Efficacy of an anti-inflammatory diet on global functioning, gut microbiome and health of patients with schizophrenia spectrum disorder, bipolar disorder, Alzheimer*s disease or Parkinson*s disease: a randomized controlled trial

Published: 26-10-2021
Last updated: 15-05-2024

The primary objective is to investigate the potential effect of the AIDP on global functioning in patients with SSD, BD, AD, and PD. Secondary objectives are to investigate whether the AIDP has a beneficial effect on cognitive functioning, well-…

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52339

Source
ToetsingOnline

Brief title
No Guts No Glory dietary intervention

Condition

- Other condition
- Schizophrenia and other psychotic disorders

Synonym
Psychiatric and neurodegenerative disorders

Health condition

bipolaire stoornis; dementie door de ziekte van Alzheimer; de ziekte van Parkinson

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Groningen
Source(s) of monetary or material Support: Hersenstichting

Intervention

Keyword: brain disorders, Dietary intervention, general health, gut microbiome

Outcome measures

Primary outcome

Primary outcome is global functioning assessed with Outcome Questionnaire 45

(OQ45).

Secondary outcome

Secondary outcomes are global functioning (assessed with Global Assessment of

Functioning, (GAF), and Individual Recovery Outcomes Counter (I.ROC)),

cognitive functioning (Brief Assessment of Cognition (BAC), Stroop Task and

Trail making task), well-being (Health-related quality of life assessed with

EuroQoL 5D, EQ-5D), and fatigue (Short Fatigue Questionnaire, SFQ).

Furthermore, we will assess various immunological and inflammation parameters

(in blood), gut health (intestinal permeability with biomarkers in blood and

gut microbiome composition and metabolomics in faeces samples), and GI symptoms

(Gastrointestinal Symptom Rating Scale, GSRS + Bristol Stool chart).

Additionally, we will examine general physical health (Body Mass Index, BMI),

metabolic syndrome features (waist and hip circumference, blood pressure, glucose and triglycerides), and physical activity (using the BAECKE questionnaire). We also assess disease-specific symptom severity (for SSD and BD the Brief Psychiatric Rating Scale (BPRS); for AD Instrumental Activity of Daily Living Questionnaire (IADL); and for PD Movement Disorders Society Unified Parkinson Disease Rating Scale (MDS-UPDRS) part III (motor examination) and Non-Motor Symptom Questionnaire, NMSQ). Furthermore, in the BD and SSD groups we assess stress and stress resilience using the short version of the Childhood Trauma Questionnaire (CTQ-SF), the Brugha List of Threatening Experiences, the 10-point version of the Perceived Stress Scale (PSS-10), and the Brief Resilience Scale (BRS), as well as by collecting heart rate variability (HRV) measures in rest using electrocardiography (ECG). Finally, as an optional measurement, we assess oral health, screened with an oral self-care questionnaire (OZ Pruntel), Oral Health Impact Profile questionnaire (OHIP), intra-oral photographs and by taking samples of the composition of the oral microbiome (by mouth rinse and swab).

Study description

Background summary

Schizophrenia spectrum disorders (SSD), bipolar disorder (BD), Alzheimer*s disease (AD), and Parkinson's disease (PD) are common brain disorders, which can severely affect patients* functioning and quality of life, with significant burden on global health. Although these four disorders are rather different, cognitive dysfunction and decreased mood are common in all four disorders. Another communality is that gastrointestinal (GI) symptoms are frequent in these disorders. Recent investigations have pointed to the gut-brain axis as a new venue for disease-modifying treatment of brain disorders, with increased

systemic inflammation stemming from increased intestinal permeability to affect brain functioning in a significant subset of patients. Gut health therefore opens a new therapeutic window, in which an anti-inflammatory dietary pattern (AIDP) may modify the course of brain disorders. By affecting the gut-brain axis, we expect direct effects on disability and symptoms of brain disorders, as brain homeostasis and plasticity may benefit from a lower inflammatory status. Reducing the body*s inflammatory status can also improve mood, cognition, well-being, stress and stress resilience, and oral health.

Study objective

The primary objective is to investigate the potential effect of the AIDP on global functioning in patients with SSD, BD, AD, and PD. Secondary objectives are to investigate whether the AIDP has a beneficial effect on cognitive functioning, well-being, fatigue, gut health (intestinal permeability and gut microbiome composition), in addition to GI symptoms, general health (BMI, somatic comorbidity, and presence and severity of metabolic syndrome features), disease-specific symptom severity, and stress and stress resilience. This project aims to provide a safe and well-tolerated dietary intervention to improve global functioning. Furthermore, knowledge will be gained on the oral health status and the composition of the oral microbiome in all diagnoses.

Study design

Randomized controlled open label trial with cross-over intervention of 12 weeks and wash-out period of 24 weeks.

Intervention

Per diagnostic group patients are 1:3 randomized to group 1 starting with the AIDP at baseline period 1, those randomized to group 2 will start the AIDP at week 36. Outcome measurements will be assessed at baseline period 1 (visit 1), week 12 (visit 2), 24 (visit 3), 36 (baseline period 2, visit 4), 48 (visit 5), and 60 (visit 6).

Study burden and risks

Participants will undergo the same measurements 6 times at home or at the UMC Groningen. Therewith they will face the (small) burden that comes with clinical visits, blood- and faeces sampling and filling out several questionnaires. The risk and burden from blood drawings are low (e.g., irritation/ hematoma). The burden and risks are considered to be acceptable, while the benefits are expected to be considerable, as both groups will receive the AIDP. Potential benefits may be higher quality of life, better well-being and general health. During the AIDP, participants will be provided with free nutrition during 12 weeks, which will be a considerable saving post for them.

For the participants in the BD and SSD groups, a baseline HRV measurement will be conducted during all measurements. The burden and risk for this measurement are considered quite low, as ECG is a non-invasive measurement method, the measurement including preparations takes 15 minutes on average, and the participant does not need to perform any task during the measurement. Besides the psychiatric and dietary assessments, an optional oral health assessment will be performed. The extra oral health assessments will be assessed only during the regular pre- and post-dietary intervention visits; for group 1 at visit 1 and 2, for group 2 at visit 4 and 5. The burden and risks are considered as low, while the benefit for the patients is that they will be informed about their oral health and that they will receive oral health care advice (recommendations will be given also on paper) when oral health is at risk or considered to be poor.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

In order to be eligible to participate in this study, a subject must meet all of the following criteria:
1. Clinical diagnosis made by medical specialist of schizophrenia, schizophreniform disorder, schizoaffective disorder, bipolar disorder type 1 or type 2, Alzheimer's disease or Parkinson's disease.
2. The participant is living in Drenthe, Friesland or Groningen.
3. The participant has the cognitive capacity* to understand what participation means, which is confirmed by clinical view of medical specialist. The participant is able and willing to provide IC.
4. Age between 18 and 80 years and sufficient command of the Dutch language.
5. Motivated and capable to use the dietary pattern (use food from the boxes) and participate in interview visits at home. The partner or other household members should support participation, or at least not be opposed to participation.
6. The participant has the ability to consume foods as prescribed, without religious, medical or sociocultural factors precluding participation or adherence to the diet.
7. The participant lives independently (not in nursing home etc.) and is willing and able to prepare fresh meals using standard kitchen equipment.

A participants legal capacity will be tested during the informed consent procedure and will be repeated halfway through the study (during the washout period, visit 3)
When a participant is or becomes incapable during the study, he/she will be excluded from further participation.

Exclusion criteria

If a potential subject meets any of the following criteria participation is not possible:
1. Pregnancy or breast-feeding (or foreseen pregnancy during study period).
2. Severe under- or overweight needing medical treatment (evaluated by GI specialists).
3. Severe bowel or liver diseases or acute/chronic pancreatitis (evaluated by GI specialists).
4. Impossible to consume exclusively delivered products due to medical reasons (e.g. allergy for nuts or other nutrients), following a special diet that cannot be combined with AIDP (e.g. for diabetes or food intolerance) or certain food preferences (e.g. vegan diet, vegetarian, or don*t eat fish).
5. Already consuming an AIDP on own initiative (evaluated with Dutch Healthy Diet-Food Frequency Questionnaire (DHD-FFQ)).
6. Current use of antibiotics (or less than 4 weeks ago), regular use of

probiotics (i.e. Yakult, Vifit, Activia) or specific prebiotics supplements and are not willing to refrain 6 weeks prior to the start of and during the entire study.

Study design

Design

Study phase:	3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	07-03-2022
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	26-10-2021
Application type:	First submission
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)
Approved WMO Date:	23-11-2022
Application type:	Amendment
Review commission:	BEBO: Stichting Beoordeling Ethiek Bio-Medisch Onderzoek (Assen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

ID: 20827
Source: Nationaal Trial Register
Title:

In other registers

Register	ID
CCMO	NL78755.056.21
OMON	NL-OMON20827