Homogeneous subgroup identification in fatigue management across chronic immune diseases through single subject research design (MyOwnResearch)

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To develop a new personalized assessment and analysis approach for identifying efficacy of self-care interventions (home-experimentation), focusing on food supplement use to reduce fatigue. This novel approach is designed to empower patients in...

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

Summary

ID

NL-OMON48216

Source
ToetsingOnline

Brief title
MyOwnResearch

Condition

- Other condition

Synonym
chronic immune diseases

Health condition

chronische immuunziekten met vermoeidheids- en darmklachten

Research involving

Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Biovis,Microbiome Center,Nutricia,SGF en Health-Holland e.a. (zie aanbiedingsbrief),Springfield Neutraceuticals,Winclove

Intervention

Keyword: Chronic immune diseases, Fatigue, Intestinal health, Single subject research design

Outcome measures

Primary outcome

Patient partly self-selected end points (up to 5) which they will choose to score on a daily basis in an app. Also symptoms of fatigue and gastro-intestinal complaints will be measured by validated questionnaires, respectively the Verkorte Vermoeidheidsvragenlijst (VVV, abbreviated fatigue questionnaire), CIS20, IBS-SSS and GI-symptoms questionnaire. Primarily for diagnoses and treatment reasons blood, saliva and fecal samples will be collected both at the start and after intervention, which will be also used for further mechanistic research. We will study if there are shifts in the microbiota composition and changes in inflammatory cytokine levels that will provide us with possible (non) responder- specific biomarker profiles.

Secondary outcome

See primary endpoints.

Study description

Background summary

Patients with a chronic immune disease that have disease-overarching intestinal complaints and fatigue comprise a very heterogeneous population, that GP*s find very hard to help. Patients hence massively experiment at home with products available in the market to remediate their complaints. This study will be conducted to explore parameters that can define the responsiveness to self-care interventions of specific subgroups. This information can then be further examined in future clinical trials. In addition, we will learn if we can empower patients to become self-researchers as a large source of useful information for subgroup definition in order to conduct more efficient clinical trials in such heterogeneous patient populations in the future (see for a new social contract Vayena et al, 2016.
One of the most common burdens reported by chronic patients, and large numbers seek remediation for, is their lack of energy (fatigue). This lack of energy, or fatigue, is impairing optimal functioning in many domains of daily life. In a survey of the SGF, 85% of patients considered chronic fatigue the most relevant focus for future research. Many chronic diseases are associated with intestinal microbial dysbiosis and impaired intestinal barrier function resulting in a low grade systemic inflammation and intestinal complaints. Activation of the immune system (inflammation) is identified as a key determinant of disease-related fatigue caused by the neuro-active properties of signal molecules (i.e. cytokines) secreted by the immune system (gut-immune-brain axis). The immune system is a complex domain where many *agents* interact, modulating health and disease states over time. The correlation of the *fitness* or *health* of the immune system with other factors, such as psychosocial and lifestyle factors, is evident but has not yet been fully understood mechanistically.

Study objective

To develop a new personalized assessment and analysis approach for identifying efficacy of self-care interventions (home-experimentation), focusing on food supplement use to reduce fatigue. This novel approach is designed to empower patients in their capacity of citizen-scientists. Target group is patients with a chronic immune disease in remission/non active state who are bothered by fatigue- and intestinal complaints (the latter pre-selects patients with possible intestinal dysbiosis).
The second aim is to garner in-depth knowledge on mechanisms explaining individual response differences to self-care interventions that will be tested by the patients (i.e., standardized probiotic formulations, personalized pre- and probiotic formulations, food supplements) using multilayer network analyses/machine learning in order to determine complaints (i.e., varies per patient) and parameters that can distinguish specific defined subpopulations for targeted RCTs.

Study design

N=1 study. The duration of MyOwnResearch is approx. 12 weeks. The study starts with the subscription on the website. Part of the subscription is a brief screening that must indicate whether the subject fullfills all conditions for participation. Subjects that can participate, start with a preparatory period of 3 weeks. Thereafter the treatment period of 8 weeks will start. The subject will be treated with the study treatment that he/she has chosen.

Intervention

1. DJ Repair. This is a mixture of glutamine, zinc and N-acetyl-L-cystein (NAC).
2. Eight fixed mixtures of probiotics, prepared by the manufacturer to achieve predefined effects.
3. A mixture of well-known approved substances (like DJ Repair,and various probiotics) specially prepared for this subject. The personalized advice is from the Microbioom Center.

Study burden and risks

Minimal risks.
Burden:
3 visits to GP
Complete questionnaires via website, weekly
Complete dairy (complaints) (app), daily.
Laboratory tests (blood 30 ml, saliva, faeces), twice.
Take a supplement (oral), daily.

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. Age 18 years and above
2. Chronic immune disease, currently in remission/non-active
3. Significant fatigue, as measured by the Short Fatigue questionnaire
4. Persistent intestinal complaints, as measured by the IBS-SSS

Exclusion criteria

1. Changes of medication or diet in the previous 3 months or during the course of the study
2. Current exacerbation of chronic immune disease;
3. Excessive alcohol intake
4. History of drug abuse
5. Antibiotic use within 6 months prior to the study start
6. Pregnancy

Study design

Design

Study type: Interventional

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:	21-05-2019
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL68059.018.19