Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating the effects of the NBS super-food dietary supplement on the symptoms of hyperactivity, attention deficiency, and appetite in adults with ADHD compared to placebo

Protocol summary

Study aim
Determining the effects of the super-food NBS supplement on the symptoms of hyperactivity and attention deficit hyperactivity disorder in adults with ADHD Determining the effects of the super-food NBS supplement on appetite in adults with ADHD

Design
A controlled clinical trial, with parallel, double-blind, randomized groups, on 50 adult patients with ADHD. We use the rand function in excel software for randomization.

Settings and conduct
The study site is a child and adolescent psychiatric clinic. 18 years and older Individuals who have been diagnosed with ADHD based on DSM 5 criteria and SADS diagnostic interview will complete the ADHD questionnaire and appetite questionnaire at the first visit after obtaining informed and free consent to participate in the study. Then they are randomly divided into two groups of super-food NBS or placebo. The psychiatrist's treatment of choice is not interrupted during the study. Assignment to groups is blinded to the researchers and patients by coding the NBS supplement and the placebo groups.

Participants/Inclusion and exclusion criteria
- Inclusion criteria: Diagnosis of ADHD by a psychiatrist based on DSM-5 diagnostic criteria, age 18 years and older - Non-inclusion criteria: celiac disease, dissatisfaction to participate in the study

Intervention groups
In the intervention group, 5 grams of wheat germ powder supplement (produced by Super Food NBS) will be received daily. In the control group, 5 grams of placebo similar to wheat germ powder (produced by Super Food NBS) is received daily.

Main outcome variables
Symptoms of hyperactivity and inattention; Appetite

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20140203016465N6**
Registration date: **2020-08-02, 1399/05/12**
Registration timing: **registered_while_recruiting**

Last update: **2020-08-02, 1399/05/12**
Update count: **0**

Registration date
2020-08-02, 1399/05/12

Registrant information

Name
Seyed-Ali Mostafavi

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

Country
Iran (Islamic Republic of)

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+98 21 5542 2002

Email address
mostafavi_a@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-07-20, 1399/04/30

Expected recruitment end date
2020-12-11, 1399/09/21

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluating the effects of the NBS super-food dietary supplement on the symptoms of hyperactivity, attention deficiency, and appetite in adults with ADHD compared to placebo

Public title
Evaluating the effects of the NBS super-food on symptoms of ADHD

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Diagnosis of ADHD by a psychiatrist based on DSM-5 diagnostic criteria Age 18 years and above

Exclusion criteria:
Celiac disease Dissatisfaction with participation in the study

Age
From **18 years** old

Gender
Both

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 Randomization unit: individual Randomization tools and randomization sequences are determined by excel software. Allocation concealment: Allocation to groups is hidden from the researcher and patients by encoding the NBS supplement and placebo groups.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study is blinded and concealed from the participants, the principal investigator, the psychiatrist, the data collectors, and those evaluating the outcome by coding the NBS supplement and placebo groups.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-Chancellor in Research Affairs, 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.1398.702

Health conditions studied

1

Description of health condition studied
Attention-deficit hyperactivity disorders

ICD-10 code
F90

ICD-10 code description
Attention-deficit hyperactivity disorders

Primary outcomes

1

Description
Score of the Adult ADHD Self-Report Scale-V1.1 (ASRS-V1.1): Symptoms Checklist

Timepoint
Baseline, week 4, and week 8

Method of measurement
The adult attention deficiency/hyperactivity rating scale

Secondary outcomes

1

Description
Rating the appetite using the visual analogue scale

Timepoint
Baseline, week 4, week 8

Method of measurement
visual analogue scale for appetite

Intervention groups

1

Description
Intervention group: daily, 5 grams of wheat germ powder

supplement (produced by Super Food NBS)

Category

Treatment - Other

2

Description

Control group: daily, 5 grams placebo of wheat germ powder (produced by Super Food NBS)

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Private Child and Adolescent Psychiatry Clinic

Full name of responsible person

Mohammad Reza Mohammadi

Street address

No. 107, Second Floor, Aria Street, West Sarv Boulevard, Sarv Square, Saadat Abad, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Ameneh Ahmadi

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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

Other

2

Sponsor

Name of organization / entity

NBS Company

Full name of responsible person

Aref Khalkhali

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No. 94, 7th Baharestan St., Fakoori Blvd., Mashhad, 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

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

Industry

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
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
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