Oraal microbioom als marker voor chronische vermoeidheid en herstel

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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...

Ethische beoordeling	Positief advies
Status	Werving gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON20156

Bron
Nationaal Trial Register

Verkorte titel
CVS-ACTA

Aandoening

chronic fatigue syndrome

Ondersteuning

Primaire sponsor: Faculteit der Maatschappij- en Gedragswetenschappen, Programmagroep: Clinical Psychology & Faculteit Tandheelkunde, Sectie: Preventieve Tandheelkunde
Overige ondersteuning: Eerste geldstroom onderzoek

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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.

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

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

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	Actieve controle groep

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	12-11-2018
Aantal proefpersonen:	250
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	05-02-2019
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL7516
Ander register	METC AMC : W18_347 # 18.404

Resultaten