A study focused at identifying disrupted biological factors and patient-tailored interventions for adolescents with Q-Fever Fatigue Syndrome

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Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON24476

Bron
NTR

Verkorte titel
QFS

Aandoening

Q-fever fatigue syndrome (QFS), Juvenile Idiopathic Arthritis (JIA) and Chronic Fatigue Syndrome (CFS/ME).

Ondersteuning

Primaire sponsor: UMC Utrecht
Overige ondersteuning: ZonMw, projectnumber 50-53000-98-566

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Fatigue severity

Toelichting onderzoek

Achtergrond van het onderzoek

Severe debilitating fatigue is the dominant symptom of Q-fever fatigue syndrome (QFS). However, little research on QFS has been done in children and adolescents on pathogenesis or therapy. The proposed study integrates biology and a psychosocial approach to create an in-depth understanding of QFS. The first part of the study focuses on etiology, by exploring the biological profile (e.g. the immunological profile, HPA axis, mitochondrial dysfunctioning, the gut microbiome) of children and adolescents with QFS.
The second part of the study focuses on treatment of fatigue complaints, by comparing the effectiveness of a patient-tailored lifestyle advice and a generic dietary advice in a RCT. In recent literature, chronic fatigue is regarded as a generic instead of a disease-specific symptom. Fatigue is considered the result of a patient-specific complex interplay of psychosocial, lifestyle and biological factors, which calls for a comparable approach for various fatigue syndromes. Considering that QFS bears resemblance to the fatigue observed in chronic disorders such as Juvenile Idiopathic Arthritis (JIA) and Chronic Fatigue Syndrome (CFS/ME), the effectiveness of both advices will be evaluated in the RCT across the three patient groups.

Doel van het onderzoek

• Overall, the patient-tailored PROfeel lifestyle advice will be more effective in reducing patients' fatigue severity than the generic dietary advice.
• Overall, the patient-tailored PROfeel lifestyle advice will have a more positive effect on patients' self-efficacy than the generic dietary advice.
• Overall, the patient-tailored PROfeel lifestyle advice will have a more positive effect on patients' quality of life than the generic dietary advice.
• Subjects who show higher response to intervention, will also show more change in immunological profile.
• Subjects who show higher response to intervention, will also show more change in the HPA axis.
• Subjects who show higher response to intervention, will also show more change in mitochondrial dysfunction.
• Subjects who show higher response to intervention, will also show more change in metabolic dysfunction.
• Subjects who show higher response to intervention, will also show more change in the gut microbiome.

Onderzoeksopzet

5 in total (4 measurement points + 1 follow-up)

Onderzoeksproduct en/of interventie

1) Patient-tailored PROfeel lifestyle advices
2) Generic dietary advice

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

All subjects must meet the following criteria:
• Age of 12-25 years old
• Able to speak, read, understand and write Dutch

Inclusion criteria for QFS-patients:
• (Suspected) diagnosis with QFS according to the Dutch Guidelines.
• Fatigue lasting for at least 6 months.
• Debilitating fatigue, with detrimental effects on daily functioning (work and/or private situation).
• Seropositive for C. Burnetii.

• No diagnoses of chronic Q-fever, recent diagnostics (<3 months ago) showing a IgG fase 1 titer <1:1024 (or 1:512 in the case of immunocompromised patients or patients with vascular prosthesis or heart defect).
• No somatic of psychiatric comorbidity that can explain fatigue at baseline.
• No history of fatigue before infection with C. Burnetii, or fatigue critically increased in severity after infection with C. Burnetii.
• For CBT: Fatigue severity subscale (CIS8) score>39

Inclusion criteria for CFS/ME patients:
• (Suspected) CFS/ME diagnosis according to the CDC criteria.
• No diagnosis of QFS.
• Fatigue severity subscale (CIS8) score >39.

Inclusion criteria for JIA patients:
• Diagnosed with JIA, at least 3 months on stable medication and a stable disease activity score (JADAS-criteria).
• No diagnosis of QFS.
• Expressing fatigue as a major complaint and CIS8 score >34 (mean +1SD).
• Being fatigued for at least 3 months.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

A potential subject who meets any of the following criteria will be excluded from participation in this study:
• Diagnosis of chronic Q-fever and active disease.
• Cognitive impairment, estimated IQ<70.
• Concomitant diagnoses that may explain the fatigue.
• Any current and predominated psychiatric comorbidity with could explain fatigue (i.e. major depression disorder, presence of suicidal risk).
• Owns no smartphone.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Cross-over
Toewijzing:	Gerandomiseerd
Blindering:	Open / niet geblindeerd

Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-09-2020
Aantal proefpersonen:	60
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nee

Ethische beoordeling

Positief advies

Datum:	21-07-2020
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	NL8789
Ander register	METC Utrecht : 20/166

Resultaten