Multiple n-of-1 self-investigation observational studies with patient-chosen products targeting the gut ecosystem to reduce chronic fatigue

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Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON48285

Source
ToetsingOnline

Brief title
MyOwnResearch (MORe)

Condition

- Other condition

Synonym
chronic diseases

Health condition

chronische ziekten met vermoeidheid en darmklachten

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Biovis,Microbiome Center NL,Nutricia,SGF;Health Holland;8 gezondheidsfondsen;zie aanbiedingsbrief,Springfield Nutraceuticals,Winclove probiotics BV

Intervention

Keyword: chronic diseases, fatigue, intestinal health, single subject research design

Outcome measures

Primary outcome

This observational study will generate knowledge on the individual and across-subjects effectiveness of self-chosen products targeting the gut ecosystem on chronic fatigue. In addition, it will gather valuable data that can be analyzed further to test and generate new hypotheses on biological mechanisms in chronic fatigue (e.g., gut microbiota, barrier and immunological function).

Secondary outcome

The study will also collect data (via EMA diaries) about complaints that the patient determines individually (eg about sleepiness, mood, etc.).

Study description

Background summary

Fatigue is commonly reported by many patients suffering from different chronic (immune) disorders and reduces quality of life of these patients to a large degree. Fatigue is regarded the result of a patient-specific complex interplay of psychosocial, lifestyle and biological (e.g., immunological) factors, and the effects of current treatment options are considered suboptimal. Current

needs of these patients are therefore unmet and alternative avenues to improve patient quality of life are desirable. Starting point for the current study is a direct link that has been found between the gut ecosystem (the gut microbiota in interaction with host immune characteristics) and chronic fatigue. We focus on fatigue in patients with a chronic (immune) disorder. For these patients, the gut ecosystem is an interesting and relevant therapeutic target with the expectation that manipulation of the gut microbiota and improving barrier function may help to alleviate chronic fatigue.
Because of large interpersonal variation in gut microbiota, manipulating the gut ecosystem is believed to have different effects in individual patients. Therefore, effectiveness of manipulating the gut ecosystem on chronic fatigue is preferably studied with a n-of-1 study approach (i.e., an idiographic approach). This approach also addresses the strong desire of patients suffering from chronic fatigue to self-investigate self-chosen products that may reduce fatigue complaints in the context of their own daily life. The current observational study will empower these patients to conduct self-investigation of the individual effectiveness of self-chosen products targeting the gut ecosystem. This study further involves a general practitioner (GP)-supported infrastructure for data collection, data analysis and interpretation, and data sharing.
In addition to idiographic analyses, a multiple n-of-1 approach also allows statistical analyses at the group level (i.e., testing the mean effect on fatigue across-subjects, denoted as a nomothetic approach). This approach will help to answer the question whether or not the use of self-chosen products targeting the gut ecosystem helps to reduce fatigue complaints across subjects. In the current study, analysis across subjects also involves analyses of scores of validated questionnaires and of pre-defined biological markers that are regarded indices of possible predictive or mediating factors of chronic fatigue. Finding (1) a mean effect across subjects during use of self-chosen products targeting the gut ecosystem on the scores of validated questionnaires and biological markers, and (2) an association between individual differences in reduction of fatigue and changes in specified biological markers, might indicate involvement of a biological mechanism.

Study objective

The objective of this study is: (1a) to investigate the individual perceived effectiveness of a self-chosen product targeting the gut ecosystem with the assumption that this may reduce fatigue in the individual patient with a chronic (immune) disorder, (1b) to assess the effectiveness of the use of products targeting the gut ecosystem on fatigue in patients with chronic (immune) disorder as a group, and (1c) to determine (across subjects) to what extent a reduction in fatigue can be associated with changes in biological markers that are hypothesized to have mechanistic relevance.

Study design

Multiple n-of-1 self-investigation observational studies with patient-chosen products.

Study burden and risks

The burden placed upon the patient by this study is that s/he adheres to a standardized measurements protocol during a 4 weeks baseline period, 8 weeks of using the self-chosen product, and 4 weeks wash-out. In this protocol, patients are asked to complete the intake questionnaire online, to complete a set of validated questionnaires online for four times, and to complete the web-based dietary recall tool three times. Patients are further enrolled in Ecologic Momentary Assessment (EMA) for tracking of their symptoms. EMA is a methodology with high-frequency assessment (i.e., several times per day) using the mobile phone. EMA provides real-time, ecologically valid (i.e. applicable in actual daily life) data in a minimally invasive or burdensome manner, taking less than a minute per assessment. This involves a small set of standard EMA questions that apply to all participants (e.g., fatigue) and several self-selected questions on symptoms or lifestyle factors that a patient hopes the product is helpful for. EMA produces intensive longitudinal idiographic data. Based on the results of single subject time series analysis, each patient will be able to evaluate a reduction in symptoms during the use of a self-chosen product. EMA starts immediately after intake and informed consent and continues during the baseline, product use, and wash-out. The patient receives personal EMA app results a few weeks afterwards. Finally, blood, saliva, and feces samples are provided by the patients at the start and end of baseline and at the end of product use.
Risks are considered minimal; except for blood draws, all assessments are non-invasive, and involves monitoring the perceived benefits of using food supplements that are approved for general use. Blood draws will be conducted by certified personnel. The assessment and data storage protocol is audited by the data safety officer of the AMC and the Clinical Research Unit (CRU) of Amsterdam UMC.
Patients benefit from participation in this study because it will provide detailed and standardized information on the perceived benefit of product use for de individual patient. In additional benefit is provided by the fact that data sharing will inform other patients on effects and benefits (or lack thereof) of a particular product. Further, post-hoc analyses of the data made available through self-analyses may improve product choice and development to better target the needs of the individual patient.

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

1. Patients are diagnosed with chronic (immune) disorder; a chronic immune disease should be currently in remission/non active as determined by the GP (or medical specialist).
2. Report significant fatigue (score ><=18), as measured by the Short fatigue questionnaire (4 questions).
3. Report persistent intestinal complaints, as measured by the IBS SSS for abdominal complaints (5 questions, score ><=175).

Exclusion criteria

1. Changes of medication or diet in the previous 3 months or during the course of the study, e.g., attending a weight loss program or changing to a vegetarian or vegan diet, or initiating new food supplements (including pro or prebiotics).
2. Current exacerbation of their chronic immune disease.
3. Excessive alcohol intake, defined as drinking more than 21 glasses of alcohol per week.
4. History of drug abuse or addiction.

5. Antibiotic use 6 months prior to the study.
6. Age below 18 or above 70 years. The upper limit of age is chosen since it is known that de immune system changes drastically above this age and this might affect the results of the study.
7. Pregnancy.
8. No access to internet and/or not using an iPhone or Android phone.

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Health services research

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	500
Type:	Anticipated

Ethics review

Not approved

Date:	03-10-2019
Application type:	First submission
Review commission:	METC Wageningen Universiteit (Wageningen)

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	NL71615.081.19