National Institute for Health and Care Excellence

Final

Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s

Evidence review D: Diagnostic tests for OSAHS, OHS and COPD–OSAHS overlap syndrome

NICE guideline NG202

Diagnostic evidence review

August 2021

Final

Developed by the National Guideline Centre, hosted by the Royal College of Physicians

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ISBN: 978-1-4731-4229-9

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1.1. Review question: What are the most clinically and cost effective diagnostic strategies for obstructive sleep apnoea/hypopnea syndrome (OSAHS), obesity hypoventilation syndrome (OHS) and COPD-OSAHS overlap syndrome, including home- and hospital-based studies, and investigations such as oximetry, capnography, respiratory polygraphy and polysomnography?

1.2. Introduction

Accurate diagnosis of obstructive sleep apnoea/hypopnea syndrome (OSAHS), obesity hypoventilation syndrome (OHS) and COPD-OSAHS overlap syndrome is important. The diagnosis is usually made using physiological measures during sleep and when awake; these measures also give an indication of disease severity.

There are different diagnostic monitoring techniques, which vary based on the number and type of variables measured. A simple diagnostic test is overnight oximetry, a two-channel sleep study recording oximetry and pulse rate. In some centres this is used as an initial screening test, in others it may be considered diagnostic along with a typical history of OSA. Limited respiratory polygraphy is a four or more channel sleep study, typically with oximetry, pulse rate, air flow and chest or abdomen effort band. This is probably the most widely used diagnostic test. Full polysomnography includes all aspects of respiratory polygraphy, along height and weight for OHS, and with electroencephalogram and electromyogram recording. The techniques can vary as to whether they are conducted in hospital or at home.

The same tests may be employed in the diagnosis of OHS and COPD-OSAHS overlap syndrome, although these conditions also require additional tests, including an assessment for respiratory failure, such as raised daytime carbon dioxide on arterial blood gas or raised venous bicarbonate. There are also diagnosis-specific tests for both OHS and COPD-OSAHS overlap syndrome (such as measurement of height and weight for OHS, and spirometry for COPD-OSAHS overlap syndrome) but these are widely agreed and not the subject of this evidence review.

In view of the variation in use of the available tests, this evidence review was performed to determine the most cost-effective diagnostic strategy for obstructive sleep apnoea/hypopnea syndrome (OSAHS), obesity hypoventilation syndrome (OHS) and COPD-OSAHS overlap syndrome.

1.3. PICO table

For full details see the review protocol in appendix A.

Table 1: PICO characteristics of review question

Population	People in whom OSAHS/OHS/COPD-OSAHS overlap syndrome is suspected based on symptoms or co-existing conditions.
Target condition	OSAHS/OHS/ COPD-OSAHS overlap syndrome
Index tests	Index test strategies include any one or more of the below: • home oximetry • home oxycapnography (OHS only) • home respiratory polygraphy • venous bicarbonate (OHS only) • hospital oxycapnography (OHS only) • hospital respiratory polygraphy
Reference standards	For diagnosis of OSAHS/ COPD-OSAHS overlap syndrome, reference standard is AHI/RDI/ODI >5 by hospital polysomnography for OSAHS For diagnosis of OHS, reference standard is hypercapnia on arterial/capillary blood gases for OHS **Test and treat** Any testing strategy compared with any other including the reference standards listed above

Statistical measures and Outcomes	**Accuracy outcomes**:
	
	• sensitivity
	• specificity
	• positive predictive values (PPV)
	• negative predictive values (NPV)
	
	Test and treat outcomes:
	
	Critical
	• mortality (dichotomous)
	• generic or disease specific quality of life (continuous)
	
	Important
	• sleepiness scores (continuous, e.g. Epworth)
	• apnoea-hypopnoea index or respiratory disturbance index (continuous)
	• oxygen desaturation index (continuous)
	• healthcare resource use (rates/dichotomous)
	• impact on co-existing conditions:
	  ○ HbA1c for diabetes (continuous)
	  ○ cardiovascular events for cardiovascular disease (dichotomous)
	  ○ systolic blood pressure for hypertension (continuous)

Study design	Single gate cross-sectional study designs will be included in the accuracy review. Two gate study designs will be excluded from the accuracy review

	RCTs will be prioritised for test and treat comparisons; if insufficient RCTs are found, non-randomised studies will be considered if they adjust for key confounders (age, BMI, co-existing conditions).

1.4. Clinical evidence

1.4.1. Included studies

OSAHS

Twenty three studies were included in the review (22 diagnostic accuracy and one test and treat study) .[76, 90, 93, 100, 119, 140, 145, 149, 151, 162, 242, 286, 297, 298, 300, 369, 430, 443, 464, 475, 490, 590, 597] Evidence from these studies is summarised in the clinical evidence summary below (Table 2 - Table 6).

The data was analysed based on severity of OSAHS: all OSAHS to include studies with AHI ≥ 5 ; moderate-severe OSAHS (AHI ≥ 15) and severe OSAHS (AHI ≥ 30).

A few studies included in the review used proxy cut-off values for AHI, for example when the index threshold was not exactly what we were looking for, or not exactly the same as the reference standard stated in the protocol (AHI=5). In home oximetry for all OSAHS population, 2 studies used proxy values for the index test: Rofail 2010[475] – ODI ≥ 7 Wiltshire 2001[590] – ODI ≥10. In home respiratory polygraphy for mild OSAHS 1 study Golpe 2002[149] used proxy values for both the index test AHI ≥10 and the reference standard AHI ≥10. In home respiratory polygraphy for moderate OSAHS 1 study MASA 2013[297] used a proxy for the index test AHI ≥ 25. In hospital respiratory polygraphy 2 studies Calleja 2002[76] and Lloberes 1996[242] used proxy values for both index test AHI ≥10 and reference standard AHI ≥10 and 1 study Marrone 2011[286] used a proxy for the reference standard AHI ≥10. All studies that used proxy cut-off values were downgraded for indirectness.

There were two studies for home oximetry in all severities OSAHS, 3 studies for home oximetry in moderate-severe OSAHS, 8 studies for home respiratory polygraphy in all severities OSAHS,4 studies for home respiratory polygraphy in moderate-severe OSAHS, 4 studies for home respiratory polygraphy in severe OSAHS, 8 studies for in centre respiratory polygraphy in all severities OSAHS, 5 studies for in centre respiratory polygraphy in moderate-severe OSAHS, and 3 studies for in centre respiratory polygraphy in severe OSAHS. Some of the studies provided data for more than one analysis.

One test and treat study compared home respiratory polygraphy with polysomnography in moderate OSAHS.

OHS

No studies were identified that assessed diagnostic tests for OHS.

COPD-OSAHS overlap syndrome

One study assessed centre respiratory polygraphy in people with COPD-OSAHS overlap syndrome.[181] Evidence from the study is summarised in the clinical evidence summary below (Table 75).

The data was analysed based on severity of COPD-OSAHS overlap syndrome: all COPD-OSAHS overlap syndrome to include studies with AHI ≥ 5 ; moderate-severe COPD-OSAHS overlap syndrome (AHI ≥ 15) and severe COPD-OSAHS overlap syndrome (AHI ≥ 30).

Study reported results for in centre respiratory polygraphy in all severities COPD-OSAHS overlap syndrome, moderate-severe COPD-OSAHS overlap syndrome and severe COPD-OSAHS overlap syndrome.

See also the study selection flow chart in appendix C, sensitivity and specificity forest plots in appendix E, and study evidence tables in appendix D.

1.4.2. Excluded studies

See the excluded studies list in appendix H.

1.4.3. Summary of clinical studies included in the evidence review

Table 2: Summary of studies included in the evidence review (diagnostic accuracy) – home oximetry– OSAHS population

Study	Population	Target condition	Index test	Reference standard	Comments
Gyulay 1993[162] Australia Cross-sectional	N = 98 recruited and analysed People referred to specialist centre for suspected obstructive sleep apnoea Age: mean 49.96 (SD 2.5) Male/female ratio: 77:21 Ethnicity: not reported	Obstructive sleep apnoea	Pulse oximetry, desaturation index ≥ 15 (4%)	Laboratory polysomnography with a prespecified diagnostic AHI ≥ 15 (no % desaturation criteria)	Setting: laboratory/at home
Rofail 2010[475] Australia Cross-sectional	N=105 recruited, 98 completed the protocol with 92 analysed over three nights, 72 analysed over first night People with suspected obstructive sleep apnoea Age: mean 46.0 (SD 11.7) Male/Female ratio (%): 77/23 Ethnicity: 89.5% Caucasian	Obstructive sleep apnoea	Single-channel, nasal airflow device, RDI; single-channel oximeter (Flow Wizard), ODI	Laboratory polysomnography with a prespecified diagnostic AHI of ≥5	Setting: Laboratory and home

Study	Population	Target condition	Index test	Reference standard	Comments
Ryan 1995[490] UK Cross-sectional	N=69 analysed People with suspected sleep apnoea/ hypopnoea syndrome Age: mean 48 (SD 12) Male/Female ratio: 57/12 Ethnicity: not reported	Sleep apnoea/ hypopnoea syndrome	Oximetry device	Laboratory polysomnography with a prespecified diagnostic AHI of ≥15	Setting: Home and laboratory
Wiltshire 2001[590] UK Cross-sectional	N=84 analysed Patients were referred from ear, nose and throat surgeons, primary-care physicians and other chest physicians for assessment of suspected SAHS using full polysomnography Age: not reported Male/female: not reported Ethnicity: not reported	Obstructive sleep apnoea hypopnea syndrome	Home oximetry (Biox 3740, Ohmeda; UK)	Laboratory polysomnography - All underwent full polysomnography within 3 days of the home studies. Patients underwent full polysomnographic study which included EEG, EOG, EMG and ECG recordings, thoraco-abdominal and nasal-oral air flow measurements and pulse oximetry.	Setting: home

Table 3: Summary of studies included in the evidence review (diagnostic accuracy) – home respiratory polygraphy – OSAHS population

Study	Population	Target condition	Index test	Reference standard	Comments
de Oliveira 2009[100] Brazil Cross-sectional	N = 157 studied, 121 analysed for home and laboratory monitoring People referred to specialist centre for suspected OSAHS Age: mean 45 (SD 12) Male/female ratio (for PSG): 113/44 Ethnicity: not reported	Obstructive sleep apnoea syndrome	Portable respiratory monitor (respiratory polygraphy; Somnocheck), post-hoc AHI cut-off of 7	Laboratory polysomnography with a prespecified diagnostic AHI >5	Setting: sleep centre/at home
Garg 2014[140] USA Cross-sectional	N = 75 recruited and analysed People with high risk of OSA recruited from primary care and sleep clinics Age: mean 44.7 (SD 10.6) Male/female ratio: 18/57 Ethnicity: African American	Obstructive sleep apnoea	Portable sleep monitor (respiratory polygraphy; WatchPAT200), AHI	In-centre polysomnography PSG with no prespecified diagnostic AHI, RDI or ODI	Setting: sleep centre and home

Study	Population	Target condition	Index test	Reference standard	Comments
Gjevre 2011[145] Canada Cross-sectional	N = 47 recruited and analysed Women referred by sleep physicians for PSG assessment of possible OSA Age: mean 52 (SD 11) Male/female ratio: all female Ethnicity	Obstructive sleep apnoea	Portable sleep monitor (respiratory polygraphy; Embletta), AHI and ODI	In-laboratory polysomnography with a prespecified diagnostic AHI >5	Setting: laboratory and home
Golpe 2002[149] Spain Cross-sectional	N = 55 recruited, 37 analysed People referred to specialist centre for suspected sleep apnoea/hypopnoea syndrome Age: mean 52.7 (SD 13.3) Male/female ratio: 53:2	Sleep apnoea/hypopnoea syndrome	Portable sleep recording device (respiratory polygraphy; Apnoeascreen-I), RDI	In-laboratory polysomnography with a prespecified diagnostic AHI ≥10	Setting: laboratory and home
Masa 2013[297] Masa 2013[300] Masa 2011[298] Spain Cross-sectional	N=366 recruited 348 completed protocol People with suspected sleep apnoea/ hypopnoea syndrome Age: mean 48.7 (SD 11.8) Male/Female ratio: 263/85	Sleep apnoea/ hypopnoea syndrome	Home respiratory polygraphy (with Breas SC20), with AHI	In-hospital polysomnography with a prespecified diagnostic AHI of ≥15	Setting: Home or hospital

Study	Population	Target condition	Index test	Reference standard	Comments
	Ethnicity: not reported				
Pereira 2013[430] Canada Cross-sectional	N=128 analysed Age: mean: 50 (SD 12.3) Male/Female: 84/44 Ethnicity: not reported	Obstructive sleep apnoea	Home RP- patients were asked to wear the Level III portable monitoring device (MediByte; Braebon Medical Corporation, Ottawa, ON) for 2 consecutive nights at home.	Laboratory polysomnography - Recordings were conducted using Sandman Elite SD32+ digital sleep recording system (Natus [Embla]; Ottawa, ON), and included 4 EEG channels (C4-A1, C3-A2, O2-A1, F3-A2), 2 EOG channels (ROC-A1, LOC-A2), submental EMG, intercostal (diaphragmatic surface) EMG, bilateral anterior tibialis EMG, ECG, respiratory piezo bands (chest and abdomen), finger pulse oximetry, a vibration snore sensor, nasal pressure airflow, and oronasal thermocouple. PSG recordings were conducted as either a diagnostic study or, in the event of severe	Setting: home

Study	Population	Target condition	Index test	Reference standard	Comments
				OSA, a split-night study.	
Polese 2013[443] Brazil Cross-sectional	N=43 analysed Age: mean 70 (SD 5) Male/Female ratio(%): 44/56 Ethnicity: not stated	Obstructive sleep apnoea	The type 3 portable device used was the Stardust II® (Philips Respironics, Inc., Murrysville, PA, USA).	Laboratory polysomnography - Full-night PSG (Embla® S7000, Embla Systems, Inc., Broomfield, CO, USA) was performed by a trained technician. Prespecified clinical AHI cut-off	Setting: Laboratory and home
Xu 2017[597] China Cross-sectional	N=80 analysed People referred for evaluation of obstructive sleep apnoea Age: mean 47 (SD 14) Male/Female ratio (%): 76/24 Ethnicity: not reported	Obstructive sleep apnoea	Portable sleep monitor (respiratory polygraphy; Nox-T3), AHI	Laboratory polysomnography with no prespecified diagnostic AHI, RDI or ODI	Setting: Laboratory and home

Table 4: Summary of studies included in the evidence review (diagnostic accuracy) hospital repiratory polygraphy – OSAHS population

Study	Population	Target condition	Index test	Reference standard	Comments
Calleja 2002[76] Spain Cross-sectional	N= 86 recruited, 79 analysed People with clinically suspected sleep apnoea syndrome referred to sleep laboratory	Sleep apnoea/ hypopnoea syndrome	In centre respiratory polygraphy (MERLIN system), post hoc cut-off of 9.8 by manual scoring	Polysomnography with AHI >/= 10	Setting: sleep laboratory

Study	Population	Target condition	Index test	Reference standard	Comments
	Age: mean 52 (SD 11.1) Male/female ratio: 77/9 Ethnicity not reported				
Claman 2001[90] USA Cross-sectional	N = 42 recruited and analysed People referred for formal sleep study to evaluate suspected OSA Age: mean 54 (SD 12.9) Male/female ratio: 31:11 Ethnicity: not reported	Obstructive sleep apnoea	In centre respiratory polygraphy (BedBugg), AHI	Polysomnography with a prespecified diagnostic AHI >15	Setting: sleep laboratory
Emsellem 1990[119] USA Cross-sectional	N = 67 studied, 63 analysed People referred to specialist centre for suspected OSA Age: mean 45 (SD not reported) Male/female ratio: not reported Ethnicity: not reported	Obstructive sleep apnoea	Portable apnoea screening system (respiratory; polygraphy; EdenTrace), with a Portable Respiratory Index (PRI)	In-centre polysomnography with a specified diagnostic AHI >5	Setting: sleep centre

Study	Population	Target condition	Index test	Reference standard	Comments
Goodrich 2009[151] USA Cross-sectional	N = 50 recruited, 48 analysed People referred to specialist centre for suspected OSA Age: mean 44 (range 22 to 69) Male/female ratio: 35/13 Ethnicity: not reported	Obstructive sleep apnoea	Portable respiratory polygraphy using Lifeshirt, AHI ≥ 5	In-centre polysomnography with no prespecified diagnostic AHI	Setting: sleep centre
Lloberes 1996[242] Spain Cross-sectional	N=76 analysed People with suspected sleep apnoea/ hypopnoea syndrome Age: mean 51 (SD 11.5) Male/Female ratio: 54/22 Ethnicity: not reported	Sleep apnoea/ hypopnoea syndrome	Partially attended night-time respiratory recording (respiratory polygraphy), with AHI	Laboratory polysomnography with a prespecified diagnostic AHI of >10	Setting: Respiratory ward or sleep laboratory
Marrone 2001[286] Italy Cross-sectional	N=50 analysed People with suspected obstructive sleep apnoea syndrome Age: 49.6 ± 10.2 (units not reported) Male/Female ratio: 40/10	Obstructive sleep apnoea syndrome	Portable sleep monitor, AH/time in bed (respiratory polygraphy; POLYMESAM)	Laboratory polysomnography with a prespecified diagnostic AHI of ≥10	Setting: Laboratory

Study	Population	Target condition	Index test	Reference standard	Comments
	Ethnicity: not reported				
Ng 2010[369] China Cross-sectional	N=90 recruited, 80 analysed People with suspected obstructive sleep apnoea syndrome Age: mean 51.4 (SD 11.9) Male/Female ratio: 63/17 Ethnicity: not reported	Obstructive sleep apnoea syndrome	Portable, three-channel airflow monitor (Embletta PDS), AHI	Laboratory polysomnography with no prespecified diagnostic AHI, RDI or ODI	Setting: Laboratory
Polese 2013[443] Brazil Cross-sectional	N=43 analysed Age: mean 70 (SD 5) Male/Female ratio(%): 44/56 Ethnicity: not stated	Obstructive sleep apnoea	The type 3 portable device used was the Stardust II® (Philips Respironics, Inc., Murrysville, PA, USA).	Laboratory polysomnography - Full-night PSG (Embla® S7000, Embla Systems, Inc., Broomfield, CO, USA) was performed by a trained technician. Prespecified clinical AHI cut-off	Setting: Laboratory and home
Reichert 2003[464] USA Cross-sectional	N=51 recruited, 44 analysed in-laboratory and 45 analysed at home and in-laboratory People with suspected obstructive sleep apnoea Age: mean 52 (range 30-83)	Obstructive sleep apnoea	Portable, five-channel diagnostic system (respiratory polygraphy; NovaSom QSG)	Laboratory polysomnography with a prespecified clinical AHI cut-off ≥15	Setting: Laboratory and home

Study	Population	Target condition	Index test	Reference standard	Comments
	Male/Female ratio: 38/13 Ethnicity: not reported				
Xu 2017[597] China Cross-sectional	N=80 analysed People referred for evaluation of obstructive sleep apnoea Age: mean 47 (SD 14) Male/Female ratio (%): 76/24 Ethnicity: not reported	Obstructive sleep apnoea	Portable sleep monitor (respiratory polygraphy; Nox-T3)	Laboratory polysomnography with no prespecified diagnostic AHI, RDI or ODI	Setting: Laboratory and home

Table 5: Summary of studies included in the evidence review (diagnostic accuracy) – home respiratory polygraphy (Overlap syndrome)

Study	Population	Target condition	Index test	Reference standard	Comments
Jen 2020[36]	N= 36 recruited, 33 analysed Adult patients with known COPD and suspected OSA Age: mean 63 (SD 7) Male/female ratio: 63% male Ethnicity not reported	Overlap syndrome	In centre respiratory polygraphy (WatchPAT 200) AHI>/=5	Polysomnography with AHI >/= 5	Setting: sleep laboratory

Study	Population	Target condition	Index test	Reference standard	Comments

Table 6: Summary of studies included in the evidence review (test and treat) -OSAHS population

Study	Intervention and comparison	Population	Outcomes	Comments
Corral 2017[93] Spain RCT	**Home respiratory polygraphy** - HRP (Embla-Embletta; Natus, Pleasanton, CA) measurements included oxygen saturation, airflow through nasal pressure, and thoracic and abdominal movements measured by piezoelectric bands. The patients transported the device to their homes with a prior detailed explanation and functional test device provided by a technician in the hospital setting. When the patients returned the device the following day, the raw data files were transmitted to a computer and scored manually, excluding artefact periods. PSG was performed in patients with invalid HRP tests after several repetitions, and the subsequent cost was added to the HRP arm. For home RP, apnoea was the absence of flow lasting 10 seconds or more, and hypopnea was a discernible decrease in flow lasting 10 seconds or more with oxygen desaturation (>3%). N= 218 **Polysomnography** - For PSG, apnoea was the absence of flow lasting 10 seconds or more, and hypopnea was a discernible decrease in flow lasting 10 seconds or more with oxygen desaturation (>3%) or arousal. N=212	Age: median (IQR) – 50 (16) ESS: median (IQR) – 13 (5) Baseline AHI: median (IQR) Home RP: 20.9 (33.4) Polysomnography: 28.5 (43.3)	EQ5D ESS AHI ODI People given CPAP Change in 24-hour systolic blood pressure Cardiovascular event rate	Moderate severity OSAHS strata population (strata based on mean AHI) Test and treat study

Study	Intervention and comparison	Population	Outcomes	Comments
	The sleep physician recommended CPAP treatment in the case of a respiratory event index (REI) greater than or equal to 5 for HRP or an AHI greater than or equal to 5 for PSG with significant clinical symptoms (i.e., ESS .12), potentially secondary to OSA or previous cardiovascular diseases, and an REI or an AHI greater than or equal to 30, with clinical symptoms having less importance. Non-CPAP treatment included only correct sleep hygiene and a hypocaloric diet. **CPAP in both arms** - In patients (both arms) with a CPAP treatment indication, the optimal pressure for home use was obtained from a single recorded automatic-CPAP home session (S8-Autoset; Resmed, Sydney, Australia) by a researcher blinded to the study arm in the coordinating centre (centralized analysis). If, after three attempts, it was impossible to determine the optimal pressure, patients received polysomnographic titration, with the extra cost.			

See appendix D for full evidence tables.

1.4.4. Quality assessment of clinical studies included in the evidence review- diagnostic studies

Table 7: Clinical evidence summary –Home oximetry (diagnostic accuracy studies) – OSAHS population

Index Test (Threshold)	Number of studies	N	Sensitivity % (95% CI)	Quality	Specificity % (95% CI)	Quality
<u>**Tests**</u>						

Index Test (Threshold)	Number of studies	N	Sensitivity % (95% CI)	Quality	Specificity % (95% CI)	Quality
Home oximetry All OSAHS (AHI ≥ 5)	2	157	Pooled[5]: 51.81% (8.20 to 92.92%)	VERY LOW[1,2,3,4] due to risk of bias, serious inconsistency, serious indirectness and very serious imprecision	Pooled[5]: 95.83% (15.31 to 99.99%)	VERY LOW[1,2,3,4] due to risk of bias, serious inconsistency, serious indirectness and very serious imprecision
Home oximetry Moderate-severe OSAHS(AHI≥15)	3	251	Pooled[5]: 35.02% (12.98 to 65.24%)	VERY LOW[1,3,4] due to risk of bias, serious indirectness and serious imprecision	Pooled[5] 99.44% (95.35 to 99.98%)	LOW[1,3] due to risk of bias, serious indirectness

(1) Risk of bias was assessed using the QUADAS-2 checklist. The evidence was downgraded by 1 increment if the majority of studies were rated at high risk of bias and downgraded by 2 increments if the majority of studies were rated at very high risk of bias.
(2) Inconsistency was assessed by inspection of the sensitivity and specificity plots. The evidence was downgraded by 1 increment if the individual studies varied across 2 areas [(for example, 50–90% and 90–100%)] and by 2 increments if the individual studies varied across 3 areas [(for example, 0–50%, 50–90% and 90–100%)].
(3) Indirectness was assessed using the QUADAS-2 checklist items referring to applicability. The evidence was downgraded by 1 increment if the majority of studies were seriously indirect, and downgraded by 2 increments if the majority of studies are very seriously indirect
(4) Imprecision was assessed based on inspection of the confidence region in the diagnostic meta-analysis or, where diagnostic meta-analysis has not been conducted, assessed according to the range of confidence intervals in the individual studies. Two clinical decision thresholds were determined at the value above which a test would be recommended (90%), and a second below which a test would be considered of no clinical use (60%).The evidence was downgraded by 1 increment when the range of the confidence interval around the point estimate crossed one threshold, and downgraded by 2 increments when the range covered two
(5) Pooled sensitivity/specificity from diagnostic meta-analysis

Table 8: Clinical evidence summary –Home respiratory polygraphy (diagnostic accuracy study) – OSAHS population

Index Test (Threshold)	Number of studies	N	Sensitivity % (95% CI)	Quality	Specificity % (95% CI)	Quality
Tests						

Index Test (Threshold)	Number of studies	N	Sensitivity % (95% CI)	Quality	Specificity % (95% CI)	Quality
Home respiratory polygraphy All OSAHS (AHI ≥ 5)	8	872	Pooled[4]: 94.65% (89.81 to 97.36%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency, and serious imprecision	Pooled[4]: 57.69% (39.87 to 74.41%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency, and serious imprecision
Home respiratory polygraphy Moderate-severe OSAHS (AHI ≥ 15)	4	628	Pooled[4]:84.2% (59.67 to 95.87%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency and very serious imprecision	Pooled[4]: 88.95% (71.07 to 96.56%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency, and serious imprecision
Home respiratory polygraphy Severe OSAHS (AHI ≥ 30)	3	244	Pooled[4]: 64.25% (28.6 to 89.74%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency, and very serious imprecision	Pooled[4]: 92.06% (68.46 to 98.28%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency, and serious imprecision

(1) Risk of bias was assessed using the QUADAS-2 checklist. The evidence was downgraded by 1 increment if the majority of studies were rated at high risk of bias and downgraded by 2 increments if the majority of studies were rated at very high risk of bias.

(2) Inconsistency was assessed by inspection of the sensitivity and specificity plots. The evidence was downgraded by 1 increment if the individual studies varied across 2 areas [(for example, 50–90% and 90–100%)] and by 2 increments if the individual studies varied across 3 areas [(for example, 0–50%, 50–90% and 90–100%)].

(3) Imprecision was assessed based on inspection of the confidence region in the diagnostic meta-analysis or, where diagnostic meta-analysis has not been conducted, assessed according to the range of confidence intervals in the individual studies. Two clinical decision thresholds were determined at the value above which a test would be recommended (90%), and a second below which a test would be considered of no clinical use (60%).The evidence was downgraded by 1 increment when the range of the confidence interval around the point estimate crossed one threshold, and downgraded by 2 increments when the range covered two

(4) Pooled sensitivity/specificity from diagnostic meta-analysis

Table 9: Clinical evidence summary –Hospital respiratory polygraphy (diagnostic accuracy study) – OSAHS population

Index Test (Threshold)	Number of studies	N	Sensitivity % (95% CI)	Quality	Specificity % (95% CI)	Quality
Tests						
In centre respiratory polygraphy All OSAHS (AHI ≥ 5)	8	510	Pooled[4]: 94.58% (87.68 to 98.59%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency, and serious imprecision	Pooled[4]: 81.33% (57.92 to 92.48%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency and very serious imprecision
In centre respiratory polygraphy Moderate-severe OSAHS (AHI ≥ 15)	5	290	Pooled[4]: 93.29% (81.22 to 98.42%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency, and serious imprecision	Pooled[4]: 92.54% (82.71 to 97.48%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency and serious imprecision
In centre respiratory polygraphy Severe OSAHS (AHI ≥ 30)	3	162	Pooled[4]: 93.59% (71.09 to 99.15%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency, and serious imprecision	Pooled[4]: 95.51% (46.92 to 99.92%)	VERY LOW[1,2,3] due to risk of bias, serious inconsistency and very serious imprecision

(1) *Risk of bias was assessed using the QUADAS-2 checklist. The evidence was downgraded by 1 increment if the majority of studies were rated at high risk of bias, and downgraded by 2 increments if the majority of studies were rated at very high risk of bias.*

(2) *Inconsistency was assessed by inspection of the sensitivity and specificity plots. The evidence was downgraded by 1 increment if the individual studies varied across 2 areas [(for example, 50–90% and 90–100%)] and by 2 increments if the individual studies varied across 3 areas [(for example, 0–50%, 50–90% and 90–100%)].*

(3) *Imprecision was assessed based on inspection of the confidence region in the diagnostic meta-analysis or, where diagnostic meta-analysis has not been conducted, assessed according to the range of confidence intervals in the individual studies. Two clinical decision thresholds were determined at the value above which a test would be recommended (90%), and a second below which a test would be considered of no clinical use (60%).The evidence was downgraded by 1 increment when the range of the confidence interval around the point estimate crossed one threshold, and downgraded by 2 increments when the range covered two*

(4) *Pooled sensitivity/specificity from diagnostic meta-analysis*

Table 10: Clinical evidence summary –Hospital respiratory polygraphy (diagnostic accuracy study)- COPD-OSAHS overlap population

Index Test (Threshold)	Number of studies	N	Sensitivity % (95% CI)	Quality	Specificity % (95% CI)	Quality
Tests						
In centre respiratory polygraphy All COPD-OSAHS overlap syndrome (AHI ≥ 5)	1	33	96% (79 to100%)	LOW[1,2] due to risk of biasand serious imprecision	56% (21 to 86%)	LOW[1,2] due to risk of bias, , and serious imprecision
In centre respiratory polygraphy Moderate-severe COPD-OSAHS overlap syndrome (AHI ≥ 15)	1	33	77% (46 to 95%)	VERY LOW[1,2] due to risk of bias and very serious imprecision	90% (68% to 99%)	LOW[1,2] due to risk of bias, , and serious imprecision
In centre respiratory polygraphy Severe COPD-OSAHS overlap syndrome (AHI ≥ 30)	1	33	89% (52% to 100%)	VERY LOW[1,2] due to risk of biasand very serious imprecision	96% (79 to 100%)	LOW[1,2] due to risk of bias, , and serious imprecision

(1) Risk of bias was assessed using the QUADAS-2 checklist. The evidence was downgraded by 1 increment if the majority of studies were rated at high risk of bias, and downgraded by 2 increments if the majority of studies were rated at very high risk of bias.

(2) Imprecision was assessed based on inspection of the confidence region in the diagnostic meta-analysis or, where diagnostic meta-analysis has not been conducted, assessed according to the range of confidence intervals in the individual studies. Two clinical decision thresholds were determined at the value above which a test would be recommended (90%), and a second below which a test would be considered of no clinical use (60%).The evidence was downgraded by 1 increment when the range of the confidence interval around the point estimate crossed one threshold, and downgraded by 2 increments when the range covered two

Table 11: Clinical evidence summary: Home RP vs Hospital PSG (test and treat)– Moderate OSAHS

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Hospital PSG	Risk difference with Home RP (95% CI)
Change in quality of life EQ5D, higher is better. Scale from: 0 to 1.	430 (1 study) 6 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias and imprecision		The mean change in EQ5D in the control groups was 0.03	The mean change in EQ5D in the intervention groups was 0.02 lower (0.05 lower to 0.01 higher)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Hospital PSG	Risk difference with Home RP (95% CI)
Change in quality of life FOSQ, higher is better Scale from: 5 to 20.	430 (1 study) 6 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias, imprecision		The mean change in FOSQ in the control groups was 6.5	The mean change in FOSQ in the intervention groups was 0.2 higher (3.09 lower to 3.49 higher)
Change in quality of life SF36 Physical, higher is better. Scale from: 0 to 100.	430 (1 study) 6 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias imprecision		The mean change in SF36 physical in the control groups was 2.6	The mean change in SF36 physical in the intervention groups was 1.4 lower (3.13 lower to 0.33 higher)
Change in quality of life SF36 mental, higher is better. Scale from: 0 to 100.	430 (1 study) 6 months	⊕⊖⊖⊖ VERY LOW1,2 due to risk of bias and imprecision		The mean change in SF36 mental in the control groups was 1.4	The mean change in SF36 mental in the intervention groups was 1.1 higher (1.16 lower to 3.36 higher)
Change in sleepiness score ESS, higher is worse. Scale from: 0 to 24.	430 (1 study) 6 months	⊕⊕⊖⊖ LOW1 due to risk of bias		The mean change in ESS in the control groups was -4.9	The mean change in ESS in the intervention groups was 0.7 higher (0.31 lower to 1.71 higher)
Mortality	No studies	N/A		Not available	Not available
AHI, higher is worse	430 (1 study) 6 months	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean AHI in the control groups was 6.8	The mean AHI in the intervention groups was 1.4 higher (1.17 lower to 3.97 higher)
ODI, higher is worse	430 (1 study) 6 months	⊕⊕⊕⊖ MODERATE1 due to risk of bias		The mean ODI in the control groups was 4.5	The mean ODI in the intervention groups was 1.4 higher (0.72 lower to 3.52 higher)
People given CPAP, higher is worse	430 (1 study) 6 months	⊕⊕⊖⊖ LOW1,2 due to risk of bias andimprecision	RR 0.79 (0.68 to 0.92)	Moderate 679 per 1000	143 fewer per 1000 (from 54 fewer to 217 fewer)

Outcomes	No of Participants (studies) Follow up	Quality of the evidence (GRADE)	Relative effect (95% CI)	Anticipated absolute effects	
				Risk with Hospital PSG	Risk difference with Home RP (95% CI)
Change in 24hr systolic BP, higher is worse	430 (1 study) 6 months	⊕⊕⊕⊝ MODERATE1 due to risk of bias		The mean change in 24hr systolic BP in the control groups was 0.3	The mean change in 24hr systolic BP in the intervention groups was 0.1 higher (1.88 lower to 2.08 higher)
CV events Per 100 patients per year, higher is worse	430 (1 study) 6 months	⊕⊕⊕⊝ MODERATE1 due to risk of bias		The mean CV events in the control groups was 7.3	The mean CV events in the intervention groups was 0.9 lower (6.9 lower to 5.1 higher)

1 Risk of bias - downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
2 Imprecision - downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs. MID for machine usage (adherence)- 1 hour; MID for Systolic and Diastolic BP – 5 mm hg; Established MIDs for SF-36 physical/mental- 2/3; FOSQ- 2 ; ESS -2.5; SAQLI – 2; EQ5D – 0.03. GRADE default MIDs (0.5XSD) used for all other continuous outcomes.

See appendix F for full GRADE tables.

1.5. Economic evidence

1.5.1. Included studies

One health economic study was identified with the relevant comparison and has been included in this review.[93] This study is summarised in the health economic evidence profile below (Table 12) and the health economic evidence table in appendix G.

1.5.2. Excluded studies

Four economic studies were excluded due to poor applicability or very serious limitations.[169, 183, 403, 530] Eight more papers were selectively excluded due to the availability of more applicable or better quality evidence.[24, 37, 175, 297, 298, 300, 301, 432] These are listed in appendix H, with reasons for exclusion given.

See also the health economic study selection flow chart in appendix F.

1.5.3. Summary of studies included in the economic evidence review

Table 12: Health economic evidence profile: Polysomnography versus Home Respiratory Polygraphy

Study	Applicability	Limitations	Other comments	Incremental cost	Incremental effects	Cost effectiveness	Uncertainty
Corral 2017[93]	Partially Applicable [(a)]	Minor Limitations [(b)]	Within trial (RCT) cost-utility analysis, with a 6month follow up.	£455 [(c)]	0.004 QALYs[(d)]	£113, 750 per QALY gained	Probability polysomnography cost effective (£20K/30K threshold): 0%/0%[(c)]

Abbreviations: QALY= quality-adjusted life years; RCT= randomised controlled trial

(a) As the study is from a Spanish perspective the study has been judged as partially applicable.

(b) While there are some limitations (see Table 13 and Table 14) due to the high incremental cost difference, clarification of these limitations would be highly unlikely to change the incremental cost-effectiveness ratio sufficiently for polysomnography to be considered cost effective.

(c) 2009 euros converted into UK pounds using purchasing power parities[404] Utilities were derived using EQ-5D, Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health]).

1.5.4. Unit costs

Table 13: UK costs of diagnostic tests

Study	Code	Cost per patient
Limited Home Study (outpatient) – considered applicable for a home respiratory polygraphy	DZ50Z	£189
Limited Sleep Study (inpatient) considered applicable for an in-hospital respiratory polygraphy	DZ50Z	£636

Source: National Schedule of NHS costs [107, 374]

Table 14: UK costs for Oximetry Test

Resource use (a)(b)(c)	Cost
Annuitized costs per use of oximetry device	£0.51
AAA batteries (d)	£0.09
Hospital based band 5 Healthare assistant (15 minutes) (e)	£6.50
Hospital based medical consultant (15 minutes) (f)	£27.25
Cost per oximetry test	**£24.36**

Sources: NHS Supply Chain 2020[373], PSSRU 2019[97]

(a) Device costs can vary. In this example, the device cost for Nonin pulse oximetry wrist device (NPC code – FBC331) has been provided with an initial outlay of £561.38. This device costs have been sourced from the NHS supply chain[372, 373]. While other brands and types of oximetry devices were available, this was a brand that the committee were familiar with at a price point that seemed reasonable for the device.

(b) Device costs were annuitized to calculate annual equivalent costs of £120.13 for the Nonin device. The formula used to calculate annuitized annual costs is as follows:

E = K – [S / (1+r)n] / A(n,r)

Where E = equivalent annual cost; K = Purchase price of the oximetry device; S = resale value; r = discount (interest) rate; n = equipment lifespan; A(n,r) = annuity factor (n years at interest rate r). The following assumptions were used: resale value of £0, discount rate of 3.5% and equipment lifespan of 5 years as advised by the committee.

(c) Annuitized costs were divided by 234 to reflect that the device could be used 4-5 times per week.. This assumption was based on committee advice where it was indicated that 48 hours would be required for the patient to do the home oximetry, return the device, and the data download to occur before the same device could be made available again.

(d) An average cost for two AAA batteries (as would be required in the Nonin device) was calculated as £0.46 from the following NPC codes from the NHS supply chain[372] – WPA106, WPA146, WPA154 and WPA215. This was then divided by 5 as the batteries would need to be replaced after every fifth patient.

(e) Staeholders advised that a band 2 healthcare assistant could prepare the oximetry device advise patients how to use the device overnight and download the data (15 minutes).. The relevant costs were sourced from the PSSRU. [96, 97]

(f) A consultant would look over the data and prepare the report (15 minutes). The relevant costs were sourced from the PSSRU. [96, 97]

The NICE guideline on preoperative testing (NG45)[361] reports the price of a blood gases test to be between £6.42 and £9.84 including laboratory and phlebotomy costs.

1.5.5. Health economic modelling

This analysis was conducted using a model covering the diagnostic and treatment pathway for symptomatic people suspected of having OSAHS (See 'Economic analysis report' for full details). Branches of this model were also used to find the most cost effective treatment for mild OSAHS (Evidence report E), the most cost effective variant of CPAP (Evidence report F) and the most cost effective oral device (Evidence report G).

1.5.5.1. Population and strategies evaluated

The modelled population were people with symptoms associated with OSAHS and the strategies compared were

- Home oximetry (Intervention for mild OSAHS)
- Home respiratory polygraphy (Intervention for mild OSAHS)
- Hospital respiratory polygraphy (Intervention for mild OSAHS)
- Home oximetry screening and then home respiratory polygraphy for those that tested negative (Intervention for mild OSAHS)
- Home oximetry (Conservative management for mild OSAHS)
- Home respiratory polygraphy (Conservative management for mild OSAHS)
- Hospital respiratory polygraphy (Conservative management for mild OSAHS)
- Home oximetry screening and then home respiratory polygraphy for those that tested negative (Conservative management for mild OSAHS)

  For all strategies, people diagnosed with moderate or severe OSAHS receive CPAP. In the 'Conservative management' strategies, people diagnosed with mild OSAHS receive only lifestyle advice. In the 'Intervention' strategies, 1/3 of people diagnosed with mild OSAHS receive CPAP, 1/3 receive custom-made mandibular advancement splints (MAS) and the remaining 1/3 receive only lifestyle advice.

1.5.5.2. Methods and data sources (Summary)

Diagnostic accuracy

Table 15: Pooled test accuracy (median of the posterior distribution)

Test threshold	Sensitivity (%)	Specificity (%)
Accuracy at detecting OSAHS (AHI>5 on polysomnography)		
Home Oximetry ODI>5	51.8	95.8
Home RP AHI >5	94.5	57.7
Hospital RP AHI > 5	95.0	81.3
Accuracy at detecting moderate/severe OSAHS (AHI>15 on polysomnography)		
Home Oximetry ODI>15	35.0	99.4
Home RP AHI >15	84.2	89.0
Hospital RP AHI > 15	93.2	92.5

See 1.4.4 for details.

- Table 15 shows the sensitivities and specificities used in the model. These are the estimates from the guideline review pooled using diagnostic meta-analysis. Where a second test was performed the accuracy of the second test was assumed to be independent of the results of the first test inm the base case. In sensitivity analyses, we explored different levels of positive correlation between test results.
- For those people with moderate or severe OSAHS who were misdiagnosed as having no OSAHS after the first test, it was assumed that they would have a second test. This is because they are likely to be markedly symptomatic, which would entail further investigation.

Treatment effects

- CPAP and MAS were assumed to have an immediate impact on quality of life (measured in terms of EQ-5D). These were estimated from randomised trials comparing each intervention with conservative management.
- CPAP was estimated to have an impact on ESS and quality of life (measured in terms of EQ-5D). ESS was estimated from randomised trials comparing CPAP with conservative management and subgrouped by severity. The ESS improvements were mapped to EQ-5D using a published mapping equation. The resulting EQ-5D improvements used in the base case analysis and were applied to the whole treatment period:

	CPAP vs conservative management	
	ESS	**EQ-5D**
Mild OSAHS	-2.870	0.028
Moderate OSAHS	-2.04	0.020
Severe OSAHS	-3.41	0.033

- For the base case, the improvement in EQ-5D was 0.023 for custom-made MAS. These were from the TOMADO trial in mild and moderate OSAHS. There was assumed to be no benefit for patients with severe OSAHS.
- Compared with conservative management, CPAP was assumed to have the same impact on the incidence of road traffic accidents, regardless of severity. A proportion of the accidents are fatal and these are associated with reduced length of life. Non-fatal accidents are associated with reduced quality of life.
- For treated patients the risk of an RTA was assumed to be the same as the general population. The treatment effect was OR=0.169, which was derived from NICE technology appraisal for CPAP in OSAHS (TA139)[362]
- Cardiovascular events were included in the model,
    - For moderate and severe OSAHS there was a modest reduction derived using QRISK from a 1.0mmHg reduction in systolic blood pressure
    - for the mild OSAHS population we assumed that CPAP had no impact
- The rate at which people drop out from using CPAP was differentiated by time and by OSAHS severity. It was assumed that when patients dropped out, their quality of life, RTA risk and CV risk returned to their baseline levels.
- The baseline probability of both cardiovascular events and RTAs were for men aged 50 at the commencement of treatment. The former was estimated using QRISK and the latter were from Department of Transport statistics.

CPAP costs

- The cost of fixed-pressure CPAP devices and consumables were extracted from the NHS Supply Chain catalogue. The unweighted mean of different devices was used in the model base case - £248. The device costs were annuitized using a discount rate of 3.5% and assuming the equipment is replaced after 7 years.
- In addition to the device the following costs were included:
    - Telemonitoring costs for the first year ResMed (£45).
    - Consumables (£121per year)
    - Education and set up was costed as a respiratory consultant-led outpatient consultation (NHS Reference cost £146)
    - 3 month and then annual follow-up was a non-consultant-led outpatient consultation. (NHS Reference cost £120)
    - It was assumed that 18% of patients using fixed-CPAP would require re-titration (£16)

MAS costs

- The unweighted average cost of custom-made mandibular advancement splints was £350. The durability of these devices in the base case was assumed to be 2 years.
- Education and set up, and 3 month and annual follow-up were done by a dentist (NHS Reference cost £113).
- The cost of a sleep study to assess treatment effectiveness was included in the first year (50% home respiratory polygraphy and 50% home oximetry).

Other costs and effects

- The cost of treating RTAs was taken from Department of Transport data.
- The cost of treatment, standardised mortality ratios and utility (quality of life) lost associated with cardiovascular events were taken from various sources.

Computations

The key outcomes were mean NHS cost per patient and mean QALYs per patient. These were calculated using a state-transition (Markov) model structure. Costs and QALYs occurring in the future were discounted at 3.5% per year to be consistent with the NICE reference case. The results were calculated both:

- Deterministically, based on the point estimates of each input parameter
- Probabilistically, based on a distribution for each input parameter (estimated using its standard error) and sampling the results 10,000 times before calculating a mean (Monte Carlo simulation.

1.5.5.3. Results

The base case results can be found in Table 16, Table 17 and Figure 1. The lowest cost strategy was Home oximetry with conservative management for mild OSAHS and the most costly was Hospital RP with Intervention for mild OSAHS. The difference between strategies in terms of the cost of treating cardiovascular events was negligible. This was partly because of the modest treatment effect assumed but also because the savings in patients treated with CPAP were offset by increased costs in those who were now surviving fatal road traffic accidents. The strategy with the greatest QALYs gained was Hospital RP with intervention. At a threshold of £20,000 per QALY, Home RP with intervention for mild OSAHS was the most cost effective strategy.

Table 16: Breakdown of mean cost (£) by diagnostic strategy in order of total cost (deterministic)

	Diagnosis	Treatment	Road traffic accidents	Cardiovascular events	Total
Oximetry (ConsM)	67	1,381	423	4,924	6,795
Screening (ConsM)	122	1,458	416	4,924	6,920
Home RP (ConsM)	190	1,955	350	4,922	7,417
Hospital RP (ConsM)	637	2,103	330	4,921	7,991
Oximetry (Interv'n)	67	2,230	315	4,925	7,536
Screening (Interv'n)	122	2,535	281	4,926	7,864
Home RP (Interv'n)	190	2,696	257	4,924	8,067
Hospital RP (Interv'n)	637	2,727	250	4,923	8,537

Table 17: Base case cost effectiveness of strategies in order of mean cost (probabilistic)

N		Mean costs	Mean QALYs	Cost per QALY gained (versus n=1)	INMB* (n versus n=1)	INMB* Rank	Probability highest INMB*	Median Rank of INMB*	95% CI of INMB rank*	
									Lower	Higher
1	Oximetry (ConsM)	6,810	13.514		0	7	6%	7	1	8
2	Screening (ConsM)	6,936	13.520	22,682	-15	8	0%	7	2	8
3	Home RP (ConsM)	7,429	13.577	9,823	641	5	1%	4	2	8
4	Oximetry (Intervention)	8,000	13.595	14,702	429	6	0%	6	3	8
5	Screening (Intervention)	7,547	13.585	10,499	667	4	1%	4	2	6
6	Hospital RP (ConsM)	7,875	13.612	10,878	893	3	7%	3	1	6
7	Home RP (Intervention)	8,078	13.644	9,765	1,328	1	72%	1	1	6
8	Hospital RP (Intervention)	8,547	13.655	12,364	1,072	2	12%	3	1	8

ConsM=Conservative management, CPAP=continuous passive airway pressure, INMB=Incremental net monetary benefit, QALY=quality-adjusted life-year, RP=respiratory polygraphy
** at £20,000 per QALY gained*

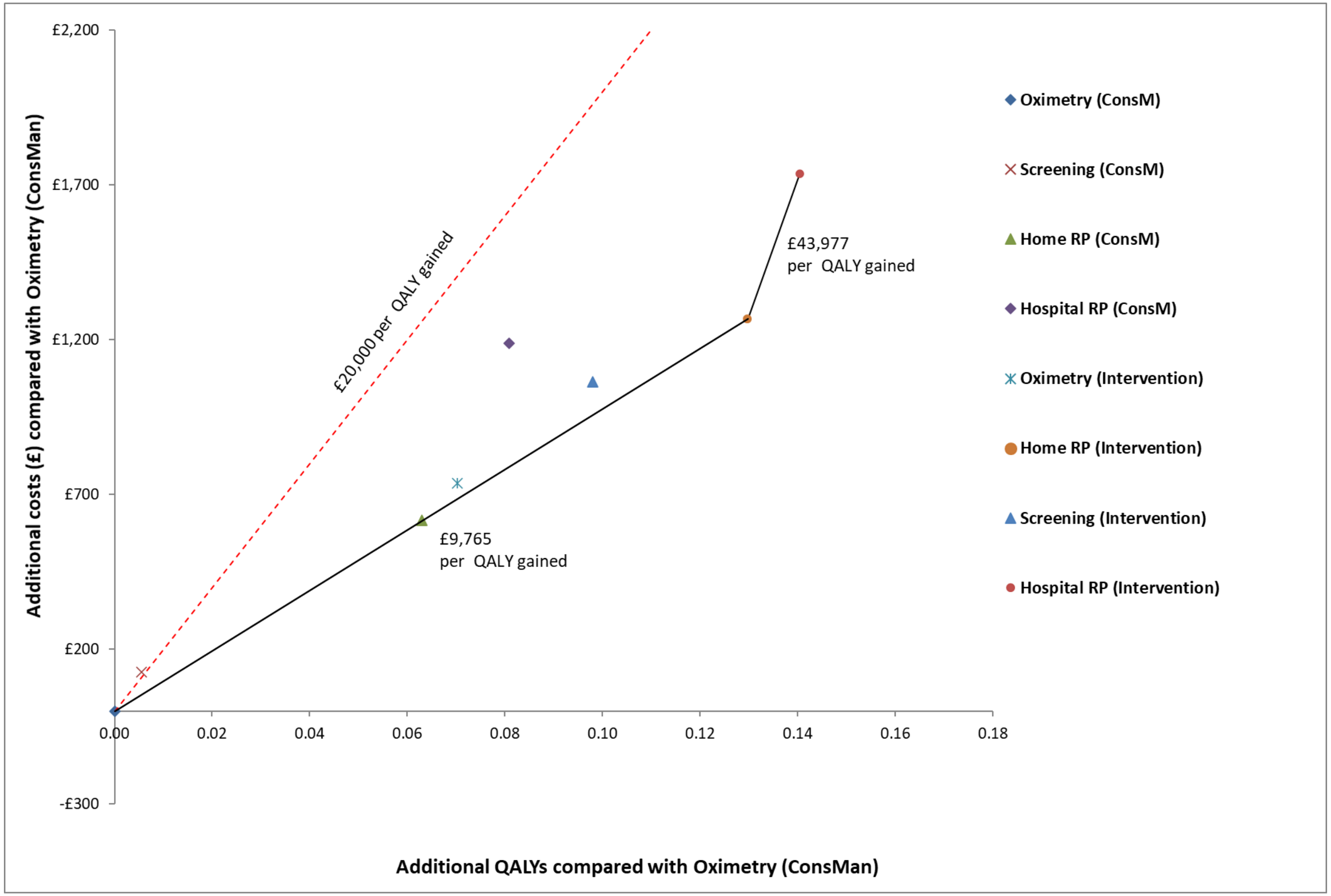

Figure 1: Base case cost effectiveness results (probabilistic)

A number of sensitivity analyses were conducted (**Table 18** and

Table 19). The ranking of treatments was quite stable across the analyses. In every scenario one of the four 'intervention' strategies was ranked first. Only in two scenarios was home respiratory polygraphy not ranked first:

- When it was assumed that all people with mild OSAHS receive CPAP then home oximetry screening was most cost effective test. We conducted a threshold analysis on the proportion of people that receive CPAP for mild OSAHS to see at which point the most cost effective strategy switches. If less than 84% of them receive CPAP, then Home respiratory polygraphy is the most cost-effective test. The reason that it switches is that if we are treating people with mild OSAHS exactly the same as people with moderate OSAHS then the need to differentiate mild OSAHS from moderate OSAHS is not important, whereas far more patients with moderate OSAHS are misdiagnosed as having Mild OSAHS with home oximetry than with home respiratory polygraphy.
- When we relaxed the assumption that that people with moderate/severe OSAHS would be retested due to persistence of symptoms then oximetry screening was the most cost effective strategy. We conducted a threshold analysis on the proportion of these misdiagnosed people that are retested to see at which point the most cost effective strategy switches. If 64% or more are re-tested, then Home respiratory polygraphy is the most cost-effective test. If it is less than that, then the screening strategy, where *all* patients testing negative are *systematically* retested yields more QALYs and is more cost effective

Table 18: Sensitivity analyses – net monetary benefit rank of diagnostic pathways (probabilistic)

Analysis	Rank of net monetary benefit at £20,000 per QALY gained							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
Base case results	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Diagnostic accuracy of strategies								
Extent of misdiagnosis is constrained (e.g. moderate OSAHS people can only be misdiagnosed as severe or mild OSAHS but not as no OSAHS)	Home RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Hospital RP (Interv'n)	Home RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)	Hospital RP (ConsM)
Retest for false negatives with persistent symptoms turned off in model	Screening (Interv'n)	Screening (ConsM)	Home RP (Interv'n)	Hospital RP (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (Interv'n)	Oximetry (ConsM)
Retest correlation of 20%	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Oximetry (Interv'n)	Hospital RP (ConsM)	Screening (ConsM)	Oximetry (ConsM)
Retest correlation of 40%	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (Interv'n)	Screening (ConsM)	Oximetry (ConsM)
Exclude Rofail (Accuracy of oximetry)	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)

Analysis	Rank of net monetary benefit at £20,000 per QALY gained							
	1	2	3	4	5	6	7	8
Exclude Wiltshire (Accuracy of oximetry)	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Include Pataka (Accuracy of oximetry)	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Oximetry (Interv'n)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Diagnostic strategies								
Retest for false negatives with persistent symptoms is Hospital RP	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
1st test in screening strategy home RP	Home RP (Interv'n)	Screening (Interv'n)	Hospital RP (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Screening (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)
2nd test in screening strategy hospital RP	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
1st test in screening strategy home RP, second test hospital RP	Home RP (Interv'n)	Screening (Interv'n)	Hospital RP (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Screening (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)
Polysomnography after second test for all False Negatives with underlying moderate/severe disease	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Polysomnography after first test for all False Negatives with underlying moderate/severe disease	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Treatment more cost effective								
CPAP ESS effect is based on ESS subgroup (not AHI subgroup)	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (Interv'n)	Oximetry (ConsM)	Screening (ConsM)
Reduce CPAP dropout rate by 20%	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
NHS and police costs	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
CPAP device lower cost	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)

Analysis	Rank of net monetary benefit at £20,000 per QALY gained							
	1	**2**	**3**	**4**	**5**	**6**	**7**	**8**
CPAP device and staff costs for education and setup are lower	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
All of the above (treatment more cost effective)	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (Interv'n)	Oximetry (ConsM)	Screening (ConsM)
Treatment less cost effective								
Increase CPAP dropout rate by 20%	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
High CPAP cost: auto-CPAP with telemonitoring	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
CPAP lifetime shorter: 5 years	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Turn off RTA treatment effects	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Oximetry (Interv'n)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Turn off CV treatment effects	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Turn off CV and RTA treatment effects	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Oximetry (Interv'n)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
All of the above (treatment less cost effective)	Home RP (Interv'n)	Screening (Interv'n)	Hospital RP (Interv'n)	Home RP (ConsM)	Oximetry (Interv'n)	Oximetry (ConsM)	Hospital RP (ConsM)	Screening (ConsM)
Cohort								
Low starting age of 30 years	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Screening (ConsM)	Oximetry (ConsM)
High starting age of 80 years	Home RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)	Hospital RP (Interv'n)	Hospital RP (ConsM)
Higher risk profile	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Lower risk profile	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Oximetry (Interv'n)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)

Analysis	Rank of net monetary benefit at £20,000 per QALY gained							
	1	2	3	4	5	6	7	8
Prevalence estimate of OSAHS is lower	Home RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Hospital RP (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Prevalence estimate of OSAHS is higher	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Oximetry (Interv'n)	Hospital RP (ConsM)	Screening (ConsM)	Oximetry (ConsM)
Other								
CV treatment effect also applies to mild OSAHS	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
False positives continue with treatment beyond 12 months	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Patients diagnosed with mild OSAHS: 100% receive CPAP	Screening (Interv'n)	Home RP (Interv'n)	Oximetry (Interv'n)	Hospital RP (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Patients diagnosed with mild OSAHS: 50% receive customised oral devices and 50% CPAP	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Patients diagnosed with mild OSAHS: 50% receive conservative management and 50% CPAP	Home RP (Interv'n)	Screening (Interv'n)	Hospital RP (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Low Home RP costs	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Home RP (ConsM)	Oximetry (Interv'n)	Hospital RP (ConsM)	Screening (ConsM)	Oximetry (ConsM)
High Home RP costs	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)
Treatment drop-out rate is the same for all levels of OSA severity	Home RP (Interv'n)	Hospital RP (Interv'n)	Screening (Interv'n)	Oximetry (Interv'n)	Home RP (ConsM)	Hospital RP (ConsM)	Oximetry (ConsM)	Screening (ConsM)

*ConsM=Conservative management, CPAP=continuous passive airway pressure, INMB=Incremental net monetary benefit, QALY=quality-adjusted life-year, RP=respiratory polygraphy, RTA=road traffic accident, * at £20,000 per QALY gained*

Table 19: Sensitivity analyses - cost per QALY gained for selected comparisons* (probabilistic)

Analysis	Cost per QALY gained		
	Home RP (ConsM) vs Oximetry (ConsM)	**Home RP (Interv'n) vs Home RP (Cons M)**	**Hospital RP (Interv'n) vs Home RP (Interv'n)**
Base case results	9,823	9,711	43,977
Diagnostic accuracy of strategies			
Extent of misdiagnosis is constrained (e.g. moderate OSAHS people can only be misdiagnosed as severe or mild OSAHS but not as no OSAHS)	13,759	9,358	733,932
Retest for false negatives with persistent symptoms turned off in model	9,077	9,711	40,943
Retest correlation of 20%	9,447	9,712	42,028
Retest correlation of 40%	9,296	9,830	42,832
Exclude Rofail (Accuracy of oximetry)	10,105	9,724	42,884
Exclude Wiltshire (Accuracy of oximetry)	10,464	9,727	42,405
Include Pataka (Accuracy of oximetry)	9,384	9,679	43,528
Diagnostic strategies			
Retest for false negatives with persistent symptoms is Hospital RP	8,886	9,788	42,937
1st test in screening strategy home RP	9,942	9,778	42,766
2nd test in screening strategy hospital RP	9,939	9,776	42,459
1st test in screening strategy home RP, second test hospital RP	9,837	9,759	43,888
Polysomnography after second test for all False Negatives with underlying moderate/severe disease	9,922	9,763	43,081
Polysomnography after first test for all False Negatives with underlying moderate/severe disease	7,956	9,699	43,246
Treatment more cost effective			
CPAP ESS effect is based on ESS subgroup (not AHI subgroup)	7,625	9,037	30,062
Reduce CPAP dropout rate by 20%	9,860	9,792	41,550
NHS and police costs	9,081	8,815	42,655
CPAP device lower cost	9,301	9,448	42,972

Analysis	Cost per QALY gained		
	Home RP (ConsM) vs Oximetry (ConsM)	Home RP (Interv'n) vs Home RP (Cons M)	Hospital RP (Interv'n) vs Home RP (Interv'n)
CPAP device and staff costs for education and setup are lower	8,915	9,183	42,990
All of the above (treatment more cost effective)	6,458	7,810	28,410
Treatment less cost effective			
Increase CPAP dropout rate by 20%	9,897	9,793	45,746
High CPAP cost: auto-CPAP with telemonitoring	11,385	10,667	45,505
CPAP lifetime shorter: 5 years	10,262	10,002	45,080
Turn off RTA treatment effects	11,885	12,369	45,809
Turn off CV treatment effects	10,102	9,771	45,035
Turn off CV and RTA treatment effects	12,203	12,437	46,631
All of the above (treatment less cost effective)	14,431	13,832	51,437
Cohort			
Low starting age of 30 years	8,269	8,272	33,786
High starting age of 80 years	15,278	12,507	106,602
Higher risk profile	10,143	10,120	47,390
Lower risk profile	10,553	10,774	42,384
Prevalence estimate of OSAHS is lower	12,050	10,672	64,506
Prevalence estimate of OSAHS is higher	9,513	9,636	41,583
Other			
CV treatment effect also applies to mild OSAHS	9,816	9,588	42,956
False positives continue with treatment beyond 12 months	9,882	9,704	43,640
Patients diagnosed with mild OSAHS: 100% receive CPAP	9,906	7,761	Dominated
Patients diagnosed with mild OSAHS: 50% receive customised oral devices and 50% CPAP	9,924	9,789	58,895
Patients diagnosed with mild OSAHS: 50% receive conservative management and 50% CPAP	9,817	7,693	54,750

Analysis	Cost per QALY gained		
	Home RP (ConsM) vs Oximetry (ConsM)	**Home RP (Interv'n) vs Home RP (Cons M)**	**Hospital RP (Interv'n) vs Home RP (Interv'n)**
Low Home RP costs	8,096	9,618	55,360
High Home RP costs	10,694	9,798	37,458
Treatment drop-out rate is the same for all levels of OSA severity	10,236	9,702	52,388

ConsM=Conservative management, CPAP=continuous passive airway pressure, INMB=Incremental net monetary benefit, QALY=quality-adjusted life-year, RP=respiratory polygraphy, RTA=road traffic accident
** The comparisons presented are those that were on the cost effectiveness frontier – see Figure 1.*

1.5.6. Health economic evidence statements

- A cost-utility analysis found that polysomnography was not cost effective compared with home respiratory polygraphy for diagnosing OSAHS (£113,800 per QALY gained). This was assessed as partially applicable with minor limitations.
- An original cost-utility analysis for symptomatic people suspected of having OSAHS, found that when only moderate and severe OSAHS is treated with CPAP and those with mild OSAHS receive conservative management:
  - home respiratory polygraphy was cost effective compared with home oximetry (£9,800 per QALY gained) and compared with screening (£8,600 per QALY gained).
  - hospital respiratory polygraphy was not cost effective compared with home respiratory polygraphy (£31,800 per QALY gained).
  - hospital respiratory polygraphy was cost effective compared with home oximetry (£14,100 per QALY gained) and compared with screening (8,600 per QALY gained).
  - Screening with home oximetry and then re-testing negatives with home respiratory polygraphy was cost effective at £30,000 per QALY but not at £20,000 per QALY compared with home oximetry alone (£22,700 per QALY gained).

  This was assessed as partially applicable with potentially serious limitations.
- An original cost-utility analysis for symptomatic people suspected of having OSAHS found that when 1/3 of people with mild OSAHS receive CPAP, 1/3 receive MAS and the remaining 1/3 receive conservative management:
  - home respiratory polygraphy was cost effective compared with home oximetry (£8,900 per QALY gained).
  - hospital respiratory polygraphy was not cost effective compared with home respiratory polygraphy (£44,000 per QALY gained).
  - hospital respiratory polygraphy was cost effective compared with home oximetry (£14,200 per QALY gained).
  - Screening with home oximetry and then re-testing negatives with home respiratory polygraphy was cost effective compared with home oximetry alone (£11,800 per QALY gained).

  This was assessed as partially applicable with potentially serious limitations.

1.6. The committee's discussion of the evidence

1.6.1. Interpreting the evidence

1.6.1.1. The diagnostic measures that matter most

Diagnostic tests

The committee reviewed the evidence on sensitivity and specificity of the various and tests. Specificity was considered most important as these tests could potentially be used in lieu of polysomnography for a final diagnosis.

All diagnostic tests (home oximetry, home RP, hospital RP) were stratified by severity as: all OSAHS (AHI≥5); moderate-severe OSAHS (AHI ≥15); severe OSAHS (AHI ≥30).

1.6.1.2. The quality of the evidence

OSAHS

Diagnostic tests

There was evidence from twenty three diagnostic accuracy studies: two studies for home oximetry (all severities OSAHS) included 73 and 84 participants respectively; three studies for home oximetry (moderate-severe OSAHS) with population size ranging from 69 to 98 participants; eight studies for home respiratory polygraphy (all severities OSAHS) with population size ranging from 37 to 348 participants; four studies for home respiratory polygraphy (moderate to severe OSAHS) including from 75 to 348 participants; four studies of home respiratory polygraphy (severe OSAHS) with population ranging from 43 to 128 participants; eight studies for hospital-based respiratory polygraphy (all severities OSAHS) with populations ranging from 43 to 80 participants; five studies for hospital-based respiratory polygraphy (moderate to severe OSAHS) with populations ranging from 42 to 80 participants; and three studies for hospital-based respiratory polygraphy (severe OSAHS) with populations ranging from 43 to 80 participants.. All studies included in the diagnostic accuracy review used polysomnography as the reference standard.

There was evidence from one medium size RCT (test and treat study) which included 430 participants comparing home respiratory polygraphy with polysomnography in moderate OSAHS.

The quality of evidence for diagnostic accuracy studies varied from moderate to very low quality; the majority of evidence was downgraded due to risk of bias, imprecision, indirectness and inconsistency. Risk of bias was most commonly due to selection bias. The committee also acknowledged that some uncertainty existed across the effect sizes seen within the evidence, with some confidence intervals crossing the MID thresholds or line of no effect. Indirectness was due to the AHI used in the studies not corresponding exactly to the AHI levels stipulated in our protocol (see section 1.4.1 above). Inconsistency was found in majority of comparisons (home oximetry all OSAHS (AHI ≥ 5) population, home respiratory polygraphy all OSAHS (AHI ≥5), moderate-severe OSAHS (AHI ≥ 15) and severe OSAHS (AHI ≥ 30) populations, hospital respiratory polygraphy all OSAHS (AHI ≥5), moderate-severe OSAHS (AHI ≥ 15) and severe OSAHS (AHI ≥ 15) populations). For inconsistency,the evidence was downgraded by 1 increment if the individual studies varied across 2 areas [(for example, 50–90% and 90–100%)] and by 2 increments if the individual studies varied across 3 areas [(for example, 0–50%, 50–90% and 90–100%)]. Subgroup analysis could not be conducted because there was no sufficient information (BMI or coexisting conditions) to conduct a subgroup analysis.. The committee took quality of the evidence in to account while interpreting the evidence for decision making.

The committee considered the clinical importance of AHI (test and treat study) on a case by case basis, taking into consideration the baseline AHI and the improvement in severity of sleep apnoea.

The quality of evidence for RCT (test and treat study) was moderate to very low due to risk of bias and imprecision. Risk of bias was most commonly due to selection bias and performance bias. The committee also acknowledged that some uncertainty existed across the effect sizes seen within the evidence, with some confidence intervals crossing the MID thresholds or line of no effect. The committee took quality of the evidence in to account while interpreting the evidence for decision making.

The committee noted that there was no formal chronological cut-off for the review, but technology is likely to have improved over the period of time studied in the included publications. However, there is no sharp demarcation in time, at which point it would be inappropriate to consider evidence and the improvement is likely to be seen with all the technical testing devices roughly to the same degree.

OHS

There was no evidence identified that assessed diagnostic tests forOHS.

COPD-OSAHS overlap syndrome

There was evidence from one diagnostic accuracy study in people with suspected COPD-OSAHS overlap syndrome. The study assessed the accuracy of hospital respiratory polygraphy (all severities COPD-OSAHS overlap syndrome) with 33 included participants, hospital respiratory polygraphy (moderate - severe COPD-OSAHS overlap syndrome) with 33 included participants and hospital respiratory polygraphy (severe COPD-OSAHS overlap syndrome) with 33 included participants. The study included in the diagnostic accuracy review used polysomnography as the reference standard.The quality of evidence for diagnostic accuracy studies varied from low to very low; the majority of evidence was downgraded due to risk of bias or imprecision. Risk of bias was most commonly due to selection bias. The committee also acknowledged that some uncertainty existed across the effect sizes seen within the evidence, with some confidence intervals crossing the MID thresholds or line of no effect. Indirectness was due to proxy AHI used in the studies. The committee took quality of the evidence in to account while interpreting the evidence for decision making.

1.6.1.3. Benefits and harms

OSAHS

Home oximetry (diagnostic accuracy studies)

The evidence from two studies reporting the diagnostic accuracy of home oximetry for all OSAHS population (AHI≥5) with a reference standard of hospital polysomnography showed low sensitivity [51.81% (8.2 to 92.2%)] and high specificity [95.83% (15.31 to 99.99%)], with very serious uncertainty around both sensitivity and specificity. The studies also had serious limitations as they excluded people with heart failure, respiratory insufficiency, COPD and anaemia. The committee agreed that this was important because these are relatively common conditions. Dips in arterial oxygen saturation are seen in these patient groups for reasons other than OSAHS, such as: artefacts, movement, and desaturation in those with baseline hypoxaemia due to a normal degree of hypoventilation, particularly in rapid eye movement sleep. These oxygen dips would reduce the diagnostic accuracy of oximetry by reducing its specificity and lead to an increase in the number of false positive results. It is also possible that people with OSAHS and only mild or minimal nocturnal desaturation would be missed, e.g. using a 4% oxygen desaturation cut-off rate. The committee noted that this could be one of the reasons for low sensitivity and took this in to account while interpreting the evidence. They agreed that it is important clinically, as the clinicians will need to to have confidence to reassure people their study results are normal

The evidence from three studies reporting the diagnostic accuracy of home oximetry in a moderate-severe population (AHI≥15) showed low sensitivity [35.02% (12.98 to 65.24%)] and high specificity [99.44% (95.35 to 99.98%)].It was noted by the committee that there was serious uncertainty around sensitivity. The committee discussed that the results were counterintuitive, as it is commonly understood that detecting moderate-severe OSAHS (AHI≥15-30) is easier than detecting mild OSAHS (AHI≥5) using home oximetry.

There was no evidence reporting home oximetry for severe OSAHS population (AHI≥30).

The committee agreed that the inconsistency observed in a number of the outcomes in home oximetry was not surprising as different studies used slightly different cut-offs for the index and reference test.

Home respiratory polygraphy (diagnostic accuracy studies)

The evidence from eight studies reporting the diagnostic accuracy for home respiratory polygraphy for all OSAHS population (AHI≥5) showed high sensitivity [94.65% (89.81 to 97.36%)] and moderate specificity [57.69% (39.87 to 74.41%)], with serious uncertainty for both sensitivity and specificity. The evidence from four studies reporting the diagnostic accuracy for home respiratory polygraphy for a moderate-severe OSAHS population

(AHI≥15) showed high sensitivity [84.2% (59.67 to 95.87%)] and high specificity [88.95% (71.07 to 96.56%)], with very serious uncertainty around sensitivity and serious uncertainty around specificity.

The evidence from three studies reporting the diagnostic accuracy for home respiratory polygraphy in a severe OSAHS population (AHI≥30) showed moderate sensitivity [64.25% (28.6 to 89.74%)] and high specificity [92.06% (68.46to 98.28%)], with very serious uncertainty around sensitivity and serious uncertainty around specificity.

The committee noted that there was an inverse relationship between sensitivity and specificity of home respiratory polygraphy in OSAHS population as sensitivity decreased and specificity increased with with higher cut-off points.

Home respiratory polygraphy RCT (test and treat studies)

The test and treat evidence showed that regardless of accuracy, a home respiratory polygraphy-based approach resulted in equivalent clinical outcomes to in centre polysomnography-based approach to diagnosis.

There was no clinically important difference for EQ5D, FOSQ, SF 36 physical and mental components, Epworth sleepiness scale, AHI, change in systolic blood pressure.The number of people given CPAP per thousand was lower in the home respiratory polygraphy group compared to the polysomnography group.The committee acknowledged that some uncertainty existed across the effect sizes seen within the evidence. The committee also noted that this evidence was only reported at 6 months and longer-term results were not available.

Hospital respiratory polygraphy (diagnostic accuracy studies)

The evidence from eight studies reporting the diagnostic accuracy for hospital respiratory polygraphy for all OSAHS population (AHI≥5) showed high sensitivity [94.68% (87.61 to 98.61%)] and moderate specificity of [81.39% (57.46 to 92.48%)] with serious uncertainty around sensitivity and very serious uncertainty around specificity.

The evidence from five studies reporting the diagnostic accuracy for hospital respiratory polygraphy for a moderate-severe OSAHS population (AHI≥15) showed high sensitivity [93.22% (81.09 to 98.39)] and high specificity [92.57% (82.79 to 97.5%)], with serious uncertainty around both sensitivity and specificity.

The evidence from four studies reporting the diagnostic accuracy for hospital respiratory polygraphy for a severe OSAHS population (AHI≥30) showed high sensitivity [94.35% (74.35 to 99.28%)] and moderate specificity [92.59% (1.8 to 99.99%)], with serious uncertainty around sensitivity and very serious uncertainty around specificity.

The committee noted that specificity of hospital respiratory polygraphy in OSAHS population increased with higher cut-off points. However even though the sensitivity was highest fo all severities OSAHS (AHI≥5) at 94.68% it was very similar to sensitivity for severe OSAHS population (AHI≥30) at 94.35%. Interestingly the lowest sensitivity was for moderate-severe OSAHS population at 93.22%.

COPD-OSAHS overlap syndrome

Hospital respiratory polygraphy (diagnostic accuracy studies)

The evidence from one study reporting the diagnostic accuracy for hospital respiratory polygraphy for all COPD-OSAHS overlap population (AHI≥5) showed high sensitivity [96% (79 to 100%)] and moderate specificity [56% (21 to 86%)], with serious uncertainty around both sensitivity and specificity.

The evidence from one study study reporting the diagnostic accuracy for hospital respiratory polygraphy for moderate-severe COPD-OSAHS overlap population (AHI≥15) showed moderate sensitivity [77%(46 to 95%)] and high specificity [90% (68 to 99%)], with very serious uncertainty around sensitivity and serious uncertainty around specificity.

The evidence from one study study reporting the diagnostic accuracy for hospital respiratory polygraphy for severe COPD-OSAHS overlap population (AHI≥30) showed moderate sensitivity [89%(52 to 100%)] and high specificity [96% (79 to 100%)], with very serious uncertainty around sensitivity and serious uncertainty around specificity.

The committee noted that specificity of hospital respiratory polygraphy in COPD-OSAHS overlap population increased with higher cut-off points. However the sensitivity was highest for all severities COPD - OSAHS (AHI≥5) at 96% and lowest for moderate-severe COPD-OSAHS population (AHI≥15) at 77% with sensitivity for severe COPD-OSAHS overlap population (AHI≥15) at 89%.

Diagnostic tests -committee's consideration of the evidence to make recommendations

OSAHS

The evidence on diagnostic tests for OSAHS was not consistent. The studies reviewed looked at diagnostic devices with a variety of monitoring channels and included different patient groups. The committee also noted that diagnostic equipment has evolved and improved over time. The committee used their clinical knowledge and experience, supported by the published evidence and by the economic model developed for this guideline to make the recommendations.

The evidence overall favoured both home and hospital respiratory polygraphy as the first-line diagnostic test most likely to give an accurate result without retesting. The committee noted that respiratory polygraphy has the added benefit of aiding the diagnosis of other conditions such as central sleep apnoea and nocturnal hypoventilation and it is better than oximetry alone in identifying artefacts in the recordings.

The use of oximetry alone, or oximetry followed by home respiratory polygraphy if initial oximetry is negative, was less cost effective than initial respiratory polygraphy The committee agreed that where access to respiratory polygraphy is limited then oximetry should be considered first. However, diagnostic strategies incorporating oximetry are still used in practice, for example by sites at which the volume of referrals exceeds the availability of home polygraphy equipment and the committee recognised that it might take time and significant resources to change this practice. They noted that in cases in which a priori suspicion of OSAHS is low, a normal oximetry result provides further evidence to rule out the diagnosis. The committee agreed that oximetry could still be an option and this would help to avoid unacceptable delays in diagnosis where there is a lack of access to respiratory polygraphy.

The committee also highlighted the potential problems of relying on oximetry for diagnosis. Oximetry may be particularly inaccurate in people with conditions such as heart failure or chronic lung disease, which can result in desaturation without the presence of OSAHS, although they agreed that a negative test is still useful. In addition, oximetry cannot reliably distinguish between obstructive or central apnoeas and nocturnal hypoventilation, which is important to help determine treatment.

The option to do the sleep study in hospital was also considered important by the committee. Hospital respiratory polygraphy may sometimes be needed when investigating alternative diagnoses alongside OSAHS, because extra monitoring channels can be utilised. It might also be an option if home respiratory polygraphy or home oximetry are impractical, for example in people who need help with the monitoring equipment, or need to travel long distances to pick up and return devices, or when a number of inpatient investigations need to be combined.

Polysomnography was the reference standard for the tests included in the review. The committee agreed that further investigation with polysomnography, which is more accurate and more expensive than respiratory polygraphy, should be an option to provide more detail on sleep fragmentation and respiratory events for people with symptoms (listed in recommendation 1.1.1) who have a negative respiratory polygraphy or oximetry result but continue to have suggestive symptoms. This may help distinguish between OSAHS and other disorders such as narcolepsy, REM sleep behaviour disorder, periodic limb movement disorders, idiopathic hypersomnolence or parasomnia which are suspected as a more likely diagnosis for the person’s symptoms, or help diagnose these disorders when they are suspected in addition to OSAHS.

Even though there was a lack of evidence for diagnostic tests for OSAHS, based on their experience the committee made strong recommendations hence they did not make any research recommendation for these tests.

Current practice is variable, with some sleep centres offering oximetry as the first-line test and others offering home respiratory polygraphy. The recommendations will help reduce this variation by encouraging the use of home respiratory polygraphy over home oximetry. Some centres will need to provide more home respiratory equipment and less home oximetry devices but improved testing should lead to fewer repeat tests and optimal treatment. The option to use home oximetry as an alternative to respiratory polygraphy will lessen the impact on resources as practice changes.

OHS

There was no evidence for diagnostic tests for people with suspected OHS, so the committee used their clinical knowledge and experience to make the recommendations.

OHS is characterised by obesity with a BMI over 30 kg/m^2 and daytime hypercapnia with a PaCO2 >6kPa.

Diagnosing OHS

OHS is one specific cause of chronic ventilatory failure, and by definition a measurement of PaCO2 from arterial or arterialised capillary blood gas, taken while the person with suspected OHS is awake, is needed to establish the diagnosis. It is current practice to measure these and although they are invasive tests obtaining the samples is generally straightforward.

The committee discussed the use of serum venous bicarbonate measurements and recognised that these may be helpful in people with suspected OHS as a preliminary test. Serum bicarbonate indirectly reflects medium and long-term PaCO2 levels and is a simpler and less painful test than blood gas measurement and a normal level is helpful in ruling out OHS if the probability of diagnosis low.. The committee therefore agreed that it could be recommended in such cases, but noted that this alone will not completely rule out OHS and that other tests are needed when clinical suspicion is high.

People with any form of chronic ventilatory failure can readily develop acute ventilatory failure if, for example, they have an intercurrent respiratory tract infection. Acute ventilatory failure is a medical emergency needing urgent treatment, and the committee agreed it is important to state that this should take priority over full investigation of any underlying chronic disease.

Diagnosing the presence of OSAHS or nocturnal hypoventilation in OHS

The committee agreed that diagnosis of concomitant OSAHS is required to ensure optimal treatment, and that this should be with either hospital or home respiratory polygraphy based on their experience and the evidence for diagnosis of OSAHS in people without OHS.

The committee agreed that transcutaneous CO_2 monitoring should also be considered at the same time, to help establish the severity of nocturnal hypoventilation.A markedly raised CO_2 level suggests non-invasive ventilation may be the treatment of choice rather than CPAP and the committee agreed this should be considered.

The committee agreed that oximetry alone as a diagnostic test is insufficient for diagnosis because it does not clearly distinguish between obstructive apnoeas and nocturnal hypoventilation. With this in mind the committee made a recommendation to not use oximetry alone to determine the presence of OSAHS in people with OHS.

The committee noted that the recommendations reflect current practice and would therefore not be expected to increase NHS cost.

Even though there was a lack of evidence for respiratory polygraphy, oximetry, arterial or arterialised capillary blood gas, transcutaneous CO2 and serum venous bicarbonate, based on their experience the committee made strong recommendations hence they did not make any research recommendation for these tests.

There was no evidence for hospital oxycapnography and home oxycapnography, the committee agreed not make a recommendation or research recommendation for these tests as they are not routinely used in diagnostic clinical practice in most centres.

COPD-OSAHS overlap syndrome

There was limited evidence from one small study for diagnostic tests in people with COPD–OSAHS overlap syndrome, suggesting that respiratory polygraphy has reasonable sensitivity and specificity in making the diagnosis. COPD and OSAHS are both common conditions and the committee were able to use their clinical knowledge and experience in addition to the formal evidence in making recommendations.

Diagnosing ventilatory failure

Ventilatory failure is a common in COPD and causes severe exacerbations of chronic obstructive pulmonary disease (COPD). Measurement of PaCO2 from arterial or arterialised capillary blood gas, taken while the person with suspected COPD-OSAHS overlap syndrome is awake, is needed to establish the diagnosis. It is current practice to measure these and although they are invasive tests obtaining the samples is generally straightforward.

People with any form of chronic ventilatory failure can readily develop acute ventilatory failure if, for example, they have an intercurrent respiratory tract infection. Acute ventilatory failure is a medical emergency needing urgent treatment, and the committee agreed it important to state that this should take take priority over full investigation of any underlying chronic disease.

The committee agreed that arterial blood gas and arterialised capillary blood gas measurements give precise information about oxygen and carbon dioxide levels and information about acid base balance at the point in time they are taken.

Diagnosing the presence of OSAHS or nocturnal hypoventilation in COPD-OSAHS overlap syndrome

The committee agreed that respiratory polygraphy (either in hospital or at home) should be recommended to establish the presence of OSAHS and nocturnal hypoventilation and also to help determine the most suitable treatment (i.e. non-invasive ventilation/CPAP), based on the evidence for OSAHS alone (see above) plus the small study directly addressing COPD-OSAHS overlap syndrome. The committee agreed that transcutaneous CO_2 monitoring with respiratory polygraphy should also be considered to help confirm nocturnal hypoventilation and severity of hypercapnia. Adding transcutaneous CO_2 monitoring with respiratory polygraphy may also help to define the relative contributions of COPD and OSAHS and therefore guide treatment choices and titration of settings. The committee noted that while transcutaneous CO2 monitoring can be carried out at home, this is not routinely incorporated into level 3 diagnostic devices, requires more frequent calibration and therefore a measure of CO2 is usually carried out as part of an in-hospital RP. The person needs to have stable COPD, without a recent exacerbation, before a clear diagnosis can be established.

The committee agreed that oximetry alone should not be used to diagnose OSAHS in this population because people with COPD are more likely to have a degree of hypoxaemia when awake, and therefore more easily exhibit falls in oxygen saturation level when asleep, making identification of apnoea episodes more difficult.

As with people with OHS, those with COPD-OSAHS overlap syndrome may present in acute ventilatory failure is a medical emergency requiring urgent treatment, and this must take priority over full investigation of any underlying chronic disease.

The committee stated that the recommendations reflect current actual practice.

Even though there was a lack of evidence for diagnostic tests for COPD-OSAHS overlap syndrome, based on their experience the committee made strong recommendations hence they did not make any research recommendation for these tests.

1.6.2. Cost effectiveness and resource use

One economic evaluation was included in this review, which evaluated the cost-effectiveness of polysomnography (PSG) compared to home respiratory polygraphy (RP) in patients suspected of OSAHS.[93] This study, conducted in Spain with costings from a Spanish health care perspective, found that PSG was not cost-effective when compared to home RP. The committee explained that current practice has evolved to perform PSG tests only when they were necessary, due to their high costs. This would include patients who remain symptomatic despite a negative respiratory polygraphy.

Some regions have used simple oximetry as a first line strategy to diagnose OSAHS due to its low costs. However, the committee noted the low sensitivity of this test compared to the home RP, and the negative long-term health outcomes (cardiovascular events and road traffic accidents) associated with a false negative diagnosis.

An original cost-utility analysis was constructed to evaluate the cost effectiveness of home RP compared to both home oximetry and in-hospital RP for patients suspected of having OSAHS, using the diagnostic accuracy evidence from the guideline's systematic review. In the model, the benefits of a successful diagnosis were improved health-related quality of life and also a reduced incidence of road traffic accidents and (for moderate or severe OSAHS) reduced cardiovascular events.

The same decision model was used to evaluate different treatments for mild OSAHS. In those analyses, CPAP was the most cost effective strategy for mild OSAHS (see Evidence report E). CPAP was also the treatment of choice for moderate and severe OSAHS on the basis of NICE technology appraisal TA139.

The diagnostic strategy with the greatest QALYs gained was Hospital RP with intervention. At a threshold of £20,000 per QALY, Home RP with intervention for mild OSAHS was the most cost effective strategy.

The committee noted some limitations with this analysis:

- The studies in the diagnostic accuracy review, on which this model was based, typically excluded people with heart failure or lung disease such as COPD. Had this not been the case, then the specificity observed might have been lower, since people with these conditions can experience drops in oxygen in the absence of OSAHS. For this reason, the specificity of oximetry in the model might have been over-estimated.
- Due to lack of evidence, the model pathway is not well developed for true negatives and false positives. We did not find evidence for the prevalence of alternative diagnoses in the relevant population and hence the model did not capture the health consequences of false positive diagnoses. Nor did it capture the cost of subsequent treatment for both true negatives and false negatives. Since home RP can assist in diagnosing other conditions (such as central sleep apnoea and nocturnal hypoventilation), there are likely to be additional benefits associated with home RP that are not captured in the model.

The committee concluded that home RP is the most cost effective first-line diagnostic test for diagnosing OSAHS and therefore they recommended it. The second most cost effective test was in-hospital RP, so the committee recommended this for occasions when home respiratory polygraphy is not feasible. However, they noted that due to the risk of transmitting infectious disease its use should be avoided wherever possible. The model did not evaluate the use of polysomnography per se but when in a sensitivity analysis it was added in to the model as a 3rd line test, it did not change the ranking of the strategies. The committee recommended that home oximetry be used as the first-line test for OSAHS where respiratory polygraphy is not practical.

Finally, the committee made consensus recommendations for the OHS and COPD-OSAHS overlap syndrome populations based on their clinical expertise, as there was no clinical or economic evidence available to steer recommendations. The consensus recommendations in the OHS and overlap syndrome populations ensure that the NHS has some guidance from the committee based on what is occurring in practice. Blood gas measurement is recommended to diagnose OHS. It is also recommended for assesing ventilatory failure in people with suspected COPD–OSAHS overlap syndrome. This is a commonly used and relatively low cost test. The committee agreed that transcutaneous CO_2 monitoring should also be considered for people with OHS or COPD–OSAHS overlap syndrome as this is useful to confirm nocturnal hypercapnia, which might indicate if non-invasive ventilation is required. This might require the use of in-hospital RP rather than home RP.

1.6.3. Other factors the committee took into account

The committee noted that home testing would be preferred by most people as it reduces the need for them to attend hospital, and they are more likely to have typical sleep episodes at home.

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Appendices

Appendix A: Review protocols

Table 20: Review protocol diagnosis of obstructive sleep apnoea/hypopnoea syndrome, obesity hypoventilation syndrome and COPD-OSAHS overlap syndrome

Field	Content
PROSPERO registration number	Not registered
Review title	Diagnostic tests
Review question	What are the most clinically and cost effective diagnostic strategies for obstructive sleep apnoea/hypopnea syndrome, obesity hypoventilation syndrome and COPD-OSAHS overlap syndrome, including home- and hospital-based studies, and investigations such as oximetry, capnography, respiratory polygraphy and polysomnography?
Objective	To determine what are the most clinically and cost effective diagnostic strategies for obstructive sleep apnoea/hypopnea syndrome, obesity hypoventilation syndrome and COPD-OSAHS overlap syndrome.
Searches	The following databases (from inception) will be searched: • Cochrane Central Register of Controlled Trials (CENTRAL) • Cochrane Database of Systematic Reviews (CDSR) • Embase • MEDLINE • Epistemonikos Searches will be restricted by: • English language studies The searches may be re-run 6 weeks before the final committee meeting and further studies retrieved for inclusion if relevant. The full search strategies will be published in the final review.
Condition or domain being studied	Obstructive sleep apnoea/hypopnoea syndrome is the most common form of sleep disordered breathing. The guideline will also cover obesity hypoventilation syndrome and COPD-OSAHS overlap syndrome overlap syndrome (the coexistence of obstructive sleep apnoea/hypopnoea syndrome and chronic obstructive pulmonary disease).
Population	Inclusion: People in whom OSAHS/OHS/ COPD-OSAHS overlap syndrome is suspected based on symptoms or co-existing conditions Population will be stratified by: Suspicion of OSAHS vs OHS vs COPD-OSAHS overlap syndrome

Intervention/Exposure/Test	Index tests strategies will include any one or more of the below: • Home oximetry • Home oxycapnography (OHS only) • Home respiratory polygraphy • Venous bicarbonate (OHS only) • Hospital oxycapnography (OHS only) • Hospital respiratory polygraphy For test and treat studies, negative test results must receive no OSAHS/OHS/ COPD-OSAHS overlap syndrome treatment and positive test results should receive some form of OSAHS/OHS/ COPD-OSAHS overlap syndrome (including CPAP, surgery, mandibular devices – directness to be assessed against results of intervention reviews elsewhere in the guideline).
Comparator/Reference standard/Confounding factors	**Accuracy** For diagnosis of OSAHS reference standard will be AHI/RDI/ODI >5 by hospital polysomnography For diagnosis of OHS reference standard will be hypercapnia on arterial/capillary blood gases **Test and treat** Any testing strategy compared with any other including the reference standards listed above
Types of study to be included	Single gate cross-sectional study designs will be included in the accuracy review. Two gate study designs will be excluded from the accuracy review RCTs will be prioritised for test and treat comparisons, if insufficient RCTs are found, non-randomised studies will be considered if they adjust for key confounders (age, BMI, co-existing conditions).
Other exclusion criteria	None
Context	NA
Primary outcomes (critical outcomes)	**Accuracy outcomes**: • Sensitivity • Specificity • PPV • NPV **Test and treat outcomes**: • Mortality (dichotomous) • Generic or disease specific quality of life (continuous)
Secondary outcomes	**Test and treat outcomes**: • Sleepiness scores (continuous, e.g. Epworth)

(important outcomes)	• Apnoea-Hypopnoea index or respiratory disturbance index (continuous)
	• Oxygen desaturation index (continuous)
	• Healthcare resource use (rates/dichotomous)
	• Impact on co-existing conditions:
	  o HbA1c for diabetes (continuous)
	  o Cardiovascular events for cardiovascular disease (dichotomous)
	  o Systolic blood pressure for hypertension (continuous)	

Data extraction (selection and coding)	EndNote will be used for reference management, sifting, citations and bibliographies. All references identified by the searches and from other sources will be screened for inclusion. 10% of the abstracts will be reviewed by two reviewers, with any disagreements resolved by discussion or, if necessary, a third independent reviewer. The full text of potentially eligible studies will be retrieved and will be assessed in line with the criteria outlined above. A standardised form will be used to extract data from studies (see Developing NICE guidelines: the manual section 6.4).	
Risk of bias (quality) assessment	Risk of bias will be assessed using the appropriate checklist as described in Developing NICE guidelines: the manual. • Diagnostic test accuracy studies: QUADAS-2 • Standard RCT checklists will be used to critically appraise individual studies for the test and treat evidence. 10% of all evidence reviews are quality assured by a senior research fellow. This includes checking: • papers were included /excluded appropriately • a sample of the data extractions • correct methods are used to synthesise data • a sample of the risk of bias assessments Disagreements between the review authors over the risk of bias in particular studies will be resolved by discussion, with involvement of a third review author where necessary.	
Strategy for data synthesis	RevMan will be used for production of paired forest plots and pairwise meta-analysis of test and treat outcomes. WinBUGS will be used for meta-analysis of diagnostic accuracy studies. GRADEpro will be used to assess the quality of evidence for each test and treat outcome. **For test and treat studies** Heterogeneity between the studies in effect measures will be assessed using the I^2 statistic and visually inspected. An I^2 value greater than 50% will be considered indicative of substantial heterogeneity. Sensitivity analyses will be conducted based on pre-specified subgroups using stratified meta-analysis to explore the heterogeneity in effect estimates. If this does not explain the heterogeneity, the results will be presented pooled using random-effects.	
Analysis of sub-groups	Subgroups that will be investigated if heterogeneity is present: • BMI – obese vs non-obese • Co-existing conditions vs no co-existing conditions	
	☐	Intervention

Type and method of review	☒	Diagnostic
	☐	Prognostic
	☐	Qualitative
	☐	Epidemiologic
	☐	Service Delivery
	☐	Other (please specify)
Language	English	
Country	England	
Anticipated or actual start date	NA	
Anticipated completion date	NA	
Named contact	5a. Named contact National Guideline Centre 5b Named contact e-mail SleepApnoHypo@nice.org.uk 5e Organisational affiliation of the review National Institute for Health and Care Excellence (NICE) and the National Guideline Centre	
Review team members	From the National Guideline Centre: Carlos Sharpin, Guideline lead Sharangini Rajesh, Senior systematic reviewer Audrius Stonkus, Systematic reviewer Emtiyaz Chowdhury (until January 2020), Health economist David Wonderling, Head of health economics Agnes Cuyas, Information specialist (till December 2019) Jill Cobb, , Information specialist	
Funding sources/sponsor	This systematic review is being completed by the National Guideline Centre which receives funding from NICE.	
Conflicts of interest	All guideline committee members and anyone who has direct input into NICE guidelines (including the evidence review team and expert witnesses) must declare any potential conflicts of interest in line with NICE's code of practice for declaring and dealing with conflicts of interest. Any relevant interests, or changes to interests, will also be declared publicly at the start of each guideline committee meeting. Before each meeting, any potential conflicts of interest will be considered by the guideline committee Chair and a senior member of the development team. Any decisions to exclude a person from all or part of a meeting will be documented. Any changes to a member's declaration of interests will be recorded in the minutes of the meeting. Declarations of interests will be published with the final guideline.	

Collaborators	Development of this systematic review will be overseen by an advisory committee who will use the review to inform the development of evidence-based recommendations in line with section 3 of Developing NICE guidelines: the manual. Members of the guideline committee are available on the NICE website: https://www.nice.org.uk/guidance/indevelopment/gid-ng10098
Other registration details	NA – not registered
Reference/URL for published protocol	NA – not registered
Dissemination plans	NICE may use a range of different methods to raise awareness of the guideline. These include standard approaches such as: • notifying registered stakeholders of publication • publicising the guideline through NICE's newsletter and alerts • issuing a press release or briefing as appropriate, posting news articles on the NICE website, using social media channels, and publicising the guideline within NICE.
Keywords	-
Details of existing review of same topic by same authors	NA
Additional information	-
Details of final publication	www.nice.org.uk

Table 21: Health economic review protocol

Review question	All questions – health economic evidence
Objectives	To identify health economic studies relevant to any of the review questions.
Search criteria	• Populations, interventions and comparators must be as specified in the clinical review protocol above. • Studies must be of a relevant health economic study design (cost–utility analysis, cost-effectiveness analysis, cost–benefit analysis, cost–consequences analysis, comparative cost analysis). • Studies must not be a letter, editorial or commentary, or a review of health economic evaluations. (Recent reviews will be ordered although not reviewed. The bibliographies will be checked for relevant studies, which will then be ordered.) • Unpublished reports will not be considered unless submitted as part of a call for evidence. • Studies must be in English.
Search strategy	A health economic study search will be undertaken using population-specific terms and a health economic study filter – see appendix B below.
Review strategy	Studies not meeting any of the search criteria above will be excluded. Studies published before 2003, abstract-only studies and studies from non-OECD countries or the USA will also be excluded.

Each remaining study will be assessed for applicability and methodological limitations using the NICE economic evaluation checklist which can be found in appendix H of Developing NICE guidelines: the manual (2014).[360]

Inclusion and exclusion criteria

- If a study is rated as both 'Directly applicable' and with 'Minor limitations' then it will be included in the guideline. A health economic evidence table will be completed and it will be included in the health economic evidence profile.
- If a study is rated as either 'Not applicable' or with 'Very serious limitations' then it will usually be excluded from the guideline. If it is excluded, then a health economic evidence table will not be completed and it will not be included in the health economic evidence profile.
- If a study is rated as 'Partially applicable', with 'Potentially serious limitations' or both then there is discretion over whether it should be included.

Where there is discretion

The health economist will make a decision based on the relative applicability and quality of the available evidence for that question, in discussion with the guideline committee if required. The ultimate aim is to include health economic studies that are helpful for decision-making in the context of the guideline and the current NHS setting. If several studies are considered of sufficiently high applicability and methodological quality that they could all be included, then the health economist, in discussion with the committee if required, may decide to include only the most applicable studies and to selectively exclude the remaining studies. All studies excluded on the basis of applicability or methodological limitations will be listed with explanation in the excluded health economic studies appendix below.

The health economist will be guided by the following hierarchies.

Setting:

- UK NHS (most applicable).
- OECD countries with predominantly public health insurance systems (for example, France, Germany, Sweden).
- OECD countries with predominantly private health insurance systems (for example, Switzerland).
- Studies set in non-OECD countries or in the USA will be excluded before being assessed for applicability and methodological limitations.

Health economic study type:

- Cost–utility analysis (most applicable).
- Other type of full economic evaluation (cost–benefit analysis, cost-effectiveness analysis, cost–consequences analysis).
- Comparative cost analysis.
- Non-comparative cost analyses including cost-of-illness studies will be excluded before being assessed for applicability and methodological limitations.

Year of analysis:

- The more recent the study, the more applicable it will be.
- Studies published in 2003 or later but that depend on unit costs and resource data entirely or predominantly from before 2003 will be rated as 'Not applicable'.
- Studies published before 2003 will be excluded before being assessed for applicability and methodological limitations.

Quality and relevance of effectiveness data used in the health economic analysis:

- The more closely the clinical effectiveness data used in the health economic analysis match with the outcomes of the studies included in the clinical review the more useful the analysis will be for decision-making in the guideline.

Appendix B: Literature search strategies

Sleep Apnoea search strategy 3 diagnostic tests/assessment

This literature search strategy was used for the following reviews;

- What are the most clinically and cost effective diagnostic strategies for obstructive sleep apnoea/hypopnea syndrome, obesity hypoventilation syndrome and COPD-OSAHS overlap syndrome, including home- and hospital-based studies, and investigations such as oximetry, capnography, respiratory polygraphy and polysomnography?

The literature searches for this review are detailed below and complied with the methodology outlined in Developing NICE guidelines: the manual.[360]

For more information, please see the Methods Report published as part of the accompanying documents for this guideline.

B.1 Clinical search literature search strategy

Searches were constructed using a PICO framework where population (P) terms were combined with Intervention (I) and in some cases Comparison (C) terms. Outcomes (O) are rarely used in search strategies for interventions as these concepts may not be well described in title, abstract or indexes and therefore difficult to retrieve. Search filters were applied to the search where appropriate.

Table 22: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline (OVID)	1946 – 6 July 2020	Exclusions Randomised controlled trials Systematic review studies Observational studies Diagnostic tests studies
Embase (OVID)	1974 – 6 July 2020	Exclusions Randomised controlled trials Systematic review studies Observational studies Diagnostic tests studies
The Cochrane Library (Wiley)	Cochrane Reviews to 2020 Issue 7 of 12 CENTRAL to 2020 Issue 7 of 12	None
Epistemonikos (Epistemonikos Foundation)	Inception – 29 November 2018	None

Medline (Ovid) search terms

1.	exp Sleep Apnea Syndromes/
2.	(sleep* adj4 (apn?ea* or hypopn?ea*)).ti,ab.
3.	(sleep* adj4 disorder* adj4 breath*).ti,ab.
4.	(OSAHS or OSA or OSAS).ti,ab.

5.	(obes* adj3 hypoventil*).ti,ab.
6.	pickwick*.ti,ab.
7.	or/1-6
8.	letter/
9.	editorial/
10.	news/
11.	exp historical article/
12.	Anecdotes as Topic/
13.	comment/
14.	case report/
15.	(letter or comment*).ti.
16.	or/8-15
17.	randomized controlled trial/ or random*.ti,ab.
18.	16 not 17
19.	animals/ not humans/
20.	exp Animals, Laboratory/
21.	exp Animal Experimentation/
22.	exp Models, Animal/
23.	exp Rodentia/
24.	(rat or rats or mouse or mice).ti.
25.	or/18-24
26.	7 not 25
27.	limit 26 to English language
28.	(exp child/ or exp pediatrics/ or exp infant/) not (exp adolescent/ or exp adult/ or exp middle age/ or exp aged/)
29.	27 not 28
30.	(Epworth or ESS or ESS-CHAD).ti,ab.
31.	(STOP-bang or stopbang or "snoring tired observed pressure").ti,ab.
32.	((sleep* or Berlin or STOP*) adj3 (questionnair* or questionair*)).ti,ab.
33.	((score* or scoring or stratif* or assess*) adj3 (system* or schem*)).ti,ab.
34.	exp Oximetry/
35.	(oxymet* or oximet*).ti,ab.
36.	Capnography/
37.	capnogra*.ti,ab.
38.	(oxi-capnogra* or oxicapnogra* or oxy-capnogra* or oxycapnogra*).ti,ab.
39.	POLYSOMNOGRAPHY/
40.	(polysomnogra* or PSG).ti,ab.
41.	(polygraph* or HRP).ti,ab.
42.	ACTIGRAPHY/
43.	actigraph.ti,ab.
44.	(venous adj3 bicarbonat*).ti,ab.
45.	or/30-44
46.	29 and 45
47.	randomized controlled trial.pt.
48.	controlled clinical trial.pt.

49.	randomi#ed.ti,ab.
50.	placebo.ab.
51.	randomly.ti,ab.
52.	Clinical Trials as topic.sh.
53.	trial.ti.
54.	or/47-53
55.	Meta-Analysis/
56.	exp Meta-Analysis as Topic/
57.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
58.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
59.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
60.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
61.	(search* adj4 literature).ab.
62.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
63.	cochrane.jw.
64.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
65.	or/55-64
66.	exp "sensitivity and specificity"/
67.	(sensitivity or specificity).ti,ab.
68.	((pre test or pretest or post test) adj probability).ti,ab.
69.	(predictive value* or PPV or NPV).ti,ab.
70.	likelihood ratio*.ti,ab.
71.	likelihood function/
72.	((area under adj4 curve) or AUC).ti,ab.
73.	(receive* operat* characteristic* or receive* operat* curve* or ROC curve*).ti,ab.
74.	(diagnos* adj3 (performance* or accurac* or utilit* or value* or efficien* or effectiveness)).ti,ab.
75.	gold standard.ab.
76.	or/66-75
77.	Epidemiologic studies/
78.	Observational study/
79.	exp Cohort studies/
80.	(cohort adj (study or studies or analys* or data)).ti,ab.
81.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
82.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
83.	Controlled Before-After Studies/
84.	Historically Controlled Study/
85.	Interrupted Time Series Analysis/
86.	(before adj2 after adj2 (study or studies or data)).ti,ab.
87.	exp case control studies/
88.	case control*.ti,ab.

89.	Cross-sectional studies/
90.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
91.	or/77-90
92.	46 and (54 or 65 or 76 or 91)

Embase (Ovid) search terms

1.	exp Sleep Disordered Breathing/
2.	(sleep* adj4 (apn?ea* or hypopn?ea*)).ti,ab.
3.	(sleep* adj4 disorder* adj4 breath*).ti,ab.
4.	(OSAHS or OSA or OSAS).ti,ab.
5.	(obes* adj3 hypoventil*).ti,ab.
6.	pickwick*.ti,ab.
7.	or/1-6
8.	letter.pt. or letter/
9.	note.pt.
10.	editorial.pt.
11.	case report/ or case study/
12.	(letter or comment*).ti.
13.	or/8-12
14.	randomized controlled trial/ or random*.ti,ab.
15.	13 not 14
16.	animal/ not human/
17.	nonhuman/
18.	exp Animal Experiment/
19.	exp Experimental Animal/
20.	animal model/
21.	exp Rodent/
22.	(rat or rats or mouse or mice).ti.
23.	or/15-22
24.	7 not 23
25.	limit 24 to English language
26.	(exp child/ or exp pediatrics/) not (exp adult/ or exp adolescent/)
27.	25 not 26
28.	(Epworth or ESS or ESS-CHAD).ti,ab.
29.	(STOP-bang or stopbang or "snoring tired observed pressure").ti,ab.
30.	((sleep* or Berlin or STOP*) adj3 (questionnair* or questionair*)).ti,ab.
31.	((score* or scoring or stratif* or assess*) adj3 (system* or schem*)).ti,ab.
32.	oximetry/ or transcutaneous oxygen monitoring/
33.	(oxymet* or oximet*).ti,ab.
34.	capnometry/
35.	capnogra*.ti,ab.
36.	(oxi-capnogra* or oxicapnogra* or oxy-capnogra* or oxycapnogra*).ti,ab.
37.	polysomnography/
38.	(polysomnogra* or PSG).ti,ab.
39.	(polygraph* or HRP).ti,ab.

40.	actimetry/
41.	actigraph.ti,ab.
42.	(venous adj3 bicarbonat*).ti,ab.
43.	or/28-42
44.	27 and 43
45.	random*.ti,ab.
46.	factorial*.ti,ab.
47.	(crossover* or cross over*).ti,ab.
48.	((doubl* or singl*) adj blind*).ti,ab.
49.	(assign* or allocat* or volunteer* or placebo*).ti,ab.
50.	crossover procedure/
51.	single blind procedure/
52.	randomized controlled trial/
53.	double blind procedure/
54.	or/45-53
55.	systematic review/
56.	meta-analysis/
57.	(meta analy* or metanaly* or metaanaly* or meta regression).ti,ab.
58.	((systematic* or evidence*) adj3 (review* or overview*)).ti,ab.
59.	(reference list* or bibliograph* or hand search* or manual search* or relevant journals).ab.
60.	(search strategy or search criteria or systematic search or study selection or data extraction).ab.
61.	(search* adj4 literature).ab.
62.	(medline or pubmed or cochrane or embase or psychlit or psyclit or psychinfo or psycinfo or cinahl or science citation index or bids or cancerlit).ab.
63.	cochrane.jw.
64.	((multiple treatment* or indirect or mixed) adj2 comparison*).ti,ab.
65.	or/55-64
66.	exp "sensitivity and specificity"/
67.	(sensitivity or specificity).ti,ab.
68.	((pre test or pretest or post test) adj probability).ti,ab.
69.	(predictive value* or PPV or NPV).ti,ab.
70.	likelihood ratio*.ti,ab.
71.	((area under adj4 curve) or AUC).ti,ab.
72.	(receive* operat* characteristic* or receive* operat* curve* or ROC curve*).ti,ab.
73.	(diagnos* adj3 (performance* or accurac* or utilit* or value* or efficien* or effectiveness)).ti,ab.
74.	diagnostic accuracy/
75.	diagnostic test accuracy study/
76.	gold standard.ab.
77.	or/66-76
78.	Clinical study/
79.	Observational study/
80.	family study/
81.	longitudinal study/

82.	retrospective study/
83.	prospective study/
84.	cohort analysis/
85.	follow-up/
86.	cohort*.ti,ab.
87.	85 and 86
88.	(cohort adj (study or studies or analys* or data)).ti,ab.
89.	((follow up or observational or uncontrolled or non randomi#ed or epidemiologic*) adj (study or studies or data)).ti,ab.
90.	((longitudinal or retrospective or prospective or cross sectional) and (study or studies or review or analys* or cohort* or data)).ti,ab.
91.	(before adj2 after adj2 (study or studies or data)).ti,ab.
92.	or/78-84,87-91
93.	exp case control study/
94.	case control*.ti,ab.
95.	cross-sectional study/
96.	(cross sectional and (study or studies or review or analys* or cohort* or data)).ti,ab.
97.	or/92-96
98.	44 and (54 or 65 or 77 or 97)

Cochrane Library (Wiley) search terms

#1.	MeSH descriptor: [Sleep Apnea Syndromes] explode all trees
#2.	(sleep* near/4 (apn?ea* or hypopn?ea*)):ti,ab
#3.	(sleep* near/4 disorder* near/4 breath*):ti,ab
#4.	(OSAHS or OSA or OSAS):ti,ab
#5.	(obes* near/3 hypoventil*):ti,ab
#6.	pickwick*:ti,ab
#7.	(OR #1-#6)
#8.	(Epworth or ESS or ESS-CHAD):ti,ab
#9.	(STOP-bang or stopbang or "snoring tired observed pressure"):ti,ab
#10.	((sleep* or Berlin or STOP*) near/3 (questionnair* or questionair*)):ti,ab
#11.	((score* or scoring or stratif* or assess*) near/3 (system* or schem*)):ti,ab
#12.	MeSH descriptor: [Oximetry] explode all trees
#13.	(oxymet* or oximet*):ti,ab
#14.	MeSH descriptor: [Capnography] this term only
#15.	capnogra*:ti,ab
#16.	(oxi-capnogra* or oxicapnogra* or oxy-capnogra* or oxycapnogra*):ti,ab
#17.	MeSH descriptor: [Polysomnography] this term only
#18.	(polysomnogra* or PSG):ti,ab
#19.	(polygraph* or HRP):ti,ab
#20.	MeSH descriptor: [Actigraphy] this term only
#21.	actigraph:ti,ab
#22.	(venous near/3 bicarbonat*):ti,ab
#23.	(OR #8-#22)
#24.	#7 and #23

Epistemonikos search terms

1.	((title:((sleep apnea syndromes) OR (sleep* AND (apn?ea* OR hypopn?ea*)) OR (sleep* AND (apn?ea* OR hypopn?ea*)) OR (sleep* AND (disorder* OR breath*)) OR (OSAHS OR OSA OR OSAS) OR (obes* AND hypoventil*) OR pickwick*) OR abstract:((sleep apnea syndromes) OR (sleep* AND (apn?ea* OR hypopn?ea*)) OR (sleep* AND (apn?ea* OR hypopn?ea*)) OR (sleep* AND (disorder* OR breath*)) OR (OSAHS OR OSA OR OSAS) OR (obes* AND hypoventil*) OR pickwick*)))

B.2 Health Economics literature search strategy

Health economic evidence was identified by conducting a broad search relating to sleep apnoea population in NHS Economic Evaluation Database (NHS EED – this ceased to be updated after March 2015) and the Health Technology Assessment database (HTA – this ceased to be updated after March 2018) with no date restrictions. NHS EED and HTA databases are hosted by the Centre for Research and Dissemination (CRD). Additional searches were run on Medline and Embase for health economics and quality of life studies.

B.2.1 Health economic studies strategy

Table 23: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	2014 – 6 July 2020	Exclusions Health economics studies
Embase	2014 – 6 July 2020	Exclusions Health economics studies
Centre for Research and Dissemination (CRD)	HTA - Inception – 31 March 2018 NHSEED - Inception to March 2015	None

Medline (Ovid) search terms

	exp Sleep Apnea Syndromes/
1.	(sleep* adj4 (apn?ea* or hypopn?ea*)).ti,ab.
2.	(sleep* adj4 disorder* adj4 breath*).ti,ab.
3.	(OSAHS or OSA or OSAS).ti,ab.
4.	(obes* adj3 hypoventil*).ti,ab.
5.	pickwick*.ti,ab.
6.	or/1-6
7.	limit 7 to English language
8.	letter/
9.	editorial/
10.	news/
11.	exp historical article/
12.	Anecdotes as Topic/
13.	comment/
14.	case report/
15.	(letter or comment*).ti.

16.	or/9-16
17.	randomized controlled trial/ or random*.ti,ab.
18.	17 not 18
19.	animals/ not humans/
20.	exp Animals, Laboratory/
21.	exp Animal Experimentation/
22.	exp Models, Animal/
23.	exp Rodentia/
24.	(rat or rats or mouse or mice).ti.
25.	or/19-25
26.	8 not 26
27.	Economics/
28.	Value of life/
29.	exp "Costs and Cost Analysis"/
30.	exp Economics, Hospital/
31.	exp Economics, Medical/
32.	Economics, Nursing/
33.	Economics, Pharmaceutical/
34.	exp "Fees and Charges"/
35.	exp Budgets/
36.	budget*.ti,ab.
37.	cost*.ti.
38.	(economic* or pharmaco?economic*).ti.
39.	(price* or pricing*).ti,ab.
40.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
41.	(financ* or fee or fees).ti,ab.
42.	(value adj2 (money or monetary)).ti,ab.
43.	or/28-43
44.	27 and 44

Embase (Ovid) search terms

1.	exp Sleep Disordered Breathing/
2.	(sleep* adj4 (apn?ea* or hypopn?ea*)).ti,ab.
3.	(sleep* adj4 disorder* adj4 breath*).ti,ab.
4.	(OSAHS or OSA or OSAS).ti,ab.
5.	(obes* adj3 hypoventil*).ti,ab.
6.	pickwick*.ti,ab.
7.	or/1-6
8.	limit 7 to English language
9.	letter.pt. or letter/
10.	note.pt.
11.	editorial.pt.
12.	case report/ or case study/

13.	(letter or comment*).ti.
14.	or/9-13
15.	randomized controlled trial/ or random*.ti,ab.
16.	14 not 15
17.	animal/ not human/
18.	nonhuman/
19.	exp Animal Experiment/
20.	exp Experimental Animal/
21.	animal model/
22.	exp Rodent/
23.	(rat or rats or mouse or mice).ti.
24.	or/16-23
25.	8 not 24
26.	health economics/
27.	exp economic evaluation/
28.	exp health care cost/
29.	exp fee/
30.	budget/
31.	funding/
32.	budget*.ti,ab.
33.	cost*.ti.
34.	(economic* or pharmaco?economic*).ti.
35.	(price* or pricing*).ti,ab.
36.	(cost* adj2 (effective* or utilit* or benefit* or minimi* or unit* or estimat* or variable*)).ab.
37.	(financ* or fee or fees).ti,ab.
38.	(value adj2 (money or monetary)).ti,ab.
39.	or/26-38
40.	25 and 39

NHS EED and HTA (CRD) search terms

#1.	MeSH DESCRIPTOR Sleep Apnea Syndromes EXPLODE ALL TREES
#2.	(sleep* adj4 (apn?ea* or hypopn?ea*))
#3.	(sleep* adj4 disorder* adj4 breath*)
#4.	(OSAHS or OSA or OSAS)
#5.	(obes* adj3 hypoventil*)
#6.	(pickwick*)
#7.	#1 OR #2 OR #3 OR #4 OR #5 OR #6

B.2.2 Quality of life studies strategy

Table 24: Database date parameters and filters used

Database	Dates searched	Search filter used
Medline	1946 – 26 November 2019	Exclusions Quality of life studies

Database	Dates searched	Search filter used
Embase	1974 – 26 November 2019	Exclusions Quality of life studies

Medline (Ovid) search terms

1.	exp Sleep Apnea Syndromes/
2.	(sleep* adj4 (apn?ea* or hypopn?ea*)).ti,ab.
3.	(sleep* adj4 disorder* adj4 breath*).ti,ab.
4.	(OSAHS or OSA or OSAS).ti,ab.
5.	(obes* adj3 hypoventil*).ti,ab.
6.	pickwick*.ti,ab.
7.	or/1-6
8.	limit 7 to English language
9.	letter/
10.	editorial/
11.	news/
12.	exp historical article/
13.	Anecdotes as Topic/
14.	comment/
15.	case report/
16.	(letter or comment*).ti.
17.	or/9-16
18.	randomized controlled trial/ or random*.ti,ab.
19.	17 not 18
20.	animals/ not humans/
21.	exp Animals, Laboratory/
22.	exp Animal Experimentation/
23.	exp Models, Animal/
24.	exp Rodentia/
25.	(rat or rats or mouse or mice).ti.
26.	or/19-25
27.	8 not 26
28.	quality-adjusted life years/
29.	sickness impact profile/
30.	(quality adj2 (wellbeing or well being)).ti,ab.
31.	sickness impact profile.ti,ab.
32.	disability adjusted life.ti,ab.
33.	(qal* or qtime* or qwb* or daly*).ti,ab.
34.	(euroqol* or eq5d* or eq 5*).ti,ab.
35.	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
36.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.

37.	(hui or hui1 or hui2 or hui3).ti,ab.
38.	(health* year* equivalent* or hye or hyes).ti,ab.
39.	discrete choice*.ti,ab.
40.	rosser.ti,ab.
41.	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
42.	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
43.	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
44.	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
45.	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
46.	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
47.	or/28-46
48.	27 and 47

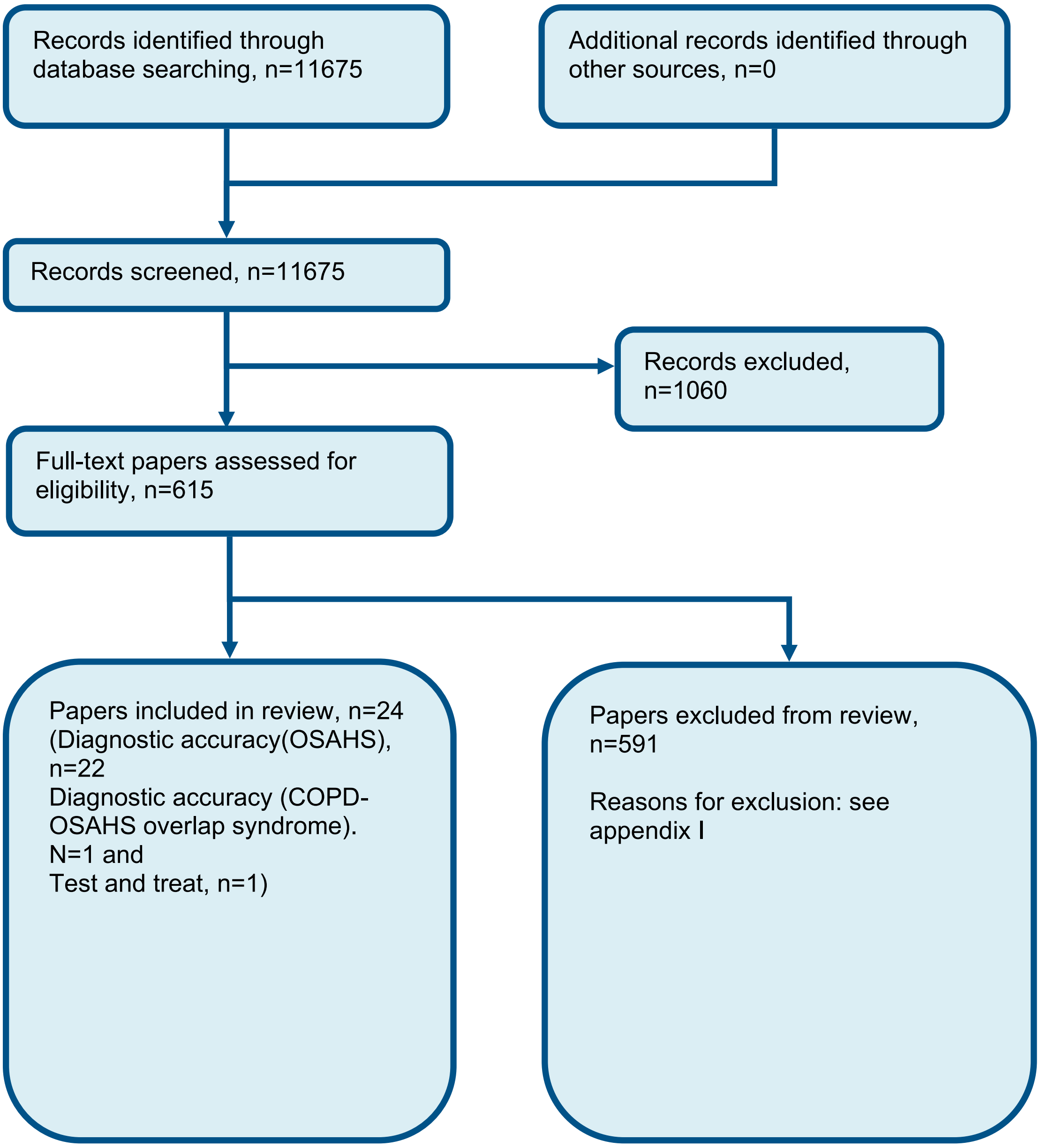
Embase (Ovid) search terms

1.	exp Sleep Disordered Breathing/
2.	(sleep* adj4 (apn?ea* or hypopn?ea*)).ti,ab.
3.	(sleep* adj4 disorder* adj4 breath*).ti,ab.
4.	(OSAHS or OSA or OSAS).ti,ab.
5.	(obes* adj3 hypoventil*).ti,ab.
6.	pickwick*.ti,ab.
7.	or/1-6
8.	limit 7 to English language
9.	letter.pt. or letter/
10.	note.pt.
11.	editorial.pt.
12.	case report/ or case study/
13.	(letter or comment*).ti.
14.	or/9-13
15.	randomized controlled trial/ or random*.ti,ab.
16.	14 not 15
17.	animal/ not human/
18.	nonhuman/
19.	exp Animal Experiment/
20.	exp Experimental Animal/
21.	animal model/
22.	exp Rodent/
23.	(rat or rats or mouse or mice).ti.
24.	or/16-23
25.	8 not 24
26.	quality adjusted life year/
27.	"quality of life index"/
28.	short form 12/ or short form 20/ or short form 36/ or short form 8/
29.	sickness impact profile/

30.	(quality adj2 (wellbeing or well being)).ti,ab.
31.	sickness impact profile.ti,ab.
32.	disability adjusted life.ti,ab.
33.	(qal* or qtime* or qwb* or daly*).ti,ab.
34.	(euroqol* or eq5d* or eq 5*).ti,ab.
35.	(qol* or hql* or hqol* or h qol* or hrqol* or hr qol*).ti,ab.
36.	(health utility* or utility score* or disutilit* or utility value*).ti,ab.
37.	(hui or hui1 or hui2 or hui3).ti,ab.
38.	(health* year* equivalent* or hye or hyes).ti,ab.
39.	discrete choice*.ti,ab.
40.	rosser.ti,ab.
41.	(willingness to pay or time tradeoff or time trade off or tto or standard gamble*).ti,ab.
42.	(sf36* or sf 36* or short form 36* or shortform 36* or shortform36*).ti,ab.
43.	(sf20 or sf 20 or short form 20 or shortform 20 or shortform20).ti,ab.
44.	(sf12* or sf 12* or short form 12* or shortform 12* or shortform12*).ti,ab.
45.	(sf8* or sf 8* or short form 8* or shortform 8* or shortform8*).ti,ab.
46.	(sf6* or sf 6* or short form 6* or shortform 6* or shortform6*).ti,ab.
47.	or/26-46
48.	25 and 47

Appendix C: Clinical evidence selection

Figure 2: Flow chart of clinical study selection for the review of diagnosis



Appendix D: Clinical evidence tables for diagnostic accuracy studies

Reference	**Calleja 2002[76]**
Study type	Cross-sectional
Study methodology	Data source: A total of 86 patients that had been referred to a sleep laboratory with a clinical diagnosis of SAS underwent cardiorespiratory polygraphy in an unattended mode using an ambulatory device (MERLIN). Analysis was carried out both automatically and manually. Conventional overnight full-channel polysomnography was performed simultaneously. Recruitment: not reported
Number of patients	n = 86 recruited, 79 analysed
Patient characteristics	Age, mean (SD): 52 (SD 11.1) Gender (male to female ratio): 77/9 Ethnicity: not reported Setting: sleep laboratory Country: Spain Inclusion criteria: not reported Exclusion criteria: not reported People with clinically suspected sleep apnoea/hypopnoea syndrome from a sleep outpatient clinic, and referred to the sleep laboratory for overnight polysomnography, were recruited to the study.
Target condition(s)	Sleep apnoea/hypopnoea syndrome

Reference	**Calleja 2002[76]**
Index test(s) and reference standard	Index test: In-centre respiratory polygraphy (MERLIN system): The MERLIN system is a cardiorespiratory polygraph for level III studies. The unattended mode was selected for this study. The system records oronasal airflow by thermistor, chest and abdominal respiratory movements, tracheal sounds, cardiac frequency, oxygen saturation, body position, and continuous positive airway pressure (CPAP) level. Recordings were scored automatically by software included in the system or manually by visual evaluation of printouts. In all patients, sensors of the polysomnographical equipment were placed first. Respiratory events included apnoeas and hypopnoeas. The criteria of manual scoring were the same as that used for polysomnography. The respiratory effect index was calculated as the sum of the number of episodes of apnoea and hypopnoea per hour of polygraphical recording both in the automatic and manual analysis of data. An experienced neurophysiologist carried out the readings of the polygraphy system. The observers were blind to the results of the other method. Manual scored AHI of 9.8, post-hoc choice of cut-off with AHI ≥10; manual scored AHI of 6.7 with AHI ≥5. Reference standard Polysomnography (PSG), with no pre-specified AHI, RDI or ODI diagnostic of sleep apnoea/hypopnoea syndrome (Alice 3; Healthdyne Technologies or the Ultrasom system – Nicolet Biomedical Inc., Madison, WI, USA): PSG consisted of continuous polygraphical recordings for an entire night and included: electro-encephalography; electro-oculography; tibial and submental electromyograms; electrocardiogram (modified V2 lead). For respiratory sensors, nasal and oral signals by thermistors were used, tracheal sounds (microphone) and the chest and abdominal effort was measured by two belt sensors (Healthdyne piezo-electric gauge; Healthdyne Technologies). Oxyhaemoglobin saturation was recorded by finger-pulse oximeter (model 340; Palco Laboratories, Santa Cruz, CA, USA) and the body position was monitored by the system. Each 30-second epoch of the recording was scored for sleep stage, breathing, oxygenation, and movement. Sleep data were staged according to the system described by Rechtschaffen and Kales. A complete cessation of the thermistor signal of ≥10 seconds was defined as apnoea. Hypopnoea was defined as a discernible reduction of ≥50% of the thermistor signal for ≥10 seconds, accompanied by a decrease of ≥3% in oxyhaemoglobin saturation and/or an electro-encephalographic arousal. An arousal was defined according to the American Sleep Disorders Association. The total number of scored apnoeas and hypopnoeas divided by the number of hours of sleep, referred to as the AHI, was determined for each participant. The observers were blind to the results of the other method. Prevalence (AHI ≥ 10) – 64 subjects Time between measurement of index test and reference standard: polysomnography and respiratory polygraphy were performed simultaneously

2×2 table All OSAS (AHI ≥ 10) Hospital RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	58	2	60	
	Index test −	6	13	19	
	Total	64	15	79	

Reference	**Calleja 2002[76]**
Statistical measures	Index text: in centre respiratory polygraphy, manually scored, AHI ≥10 (≥3% oxygen desaturation) Sensitivity: 90.6% Specificity: 86.7% Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval) All OSA (AHI≥5): 0.976 (0.945 – 1006) Moderate-severe (AHI≥15): 0.954 (0.910 – 0.998) Severe (AHI≥30): 0.931 (0.863 - 0.999)
Source of funding	Supported by a grant from the Department of Health, Basque Government
Limitations	Risk of bias: Serious. Enrolment method unclear and inclusion/exclusion criteria not reported Indirectness: Serious. Proxy AHI ≥10 for index test was used.
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Claman 2001[90]**
Study type	Cross-sectional
Study methodology	Data source: Simultaneous sleep monitoring was performed by formal polysomnography and by Bedbugg. Monitoring was performed in a university sleep centre in 42 subjects who had previously been scheduled for polysomnography. Recruitment: consecutive
Number of patients	n = 42 recruited and analysed
Patient characteristics	Age, mean (SD): 54 (SD 12.9) Gender (male to female ratio): 31/11

Reference	Claman 2001[90]
	Ethnicity: not reported Setting: sleep laboratory Country: USA Inclusion criteria: age over 18 years; clinical suspicion of uncomplicated obstructive sleep apnoea; patients already scheduled for full polysomnography. Exclusion criteria: exhibited flu-like symptoms; primary complaint of insomnia; suspected respiratory failure or hypoventilation; suspected narcolepsy or idiopathic hypersomnia. In addition, patients who had a family member present during the sleep study period were excluded, since the Bedbugg monitor is sensitive to sound.
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	Index test: In-centre respiratory polygraphy (BedBugg): The BedBugg respiration sensor houses two microphones, one to measure respiration based on sound characteristics, and one for recording snoring intensity and ambient noise. The respiration sensor rests on the patient's upper lip and detects both nasal and oral airflow. The pulse oximeter is attached to the patient's index finger to measure blood oxygen saturation levels. The effort sensor is a soft, thin Tygon tube that is placed around the patient's upper midsection to detect respiratory effort. The Bedbugg had sufficient memory to record three consecutive nights of sleep. The data are scored by computer algorithm, and a detailed summary sent to the physician for diagnostic interpretation. For this study, a single night sleep was performed for direct comparison to PSG. AHI was determined based on the total duration of recorded data. Reference standard Polysomnography (PSG) with a pre-specified AHI >15 diagnostic of obstructive sleep apnoea: PSG was performed by technologists and included: EEG, EOG and EMG for sleep staging. Respiratory events were classified based on thermistor airflow, and thoracic and abdominal piezobands for effort. The BedBugg system performed a simultaneous recording using three additional sensors that provided five channels of data: airflow based on sound characteristics, snoring volume, respiratory effort, oxygen saturation, and heart rate derived from the oximetry signal. Each participants was hooked up to the three additional BedBugg sensors (respiration, effort, and Nonin 8500 finger oximeter) for the one-night sleep study, in addition to the electrodes used for a regular PSG study. The PSG airflow sensor and the BedBugg respiratory effort sensor were both placed between the upper lip and nose. The PSG data were scored manually by the technologist, using usual guidelines for sleep staging. Apnoea was defined as lack of airflow for 10 seconds. The hypopnoea criteria were a 50% reduction in airflow accompanied by at least a 4% oxygen desaturation. The data from the BedBugg recording unit were analysed using the BedBugg software. Outcome measures included number and duration of apnoeas and hypopnoeas, AHI, and oxygen saturation as derived by PSG standard and by BedBugg. For PSG, the AHI was based on sleep time. An AHI of greater than 15 was prespecified as positive for apnoea, and less than 15 as negative for apnoea.

<table>
<tr><td>Reference</td><td colspan="5">Claman 2001[90]</td></tr>
<tr><td></td><td colspan="5"><u>Prevalence – 21 subjects had AHI>15</u>

Time between measurement of index test and reference standard: simultaneous PSG and respiratory polygraphy in the sleep laboratory.</td></tr>
<tr><td rowspan="4">2×2 table Moderate-severe (AHI ≥ 15)</td><td></td><td>Reference standard +</td><td>Reference standard −</td><td>Total</td><td rowspan="4">Calculated by NGC</td></tr>
<tr><td>Index test +</td><td>18</td><td>1</td><td>19</td></tr>
<tr><td>Index test −</td><td>3</td><td>20</td><td>23</td></tr>
<tr><td>Total</td><td>21</td><td>21</td><td>42</td></tr>
<tr><td>Statistical measures</td><td colspan="5"><u>Index text: in centre respiratory polygraphy, AHI ≥15 (≥4% oxygen desaturation)</u>
Sensitivity: 86%
Specificity: 95%
Positive predictive value: 94%
Negative predictive value: 87.5%
Area under the curve, manually scored, (95% confidence interval): not reported</td></tr>
<tr><td>Source of funding</td><td colspan="5">Supported by Sleep Solutions, Inc, Palo Alto, CA</td></tr>
<tr><td>Limitations</td><td colspan="5">Risk of bias: Serious. Inclusion/exclusion criteria not reported, and the test results could have been interpreted with knowledge of the other test results.
Indirectness: None</td></tr>
<tr><td>Comments</td><td colspan="5">Paper only provides totals and not TP, FP, FN, or TN.

These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.</td></tr>
</table>

Reference	**de Oliveira 2009[100]**
Study type	Cross-sectional

Reference	de Oliveira 2009[100]
Study methodology	Data source: Patients with suspected OSAHS were submitted, in random order, to PM at the sleep laboratory concurrently with PSG (lab-PM) or at home-PM. Recruitment: consecutive
Number of patients	n = 157 studied, 121 analysed for home and laboratory monitoring
Patient characteristics	Age, mean (SD): 45 (SD 12) Gender (male to female ratio for PSG): 113/44 Ethnicity: not reported Setting: sleep centre/ at home Country: Brazil Inclusion criteria: not reported Exclusion criteria: pregnant women; patients with severe comorbidities (‘cancer, heart failure, etc’) or difficulties that would interfere with the examinations; patients residing outside the metropolitan area of Porto Alegre (Rio Grande do Sul, Brazil). Study participants were >18 years of age and referred for evaluation of suspected OSAS.
Target condition(s)	Obstructive sleep apnoea syndrome
Index test(s) and reference standard	Index test: Portable respiratory monitor (Somnocheck type 3 monitor, Weinmann GmbH, Hamburg, Germany): the Somnocheck monitor had a position sensor, pressure transducer, and pulse oximeter. The unit was adjusted to the participant’s chest using a belt, and the nasal cannula was used to record airflow and snoring. The pulse oximeter recorded both oxygen saturation and heart rate. For the laboratory monitoring, a technician could help the participant when the monitor’s alarms sounded. For the home study, the equipment was handed out to the participants, who were instructed on its use. For the home monitoring, the participants were instructed on how to wear the equipment as well as on how to relocate the sensors if the lost signal alarm sounded. Recordings shorter than 4 hours of artefact-free tracings were discarded. The portable monitor AHI was defined as the total number of apnoeas and hypopnoeas divided by the number of hours of artefact-free recording. Information from the sleep diary and position recording were used to exclude stretches of the recording in which wakefulness was indirectly deduced. The data were analysed manually. (Post-hoc choice of AHI threshold, 7 as cut-off point with PSG AHI ≥5)

Reference	**de Oliveira 2009[100]**
	<u>Reference standard</u> Laboratory polysomnography (PSG) with a diagnostic AHI ≥5 diagnostic for obstructive sleep apnoea syndrome: all participants completed nocturnal PSG, which included: EEG; electro-oculogram (left and right eyes); submental and anterior pretibial electromyograms and ECG. Airflow was measured by a nasal cannula attached to a pressure transducer through a Y-tube to allow connection to a pressure port of the portable monitor on the laboratory monitoring night. Arterial oxygen saturation was measured by a pulse oximeter. Sleep staging was performed using Rechtschaffen and Kales criteria. (In centre PSG, AHI 5 or more), prevalence was 87 %. Technicians were allowed to intervene in laboratory PSG and portable monitor studies in the case of technical issues. For both PSG and the portable monitor, apnoeas, hypopnoeas and AHI were defined according to standard criteria. Time between measurement of index test and reference standard: the sleep studies were carried out in the laboratory and at home on two different nights and with a maximum interval of 48 hours; PSG and the Somnocheck were used simultaneously in the laboratory. Prevalence AHI≥5 = 87% (105 participants)

2×2 table

	Reference standard +	Reference standard −	Total	Calculated by NGC
Index test +	101	6	107	
Index test −	4	10	14	
Total	105	16	121	

Statistical measures	<u>Index text, home portable respiratory monitor, (AHI≥5)</u> Sensitivity: 96.2% Specificity: 64.7% Positive predictive value: 94.3% Negative predictive value: 73.3% Area under the curve, manually scored, (95% confidence interval) All OSA (AHI≥5): 0.96 (0.91 – 0.96) Moderate-severe (AHI≥15): 0.91 (0.85 – 0.96) Severe (AHI≥30): 0.92 (0.86 – 0.96)

Reference	**de Oliveira 2009[100]**
Source of funding	Not reported
Limitations	Risk of bias: Very serious. Unclear if study avoided inappropriate exclusions, the test results could have been interpreted with knowledge of the other test results, and 23% of study participants who underwent PSG were excluded from the analysis (36/157). Unclear if prevalence reported in the study was for all people who underwent polysomnography (149 patients) or just home respiratory polygraphy (121 patients) Indirectness: None
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Emsellem 1990[119]**
Study type	Cross-sectional
Study methodology	Data source: Sixty-seven patients referred to a sleep laboratory with a tentative diagnosis of obstructive sleep apnea were examined with a device designed for home use as an apnea screening system. Recruitment: consecutive
Number of patients	n = 67 studied, 63 analysed
Patient characteristics	Age, mean (SD): 45 (SD not reported) Gender (male to female ratio): not reported Ethnicity: not reported Setting: sleep centre Country: USA Inclusion criteria: referral to the George Washington University Sleep Study Center or the Fairview Southdale Hospital Sleep Center with a tentative diagnosis of obstructive sleep apnoea. Exclusion criteria: not reported

Reference	**Emsellem 1990**[119]
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	Index test: In-centre apnoea screening system (EdenTrace Model 2700 Multichannel Recorder – Edentec, Eden Prairie, Minn): The EdenTrace is a four-channel device measuring nasal/oral airflow by a thermistor or end tidal CO_2 gauge placed over the philtrum, chest wall movement by impedance, cardiac rhythm by ECG; and blood oxygen saturation by interfacing with a pulse oximeter. Output of the EdenTrace nasal/oral airflow channel was also interfaced directly to the (Grass or Nihon Kohden) standard polygraph to provide a precise temporal comparison of activity recorded by both systems. The presence and degree of oxygen desaturation was evaluated in all patients studied with the EdenTrace system. An AHI could not be calculated on the portable studies for lack of an EEG channel to document total sleep time. A separate index, the portable respiratory index was calculated by dividing the total number of disordered breathing events by the quiet recording time and multiplying by 60. Reference standard In-centre polysomnography (PSG) with a specified AHI >5 diagnostic of obstructive sleep apnoea: PSG parameters included electroencephalogram, chin electromyogram, anterior tibial electromyogram, electro-oculogram, electrocardiogram, tracings from nasal and oral respiration monitors (thermistor or end tidal CO_2 gauge), chest wall and abdominal excursion monitors (mercury strain gauges or Respitrace system [Ambulatory Monitoring, Inc., Ardsley, NY]), and ear oximeters (Biox IIA, [Ohmeda, Boulder, Colo], or Nellcor 100 [Nellcor Inc., Hayward, Calif]). All devices were connected to a 17 channel electroencephalograph (Nihon Kohden, Irvine, Calif) or polygraph (Grass Instruments Co., Quincy, Mass), and the resultant polysomnogram was recorded overnight. (PSG AHI >5), prevalence 39 subjects Episodes of apnoea and hypopnoea were scored together as disordered breathing events. A disordered breathing event was defined as a 50% or greater decrease in the amplitude of airflow lasting a minimum of 10 seconds. An AHI was calculated by dividing the total number of disordered breathing events by the total sleep time in minutes, then multiplying by 60. Time between measurement of index test and reference standard: simultaneous PSG and apnoea screening system

2×2 table

	Reference standard +	Reference standard −	Total	Provided in the paper
Index test +	37	1	38	
Index test −	2	23	25	
Total	39	24	63	

Reference	**Emsellem 1990[119]**
Statistical measures	Index text, apnoea screening system, PSG AHI >5, in-centre Sensitivity: 95% Specificity: 96% Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval): not reported
Source of funding	Not reported
Limitations	Risk of bias: Serious. Exclusion criteria not reported and the test results could have been interpreted with knowledge of the other test results Indirectness: None
Comments	Paper provides totals and TP, FP, FN, or TN. .

Reference	**Garg 2014[140]**
Study type	
Study methodology	Data source: Randomised crossover study of home PM (WatchPAT200) and in-laboratory simultaneous PSG and PM in 75 urban African Americans with high pre-test probability of OSA, identified with the Berlin questionnaire. Recruitment: unclear; randomised to home portable monitor or in-laboratory polysomnography and portable monitoring
Number of patients	n = 75 recruited and analysed
Patient characteristics	Age, mean (SD): 44.7 (10.6) Gender (male to female ratio): 18/57 Ethnicity: African American Setting: sleep centre Country: USA

Reference	Garg 2014[140]
	Inclusion criteria: not reported Exclusion criteria: past treatment of OSA (medical, dental, or surgical); other primary sleep disorder(s) by history (restless legs syndrome, insomnia, shift work); active uncontrolled medical conditions/immobility (congestive heart failure, severe COPD/asthma with frequent exacerbations in the preceding 6 months, severe arthritis/deformity of fingers); current drug (any non-prescription drug use besides over-the-counter drugs) or significant alcohol use (≥5 days per week); no current residential address or contact phone number; pregnancy; current drug therapy short acting nitrates or alpha blockers; cardiac pacemaker African Americans, age ≥18 years at a single tertiary care center, with high risk for OSA (defined by the Berlin Questionnaire) were recruited.
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	Index test: Portable sleep monitor (WatchPAT200, Itamar Medical Inc): Home and in-laboratory test sessions were performed within 4 days of each other by all participants. A brief training session was conducted the day before home test session in the sleep laboratory for each participant including watching a 10 minute manufacturer provided instruction video on the application of WatchPAT200 and an up to 10 minute question-answer session with a registered polysomnography technician experienced in the application of WatchPAT200. In-laboratory portable monitoring was applied by a registered polysomnography technician concurrently with PSG channels. The technician did not troubleshoot for portable monitor technical problems such as the PAT probe coming loose during PSG. Automated software scoring was used for the AHI (zzzPAT, version 4.2.67.1a, Itamar Medical Ltd.) Specifically, a respiratory event was scored by the software if 1 to 3 criteria were met: (1) ≥30% PAT amplitude reduction together with a pulse rate accelerometer of 10% (2) ≥30% PAT amplitude reduction together with 3% oxyhaemoglobin desaturation, or (3) ≥4% oxyhaemoglobin desaturation. Data download were visually inspected by a board-certified sleep physician (blinded to home vs. in-laboratory portable monitor assignment) to make a determination of technical failure. Portable monitor tests where estimated total sleep time was ≤2 hours or PAT and oximetry data of interpretable quality did not meet published acceptable standards for minimum duration (≥4 hours per recording) were deemed ‘technical failures’. Reference standard In-centre polysomnography (PSG) with no prespecified diagnostic AHI, RDI or ODI for obstructive sleep apnoea: a standard montage included electroencephalogram, bilateral electro-oculograms, electromyogram (submental, bilateral anterior tibial), electrocardiogram, oronasal airflow (thermistor and nasal pressure transducer), thoraco-abdominal motion (piezo-crystal, EPM Systems), arterial oxygen saturation by pulse oximetry, and body position. All signals including digital infrared video were acquired, processed and stored using the ALICE5 digital systems (Phillips Respironics). The PSG was scored according to published criteria. Hypopnoeas were defined as ≥30% reduction in airflow associated with ≥4% oxygen desaturation. Scoring was performed by a single registered polysomnography

<table>
<tr><td>Reference</td><td colspan="5">Garg 2014[140]</td></tr>
<tr><td></td><td colspan="5">technician and board certified sleep medicine physician blinded to participant identity, randomisation order, and test results from alternative tests (home and in-laboratory portable monitoring).

(PSG AHI ≥5 and PSG AHI ≥15 analysed below), prevalence: AHI≥5 =53 subjects, AHI≥15 = 41 subjects

Time between measurement of index test and reference standard: simultaneous in-centre PSG and portable monitoring</td></tr>
<tr><td rowspan="4">2×2 table All OSAS (AHI ≥5)</td><td></td><td>Reference standard +</td><td>Reference standard −</td><td>Total</td><td rowspan="4">Calculated by NGC</td></tr>
<tr><td>Index test +</td><td>51</td><td>13</td><td>64</td></tr>
<tr><td>Index test −</td><td>2</td><td>9</td><td>11</td></tr>
<tr><td>Total</td><td>53</td><td>22</td><td>75</td></tr>
<tr><td rowspan="4">2×2 table Moderate-severe OSAS (AHI ≥15)</td><td></td><td>Reference standard +</td><td>Reference standard −</td><td>Total</td><td rowspan="4">Calculated by NGC</td></tr>
<tr><td>Index test +</td><td>38</td><td>8</td><td>46</td></tr>
<tr><td>Index test −</td><td>3</td><td>26</td><td>29</td></tr>
<tr><td>Total</td><td>41</td><td>34</td><td>75</td></tr>
<tr><td>Statistical measures</td><td colspan="5"><u>Index text, portable sleep monitor (WatchPAT200), AHI ≥5, at home</u>
Sensitivity: 96%
Specificity: 43%
Positive predictive value: 79%
Negative predictive value: 82%

<u>Index text, portable sleep monitor (WatchPAT200), AHI ≥15, at home</u>
Sensitivity: 92%
Specificity: 77%
Positive predictive value: 83%
Negative predictive value: 88%

Area under the curve, manually scored, (95% confidence interval)
All OSA (AHI≥5): 0.9093 (CI not reported)
Moderate-severe (AHI≥15): 0.9224 (CI not reported)
Severe (AHI≥30): not reported</td></tr>
<tr><td>Source of funding</td><td colspan="5">Supported by NIH KM1CA156717 Career Development Award in Comparative Effectiveness Research from the National Cancer Institute</td></tr>
</table>

Reference	**Garg 2014[140]**
Limitations	Risk of bias: Serious. Enrollment method unclear, unclear if all study exclusion criteria appropriate, and unclear whether the index test was interpreted without knowledge of the reference standard Indirectness: None
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Gjevre 2011[145]**
Study type	Cross-sectional
Study methodology	Data source: Consecutive women scheduled for routine PSG testing for evaluation of clinically suspected OSA and who met inclusion/exclusion criteria, were invited to participate. An in-home Embletta portable monitor test was performed one week before or after diagnostic PSG. Recruitment: consecutive
Number of patients	n = 47 recruited and analysed
Patient characteristics	Age, mean (SD): 52 (11) Gender (male to female ratio): all women Ethnicity: Setting: sleep centre and home Country: Canada Inclusion criteria: 21 to 70 years old, and able to provide informed consent Exclusion criteria: referring sleep physician's strong suspicion of another primary sleep disorder (e.g., primary insomnia, narcolepsy, restless legs syndrome, a parasomnia or nocturnal seizures), regular shift work in the previous six months, history of lung disease, congestive heart failure, unstable angina, cerebrovascular accident or pregnancy in the previous six months, neuromuscular disease or renal failure

Reference	Gjevre 2011[145]				
Target condition(s)	Obstructive sleep apnoea				
Index test(s) and reference standard	Index test: Portable sleep monitor (Embletta, model 2601-1 PDS X10Xact Trace [Embletta, USA]), at home (with AHI and ODI): unattended, in-home monitoring included monitoring of oxygen saturation, heart rate, ribcage and abdominal movements, nasal airflow pressure, thermal flow, snoring and body position. In the afternoon before the test, an experienced technician taught the patient how to apply the device in the home. A registered sleep technologist, blinded to other patient and PSG data, scored the in-home monitoring tests, which were then reviewed and verified by a single blinded sleep physician. Major outcomes included AHI (using the American Academy of Sleep Medicine alternative criteria for apnoea and hypopnoea [50% drop in nasal pressure from baseline and a 3% desaturation]) and the oxygen desaturation index (number of events/hour when the oxygen saturation decreases by >3%. The patient recorded the approximate time of sleep onset and awakening in a sleep log. The sleep log data were used to estimate sleep duration. In the event of a technically suboptimal Embletta study, the study was repeated. Reference standard In-laboratory polysomnography (PSG) with a pre-specified AHI >5 diagnostic of obstructive sleep apnoea: a 15-lead diagnostic PSG was performed in the sleep laboratory. PSG recordings included: electroencephalogram, electro-oculogram, submental electromyogram, pulse oximetry, an oronasal airflow pressure sensor, chest and ribcage movement using piezoelectric belts, snore (vibration sensor), intercostal diaphragmatic and anterior tibialis electromyography, and an electrocardiogram. Sleep position was recorded by the sleep technician and confirmed by an all-night infrared video camera. Signals were recorded digitally using Sandman software (Mallinckrodt Inc, Canada). Scoring was performed by a registered sleep technician, and subsequently reviewed and verified by a single blinded sleep physician. Sleep staging was analysed using AASM criteria. The AHI was determined using the AASM alternative criteria, and the results were scored blinded. OSA was defined as >5 apnoeas/hour of sleep (of at least 10 seconds duration) and/or hypopnoeas/hour of sleep (at least a 50% decrease in flow for at least 10 seconds duration, with either a 3% decrease in oxygen saturation or a significant activation in the electroencephalogram/hour of sleep. (PSG AHI >5) Prevalence AHI≥5 =32 subjects Time between measurement of index test and reference standard: portable monitoring with Embletta was undertaken in random sequence order one week before or after PSG.				
2×2 table all OSAS (AHI ≥ 5)		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	29	6	35	
	Index test −	3	9	12	
	Total	32	15	47	

Reference	**Gjevre 2011[145]**
Statistical measures	Index text, portable sleep monitor (Embleta, model 2601-1 PDS X10Xact Trace), AHI ≥ 5, at home Sensitivity: 90.6% Specificity: 60% Positive predictive value: 82.86% Negative predictive value: 75% Area under the curve, manually scored, (95% confidence interval): 0.879 (0.782 to 0.976)
Source of funding	The study was funded by a grant from the Saskatchewan Health Research Foundation
Limitations	Risk of bias: Serious. Unclear if all study exclusion criteria appropriate, and unclear whether the reference standard was interpreted without knowledge of the index test Indirectness: None
Comments	All female study population; Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Golpe 2002[149]**
Study type	Cross-sectional
Study methodology	Data source: prospective case-study, sleep disorders unit of the tertiary referral university hospital. Recruitment: unclear; for portable monitoring, study participants were randomised to home monitoring with technician intervention in the set-up of the equipment, or to a 15-20 minute training period in the hospital provided by a technician, as well as written instructions regarding the use of the sleep-recording device – the latter group had the home study performed with the patient's own set-up of the equipment
Number of patients	n = 55 recruited, 37 analysed
Patient characteristics	Age, mean (SD): 52.7 (13.3) Gender (male to female ratio): 53/2

Reference	Golpe 2002[149]
	Ethnicity: Setting: sleep centre Country: Spain Inclusion criteria: patients referred to the sleep-disorders unit for evaluation of suspected OSAHS who lived within 30km of the hospital. All patients had to have at least two of the following: loud snoring, observed apnoeas, and daytime drowsiness, and were judged by one of the authors to require a sleep study (snoring and apnoeas were assessed using a questionnaire that was filled out by the patient. Drowsiness was assessed using the Epworth sleepiness scale score, whereby a score ≥11 was considered pathologic). Exclusion criteria: physical or mental impairment that precluded the use of the equipment
Target condition(s)	Sleep apnoea/hypopnoea syndrome
Index test(s) and reference standard	<u>Index test:</u> Portable sleep recording device (Apnoescreen-I: CNS-Jaëger; Höchberg, Germany), at home: this five-channel recording device produces a computerised recording of variations in oronasal airflow (measured by thermistor), body position, wrist actimetry, pulse rate, and arterial oxygen saturation (measured by finger pulse oximetry). Study participants were randomised to home monitoring with technician intervention in the set-up of the equipment, or to a 15-20 minute training period in the hospital provided by a technician, as well as written instructions regarding the use of the sleep-recording device – the latter group had the home study performed with the patient's own set-up of the equipment. The recording device estimates the total sleep time from the wrist actimetry registry, eliminating from the total registry time those periods with high activity. It automatically calculates the number of apnoeas plus hypoponeas per hour of estimated sleep time. It also provides parameters derived from the oximetry record, including the number of desaturations ≥4% per hour of estimated sleep time, and the cumulative percentages of sleep time at saturations <90%. Additionally, manual analysis was undertaken. The graphic display of the sleep-recording device does not allow to measure manually with accuracy at the level of desaturation. Therefore, no definite threshold for the desaturations was used, and any discernible drop in saturation was considered to be significant. The total number of apnoeas plus hypopnoeas was divided by the registry time and the sleep time in hours (as calculated by the equipment software), obtaining the manual RDI per hour of registry time and the manual RDI per hour of sleep time, respectively. <u>Reference standard</u> In-laboratory polysomnography (PSG) with a prespecified AHI ≥10 diagnostic of sleep apnoea/hypopnoea syndrome: PSG included EEG, chin electromyogram, electro-oculogram, ECG, thoraco-abdominal movement by piezoelectric bands placed over the thorax and abdomen, oronasal flow by thermistor, tibial electromyograms, oxygen saturation with a finger sensor (Oxypleth; Novametrix Medical Systems; Wallingford, CT), body position, and snoring. All signals were recorded through a 14-channel polygraph (Medelec; Vickers

<table>
<tr><th>Reference</th><th colspan="5">Golpe 2002[149]</th></tr>
<tr><td></td><td colspan="5">Medical; Basingstoke, Hampshire, UK). One of the authors carried out the PSG analysis, blind to the result of the home study device recording. PSG records were scored in 30-second epochs.

Apnoea was defined as a complete cessation of airflow lasting ≥10 seconds. Hypopnoea was defined as a discernible reduction in respiratory airflow lasting ≥10 seconds and accompanied by a decrease of ≥4% in oxygen saturation and/or an arousal. This definition of hypopnoea is in accordance with the current guidelines of the Spanish Society of Pulmonology and Thoracic Surgery. The reason for counting ‘discernible’ reductions in respiratory airflow instead of using a numerical threshold is that thermistors only allow a qualitative estimation of airflow. The AHI was calculated as the average number of episodes of apnoea and hypopnoea per hour of sleep. A cut-off point of 10 was used to diagnose SAHS. Arousals were defined according to a report from the American Sleep Disorders Association Atlas task force. Sleep data were staged according to the system of Rechtschaffen and Kales.

Prevalence – 19 subjects

Time between measurement of index test and reference standard: In-laboratory PSG was performed within one month of the home sleep monitoring</td></tr>
<tr><td rowspan="4">2×2 table All OSA (AHI≥10)</td><td></td><td>Reference standard +</td><td>Reference standard −</td><td>Total</td><td rowspan="4">Provided by the study, doubtful studies excluded from analysis</td></tr>
<tr><td>Index test +</td><td>18</td><td>3</td><td>21</td></tr>
<tr><td>Index test −</td><td>1</td><td>15</td><td>16</td></tr>
<tr><td>Total</td><td>19</td><td>18</td><td>37</td></tr>
<tr><td>Statistical measures</td><td colspan="5"><u>Index text, portable sleep recording device, at home, AHI ≥10</u>
Sensitivity: 94.7% Calculated by NGC
Specificity: 83.3% Calculated by NGC
Positive predictive value: not reported
Negative predictive value: not reported

Area under the curve, manually scored, (95% confidence interval): not reported</td></tr>
<tr><td>Source of funding</td><td colspan="5">Supported by a grant from Fundación Marqués de Valdecilla</td></tr>
<tr><td>Limitations</td><td colspan="5">Risk of bias: Serious. Enrollment method unclear; unclear if all study exclusion criteria appropriate; unclear whether the index test was interpreted without knowledge of the reference standard, and 33% of recruited study participants were not included in the analysis (18/55)
Indirectness: Serious. Proxy AHI ≥10 for index test was used.</td></tr>
</table>

Reference	**Golpe 2002[149]**
Comments	Paper only provides TP, FP, FN, or TN. Sensitivity and specificity have been calculated using diagnostic calculation spreadsheet using TP, FP, FN or TN

Reference	**Goodrich 2009[151]**
Study type	Cross-sectional
Study methodology	Data source: PSG was performed with simultaneous utilisation of the Lifeshirt on 50 individuals who met screening criteria for obstructive sleep apnea. Participants came to the sleep laboratory approximately 2 h before their normal bedtime Recruitment: consecutive
Number of patients	n = 50 recruited, 48 analysed
Patient characteristics	Age, mean (SD): 44 (range 22 to 69) Gender (male to female ratio): 35/13 Ethnicity: not reported Setting: sleep centre Country: USA Inclusion criteria: symptoms suggestive of obstructive sleep apnoea (e.g. reports of regular snoring, gasping or choking for air while attempting to sleep, and daytime sleepiness); heartburn at least three times per week; and use of over-the-counter medications for heartburn several times per week. Exclusion criteria: history of abdominal surgery, significant respiratory illnesses such as chronic obstructive pulmonary disease or asthma, neurological or psychiatric disorders requiring regular medication, significant medical conditions such as chronic renal or liver disease, and a history of Barrett's oesophagus.
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	Index test: Portable respiratory polygraphy (Lifeshirt, Vivometrics; Ventura, CA), in-centre: the Lifeshirt is a form-fitting vest. Sensors embedded within the shirt are capable of monitoring a range of physiological parameters. In this study, sleep technicians prepared each patient for sleep, and ensured that the Lifeshirt was operating correctly. All Lifeshirt data were scored by automated analysis by Vivometrics, and

Reference	Goodrich 2009[151]
	completely independent of the PSG scoring. Technicians at Vivometrics review all computer results; when there is any discrepancy between the automated analysis and the technician (e.g. due to artefact), the technician can restore part or all of the sleep study to make it more accurate. The Lifeshirt uses an algorithm that distinguishes between apnoeas and hypopnoeas with the following definitions: obstructive apnoea is a reduction in tidal volume of more than 75% compared to baseline with continuing efforts to breathe seen in the ribcage and abdomen, with ≥3% oxygen desaturation. Central apnoea consists of a complete cessation of respiratory efforts in the ribcage and abdomen (i.e. tidal volume equal to zero), with a ≥3% oxygen desaturation. Hypopnoea is a drop in tidal volume of greater than 25% and less than 50% compared to baseline in combination with ≥3% oxygen desaturation. All apnoeas and hypopnoeas must be at least 10 seconds in length. Since the Lifeshirt did not measure EEG, the AHI was based on apnoeas and hypopnoeas per hour of monitoring. The Lifeshirt measures ventilation through respiratory inductive plethsymography bands that are located at the ribcage and abdomen. A proprietary algorithm computes breath volume and compares it to the median breath volume of the preceding two-minute interval in order to detect respiratory events. <u>Reference standard</u> In-centre polysomnography (PSG) with no prespecified AHI diagnostic of obstructive sleep apnoea: study participants arrived at the sleep laboratory two hours before bedtime. Experienced sleep technicians prepared the patients for complete PSG including electroencephalography; chin and leg electromyography; electrocardiography; electro-oculography; airflow; respiratory effort (chest and abdominal belts), and oxygen saturation. A nasal cannula was used for airflow. Sleep stages were scored manually according to Recthschaffen and Kales' criteria. Obstructive sleep apnoea was defined as a drop in airflow of at least 80% but with continuing respiratory efforts seen in the chest and abdomen. Central apnoea also consisted of a drop in airflow of at least 80% accompanied by a similar decrease in both chest and abdominal belts. A hypopnoea was defined as a decrease in airflow of at least 30% that was accompanied by an oxygen desaturation of at least 3%. Respiratory events had to last at least 10 seconds to qualify as apnoeas or hypopnoeas. The AHI consisted of the number of apnoeas and hypopnoeas per hour of sleep. Arousals were scored to the criteria set forth by the American Sleep Disorders Association. The studies were scored by experienced staff who were blinded to the results of the Lifeshirt data. PSG AHI ≥5, AHI≥15 and AHI≥30 analysed below. Prevalence AHI ≥5 = 39 subjects, AHI ≥15 = 15 subjects, AHI ≥30 =8 Time between measurement of index test and reference standard: simultaneous PSG and Lifeshirt recordings

2×2 table All OSAS (AHI ≥ 5)		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	33	3	36	
	Index test −	6	6	12	
	Total	39	9	48	

Reference	Goodrich 2009[151]				
2×2 table moderate-severe OSAS (AHI ≥ 15)		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	13	6	19	
	Index test −	2	27	29	
	Total	15	33	48	
2×2 table Severe OSAS (AHI ≥ 30)		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	7	0	7	
	Index test −	1	40	41	
	Total	8	40	48	
Statistical measures	Index text, portable respiratory polygraphy, AHI >5, in-centre Sensitivity: 85% Specificity: 67% Positive predictive value: not reported Negative predictive value: not reported Index text, portable respiratory polygraphy, AHI >15, in-centre Sensitivity: 87% Specificity: 82% Positive predictive value: not reported Negative predictive value: not reported Index text, portable respiratory polygraphy, AHI >30, in-centre Sensitivity: 88% Specificity: 100% Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval) All OSA (AHI≥5): 0.76 (CI not provided) Moderate-severe (AHI≥15): 0.84 (CI not provided) Severe (AHI≥30): 0.94 (CI not provided)				

Reference	**Goodrich 2009**[151]
Source of funding	The manufacturer of the Lifeshirt loaned the authors the Lifeshirts used in this study. No financial support was provided for this project.
Limitations	Risk of bias: None overall although unclear if all study exclusion criteria appropriate; 4% of recruited study participants were not included in analysis Indirectness: None
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Gyulay 1993**[162]
Study type	Cross-sectional
Study methodology	Data source: patients referred for assessment of snoring and/or daytime somnolence were assessed clinically and then underwent both unsupervised oximetry in their homes and formal polysomnography. Recruitment: consecutive
Number of patients	n = 98 recruited and analysed
Patient characteristics	Age, mean (SD): 49.96 (2.5) Gender (male to female ratio): 77/21 Ethnicity: not reported Setting: sleep centre and home Country: Australia Inclusion criteria: not reported Exclusion criteria: not reported The study population included patients referred to a specialist sleep centre because of a question of OSA. All were habitual snorers; those identified as having significant chronic lung disease were not included. Patients found at oximetry to have arterial oxygen desaturation (SaO_2 ≤90%) during wakefulness were not excluded. Twenty patients were not included because they lived too far from the laboratory for overnight oximetry to be feasible.

Reference	Gyulay 1993[162]
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	<u>Index test:</u> Pulse oximetry (Model Biox 3700; Ohmeda, Boulder, CO) with a desaturation index ≥15 (4%), at home: the pulse oximeter recorded saturation continuously, but stored the lowest value recorded in a 12-second epoch. The alarm circuits of the oximeters were inactivated. The patients were instructed to turn the oximeter on at lights out and to turn it off when they got up the next morning. No instructions on alcohol consumption or other aspects of sleep routine were given. When the oximeter was returned, patients filled out at hospital sleep questionnaire, and patients reporting no sleep or very poor sleep were asked to have a second night of oximetry. The number of falls of 2% or more, 3% or more, and 4% or more from baseline were calculated by computer analysis. The first desaturation was recorded when a single reading lower than baseline SaO_2 by the appropriate amount (2%, 3% or 4%) was observed. The desaturation event was considered to end when SaO_2 rose 2% if 2% desaturations were being counted or 3% if 3% or 4% desaturations counted. If a further fall occurred, a second event was counted. An event was also considered to end if SaO_2 remained below baseline by the appropriate amount for more than 3 minutes, and a second event was counted even if SaO_2 fell no lower. Events longer than 3 minutes were enumerated separately by the computer and subtracted from the total before calculation of the desaturation index (DI). The DI was calculated for 2%, 3% and 4% falls in SaO_2. No rules for interpretation of the data were offered, but after inspecting these, the clinicians reviewed their estimates of the likelihood of clinically significant OSA. (DI4% ≥15) <u>Reference standard</u> Laboratory polysomnography (PSG) with a prespecified AHI ≥15 (no % desaturation criteria) diagnostic of obstructive sleep apnoea: PSG was analysed manually without knowledge of the oximetry result. Methods and equipment not reported in detail; apnoea was defined as cessation of oronasal airflow for more than 10 seconds, and hypopnoea as a reduction of oronasal airflow to 50% or less of the value prevailing during preceding normal breathing for at least 10 seconds. Desaturation was not a criterion for scoring either apnoea or hypopnoea. OSA was defined as AHI ≥15. With these data the clinicians made a decision on the need for nasal CPAP treatment. Prevalence (AHI≥15) = 43 patients Time between measurement of index test and reference standard: laboratory PSG was performed between 2 weeks and 3 months after home pulse oximetry

2×2 table Moderate-severe (AHI ≥15)

	Reference standard +	Reference standard −	Total	
Index test +	17	1	18	Calculated by NGC
Index test −	26	54	80	
Total	43	55	98	

Reference	**Gyulay 1993[162]**
Statistical measures	Index text, pulse oximetry, desaturation index ≥15 (4%), at home Sensitivity: 40% Specificity: 98% Positive predictive value: Not reported Negative predictive value: Not reported Area under the curve, manually scored, (95% confidence interval): not reported
Source of funding	Supported by the National Health and Medical Research Council of Australia
Limitations	Risk of bias: Serious. inclusion/exclusion criteria reported incompletely, and the index test could have been interpreted with knowledge of the reference standard results. Indirectness: None
Comments	 % oxygen desaturation not included in AHI criteria. Details not reported on the timing and number of repeated oximetry tests; Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Jen 2020[181]**
Study type	Cross-sectional
Study methodology	Data source: not stated Recruitment: consecutive
Number of patients	n = 33 analysed
Patient characteristics	Age, mean (SD): 63 (7); Gender (male to female ratio): 61% male Ethnicity: not reported Setting: sleep laboratory

Reference	Jen 2020[181]
	Country: USA Inclusion criteria: Adult patients (18 years of age) with known COPD as diagnosed by a pulmonologist (defined as Global Initiative for Chronic Obstructive Lung Disease, GOLD stage 2 or higher and ≥10 pack-years of smoking history) were screenedbetween July 2015 and August 2016. Recruitment was performed outside any clinical care via flyers posted in the community and pulmonary clinics, and from a local community study of COPD. Exclusion criteria: for the study were unstable COPD or active cardiovascular disease, defined as recent hospitalisation within 3 months; medical conditions that would affect the diagnostic accuracy or application of WatchPAT including history of peripheral vascular disease, peripheral neuropathy, non-sinus cardiac rhythm, permanent pacemaker, finger deformity that precluded adequate sensor application. Informed consent was obtained from all participants after the protocol was approved by the Human Research Protections Program/Institutional Review Board of University of California, San Diego.
Target condition(s)	Overlap syndrome
Index test(s) and reference standard	Index test At the same time as the in-lab PSG, all subjects simultaneously wore the WatchPAT 200 (Itamar Medical Ltd.,Caesarea, Israel). WatchPAT 200 is a device worn around the wrist with one finger probe and separate snoring sensor. The finger probe records the peripheral arterial tonometry (PAT) signal, heart rate, oxygen saturation with an actigraph built in with the recording device on the wrist. Sleep time was estimated by the actigraphy signal, and sleep stage was determined through PAT analysis, the details of which have been previously described [19]. Respiratory events were identified using a combination of PAT signal attenuation, heart rate changes, and desaturation on pulse oximetry and analyzed by the WatchPAT proprietary software algorithm . Only the automated scoring of WatchPAT studies was used. Reference standard All subjects underwent a standard in-laboratory overnight PSG. Signals recorded included: electrooculography (EOG), electrocardiography (ECG), submental and tibial electromyography (EMG), electroencephalography (EEG), chest and abdominal respiratory movement, nasal and oral airflow (measured by a mask with pneumotach; if the subjects were unable to tolerate the mask, nasal–oral thermistor and nasal pressure were used), oxygen saturation, and snoring intensity. Subjects were encouraged to sleep supine. All of the PSGs were scored by one registered polysomnographic technologist (RPSGT) according to the American Academy of Sleep Medicine guidelines (Chicago criteria) . The scoring was completed without knowledge of the WatchPAT results. Prevalence: AHI≥5 = 72.7% (24 subjects), AHI ≥15 = 39.4% (13 subjects), AHI ≥30 = 27.3% (9 subjects)

Reference	**Jen 2020**[181]				
	Time between measurement of index test and reference standard: at the same time				
2×2 table AHI≥5		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	23	4	27	
	Index test −	1	5	6	
	Total	24	9	33	
2×2 table AHI≥15		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	12	7	19	
	Index test −	1	13	14	
	Total	13	20	33	
2×2 table AHI≥30		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	8	1	9	
	Index test −	1	23	24	
	Total	9	24	33	
Statistical measures	<u>Index text: partially attended night-time recording, AHI≥5</u> Sensitivity 95.8% Specificity 55.6% Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval) : not reported <u>Index text: partially attended night-time recording, AHI≥15</u> Sensitivity 92.3% Specificity 65% Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval) : not reported <u>Index text: partially attended night-time recording, AHI≥30</u>				

Reference	**Jen 2020**[181]
	Sensitivity 88.9% Specificity 95.8% Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval) : not reported
Source of funding	This study was supported by Fondo de Investigaciones Sanitarias, Commissionat per Universitats i Recerca de la Generalitat de Catalunya
Limitations	Risk of bias: Serious. Indirectness: None
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Lloberes 1996**[242]
Study type	Cross-sectional
Study methodology	Data source: not stated Recruitment: ‘patients…studied at random’
Number of patients	n = 76 analysed
Patient characteristics	Age, mean (SD): 51 (11.5); range 24-82 Gender (male to female ratio): 54/22 Ethnicity: not reported Setting: respiratory ward or sleep laboratory

Reference	**Lloberes 1996**[242]
	Country: Spain Inclusion criteria: not reported Exclusion criteria: not reported The study population included adults with a mean body mass index of 31 (5.7) kg/m^2 (range 17-48) referred to a sleep clinic for evaluation of OSAHS during a three month period
Target condition(s)	Sleep apnoea/ hypopnoea syndrome
Index test(s) and reference standard	<u>Index test</u> Partially attended night-time respiratory recording: the intended use of this index test was to assess whether simplified respiratory recording could reduce the requirement for full polysomnography. The respiratory recording was performed using a Densa Pneumograph (Densa Ltd, Flint, UK) which measures oronasal airflow by a thermistor and chest and abdominal motion using strain gauges. The pulse oximeter was the same as that used for full polysomnography. A trained nurse connected the patient to the monitoring system in approximately 10 minutes. The recording could be observed throughout the night on a computer screen located in front of the nurse’s desk, allowing easy detection of any technical abnormality. Apnoea and hypopnoea were defined, respectively, as a reduction of at least 80% or 50% in airflow, both associated with a higher than 2% dip in arterial oxygen saturation with respect to the previous 30 seconds. The number of reductions in phase angle between chest and abdominal waveforms per hour higher than 10 was also assessed. <u>Reference standard</u> Laboratory polysomnography (PSG) with prespecified apnoea/hypopnoea index (AHI) of >10 diagnostic of OSAHS. 28% of participants had an AHI-PSG <10. PSG included electroencephalographic, chin electromyographic and electro-oculographic recordings (to standard criteria), arterial oxygen saturation (measured continuously with a finger probe using a pulse oximeter – 504 Critical Care System Inc, Waukesha, USA), rib cage and abdominal motion (monitored by piezoelectric bands placed on the thorax and abdomen – Reso-Ez, Bionic, Midlothian, Virginia, USA), and airflow recordings (using a thermistor). All signals were recorded continuously on a polygraph (Nicloet 1A98 Madison, Wisconsin, USA). The technician spent 30 minutes connecting the patient to the monitoring system, three hours manually scoring the recording, and stayed with the patient all night. Analysis of full PSG and the index test was carried out by the same individuals blinded to the result of the other study. The mean AHI obtained using the index test was compared with that obtained with full PSG. Prevalence AHI≥10 = 55 subjects Time between measurement of index test and reference standard: on two different nights within three weeks

Reference	**Lloberes 1996[242]**				
2×2 table, AHI≥10		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	45	2	47	
	Index test −	10	19	29	
	Total	55	21	76	
Statistical measures	<u>Index text: partially attended night-time recording, AHI</u> Sensitivity 82% Specificity 90% Positive predictive value: 96% Negative predictive value: 65.5% Area under the curve, manually scored, (95% confidence interval) : not reported				
Source of funding	This study was supported by Fondo de Investigaciones Sanitarias, Commissionat per Universitats i Recerca de la Generalitat de Catalunya				
Limitations	Risk of bias: Serious. Enrollment method unclear; inclusion/exclusion criteria not reported Indirectness: serious, proxy values AHI ≥ 10 used for both index test and reference standard				
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.				

Reference	**Marrone 2001[286]**
Study type	Cross-sectional
Study methodology	Data source: he reliability of a POLYMESAM (PM) instrument in the detection of ventilatory disorders and in the diagnosis of obstructive sleep apnea syndrome (OSAS) was evaluated in 50 subjects suspected for OSAS, simultaneously studied by polysomnography (PSG) in a sleep laboratory. Recruitment: consecutive

Reference	Marrone 2001[286]
Number of patients	n = 50 analysed
Patient characteristics	Age, mean (SD): 49.6 ± 10.2 (units not reported) Gender (male to female ratio): 40/10 Ethnicity: not reported Setting: laboratory Country: Italy Inclusion criteria: not reported Exclusion criteria: not reported Study participants had a history of heavy snoring but showed a variable degree of subjective somnolence (Epworth score 10.2 ± 4.3).
Target condition(s)	Obstructive sleep apnoea syndrome
Index test(s) and reference standard	<u>Index test</u> Portable sleep monitor (POLYMESAM): this device consists of a recorder, to which multiple sensors are linked for the detection of the following signals: oxyhaemoglobin saturation (by a finger sensor), heart rate [derived from three ECG electrodes on the chest], snoring sound (by a microphone placed on the thyroid cartilage), body posture, oronasal airflow (by a three-fold thermocouple sensor for both nostrils and mouth), thoracic and abdominal movements (by stretch belts), and optionally, either limb activity or continuous positive airway pressure (CPAP). The system can work as a stationary or as an ambulant recorder. Software for automatic analysis is provided; however, all raw data can be visualised on the computer so that the automatic analysis can be manually corrected, with the exception of ECG that can be visualised only as heart rate. The duration of the recording by the monitor was predetermined. <u>Reference standard</u> Laboratory polysomnography (PSG) with a prespecified AHI of ≥10 diagnostic of obstructive sleep apnoea syndrome: PSG was recorded by a computerised system (Somnostar, Sensormedics, Yorba Linda, CA, USA). A standard montage was used, including two electroencephalograms, right and left electro-oculograms, submental electromyogram, oronasal airflow by thermocouple, thoracic and abdominal movements by piezoelectric belts, oxyhaemoglobin saturation, electrocardiogram, and body posture. A technician was in attendance of the patients; he controlled PSG recording and was allowed to fix any failing signal, but he could not visualise signals recorded by the portable sleep monitor. After an automatic scoring of both recordings, the whole computerised analyses were corrected manually. On both recording of each patient, the following events were scored: central apnoeas (Ac), defined

<table>
<tr><th>Reference</th><th>Marrone 2001[286]</th></tr>
<tr><td></td><td>as absence of airflow for at least ten seconds, associated with the lack of any thoraco-abdominal movement; obstructive apnoeas (Ao), defined as absence of airflow for at least ten seconds, associated with the persistence of thoraco-abdominal movements; mixed apnoeas (Am), defined as events starting as central apnoeas and coming to an end as obstructive apnoeas; hypopnoeas (H), defined as discernible reductions in the airflow signal for at least 10 seconds, associated with a decrease in oxyhaemoglobin saturation by at least 4%. The duration of each event was measured. The frequency of each kind of event was normalised per hour of time in bed (TIB), so as to obtain the following indices: Ac/TIB, Ao/TIB, Am/TIB and H/TIB; in addition, the frequency of apnoeas and hypopnoeas per hour of TIB (AH/TIB) was calculated. Two people analysed the recordings. Each scorer analysed 25 portable monitor and 25 PSG recordings, and was blinded to the results obtained within the paired recording.Prevalence AHI≥10 = 42 subjects

Time between measurement of index test and reference standard: simultaneous recording by PSG and the portable monitoring device.</td></tr>
<tr><td>2×2 table</td><td>
<table>
<tr><th></th><th>Reference standard +</th><th>Reference standard −</th><th>Total</th><th>Calculated by NGC</th></tr>
<tr><td>Index test +</td><td>45</td><td>1</td><td>46</td><td></td></tr>
<tr><td>Index test −</td><td>0</td><td>4</td><td>4</td><td></td></tr>
<tr><td>Total</td><td>42</td><td>8</td><td>50</td><td></td></tr>
</table>
</td></tr>
<tr><td>Statistical measures</td><td><u>Index text, portable sleep monitor (POLYMESAM), AHI/TIB ≥5</u>
Sensitivity 100%
Specificity 71.4%
Positive predictive value: 95.5%
Negative predictive value: 100%

Area under the curve, manually scored, (95% confidence interval) : not provided</td></tr>
<tr><td>Source of funding</td><td>Not reported</td></tr>
<tr><td>Limitations</td><td>Risk of bias: Serious. Inclusion/exclusion criteria not reported
Indirectness: Serious. Proxy AHI ≥10 used for reference standard</td></tr>
<tr><td>Comments</td><td>Paper only provides totals and not TP, FP, FN, or TN.

These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.</td></tr>
</table>

Reference	**Masa 2013[297] (Masa 2013[300]; Masa 2011[298])**
Study type	Cross-sectional
Study methodology	Data source: suspected OSAHS patients in a multicentre study assigned to home and hospital protocols at random Recruitment: 'randomised'
Number of patients	n = 366 randomised, 348 completed protocol
Patient characteristics	Age, mean (SD): 48.7 (11.8) Gender (male to female ratio): 263/85 Ethnicity: not reported Setting: Home or hospital Country: Spain Inclusion criteria: patients between 18 and 70 years old, referred to pulmonary clinics at eight hospitals in Spain for suspected OSAHS, due to snoring, observed apnoeas, sleepiness (Epworth sleepiness scale >10) or morning fatigue. Patients with other suspected sleep disordered were not included Exclusion criteria: patients with severe heart disease, those who were unable to set up the home respiratory polygraphy instrument in a trial and those who refused to participate in the study
Target condition(s)	Sleep apnoea/ hypopnoea syndrome
Index test(s) and reference standard	Index test Home respiratory polygraphy (HRP): HRP (Breas SC20; Breas Medical AB, Mölnlycke, Sweden) measurements included: oxygen saturation (model 8000 J; Nonin Medical; Plymouth, MN, USA), airflow through a nasal cannula, and thoracic and abdominal movements measured by piezoelectric bands (Pro-Tech reference 1295; Respironics, Pittsburgh, PA, USA), which also measured body position. The intended use of the index test was to assess whether home polygraphy could reduce the requirement for in-hospital polysomnography. All patients were instructed on home use of the HRP device by a technician in the hospital setting before randomisation. Trained personnel from continuous positive airway pressure service companies in each hospital area, acting as transport companies, moved the HRP instruments from home to home. No additional assistance was provided by the transport services to help the patients set up the HRP devices. The same technician in each centre scored the raw data, following manual and automatic scoring protocols. In the manual scoring protocol, the total number of apnoeas and hypopnoeas was divided by the recording time, excluding 'invalid time' (time with a bad

Reference	Masa 2013[297] (Masa 2013[300]; Masa 2011[298])				
	signal that prevented scoring). For automatic scoring, the total number of apnoeas and hypopnoeas was divided by recorded time with no exclusions Reference standard In-hospital polysomnography (PSG) with an apnoea/hypopnoea index (AHI) of ≥15 diagnostic of OSAHS. PSG included electroencephalogram, electro-oculogram and electromyogram. Flow tracing was provided by a nasal cannula and thoracoabdominal motion by piezoelectric bands. Oxygen saturation was measured with a finger pulse oximeter. The PSG was analysed manually, according to the Rechtschaffen and Kales and the American Sleep Disorders Association 1992 criteria for sleep periods and arousals and according to the Spanish Sleep Network rule for respiratory scoring. Time between measurement of index test and reference standard: patients underwent PSG and HRP in a random order – once the first test was begun, the second test was scheduled for within the next 3 days. For PSG, an apnoea was defined as the absence of airflow (≥90% reduction) for ≥10 seconds and a hypopnoea as a discernible airflow or band reduction (≥30% and <90%) of ≥10 seconds duration with a ≥3% drop in oxygen saturation or final arousal. For HRP, apnoeas and hypopnoeas were defined in the same way, but without the final arousal criteria for hypopnoeas. For automatic scoring, apnoea/hypopnoea events were predicted with both flow reduction and desaturation detection, using a previously published regression equation. The number of apnoeas and hypopnoeas was divided by recording time for HRP and sleep time for PSG Prevalence: AHI≥5 = 90% (313 subjects), AHI≥15 = 75% (261 subjects)				
2×2 table All OSAS (AHI ≥ 5)		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	307	24	331	
	Index test −	6	11	17	
	Total	313	35	348	
2×2 table Moderate-severe OSAS (AHI ≥ 25)		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test +	175	7	182	
	Index test −	86	80	166	
	Total	261	87	348	

Reference	Masa 2013[297] (Masa 2013[300]; Masa 2011[298])
Statistical measures	Index text home respiratory polygraphy (manual scoring), AHI ≥5 Sensitivity 98% Specificity 31% Positive predictive value: not reported Negative predictive value: not reported Index text home respiratory polygraphy (manual scoring), AHI ≥25 Sensitivity 67 % Specificity 92% Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval) All OSA (AHI≥5): not reported Moderate-severe (AHI≥15): 0.901 (0.867 – 0.936 Severe (AHI≥30): not reported
Source of funding	Instituto de Salud Carlos III (Fondo de Investigaciones Sanitarias, Ministerio de Sanidad y Consumo), Spanish Respiratory Society, Telefonica SA, Air Liquide and Breas Medical. Also the Ministerio de Ciencia e Innovación
Limitations	Risk of bias: Very serious. High differential rate of repeated recordings, with HRP repeated 52 times in 359 patients (once or twice per patient) compared with one repetition of PSG in nine patients. Unclear if study avoided inappropriate exclusions, unclear reasons for exclusion of three randomised participants who completed the protocol, and the test results could have been interpreted with knowledge of the other test results – the same technician scored both tests Indirectness: Serious proxy value AHI≥25 used for index test in moderate OSAHS population
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Ng 2010[369]**
Study type	Cross-sectional
Study methodology	Data source: This study aimed to evaluate the diagnostic accuracy of Embletta portable diagnostic system (PDS, Medcare, Reykjavik, Iceland) for the screening of sleep apnoea in clinical practice. Recruitment: consecutive
Number of patients	n = 80 analysed
Patient characteristics	Age, mean (SD): 51.4 (11.9) Gender (male to female ratio): 63/17 Ethnicity: not reported Setting: laboratory Country: China Inclusion criteria: not reported Exclusion criteria: not reported Included participants had suspected obstructive sleep apnoea syndrome (OSAS). All participants with possible OSAHS had either self-reported daytime sleepiness that interfered with daytime function or two of the following symptoms: choking or gasping during sleep, daytime fatigue and impaired concentration.
Target condition(s)	Obstructive sleep apnoea syndrome
Index test(s) and reference standard	Index test Portable, three-channel airflow monitor (Embletta PDS): the PDS consisted of a pocket-sized digital recording device. It is a multi-channel screening tool that measures airflow through a nasal cannula connected to a pressure transducer, providing an AHI based on recording time. It also detects both respiratory and abdominal efforts through the effort sensor and can differentiate between obstructive and central events. The body position was detected by in-built sensors without confirmation by infrared camera. Technologists were not able to view the signals or correct sensor problems associated with the PDS during the course of the study. Respiratory events were scored when desaturation of at least 4% occurred in the absence of moving artefacts and irrespective of coexisting changes in snoring or heart rate. The PDS operates on battery power, with the internal memory storage of 16MB, which allows approximately 12 hours of data collection. The PDS default settings for apnoeas and hypopnoeas were used in this study. An apnoea was defined as a decrease in airflow by 80% of baseline for at least 10 seconds. The PDS default maximum apnoea duration was set at 80 seconds. A hypopnoea

Reference	Ng 2010[369]
	was defined as a decrease in airflow by 50% of baseline for at least 10 seconds. The PDS default maximum hypopnoea duration was set at 100 seconds. The PDS AHI used for analysis was automatically analysed by the PDS software. Data were included in the analysis if the total recorded evaluation time of 4 hours or longer was obtained during the PDS study. Records of the index test and reference standard were analysed in a double-blinded fashion. <u>Reference standard</u> Laboratory polysomnography with no prespecified AHI, RDI or ODI for diagnosis of obstructive sleep apnoea syndrome: overnight diagnostic PSG was performed for every participant, recording electroencephalogram, electro-oculogram, submental electromyogram, bilateral anterior tibial electromyogram, ECG, chest and abdominal wall movement by inductance plethysmography, airflow measured by nasal pressure transducer and supplemented by an oral thermister, and finger pulse oximetry. Sleep stages were scored according to standard criteria by Rechtschaffen and Kales. Apnoea was defined as cessation of airflow for >10 seconds and hypopnoea as a reduction of airflow of ≥30% for >10 seconds plus an oxygen desaturation of >4 % or an arousal. Participants wore 2 nasal cannulae, with one for the PDS and the other for PSG. Prevalence: AHI≥5 = 66 subjects, AHI≥15 = 41 subjects Time between measurement of index test and reference standard: simultaneous sleep study with the portable airflow monitor and PSG

2×2 table All OSA (AHI ≥ 5) Hospital RP

	Reference standard +	Reference standard −	Total	
Index test +	61	2	63	Calculated by NGC
Index test −	5	12	17	
Total	66	14	80	

2×2 table All OSA (AHI ≥ 15) Hospital RP

	Reference standard +	Reference standard −	Total	
Index test +	36	2	38	Calculated by NGC
Index test −	5	37	42	
Total	41	39	80	

Reference	Ng 2010[369]
Statistical measures	Index text, portable, three-channel airflow monitor AHI>5 Sensitivity 92.4% Specificity 85.7% Positive predictive value: 96.8% Negative predictive value: 70.6% Index text, portable, three-channel airflow monitor AHI>15 Sensitivity 88% Specificity 95% Positive predictive value: 94.7% Negative predictive value: 88.1% Area under the curve, manually scored, (95% confidence interval) All OSA (AHI≥5): 0.948 (CI not provided) Moderate-severe (AHI≥15): 0.985 (CI not provided) Severe (AHI≥30): not provided
Source of funding	The Respiratory Research Fund, The Chinese University of Hong Kong
Limitations	Risk of bias: Serious. Exclusion criteria not reported and 10/90 participants (11%) were excluded from analysis due to technical problems with the portable monitoring device Indirectness: None
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals

Reference	Pereira 2013[430]
Study type	Cross-sectional
Study methodology	Data source: this study aimed to evaluate the combined diagnostic utility of a level III PM in diagnosis and exclusion of OSA, as compared with in-laboratory polysomnography (PSG) derived apnea hypopnea index (AHI) Recruitment: Consecutive

Reference	**Pereira 2013[430]**
Number of patients	N= 128 analysed
Patient characteristics	Age, mean (SD): 50(12.3) Gender (male to female ratio,): 84/47 Ethnicity: Not stated Setting: Sleep disorders clinic Country: Canada Inclusion criteria: the ability to apply the Level III monitoring equipment without supervision (after brief initial training) and a primary residence within 100 miles of the sleep clinic (for returning the PM equipment). Exclusion criteria: included known COPD, congestive heart failure, or uncontrolled asthma.
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	Index test - They were asked to wear the Level III portable monitoring device (MediByte; Braebon Medical Corporation, Ottawa, ON) for 2 consecutive nights at home. The first night of recording was used in the analysis, with the second night as a back-up if recording from the first night did not provide sufficient data. The PM device consists of 2 inductance bands for thoracic and abdomen measurement, a nasal cannula pressure transducer airflow signal, finger pulse oximetry, and a body position sensor. Patients were given the option to either manually turn on the device before switching off the lights at night and turn off the device once awake in the morning, or to have the device start and stop automatically at predetermined times. Reference standard- Following completion of home testing, patients attended the Sleep Disorders Laboratory at Kingston General Hospital for a full overnight PSG. Recordings were conducted using Sandman Elite SD32+ digital sleep recording system (Natus [Embla]; Ottawa, ON), and included 4 EEG channels (C4-A1, C3-A2, O2-A1, F3-A2), 2 EOG channels (ROC-A1, LOC-A2), submental EMG, intercostal (diaphragmatic surface) EMG, bilateral anterior tibialis EMG, ECG, respiratory piezo bands (chest and abdomen), finger pulse oximetry, a vibration snore sensor, nasal pressure airflow, and oronasal thermocouple. PSG recordings were conducted as either a diagnostic study or, in the event of severe OSA, a split-night study. For split-night studies, the initial diagnostic period was followed by the introduction of treatment during the night, and only the diagnostic part of the recording was used for comparison. Prevalence: AHI≥5 = 116 subjects, AHI≥15 = 88 subjects, AHI≥30 = 56 subjects

Reference	**Pereira 2013[430]**				
2×2 table All OSA (AHI ≥5) Home RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	101	4	105	
	Index test 1−	15	8	23	
	Total	116	12	128	
2×2 table moderate-severe (AHI ≥15) Home RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	68	2	70	
	Index test 1−	20	38	58	
	Total	88	40	128	
2×2 table Severe (AHI ≥30) Home RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	28	5	33	
	Index test 1−	28	67	95	
	Total	56	72	128	
Statistical measures	Index test 1, portable sleep monitor, at home, AHI ≥5 (4% oxygen desaturation) Sensitivity 87% Specificity 67 % Positive predictive value: 96.2% Negative predictive value: 34.2% Index test 2, portable sleep monitor, at home, AHI ≥15 Sensitivity 77% Specificity 95% Positive predictive value: 97.1% Negative predictive value: 65.5% Index test 3, portable sleep monitor, at home, AHI ≥30 Sensitivity 50% Specificity 93% Positive predictive value: 84.8% Negative predictive value: 70.5 % Area under the curve, various PSG AHI cut-offs based on combination of ≥2 high scoring questionnaires and a PM RDI ≥10 events/h, (95% confidence interval) All OSA (AHI≥5): 0.773 (CI not provided)				

Reference	Pereira 2013[430]
	Moderate-severe (AHI≥15): 0.801 (CI not provided) Severe (AHI≥30): 0.716 (CI not provided)
Source of funding	The authors thank BRAEBON Medical Corporation for providing MediByte units for the purposes of the study, and the technologists at Kingston General Hospital Sleep Disorders Laboratory for assistance.
Limitations	Risk of bias: Serious risk of bias Indirectness: none
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	Polese 2013[443]
Study type	Cross-sectional
Study methodology	Data source: The aim of our study was to evaluate the effectiveness of at home portable monitoring (PM) in elderly patients Recruitment: Consecutive
Number of patients	N= 43 analysed
Patient characteristics	Age, mean (SD) = 70(5) Gender (male to female ratio): 44/56 (%) Ethnicity: Not stated Setting: Sleep institute Country: Brazil

Reference	Polese 2013[443]
	Inclusion criteria: included those aged ≥65 years (the World Health Organization's definition of elderly), both genders, and with suspected OSAHS, i.e., complaints of daytime sleepiness, loud snoring, and apnea witnessed by a bed partner Exclusion criteria: patients with a suspicion of other sleep disorders, those who had previously undergone PSG or treated for OSAHS, patients with severe or unstable medical illnesses, those who are on oxygen therapy, and those who are using hypnotics, alcohol, or recreational drugs.
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	<u>Index test</u> - The type 3 portable device used was the Stardust II® (Philips Respironics, Inc., Murrysville, PA, USA), which has been shown to be capable of diagnosing OSAS in a non-elderly population. The Stardust records include SpO2 (finger sensor), heart rate (finger sensor), airflow (nasal pressure), respiratory effort (belt with piezoelectric sensor set at the lower sternum), and body position (device positioned at the lower sternum). Data are collected and stored on internal memory in the device. The data are then downloaded to a computer for automated analysis by the host software (Stardust Host Software, Philips Respironics, Inc., USA). A trained PSG technician applied the PM and sensors used for the PSG recording during the overnight PSG in the sleep lab. A research assistant instructed the patients how to use PM at home. The explanation included verbal and written instructions to illustrate the correct hook-up of the PM and included diagrams and a brief practical demonstration. During training, patients were asked to indicate “lights out” and “lights on” and any time during the night he/she remained awake for more than 15 min. <u>Reference standard</u> - Laboratory polysomnography - Full-night PSG (Embla® S7000, Embla Systems, Inc.,Broomfield, CO, USA) was performed by a trained technician. The PSG montage included electroencephalogram, electrooculogram, electromyogram (submental region and bilateral anterior tibialis muscle), airflow (nasal pressure and thermistor), respiratory effort of thorax and abdomen (inductance plethysmography), oxyhemoglobin saturation (SpO2), snoring, body position, and video monitoring. Prevalence (Home RP): AHI ≥ 5 = 93% (36 subjects), AHI ≥ 30 = 72% (28 subjects); Prevalence (Hospital RP) AHI ≥5 = 93% (35 subjects), AHI≥30 = 72% (27 subjects)

2×2 table All OSA (AHI ≥5) Home RP

	Reference standard +	Reference standard −	Total	Calculated by NGC
Index test 1+	32	2	35	
Index test 1−	4	1	5	
Total	36	3	39	

2×2 table Severe (AHI ≥30)

	Reference standard +	Reference standard −	Total	Calculated by NGC
Index test 1+	22	2	25	

Reference	**Polese 2013[443]**				
Home RP	Index test 1−	6	9	14	
	Total	28	11	39	
2×2 table All OSA (AHI ≥5) Hospital RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	35	3	38	
	Index test 1−	0	0	0	
	Total	35	3	38	
2×2 table Severe (AHI ≥30) Hospital RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	24	4	28	
	Index test 1−	3	7	10	
	Total	27	11	38	
Statistical measures	<u>Index test 1, portable sleep monitor, at home, AHI ≥5</u> Sensitivity 90% Specificity 30% Positive predictive value: 90% Negative predictive value: 60% <u>Index test 2, portable sleep monitor, at home, AHI ≥30</u> Sensitivity 80% Specificity 80% Positive predictive value: 70% Negative predictive value: 15% <u>Index test 3, portable sleep monitor, at hospital, AHI ≥5</u> Sensitivity 100% Specificity 0% Positive predictive value: 1% Negative predictive value: 0% <u>Index test 4, portable sleep monitor, at hospital, AHI ≥30</u> Sensitivity 90% Specificity 68% Positive predictive value: 71% Negative predictive value: 0.1%				

Reference	Polese 2013[443]
	Area under the curve, manually scored, (95% confidence interval) - Home All OSA (AHI≥5): 0.83 (CI not provided) Moderate-severe (AHI≥15): 0.85 (CI not provided) Severe (AHI≥30): 0.85 (CI not provided) Area under the curve, manually scored, (95% confidence interval) - Hospital All OSA (AHI≥5): 0.93 (CI not provided) Moderate-severe (AHI≥15): 0.99 (CI not provided) Severe (AHI≥30): 0.90 (CI not provided)
Source of funding	Funding not reported
Limitations	Risk of bias: Serious risk of bias. Complete loss of data 9.3% of PM home recordings. In the PM home group, partial data loss was observed in 44 % of the recordings: six recordings showed a partial loss of pulse oximetry, airflow signal loss in eight recordings, and chest signal band loss in five patients. The data from these recordings were included in the analysis because more than 75 % of each recording was acceptable. Indirectness: none
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, and totals. PPV and NPV values reported in the paper appear to be very inaccurate so these values were not used in the analysis.

Reference	Reichert 2003[464]
Study type	Cross -sectional
Study methodology	Data source: Fifty-one consecutive adults referred to the sleep lab for suspicion of OSA underwent one night of in-lab, simultaneous recording of PSG and NovaSom QSG in addition to using the NovaSom QSG at home for three nights. Recruitment: consecutive

Reference	Reichert 2003[464]
Number of patients	n = 51 recruited, 44 analysed in-laboratory and 45 analysed at home and in-laboratory
Patient characteristics	Age, mean (range): 52 (30-83) Gender (male to female ratio): 38/13 Ethnicity: not reported Setting: laboratory and home Country: USA Inclusion criteria: not reported Exclusion criteria: not reported Adults were referred to the sleep laboratory by a large pool of community physicians due to a clinical suspicion of OSA, based on symptoms including snoring, witnessed apnoea and excessive daytime sleepiness, and they were scheduled for overnight in-lab polysomnography.
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	Index test Portable, five-channel home diagnostic system (NovaSom QSG): participants performed home NovaSom QSG study either before or after their in-lab study. To minimise order bias, half of the home recordings were performed before in-lab recordings and half were performed after in-lab recordings, according to the order of referral to the centre. They were instructed to use the diagnostic system at home for three nights but received no instructions on how to use it; Instructions for use, a Quick Guide and an instructional video were provided with the diagnostic system, in addition to a 24 hour helpline. The NovaSom QSG, manufactured by Sleep Solutions Incorporated, measures nasal and oral airflow (using sound), oxygen saturation, heart rate, respiration effort and snoring sound intensity. The system consists of a bedside unit, a patient module (worn on the patient's wrist) and three body sensors: airflow, finger oximeter and respiratory effort. It is self-administered and used unattended in the home to record three nights of data. The effort sensor is thin Tygon tubing placed around the chest and is connected to a pressure transducer in the patient module. The finger sensor is a Nonin Adult Flexi-form 7000A. Testing was unattended and self-administered by the participant at home. The system used voice alerts to wake the patient if any of the sensors became dislodged during the night. The NovaSom QSG does not differentiate between wake and sleep, so the AHI measurement is based on total recording time as opposed to total sleep time. The diagnostic system scoring was automated, using proprietary algorithms. The technologist was blinded to the NovaSom QSG signal both during recording and scoring of the data. Some of the in-lab NovaSom QSG recordings were interrupted due to a split night protocol.

Reference	Reichert 2003[464]
	Reference standard Laboratory polysomnography (PSG) with a prespecified clinical AHI cut-off ≥15: PSG included two channels of electroencephalogram, electro-oculogram, submentalis electromyogram, electrocardiography, anterior tibialis EMG, diaphragmatic EMG, microphone (snoring sounds), end tidal CO_2, nasal-oral airflow (thermocouple), abdominal and thoracic respiration using piezo sensors, and oximetry (Novametrix), all processed through a Grass polygraph and recorded by a Sandman Diagnostics System. Each PSG was staged for sleep according to the Rechtschaffen and Kales criteria by a trained, blinded technologist. Respiratory events from the PSG recording were manually scored by the technologist. For both PSG and the NovaSom QSG, an apnoea was defined as cessation of airflow for 10 seconds or longer and hypopnoea was defined as ≥50% reduction in airflow for 10 seconds or longer accompanied by a ≥2% decrease in oxygen haemoglobin saturation. Some of the PSG recordings were interrupted due to a split night protocol (40/44 in-lab recordings). Prevalence: AHI ≥15 = 20 subjects Time between measurement of index test and reference standard: simultaneous in-lab PSG and NovaSom QSG. Home NovaSom QSG was also performed within 7 days of the lab test.

2×2 table moderate-severe OSAS (AHI ≥ 15)

	Reference standard +	Reference standard −	Total	Calculated by NGC
Index test 2+	20	2	22	
Index test 2 −	1	21	22	
Total	21	23	44	

Statistical measures	Index text , portable, five-channel diagnostic system in-lab (automated scoring) , AHI ≥15 Sensitivity 95% Specificity 91% Positive predictive value: 91% Negative predictive value: 96% Area under the curve, manually scored, (95% confidence interval) : not reported
Source of funding	Financial support was received from the Sequoia Hospital Pulmonary Research Fund
Limitations	Risk of bias: Serious. Inclusion/exclusion criteria not reported, and unclear whether the index test was interpreted without knowledge of the reference standard. Approximately 12% missing data for the home and in-laboratory testing, and 14% for the in-laboratory testing Indirectness: None
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Reference	**Rofail 2010[475]**
Study type	Cross-sectional
Study methodology	Data source: All patients had laboratory PSG and 2 sets of 3 consecutive nights on each device; nasal airflow (Flow Wizard, DiagnoseIT, Australia) and oximetry (Radical Set, Masimo, USA) at home in random order Recruitment: consecutive
Number of patients	n = 105 recruited, 98 completed the protocol with 92 analysed over three nights, 72 analysed over first night
Patient characteristics	Age, mean (SD): 46.0 (11.7) Gender (male to female ratio, %): 77/23 (total numbers unclear) Ethnicity: 89.5% Caucasian (total numbers unclear) Setting: laboratory and home Country: Australia Inclusion criteria: not reported Exclusion criteria: patients with complex, unstable medical conditions, such as congestive heart failure, severe chronic obstructive pulmonary disease, interstitial lung disease, dependency on home oxygen, severe obesity (BMI over 45 kg/m^2), neuromuscular disorder, inability to apply the diagnostic device (e.g. severe osteoarthritis), unstable psychiatric illness and/or history of current or previous drug and alcohol dependence including those in drug and alcohol rehabilitation, shift workers, known history of other sleep disorders, patients unable to understand the patient information sheets and those enrolled on other clinical research studies. In addition, those who lived in remote areas (>40km away from the study site), and those who presented when all of the available nasal flow monitors and oximeters were in use could not be recruited for the home study. Study participants were referred to the Sleep Disorders Clinic for evaluation of possible OSA.
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	<u>Index tests</u> Single-channel, nasal airflow device, RDI (Flow Wizard, DiagnoseIT, Sydney, Australia): The Flow Wizard recorded nasal airflow pressure via nasal cannulae. Automated nasal flow RDI calculations were based on the artefact-free flow recording time. Respiratory

Reference	Rofail 2010[475]
	disturbances included apnoeas, defined as a decrease in the amplitude of the airflow signal by ≥90% for ≥10 seconds, and hypopnoeas, a reduction in the amplitude of the respiratory signal ≥50% for ≥10 seconds. The recordings were automatically scored without manual editing. In the home, two types of nasal cannula were used: the Comfort Plus Soft Tip adult nasal cannula (Wedmed, Arizona, USA) was used in the first 53 patients, and the Pro-Flow adult nasal cannula (ProTech, Washington, USA) was used in the following 52 patients. Single-channel oximeter, ODI (Radical Set, Masimo, CA, USA): The Radical Set was set to a short (2-second) averaging time and a high sampling rate (80 Hz). The ODI (3%) was calculated as the number of desaturation events ≥3% divided by the total time in bed. Download 2001 v. 2.6.0 (Stowood Scientific Instruments, Oxford, UK) was used to analyse the tracing. The recordings were automatically scored without manual editing. For nasal flow and oximetry, the data were included in the analysis and regarded as sufficient if ≥3 hours of good quality recording was obtained over one study night and ≥6 hours over all three nights combined. For nasal flow, the duration of good quality recording was defined as the total recording duration minus poor quality signal time (defined by very low mean maximum pressure for 20 breaths and prolonged loss of flow signal >2 minutes as per software algorithm). For oximetry, good quality recording duration was the analysis duration minus artefact time as per the software algorithm. The data reported for all three nights was the total number of events divided by total good quality time over the three nights. <u>Reference standard</u> Laboratory polysomnography (PSG) with a prespecified AHI of ≥5 diagnostic of OSA: computerised, attended full PSG recordings were performed (Alice 5, Respironics, Murrysville PA, USA) and included electroencephalography, electro-oculography, and submental and tibialis anterior electromyography for sleep staging according to Rechtschaffen and Kales criteria. Also, thoracic and abdominal piezoelectric respiratory movement sensors, oxygen saturation, nasal pressure via adults nasal cannulae (Pro-Tech, Washington, USA), body position, snoring, and electrocardiogram were monitored. Apnoeas were defined as complete cessation of airflow and hypopnoeas were defined as flow reduction >50% associated with either a 3% desaturation or an arousal. The PSG recordings were scored independently by trained sleep technicians blinded to the portable monitor results. PSG recordings were included in the analysis and regarded as sufficient if ≥3 hours of total sleep time was obtained. Time between measurement of index test and reference standard: home and in-laboratory recordings were performed within an 8-week period. The patients performed home recordings for two consecutive 3-night sequences. The two sequences, performed in random order, were three nights on the nasal flow monitor and three nights on the oximeter. They were instructed to use the device for a minimum of 6 hours per night. The two sequences conducted at home and the in-laboratory PSG were performed in random order. The patients, research staff, and their physician were blinded to all the results until the completion of all components of the study. Prevalence (AHI ≥ 5) = 70.5% (51 subjects)

Reference	**Rofail 2010[475]**				
2×2 table aAll OSAS (ODI ≥ 7)		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	32	4	36	
	Index test 1−	19	18	36	
	Total	51	22	72	
Statistical measures	Index test, single-channel oximeter, automatic scoring over first night, ODI (3%) >7 Sensitivity 63% Specificity 83% Positive predictive value: Not reported Negative predictive value: Not reported Area under the curve, manually scored, (95% confidence interval) : not reported				
Source of funding	Departmental research support from Respironics, Resmed, Covidien, Fisher-Paykel, Sanofi-Aventis, Actelion, Impax, DiagnoseIT, and Arena has consulted for and has financial interests in DiagnoseIT.				
Limitations	Risk of bias: Serious. Unclear if all study exclusions appropriate as part of study exclusion criteria, and there were missing data for 27% of first night analyses, as a proportion of those who completed the full protocol. Indirectness: serious proxy ODI>7 was used for index test				
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals				

Reference	**Ryan 1995[490]**
Study type	Cross-sectional
Study methodology	Data source: patients referred to a district general hospital sleep clinic were recruited. After initial clinical assessment, overnight pulse oximetry measurements were performed, followed by full polysomnography at the regional laboratory. Recruitment: ‘the first 100 participants who satisfied inclusion criteria’
Number of patients	n = 69 analysed

Reference	**Ryan 1995[490]**
Patient characteristics	Age, mean (SD): 48 (12) Gender (male to female ratio): 57/12 Ethnicity: not reported Setting: Home and laboratory Country: UK Inclusion criteria: not reported Exclusion criteria: Under 16 years of age, had an awake baseline oxygen saturation of 90% or less, or known cardiorespiratory, neuromuscular or skeletal disease
Target condition(s)	Sleep apnoea/hypopnoea syndrome
Index test(s) and reference standard	Index test Oximetry device: overnight home pulse oximetry with a finger flexiprobe. This system samples every second but prints out the value at each 10 second interval. The oximetry trace was read by two respiratory physicians unaware of the clinical details. The number of desaturations was counted manually. The physicians were a consultant and a senior registrar with two or three years' experience of running a respiratory sleep clinic. Using the British Thoracic Society oximetry criteria, a diagnosis of 'SAHS positive' or 'SAHS negative' was made. Reference standard Laboratory polysomnography (PSG) with a prespecified AHI of ≥15 diagnostic of sleep apnoea/hypopnoea syndrome. PSG included oximetry (Ohmeda pulse oximeter 3700), respitrace recordings of abdominal and chest wall movements (Airshield impedance apnoea monitor), video recording of respiratory movements (Cannon vision E video camera with Akai recorder), two lead EEG, EMG, ECG and nasal and oral airflow measurements (Edentec airflow thermistor and PK Morgan Capnograph 901-MK2) using the Neuroscience Sleepmaster system and software version X5.2D. Apnoeas were diagnosed on the basis of no airflow for at least 10 seconds and a desaturation of >4% in the following 30 seconds. Hypopnoeas were defined as reduction in chest wall movement (>25%), reduced abdominal wall movement (>15%), and paradoxical movement with airflow reduction of >25%. The criteria of Rechtschaffen and Kales were used for sleep staging. These and respiratory events were computer analysed with manual editing. Time between measurement of index test and reference standard: not reported Prevalence AHI ≥15 = 32 subjects

Reference	Ryan 1995[490]				
2×2 table Moderate – severe (AHI ≥ 15)		Reference standard +	Reference standard −	Total	TP and TN reported in the paper
	Index test +	10	0	10	
	Index test −	22	37	59	
	Total	32	37	69	
Statistical measures	Index text oximetry device: overnight home pulse oximetry, with AHI ≥15 Sensitivity 31% Specificity 100% Positive predictive value: 100% Negative predictive value: 63% Area under the curve, manually scored, (95% confidence interval): not reported				
Source of funding	Not reported				
Limitations	Risk of bias: Very serious. Enrollment method unclear; unclear if all study exclusions appropriate, and test results could have been interpreted with knowledge of the other test results Indirectness: None				
Comments	Paper provides totals and not TP and TN. FN and FP have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, TP, TN, PPV, NPV and totals.				

Reference	Wiltshire 2001[590]
Study type	Cross-sectional
Study methodology	Data source: patients were referred from ear, nose, and throat surgeons, primary-care physicians, and other chest physicians for assessment of suspected SAHS using full polysomnography. Recruitment: 100 consecutive patients were studied
Number of patients	84 analysed

Reference	Wiltshire 2001[590]
Patient characteristics	Age, mean (SD): Gender (male to female ratio, %): Ethnicity: Not stated Setting: Not stated Country: UK Inclusion criteria: Patients with suspected OSAHS Exclusion criteria: not stated
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	Index test – Home oximetry. The oximeters used in this study were Biox 3740 (Ohmeda UK). For the home and laboratory, studies oximeters were identical, including the software version (version 9) and the default settings. Signal averaging defaulted to 6 s in this software. Finger- clip oximeter probe was used in all studies. These oximeters have a memory storage capability of 8 h, storing a data point every 12 s. this memory capability was used in the home studies and some of the laboratory studies for comparison. Recordings online in the laboratory studies recorded a data point every 2 s. These oximeters also have pulse waveforms that provide an indication of signal strength. It was not possible to evaluate whether good signal strength was obtained in the home studies. In the laboratory studies, the pulse waveform was monitored throughout the night to ensure good quality signal strength. Reference standard – laboratory polysomnography. All underwent full polysomnography within 3 days of the home studies. Patients underwent foll polysomnographic study that included EEG, electrooculography, electromyography, and ECG recordings, thoraco abdominal and nasal-oral air flow measurements and pulse oximetry. The signals were recorded online using the SleepLab system. Video sound recording was made throughout the night. Patients went to bed at their normal bedtime; if they consumed alcohol on home study night, they were allowed to consume similar quantities on the night of the study. Prevalence AHI ≥10 = 32 subjects; AHI ≥15 =23 subjects

2×2 table moderate-severe (ODI ≥10) Home oximetry

	Reference standard +	Reference standard −	Total
Index test 1+	13	0	13
Index test 1−	19	52	71
Total	32	52	84

TP, TN, FN were provided by the paper FP were calculated by NGC

Reference	**Wiltshire 2001[590]**				
2×2 table moderate-severe (ODI ≥15) Home oximetry		Reference standard +	Reference standard −	Total	TP, TN, FN were provided by the paper FP were calculated by NGC
	Index test 1+	8	0	8	
	Index test 1−	15	61	76	
	Total	23	61	84	
Statistical measures	<u>Index test 1, portable sleep monitor, at home, ODI ≥10</u> Sensitivity – 41% Specificity – 100 % Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval): not reported <u>Index test 2, portable sleep monitor, at home, ODI ≥15</u> Sensitivity – 35% Specificity – 100 % Positive predictive value: not reported Negative predictive value: not reported Area under the curve, manually scored, (95% confidence interval): not reported				
Source of funding	Funding not stated				
Limitations	Risk of bias: serious risk of bias Indirectness: Serious indirectness, Proxy ODI>10 was used for index testin mild OSAHS population				
Comments	Paper only provides totals and TP, FN and TN. FP have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, TP,FN,TN, PPV, NPV and totals.				

Reference	Xu 2017[597]
Study type	Cross-sectional
Study methodology	Data source: Eighty Chinese adults underwent overnight, unattended home sleep apnea testing (HSAT) with the Nox-T3 portable monitor followed by an overnight in-laboratory polysomnogram (PSG) with simultaneous portable monitor recording Recruitment: not reported
Number of patients	n = 80 analysed
Patient characteristics	Age, mean (SD): 47 (14) Gender (male to female ratio, %): 76/24 Ethnicity: not reported Setting: laboratory and home Country: China Inclusion criteria: not reported Exclusion criteria: no telephone access or inability to return for follow-up; prior diagnosis of central sleep apnoea/Cheyne-Stokes respiration, obesity hypoventilation syndrome, narcolepsy, rapid eye movement behaviour disorder, chronic obstructive pulmonary disease, or heart failure; shift work; regular jet lag or irregular work schedules by history over the past 3 months; supplemental oxygen therapy (daytime or nocturnal); or a clinically unstable medical condition as defined by a change in medications in the previous month, or a new medical diagnosis in the previous 2 months (e.g. myocardial infarction, active infection, thyroid disease, depression or psychosis, cirrhosis, surgery, or cancer). Study participants were referred for evaluation of OSA and were between the ages of 18 and 80 years with no previous testing or treatment for OSA.
Target condition(s)	Obstructive sleep apnoea
Index test(s) and reference standard	<u>Index test</u> Portable sleep monitor, AHI (Nox-T3, Nox Medical Inc. Reykjavik, Iceland): the Nox-T3 recorded nasal pressure, rib cage and abdominal movement by inductance plethysmography, snoring, body position, activity, and heart rate and oxygen saturation by pulse oximetry. Participants in the home study came to the sleep centre to receive instructions on how to perform the recording. During the session, a trained sleep technologist demonstrated how to apply the sensors and the participant was then asked to apply the sensors.

Reference	Xu 2017[597]
	After the technician confirmed proper placement, the sensors were removed, and the participant reapplied the sensors at home just prior to bedtime. During in-laboratory testing, the sleep technologist applied the portable monitor sensors and initiated the recording. Separate sensors were used for the simultaneous portable monitor and PSG recordings. Therefore, participants wore two sets of nasal cannula, two sets of rib cage and abdominal belts, and two pulse oximeters in the laboratory. A successful home monitoring study required at least three hours of recording containing the oxygen saturation and at least one of the respiratory signals (airflow, rib cage movement, abdominal movement). If the initial home monitoring was unsuccessful, the participant took a portable monitor home after the PSG and undertook another home study. If the second attempt was unsuccessful, the home study was not repeated. The quality of the home study was assessed by automated analysis of the signal quality for oxygen saturation, airflow, abdominal movement, and thoracic movement. The automated analysis scores artefacts when the signal is absent or deemed to be invalid. Analysis start- and stop time on the portable monitor recordings were manually determined based on the participants' responses on a morning questionnaire and the activity signal on the recording. The scorer was blinded to whether the portable monitor recording was performed at home or in the laboratory and to a particular participant's PSG results. The portable monitor recordings were initially scored automatically using Noxturnal software. The software programme defined apnoeas as ≥90% reduction in airflow from baseline for at least 10 seconds. Obstructive apnoeas were defined as an apnoea associated with respiratory effort and central apnoeas were defined as an apnoea during which respiratory effort was absent. Mixed apnoeas were defined as an apnoea during which respiratory effort was initially absent but appeared during the latter part of the event. Hypopnoeas were defined as a ≥30% reduction in a respiratory signal for ≥10 seconds associated with a ≥4% reduction in oxygen saturation. The recordings were then manually edited by an experienced PSG technologist with the aid of the software programme using 2012 American Academy of Sleep Medicine scoring criteria. The same start and stop time selected for the automatic scoring was used for the manually edited scoring. Two separate manually edited scorings were performed using different definitions for hypopnoea: the same criteria used for automatic scoring; hypopnoeas defined by a ≥30% reduction in respiratory signal for at least 10 seconds associated with a ≥3% reduction in oxygen saturation. When the portable monitor recording for nasal pressure was absent or not able to be scored throughout the recording or during portions of the recording, the flow signal derived from the rib cage and abdominal respiratory inductance plethysmography signals were used for the scoring. The AHI on the Nox-T3 recordings was calculated as the average number of apnoeas and hypopnoeas per hour of analysis time. <u>Reference standard</u> Laboratory polysomnography (PSG) with no prespecified diagnostic AHI, RDI or ODI: PSG was performed according to the American Academy of Sleep Medicine recommendations. The following signals were recorded: electroencephalogram; bilateral electro-oculogram; chin muscle electromyogram; oronasal thermistor; nasal pressure; rib cage and abdominal movement; electrocardiogram; snoring; body position; bilateral anterior tibialis electromyograms; heart rate and oxygen saturation by pulse oximetry. Using American Academy of Sleep Medicine 2012 scoring criteria, PSG was scored manually with the aid of computer software by an experienced sleep technologist without knowledge of the results of the portable monitor recordings. Apnoeas were scored when there was ≥90% reduction in airflow from baseline for ≥10 seconds on the oronasal thermistor signal. The same criteria used to identify obstructive, central and mixed apnoeas on the portable monitor recordings were used to score those events on PSG. Two separate PSG scorings were performed using different definitions for hypopnoea: events with ≥30% reduction in airflow from baseline for ≥10 seconds accompanied by ≥4% oxygen desaturation; events with ≥30% reduction in airflow from baseline for ≥10 seconds associated with ≥3%

Reference	Xu 2017[597]				
	reduction in oxygen saturation and/or an arousal. AHI on PSG was calculated as the average number of apnoeas and hypopnoeas per hour of sleep. Time between measurement of index test and reference standard: laboratory PSG and portable monitoring were performed simultaneous and within 1 week after the portable sleep monitoring at home. Prevalence (Home RP): AHI ≥5 = 83% (64 subjects), AHI ≥15 = 55% (42 subjects), AHI ≥30 = 39% (30 subjects), Prevalence (Hospital RP): AHI ≥5 = 84% (64 subjects), AHI ≥15 = 55% (42 subjects), AHI ≥5 = 40% (30 subjects)				
2×2 table All OSA (AHI ≥5) Home RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	61	4	65	
	Index test 1−	3	9	12	
	Total	64	13	77	
2×2 table moderate-severe (AHI ≥15) Home RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	39	5	44	
	Index test 1−	3	30	33	
	Total	42	35	77	
2×2 table Severe (AHI ≥30) Home RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	19	3	22	
	Index test 1−	11	44	55	
	Total	30	47	77	
2×2 table All OSA (AHI ≥5) Hospital RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	62	3	65	
	Index test 1−	2	9	11	
	Total	64	12	76	
2×2 table Moderate-severe OSA (AHI ≥5) Hospital RP		Reference standard +	Reference standard −	Total	Calculated by NGC
	Index test 1+	42	2	44	
	Index test 1−	0	32	32	
	Total	42	34	76	
		Reference standard +	Reference standard −	Total	Calculated by NGC

Reference	Xu 2017[597]				
2×2 table severe OSA (AHI ≥5) Hospital RP	Index test 1+	29	1	30	
	Index test 1−	1	45	46	
	Total	30	46	76	
Statistical measures	<u>Index test 1, portable sleep monitor, at home, AHI ≥5 (4% oxygen desaturation)</u> Sensitivity 95% Specificity 69% Positive predictive value: 94% Negative predictive value: 75% <u>Index test 2, portable sleep monitor, at home, AHI ≥15</u> Sensitivity 93% Specificity 85% Positive predictive value: 89% Negative predictive value: 91% <u>Index test 3, portable sleep monitor, at home, AHI ≥30</u> Sensitivity 63% Specificity 93% Positive predictive value: 86% Negative predictive value: 80% <u>Index test 4, portable sleep monitor, in-laboratory, AHI ≥5 (4% oxygen desaturation)</u> Sensitivity 97% Specificity 75% Positive predictive value: 95% Negative predictive value: 82% <u>Index test 4, portable sleep monitor, in-laboratory, AHI ≥15</u> Sensitivity 100% Specificity 94% Positive predictive value: 95% Negative predictive value: 100% <u>Index test 4, portable sleep monitor, in-laboratory, AHI ≥30</u> Sensitivity 97%				

Reference	Xu 2017[597]
	Specificity 98% Positive predictive value: 97% Negative predictive value: 98% Area under the curve, manually scored, (95% confidence interval): Home – not reported Area under the curve, manually scored, (95% confidence interval): Hospital – not reported
Source of funding	Phillips Respironics Foundation and grants from the Ministry of Science and Technology and Beijing Municipal Science and Technology Commission
Limitations	Risk of bias: Serious. Unclear if all study exclusions appropriate as part of study exclusion criteria Indirectness: None
Comments	Paper only provides totals and not TP, FP, FN, or TN. These have been calculated using diagnostic calculation spreadsheet using sensitivity, specificity, PPV, NPV and totals.

Appendix E: Clinical evidence table for test and treat study

Study	Conventional Polysomnography Is Not Necessary for the Management of Most Patients with Suspected Obstructive Sleep Apnea trial: Corral 2017[93]
Study type	RCT (Patient randomised; Parallel)
Number of studies (number of participants)	1 (n=430)
Countries and setting	Conducted in Spain; Setting: 12 tertiary hospitals
Line of therapy	1st line
Duration of study	Intervention + follow up: 6 months follow up
Method of assessment of guideline condition	Adequate method of assessment/diagnosis
Stratum	Moderate-severe: n/a
Subgroup analysis within study	Not applicable: n/a
Inclusion criteria	Patients between 18 and 70 years of age who were referred for pulmonary consultations because of suspected OSA at 12 tertiary hospitals in Spain (see online supplement). Other inclusion criteria were (1) snoring or sleep apnoea's observed by a partner, (2) ESS greater than or equal to 10, and (3) absence of clinical suspicion of any other sleep pathology that could cause daytime sleepiness (e.g., narcolepsy).
Exclusion criteria	1) psychophysical inability to complete the questionnaires; (2) documented structural or coronary cardiopathy that was not controlled by medical treatment; (3) Cheyne-Stokes syndrome; (4) patients with uvulopalatopharyngoplasty, which can prevent effective CPAP treatment; (5) very severe nasal obstruction, which can prevent CPAP treatment; and (6) an inability to provide informed consent.
Recruitment/selection of patients	Consecutive
Age, gender and ethnicity	Age - Median (IQR): 50 (16). Gender (M:F): male 70.5%. Ethnicity: not stated
Further population details	1. BMI: BMI >/=30 (median (IQR) = 30.7(7.3). 2. Co-existing conditions: T2DM (overall - 9.3% (Home RP - 10.6%; Polysomnography - 8%)). 3. Gender: Not applicable (70.5% male). 4. High risk occupation group: Not stated / Unclear 5. Race: Not stated / Unclear 6. Sleepiness: ESS >9 (Median (IQR) - 13(5)).
Indirectness of population	No indirectness
Interventions	(n=218) Intervention 1: Home respiratory polygraphy. HRP (Embla-Embletta; Natus,Pleasanton, CA) measurements included oxygen saturation, airflow through nasal pressure, and thoracic and abdominal movements measured by piezoelectric

	bands. The patients transported the device to their homes with a prior detailed explanation and functional test device provided by a technician in the hospital setting. When the patients returned the device the following day, the raw data files were transmitted to a computer and scored manually, excluding artifact periods. PSG was performed in patients with invalid HRP tests after several repetitions, and the subsequent cost was added to the HRP arm. Duration 6 months. Concurrent medication/care: A sleep physician specialist at each centre (always the same individual) made the therapeutic decision based on a standardized set of variables, including clinical symptoms and results from HRP or PSG, using the same website. The treatment decision was guided using the Spanish Sleep Network guidelines. The sleep physician recommended CPAP treatment in the case of a respiratory event index (REI) greater than or equal to 5 for HRP or an AHI greater than or equal to 5 for PSG with significant clinical symptoms (i.e., ESS >12), potentially secondary to OSA or previous cardiovascular diseases, and an REI or an AHI greater than or equal to 30, with clinical symptoms having less importance. Non-CPAP treatment included only correct sleep hygiene and a hypocaloric diet. Indirectness: No indirectness Further details: 1. Intervention type: Electronic (The sleep physician recommended CPAP treatment in the case of a respiratory event index (REI) greater than or equal to 5 for HRP or an AHI greater than or equal to 5 for PSG with significant clinical symptoms (i.e., ESS >12),). (n=212) Intervention 2: Hospital respiratory polygraphy - Hospital polysomnography. We used standard protocols to perform PSGs and analyse the results. PSG and HRP studies with less than 3 recorded hours were repeated on two other occasions, and the costs were included in the overall cost calculation. For PSG, apnoea was the absence of flow lasting 10 seconds or more, and hypopnea was a discernible decrease in flow lasting 10 seconds or more with oxygen desaturation (>3%) or arousal. For HRP, the definitions were the same but without the final arousal criteria. Duration 6 months. Concurrent medication/care: A sleep physician specialist at each centre (always the same individual) made the therapeutic decision based on a standardized set of variables, including clinical symptoms and results from HRP or PSG, using the same website. The treatment decision was guided using the Spanish Sleep Network guidelines. The sleep physician recommended CPAP treatment in the case of a respiratory event index (REI) greater than or equal to 5 for HRP or an AHI greater than or equal to 5 for PSG with significant clinical symptoms (i.e., ESS >12), potentially secondary to OSA or previous cardiovascular diseases, and an REI or an AHI greater than or equal to 30, with clinical symptoms having less importance. Non-CPAP treatment included only correct sleep hygiene and a hypocaloric diet. Indirectness: No indirectness Further details: 1. Intervention type: Electronic (The sleep physician recommended CPAP treatment in the case of a respiratory event index (REI) greater than or equal to 5 for HRP or an AHI greater than or equal to 5 for PSG with significant clinical symptoms (i.e., ESS >12)).

Funding	Funding not stated

RESULTS (NUMBERS ANALYSED) AND RISK OF BIAS FOR COMPARISON: HOME RESPIRATORY POLYGRAPHY versus HOSPITAL POLYSOMNOGRAPHY

Protocol outcome 1: Quality of life at >1 month
- Actual outcome for Moderate-severe: Change in quality of life EQ5D at 6 months; Group 1: mean 0.01 (SD 0.17); n=218, Group 2: mean 0.03 (SD 0.16); n=212
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30
- Actual outcome for Moderate-severe: FOSQ - Change score at 6 months; Group 1: mean 6.7 (SD 16.7); n=218, Group 2: mean 6.5 (SD 18.1); n=212
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30
- Actual outcome for Moderate-severe: SF36 Physical - change score at 6 months; Group 1: mean 1.2 (SD 9.2); n=218, Group 2: mean 2.6 (SD 9.1); n=212
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30
- Actual outcome for Moderate-severe: SF36 mental - change score at 6 months; Group 1: mean 2.5 (SD 12.2); n=218, Group 2: mean 1.4 (SD 11.7); n=212
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30

Protocol outcome 2: Sleepiness score at >1 month
- Actual outcome for Moderate-severe: Change in sleepiness score ESS at 6 months; Group 1: mean -4.2 (SD 5.4); n=218, Group 2: mean -4.9 (SD 5.3); n=212
Risk of bias: All domain - Very high, Selection - High, Blinding - High, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30

Protocol outcome 3: AHI/RDI at >1 month
- Actual outcome for Moderate-severe: AHI at 6 months; MD; Comments: mean difference - mean (SD) - 1.4(18.9);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30

Protocol outcome 4: ODI at >1 month
- Actual outcome for Moderate-severe: ODI at 6 months; MD; , Comments: mean difference - mean(SD) - 1.4(15.7);
Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30

Protocol outcome 5: Patient preference at >1 month
- Actual outcome for Moderate-severe: Healthcare resource use People given CPAP at 6 months; Group 1: 116/218, Group 2: 143/212

Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30 Protocol outcome 6: Systolic blood pressure for hypertension at >1 month - Actual outcome for Moderate-severe: Change in 24 hr systolic blood pressure at 6 months; Group 1: mean 0.4 (SD 9.9); n=218, Group 2: mean 0.3 (SD 11); n=212 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30 Protocol outcome 7: Cardiovascular events at >1 month - Actual outcome for Moderate-severe: Cardiovascular events at 6 months; Group 1: mean 6.4 (SD 30.7); n=218, Group 2: mean 7.3 (SD 32.7); n=212 Risk of bias: All domain - High, Selection - High, Blinding - Low, Incomplete outcome data - Low, Outcome reporting - Low, Measurement - Low, Crossover - Low; Indirectness of outcome: No indirectness ; Group 1 Number missing: 17; Group 2 Number missing: 30	
Protocol outcomes not reported by the study	Mortality at >1 month; HbA1c for diabetes at >1 month

Appendix F:Coupled sensitivity and specificity forest plots and sROC curves

F.1 Coupled sensitivity and specificity forest plots

Figure 3: Home oximetry All OSAHS (AHI ≥ 5)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Rofail 2010	32	4	19	18	0.63 [0.48, 0.76]	0.82 [0.60, 0.95]
Wiltshire 2001	13	0	19	52	0.41 [0.24, 0.59]	1.00 [0.93, 1.00]

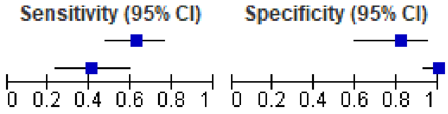


Figure 4: Home oximetry Moderate-severe OSAHS (AHI ≥ 15)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Gyulay 1993	17	1	26	54	0.40 [0.25, 0.56]	0.98 [0.90, 1.00]
Ryan 1995	10	0	22	37	0.31 [0.16, 0.50]	1.00 [0.91, 1.00]
Wiltshire 2001	8	0	15	61	0.35 [0.16, 0.57]	1.00 [0.94, 1.00]

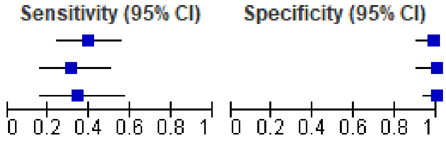


Figure 5: Home respiratory polygraphy all OSAHS (AHI ≥ 5)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
de Oliveira 2009	101	6	4	10	0.96 [0.91, 0.99]	0.63 [0.35, 0.85]
Garg 2014	51	13	2	9	0.96 [0.87, 1.00]	0.41 [0.21, 0.64]
Gjevre 2011	29	6	3	9	0.91 [0.75, 0.98]	0.60 [0.32, 0.84]
Golpe 2002	18	3	1	15	0.95 [0.74, 1.00]	0.83 [0.59, 0.96]
Masa 2013	307	24	6	11	0.98 [0.96, 0.99]	0.31 [0.17, 0.49]
Pereira 2013	101	4	15	8	0.87 [0.80, 0.93]	0.67 [0.35, 0.90]
Polese 2013	32	2	4	1	0.89 [0.74, 0.97]	0.33 [0.01, 0.91]
Xu 2017	61	4	3	9	0.95 [0.87, 0.99]	0.69 [0.39, 0.91]

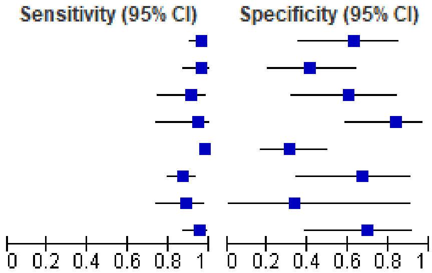


Figure 6: Home respiratory polygraphy moderate-severe OSAHS (AHI ≥ 15)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Garg 2014	38	8	3	26	0.93 [0.80, 0.98]	0.76 [0.59, 0.89]
Masa 2013	175	7	86	80	0.67 [0.61, 0.73]	0.92 [0.84, 0.97]
Pereira 2013	68	2	20	38	0.77 [0.67, 0.86]	0.95 [0.83, 0.99]
Xu 2017	39	5	3	30	0.93 [0.81, 0.99]	0.86 [0.70, 0.95]

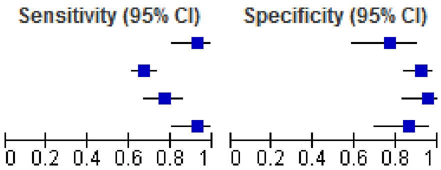


Figure 7: Home respiratory polygraphy severe OSAHS (AHI ≥ 30)

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Pereira 2013	28	5	28	67	0.50 [0.36, 0.64]	0.93 [0.85, 0.98]
Polese 2013	22	2	6	9	0.79 [0.59, 0.92]	0.82 [0.48, 0.98]
Xu 2017	19	3	11	44	0.63 [0.44, 0.80]	0.94 [0.82, 0.99]

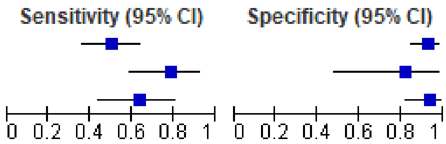


Figure 8: Centre respiratory polygraphy all OSAHS

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Calleja 2002	58	2	6	13	0.91 [0.81, 0.96]	0.87 [0.60, 0.98]
Emsellem 1990	37	1	2	23	0.95 [0.83, 0.99]	0.96 [0.79, 1.00]
Goodrich 2009	33	3	6	6	0.85 [0.69, 0.94]	0.67 [0.30, 0.93]
Lloberes 1996	45	2	10	19	0.82 [0.69, 0.91]	0.90 [0.70, 0.99]
Marrone 2001	45	1	0	4	1.00 [0.92, 1.00]	0.80 [0.28, 0.99]
Ng 2010	61	2	5	12	0.92 [0.83, 0.97]	0.86 [0.57, 0.98]
Polese 2013	35	3	0	0	1.00 [0.90, 1.00]	0.00 [0.00, 0.71]
Xu 2017	62	3	2	9	0.97 [0.89, 1.00]	0.75 [0.43, 0.95]

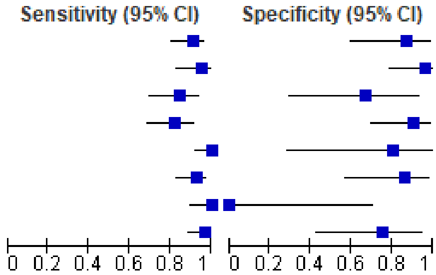


Figure 9: Centre respiratory polygraphy moderate-severe OSAHS

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Claman 2001	18	1	3	20	0.86 [0.64, 0.97]	0.95 [0.76, 1.00]
Goodrich 2009	13	6	2	27	0.87 [0.60, 0.98]	0.82 [0.65, 0.93]
Ng 2010	36	2	5	37	0.88 [0.74, 0.96]	0.95 [0.83, 0.99]
Reichert 2003	20	2	1	21	0.95 [0.76, 1.00]	0.91 [0.72, 0.99]
Xu 2017	42	2	0	32	1.00 [0.92, 1.00]	0.94 [0.80, 0.99]

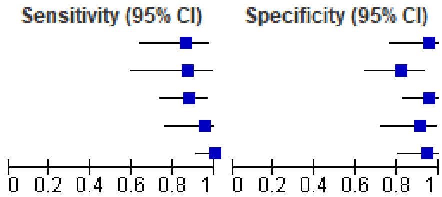
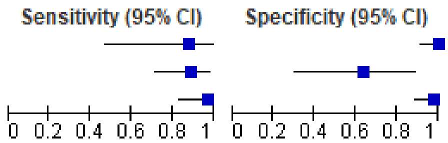


Figure 10: Centre respiratory polygraphy severe OSAHS

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Goodrich 2009	7	0	1	40	0.88 [0.47, 1.00]	1.00 [0.91, 1.00]
Polese 2013	24	4	3	7	0.89 [0.71, 0.98]	0.64 [0.31, 0.89]
Xu 2017	29	1	1	45	0.97 [0.83, 1.00]	0.98 [0.88, 1.00]



F.2 Centre respiratory polygraphy COPD-OSAHS overlap syndrome

Figure 11: Centre respiratory polygraphy all COPD-OSAHS overlap syndrome

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Jen 2020	23	4	1	5	0.96 [0.79, 1.00]	0.56 [0.21, 0.86]

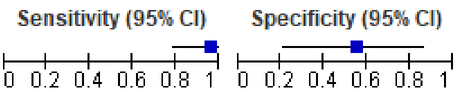


Figure 12: Centre respiratory polygraphy moderate-severe COPD-OSAHS overlap syndrome

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Jen 2020	10	2	3	18	0.77 [0.46, 0.95]	0.90 [0.68, 0.99]

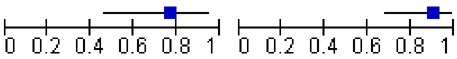
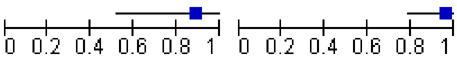


Figure 13: Centre respiratory polygraphy severe COPD-OSAHS overlap syndrome

Study	TP	FP	FN	TN	Sensitivity (95% CI)	Specificity (95% CI)
Jen 2020	8	1	1	23	0.89 [0.52, 1.00]	0.96 [0.79, 1.00]



F.3 Home RP vs Hospital PSG – Test and treat –moderate OSAHS

Figure 14: Change in EQ5D, 0.59-1 (higher is better)

	HRP			PSG				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Corral 2017	0.01	0.17	218	0.03	0.16	212	100.0%	-0.02 [-0.05, 0.01]
Total (95% CI)			**218**			**212**	**100.0%**	**-0.02 [-0.05, 0.01]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.26 (P = 0.21)

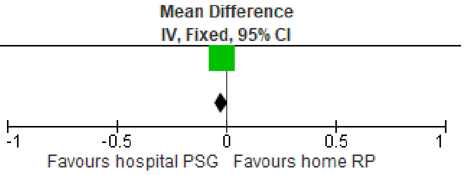


Figure 15: Change in FOSQ, 5-20 (higher is better)

	HRP			PSG				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Corral 2017	6.7	16.7	218	6.5	18.1	212	100.0%	0.20 [-3.09, 3.49]
Total (95% CI)			**218**			**212**	**100.0%**	**0.20 [-3.09, 3.49]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.12 (P = 0.91)

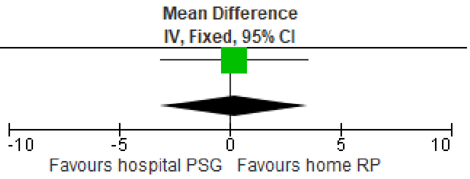


Figure 16: Change in SF36 physical component, 0-100 (higher is better)

	HRP			PSG				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Corral 2017	1.2	9.2	218	2.6	9.1	212	100.0%	-1.40 [-3.13, 0.33]
Total (95% CI)			**218**			**212**	**100.0%**	**-1.40 [-3.13, 0.33]**

Heterogeneity: Not applicable
Test for overall effect: Z = 1.59 (P = 0.11)

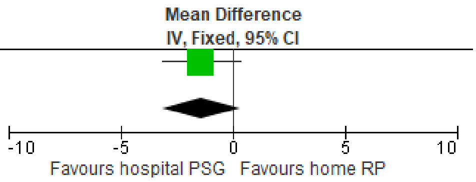


Figure 17: Change in SF36 mental component, 0-100 (higher is better)

	HRP			PSG				Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI
Corral 2017	2.5	12.2	218	1.4	11.7	212	100.0%	1.10 [-1.16, 3.36]
Total (95% CI)			**218**			**212**	**100.0%**	**1.10 [-1.16, 3.36]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.95 (P = 0.34)

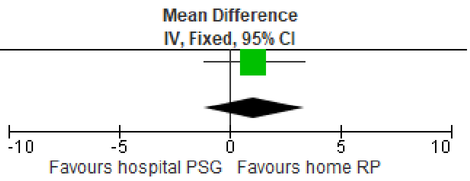


Figure 18: Change in ESS, 0-24 (lower is better)

	HRP			PSG				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Corral 2017	-4.2	5.4	218	-4.9	5.3	212	100.0%	0.70 [-0.31, 1.71]	
Total (95% CI)			**218**			**212**	**100.0%**	**0.70 [-0.31, 1.71]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 1.36 (P = 0.17)

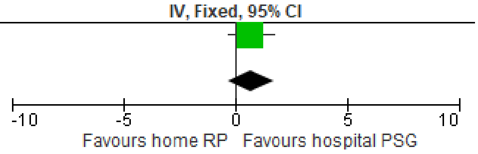


Figure 19: AHI, lower is better

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Corral 2017	1.4	1.31	100.0%	1.40 [-1.17, 3.97]	
Total (95% CI)			**100.0%**	**1.40 [-1.17, 3.97]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 1.07 (P = 0.29)

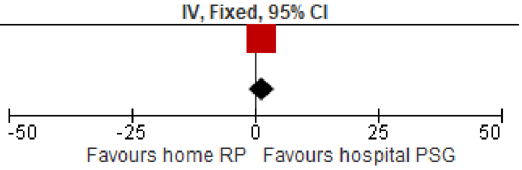


Figure 20: ODI, lower is better

Study or Subgroup	Mean Difference	SE	Weight	Mean Difference IV, Fixed, 95% CI	Mean Difference IV, Fixed, 95% CI
Corral 2017	1.4	1.08	100.0%	1.40 [-0.72, 3.52]	
Total (95% CI)			**100.0%**	**1.40 [-0.72, 3.52]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 1.30 (P = 0.19)

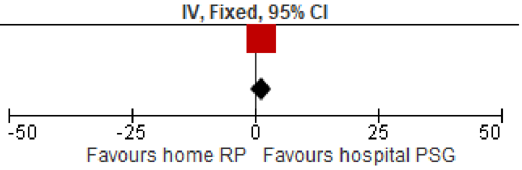


Figure 21: People given CPAP, lower is better

	HRP		PSG			Risk Ratio	Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Fixed, 95% CI	M-H, Fixed, 95% CI
Corral 2017	116	218	143	212	100.0%	0.79 [0.68, 0.92]	
Total (95% CI)		**218**		**212**	**100.0%**	**0.79 [0.68, 0.92]**	
Total events	116		143				

Heterogeneity: Not applicable
Test for overall effect: Z = 2.99 (P = 0.003)

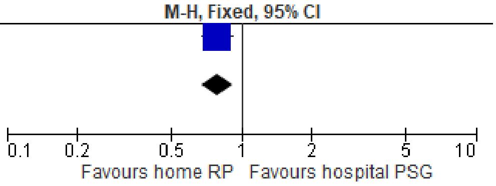


Figure 22: Change in 24hr systolic BP, Higher is worse

	HRP			PSG				Mean Difference	Mean Difference
Study or Subgroup	Mean	SD	Total	Mean	SD	Total	Weight	IV, Fixed, 95% CI	IV, Fixed, 95% CI
Corral 2017	0.4	9.9	218	0.3	11	212	100.0%	0.10 [-1.88, 2.08]	
Total (95% CI)			**218**			**212**	**100.0%**	**0.10 [-1.88, 2.08]**	

Heterogeneity: Not applicable
Test for overall effect: Z = 0.10 (P = 0.92)

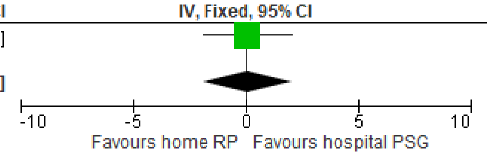
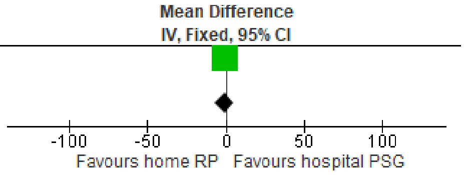


Figure 23: CV event rate, lower is better

Study or Subgroup	HRP Mean	HRP SD	HRP Total	PSG Mean	PSG SD	PSG Total	Weight	Mean Difference IV, Fixed, 95% CI
Corral 2017	6.4	30.7	218	7.3	32.7	212	100.0%	-0.90 [-6.90, 5.10]
Total (95% CI)			**218**			**212**	**100.0%**	**-0.90 [-6.90, 5.10]**

Heterogeneity: Not applicable
Test for overall effect: Z = 0.29 (P = 0.77)



sROC curves

Figure 24: Home oximetry All OSAHS (AHI ≥ 5)

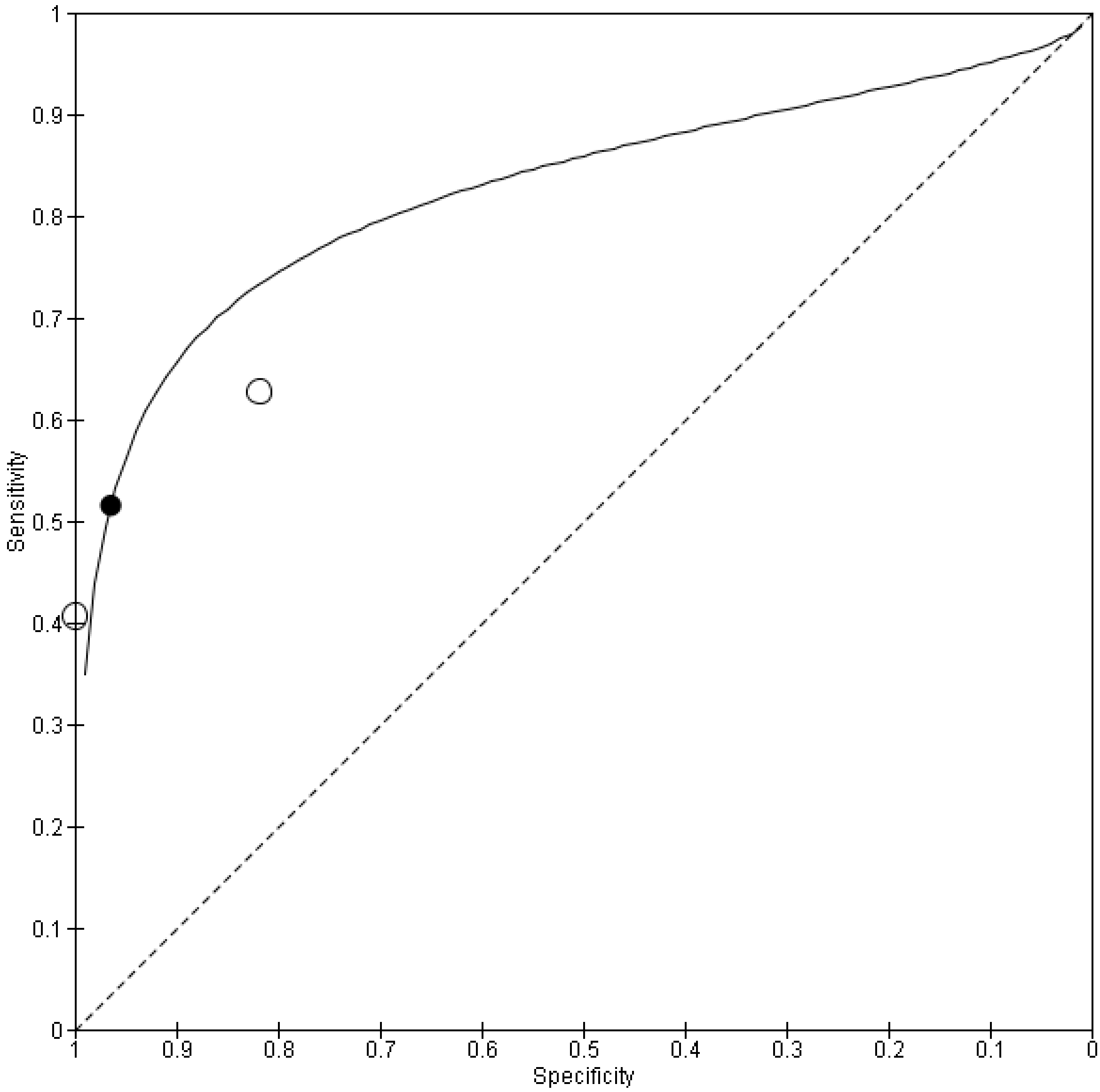


Figure 25: Home oximetry moderate-severe OSAHS (AHI ≥ 15)

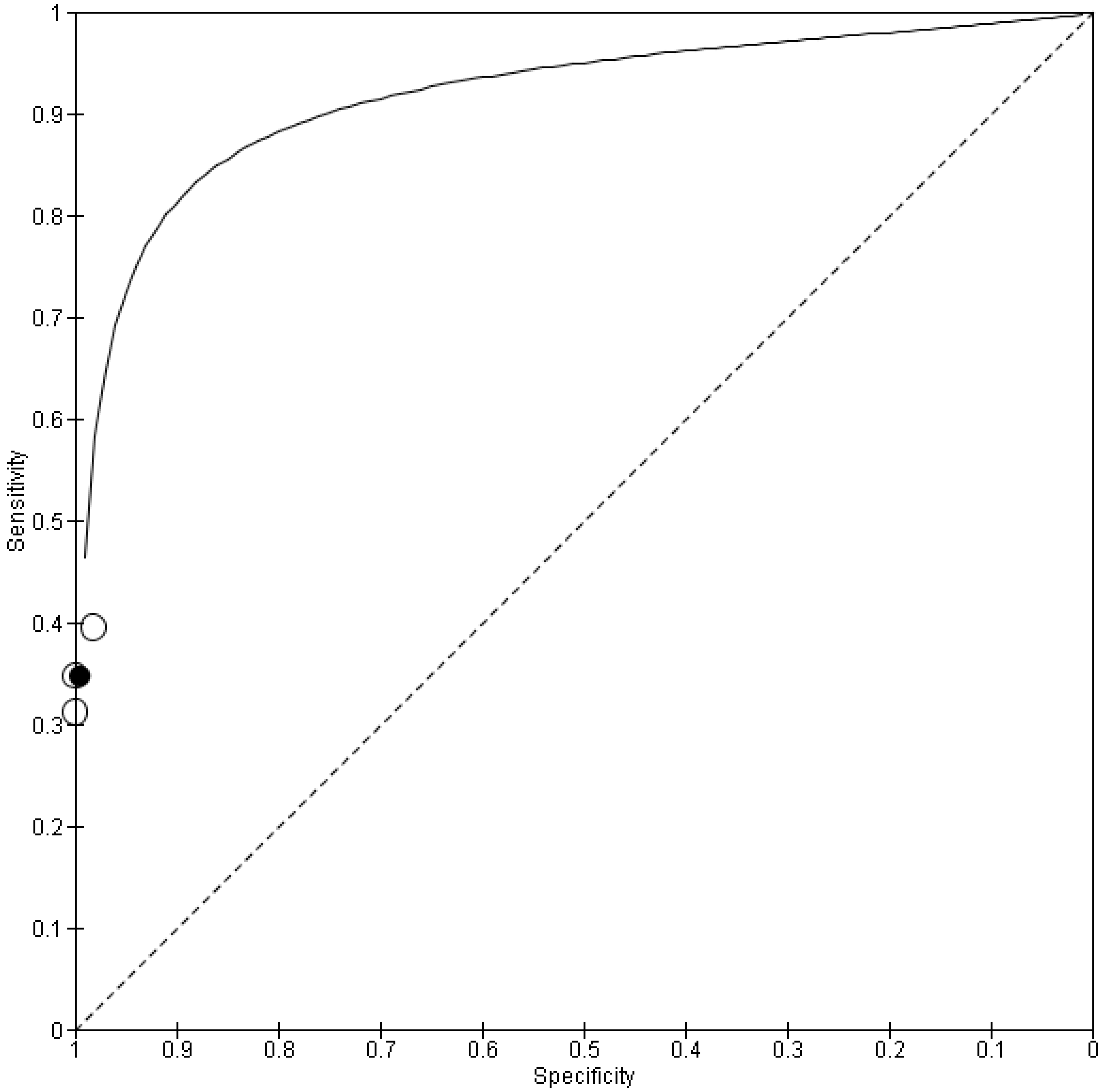


Figure 26: Home respiratory polygraphy all OSAHS (AHI ≥ 5)

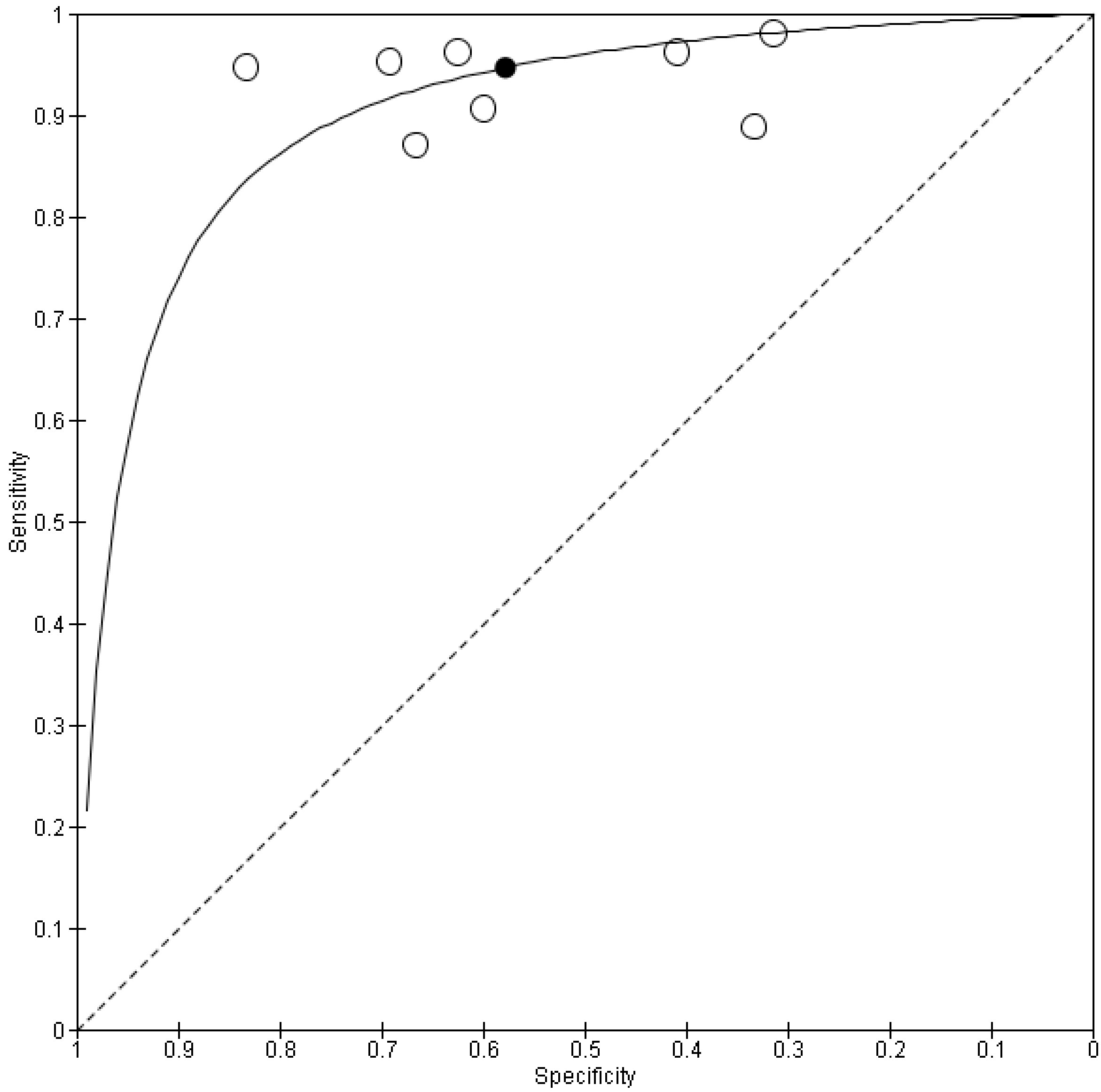

1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Sensitivity
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Specificity

Figure 27: Home respiratory polygraphy moderate-severe OSAHS (AHI ≥ 15)

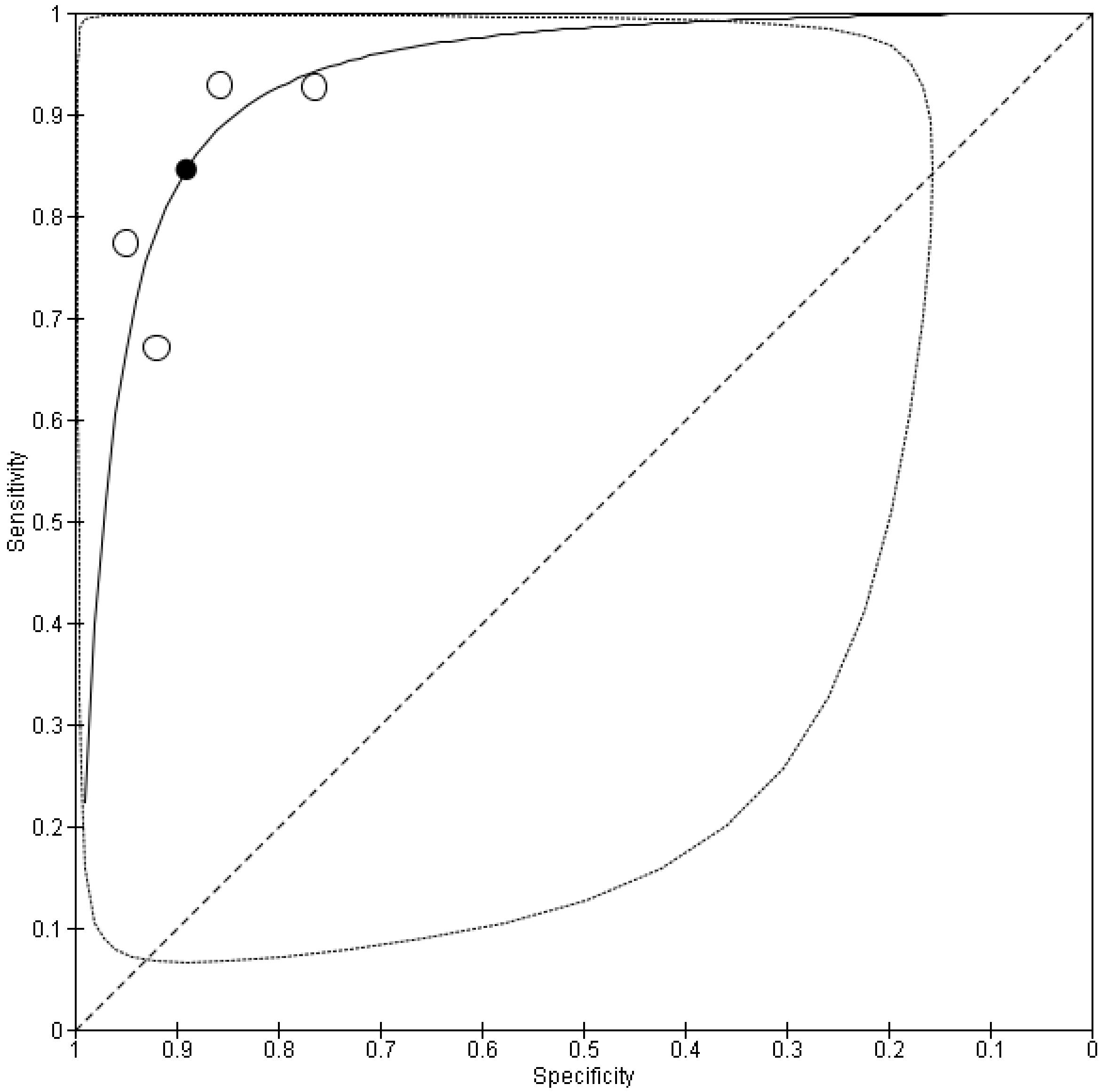


Figure 28: Home respiratory polygraphy severe OSAHS (AHI ≥ 30)

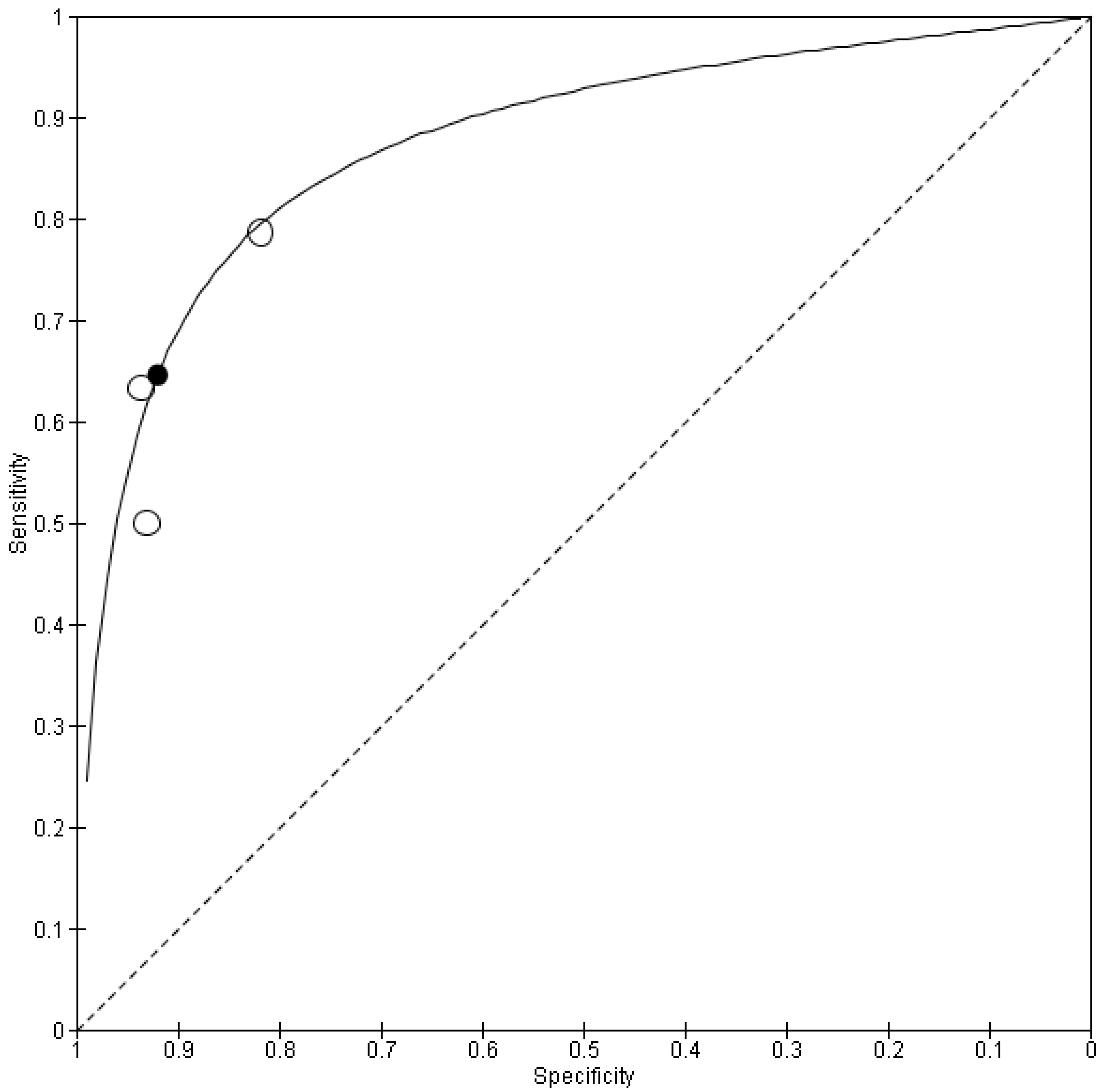


Figure 29: Centre respiratory polygraphy all OSAHS (AHI ≥ 5)

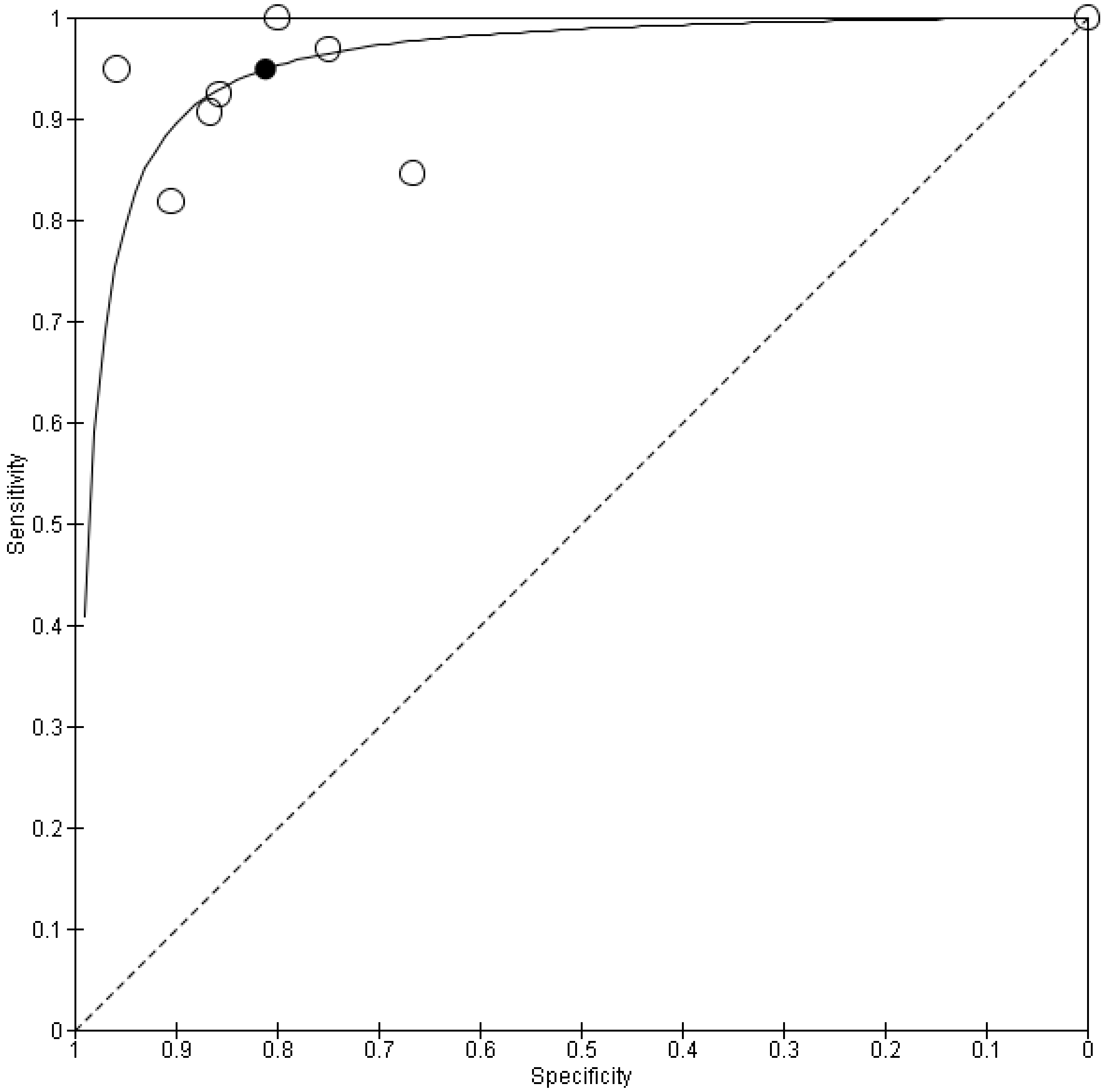


Figure 30: Centre respiratory polygraphy moderate-severe OSAHS (AHI ≥ 15)

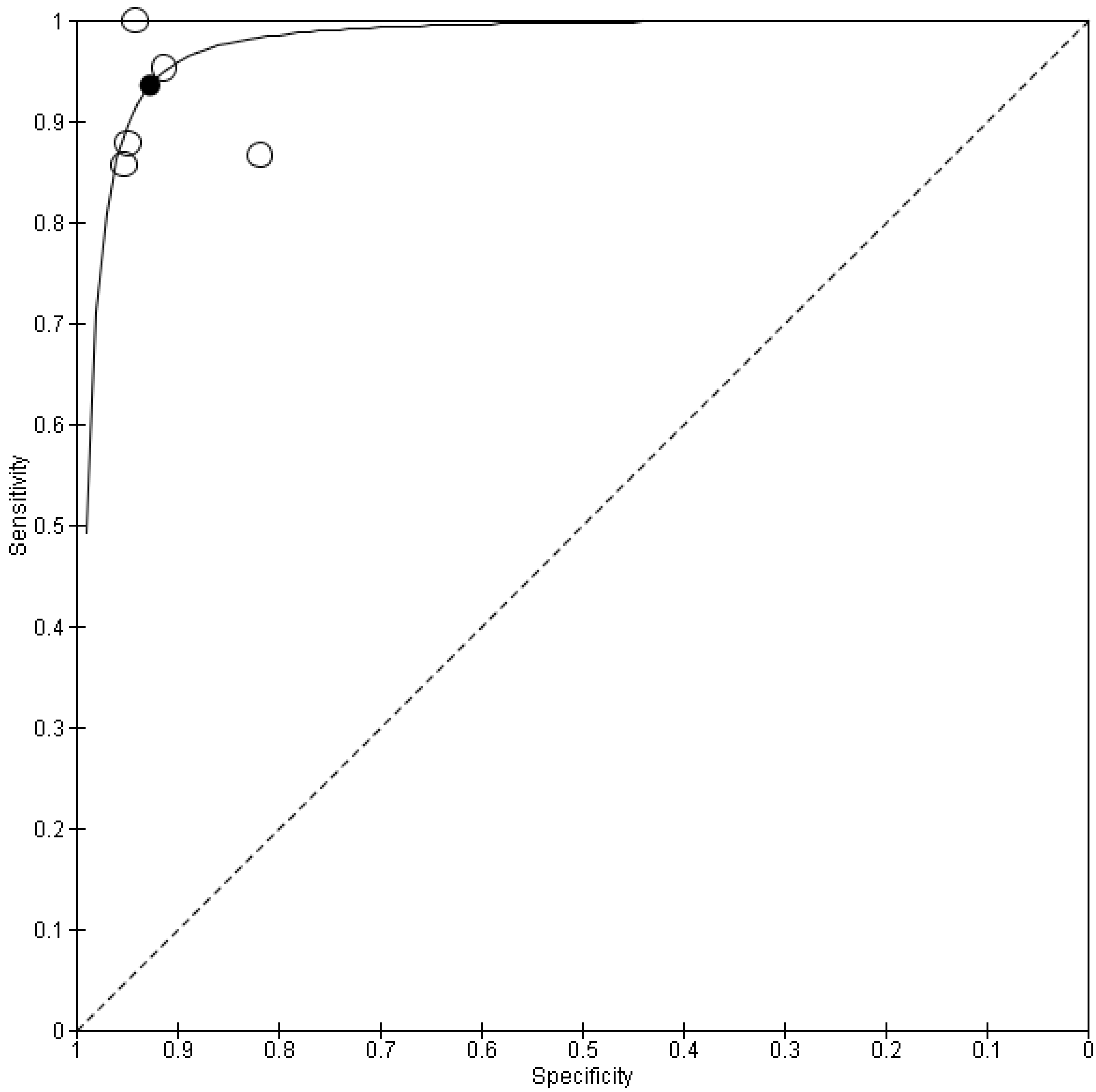


Figure 31: Centre respiratory polygraphy severe OSAHS (AHI ≥ 30)

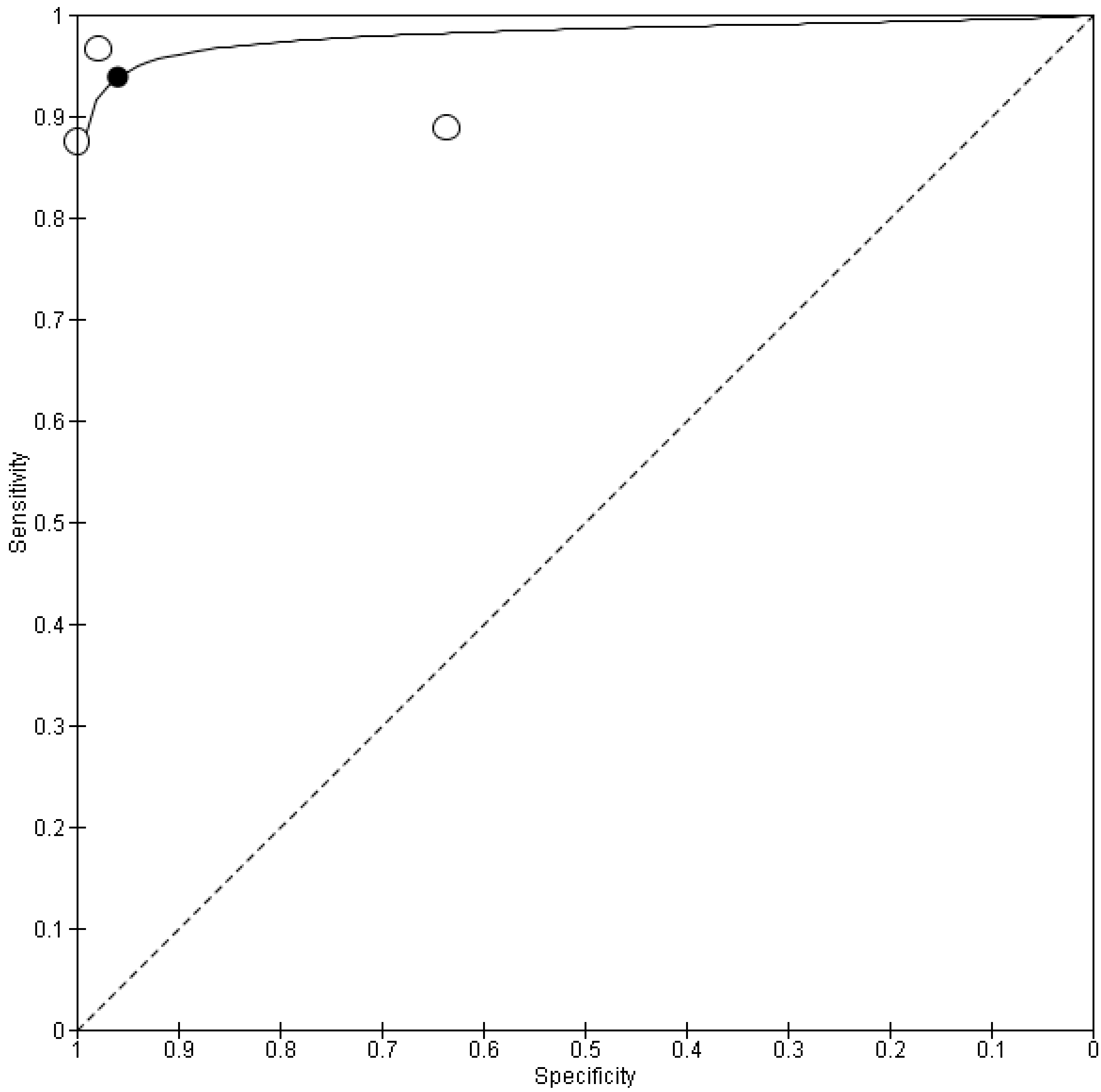


Figure 32: Centre respiratory polygraphy all COPD-OSAHS overlap syndrome (AHI ≥ 5)

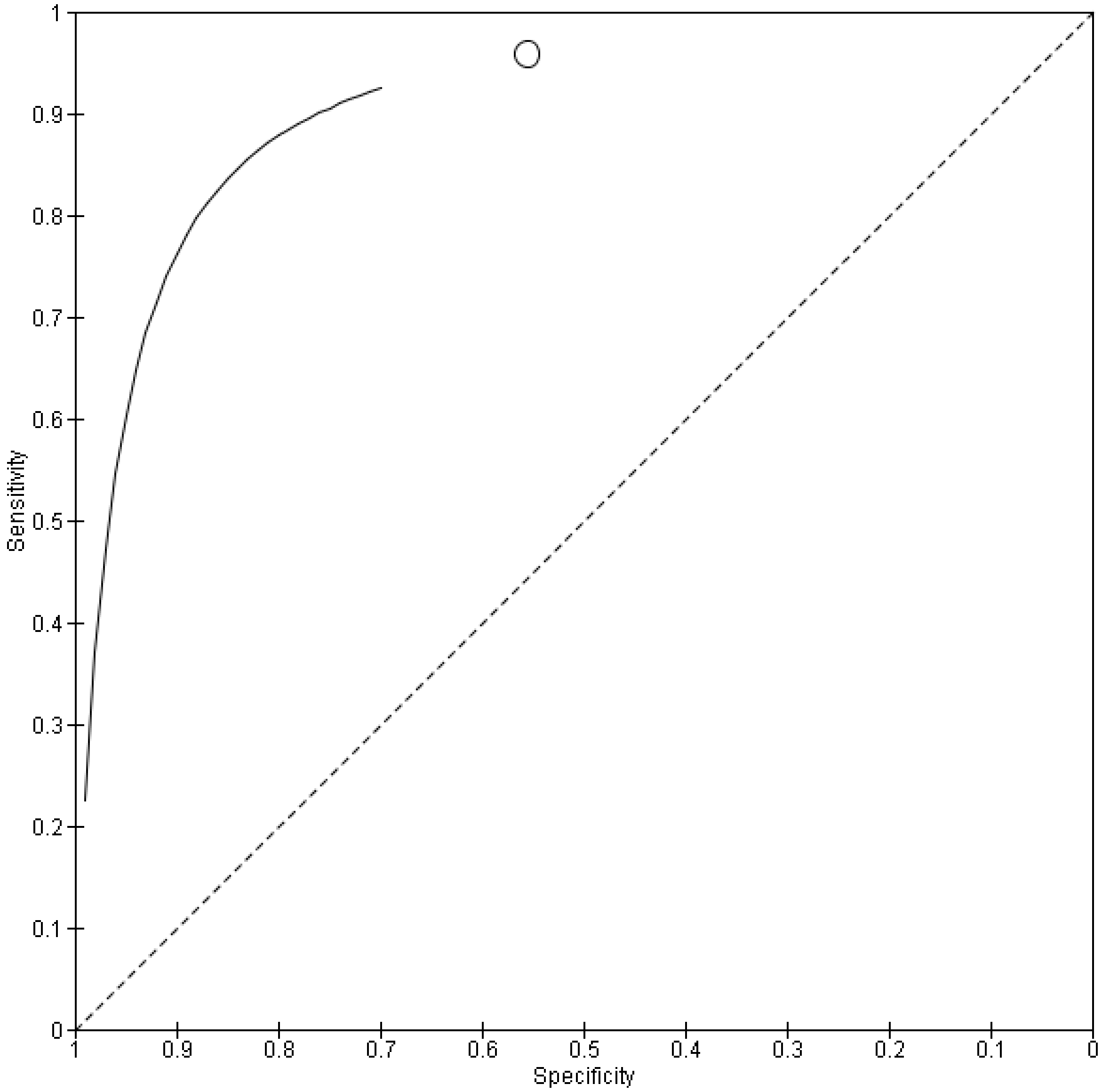


Figure 33: Centre respiratory polygraphy severe OSAHS (AHI ≥ 15)

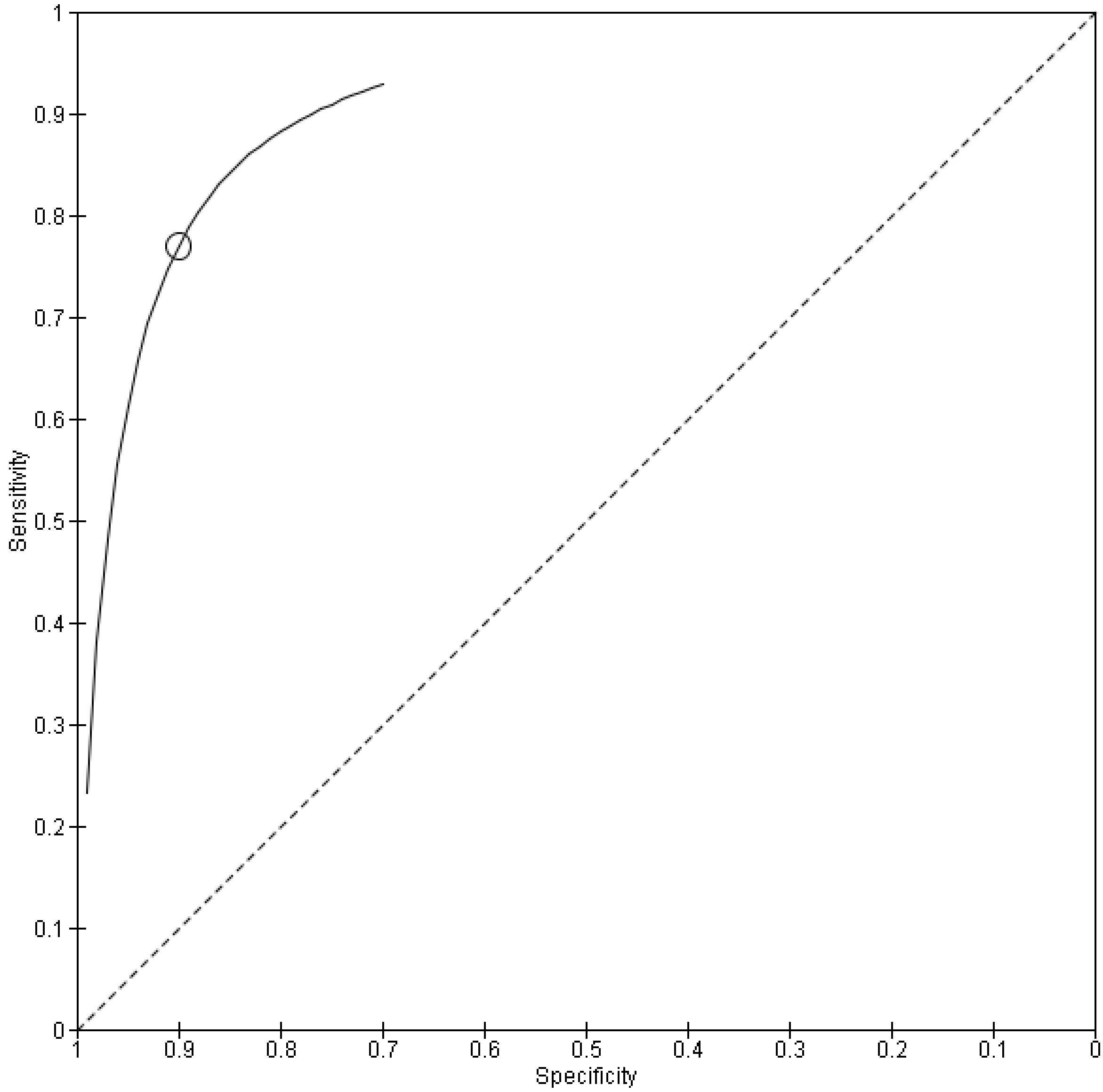
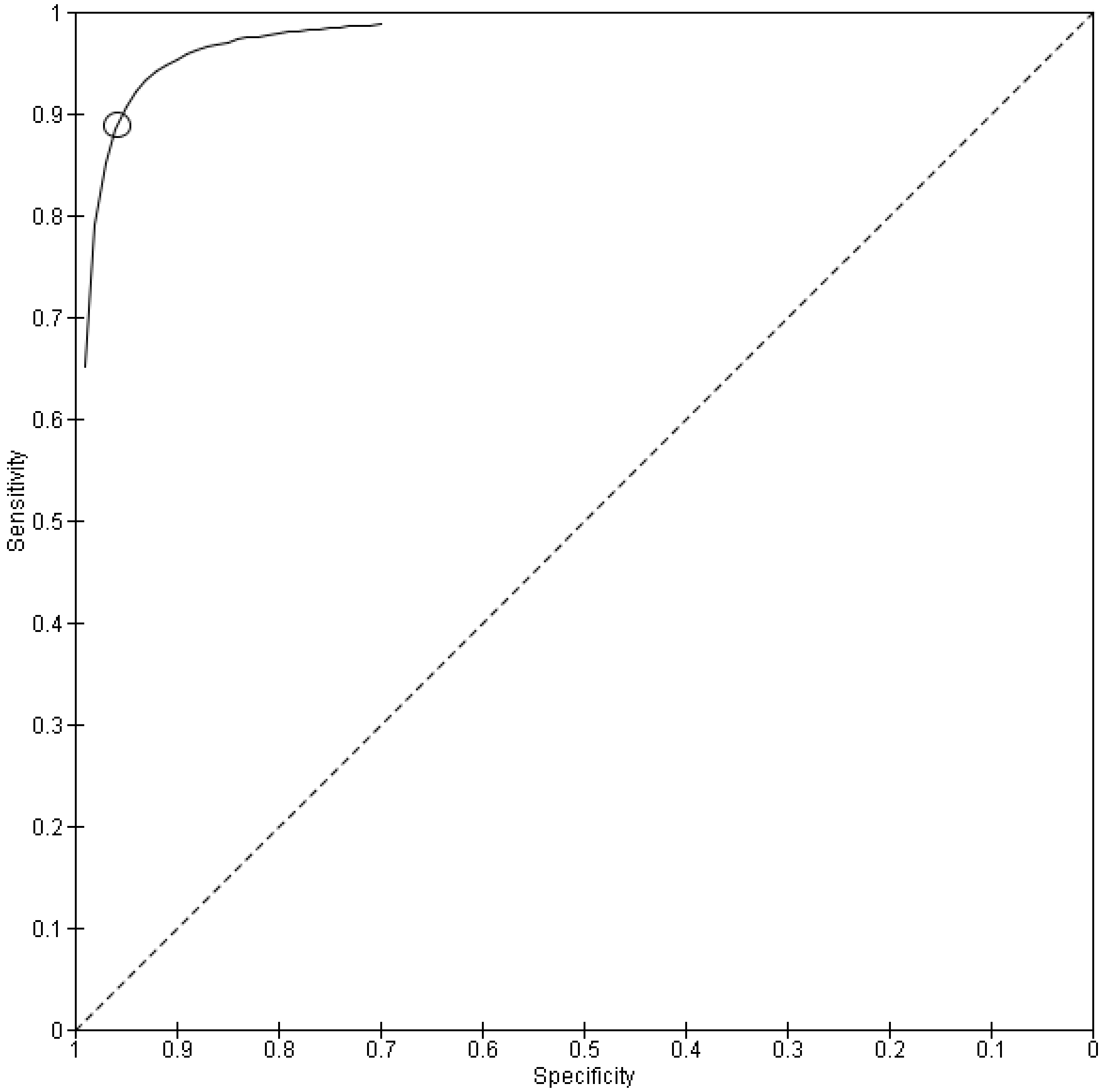


Figure 34: Centre respiratory polygraphy severe OSAHS (AHI ≥ 30)


1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Sensitivity
1
0.9
0.8
0.7
0.6
0.5
0.4
0.3
0.2
0.1
0
Specificity

Appendix G: GRADE tables

Table 25: Clinical evidence profile: Home RP compared to hospital polysomnography- moderate OSAHS (Test and treat study)

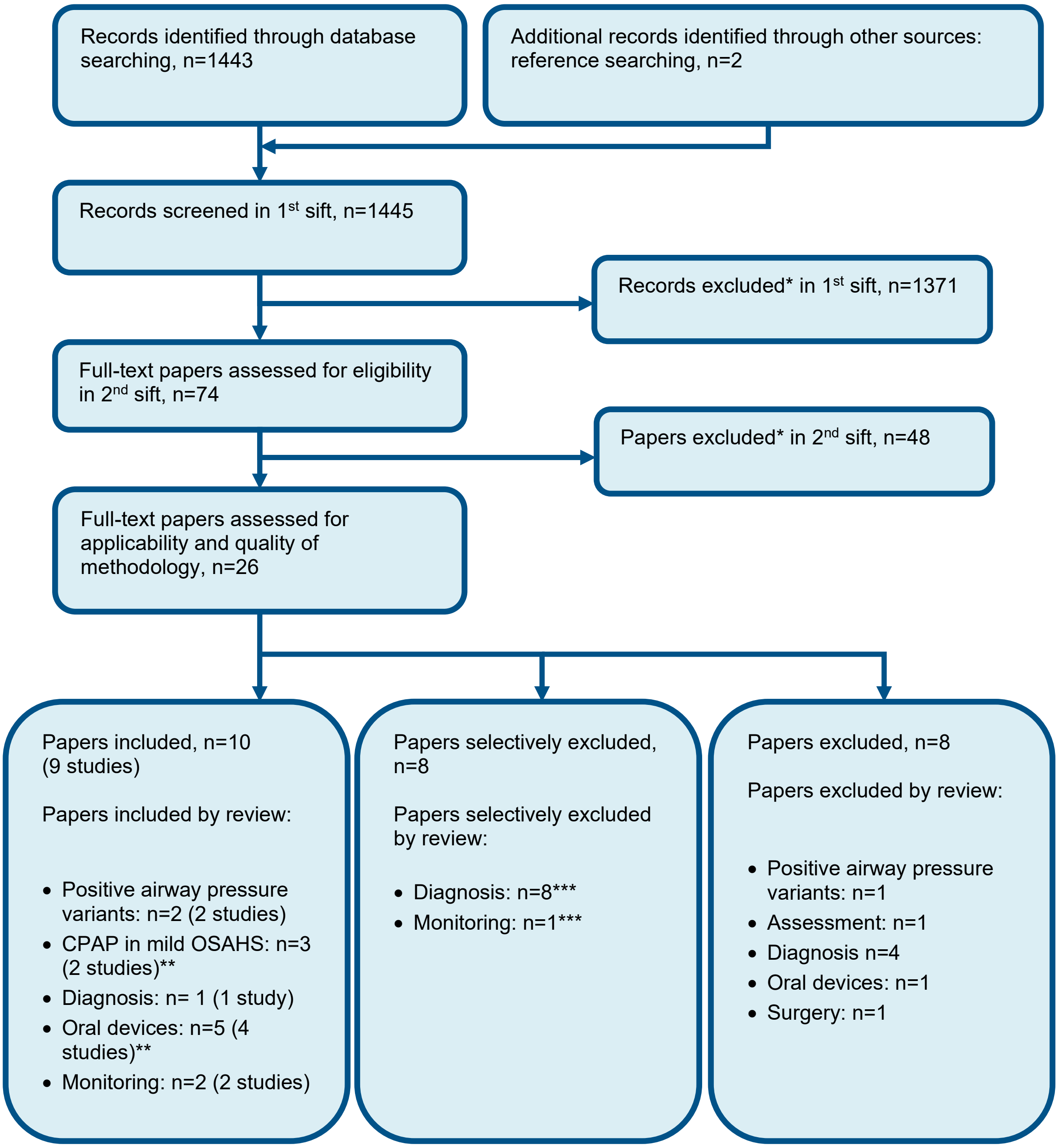
Quality assessment							No of patients		Effect		Quality	Importance
No of studies	Design	Risk of bias	Inconsistency	Indirectness	Imprecision	Other considerations	Home RP	Hospital PSG	Relative (95% CI)	Absolute		
Change in EQ5D (follow-up 6 months; measured with: EQ5D, higher is better; range of scores: 0-1; Better indicated by higher values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	None	218	212	-	MD 0.02 lower (0.05 lower to 0.01 higher)	⊕OOO VERY LOW	CRITICAL
Change in FOSQ (follow-up mean 6 months; range of scores: 5-20; Better indicated by higher values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	very serious[2]	None	218	212	-	MD 0.2 higher (3.09 lower to 3.49 higher)	⊕OOO VERY LOW	CRITICAL
Change in SF36 Physical (follow-up mean 6 months; Better indicated by higher values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	None	218	212	-	MD 1.4 lower (3.13 lower to 0.33 higher)	⊕OOO VERY LOW	CRITICAL
Change in SF36 mental (follow-up mean 6 months; Better indicated by higher values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	serious[2]	None	218	212	-	MD 1.1 higher (1.16 lower to 3.36 higher)	⊕OOO VERY LOW	CRITICAL
Change in sleepiness score (follow-up 6 months; measured with: ESS, higher is worse; range of scores: 0-24; Better indicated by lower values)												
1	randomised trials	very serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	None	218	212	-	MD 0.7 higher (0.31 lower to 1.71 higher)	⊕⊕OO LOW	IMPORTANT

AHI (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	None	218	212	-	MD 1.4 higher (1.17 lower to 3.97 higher)	⊕⊕⊕O MODERATE	IMPORTANT
ODI (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	None	218	212	-	MD 1.4 higher (0.72 lower to 3.52 higher)	⊕⊕⊕O MODERATE	IMPORTANT
People given CPAP (follow-up 6 months; Better indicated by lower values))												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	serious[2]	None	116/218 (53.2%)	67.9%	RR 0.79 (0.68 to 0.92)	143 fewer per 1000 (from 54 fewer to 217 fewer)	⊕⊕OO LOW	IMPORTANT
Change in 24hr systolic BP (follow-up 6 months; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	None	218	212	-	MD 0.1 higher (1.88 lower to 2.08 higher)	⊕⊕⊕O MODERATE	IMPORTANT
CV events (follow-up 6 months; measured with: Per 100 patients per year; Better indicated by lower values)												
1	randomised trials	serious[1]	no serious inconsistency	no serious indirectness	no serious imprecision	None	218	212	-	MD 0.9 lower (6.9 lower to 5.1 higher)	⊕⊕⊕O MODERATE	IMPORTANT

[1] Downgraded by 1 increment if the majority of the evidence was at high risk of bias, and downgraded by 2 increments if the majority of the evidence was at very high risk of bias
[2] Downgraded by 1 increment if the confidence interval crossed one MID or by 2 increments if the confidence interval crossed both MIDs. MID for machine usage (adherence)- 1 hour; MID for Systolic and Diastolic BP – 5 mm hg; Established MIDs for SF-36 physical/mental- 2/3; FOSQ- 2 ; ESS -2.5; SAQLI – 2. GRADE default MIDs (0.5XSD) used for all other continuous outcomes.

Appendix H: Health economic evidence selection

Figure 35: Flow chart of health economic study selection for the guideline



* Non-relevant population, intervention, comparison, design or setting; non-English language
** Two studies (in three papers) were included for two different questions
*** One study was considered for two different questions

Appendix I: Health economic evidence tables

Study	Corral 2017[93]			
Study details	**Population & interventions**	**Costs**	**Health outcomes**	**Cost effectiveness**
Economic analysis: Cost-utility analysis **Study design:** Within trial analysis (RCT) **Approach to analysis:** Mean costs and mean QALYs compared over the duration of the study period (6 months). **Perspective:** Spanish provider perspective[a] **Follow-up**: 6 months **Treatment effect duration:** 6 months **Discounting:** Costs = NR Outcomes = NR	**Population:** Patients between the ages of 18-70 referred for pulmonary consultations because of suspected obstructive sleep apnoea (OSA). **Cohort settings:** Median age: 50 N = 430 Drop out: 47 (10.9%) **Intervention 1: (n=201)** <u>Home Respiratory Polygraphy (HRP):</u> (1) Patients were explained by a technician in the hospital how to use the HRP (Embla-Embletta) and then took the device home with them. (2) The patients return the device the next day and the raw data is transmitted to a computer for manual scoring analysis. Those patients that had an invalid HRP test underwent repeat tests with the option to perform a polysomnography test in the hospital if the HRP test continued to be invalid. (3) Therapeutic decision making is conducted (by the same sleep physician) using the Spanish Sleep Network guidelines. CPAP treatment was recommended to patients with a respiratory event index ≥ 5 or an AHI ≥ 5.	**Total costs (mean per patient):** Intervention 1: £292 Intervention 2: £747 Incremental (2−1): £455 (95% CI: NR[b]) **Currency & cost year:** 2014 euros (presented here as 2014 UK pounds [c]) **Cost components incorporated:** HRP and PSG tests (including staff time, equipment, consumable and use of hospital sleep laboratory and repetition of tests when necessary), cost of auto-CPAP titration (including repetition if necessary), cost of CPAP, cost of PSG titration where auto CPAP repetitions were invalid.	**QALYs (mean per patient):** Incremental (2−1): 0.004 (95% CI: 0 to 0.01; p=NR)	**ICER (Intervention 2 versus Intervention 1):** £113,750 per QALY gained **Analysis of uncertainty:** A probabilistic sensitivity analysis (PSA) was conducted which reported that the estimated probability PSG was more expensive than HRP was 100% and that the probability it was more effective was 83%. Probability Intervention 2 cost effective (£20K/30K threshold): 0%/0%[d]

	(4) CPAP patients received auto-CPAP titration; if an optimal pressure was not achieved after three attempts, a polysomnographic titration was provided. **Intervention 2:** Hospital Polysomnography (PSG): (1) Patients received a PSG test and this was repeated where the test was invalid i.e. less than three hours of data was recorded (2) The same as (3) and (4) from intervention 1.			
Data sources				
Health outcomes: Health-related quality of life (EQ-5D) reported directly from patients. **Quality-of-life weights:** The EQ-5D tariff used was not stated. **Cost sources:** Resource use from within RCT; costs reported as the mean costs incurred per patient for the trial duration (2012 – 2015) by the 12 Spanish hospitals taking part in the study. HRP and PSG test costs calculated using a linear five-year depreciation of equipment. Cost of using sleep laboratory calculated using the proportional burden of using the laboratory on the general budget of the 12 hospitals.				
Comments				
Source of funding: Supported by The Spanish society of Pneumology and Thoracic Surgery also known as SEPAR. **Limitations:** The authors have not reported the mean time required to teach patients about using a HRP device neither have they explicitly stated whether this cost has been included in the analysis. The study protocol was unclear on how many invalid HRP tests would necessitate a PSG test. The study was conducted over three years (May 2012 to June 2015) however the costs incurred in each year have not been reported individually. The authors state the PSA's incremental costs were from the year 2015. However, it is unclear whether the PSA includes costs only incurred in the year 2015 or whether the costs from 2012, 2013, 2014 and 2015 have been adjusted so that all costs are now reflecting 2015 costs. There was also a lack of clarity around the health outcomes with the authors reporting a 0.02 incremental change in the EQ-5D but a substantially lower incremental change of 0.004 in QALYs. Despite these limitations, as the incremental cost difference is so large, it is highly unlikely that clarification of these limitations would result in a new ICER which is cost-effective at the £20k threshold.				
Overall applicability: Partially Applicable [(e)] **Overall quality:** Minor limitations [(f)]				

Abbreviations: AHI = apnoea hypopnoea index; CPAP= continuous positive airway pressure; 95% CI= 95% confidence interval; EQ-5D= Euroqol 5 dimensions (scale: 0.0 [death] to 1.0 [full health], negative values mean worse than death); ICER= incremental cost-effectiveness ratio; NR= not reported; QALYs= quality-adjusted life years

(a) The study also presented patient costs. All costs and ICERs were recalculated by the National Guideline Centre to report a provider perspective, in keeping with the NICE reference case.

(b) Confidence intervals can no longer be reported as the costs had to be recalculated so that only the provider perspective is reported.

(c) Converted using [2014] purchasing power parities[404]

(d) The ICER (x-axis) on the paper's cost-effectiveness acceptability curve included patient costs. However removing these costs would still result in 0%/0% probability that intervention 2 is cost-effective at £20k/£30k thresholds.

(e) Directly applicable / Partially applicable / Not applicable

(f) *Minor limitations / Potentially serious limitations / Very serious limitations*

Appendix J: Excluded studies

J.1 Excluded clinical studies

Table 26: Studies excluded from the clinical review

Reference	Exclusion Reason
Aaronson 2012[2]	Inappropriate index test – hospital oximetry, ODI recorded using polygraph Inappropriate population -stroke patients
Aaronson 2014[1]	Inappropriate index test - SAS questionnaire Inappropriate reference standard - hospital oximetry
Abad 2016[3]	Inappropriate index test – SleepWise nonintrusive video system
Abdelghani 2004[4]	Inappropriate reference standard – PSG at home or in hospital
Abdeyrim 2015[7]	No usable outcomes – no diagnostic accuracy data
Abdeyrim 2016[5]	Inappropriate study design – case control study/ no diagnostic accuracy study
Abdeyrim 2016[6]	Inappropriate index test - impulse oscillometry
Abdullah 2018[8]	Inappropriate index test - The Bahasa Malaysia version of the STOP-BANG questionnaire
Abeyratne 2005[10]	Inappropriate study design - novel feature termed the 'intra-snore-pitch-jump' (ISPJ) to diagnose OSA.
Abeyratne 2013[9]	Inappropriate index test - snore based multi-feature class OSA screening tool
Abraham 2006[11]	Inappropriate population - class III systolic heart failure patients with suspected sleep disordered breathing Inappropriate index test - cardiorespiratory testing system (ClearPath).
Abrahamyan 2018[12]	Systematic review - references checked
Abrishami 2010[13]	Systematic review - references checked
Abumuamar 2018[14]	Inappropriate index test – Stop-Bang questionnaire Inappropriate population- patients with atrial fibrillation
Acharya 2011[15]	Inappropriate index test – electrocardiogram signals
Adachi 2003[16]	Inappropriate index test – pulse rate rise

Reference	Exclusion Reason
Adams 2016[17]	Inappropriate reference standard – home unattended polysomnography
Ahmadi 2008[18]	Inappropriate index test Berlin questionnaire
Akhter 2018[19]	Inappropriate index test – snoring sound
Alakuijala 2016[20]	Inappropriate index test – snoring sound
Alchakaki 2016[21]	Inappropriate index test – snoring sound
Alhouqani 2015[22]	Inappropriate index test – Arabic version of stop bang questionnaire
Almazaydeh 2012[23]	Inappropriate index test – ECG data
Alshaer 2013[25]	Inappropriate index test – acoustic analysis of breathing sounds
Alshaer 2016[26]	Inappropriate index test - cordless acoustic portable device (BresoDx™)
Alvarez 2006[29]	Inappropriate index test – hospital oximetry
Alvarez 2006[32]	Inappropriate index test - nocturnal oximetry using Cross Approximate Entropy (Cross-ApEn).
Alvarez 2007[31]	Inappropriate index test – hospital oximetry
Alvarez 2009[30]	Inappropriate index test – hospital oximetry
Alvarez 2010[28]	Inappropriate index test – oxygen desaturation derived from PSG
Alvarez 2020[27]	Inappropriate reference standard - home polysomnography
Amra 2013[34]	Inappropriate index test - pulmonary function tests Inappropriate population – patients with sleep disordered breathing
Amra 2018[35]	Systematic review - references checked
Amra 2018[33]	Inappropriate index test - questionnaires
Andres-Blanco 2017[36]	Inappropriate index test – laboratory oximetry
Andreu 2012[37]	Inappropriate study design – RCT patients with negative tests were also followed up
Araujo 2018[38]	Inappropriate index test – Apnea link Tm single channel device
Arrazola-Cortes 2017[39]	Inappropriate study design – all patients underwent polysomnography only
Arunsurat 2016[40]	Inappropriate study design – not a diagnostic accuracy study, patients got Berlin questionnaire, no reference standard
Assefa 2016[41]	Inappropriate index test – ApneaStrip device
Aurora 2018[42]	Inappropriate population – Patients with heart failure scored for obstructive

Reference	Exclusion Reason
	and central disordered breathing (ApneaLink Plus) Inappropriate index test - The nasal pressure transducers for polysomnography and respiratory polygraphy units were connected to one nasal cannula through a three-way valve for contemporaneous nasal airflow measurement. The two recording systems were synchronized such that the both tests had equivalent total recording time
Avincsal 2017[43]	Inappropriate index test – modified Stop Bang questionnaire, using modified modified Mallampi score
Ayappa 2008[44]	Inappropriate population – patients with suspected sleep disordered breathing Inappropriate index test The ARES™ consists of the Unicorder device, a self-administered questionnaire, and off-line analysis software.
Ayas 2003[45]	Inappropriate population – patients without suspected OSA
Babaeizadeh 2011[46]	Inappropriate index test-–electrocardiogram derived respiration.Inappropriate population - sleep disordered breathing
Bagnato 2000[47]	Inappropriate index test – AutoSettm (AS) system
BaHammam 2015[48]	Inappropriate index test – Arabic version of Stop Bang questionnaire
BaHammam 2011[49]	Inappropriate index test - ApneaLink™ (AL) is a single-channel type-4 device
Ballester 2000[50]	Inappropriate population – general population
Baltzan 2000[51]	Inappropriate test not oximetry alone - OxiFlow (OF) device which combines oximetry with recording of thermistor airflow.
Banhiran 2014[52]	Inappropriate index test – home polysomnography
Banhiran 2014[53]	Inappropriate index test – Stop-Bang questionnaire
Barak-Shinar 2013[54]	Inappropriate population – Sleep disordered breathing
Barreiro 2003[55]	Inappropriate comparison – polysomnography automatic reading

Reference	Exclusion Reason
	was compared to polysomnography manual reading
Bausmer 2010[56]	No relevant outcomes – no diagnostic accuracy data
Bauters 2020[57]	Inappropriate reference standard – home polygraphy
Beattie 2013[58]	Inappropriate index test – LC system consists of pressure sensors (i.e. LCs) that are placed under the supports of a bed. The LCs detect movement on the bed as fluctuations in the forces supported by each of the bed legs.
Behar 2015[59]	Inappropriate index test – Machine learning, screening application for smartphones was analysed
Behar 2020[60]	Inappropriate index test OxyDOSA, a published machine learning model, was trained to distinguish between non-OSA and OSA individuals using the ODI computed while including versus excluding overnight desaturations overlapping with a wake period, thus mimicking portable and PSG oximetry analyses, respectively
Ben-Israel 2012[61]	Inappropriate index test - Snore sounds were recorded using a directional condenser microphone placed 1 m above the bed.
Berry 2008[62]	Inappropriate index test – RCT patients randomised to PM-APAP and polysomnography, no diagnostic accuracy data
Best 2013[63]	Inappropriate index test - Berlin questionnaire Inappropriate population – patients with treatment resistant depression
Bille 2015[64]	Inappropriate reference standard - cardiorespiratory monitoring
Bingol 2016[65]	Inappropriate index test – Stop – Bang questionnaire was used to predict OHS syndrome, polysomnography was used as a reference standard
Bohning 2011[66]	Inappropriate index test – hospital oximetry
Borsini 2015[68]	Inappropriate reference standard – respiratory polygraphy
Borsini 2019[67]	Inappropriate reference standard - respiratory polygraphy
Boynton 2013 [69]	Not a diagnostic test – Stop-Bang questionnaire
Bradley 1995[70]	–unclear what population was included

Reference	Exclusion Reason
Braganza 2020[71]	Inappropriate study design - non diagnostic accuracy study, study looked at threshold values for excluding CPAP failure
Bravata 2018[72]	Inappropriate index test - patients were randomised to enhanced intervention, standard intervention and control group.
Brown 2014[73]	Inappropriate population – patients within 45 days of stroke onset, patients with predominantly central sleep apnoea were not excluded. Inappropriate index test – ApneaLink Plus – 3 channels
Bsoul 2011[74]	Inappropriate index test - Real-time sleep apnea monitor using single-lead ECG
Cai 2013[75]	Inappropriate index test – Chinese version of ESS questionnaire
Carter 2004[77]	Inappropriate index test – LifeShirt (LS, VivoMetrics, Inc; Ventura CA)
Chai-Coetzer 2017[78]	Inappropriate comparison – RCT, patients randomised full PSG and home RP all participants including those with negative tests were followed up
Chen 2011[79]	Inappropriate index test- - Chinese ESS. Inappropriate population-sleep disordered breathing
Chiner 1999[80]	Inappropriate index test – hospital oximetry
Chiu 2017[81]	Systematic review - references checked
Christensson 2018[82]	Inappropriate reference standard- hospital polygraphy
Chu 2020[83]	Inappropriate index test - patients were randomised to high flux haemodialysis (HF-HD) followed by 2 month haemodiafiltration or vice-versa with 1 month washout via HF-HD
Chung 2007[86]	Inappropriate population – sleep disordered breathing
Chung 2008[89]	Inappropriate population – surgical patients Inappropriate index test - questionnaires
Chung 2012[84]	Inappropriate reference standard – sleep disordered breathing
Chung 2012[85]	Inappropriate index test – questionnaires Inappropriate population – preoperative patients
Chung 2013[88]	Inappropriate index test – questionnaires Inappropriate population – preoperative patients
Chung 2014[87]	Inappropriate index test – questionnaires

Reference	Exclusion Reason
	Inappropriate population – preoperative patients
Clark 2009[91]	Inappropriate reference standard – Embletta polygraphy
Cooper 1991[92]	Inappropriate index test - Biox IIA ear oximeter with the output signal connected to a Rikadenki three channel chart recorder.
Cowan 2014[94]	Inappropriate index test – questionnaires
Crowley 2013[95]	Inappropriate population – sleep disordered breathing
Damiani 2013[98]	Inappropriate index test ESS questionnaire
de Carvalho 2020[99]	Inappropriate study design - Study investigated if WatchPat reduces time to diagnosis and treatment, no diagnostic accuracy study
de Silva 2011[101]	Inappropriate index test – snoring sounds
de Vries 2015[103]	Inappropriate population– patients with heart failure. Inappropriate index test /2 channel sleep screening tool
de Vries 2018[102]	Inappropriate population – bariatric surgery patients Inappropriate study design – optimal cut off values(ODI 1.95) were compared to polysomnography
Deflandre 2017[104]	Inappropriate index test – Stop-Bang questionnaire Inappropriate population – surgical patients
Deflandre 2018[105]	Inappropriate comparison – questionnaires compared with each other
del Campo 2006[106]	Inappropriate index test – hospital oximetry
Dette 2016[108]	Inappropriate population – sleep disordered breathing
Donovan 2020[109]	inappropriate refrence standard - home polygraphy
Doshi 2015[110]	Inappropriate reference standard – portable monitoring
Douglas 1992[111]	Inappropriate index test - polysomnography
Duarte 2017[113]	Inappropriate index test – Portuguese Stop-bang questionnaire
Duarte 2020[112]	Inappropriate reference standard - home polysomnography
Dzieciolowska-Baran 2020 [114]	inappropriate study design- Book chapter. / inappropriate index test - / Data were collected using Brief ICF-Sleep Disorders and Obesity Core Set Polysomnography

Reference	Exclusion Reason
	was performed and basic characteristics of the patients were recorded.
Ebben 2016[115]	Inappropriate index test – hospital oximetry
Ehsan 2020[116]	Inappropriate index test - accuracy of combined home and hospital oximetry in infants was analysed
El Shayeb 2014[117]	Systematic review - references checked
Ellingsen 2020[118]	inappropriate study design - non diagnostic accuracy study, study looked at threshold values for excluding CPAP failure
Epstein 1998[120]	Inappropriate index test - hospital oximetry
Eris Gulbay 2014[121]	Inappropriate study design – not diagnostic accuracy study
Erman 2007[122]	Inappropriate index test- single channel ApneaLink
Ernst 2015[123]	Inappropriate population - snoring, sleep apnea, or diurnal somnolence
Esnaola 1996[124]	No relevant outcomes - selected cut-off points corresponding to the specificity closest to 0.97
Fabius 2019[125]	Inappropriate reference standard - portable monitoring
Faria 2015[126]	Inappropriate index test – Berlin and ESS questionnaires
Farney 1986[127]	Inappropriate index test – hospital oximetry
Fasbender 2019[128]	Inappropriate index test - photoplethysmography
Fawale 2016[129]	No relevant outcomes – no diagnostic accuracy data
Felfeli 2020[130]	Inappropriate index test - patients were randomised to high flux haemodialysis (HF-HD) followed by 2 month haemodiafiltration or vice-versa with 1 month washout via HF-HD
Firat 2012[131]	Inappropriate population - all heavy-vehicle driver's license applicants
Fletcher 2000[132]	Inappropriate reference standard – no polysomnography
Forni Ogna 2015[133]	Inappropriate population – hemodialysis patients
Frangopoulos 2019 [134]	inappropriate reference standard- no polysomnography
Fry 1998[135]	No relevant outcomes – no diagnostic accuracy data
Fuller 2014[136]	Inappropriate comparison – patients randomised to risk assessment only vs risk assessment+ nasal flow group
Gabryelska 2020[137]	inappropriate index test - BOAH scale

Reference	Exclusion Reason
Gagnadoux 2002[138]	Inappropriate index test – home polysomnography
Gantner 2010[139]	Inappropriate reference standard – home polysomnography
Gasa 2013[141]	Inappropriate population- bariatric patients Inappropriate study design – predictive models using anthropometric and clinical predictors were analysed
Geessinck 2018[142]	Inappropriate study design – Markov model
Gergely 2009[143]	Inappropriate index test – sleep strip
Giampa 2018[144]	Inappropriate index test – NoSAS questionnaire
Glantz 2013[146]	Inappropriate population – coronary artery disease patients No relevant outcomes – no diagnostic accuracy data
Glazer 2018[147]	Inappropriate index test - questionnaires Inappropriate population- bariatric patients
Goldstein 2018[148]	Inappropriate index test – HSAT, no diagnostic accuracy data
Golpe 1999[150]	No relevant outcomes – validity indices of oximetry parameters were calculated
Graco 2018[152]	Inappropriate population - chronic tetraplegia Inappropriate index test – tetraplegia specific questionnaire
Gros 2015[153]	Inappropriate population – Parkinson's disease Inappropriate index test – Embletta gold Natus, three channels
Grover 2008[155]	Inappropriate population – sleep disordered breathing
Grover 2018[154]	No relevant outcomes – no diagnostic accuracy data
Gu 2020[156]	Inappropriate index test - Belun ring platform, which captures oxygen saturation, photophlethysmography accelerometers signals
Gugger 1997[157]	Inappropriate index test – Resmed AutoSet
Guimaraes 2012[158]	Not in English
Gumb 2018[159]	Inappropriate population – patients recruited without regard to OSA symptoms
Gunduz 2018[160]	No relevant outcomes – no diagnostic accuracy data
Gupta 2016[161]	Inappropriate index test - Hindi Berlin questionnaire
Ha 2014[163]	Inappropriate index test – Chinese questionnaires

Reference	Exclusion Reason
Hara 2006[165]	Inappropriate index test – voice programme
Hashizaki 2014[166]	Inappropriate index test - contactless biomotion sensor
Heneghan 2008[167]	Inappropriate index test - Electrocardiogram recording
Herer 2002[168]	Inappropriate index test hospital oximetry
Hesselbacher 2012[170]	Not a diagnostic test – ESS questionnaire
Hilmisson 2019[171]	Inappropriate index test - ECG analysis
Holmedahl 2019[172]	Inappropriate index test - patients were randomised to enhanced intervention, standard intervention and control group. Not test and treat study, patients were randomised to beetroot juice containing nitrate or placebo
Hong 2018[173]	Inappropriate population – sleep disordered breathing
Horvath 2018[174]	Inappropriate reference standard – hospital polygraphy Inappropriate population – bariatric surgery patients
Hui 2017[175]	Inappropriate index test - ambulatory approach versus the hospital-based approach
Hussain 2003[176]	Inappropriate study design - patients with normal oximetry results were recruited
Iber 2004[177]	Inappropriate index test – home polysomnography
Ibrahim 2007[178]	No relevant outcomes – nodiagnostic accuracy data
Ioachimescu 2020[179]	Inappropriate study design - non diagnostic accuracy study, study analysed performance of peripheral arterial tonometry
Isaac 2017[180]	Inappropriate population – patients admitted for any medical reason
Jen 2020[181]	Inappropriate study design - no diagnostic accuracy data.wrong population COPD patients not overlap syndrome
Jobin 2007[182]	Systematic review - references checked
Kahal 2020[184]	Inappropriate comparison - respiratory poligraphy manual scoring compared to respiratory polygraphy automatic scoring
Kaminska 2010[185]	Systematic review - references checked
Karakoc 2014[186]	Inappropriate reference standard – no polysomnography
Karaloglu 2017[187]	Inappropriate comparison – polysomnography vs polysomnography

Reference	Exclusion Reason
Katzan 2016[188]	Inappropriate population – cerebrovascular patients (ischemic stroke, intracerebral haemorrhage and carotid occlusion
Khandoker 2009[189]	Inappropriate index test - short-term electrocardiogram recordings
Kicinski 2016[190]	Inappropriate population – sleep disordered breathing
Kiely 1996[191]	Inappropriate index test -ResCare Autoset
Kim 2015[192]	Inappropriate index test – Korean questionnaires
Kim 2015[193]	Inappropriate study design - economic analysis
Korvel-Hanquist 2018[194]	Inappropriate index test – Danish Stop Bang questionnaire
Kristiansen 2020[195]	Inappropriate comparison - manual respiratory polygraphy compared to automatic respiratory polygraphy
Kukwa 2020[196]	Inappropriate study design - study comparing in-laboratory PSG and HSAT using a peripheral arterial tone (PAT) technology device. No diagnostic accuracy data
Kum 2015[198]	Inappropriate index test – Turkish ESS questionnaire
Kum 2018[197]	Inappropriate index test – oximetry from polysomnography
Kuna 2011[199]	Inappropriate index test – analysis under 3 conditions 1. traditional PSG, 2. modified PSG + Lifeshirt, 3. Lifeshirt at home. Lifeshirt – 3 channels
Lachapelle 2019[200]	Inappropriate population – patients with inconclusive home study results were included in the analysis
Lado 2011[201]	Inappropriate index test – assessment of ECG databases
Lajoie 2020[202]	Inappropriate study design - aim of the study was to determine the accuracy of home oximetry to distinguish between nocturnal oximetry desaturation relapsed to COPD alone or to sleep apnoea in patients with moderate to severe COPD who have significant nocturnal hypoxemia with clinical changes in saturation. no relevant outcomes - no sensitivity or specificity data
Lam 2010[203]	Inappropriate population – patients screened from diabetes mellitus database Inappropriate relevant outcomes – no diagnostic accuracy data
Laohasiriwong 2013[204]	No relevant outcomes – no diagnostic accuracy data

Reference	Exclusion Reason
Laporta 2012[205]	Inappropriate population – Ischemic heart disease patients Inappropriate – index test, Berlin questionnaire
Laranjeira 2018[206]	Inappropriate study design – not a diagnostic accuracy study
Lauritzen 2018[207]	Inappropriate index test – Danish Berlin questionnaire
Lazaro 2020[208]	Not in English
Le 2016[209]	Inappropriate study design – not diagnostic accuracy study
Leclerc 2014[210]	No relevant outcomes - No diagnostic accuracy data
Lee 2008[211]	Inappropriate index test – multisensory manometry No relevant outcomes – no diagnostic accuracy data
Lee 2011[215]	Inappropriate population – patients with diagnosed OSA
Lee 2012[219]	Inappropriate population – patients with diagnosed OSA
Lee 2013[214]	Inappropriate study design - snoring detection method based on hidden Markov models
Lee 2015[213]	Inappropriate study design - Nasal pressure recordings for automatic snoring detection
Lee 2015[217]	Inappropriate population – patients with diagnosed OSA
Lee 2015[218]	Inappropriate population – patients with diagnosed OSA
Lee 2016[212]	Inappropriate population – patients with diagnosed OSA
Lee 2016[216]	Inappropriate population – patients with diagnosed OSA
Leitzen 2014[220]	No relevant outcomes – no diagnostic accuracy data
Lentini 2006[221]	Inappropriate index test – serum creatine phosphokinase
Leppanen 2016[222]	Inappropriate study design – study analysed RemLogic™ plug-in
Levartovsky 2016[223]	Inappropriate index test – breathing and snoring sounds recorded by polysomnography
Levendowski 2009[224]	Inappropriate population – untreated OSA patients
Levendowski 2015[226]	Inappropriate index test- neck device measuring loud snoring
Levendowski 2018[225]	No usable outcomes – no diagnostic accuracy data
Levy 1996[227]	Inappropriate index test – hospital oximetry
Li 2014[230]	Inappropriate population – confirmed OSA

Reference	Exclusion Reason
Li 2017[229]	Inappropriate index test - photoplethysmograph
Li 2018[228]	Inappropriate index test - single-lead ECG signal
Liam 1996[231]	Inappropriate index test – Edentrace II
Liang-Wen Hang 2015[164]	Inappropriate index test – hospital oximetry
Liesching 2004[232]	No diagnostic accuracy data. Inappropriate index test -SNAP technology sleep sonography
Lim 2008[234]	No index test – polysomnography data was analysed
Lim 2018[233]	Inappropriate index test – Soft palate length with velum obstruction
Lin 2009[235]	Inappropriate population – patients with diagnosed OSA
Ling 2012[236]	Inappropriate index test – hospital oximetry
Linz 2018[237]	Inappropriate index test - hospital oximetry
Lipatov 2018[238]	Inappropriate population – patients with negative polysomnography
Littner 2005[239]	Inappropriate study design – Literature review
Liu 2012[240]	No relevant outcomes – no diagnostic accuracy data
Liu 2017[241]	Inappropriate index test – support vector machine was used to predict model for severity of OSA
Lloberes 2001[243]	No relevant outcomes – no diagnostic accuracy data
Lopes 2008[244]	Inappropriate study design – not a diagnostic accuracy study
Lopez-Acevedo 2009[246]	Inappropriate study design – not a diagnostic accuracy study
Lopez-Acevedo 2009[245]	Inappropriate study design – not a diagnostic accuracy study
Lu 2017[247]	Inappropriate population – asthma patients
Lucey 2016[248]	Inappropriate index test – single channel EEG
Luo 2014[249]	Inappropriate index test – Chinese questionnaires
Luo 2014[250]	Inappropriate index test – Chinese questionnaires
Luo 2015[251]	Inappropriate index test - nomogram
Macavei 2013[252]	Inappropriate reference standard – partial pressure of carbon dioxide (pCO2)
MacGregor 2013[253]	Inappropriate index test - tracheal breath sounds
MacGregor 2014[254]	Inappropriate study design – conference proceedings
Mador 2005[255]	Inappropriate study design – not a diagnostic accuracy study

Reference	Exclusion Reason
Maeder 2015[256]	Inappropriate study design – not a diagnostic accuracy study
Maestri 2011[257]	Inappropriate study design – not a diagnostic accuracy study
Magalang 2003[258]	Inappropriate index test – hospital oximetry
Magnusdottir 2018[259]	Inappropriate index test - single-lead electrocardiogram signal
Mahakit 2012[260]	Inappropriate index test – daytime polysomnography
Maier 2006[261]	Inappropriate index test - electrocardiogram
Maier 2011[263]	Inappropriate index test - electrocardiogram
Maier 2014[262]	Inappropriate index test - electrocardiogram
Maimon 2010[264]	Inappropriate index test - snoring
Maislin 1995[265]	Inappropriate study design – not diagnostic accuracy study
Makarie Rofail 2008[266]	Inappropriate index test – nasal flow
Malbois 2010[267]	Inappropriate comparison – oximetry compared to polygraphy
Man 1995[268]	Inappropriate population - SDB
Mandal 2014[269]	Inappropriate population – sleep disordered breathing
Manoochehri 2018[270]	Inappropriate index test – models LRM and C5.0
Manoochehri 2018[271]	Inappropriate index test – support vector machine based algorithm
Manser 2001[272]	Inappropriate study design – different scoring methods analysed, not diagnostic accuracy study
Manuel 2015[273]	Inappropriate study design – not a diagnostic accuracy study
Maranate 2015[274]	Inappropriate index test – not a diagnostic accuracy study
Marcos 2007[277]	Inappropriate study design – conference proceedings
Marcos 2008[278]	Inappropriate population – patients with atrial fibrilation
Marcos 2008[281]	Inappropriate index test – not a diagnostic accuracy study
Marcos 2009[280]	not a diagnostic accuracy study
Marcos 2009[279]	not a diagnostic accuracy study
Marcos 2010[276]	not a diagnostic accuracy study
Marcos 2010[282]	not a diagnostic accuracy study
Marcos 2011[283]	not a diagnostic accuracy study
Marcos 2012[275]	not a diagnostic accuracy study
Marcos 2016[284]	not a diagnostic accuracy study
Margallo 2014[285]	Inappropriate population- patients with resistant hypertension

Reference	Exclusion Reason
	Inappropriate index test - questionnaires
Martinez 2005[292]	Inappropriate index test – hospital oximetry
Martinez 2009[291]	Inappropriate study design – not a diagnostic accuracy study
Martinez 2011[289]	Inappropriate population – sleep disordered breathing
Martinez 2012[290]	Inappropriate reference standard – home polysomnography Inappropriate population – coronary artery disease/angina complaints
Martinez-Garcia 2018[288]	Inappropriate population – patients with resistant hypertension No relevant outcomes – no diagnostic accuracy data
Martinot 2017[293]	Inappropriate index test – Mandibular position and movements
Martinot 2017[294]	Inappropriate population – sleep disordered breathing
Martins 2020[295]	no relevant outcomes -sensitivity and specificity not reported
Marti-Soler 2016[287]	Inappropriate population – sleep disordered breathing
Masa 2011[299]	patients randomised to home RP vs hospital PSG, no relevant outcomes
Masa 2013[296]	no relevant outcomes
Masa 2014 [301]	Inappropriate index test- single channel (ApneaLink; Resmed)
Masa 2011[298]	no relevant outcomes
Masa 2013[297]	no relevant outcomes
Masa 2013[300]	no relevant outcomes
Massie 2018[302]	Inappropriate index test – hospital NightOWL
Maury 2013[303]	Inappropriate index test – oximetry + nasal flow
Maury 2014[304]	Inappropriate population – sleep disordered breathing
Mayer 1998[306]	Inappropriate population – snoring or suspected OSAHS
Mayer 2019[305]	Inappropriate index test - different heart rate accelaration and pulse transit time cut-offs calculated with total sleep time, all patients underwent polysomnography
Maziere 2014[307]	Inappropriate reference standard – hospital pulse oximetry
Mazza 2017[308]	Inappropriate population – atrial fibrillation patients who received dual-chamber pacemaker No relevant outcomes – no diagnostic accuracy data

Reference	Exclusion Reason
McArdle 2000[309]	No index test – long term outcomes were assessed in people from CPAP trial
McArdle 2020[310]	inappropriate study design - non diagnostic accuracy study, study analysed performance of peripheral arterial tonometry
McCall 2009[311]	Inappropriate population – depressed patients with insomnia No usable outcomes – no diagnostic accuracy data
McCarter 2014[312]	Inappropriate index test – study analysed RSWA phasic burst durations
McIsaac 2015[313]	Inappropriate study design - accuracy of case-ascertainment algorithms for identifying patients with OSA
McMahon 2017[314]	Inappropriate index test – STOP-BANG and Berlin questionnaires Inappropriate population – Sleep disordered breathing patients
McMillan 2015[315]	Inappropriate study design – health technology assessment
Medarov 2020[316]	Inappropriate reference standard - home polysomnography vs hospinal polysomnography
Mehra 2008[317]	Inappropriate index test-– wrist actigraphy. Inappropriate population -sleep disordered breathing
Meissner 2014[318]	Inappropriate study index test – multiple system atrophy/ home RP (oximetry, nasal flow, abdominal movements) polysomnography performed after 4 weeks.
Mendelson 1994[319]	Inappropriate study design – not a diagnostic accuracy study
Mendez 2010[320]	Inappropriate index test - ECG based on empirical mode decomposition and wavelet analysis
Meng 2016[321]	Inappropriate index test - micromovement sensitive mattress
Mergen 2019[322]	No relevant outcomes - specificity was not reported
Mesquita 2012[323]	Inappropriate index test – respiratory sounds
Methipisit 2016[324]	Inappropriate index test – linguistic validation of THAI version ESS questionnaire
Meurgey 2018[325]	Inappropriate population – sleep disordered breathing in bariatric patients
Michaelson 2006[326]	Inappropriate index test – SNAP testing

Reference	Exclusion Reason
Mihaicuta 2017[327]	Inappropriate study design – not diagnostic accuracy study, patient network analysis
Miller 2018[328]	Inappropriate analysis – unclear calculations
Miller 2018[329]	Systematic review - references checked
Minic 2014[330]	Inappropriate population - Sleep disordered breathing in group 1 pulmonary arterial hypertension
Miyata 2020[331]	inappropriate index test - sheet like device called SD 102 with SPO2 monitoring
Mokhlesi 2007[332]	No index test – prevalence in OHS was measured in the population with confirmed OSA
Morales 2012[333]	Inappropriate index test – single channel ResCare AutoSet
Morales Divo 2009[334]	Inappropriate index test - ApneaGraph
Morgan 2010[335]	No index test. Inappropriate population - Effects of Sleep-disordered Breathing on Cerebrovascular Regulation
Morgenstern 2010[337]	No index test. Inappropriate population – study assessed automatic differentiation of central hypopnea
Morgenstern 2013[336]	Inappropriate index test – nasal airflow
Morillo 2009[339]	Inappropriate index test - Poincare analysis of an overnight arterial oxygen saturation
Morillo 2013[338]	Inappropriate study design - Probabilistic neural network approach for the detection
Moro 2016[340]	Inappropriate index test – economical study
Morrell 2012[341]	Inappropriate population – sleep disordered breathing
Morris 2005[342]	Inappropriate index test - acoustic rhinometry
Morris 2008[343]	Inappropriate index test – snoring severity score
Mou 2019[344]	Inappropriate index test – validation of STOP-Bang among clinically referred patients and tested alternative scoring designs on tool performance, with a focus on gender differences in OSA.
Mueller 2006[345]	Inappropriate index test - transthoracic impedance recording integrated into a Holter ECG system
Mulgrew 2007[346]	Inappropriate index test - compared standard PSG with ambulatory CPAP titration in high-risk patients identified by a diagnostic algorithm.
Munoz-Ferrer 2020[347]	Inappropriate index test - the study aimed to evaluate the degree of measurement agreement between stepwise, in laboratory attended polysomnography and a home,

Reference	Exclusion Reason
	no sleep apnea test diagnostic accuracy data
Musman 2011[348]	Economic model with no new clinical evidence
Mutlu 2020[349]	No relevant outcomes- no diagnostic accuracy data
Nagappa 2015[350]	Systematic review - references checked
Nagubadi 2016[351]	Inappropriate population – sleep disordered breathing
Nahapetian 2016[352]	No index test – prevalence in OHS was measured in the population with confirmed OSA
Nakano 2004[354]	Inappropriate index test - Tracheal Sound Analysis
Nakano 2004[356]	No index test. Inappropriate comparison – BMI compared to ODI
Nakano 2007[357]	Inappropriate index test – single channel airflow signal
Nakano 2008[353]	Inappropriate index test – snoring intensity.No diagnostic accuracy data
Nakano 2014[355]	Inappropriate index test - Somnie (1 channel)
Netzer 1999[363]	Inappropriate index test – snoring sound recorded via smartphone
Nakano 2008[358]	No appropriate index test- the study aimed to evaluate the degree of measurement agreement between stepwise, in laboratory attended polysomnography and a home, no sleep apnea test diagnostic accuracy data
Narayan 2019[359]	Inappropriate index test - smartphone-recorded sounds validated by polysomnography
Ng 2007[367]	Inappropriate reference standard – home respiratory polygraphy
Ng 2008[365]	Inappropriate index test – snore signals
Ng 2009[364]	Inappropriate index test - frequencies of snore signals
Ng 2009[366]	Inappropriate index test — snore signals
Ng 2017[371]	No appropriate index test - acoustical and perceptual impacts of changing the cross-sectional areas (CSA) of the pharynx and oral cavity on the production of snores
Ng 2019[370]	Inappropriate test - Apnea link-ox (3 channels)
Ng 2009[368]	No appropriate index test – study investigated acoustical and perceptual impacts of changing the cross sectional areas (CSA) of the pharynx and oral cavity on the production of snores
Nicholl 2012[376]	Inappropriate study design – not a diagnostic accuracy study

Reference	Exclusion Reason
Nicholl 2013[375]	Inappropriate population patients with CKD and end-stage renal disease Inappropriate reference standard –home cardiopulmonary study
Nigro 2009[377]	Inappropriate index test – hospital oximetry
Nigro 2011[384]	inappropriate test - ApneaLink (1 channel)
Nigro 2012[381]	inappropriate test - ApneaLink (1 channel)
Nigro 2012[383]	Inappropriate index test – hospital oximetry
Nigro 2015[385]	Inappropriate index test - diagnostic accuracy of autoscoring from auto-CPAP using different cut-off points
Nigro 2016[380]	Inappropriate study design – accuracy of clinical criteria to diagnose OSA and prescribe CPAP
Nigro 2011[379]	Inappropriate index test - Apnea link single channel
Nigro 2013[382]	Inappropriate test - Apnea link-ox (3 channels)
Nigro 2012[386]	Inappropriate study design- skilled observer compared to observer with no experience
Nigro 2010[387]	Inappropriate index test –ApneaLink 1 channel
Nigro 2019[378]	Inappropriate index test - pulse oximetry recorded from hospital polysomnography
Niijima 2007[388]	Inappropriate population- Not OSAHS. not diagnostic accuracy study
Nilius 2017[389]	Inappropriate study design – not diagnostic accuracy study, study assessed diagnostic agreement between PSG vs PDX
Nishiyama 2014[390]	Inappropriate index test – polysomnography recordings
Norman 2017[391]	Inappropriate comparison – Polysomnography at home vs polysomnography in hospital
Novkovic 2019[392]	no relevant outcomes - no diagnostic accuracy data
O'Brien 2007[393]	Inappropriate study design – conference paper on ECG derived respiratory signals
O'Driscoll 2013[394]	No relevant outcomes - accuracy data for determination of sleep and wake between SenseWear and PSG
Oeverland 2002[395]	Inappropriate population – Sleep disordered breathing
Oktay 2011[396]	inappropriate test - ApneaLink-ox (1 channel)
Oliveira 2012[397]	Inappropriate index test – Stardust, 3 channel portable recorder
Oliveira 2015[398]	Inappropriate index test – Stardust II 3 channel recorder

Reference	Exclusion Reason
Olson 1999[399]	Inappropriate index test – diagnostic accuracy of cumulative percentage time at SaO2 < 90% (CT90) and a saturation variability index
Onder 2012[400]	No relevant outcomes – no diagnostic accuracy data
Onen 2008[401]	Inappropriate index test - Observation-based Nocturnal Sleep Inventory
Ong 2010[402]	Inappropriate index test – simplified Stop-Bang questionnaire
Ortiz-Tudela 2014[405]	Inappropriate index test - wrist Temperature, motor Activity and body Position (TAP
Ozegowski 2007[406]	Inappropriate index test - ambulatory ECG
Ozmen 2011[407]	Inappropriate index test – sleep strip, 3 channels
Pallin 2014[408]	Inappropriate index test – SleepMinderTM biomotion sensor
Pamidi 2011[409]	No usable outcomes – no diagnostic accuracy data
Panchasara 2017[410]	Inappropriate study design – not diagnostic accuracy study
Pang 2006[411]	Inappropriate index test - SleepStrip
Pang 2007[412]	No usable outcomes – prevalence not reported
Park 2015[413]	Inappropriate index test – polysomnography automated vs polysomnography manual methods
Park 2015[414]	Inappropriate population – sleep disordered breathing
Parra 1997[415]	No usable outcomes – diagnostic accuracy presented on a ROC curve only
Passali 2011[416]	No usable outcomes – no diagnostic accuracy data
Pataka 2014[417]	Inappropriate index test - questionnaires
Pataka 2016[420]	Inappropriate analysis - unclear calculation methods used, sensitivity and specificity was calculated including symptoms however it is unclear from the paper how those symptoms were used
Pataka 2019[418]	Inappropriate index test - questionnaires
Pataka 2020[419]	Inappropriate reference standard - Embla Embletta® GOLD Portable respiratory polygraphy REI>15
Patout 2020[421]	Inappropriate index test - patients randomised to automised expiratory positive airway pressure (AVAPS-AE) or pressure support ventilation (ST)

Reference	Exclusion Reason
Peker 2018[422]	No usable outcomes - no diagnostic accuracy data
Pelletier-Fleury 2001[423]	Inappropriate index test – home polysomnography
Penacoba 2020[424]	Inappropriate study design - non diagnostic accuracy study, diagnostic agreement between primary and specialized care was measured
Peng 2018[425]	Inappropriate population – suspected sleep disordered breathing
Penzel 2002[426]	Inappropriate population - patients with obstructive sleep apnea and arterial hypertension
Penzel 2004[427]	No relevant outcomes – no diagnostic accuracy data
Penzel 2004[428]	Inappropriate study design – conference paper
Pepin 2009[429]	Inappropriate index test - ECG Holter device including a nasal pressure
Peto 2017[431]	Inappropriate index test – Brussels questionnaire
Phua 2020[432]	Inappropriate study design - Study investigated if WatchPat reduces time to diagnosis and treatment, no diagnostic accuracy study
Pichel 2006[433]	No usable outcomes – No diagnostic accuracy data
Pietzsch 2011[434]	Economic model with no new clinical evidence
Pihtili 2017[435]	Inappropriate study design – not a diagnostic accuracy study, study investigatedfrequency of predictors of OHS in obese patients
Pillar 1994[436]	No usable outcomes – diagnostic accuracy of OSA predictions made from questionnaires, clinical interviews and physical examinations
Pinna 2014[437]	Inappropriate population – sleep disordered breathing in heart failure patients
Pinto 2015[438]	Inappropriate index test – peripheral arterial tonometry
Pissulin 2018[439]	Inappropriate index test – questionnaires in overlap syndrome
Pittman 2004[440]	Inappropriate index test – home and hospital watchPAT 100
Pittman 2004[441]	Inappropriate index test - Polysomnography
Planes 2010[442]	Inappropriate comparison – automatic polysomnography scoring compared to manual scoring polysomnography at home

Reference	Exclusion Reason
Popovic 2009[444]	Inappropriate index test – ARESTM Unicorder, Advanced Brain Monitoring.no diagnostic accuracy data
Pouliot 1997[445]	No relevant outcomes
Poupard 2012[446]	Inappropriate index test- - ECG Holter monitor. inappropriate population -sleep disordered breathing
Poupard 2012[447]	Inappropriate index test – hospital oximetry
Pradhan 1996[448]	Inappropriate index test – Pittsburgh sleep quality index
Prasad 2017[449]	Inappropriate index test - questionnaires
Prikladnicki 2018[450]	Inappropriate index test - Orofacial Myofunctional Evaluation with Scores
Quaranta 2016[451]	Inappropriate reference standard - Somnea, polygraphy
Quintana-Gallego 2004[452]	Inappropriate population – sleep disordered breathing in heart failure
Rajeswari 2020[453]	Inappropriate study design - not a diagnostic accuracy study, different questionnaires were compared, no polysomnography
Randerath 2013[454]	Inappropriate index - oesophageal manometry
Rashid 2020[455]	systematic review references checked
Rathnayake 2010[456]	Inappropriate index test– single channel airflow measurement . Inappropriate population -sleep disordered breathing
Rauhala 2009[457]	Inappropriate index test - Periodic limb movement screening
Rauscher 1993[458]	Inappropriate index test – hospital oximetry
Ravelo-Garcia 2014[459]	Inappropriate index test – electrocardiogram
Raymond 2003[460]	Inappropriate index test - Combined index of heart rate variability and oximetry, hospital setting
Rebelo-Marques 2018[461]	Inappropriate index test – Portuguese version of Stop Bang questionnaire
Reda 2001[462]	Inappropriate index test - pharyngo-esophageal manometry.
Rees 1998[463]	No relevant outcomes – no diagnostic accuracy data
Reis 2015[465]	Inappropriate index test - Portuguese version of the STOP-Bang questionnaire
Reisch 2000[466]	Inappropriate comparison – forced oscillation techniques compared to three standard polysomnographic signals
Reuven 2001[467]	No relevant outcomes - economic analysis with no diagnostic accuracy data
Roche 1999[470]	Inappropriate index test - heart rate variability
Roche 2002[469]	Inappropriate index test - ECG Holter monitoring

Reference	Exclusion Reason
Roche 2002[472]	Inappropriate index test – hospital oximetry
Roche 2004[471]	Inappropriate index test - electrocardiogram Holter monitoring
Roche 2007[468]	Inappropriate index test - electrocardiogram Holter monitoring
Rodrigues Filho 2020[473]	Inappropriate index test - oximetry of all PSG performed by the LabSono
Rodsutti 2004[474]	Inappropriate study design – not diagnostic accuracy study
Rofail 2010[477]	Inappropriate index test - single channel nasal airflow
Rofail 2010[476]	Inappropriate index test - single channel nasal airflow
Rolon 2017[478]	Inappropriate reference standard – polysomnography using only oximetry signals
Romano 2011[479]	Inappropriate index test - diurnal negative expiratory pressure test
Romem 2014[480]	Inappropriate index test – hospital oximetry
Romero-Lopez 2011[481]	Inappropriate index test – Spanish language questionnaire
Rosen 2012[482]	Inappropriate index test – patients were randomised to hospital polysomnography and portable monitoring, patients with ahi>15 started CPAP therapy
Rosen 2018[483]	Inappropriate study design - literature review
Rosenthal 2008[484]	Inappropriate index test – ESS questionnaire
Rosenwein 2015[485]	Inappropriate index test - non-contact audio recordings
Ross 1998[487]	Systematic review - references checked
Ross 2000[488]	Systematic review - references checked
Ross 2000[486]	Abstract only
Rowley 2000[489]	Inappropriate index test - Global Sleep Assessment Questionnaire
Ryan 1995[490]	Inappropriate index test
Saarelainen 2003[491]	Inappropriate index test - whole-body impedance cardiography
Saha 2020[492]	Inappropriate index test - patch wearable device used to record respiratory sounds and neck position and movement
Saleh 2011[493]	Inappropriate index test - Arabic version of Berlin questionnaire
Sangkum 2017[494]	Inappropriate study design
Santaolalla Montoya 2007[495]	Inappropriate index test – clinical prediction algorithm using various epidemiological parameters

Reference	Exclusion Reason
Saricam 2020[496]	Inappropriate reference standard - Berlin questionnaire
Savage 2016[497]	Inappropriate population – sleep disordered breathing in patients with heart failure
Scarlata 2013[498]	Inappropriate index test – ESS and PSQI questionnaires
Schafer 1997[499]	Inappropriate index test – oximetry measured with a four channel MESAM 4 device
Scharf 2004[500]	Inappropriate index test – cardiac pacemaker
Senaratna 2019[501]	Systematic review - references checked
Senn 2006[502]	Inappropriate index test – patients randomised to CPAP vs polysomnography
Sergi 1998[503]	Inappropriate comparison – daytime polysomnography was compared to daytime polysomnography
Series 1991[504]	Inappropriate comparison – daytime polysomnography was compared to daytime polysomnography
Sériès 1993[506]	Inappropriate study design - interpretation was not based on the occurrence of minimal decrease in the Sa02 level or having value below fixed threshold
Series 1999[505]	Inappropriate index test – nasal pressure tracing
Serrano 2018[507]	Inappropriate study design – clinical prediction rules were analysed
Sert Kuniyoshi 2011[508]	Inappropriate population – sleep disordered breathing in patients with a recent myocardial infarction
Sforza 2007[509]	Inappropriate study design - heart-rate variability (HRV) measures on the degree of sleep fragmentation.
Shalaby 2006[510]	Inappropriate index test - The pacemaker trans-thoracic impedance signal
Shams 2012[511]	Inappropriate index test - tracheal breath sounds
Shi 2018[512]	Inappropriate study design – conference paper, algorithm analysis
Shin 2010[513]	Inappropriate study design – algorithm analysis
Shochat 2002[514]	Inappropriate index test - SleepStrip
Shokrollahi 2016[515]	Inappropriate study design – conference paper, snoring sound analysis
Siegel 2000[516]	Inappropriate index test – ultrasonic imaging
Silva 2011[517]	Inappropriate population – sleep disordered breathing

Reference	Exclusion Reason
Sivam 2018[518]	Inappropriate index test – oximetry and transcutaneous CO2 measured during polysomnography in OHS population
Skiba 2015[519]	No index test – retrospective review of Polysomnography results
Skomro 2007[520]	Inappropriate study design - retrospective study of all patients who had been offered empirical CPAP therapy for suspected OSA was conducted.
Smith 2020[521]	Inappropriate index test- 2 channel apnealink tm, oximetry and nasal flow
Sola-Soler 2007[524]	Inappropriate study design – conference paper
Sola-Soler 2012[522]	Inappropriate index test - snoring analysis
Sola-Soler 2014[523]	Inappropriate index test - tracheal breath sound analysis
Sommermeyer 2012[525]	No index test – cardiorespiratory polygraphy was used,
Song 2016[526]	Inappropriate study design - Markov model from ECG Signals
Stein 2003[527]	Inappropriate index test- Holter recordings
Stelmach-Mardas 2017[528]	Inappropriate index test – Berlin questionnaire
Stendardo 2018[529]	Inappropriate study design – not diagnostic accuracy study
Stoohs 1990[531]	Inappropriate index test – MESAM device
Stoohs 1992[532]	Inappropriate index test – MESAM device
Su 2004[534]	Inappropriate index test – SNAP digital recorder
Su 2012[533]	No usable outcomes – no diagnostic accuracy data
Subramanian 2011[535]	Inappropriate index test – NAMES assessment
Suksakorn 2014[536]	Inappropriate index test – Thai version of Berlin questionnaire in patients with sleep disordered breathing
Sun 2011[537]	Inappropriate study design – artificial intelligence method to screen OSA
Sun 2019[538]	inappropriate study design - patients completed, home portable monitoring and echocardiography
Takama 2010[539]	Inappropriate population – sleep disordered breathing in patients with cardiovascular disease
Takeda 2006[540]	Inappropriate index test – Apnomonitor III test, not oximetry alone
Tanaka 2009[541]	No usable outcomes – no diagnostic accuracy data
Tauman 2006[542]	No usable outcomes no diagnostic accuracy data

Reference	Exclusion Reason
Teferra 2014[543]	Inappropriate study design – analysis of artificial neural network sleep apnea tool for sleep studies
Teklu 2020[544]	Inappropriate study design/inappropriate comparison- no diagnostic accuracy data
Teramoto 2002[545]	Inappropriate index test – hospital oximetry
Terjung 2016[547]	Inappropriate population - mixed OSA and PLM population
Terjung 2018[546]	Inappropriate index test – VitaLog, no diagnostic accuracy data
Thong 2008[548]	No relevant outcomes – no diagnostic accuracy data
Thornton 2012[549]	No index test - previously scored polysomnography was reviewed
Tian 2005[550]	Inappropriate study design conference paper
Tiihonen 2009[551]	Inappropriate reference standard – hospital polygraphy
Ting 2014[552]	Inappropriate study design – validation of prediction system to diagnose OSA
To 2012 [553]	Inappropriate index test – ARES (apnea risk evaluation system)
To 2009[554]	Inappropriate study design – CPAP compared with portable sleep monitoring
Tong 2014[555]	Inappropriate index test - ECG derived respiration
Topor 2020[556]	Inappropriate index test - MATRx plus (ZephyrSleep Technologies) - level 3 device cosists of microphone and accelerometer
Traxdorf 2017[557]	Inappropriate index test – Erlangen questionnaire
Tsai 2003[558]	Inappropriate index test – decision rule (cricomental space, pharyngeal grade)
Tsukahara 2014[559]	Inappropriate index test – sheet type portable monitor SD-101
Ugon 2016[560]	No relevant outcomes – no diagnostic accuracy study
Ulasli 2014[561]	Inappropriate index test – Berlin and ESS questionnaires
Unal 2002[562]	Inappropriate index test – polysomnography recordings were analysed
Ustun 2016[563]	Inappropriate index test – SLIM and 7 state of the art classification methods
Valipour 2007[564]	No relevant outcomes – no diagnostic accuracy data
Van Brunt 1997[565]	Inappropriate index test – snoring sounds
Van Meerhaeghe 2004[566]	Inappropriate index test – NEP (negative pressure) procedure
Van Surell 1995[567]	Inappropriate Index test – CID 102 device

Reference	Exclusion Reason
Vana 2013[568]	Inappropriate study design – artificial neural networks for the recognition of three different patterns in the respiration signals were analysed
Varady 2002[569]	No relevant outcomes – no diagnostic accuracy data
Vaughan 2016[570]	Not in English
Vaz 2011[571]	Inappropriate index test – hospital oximetry
Vazquez 2000[572]	Inappropriate index test - hospital oximetry
Ventura 2007[573]	Inappropriate Index test – CID 102 device
Victor Marcos 2008[574]	Inappropriate index test – oxygen saturation recordings were used. The performance of two different ensemble classifiers was analysed.
Virkkula 2002[576]	No usable outcomes – no diagnostic accuracy data
Virkkula 2005[575]	No usable outcomes – no diagnostic accuracy data
Wang 2014[577]	No usable outcomes – no diagnostic accuracy data
Ward 2009[578]	Abstract only
Ward 2012[580]	Inappropriate index test - Hospital oximetry
Ward 2015[579]	Inappropriate test - ApneaLink (3 channels)
Weinreich 2008[581]	Inappropriate population – 11 patients with OSA, 10 with hypopnea, 11 with Cheyne-Strokes respiration and 5 with normal breathing
Weinreich 2014[582]	Inappropriate index test – SleepMinder
Westerlund 2014[583]	Inappropriate index test - non-contact device emits a very weak electromagnetic radiation and detects body movement by measuring the Doppler effect
White 1994[585]	Inappropriate index test - Karolinska Sleep Questionnaire
White 1995[584]	Inappropriate index test - sound recording and oxygen saturation
Whitelaw 2005[586]	Inappropriate index test - Healthdyne NightWatch (NW) System
Wieczorek 2018[587]	Inappropriate index test – PADSS (Paris Arousal Disorder Severity Scale)
Williams 1991[588]	Inappropriate index test – hospital oximetry + clinical score
Williams 2017[589]	No usable outcomes – no diagnostic accuracy data
Wong 2008[591]	Inappropriate index test – nasal flow monitor
Wu 2017[592]	Inappropriate index test – fuzzy evaluation system (NFES)
Wu 2020[593]	no relevant outcomes - no diagnostic accuracy data

Reference	Exclusion Reason
Xie 2012[594]	Inappropriate index test – ECG and Peripheral SpO2 from polysomnography
Xie 2020[595]	Inappropriate index test - Data were collected using Brief ICF-Sleep Disorders and Obesity Core Set
Xiong 2019[596]	Inappropriate index test - questionnaire
Yaddanapudi 2018[598]	Inappropriate population– stroke patients who underwent HRPO, no diagnostic accuracy. no relevant outcomes data
Yagi 2009[599]	No usable outcomes – Only sensitivity and positive predictive values presented in the paper
Yalamanchali 2013[600]	Systematic review - references checked
Yamaguchi 2007[601]	Inappropriate index test - SleepStrip
Yamashiro 1995[602]	Inappropriate population – Sleep disordered breathing
Yang 2011[603]	Inappropriate index test - plethysmography
Yang 2013[604]	Inappropriate study design – literature review
Yin 2005[606]	No relevant outcomes – no diagnostic accuracy data
Yin 2006[605]	No usable outcomes – study reported only sensitivity and positive predictive value, prevalence unclear
Yuceege 2014[608]	Inappropriate index test - neck/thyromental distance
Yousif 2020[607]	Inappropriate comparison/ inappropriate index test/inappropriate reference standard- index test HCO3 and reference standard polysomnography
Yuceege 2015[609]	Inappropriate index test – Turkish version Berlin questionnaire + gender
Yunus 2013[610]	Inappropriate index test – Malay version of Berlin questionnaire
Zaffaroni 2009[611]	Inappropriate index test – SleepMinder
Zaffaroni 2013[612]	Inappropriate index test – SleepMinder
Zamarron 1999[616]	Inappropriate index test – hospital oximetry
Zamarron 2001[615]	Inappropriate index test – hospital oximetry
Zamarron 2003[613]	Inappropriate index test – hospital oximetry
Zamarron 2006[614]	Inappropriate index test – hospital oximetry
Zarei 2018[617]	Inappropriate index test - Single-Lead ECG Signal.
Zhang 2011[618]	Inappropriate population– sleep disordered breathing.no diagnostic accuracy data no relevant outcomes
Zhang 2018[619]	Not in English
Zhou 2020[620]	Inappropriate index test - questionnaire
Zhu 2020[621]	Inappropriate index test - patch wearable device used to record respiratory sounds and neck position and movement

Reference	Exclusion Reason
Zou 2013[622]	Inappropriate index test – ESS questionnaire (cut off 9)
Zou 2015[623]	Inappropriate index test - The SleepView device is a 2-channel diagnostic tool designed for screening of sleep-disordered breathing
Zucconi 1996[624]	Inappropriate index test - unattended recording device (MicroDigitrapper-S) (M-S).
Zywietz 2004[625]	Inappropriate index test - single channel ECG

J.2 Excluded health economic studies

Published health economic studies that met the inclusion criteria (relevant population, comparators, economic study design, published 2003 or later and not from non-OECD country or USA) but that were excluded following appraisal of applicability and methodological quality are listed below:

Table 27: Studies excluded from the health economic review

Reference	Reason for exclusion
Alonso Alvarez 2008[24]	This study was assessed as partially applicable with potentially serious limitations. However, the committee judged that other available evidence by Corral 2017[93] was of greater methodological quality as it considered downstream health and cost consequences following the diagnostic test.
Andreu 2012[37]	This study was assessed as partially applicable with potentially serious limitations. However, as QALYs cannot be calculated, the committee judged that other available evidence by Corral 2017[93] was of greater methodological quality.
Hernandez-Bendezu 2018[169]	This study was assessed as having very serious limitations. The study did not use randomised evidence. Furthermore it did not calculate health outcomes and was conducted from a Mexican perspective.
Hui 2017[175]	This study was assessed as partially applicable with potentially serious limitations. However, the committee judged that other available evidence by Corral 2017[93] was of greater applicability, since this study did not calculate QALYs and the setting was Hong Kong.
Jurado Gamez 2007[183]	This study was assessed as not applicable because the costs used in the analysis were from sources before 2003.
Masa 2011[298]	This study was assessed as partially applicable with potentially serious limitations. However, the committee judged that other available evidence by Corral 2017[93] was of greater methodological quality as it considered downstream health and cost consequences following the diagnostic test.
Masa 2013[297]	This study was assessed as partially applicable with potentially serious limitations. However, the committee judged that other available evidence by Corral 2017[93] was of greater methodological quality as it considered downstream health and cost consequences following the diagnostic test.

Reference	Reason for exclusion
Masa 2013[300]	This study was assessed as partially applicable with potentially serious limitations. However, the committee judged that other available evidence by Corral 2017[93] was of greater methodological quality as it considered downstream health and cost consequences following the diagnostic test.
Masa 2014[301]	This study was assessed as partially applicable with potentially serious limitations. However, the committee judged that other available evidence by Corral 2017[93] was of greater methodological quality as it considered downstream health and cost consequences following the diagnostic test.
Ontario Ministry of Health and Long-Term Care 2006[403]	This study was assessed as partially applicable with very serious limitations because the authors have not indicated where data for costs or outcomes have been sourced.
Phua 2020[432]	This study was assessed as partially applicable with potentially serious limitations. However, the committee judged that other available evidence by Corral 2017[93] was of greater methodological quality as it considered downstream health and cost consequences following the diagnostic test.
Steward 2017[530]	This study was assessed as partially applicable with very serious limitations because the inclusion criteria (risk of OSAHS) for separate arms of the trials are not consistent.