Sleep and fatigue assessment in the home environment with digital technology

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The objective is to find the most promising digital / objective sleep and fatigue parameters, which can be assessed with digital technologies in the home environment.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal inflammatory conditions
Study type	Observational non invasive

Summary

ID

NL-OMON54900

Source
ToetsingOnline

Brief title
IDEA-FAST part A

Condition

- Gastrointestinal inflammatory conditions

Synonym
Crohn's disease, Inflammatory bowel disease, ulcerative colitis

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: The EU-funded IMI consortium called IDEA-FAST (EC Grant Agreement 853981)

Intervention

Keyword: Chronic disease, Digital technology, Sleep and fatigue

Outcome measures

Primary outcome

Digital measures with best correlations with the patient-reported measures of sleep disturbances and fatigue as well as the clinical outcome measures will be considered for further investigations in the subsequent larger study (part B, not included in this proposal).

Secondary outcome

Na

Study description

Background summary

Existing measures of sleep disturbances and fatigue based on subjective, self-reported measures have many limitations for use in clinical studies and therapeutic development. Objective measures are either not available or in the case of sleep, are expensive and labour intensive (polysomnography) and are inconvenient to the patients. Furthermore, existing measures are unsuitable for use in ecological settings. This observational study aims to define the most useful objective parameters for sleep disturbances and fatigue, as assessed with home-based / mobile digital devices in patients suffering from PD, HD, IBD, PSS, RA or SLE, as sleep disturbances and fatigue are prevalent and burdensome in these diseases.

Study objective

The objective is to find the most promising digital / objective sleep and fatigue parameters, which can be assessed with digital technologies in the home environment.

Study design

The study (part A of the IDEA-FAST project) has an exploratory design, and thus

does not focus on a *single* primary outcome measure. Our primary goal, however, is to identify promising digital measurements (endpoints) of sleep disturbances and fatigue that can be used in the ecological settings. This goal will be achieved by comparing measures collected through novel digital tools with traditional i) clinical outcomes (e.g., surveys) and ii) patient-reported outcomes (questionnaires and diaries). Digital measures with best correlations with the patient-reported measures of sleep disturbances and fatigue as well as the clinical outcome measures will be considered for further investigations in the subsequent larger study (part B, not included in this proposal). A sample of 180 participants will be recruited across the four sites to represent the disease cohorts of interest in IDEA-FAST.

Study burden and risks

We do not perceive there to be any meaningful risks associated with participation in this study. The sensors that will be used are CE-certified, non-invasive and operate on very low power.

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

Age > 18 years, both genders
• Anticipated availability for using multiple study devices over the period of 60 days, with appropriate breaks within this period.
• Willingness to comply with the study protocol including the use of the digital devices and technologies.
• Previous use of a smartphone for at least 3 months.
• Ability to understand oral and/or written instructions in relation to the study protocol and Informed Consent in English or the native language of the country in residence with or without reasonable assistance.
• Willingness to sign the IRB-approved Informed Consent Form (ICF) having had enough time and opportunity to think about his/her participation in the study.
• Ability to walk independently, to sit and stand, socialise, communicate and capable of carrying out the various procedures proposed in the study, according to the opinion of the Investigator.
• MoCA > 15

For IBD patients
Established diagnosis of Ulcerative Colitis or Crohn's Disease based on the European Crohn's and Colitis Organisation - European Society of Gastrointestinal and Abdominal Radiology (ECCO-ESGAR) guideline [9].
• Diagnosis >=3 months before study entry

Exclusion criteria

• Primary diagnosis of major sleep disorders (i.e., insomnia, obstructive sleep apnoea, central apnoea, narcolepsy and hypersomnia).
• Primary diagnosis of chronic fatigue syndrome.
• Presence of respiratory, cardiovascular, metabolic disorders or physical traumas that required hospitalization in the 3 months preceding the study enrollment or based on severity assessed by the PI as potentially interfering with the study execution.
• Cognitive impairment resulting in an inability to walk or to understand the intention of the project.
• Diagnosis of major psychiatric disorders according to DSM5 that can affect the execution of the study.
• Recent suicidal attempt (active, interrupted, aborted) within the past five

years or report suicidal ideation within the past 6 months.
• Substance or ethanol abuse that may interfere with the patient's behavior, and sleep patterns.
• Close affiliation with the investigational site (e.g. employee or student of the investigational site)
• Diagnosis of cancer within the past 3 years, except basal or squamous skin cancer, which has been adequately treated.
• Visual impairment, as judged by the investigator

For IBD patients
• • No established diagnosis of Ulcerative Colitis or Crohn's Disease based on the European Crohn's and Colitis Organisation - European Society of Gastrointestinal and Abdominal Radiology (ECCO-ESGAR) guideline [9].
• Diagnosis <3 months before study entry

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-02-2021
Enrollment:	28
Type:	Actual

Medical products/devices used

Generic name:	Backsensor: Movemonitor by McRoberts;Wristsensor - Option A: Axivity AX6;Legsensor: Fibion;RF-based
Registration:	Yes - CE intended use

Ethics review

Approved WMO Date:	02-11-2020
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	11-02-2021
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

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	NL73780.078.20