Street address
Psychiatry and Psychology Research Center, Roozbeh Hospital, South Kargar Street, Tehran, Iran
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Tehran
Province
Tehran
Postal code
1333795914
Phone
+98 21 5541 3540
Email
pprct@tums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source
Psychiatry and Psychology Research Center
Proportion provided by this source
50

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

2

Sponsor
Name of organization / entity
NBS Company
Full name of responsible person
Aref Khalkhali
Street address
No. 94, 7th Baharestan St., Fakoori Blvd., Mashhad, Iran
City
Mashhad
Province
Razavi Khorasan
Postal code
1333795914
Phone
+98 51 3868 5721
Email
arfkhlkhaly@gmail.com
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
NBS Company
Proportion provided by this source
50
Public or private sector
Private
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
Tehran University of Medical Sciences
Full name of responsible person
Seyed-Ali Mostafavi
Position
Assistant professor
Latest degree
Ph.D.
Other areas of specialty/work
Nutrition
Street address
Psychiatric Research Center, Roozbeh Hospital, South Kargar Street, Tehran, Iran
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Person responsible for scientific inquiries

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Person responsible for updating data

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Position
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Other areas of specialty/work
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mostafavi_a@sina.tums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
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 is potentially shareable after individual identifications being removed
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
The analyzes used in the article are allowed on the delivered data.
From where data/document is obtainable
Requests for data/documentation should only be sent via email to the developer. Responsible person: Dr. Seyed Ali Mostafavi E-Mail: Mostafavi_a@sina.tums.ac.ir
What processes are involved for a request to access data/document
After receiving the email requesting documents or data files, this information will be sent to the requesting email as soon as possible.
Comments