Meaningful digital biomarkers for longitudinal monitoring of obstructive sleep apnea around diagnosis and during titration of treatment with CPAP or MAD

Published: 16-04-2025
Last updated: 16-05-2025

Primary Objective: Assess which digital health metrics are relevant to monitor for patients with (or highly suspected of having) obstructive sleep apnea before and after diagnosis, and during titration of treatment with continuous positive airway…

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON57436

Source
ToetsingOnline

Brief title
Digital biomarkers for OSA monitoring

Condition

- Other condition
- Upper respiratory tract disorders (excl infections)

Synonym
Obstructive sleep apnea, sleep apnea

Health condition

Obstructieve slaapapneu

Research involving
Human

Sponsors and support

Primary sponsor: TNO
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Diagnosis, Digital biomarkers, Obstructive Sleep Apnea, Treatment outcome

Outcome measures

Primary outcome

Primary endpoints

Digital health metrics and EMA items

The quantitative assessment will statistically explore the relationship between digital OSA-related health metrics that are continuously collected using sensor-based digital health technologies with subjective data that is collected via a short EMA questionnaire that is administered each morning . As such, the subjective morning EMA data can be seen as the study*s primary endpoint, whereas the objective nocturnal digital health data are the key study parameters of interest that may be related to the subjective data.

Exit survey and interviews

Study participants will fill out a survey about meaningfulness of assessed digital health parameters based on the personal health data report that they receive at the end of study (survey is included as attachment). Additionally, a representative sample of participants is invited for a semi-structured interview to establish meaningfulness and actionability of each health

parameter in the patient data report, that they receive after the final night of measurements (interview guide is included as attachment).

Secondary outcome

Secondary endpoints

PROM

The Quebec Sleep Questionnaire (QSQ) is a 32-item scale that evaluates the impact of OSA over the past 4 weeks in five different domains, namely hypersomnolence, daytime symptoms, nighttime symptoms, emotions, and social interaction. The QSQ will be taken at study onset, at the start of the patient*s treatment and 1 and 2 months after treatment initiation.
These data will be used to at least (1) describe the patient sample to aid the interpretation of the generalizability of the current study using T0 QSQ data, as well as potentially (2) describe the patients* complaints in the descriptive secondary endpoint, (3) help predict the PG-related OSA diagnosis outcomes in the related secondary objective using T0 QSQ data, and (4) explore to what degree the trends in the daily EMA items and/or daily OSA-related digital health metrics relate to QSQ outcomes.

Study description

Background summary

Obstructive Sleep Apnea (OSA) is a common chronic sleep breathing disorder characterized by intermittent breath stops leading to hypoxemia and reduced sleep quality (Lv et al., 2023).Untreated OSA is associated with increased risk for adverse cardiac outcomes (Lv et al., 2023). OSA is diagnosed through a single-night sleep study and most frequently prescribed treatments are continuous positive airway pressure (CPAP) and mandibular advancement device

(MAD) (Heijn Van Mechelen et al., 2021; Luong et al., 2024). Currently, objective data collection is limited to a single-night sleep study at diagnosis and a few metrics returned by machines used for continuous positive airway pressure (CPAP) therapy during use. MAD treatment outcome assessments are based on subjective report of symptoms. A previous study including a survey and interviews with individuals with OSA revealed a strong need for objective OSA monitoring. Sensor-based digital health technologies offer the opportunity to objectively and longitudinally assess OSA health metrics, enhancing diagnostic accuracy, facilitating more effective treatment titration, and improving self-management abilities.

Study objective

Primary Objective:
Assess which digital health metrics are relevant to monitor for patients with (or highly suspected of having) obstructive sleep apnea before and after diagnosis, and during titration of treatment with continuous positive airway pressure (CPAP) or mandibular advancement device (MAD) in the Netherlands.

Secondary Objective(s):
• Explore longitudinal trends in digital OSA-related health metrics within the context of Quebec Sleep Questionnaire (QSQ, Patient-reported outcome measure) during the first 2 months of CPAP or MAD treatment.
• Explore if polygraphy (PG) based OSA diagnosis can be predicted using digital OSA-related health metrics and QSQ. Assess which digital health metrics are relevant to monitor for patients with (or highly suspected of having) obstructive sleep apnea before and after diagnosis, and during titration of treatment with continuous positive airway pressure (CPAP) or mandibular advancement device (MAD) in the Netherlands.

Study design

Prospective single-center observational longitudinal mixed-method study.

Study burden and risks

Burden
The total burden for the participant during the study consists of 2 visits to ZMC to collect devices and receive instructions at start of study and return devices at the end of study. Since this will be combined with installation of PG/PSG devices following standard of care, this does not require extra clinic visits. Devices will be returned to ZMC at end of study together with PSG/PG devices. During the observational phase, participants will need to wear the Corsano cardio watch 24/7, but can follow their usual lifestyle. Potential risks include allergic reactions to the bracelet, which is made of fabric. Filling out short daily questionnaires (max 5 mins), 4 times a long

questionnaire (max 15 mins) and finally an exit survey (max 10 minutes) and for 10-15 participants a 45 min interview is the required time investment of participants.

Benefits
Participants will receive a comprehensive report with their personal health metrics collected before and after treatment initiation. Based on insights from a survey and interviews with OSA patients done in previous projects, we suspect that these data will be highly valued by the participating patients as it will provide objective insights into treatment outcomes that may contribute to enhanced self-management abilities and shared clinical decision making.

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

• Clinically relevant symptoms, at physician*s discretion.
o Reduced emotional wellbeing
• High OSA risk based on STOP-BANG questionnaire
• >=18 years old
• In possession of a Smartphone running on a recent version of iOS or Android
• Proficient in the Dutch language, enabling them to understand and complete questionnaires without assistance.

Exclusion criteria

• (Night) shift workers
• 4 or more alcoholic drinks per day on a regular basis or use of recreational drugs

Following conditions might not return reliable digital OSA data, as the Withings Sleep Analyzer algorithm is not trained or tested in these contexts. Therefore (suspicion) of below conditions are listed as exclusion criteria:
• Presence of acute or severe chronic respiratory muscle weakness due to neuromuscular condition
• Awake hypoventilation
• Suspicion of sleep-related hypoventilation
• Chronic opiod medication

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-04-2025

Enrollment:	40
Type:	Anticipated

Ethics review

Approved WMO Date:	16-04-2025
Application type:	First submission
Review commission:	METC Brabant (Tilburg)

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	NL88687.028.25