No Guts No Glory dietary intervention

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We hypothesise that an anti-inflammatory dietary pattern (AIDP) has a beneficial effect on gut microbiome (diversity and permeability), thereby improving global functioning (measured with Outcome Questionnaire 45, OQ-45), and health of patients with...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Manic and bipolar mood disorders and disturbances
Study type	Interventional

Summary

ID

NL-OMON20827

Source
NTR

Brief title
NGNG

Condition

- Manic and bipolar mood disorders and disturbances

Health condition

schizophrenia spectrum disorders bipolar disorder Parkinson's disease

Research involving
Human

Sponsors and support

Primary sponsor: de Hersenstichting
Source(s) of monetary or material Support: Hersenstichting

Intervention

- Food (substances)

Explanation

Outcome measures

Primary outcome

Primary outcome is global functioning assessed with Outcome Questionnaire 45 (OQ-45).

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), 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 three disorders are rather

different, cognitive dysfunction and decreased mood are common in all three 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 and well-being.

Study objective

We hypothesise that an anti-inflammatory dietary pattern (AIDP) has a beneficial effect on gut microbiome (diversity and permeability), thereby improving global functioning (measured with Outcome Questionnaire 45, OQ-45), and health of patients with schizophrenia spectrum disorder, bipolar disorder, or Parkinson's disease <

Study design

Randomized controlled open label trial with cross-over intervention of 12 weeks and wash-out period of 24 weeks. Baseline first intervention period (week 1), end of intervention period 1 (week 12), follow-up intervention period 1 in wash-out (week 24), baseline second intervention period (week 36), end of intervention period 2 (week 48), and follow-up intervention period 2 (week 60).

Intervention

Anti-inflammatory dietary pattern

Contacts

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Eligibility criteria

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

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:	2-3
Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

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

IPD sharing statement

Plan to share IPD: Undecided

Ethics review

Approved WMO

Date:	26-10-2021
Application type:	First submission
Review commission:	Stichting Beoordeling Ethiek Biomedisch Onderzoek Dr. Nassaulaan 10 9401 HK Assen 059 2405871 info@stbebo.nl

Study registrations

Followed up by the following (possibly more current) registration

ID: 52339
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL9851
CCMO	NL78755.056.21
OMON	NL-OMON52339

Study results