Purpose

Subjects will answer the following questionnaire and tests:

- Symptom severity and improvement will be measured using ADHA Rating scale IV (ADHD RS)
- Demographic Questionnaire - composed by the researchers
- Family Eating Habits Questionnaire (FEAHQ-33)
- Food Frequency Questionnaire (FFQ)
- Test MOXO

The subjects will take the study product for six months.

After six months the subject will fill once again all the questionnaires.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Attention Deficit Hyperactivity Disorder (ADHD)</td>
<td>Dietary Supplement: Probiotic Dietary Supplement: Placebo</td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design: Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Official Title: A Double-Blind Placebo Controlled Study of Probiotic Supplement as Treatment for Students With Attention Deficit Hyperactivity Disorder (ADHD)

Resource links provided by NLM:
MedlinePlus related topics: Attention Deficit Hyperactivity Disorder Dietary Supplements
U.S. FDA Resources

Further study details as provided by Tel Hai College:

Primary Outcome Measures:
- Reduce symptoms of attention deficit measured by MOXO test [ Time Frame: Six month ]
  [ Designated as safety issue: No ]
After six month of treatment reduce symptoms of attention deficit will be measured by MOXO test

Estimated Enrollment: 80
Study Start Date: November 2016
Estimated Study Completion Date: November 2017
Estimated Primary Completion Date: November 2017 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Active Comparator: Probiotic</td>
<td>Dietary Supplement: Probiotic Probiotic</td>
</tr>
<tr>
<td>Probiotic capsules: two capsules twice a day</td>
<td></td>
</tr>
<tr>
<td>Placebo Comparator: Placebo</td>
<td>Dietary Supplement: Placebo Probiotics capsules without the active ingredient</td>
</tr>
<tr>
<td>Probiotic capsules without the active ingredient: two capsules twice a day</td>
<td></td>
</tr>
</tbody>
</table>

Detailed Description:
Computerized performance test MOXO - the test has been developed in Israel by Neurotech Company. The test's goal is to assess and define a participant's performance according to the four indices of Attention Deficit Hyperactivity Disorder: Attention, Hyperactivity, Impulsivity, and Timing with adjustment for age.

Subjects will answer the following questionnaire and tests:
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Demographic Questionnaire - composed by the researchers

Family Eating Habits Questionnaire (FEAHQ-33)

Food Frequency Questionnaire (FFQ)

Test MOXO
The subjects will take the study product for six months.
After six months the subject will fill once again all the questionnaires.

Eligibility

Ages Eligible for Study: 19 Years to 30 Years (Adult)
Genders Eligible for Study: Both
Accepts Healthy Volunteers: Yes

Criteria

Inclusion Criteria:

- Students registered in the college's Support Center for Students with Learning Disabilities and who have been diagnosed by a computerized didactic assessment -MATAL - as well as an attention diagnosis by a psychiatrist or a neurologist,
- Students who are not treated by medication or alternative treatment,
- Students who are not due to complete their education at Tel Hai College during the study period,
- Students who have signed on an informed consent form,
- No dairy intolerance (student can consume milk without any adverse effects),
- No soy allergy,
- Not currently taking any antibiotics or probiotics,
- Not pregnant or planning to become pregnant during the study period,
- Not been diagnosed with any of the following:
  - Cancer
  - HIV/AIDS
  - Crohn's disease
  - Ulcerative colitis
  - Immune compromised illness
  - Other serious illness

Exclusion Criteria:

- Students treated by any type of treatment for Attention Deficit Hyperactivity Disorder,
- Students who have not been assessed by MATAL and a psychiatrist,
- Students who take antibiotics.

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.
Please refer to this study by its ClinicalTrials.gov identifier: NCT02908802

Contacts

Contact: Snait Tamir, Professor   snait@telhai.ac.il

Sponsors and Collaborators

Tel Hai College

Investigators

Study Director:   Snait Tamir, Professor   snait@telhai.ac.il

More Information

Responsible Party:   Tel Hai College
ClinicalTrials.gov Identifier:   NCT02908802   History of Changes
Other Study ID Numbers:   40-16
Study First Received:   September 18, 2016
Last Updated:   September 20, 2016
Health Authority:   Israel: Israeli Health Ministry Pharmaceutical Administration

Individual Participant Data

Plan to Share IPD:   No

Additional relevant MeSH terms:
Attention Deficit Disorder with Hyperactivity   Dyskinesias
Hyperkinesis   Neurologic Manifestations
Attention Deficit and Disruptive Behavior Disorders   Nervous System Diseases
Neurodevelopmental Disorders   Signs and Symptoms
Mental Disorders

ClinicalTrials.gov processed this record on September 21, 2016