# Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales.  The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

| | |
|---|---|
| **Topic exploration report number:** | TER315 |
| **Topic:** | Portable devices that analyse mandibular movements for the diagnosis of obstructive sleep apnoea |
| **Summary of findings:** | Four primary studies were identified through the searches conducted. Three of the studies evaluated the intervention in adult populations while the other one considered a paediatric cohort. Two different technologies were covered in the identified studies.

The analysis of mandibular movements conducted with portable/at-home devices for the diagnosis of obstructive sleep apnoea shows a comparable diagnostic accuracy to the current standard of care. However, ultiple areas of uncertainty exist regarding the target population, the various types of the technologies used for the intervention, the regulatory approval of technologies that embed digital health technologies and whether the intervention replaces or is used in conjunction with the current standard of care. High quality clinical trials conducted in line with the guidance detailed in the NICE Evidence Standard Framework for Digital Health Technologies and the Cochrane Handbook for Systematic Reviews of Diagnostic Test Accuracy could enable a full health technology assessment in the future. |

## Introduction and aims

Obstructive sleep apnoea (OSA) is a sleep-related breathing disorder, characterised by recurrent episodes of complete or partial obstruction of the upper airway during sleep. OSA currently affects approximately one billion people worldwide resulting in a high socioeconomic and healthcare burden (Pépin et al. 2020). Polysomnography is currently the gold standard for the diagnosis of OSA; however, portable devices that analyse the patterns of mandibular movements could represent a promising alternative for the diagnosis of OSA.

Health Technology Wales researchers searched for evidence on portable devices that analyse mandibular movements for the diagnosis of sleep apnoea.

## Evidence overview

No relevant HTAs, guidance or systematic reviews were identified which considered portable devices that analyse mandibular movements for the diagnosis of sleep apnoea.

### Individual studies

Through the searches conducted, a total of four primary studies were identified to be pertinent. Pépin et al. (2020) evaluated in a prospective diagnostic study if mandibular movement monitoring during sleep coupled with automated analysis by machine learning is appropriate for the diagnosis of OSA. The study was conducted in a population of 376 adults that underwent overnight in-laboratory polysomnography (reference standard) with simultaneous mandibular movement monitoring achieved through a sensor called Sunrise. The authors concluded that the automatic analysis of mandibular movement patterns could represent a promising approach for the diagnosis of OSA.

In the study conducted by Le-Dong et al. (2021), the authors evaluated simultaneous recordings of mandibular movements using the Sunrise system in 1026 adults with suspected OSA referred for in-laboratory polysomnography. The study established that mandibular movement signals acquired from the system is suitable for automated sleep staging in adults presenting a broad spectrum of OSA severity.

Another prospective study by Martinot et al. (2017) evaluated the suitability of mandibular movement monitoring for the diagnosis of sleep apnoea. The study conducted in 87 adults referred for consecutive in-laboratory polysomnography and magnetometer-derived mandibular movement signals through a mid-sagittal sensor called Brizzy. The respiratory disturbance index showed highly concordant results between the two tests, suggesting that mandibular movement monitoring could emerge as a useful tool in the diagnosis of OSA.

Lastly, the study by Martinot et al. (2021) also evaluated prospectively the accuracy of the Sunrise system for diagnosing OSA in comparison to in-laboratory polysomnography in a cohort of 140 children. The authors concluded that the system based on mandibular movement analysis displays an acceptable accuracy for the diagnosis of moderate to severe OSA in symptomatic children.

The Sunrise system incorporates a digital health technology (DHT) and was determined to be a Tier C technology according to the [Evidence Standards Framework for Digital Health Technologies](). Technologies within this classification are DHTs designed to provide or guide treatment, active monitoring and clinical calculations, to provide or guide a diagnosis, for preventative behaviour change, or to allow self-management of a diagnosed condition. For technologies with this classification, it is recommended that high quality randomised controlled studies or studies

comparing the DHT with a relevant comparator is produced to demonstrate the effectiveness of the technology.

### Ongoing research

One relevant ongoing clinical trial was identified that aims to validate the integrated digital solution Sunrise in comparison to polysomnography for OSA. The estimated completion date for the trial is March 2024.

## Areas of uncertainty

Although the identified evidence highlighted a comparable diagnostic accuracy of the portable devices that analyse mandibular movement to the current gold standard for the diagnosis of OSA, some areas of uncertainty remain to be elucidated. These include:

- The patient population that could benefit most from the intervention (e.g. paediatric or adult population).
- If the novel diagnostic approach detects the various stages and severity of the disease accordingly.
- The criteria for referral for a sleep study and if the technology is used in conjunction or replaces the current standard of care.
- The specific portable device that ensures the best benefits for the intervention as multiple sensors were identified.
- As no economic evaluations were identified, it is unclear if the costs of the intervention offer a better value proposition than the current standard of care.

# Literature search results

| Health technology assessments and guidance |
|---|

NICE
No evidence found.

Healthcare Improvement Scotland
No evidence found.

Hand search published SIGN Guidelines
No evidence found.

Health Information and Quality Authority
No evidence found.

EUnetHTA
No evidence found.

International HTA Database
No evidence found.

International Guidelines Library
No evidence found.

| Evidence reviews and economic evaluations |
|---|

https://www.epistemonikos.org/en/
No evidence found.

https://www.tripdatabase.com/
No evidence found.

Cochrane library
No evidence found.

Medline (via Ovid or Pubmed)
No evidence found.

| Individual studies |
|---|

https://www.epistemonikos.org/en/
No evidence found.

https://www.tripdatabase.com/
No evidence found.

Cochrane library
No evidence found.

Medline (via Ovid or Pubmed)

Martinot JB, Borel JC, Cuthbert V, et al. (2017). Mandibular position and movements: suitability for diagnosis of sleep apnoea. Respirology. 22(3): 567-74.

Martinot JB, Cuthbert V, Le-Dong NN, et al. (2021). Clinical validation of a mandibular movement signal based system for the diagnosis of pediatric sleep apnea. Pediatr Pulmonol. doi: 10.1002/ppul.25320

Pépin JL, Letesson C, Le-Dong NN, et al. (2020). Assessment of Mandibular Movement Monitoring With Machine Learning Analysis for the Diagnosis of Obstructive Sleep Apnea. JAMA Netw Open. 3(1): e1919657. doi: 10.1001/jamanetworkopen.2019.19657

| Ongoing research |
|---|

No protocols identified.

https://scanmedicine.com/clinicaltrials
*Searched*

NCT05057975 - Validation of an Integrated Digital Solution (SUNrise®) Versus Polysomnography for Obstructive Sleep Apnea Diagnosis (SUNSAS). Interventional, randomised, parallel, open label, multicentre and national. Estimated study completion date: March 2024.

**Evidence provided by the topic proposer**

Le-Dong N-N, Martinot J-B, Coumans N, et al. (2021). Machine Learning-based Sleep Staging in Sleep Apnea Patients Using a Single Mandibular Movement Signal. American journal of respiratory and critical care medicine. (ja).

| Date of search: | October 2021 |
|---|---|
| Concepts used: | mandibular/mandible movements AND sleep apnea/apnoea, Sunrise |