GOSAT: The role of Galacto-oligosaccharides (GOS) in the recovery from dysbiosis in patients on long-term atypical antipsychotic treatment

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Ethical review	Approved WMO
Status	Recruiting
Health condition type	Schizophrenia and other psychotic disorders
Study type	Interventional

Summary

ID

NL-OMON53429

Source
ToetsingOnline

Brief title
Prebiotics among users of atypical antipsychotics

Condition

- Schizophrenia and other psychotic disorders

Synonym
dysbiosis; upset bowels

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Campina,FrieslandCampina

Intervention

Keyword: atypical antipsychotics, dysbiosis, prebiotics, psychiatric patients

Outcome measures

Primary outcome

The primary endpoint is the change in Bifidobacteria in fecal samples from week 0 to week 6.

Secondary outcome

The secondary objective is to assess the effects of GOS on mental wellbeing (i.e., Depression Anxiety Stress Scale (DASS-21), self-rated health (SRH), Quality of life (EQ-5D), Social Dysfunction and Aggression Scale (SDAS), happiness, Patient Health Questionnaire (PHQ), and Clinical Global Impression (CGI)), and sleep (i.e., Insomnia Rating Scale (IRS)), and metabolic parameters (i.e., waist circumference (WC), systolic and diastolic blood pressure, body mass index (BMI), and waist-to-hip ratio (WHR)). We hypothesize that GOS+2*FL supplementation will improve gut health, and mental wellbeing, sleep, and metabolic parameters. Other outcomes that are assessed include the FiberScreen tool, the form of human faeces (Bristol Stool Chart), side effects and the defined daily dosis (DDD) of antipsychotic medication.

Study description

Background summary

Atypical antipsychotic (AAP) drugs are the gold-standard treatment for psychotic patients but are nowadays also widely prescribed among people with

other mental disorders (Morrens, Destoop, Cleymans, S, & Dom, 2015). Notwithstanding the benefits of AAP in terms of symptom improvement, there are severe adverse effects including the metabolic syndrome (van Alphen et al., 2012). A novel hypothesis is that part of these undesirable effects of antipsychotics could be mediated by their deleterious effects on the microbiome (Maier et al., 2018). This may result in dysbiosis, the disruption of bacterial species of the gut microbiota. Recently, dysbiosis has been linked to poor quality of life, depression and anxiety through the gut-brain axis (Valles-Colomer et al., 2019). Mounting evidence proposes that prebiotic consumption may be helpful in the recovery of dysbiosis, although this effect is unclear among long-term antipsychotic users.

Study objective

The main objective of this study is to assess the potential beneficial effects of the prebiotic Galacto-oligosaccharides (GOS) in combination with 2*-fucosyllactose (2*-FL) on the gut microbiota, by showing a relative increase in Bifidobacteria in fecal samples following intervention.

Study design

The study is a single-arm pilot study (non-randomized and non-blinded).

Intervention

Following a run-in period of 4 weeks (no intervention but all other aspects of the study), the participants will consume GOSplus (7.0 g BiotisTMGOS + 0.7 g 2*-FL) daily during the first consumption moment of the day (preferably in the morning) for 42 days.

Study burden and risks

Patients who wish to participate fill out questionnaires (30 min) at 5 points (t0, t1, t2, t3, and t4). Also, we collect data via sampling of feces, measurements of weight, height and waist circumference (20 min). Data collection will take a maximum of 60 minutes per measurement moment and take place where the participants receive care. Based on literature, GOSplus is safe to use, however the participants can experience, often temporary, some flatulence and bloating as is often seen with prebiotic consumption. Due to the potential of GOSplus to decrease stress, the quality of life and metabolic health may increase in the patients recruited for this study.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

• age between 18 - 75 years • who receive atypical antipsychotic medication (>=0.5 defined daily dose [DDD], olanzapine, risperidone, clozapine, quetiapine, and aripiprazol) within the preceding eight weeks • who are overweight or obese (BMI >25 kg/m2)

Exclusion criteria

• pregnancy
• breastfeeding
• expected discharge or transfer within 10 weeks
• contra-indication for prebiotics
• continuous use of pre-, pro-, or synbiotics (within the preceding 4 weeks)

• recent (8 week) use or continuous use of antibiotics
• cow's milk allergy/lactose intolerance

Study design

Design

Study type: Interventional

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	29-11-2023
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	29-08-2023
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-10-2023
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	25-03-2024

Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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

No registrations found.

In other registers

Register	ID
CCMO	NL81636.058.22