Oraal microbioom als marker voor chronische vermoeidheid en herstel

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON20156

Source
Nationaal Trial Register

Brief title
CVS-ACTA

Health condition

chronic fatigue syndrome

Sponsors and support

Primary sponsor: Faculteit der Maatschappij- en Gedragswetenschappen, Programmagroep: Clinical Psychology & Faculteit Tandheelkunde, Sectie: Preventieve Tandheelkunde
Source(s) of monetary or material Support: Eerste geldstroom onderzoek

Intervention

Outcome measures

Primary outcome

Oral microbiome

Secondary outcome

Fatigue, well-being, demographics, health and health behaviors

Study description

Background summary

The prevalence of individuals diagnosed with chronic fatigue syndrome without known organic cause approximates 2% (Johnston, Brenu et al. 2013), mounting to an estimated 250.000 adults afflicted with this condition in the Netherlands alone. Objective biological markers for diagnosis, early detection, or treatment efficacy are currently lacking. The oral microbiome provides a non-invasive, readily accessible source of potentially relevant biomarkers. The current study aims to determine;
1) if chronic fatigue in otherwise systemically healthy individuals is associated with distinguishable oral microbial eco-type, and
2) if oral microbial profile alters over the course of (successful) intervention to treat chronic fatigue.
For this purpose the oral microbiome will be assessed in 150 patients referred to the Nederlands Kenniscentrum Chronische Vermoeidheid (NKCV; Amsterdam UMC) pre- and post-treatment. Pre-treatment microbial profile will be compared to those of 100 healthy controls, i.e., without significant fatigue. Analyses will take potential confounding and moderation by life style and psychological factors into account.

Study objective

The present study will assess the composition of the oral microbiome in patients who have been referred to the NKCV (Nederlands Kenniscentrum Chronische Vermoeidheid) for treatment for complaints of severe and protracted fatigue. Objective biological markers for diagnosis, early detection, or treatment efficacy are currently lacking (Klimas, Broderick et al. 2012), and the oral microbiome provides a non-invasive, readily accessible source of potentially relevant biomarkers. While several studies have found dysbiosis (i.e., reduced microbial diversity and altered composition) in the gut microbiome of chronic fatigue patients (Giloteaux, Goodrich et al. 2016, Nagy-Szakal, Williams et al. 2017), the oral microbiome has not been assessed in this population. Hence, the current exploratory analyses had 3 main objectives: The first objective was to determine if composition of the oral microbiome can be used to differentiate chronic fatigue patients from non-symptomatic controls (i.e., identifying distinguishable ‘ecotypes’) (Zaura, Brandt et al. 2017). The second objective was to determine if such microbial parameters may predict treatment efficacy, i.e., reduction of symptoms of fatigue. For the present study patients will receive cognitive behavioral treatment (CBT) to alleviate fatigue, which is the main evidence-based effective treatment for chronic fatigue (Knoop, Prins et al. 2010). Approximately 70% of patients achieve a clinically relevant reduction of fatigue symptoms. However, substantial individual differences are apparent and there is currently little understanding on why some patients benefit from treatment more than others. Finally, the present analyses aimed to establish if improvements in symptomatology are paralleled by changes in the oral microbiome.

Study design

t = 0 (both NKCV patients and control group) and t= 12 months (only NKCV patients)

Intervention

No interventions: observational study of before and after 'usual care'

Contacts

Public
ACTA
Dr. C.M.C. Volgenant

+31205980596
Scientific
ACTA
Dr. C.M.C. Volgenant

+31205980596

Eligibility criteria

Inclusion criteria

age > 18
proficiency in Dutch language
reporting significant fatigue as determined by a score of ≥35 on the fatigue severity subscale of the Checklist Individual Strength (a CIS-20), whereby symptoms are experienced for at least 6 months as established by self-report

Exclusion criteria

smoking
currently being diagnosed with a co-morbidity that may explain the presence of severe fatigue, including major depressive disorder or other psychiatric disorder;
receiving psychotherapeutic treatment other than provided by the NKCV

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	12-11-2018
Enrollment:	250
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion

Date:	05-02-2019
Application type:	First submission

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
NTR-new	NL7516
Other	METC AMC : W18_347 # 18.404

Study results