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

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON24476

Source
NTR

Brief title
QFS

Health condition

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

Sponsors and support

Primary sponsor: UMC Utrecht
Source(s) of monetary or material Support: ZonMw, projectnumber 50-53000-98-566

Intervention

Outcome measures

Primary outcome

Fatigue severity

Secondary outcome

Self-efficacy and quality of life

Study description

Background summary

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.

Study objective

• 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.

Study design

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

Intervention

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

Contacts

Public
UMC Utrecht
Anouk Vroegindeweij

+31 6 5017 75 78
Scientific
UMC Utrecht
Anouk Vroegindeweij

+31 6 5017 75 78

Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL
Recruitment status: Pending

Start date (anticipated):	01-09-2020
Enrollment:	60
Type:	Anticipated

IPD sharing statement

Plan to share IPD: No

Ethics review

Positive opinion Date:	21-07-2020
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	NL8789
Other	METC Utrecht : 20/166

Study results