Technoleg Iechyd Cymru
Health Technology Wales

Evidence Appraisal Report [1]

Wearable and bed-based technologies to detect tonic-clonic seizures in people with epilepsy

Appraisal summary

Why did Health Technology Wales (HTW) appraise this topic?

Epilepsy is a common chronic neurological condition affecting people of all ages. Tonic–clonic seizures, whether generalised from onset or evolving from focal seizures, pose major risks, including serious injury, and are the strongest predictor of sudden unexpected death in epilepsy (Beniczky et al. 2021). A tonic–clonic seizure typically begins with a tonic phase (loss of consciousness and generalised muscle stiffening), followed by a clonic phase of rhythmic jerking of the limbs (Epilepsy Action 2026b). Many people with tonic–clonic seizures experience significant harm each year, and reliable real-time detection is needed, but no gold-standard method currently exists to detect seizures outside of the hospital setting (Komal et al. 2024).

Out of hospital, most people rely on informal monitoring of seizure activity, such as caregiver supervision or baby monitors, which are often unreliable. Commercial seizure-detection devices are widely available but are mostly unregulated as medical devices, leaving people with epilepsy and their families to choose and fund devices themselves.

Non-invasive tonic-clonic seizure-detection technologies use physiological sensors, such as accelerometry (ACM, acceleration of the body); electromyography (EMG, muscle activity); electrocardiography (ECG, heart's electrical activity); electrodermal activity (EDA, skin moisture); photoplethysmography (PPG, light sensor measuring the pulse); or piezoelectric motion detection (pressure sensor that detects tiny vibrations), to identify seizure-related changes and alert caregivers in real-time, sometimes with location information. These devices can be wearable (for example, wrist or armband sensors) or positioned near the body (for example, under-mattress sensors) and may use single-sensor (unimodal) or multi-sensor (multimodal) systems.

Clinical guidelines emphasise that detecting tonic–clonic seizures is a priority for reducing seizure-related harm and mortality (Beniczky et al. 2021). The need for improved real-time detection in the home, particularly in unattended patients during night-time hours, was highlighted by a consultant neurologist who proposed this topic for review.

[1] Cyfieithu dogfennau HTW wedi'u cyhoeddi o'r Saesneg i'r Gymraeg
Translation of published technical HTW documents from English into Welsh

What evidence did HTW find?

We searched for evidence that could be used to answer the review question: What is the clinical and cost effectiveness of wearable or bed-based technologies for the detection of tonic-clonic seizures in people with epilepsy?

We identified eight seizure-detection devices with evidence of regulatory approval for use as a medical device in the UK. Some of these devices were included in twelve observational, mainly single-arm, studies (Arends et al. 2018, Beniczky et al. 2013, Carlson et al. 2009, Fulton et al. 2013, Hadady et al. 2023, Lazeron et al. 2022, Meritam et al. 2018, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2021, Onorati et al. 2017, van Westrhenen et al. 2023) in two systematic reviews by Komal et al. (2024) and Meritam Larsen & Beniczky (2023). These studies included 758 adults and children with 3,256 predominantly tonic-clonic seizures. An additional single-arm observational study published since these systematic reviews was also included (Jahani et al. 2026).

Reported sensitivities of the ACM-based unimodal and multimodal wristbands and armbands were similar between studies (79% to 100%). There was wide variation in the false-alarm rate of the ACM-based unimodal and multimodal devices, but most evidence for these devices estimated a false-alarm rate of less than 0.03 per hour. Estimates of the positive predictive value suggest that around half of the alarms from the multimodal armbands and wristbands are true seizures. Under-mattress devices showed the greatest variation in performance: older movement-only systems performed poorly with frequent false alarms, whereas newer under-mattress piezoelectric motion-detection sensors performed much better, reaching up to 89% sensitivity with low false-alarm rates (less than 0.02 false alarms per hour). In general, there is a trade-off between sensitivity and the false-positive rate, with false alarms increasing with increasing sensitivity.

Most of the studies focused on technical-performance metrics (sensitivity and false-alarm rate). Limited evidence was identified for patient-centred outcomes, and the real-world accuracy and long-term effectiveness of the devices is uncertain. No evidence was identified for the effect of epilepsy alarms on seizure-related mortality.

Two caregiver-reported studies found that home-use of ACM wristwatches, and multimodal ACM and PPG armbands reduced seizure-related injuries by roughly 25% to 40%, mainly because alerts enabled timely caregiver intervention (Hadady et al. 2023, Meritam et al. 2018). One study found that an under-mattress seizure-detection device increased nursing intervention during convulsive seizures (Nouboue et al. 2023).

A multimodal ACM + PPG seizure-detection armband statistically significantly reduced caregiver stress over two months of their child wearing the device, but caregiver stress levels still remained high throughout (van Westrhenen et al. 2023). The device did not improve caregivers' overall quality of life or sleep quality (van Westrhenen et al. 2023). Most quality-of-life data were for caregivers, with a small number of patients completing a non-validated quality-of-life questionnaire in one study.

Questionnaires, usually completed by caregivers, assessed usability of the devices (Arends et al. 2018, Beniczky et al. 2013, Meritam et al. 2018). ACM devices often produced false alarms during routine movements, and approximately 10% stopped using them due to issues such as perceived high false-alarm rates or difficulty operating the device. Multimodal armbands were viewed as being user-friendly amongst adults with additional learning needs. Wearability problems, mainly mild skin irritation or tightness, were uncommon and typically resolved with strap or sensor adjustments (Arends et al. 2018, Beniczky et al. 2013, Meritam et al. 2018). One study also found that ACM wristwatches helped improve seizure-logging for around half of users (Meritam et al. 2018).

One study was identified that assessed the cost-effectiveness of wearable technologies for the detection of tonic-clonic seizures in people with epilepsy. The analysis was conducted on data from the PROMISE trial, which evaluated the use of Nightwatch in children living at home. Base case results demonstrated that Nightwatch was cost-effective, but the analysis was associated with potentially serious limitations, being limited mostly by the study design of the PROMISE trial. It was deemed that there was an insufficient evidence base to develop an economic model to evaluate the cost-effectiveness of wearable or bed-based technologies from the Welsh perspective. Costs from commercial websites and calculations from the National Schedule of Reference Costs suggest that wearable and bed-based technologies are a cheaper alternative to video-electroencephalography (video-EEG) to detect tonic-clonic seizures, but they may detect fewer seizures.

Experts contacted by HTW, and a Focus Group conducted by HTW and Epilepsy Action, reported that many people with epilepsy value these devices despite limited evidence of effectiveness. This appears to be due to the increased sense of security for those living alone with epilepsy, the potential for a reduction in caregiver concern and stress, and the potential for a reduction in seizure-related injuries.

What was the outcome of HTW's appraisal?

HTW is a national body working to improve quality of care in Wales. We collaborate with partners across health, social care, and industry to issue independent guidance that informs commissioning within Wales health and social care. We are supported by an Assessment Group, who ensure our work adheres to high standards of methodological and scientific rigour, and an Appraisal Panel, who consider evidence within the Welsh context and produce HTW guidance. More details on our appraisal process, the assessment group, and the appraisal panel can be found on the HTW website.

In this case, the HTW Assessment Group considered the evidence presented in this Evidence Appraisal Report (EAR076) and concluded there was sufficient evidence for the development of guidance. Please refer to the HTW website for full guidance details.

Evidence Appraisal Report 076 follows below and provides full details for this topic. More comprehensive details of the HTW Guidance and HTW Appraisal Panel considerations can be found on the HTW website.

1. Purpose of the Evidence Appraisal Report

This report aims to identify and summarise evidence that addresses the following question: What is the clinical and cost effectiveness of wearable or bed-based technologies for the detection of tonic-clonic seizures in people with epilepsy?

Evidence Appraisal Reports are based on rapid systematic literature searches, with the aim of identifying the best published evidence on the effectiveness and cost-effectiveness of health and social care technologies and models of care and support. Researchers critically evaluate this evidence. The draft Evidence Appraisal Report is reviewed by experts and by Health Technology Wales multidisciplinary advisory groups before publication.

2. Context

Epilepsy is a chronic non-communicable disease of the brain that affects people of all ages (WHO 2024). Epilepsy is defined by any of the following conditions:

- At least two unprovoked (or reflex) seizures occurring more than 24 hours apart.
- One unprovoked (or reflex) seizure and a probability of further seizures similar to the general recurrence risk (at least 60%) after two unprovoked seizures, occurring over the next 10 years.
- Diagnosis of an epilepsy syndrome (Fisher et al. 2014).

Epilepsy is one of the most common neurological diseases worldwide (WHO 2024). Approximately one-third of people with epilepsy are not seizure-free, despite adequate treatment (Beniczky et al. 2021). In Wales, approximately 1-in-94 people have epilepsy (Epilepsy Wales), equating to approximately 35,500 people. This is a higher prevalence than in England or Scotland (Epilepsy Action Cymru 2025).

Seizure episodes are a result of excessive electrical discharges in a group of brain cells (WHO 2024). Different parts of the brain can be the site of such discharges (WHO 2024). A tonic-clonic seizure is a type of epileptic seizure that typically begins with a tonic phase, involving loss of consciousness and generalised muscle stiffening, followed by a clonic phase of rhythmic jerking of the limbs (Epilepsy Action 2026b). These seizures may be generalised from onset (generalised tonic-clonic seizures, GTCS), meaning they affect both sides of the brain from the start, or may arise as focal seizures in one side of the brain and spread bilaterally (focal-to-bilateral tonic-clonic seizures, FBTCS) (Epilepsy Action 2026b).

Experts contacted by HTW stated that the prevalence of GTCS depends on the type and cause of epilepsy. In people with generalised epilepsy, prevalence has been estimated at 86% (Asadi-Pooya & Homayoun 2020), and at approximately 79% in people with a focal epilepsy (Schmidt et al. 1983).

Experts estimated that approximately 13,000 to 29,200 people in Wales have GTCS. However, they acknowledged that estimating the number of people with uncontrolled GTCS is challenging. GTCS may occur in isolation in response to risk factors such as stress, alcohol or drug use, but such cases would not typically require continuous monitoring with a seizure-detection device. One expert estimated that approximately 4,700 to 5,300 people in Wales have uncontrolled GTCS.

People experiencing tonic-clonic seizures are not able to call for help during seizures, and the unpredictability of seizure occurrence is distressing for patients and caregivers (Beniczky et al. 2021). These people often lack efficient and effective monitoring (Komal et al. 2024). GTCS, including FBTCS, is the primary risk factor for sudden unexpected death in epilepsy (SUDEP), particularly in unattended patients during night-time hours (Beniczky et al. 2021). The risk of

premature death in people with epilepsy is up to three times higher than for the general population (WHO 2024). Experts contacted by HTW stated that the risk of SUDEP in epilepsy is around one in 1,000 per year, increasing to 1 in 100 per year to those with uncontrolled GTCS. Each year, 25% of people with GTCS experience at least one serious injury related to the GTCS, causing disability or requiring hospitalisation or surgical intervention (Beniczky et al. 2021).

Approximately half of the people with epilepsy have coexisting physical or psychiatric conditions (WHO 2019). People with epilepsy are significantly more likely to experience mental health challenges, with rates of depression and anxiety higher than in the general population (Epilepsy Action Cymru 2025). Intellectual disability is the most common comorbidity in children with epilepsy (30% to 40%) (WHO 2019). Epilepsy is also commonly associated with neurodegenerative diseases (WHO 2019).

3. Health technology

The topic proposer has identified a pressing need to be able to detect seizures, especially tonic-clonic seizures, and to alert others in real-time (by phone or pager, sometimes with GPS tracking) of when, and sometimes where, a person with epilepsy has a seizure. This is of particular importance for people with epilepsy who live or sleep alone.

There is no gold standard to detect seizures outside of the hospital environment (Komal et al. 2024). Current standard of care may involve one-to-one human supervision, such as the caregiver sleeping-in or regularly checking on the person with epilepsy. There is some use of low-tech audio monitoring, such as baby monitors, to try to detect possible seizures in sleep, but the topic proposer reports that this is not reliable. There are many devices monitoring physiological signal(s) commercially available in Wales, but most are not regulated for use as medical devices. People with epilepsy are left to explore these technologies themselves, and either self-fund them or seek funding support from their local authority or charities (Epilepsy Action 2026a). Experts contacted by HTW suggest that wearable seizure-detection devices are already in use in the social care setting in Wales and may be used to support independent living versus the need for residential care or a live-in carer.

Electroencephalogram (EEG) measurement, which involves a specialist placing 10 to 20 electrodes on a person's scalp to record brain activity, may be used to detect seizures, but is traditionally used for diagnosing and classifying epileptic and non-epileptic events, and is typically undertaken in a hospital setting or under regulated-home monitoring. This type of EEG monitoring cannot be continuously used in a home environment (Komal et al. 2024).

Non-invasive, remote-monitoring seizure technologies detect and record seizure frequency in ambulatory settings (Komal et al. 2024). The primary function of remote seizure-detection devices is to continuously record the biomarkers linked to the seizure severity and generate real-time alert notifications to caregivers. Some devices are also able to provide the location of the person having the seizure. Although remote-monitoring devices do not reduce the severity of seizures themselves, early-alarm intervention may safeguard people with epilepsy from harm related to seizures, and also provide data to support the effective administration of medication and support the long-term management of the patient (Komal et al. 2024).

The devices are usually worn on the body, hence the term ‘wearable’ seizure detection devices (Komal et al. 2024). Alternatively, devices can be positioned near the body, such as under a bed mattress, or as a sheet with embedded sensors, for continuous physiological signal measurements. The devices are equipped with built-in sensor functionality, such as EEG, electromyography (EMG, records muscle activity through electrical-signal measurements), accelerometry (ACM, quantifies change in motion in x, y, or z direction), electrocardiography (ECG,

measures electrical activity through the heartbeat), electrodermal activity (EDA, records electric conductance in response to sweating), photoplethysmography (PPG, measures blood circulation using a light-source and photodetector), and piezoelectric motion-detection sensors (pressure sensor that detects tiny vibrations). Some devices measure one of these physiological-signal modalities (unimodal), and some measure more than one (multimodal). Because of the easy-to-recognise motion profile of GCTS, many remote monitoring seizure-detection devices are primarily designed to detect GTCS (Komal et al. 2024).

Table 1 provides a list of the tonic-clonic seizure-detection devices with regulatory approval in the UK, which we identified at the time that this report was produced. We excluded devices which have been withdrawn from the UK market, and devices which only have American Food and Drug Administration (FDA) clearance. We excluded devices that solely measured EEG, as these are usually fitted by specialists and used for diagnosis in the hospital setting. Please note that this list may not be exhaustive, and we do not endorse any particular device.

Table 1 – Summary of tonic-clonic seizure-detection alarms with regulatory approval in the UK

Device name	Manufacturer	Alert method(s)	Detection method(s)	GPS location detection	Design	Age	Intended time of use	Intended place of use	Regulatory approval
Companion Mini	iTs Designs Ltd, UK	If a potential seizure is detected, Companion Mini sends an alert to the included pager	Piezoelectric motion sensor	No	Under-mattress	3 years and up	Night	Home	- MHRA Class I - CE-mark Class I
Emfit Epilepsy Alarm	Abilia AB, Sweden	If a potential seizure is detected, the sensor sends a signal to the control unit (positioned on a wall or bedside table), which sounds an alarm. It is also possible for further alarms to be sent to a pager or mobile phone	Piezoelectric motion sensor	No	Under-mattress	NR but the manufacturer's website states that it can be used in people under 15 kg and over 75 kg	Night	Home or care homes	- MHRA Class I - The manufacturer's website states that Emfit is CE-mark Class I, but we could not find evidence of this
Epi-Care free	Danish Care Technology, Denmark	If a potential seizure is detected, alerts are sent to an included pager and control unit	ACM, gyroscope	No	Wristband	10 years and up	Day and night	Home, care homes, hospitals and institutions	CE-mark Class I
Epi-Care mobile	Danish Care Technology, Denmark	If a potential seizure is detected, alerts are sent to the mobile phone and onwards to any designated emergency contact(s). Alerts can inform the caregiver(s) of the location of the person having the seizure	ACM, gyroscope	Yes	Wristband	10 years and up	Day and night	Home, care homes, hospitals and institutions	CE-mark Class I
EpiMonitor (EmbracePlus wearable and	Empatica S.r.L., Italy	If a potential seizure is detected, EpiMonitor sends a call and text message to the mobile	ACM, EDA, gyroscope, PPG, temperature	Yes	Wristband	6 years and up	Day and night	Home, care homes, hospitals	- MHRA Class IIa - CE-mark Class IIa - According to the manufacturer's

Device name	Manufacturer	Alert method(s)	Detection method(s)	GPS location detection	Design	Age	Intended time of use	Intended place of use	Regulatory approval
EpiMonitor smartphone app)		phone of the caregiver(s). Alerts can inform the caregiver(s) of the location of the person having the seizure						and institutions	website, the older versions of the wristband (Embrace and Embrace2, which do not have PPG detection) are no longer available and has been replaced by the EpiMonitor system
MP5 and MP5v2	Medpage Ltd, UK	If a potential seizure is detected, the alarm monitor sends a signal to a pager, which consists of a flashing light and beeping. The manufacturer's website states that MP5v2 is an updated version of MP5, which has improved movement detection	Movement sensor, sound sensor	No	Under-mattress	All ages (the manufacturer's website states that MP5 is suitable for adults in single beds, and the MP5v2 is suitable for younger people or different bed sizes)	Night	Home, care homes, hospitals and institutions	- The MHRA document a Class I seizure-detection device for Medpage Ltd, but the device name is NR - The manufacturer's website states that MP5 and MP5v2 are CE-marked, but we could not find evidence of this
NightWatch +	LivAssured B.V., The Netherlands	If a potential seizure is detected, a warning is transmitted from the sensor to the paired alarm system, notifying caregivers	ACM, PPG	No	Armband	4 years and up	Night	Home	- MHRA Class IIa - CE-mark Class IIa

Device name	Manufacturer	Alert method(s)	Detection method(s)	GPS location detection	Design	Age	Intended time of use	Intended place of use	Regulatory approval
NightWatch + PRO	LivAssured B.V., The Netherlands	NightWatch+ PRO can be integrated with nurse-call systems to alert care staff, if a potential seizure is detected	ACM, PPG	No	Armband	4 years and up	Night	Care homes, hospitals and institutions	- MHRA Class IIa - CE-mark Class IIa

The information in this table came from Epilepsy Alarms UK (2026) and the manufacturers' websites in February 2026

Abbreviations: ACM, accelerometry; EDA, electrodermal activity; GPS, Global Positioning System; kg, kilograms; MHRA, Medicines and Healthcare products Regulatory Agency; NR, not reported; PPG, photoplethysmography

4. Guidelines and guidance

HTW appraised at-home video-monitoring for the diagnosis and management of epilepsy, including the Nelli-hybrid system (Neuro Event Labs, Finland), and recommended that, although it showed promise, the clinical and economic evidence was insufficient to support routine adoption in NHS Wales (Health Technology Wales 2025). We therefore did not include seizure-detection devices utilising video- or audio-input alone in this appraisal.

National Institute for Health and Care Excellence (NICE) guideline [NG217] included an evidence review on night monitors, wearable devices and apps for use in people with epilepsy (NICE 2025). The review searched for relevant randomised controlled trials published up until May 2021. No evidence was found on digital technologies. The committee noted that some people do use commercially available devices, such as night monitors and alarms, as self- management tools, but that evidence is lacking to support this use, although the committee acknowledged that some monitor tools may be of benefit to people with epilepsy (NICE 2025).

A joint working group of the International League Against Epilepsy (ILAE) and the International Federation of Clinical Neurophysiology (IFCN) published a clinical-practice guideline on automated seizure detection using wearable devices (Beniczky et al. 2021). Using the Grading of Recommendations, Assessment, Development and Evaluation (GRADE) method, a systematic review of three high-quality studies (Arends et al. 2018, Beniczky et al. 2018, Beniczky et al. 2013) gave a weak/conditional recommendation to use clinically validated wearable devices for the automated detection of GTCS and FBTCS when significant safety concerns exist, especially in unsupervised patients who do not share a bedroom, but where alarms can result in rapid intervention within five minutes. Despite this recommendation, the guidelines state that it was uncertain as to whether use of such devices resulted in meaningful clinical outcomes for people with epilepsy, such as reduction in seizure-related injuries or SUDEP, or an increase in quality of life (Beniczky et al. 2021).

5. Effectiveness

We searched for evidence that could be used to answer the review question: What is the clinical and cost effectiveness of wearable or bed-based technologies for the detection of tonic-clonic seizures in people with epilepsy?

For details on the methodology used to identify evidence for this report, refer to Appendix 1.

5.1 Overview

We only included non-invasive wearable and bed-based real-time seizure-detection alarms with evidence of regulatory approval in the UK (Table 1). Some of the primary studies in the included systematic reviews were not included in this appraisal, as they either included discontinued devices, only included devices with regulatory approval in the USA, or we could not find evidence of a CE-mark, UKCA mark, or MHRA-regulatory approval. We did not include studies that used unimodal-EEG devices, nor devices that solely used audio and/or video monitoring. Where possible, we only included data in the systematic reviews specific to GTCS, including FBTCS. We included devices with and without GPS-location tracking: we only identified two-out-of-eight UK-regulated devices with this function. Appendix 2 gives full details of the studies selected for inclusion in the review.

We included two systematic reviews of observational studies in the effectiveness section of this appraisal (Komal et al. 2024, Meritam Larsen & Beniczky 2023). The systematic reviews by Komal

et al. (2024) and Meritam Larsen & Beniczky (2023) included 12 relevant, mainly prospective, single-arm, primary studies of 758 adults and children with 3,256 predominantly tonic-clonic seizures (Arends et al. 2018, Beniczky et al. 2013, Carlson et al. 2009, Fulton et al. 2013, Hadady et al. 2023, Lazeron et al. 2022, Meritam et al. 2018, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2021, Onorati et al. 2017, van Westrhenen et al. 2023). Although most of the studies appeared in both systematic reviews, the reviews included some different outcomes to each other. We also identified an additional prospective observational study, published since the systematic reviews, involving 72 people using a multimodal ACM and EDA wristband/wristwatch called Embrace2 (Empatica S.r.L., Italy) in the epilepsy monitoring unit (Jahani et al. 2026). Detailed study-design characteristics of these systematic reviews and primary studies are reported in Appendix 5.

Most of the primary studies in the systematic reviews were conducted in the epilepsy monitoring unit and used video-EEG as the reference standard for seizure detection. Four of the studies took place in the home setting (Hadady et al. 2023, Lazeron et al. 2022, Meritam et al. 2018, van Westrhenen et al. 2023), and two studies were conducted in a residential-care setting (Arends et al. 2018, Lazeron et al. 2022). Two studies included people with epilepsy and learning disabilities (Arends et al. 2018, van Westrhenen et al. 2023). Most studies included adults and children, with two studies only including adults (Narechania et al. 2013, Nouboue et al. 2023).

The ILAE and IFCN published standards that categorise studies into five phases (0 to 4), each considered to evaluate remote-monitoring seizure-detection devices (Beniczky et al. 2021). According to these standards, phase 3 and 4 studies equate to high-level evidence, with phase 4 evidence being real-world studies set in the home-environment (Beniczky et al. 2021). Many participants in the phase 4 studies had severe epilepsy and intellectual disabilities and were living in residential-care settings. Where possible, we summarised data for phase 4 studies separately (Arends et al. 2018, Meritam et al. 2018, van Westrhenen et al. 2023).

Wristband/wristwatch alarms were the most frequently reported seizure-detection devices included in the systematic reviews (five studies): three studies used the unimodal Epi-Care ACM device (Danish Care Technology, Denmark) (Beniczky et al. 2013, Hadady et al. 2023, Meritam et al. 2018), and three studies used a multimodal ACM and EDA wristband/wristwatch called Embrace (Empatica S.r.L., Italy) (Hadady et al. 2023, Onorati et al. 2021, Onorati et al. 2017).

Four studies in the systematic reviews investigated NightWatch (LivAssured B.V., The Netherlands), a multimodal upper-arm band using ACM and PPG sensors (Arends et al. 2018, Hadady et al. 2023, Lazeron et al. 2022, van Westrhenen et al. 2023).

Four studies in the systematic reviews assessed under-mattress motion seizure-detection alarms (four studies): two of these studies included the Emfit under-mattress piezoelectric motion-sensor alarm (Abilia AB, Sweden) (Narechania et al. 2013, Nouboue et al. 2023), and two studies included the MP5 under-mattress motion alarm (Medpage Ltd, UK) (Carlson et al. 2009, Fulton et al. 2013).

Although the observational study by Nouboue et al. (2023) was included in the systematic review by Komal et al. (2024), we reported it as a primary study for the resource-use outcome as this outcome was not included in the systematic review.

5.2 Diagnostic accuracy

Seizure-detection device accuracy is assessed using device sensitivity (accurate seizure detection) and false-alarm rates (false-seizure prediction) (Komal et al. 2024).

5.2.1 Sensitivity (Table 2)

Across the 11 included observational studies of 516 people with tonic-clonic seizures, included in the systematic reviews by Komal et al. (2024) and Meritam Larsen & Beniczky (2023), and the additional observational study of 72 people published since the systematic reviews, the sensitivity of epilepsy-alarm devices varied widely, ranging from 11.1% to 100% (Arends et al. 2018, Beniczky et al. 2013, Carlson et al. 2009, Fulton et al. 2013, Jahani et al. 2026, Lazeron et al. 2022, Meritam et al. 2018, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2017, Onorati et al. 2021, van Westrhenen et al. 2023). The sensitivity reported in each study is displayed in Figure 1, stratified by device type.

Wristwatch devices using ACM-sensors alone reported median sensitivities of approximately 90% (Beniczky et al. 2013, Meritam et al. 2018), while multimodal-wristwatch devices combining ACM with EDA, achieved a higher sensitivity of 92% to 100% (Jahani et al. 2026, Onorati et al. 2017, Onorati et al. 2021). Sensitivity of the ACM and EDA wristwatch device was similar for adults and children (94% versus 92%, respectively) (Onorati et al. 2021).

Multimodal-armband devices combining ACM with PPG sometimes achieved higher sensitivities than ACM-devices alone, with a median sensitivity of 79% to 100% (Arends et al. 2018, Lazeron et al. 2022, van Westrhenen et al. 2023).

Under-mattress devices demonstrated highly variable performance, with older movement-based devices reporting lower sensitivities (ranging from 11.1% to 62.5%) (Carlson et al. 2009, Fulton et al. 2013), and more recent piezoelectric-movement alarms reporting higher sensitivities of between 69.6% and 88.8% (Narechania et al. 2013, Nouboue et al. 2023).

Across the three phase-4 studies, multimodal ACM and PPG devices showed high real-world performance, with sensitivities ranging from 81% in adults with intellectual disabilities in residential care (Arends et al. 2018) to 100% median sensitivity (range 71% to 100%) in children at home, some of whom had intellectual disabilities (van Westrhenen et al. 2023). An ACM-wristband device used in mixed-age community users showed around 90% sensitivity (Meritam et al. 2018).

5.2.2 False-alarm rate (Table 3 and Table 4)

In the systematic review of 10 observational studies by Komal et al. (2024), and the observational study published since the systematic reviews, false-alarm rates varied widely across studies and device types, ranging from near-zero to several alarms per night (Arends et al. 2018, Beniczky et al. 2013, Carlson et al. 2009, Fulton et al. 2013, Jahani et al. 2026, Lazeron et al. 2022, Meritam et al. 2018, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2017, van Westrhenen et al. 2023). The false-alarm rates reported in the studies are reported in Table 3. As the studies used different units to assess the false-alarm rate, we estimated the hourly false-alarm rate in each of the studies, which are displayed in Figure 1 and Table 4.

False-alarm rates of unimodal ACM wristwatch alarms, and multimodal wristwatches measuring ACM and EDA ranged from 0.077 to 1.26 per day (Beniczky et al. 2013, Jahani et al. 2026, Meritam et al. 2018, Onorati et al. 2017, Onorati et al. 2021). The estimated hourly false-alarm rate of these devices ranged from 0.003 to 0.05 (Table 4). The study by Onorati et al. (2021) reported that adults had fewer false alarms than children (0.57 per day versus 1.26 false alarms per day). This equates to an hourly false-alarm rate of 0.02 for adults and 0.05 for children (Table 4). During rest periods, there were no false-alarms for any patients, lower than during activity periods (Onorati et al. 2021).

Multimodal armband devices measuring ACM and PPG reported false-alarm rates of 0.003 to 0.04 per hour (Arends et al. 2018, Lazeron et al. 2022, van Westrhenen et al. 2023).

Across the three phase-4 studies, multimodal ACM and PPG devices showed low real-world false-alarm rates, ranging from around 0.04 false alarms per hour in children at home (van Westrhenen et al. 2023) to similarly low nightly false-alarm rates in adults with intellectual disabilities in residential care (0.03 false alarms per night) (Arends et al. 2018). An ACM-wristband device used in mixed-age community users also showed a low false-alarm burden of approximately 0.1 per day (Meritam et al. 2018).

Early bed-based movement alarms were associated with multiple false alarms per night (4.2 false alarms per night) (Carlson et al. 2009), but more recent under-mattress piezoelectric sensors had fewer false alarms, with a rate of 0.007 to 0.13 false alarms per night (Narechania et al. 2013, Nouboue et al. 2023). We estimated that this would equate to a range of 0.0006 to 0.01 false alarms per hour for piezoelectric-based under-mattress alarms, and 0.35 false alarms per hour for older movement-based under-mattress alarms (Table 4).

Figure 1 shows the number of false alarms expected over the course of a 12-hour night, with older under-mattress movement-based devices resulting in the highest number of expected false alarms in the night (Carlson et al. 2009), and all other types of epilepsy alarms (including piezoelectric-based under-mattress devices) having some evidence that there would be less-than-one false-positive alarm anticipated over the course of four-nights (Arends et al. 2018, Beniczky et al. 2013, Lazeron et al. 2022, Meritam et al. 2018, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2017).

5.2.2.1 Comparison of sensitivity versus false-alarm rate (Figure 1)

Figure 1 shows that whilst sensitivity of the individual devices is quite similar between the studies, there is wide variation in the false-positive rate values. The false-positive rates in Figure 1 have been converted to hourly rates to make the units more consistent and comparable. The majority of devices in Figure 1 have less than 0.02 false alarms per hour (Arends et al. 2018, Beniczky et al. 2013, Lazeron et al. 2022, Meritam et al. 2018, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2017). In general, there is a trade-off between sensitivity and the false-positive rate; as sensitivity increases, so does the false-positive rate.

5.2.3 Positive predictive value (Table 4)

The positive predictive value (PPV) is the probability that, when the device alarm sounds, it is indicating a seizure (true positive) rather than a false alarm. An early bed-based movement alarm had a low PPV (3%) (Carlson et al. 2009), but a more recent under-mattress piezoelectric sensor had PPV of 43% (Narechania et al. 2013).

Multimodal-armband devices combining ACM with PPG had PPV ranging from 24% to 58% (Arends et al. 2018, Lazeron et al. 2022, van Westrhenen et al. 2023). Multimodal-wristband devices combining ACM with EDA had PPV ranging from 14% to 54% (Jahani et al. 2026, Onorati et al. 2021, Onorati et al. 2017). This suggests that around half of the alarms from these armband and wristband devices are true seizures.

5.3 Seizure-related mortality

We did not identify any relevant evidence reporting the effect of seizure-detection alarms on seizure-related deaths. ILAE and IFCN clinical-practice guidelines stated that it was uncertain as to whether use of such devices resulted in a reduction of SUDEP (Beniczky et al. 2021).

5.4 Seizure-related injuries (Table 5)

Two observational studies in the systematic review by Meritam Larsen & Beniczky (2023), involving questionnaires mainly completed by caregivers of 313 adults and children who experienced bilateral tonic-clonic seizures, reported that unimodal-ACM wristwatches and multimodal armbands used at home reduced the number of seizure-related injuries by 25% to 40% (Hadady et al. 2023, Meritam et al. 2018). Most of these devices did not have GPS-location tracking. Users considered that the timely alert helped in repositioning the patients or removing objects adjacent to them, which could have caused injuries (Meritam et al. 2018).

Another observational study, published since the systematic reviews, of 72 adults with GTCS and FBTCS reported no injuries or harm occurring during seizure recordings with a multimodal ACM and EDA wristwatch in an epilepsy monitoring unit (Jahani et al. 2026).

5.5 Quality of life (Table 6)

Two observational studies of 295 people with epilepsy, in the systematic review by Meritam Larsen & Beniczky (2023), assessed the quality of life of people using unimodal-ACM wristwatches and multimodal wristwatches or armbands at home (Hadady et al. 2023, van Westrhenen et al. 2023). In one study, participants reported improved quality of life with all devices, with a median score of 6 on a 7-point Likert scale (interquartile range: 5 to 7 [a higher score indicating better quality of life]) (Hadady et al. 2023). There was no statistically significant difference in quality of life between the validated devices, but quality of life was significantly lower for non-validated devices. However, baseline (pre-intervention) quality-of-life scores were not reported in the study, only that there was an 'improvement'. Additionally, the survey was mainly completed by the caregiver, only being completed by the patient themselves in 28% of cases (Hadady et al. 2023).

The second study found a statistically-significant reduction in caregiver stress after two months of using a multimodal-armband seizure-detection device, compared with a two-month baseline period without a device. The mean Caregiver Strain Index (CSI) score, however, was over seven throughout the study indicating high levels of caregiver stress (CSI: 7.1 versus 8.0; $p = 0.032$) (van Westrhenen et al. 2023). The median difference in stress score was -1, and nine caregivers indicated that two-or-more-items (of 13) on the CSI were no longer difficult for them to handle (van Westrhenen et al. 2023).

No significant changes were observed in caregivers' overall quality of life, measured using the EuroQol five-dimension five-level scale (EQ-5D-5L, mean score 0.9 at both time points), or in sleep quality, assessed with the Pittsburgh Sleep Quality Index (PSQI, mean score 6.7 versus 7.9; $p = 0.117$) (van Westrhenen et al. 2023).

5.6 Patient-reported outcomes (Table 7)

All primary studies reported below were observational in nature and most were included in the systematic review by Komal et al. (2024). One additional study was published since the systematic review (Jahani et al. 2026).

5.6.1 Usability

One study of 20 adults and children with GTCS reported that physical activity affected the performance of an ACM-wristwatch epilepsy alarm (Beniczky et al. 2013). In this study, six-out-of-40 false alarms occurred due to teeth-brushing, and 34-out-of-40 false alarms occurred during voluntary rhythmic movements of the arms (playing cards, playing backgammon, and winding up the cable of the device amplifier) (Beniczky et al. 2013). Another study of 72 adults using a multimodal ACM and EDA wristwatch for GTCS and FBTCS reported that 20-out-of-29 false alarms were associated with toothbrushing, four with scratching or hand-shaking, and five had no identifiable cause (Jahani et al. 2026).

In 10% of cases of 71 adults and children, mainly with bilateral tonic-clonic seizures, use of the ACM wristwatch was discontinued due to reasons related to the device (Meritam et al. 2018). Four of these discontinuations occurred due to a perceived unacceptably high false-alarm rate, one because the device was damaged during a seizure and was not replaced, and two due to the patient being unable to use the device (Meritam et al. 2018).

The study by Arends et al. (2018), of 20 adults and children with major seizures (including GTCS) and intellectual disability, reported that mean user-friendliness of a multimodal armband seizure-detection alarm was rated at 7.3 out of 10 (with lower scores indicating poorer usability).

5.6.2 Comfort/wearability

In the systematic review by Komal et al. (2024), two studies of adults and children with major seizures, including tonic-clonic seizures, reported that adverse events were mild. Of the 99 people included in the studies, there were seven reported cases of rash or skin irritation from the armband or wristwatch, and five reported cases of the device being too tight (Arends et al. 2018, Meritam et al. 2018). One of the studies included 28 people with epilepsy and learning difficulties in a residential-care setting, and reported that the skin irritation was eliminated in three cases by ensuring that the armband wasn't too tight and by removing the paint on the surface of the sensor (Arends et al. 2018). The same study reported that all reported cases of the armband not fitting were prevented by changing the texture and attachment of the elastic band of the armband device (Arends et al. 2018).

Another observational study, published since the systematic reviews, of 72 adults with GTCS and FBTCS reported no adverse events during seizure recordings with a multimodal ACM and EDA wristwatch (Jahani et al. 2026).

5.6.3 Seizure-management

One study of 71 adults and children, mainly with bilateral tonic-clonic seizures, reported that use of an ACM wristwatch influenced the number of seizures logged into a seizure diary in 55% of the patients (Meritam et al. 2018). However, the questionnaire was only completed by the patient in 17% of cases and was mainly completed by the caregiver (Meritam et al. 2018).

5.7 Resource use (Table 8)

One study of 55 people with epilepsy reported that an under-mattress device in an epilepsy monitoring unit significantly increased the likelihood that nurses intervened during convulsive seizures (Nouboue et al. 2023). When the alarm was triggered during a convulsive seizure (12 times), nurses intervened every time. When there was no alarm, nurses intervened in 57% of convulsive seizures (4/7 times). However, most of the convulsive seizures were focal seizures with tonic movements (Nouboue et al. 2023).

Another observational study, published since the systematic reviews, reported findings from 72 adults with GTCS and FBTCS using a multimodal ACM and EDA wristwatch in an epilepsy monitoring unit (Jahani et al. 2026). Of the 15 alerts that were successfully delivered to nurses, seven occurred during overnight and weekend shifts when specialised EEG personnel were typically unavailable in the epilepsy monitoring unit. In three of these seven cases, intervention was initiated by the shift nurse in response to the generated alert of the device, with a median intervention time of 23 seconds following alert generation. In four of the seven cases, intervention took place by healthcare professionals before the generated alert of the device. One alert failed due to Wi-Fi loss (Jahani et al. 2026).

Table 2 – Sensitivity of tonic-clonic seizure-detection devices

Evidence source(s)	Number of people with epilepsy / number of seizures	Population / study characteristics	Absolute effect	Comments on reliability
10 observational studies by Arends et al. (2018), Beniczky et al. (2013), Carlson et al. (2009), Fulton et al. (2013), Lazeron et al. (2022), Meritam et al. (2018), Narechania et al. (2013), Nouboue et al. (2023), Onorati et al. (2017), van Westrhenen et al. (2023) in the SR by Komal et al. (2024)	364 / 3,220	- Age of participants: Adults, 2 studies; Children, 4 studies; Adults and children, 4 studies - Setting: EMU, 6 studies; Home, 2 studies; Residential care, 1 study; Residential care or home, 1 study - Recording length (range): 2 months to 15 months (median time) - Detection latency (range): 5 seconds to 151 seconds - Devices used and modalities: **Armband (NightWatch, ACM and PPG)**, 3 studies (Arends et al. 2018, Lazeron et al. 2022, van Westrhenen et al. 2023); **Bed mattress (Emfit, movement)**, 2 studies (Narechania et al. 2013, Nouboue et al. 2023); **Bed mattress (MP5, movement)**, 2 studies (Carlson et al. 2009, Fulton et al. 2013); **Wristwatch (Epi-Care, ACM)**, 2 studies (Beniczky et al. 2013, Meritam et al. 2018); **Wristwatch (Embrace, ACM and EDA)**, 1 study (Onorati et al. 2017) - Modalities of devices: Multimodal: 4 studies (ACM + PPG, 3 studies; ACM + EDA, 1 study); Unimodal: 6 studies (movement, 4 studies; ACM, 2 studies) - Reference standard:	Overall range: 11.1% to 100%: Range by modality of device: - ACM: 89.7% to 90% (median) - ACM and EDA: 92% to 94.6% - ACM and PPG: 79% to 100% (median per participant); 71% to 100% (individual participant range) - Movement: 11.1 % to 88.8%	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, 5 studies were assessed as being high-level evidence, and 4 studies were assessed as moderate evidence - Using the GRADE method, the SR by Beniczky et al. (2021) assessed the primary studies by Arends et al. (2018) and Beniczky et al. (2013) as high quality. The certainty of the other studies was not assessed - There is a potential "unit-of-analysis" issue, as some patients have multiple seizures. Sensitivity could be calculated per patient or overall for all seizures

Evidence source(s)	Number of people with epilepsy / number of seizures	Population / study characteristics	Absolute effect	Comments on reliability
		Video-EEG, 6 studies; Video recordings without EEG, 3 studies; Account provided by patients and caregivers: 1 study		
1 observational study by Onorati et al. (2021) in the SR by Meritam Larsen & Beniczky (2023)	152 / 36	- Adults and children with TCS (includes GTCS and FBTCS) - EMU setting - Recording length: 14 months - Detection latency: 37 seconds - Wristwatch (Embrace) - ACM and EDA - Reference standard: Video-EEG	- Adults: 94% - Children: 92%	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, this study was assessed as being high-level evidence
1 observational study by Jahani et al. (2026)	72 / 19 N.B. 15/72 participants had 19 FBTCS or GTCS	- Adults with GTCS, FBTCS or focal seizures - EMU setting - Recording length: 5.1 days per patient (average) with a range of 2 to 16 days - Detection latency for FBTCS: 80 seconds (median) with a range of 45 to 480 seconds - Detection latency for GTCS: 25 seconds - Wristwatch (Embrace2) - ACM and EDA - Reference standard: Video-EEG	- FBTCS: 15/15 (100%) - GTCS: 1/1 (100%) - Focal seizures: 0/510 (0%)	- A total of 18 FBTCS and 1 GTCS seizure occurred: 3 of these occurred when the patient was not wearing the device - 1 patient had a detection latency of 480 seconds due to an initially subtle seizure onset, which was not clinically recognised until secondary generalisation

Abbreviations: ACM, accelerometer; EDA, electrodermal activity; EEG, electroencephalography; EMU, epilepsy monitoring unit; FBTCS, focal-to-bilateral tonic-clonic seizures; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; GTCS, generalised tonic-clonic seizures; IFCN, International Federation of Clinical Neurophysiology; ILAE, International League Against Epilepsy; NR, not reported; PPG, photoplethysmography; SR, systematic review; TCS, tonic-clonic seizure; vs, versus

Table 3 – Study-reported false-alarm rates of tonic-clonic seizure-detection devices

Evidence source(s)	Number of people with epilepsy / number of seizures	Population / study characteristics	Absolute effect	Comments on reliability
10 observational studies by Arends et al. (2018), Beniczky et al. (2013), Carlson et al. (2009), Fulton et al. (2013), Lazeron et al. (2022), Meritam et al. (2018), Narechania et al. (2013), Nouboue et al. (2023), Onorati et al. (2017), van Westrhenen et al. (2023) in the SR by Komal et al. (2024)	364 / 3,220	- Age of participants: Adults, 2 studies; Children, 4 studies; Adults and children, 4 studies - Setting: EMU, 6 studies; Home, 2 studies; Residential care, 1 study; Residential care or home, 1 study - Recording length (range): 2 months to 15 months (median time) - Detection latency (range): 5 seconds to 151 seconds - Devices used and modalities: **Armband** (**NightWatch, ACM and PPG**), 3 studies (Arends et al. 2018, Lazeron et al. 2022, van Westrhenen et al. 2023); **Bed mattress** (**Emfit, movement**), 2 studies (Narechania et al. 2013, Nouboue et al. 2023); **Bed mattress** (**MP5, movement**), 2 studies (Carlson et al. 2009, Fulton et al. 2013); **Wristwatch** (**Epi-Care, ACM**), 2 studies (Beniczky et al. 2013, Meritam et al. 2018); **Wristwatch** (**Embrace, ACM and EDA**), 1 study (Onorati et al. 2017) - Modalities of devices: Multimodal: 4 studies (ACM + PPG, 3 studies; ACM + EDA, 1 study); Unimodal: 6 studies (movement, 4 studies; ACM, 2 studies) - Reference standard: Video-EEG, 6 studies; Video recordings without EEG, 3 studies; Account provided by patients and caregivers: 1 study	Overall range per day for ACM devices, and ACM + EDA devices: 0.1 (median) to 1.26 Overall range per night for under-mattress devices: 0.007 to 4.2 Overall range per hour of ACM + PPG devices: 0.008 to 0.04	- FAR NR in 1 study (Fulton et al. 2013) - It is unclear what cut-offs are considered high/low FARs - Different studies reported the FAR using different time units (per hour, per night, or per day), which limited direct comparability across studies. However, Figure 1 aims to address this uncertainty - According to ILAE and IFCN standards for testing and validation for seizure detection devices, 5 studies were assessed as being high-level evidence, and 4 studies were assessed as moderate evidence - Using the GRADE method, the SR by Beniczky et al. (2021) assessed the primary studies by Arends et al. (2018) and Beniczky et al. (2013) as high quality. The certainty of the other studies was not assessed

Evidence source(s)	Number of people with epilepsy / number of seizures	Population / study characteristics	Absolute effect	Comments on reliability
1 observational study by Onorati et al. (2021) in the SR by Meritam Larsen & Beniczky (2023)	152 / 36	- Adults and children with TCS (GTCS and FBTCS) - EMU setting - Recording length: 14 months - Detection latency: 37 seconds - Wristwatch (Embrace) - ACM and EDA - Reference standard: Video-EEG	- Adults: 0.57 per day - Children: 1.26 per day - No false alarms during rest periods	According to ILAE and IFCN standards for testing and validation for seizure detection devices, this study was assessed as being high-level evidence
1 observational study by Jahani et al. (2026)	72 / 19 N.B. 15/72 participants had 19 FBTCS or GTCS	- Adults with GTCS, FBTCS or focal seizures - EMU setting - Recording length: 5.1 days per patient (average) with a range of 2 to 16 days - Detection latency for FBTCS: 80 seconds (median) with a range of 45 to 480 seconds - Detection latency for GTCS: 25 seconds - Wristwatch (Embrace2) - ACM and EDA - Reference standard: Video-EEG	29 false alarms (0.077 per 24 hours)	

Abbreviations: ACM, accelerometer; EDA, electrodermal activity; EEG, electroencephalography; EMU, epilepsy monitoring unit; FAR, false-alarm rate; FBTCS, focal-to-bilateral tonic-clonic seizures; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; GTCS, generalised tonic-clonic seizures; IFCN, International Federation of Clinical Neurophysiology; ILAE, International League Against Epilepsy; NR, not reported; PPG, photoplethysmography; SR, systematic review; TCS, tonic-clonic seizure; vs, versus

Table 4 – Estimated hourly false-alarm rates and positive predictive values of tonic-clonic seizure-detection devices

Study	Device	Modality	False-alarm rate reported in study	False-alarm rate unit	Hourly false-alarm rate*	Positive predictive value
Arends et al. (2018)	NightWatch armband	ACM + PPG	0.03	night	**0.0025**	**49%**[b]
Beniczky et al. (2013)	Epi-Care wristband	ACM	0.2	day	**0.008333**	**46%**[c]
Carlson et al. (2009)	MP5 under-mattress	Movement	4.2	night	**0.35**	**3%**
Fulton et al. (2013)	MP5 under-mattress	Movement	NR	NR	**NR**	**NR**
Jahani et al. (2026)	Embrace2 wristband	ACM + EDA	0.077	day	**0.003208**	**36%**[c]
Lazeron et al. (2022)	NightWatch armband	ACM + PPG	0.008	hour	**0.008**	**58%**[b]
Meritam et al. (2018)	Epi-Care wristband	ACM	0.1	day	**0.004167**	**NR**
Narechania et al. (2013)	Emfit under-mattress	Movement (piezoelectric)	0.13	night	**0.010833**	**43%**
Nouboue et al. (2023)	Emfit under-mattress	Movement (piezoelectric)	0.007	night	**0.000583**	**NR**
Onorati et al. (2017)	Embrace wristband	ACM + EDA	0.2	day	**0.008333**	**54%**[c]
Onorati et al. (2021) (adults)	Embrace wristband	ACM + EDA	0.57	day	**0.02375**	**17%**[c]
Onorati et al. (2021) (children)	Embrace wristband	ACM + EDA	1.26	day	**0.0525**	**14%**[c]
van Westrhenen et al. (2023)	NightWatch armband	ACM + PPG	0.04	hour	**0.04**	**24%**[b]

Abbreviations: ACM, accelerometry; EDA, electrodermal activity; NR, not reported; PPG, photoplethysmography

*Hourly false-alarm rates were calculated by dividing reported daily rates by 24 and nightly rates by 12
[b] median positive predictive value in per-patient analysis
[c] positive predictive value calculated using reported true positive and false positive (false alarm) counts

Figure 1. Epilepsy alarm device performance: Comparison of sensitivity versus the false-positive rate, with expected false alarms during a 12-hour night

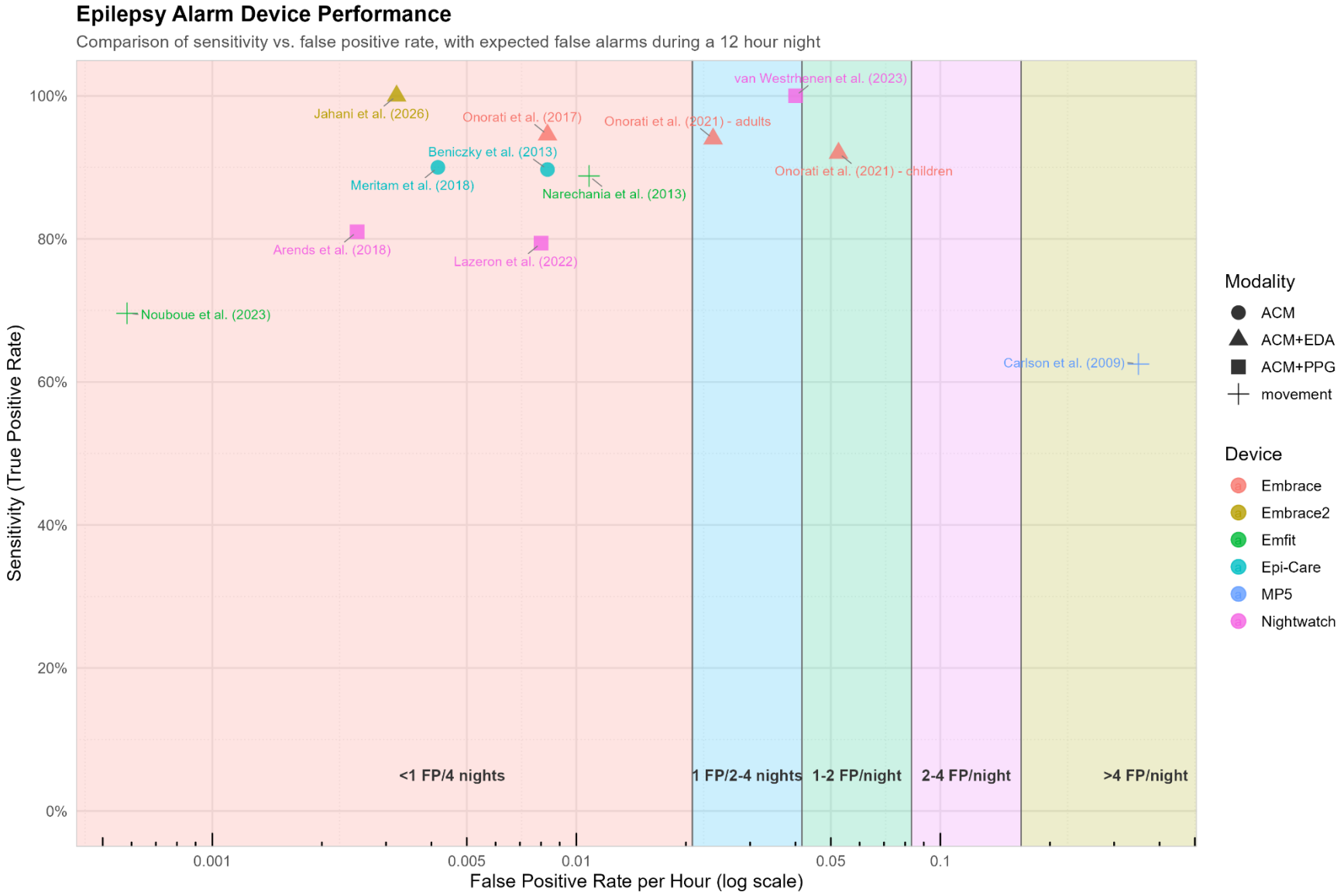

Table 5 – Seizure-related injuries in people using tonic-clonic seizure-detection devices

Evidence source(s)	Number of people with epilepsy / number of seizures	Population	Absolute effect	Comments on reliability
1 observational study by Meritam et al. (2018) in SR by Meritam Larsen & Beniczky (2023)	71 / NA (in-field study)	- BTCS (49% had BTCS only, 59% had both BTCS and other seizure types) - Median age: 27 years (range: 7 to 72 years) - Home setting: 46%, Institution setting: 44%, Both home and institution settings: 10% - Median time using device: 15 months - Wristwatch (Epi-Care): Epi-Care Free: 75%, Epi-Care Mobile: 24% - ACM - Modified PSSUQ used during a telephone interview - PSSUQ mainly completed by caregiver. The patient completed PSSUQ in 17% of cases	Patients/caregivers considered that the device resulted in fewer injuries in 40% of the patients (18/45)	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, this study was assessed as being high-level evidence - Outcomes relied on patient and caregiver report, introducing potential recall and selection bias
1 observational study by Hadady et al. (2023) in SR by Meritam Larsen & Beniczky (2023)	242 / NR	- 87% of patients had BTCS/GTCS - Median age: 17 years (range 1 to 82 years) - Home setting (36% lived alone/did not share a bedroom) - Median time using device: 14 months - 209 participants used validated devices: 36% used NightWatch (armband: ACM, PPG), 30% used Embrace (wristband: ACM, EDA, PPG), and 19% used Epi-Care (wristband: ACM) - Survey mainly completed by caregiver. The patient completed it in 28% of cases	Patients who experienced a decrease in injuries due to the device: - Overall: 30.24% - Embrace: 35.62% - Epi-Care: 31.11% - NightWatch: 25.29%	Outcomes relied on patient and caregiver report, introducing potential recall and selection bias
1 observational study by Jahani et al. (2026)	72 / 19 N.B. 15/72 participants had 19 FBTCS or GTCS	- Adults with GTCS, FBTCS or focal seizures - EMU setting - Recording length: 5.1 days per patient (average) with a range of 2 to 16 days - Detection latency for FBTCS: 80 seconds (median) with a range of 45 to 480 seconds - Detection latency for GTCS: 25 seconds - Wristwatch (Embrace2) - ACM and EDA - Reference standard: Video-EEG	0 reported injuries or harm whilst wearing the device	No comparative data

Abbreviations: ACM, accelerometer; BTCS, bilateral tonic-clonic seizure; EDA, electrodermal activity; GTCS, generalised tonic-clonic seizures; IFCN, International Federation of Clinical Neurophysiology; ILAE, International League Against Epilepsy; NA, not applicable; NR, not reported; PPG, photoplethysmography; PSSUQ, Post-Study System Usability Questionnaire

Table 6 – Quality of life in people using tonic-clonic seizure-detection devices

Evidence source(s)	Number of people with epilepsy / number of seizures	Population	Absolute effect	Comments on reliability
1 observational study by Hadady et al. (2023) in SR by Meritam Larsen & Beniczky (2023)	242 / NR	- 87% of patients had BTCS/GTCS - Median age: 17 years (range 1 to 82 years) - Home setting (36% lived alone/did not share a bedroom) - Median time using device: 14 months - 209 participants used validated devices: 36% used NightWatch (armband: ACM, PPG), 30% used Embrace (wristband: ACM, EDA, PPG), and 19% used Epi-Care (wristband: ACM) - Survey mainly completed by caregiver. The patient completed it in 28% of cases	Median score (IQR) on 7-point Likert scale*: - Overall: 6 (5 to 7) - Embrace: 6 (5 to 7) - Epi-Care: 5 (3.25 to 6) - NightWatch: 6 (5 to 7) There was no statistically significant difference between the validated devices above, but QoL was significantly lower for non-validated devices: median score of 4 on 7-point Likert scale* (IQR: 1 to 7), p = 0.009	- QoL based on self-reported Likert-scale ratings, and no pre-post analysis was performed using a validated QoL instrument - The study reports that QoL improved with the seizure alarms, but baseline (pre-intervention) scores NR in the study
1 observational study by van Westrhenen et al. (2023) in SR by Meritam Larsen & Beniczky (2023)	53 / 552	- 1 or more weekly nocturnal major motor seizures - Mean age: 9.7 ± 3.6 years (range: 4 to 16 years) - 68% had a learning disability - Home setting - Armband (NightWatch) - ACM, PPG - Comparison was between a 2-month baseline period without any seizure detection device (usual care), and the following 2-months using NightWatch - NightWatch was used alongside a video camera and audio sensor	- Caregivers' stress: mean total CSI† score = 8.0 vs 7.1, p = 0.032 **Favours wearable device** - Caregivers' quality of sleep: mean total PSQI‡ score = 7.9 vs. 6.7, p = 0.117 **No significant difference between baseline and intervention** - Caregivers' QoL (EQ-5D-5L§): mean total EQ-5D-5L score = 0.9 vs 0.9 **No significant difference between baseline and intervention**	- A CSI score above 7 indicates a high-stress level, indicating high caregiver stress despite using the intervention - The minimally important difference of CSI is uncertain - The intervention period was short (2 months) - According to ILAE and IFCN standards for testing and validation for seizure detection devices, this study was assessed as being high-level evidence - The intervention combined NightWatch with video/audio monitoring - The proportion of children with TCS was NR - Online questionnaires were fully completed by 47% of caregivers

Evidence source(s)	Number of people with epilepsy / number of seizures	Population	Absolute effect	Comments on reliability
				- Originally defined skin pigmentation as an exclusion criterion due to the use of PPG. After validation of NightWatch on pigmented skin, this exclusion criterion was removed

* Likert scale: 7-points, where a higher score equals a better outcome
† CSI: 13 items, each carrying 1 point, with a score of 7 indicating a high-stress level
‡ PSQI: scores range from 0 (no difficulty sleeping) to 21 (severe difficulties sleeping)
§ EQ-5D-5L: scores range from 0 (the worst health you can imagine) to 100 (the best health you can imagine)

Abbreviations: ACM, accelerometer; BTCS, bilateral tonic-clonic seizure; CSI, Caregiver Strain Index; EDA, electrodermal activity; EQ-5D-5L, EuroQol five- dimension five- level scale; GTCS, generalised tonic-clonic seizures; IFCN, International Federation of Clinical Neurophysiology; ILAE, International League Against Epilepsy; IQR, inter-quartile range; NR, not reported; PPG, photoplethysmography; PSQI, Pittsburgh Sleep Quality Index; QoL, quality of life

Table 7 – Patient-reported outcomes for tonic-clonic seizure-detection devices

Outcome	Evidence source(s)	Number of people with epilepsy / number of seizures	Population	Absolute effect	Comments on reliability
Usability: Effect of physical activity on the performance of the device	1 observational study by Beniczky et al. (2013) in SR by Komal et al. (2024)	20 / 39	- Adults and children with GTCS - EMU setting - Wristwatch (EpiCare) - ACM - Device latency: 12 to 35 seconds - Recording length: > 6 months - Reference standard: Video-EEG	- 6/40 false alarms occurred due to teeth-brushing - 34/40 false alarms occurred during voluntary rhythmic movements of the arms (playing cards, playing backgammon, and winding up the cable of the amplifier)	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, these studies were assessed as being high-level evidence - Using the GRADE method, the SR by Beniczky et al. (2021) assessed the primary study by Beniczky et al. (2013) as high quality
Usability: Effect of physical activity on the performance of the device	1 observational study by Jahani et al. (2026)	72 / 19 N.B. 15/72 participants had 19 FBTCS or GTCS	- Adults with GTCS, FBTCS or focal seizures - EMU setting - Recording length: 5.1 days per patient (average) with a range of 2 to 16 days - Detection latency for FBTCS: 80 seconds (median) with a range of 45 to 480 seconds - Detection latency for GTCS: 25 seconds - Wristwatch (Embrace2) - ACM and EDA - Reference standard: Video-EEG	- 20/29 false alarms occurred due to teeth-brushing - 4/29 false alarms occurred due to scratching or hand-shaking - 5/29 false alarms had no identifiable cause	-
Usability: discontinuation of device	1 observational study by Meritam et al. (2018) in SR by Komal et al. (2024)	71 / NA (in-field study)	- BTCS (49% had BTCS only, 59% had both BTCS and other seizure types) - Median age: 27 years (range: 7 to 72 years) - Home setting: 46%, Institution setting: 44%, Both home and institution settings: 10% - Median time using device: 15 months	In 7 cases (10%), use of the device was discontinued due to reasons related to the device: - Unacceptably high FAR (n = 4) - Patient not being able to use it (n = 2)	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, this study was assessed as being high-level evidence - Outcomes relied on patient and caregiver report, introducing

Outcome	Evidence source(s)	Number of people with epilepsy / number of seizures	Population	Absolute effect	Comments on reliability
			- Wristwatch (Epi-Care): Epi-Care Free: 75%, Epi-Care Mobile: 24% - ACM - Modified PSSUQ used during a telephone interview - PSSUQ mainly completed by caregiver. The patient completed PSSUQ in 17% of cases	- Damaged device during a seizure not being replaced afterward (n = 1)	potential recall and selection bias
Usability: ease of use	1 observational study by Arends et al. (2018) in SR by Komal et al. (2024)	28 / 809	- Adults and children in a residential-care setting with major seizures (including GTCS) and intellectual disability - Mean age: 29.1 years, range 15 to 67 years - Armband (NightWatch) - ACM and PPG - Recording length: 2 to 3 months	Mean user-friendliness of the device: grade of 7.3 on a scale from 1 to 10 (1 being the lowest user-friendliness)	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, these studies were assessed as being high-level evidence - Using the GRADE method, the SR by Beniczky et al. (2021) assessed this primary study as high quality - No validated questionnaire is named in the study
Comfort / wearability	2 observational studies by Arends et al. (2018), Meritam et al. (2018) in the SR by Komal et al. (2024)	99 / 809	Adults and children with major seizures, including TCS Home setting, 1 study; Residential care, 1 study Patients had epilepsy and learning disabilities in 1 study Recording length: 2 to 15 months (median) Armband (NightWatch) in 1 study (ACM and PPG); Wristwatch (Epi-Care) in 1 study (ACM) Questionnaires completed by caregivers PSSUQ used in 1 study, no validated questionnaire is named in 1 study	- Rash or skin irritation from the device: n = 7 - Improper fit of the device (too tight): n = 5	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, these studies were assessed as being high-level evidence - Using the GRADE method, the SR by Beniczky et al. (2021) assessed the primary study by Arends et al. (2018) as high quality. The other study was not assessed

Outcome	Evidence source(s)	Number of people with epilepsy / number of seizures	Population	Absolute effect	Comments on reliability
Comfort / wearability	1 observational study by Jahani et al. (2026)	72 / 19 N.B. 15/72 participants had 19 FBTCS or GTCS	- Adults with GTCS, FBTCS or focal seizures - EMU setting - Recording length: 5.1 days per patient (average) with a range of 2 to 16 days - Detection latency for FBTCS: 80 seconds (median) with a range of 45 to 480 seconds - Detection latency for GTCS: 25 seconds - Wristwatch (Embrace2) - ACM and EDA Reference standard: Video-EEG	0 adverse events were reported	-
Patient-reported seizure management	1 observational study by Meritam et al. (2018) in SR by Komal et al. (2024)	71 / NA (in-field study)	- BTCS (49% had BTCS only, 59% had both BTCS and other seizure types) - Median age: 27 years (range: 7 to 72 years) - Home setting: 46%, Institution setting: 44%, Both home and institution settings: 10% - Median time using device: 15 months - Wristwatch (Epi-Care): Epi-Care Free: 75%, Epi-Care Mobile: 24% - ACM - Modified PSSUQ used during a telephone interview - PSSUQ mainly completed by caregiver. The patient completed PSSUQ in 17% of cases	The device influenced the number of seizures logged into the seizure diary in 55% of the patients	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, this study was assessed as being high-level evidence - Outcomes relied on patient and caregiver report, introducing potential recall and selection bias

Abbreviations: ACM, accelerometer; BTCS, bilateral tonic-clonic seizure; EDA, electrodermal activity; FAR, false-alarm rate; GRADE, Grading of Recommendations Assessment, Development and Evaluation; GTCS, generalised tonic-clonic seizures; IFCN, International Federation of Clinical Neurophysiology; ILAE, International League Against Epilepsy; NA, not applicable; NR, not reported; PPG, photoplethysmography; PSSUQ, Post-Study System Usability Questionnaire; SR, systematic review; TCS, tonic-clonic seizures

Table 8 – Resource use of tonic-clonic seizure detection devices

Evidence source(s)	Number of people with epilepsy / number of seizures	Population	Absolute effect	Comments
1 observational study by Nouboue et al. (2023)	55 / 23	- Adults with convulsive seizures (14 focal seizures with clonic movements, 8 FBTCS, 1 GTCS) - Under-mattress alarm (Emfit) - Movement sensor - EMU setting - Device latency: 5 seconds - Recording length: 6 months - Reference standard: Video-EEG	Frequency of nurses' intervention during convulsive seizures: - 100% (12/12) when the alarm triggered - 57% (4/7) without alarm triggering, $p < 0.02$ **More frequent intervention with device-alarm triggering**	- According to ILAE and IFCN standards for testing and validation for seizure detection devices, this study was assessed as being moderate-level evidence - Most patients with convulsive seizures had focal seizures with clonic movements
1 observational study by Jahani et al. (2026)	72 / 19 N.B. 15/72 participants had 19 FBTCS or GTCS	- Adults with GTCS, FBTCS or focal seizures - EMU setting - Recording length: 5.1 days per patient (average) with a range of 2 to 16 days - Detection latency for FBTCS: 80 seconds (median) with a range of 45 to 480 seconds - Detection latency for GTCS: 25 seconds - Wristwatch (Embrace2) - ACM and EDA - Reference standard: Video-EEG - 7/15 alerts successfully delivered during early-morning/late-night/weekend shifts when trained EEG technicians were not present in the EMU surveillance room	- 15/16 alerts were successfully delivered - 1/16 alerts was unsuccessfully delivered due to temporary Wi-Fi disconnection - 3/7 alerts during unsociable hours resulted in intervention in response to the alert (median intervention time 25 seconds; range 15 to 30 seconds) - Intervention took place by beneficiary attendants before the generated alert of the device for 4/7 alerts during unsociable hours	-

Abbreviations: EEG, electroencephalogram; EMU, epilepsy monitoring unit; FBTCS, focal-to-bilateral tonic-clonic seizures; GTCS, generalised tonic-clonic seizures; IFCN, International Federation of Clinical Neurophysiology; ILAE, International League Against Epilepsy

5.8 Ongoing studies

Table 9 – Summary of ongoing primary studies

We identified one ongoing pre-post study involving 44 adults with epilepsy living in long-term care facilities in the Netherlands who experience at least one suspected major nocturnal seizure per month requiring medical assistance. Following a three-month usual-care baseline, participants will use either the NightWatch or Epi-Care Free seizure-detection device for 12 months. The primary outcome is the number of valid and missed caregiver visits following an alarm, with secondary outcomes including quality of life and cost-effectiveness, areas for which current evidence is limited. It is estimated that this study will not be completed before 2028.

Study information	Status	Research question and outcome measures
Registration: NL-OMON57154, https://onderzoekmetmensen.nl/en/trial/57154 **Country:** The Netherlands **Target recruitment**: 44 participants **Follow-up:** Baseline period of 3 months, followed by 12 months using the device	Recruiting **Last updated:** 11 September 2025	To determine what the differences are between care as usual and care where a seizure-detection device is used in addition to care as usual. Specifically, this study will compare the number of missed and correct visits from healthcare workers after an epileptic seizure, as well as cost-effectiveness, quality of life, user experience and number of complications **Population:** Adults living in long-term care facilities with at least 1 suspected major, night-time epileptic seizure that requires medical assistance per month (including tonic-clonic seizures, tonic seizures longer than 30 seconds and/or hypermotor seizures) **Intervention:** After a baseline period of 3 months, participants will start wearing a seizure-detection device (random allocation to either NightWatch or Epi-Care Free) **Comparator:** Pre-post study in which an intervention will take place after a baseline period. Differences between NightWatch and Epi-Care Free **Primary Outcome Measure:** Number of valid and missed visits by caregivers to clients following an alarm **Secondary Outcome Measure:** Effect of seizure-detection devices on patient quality of life (both general and disease-specific), number of complications after 12 months, user-experience of both healthcare workers and patients, cost effectiveness

5.9 Certainty of the evidence

The ILAE and IFCN published standards that categorise studies into five phases (0 to 4), each considered to evaluate remote-monitoring seizure-detection devices (Beniczky et al. 2021). According to these standards, a similar number of phase 2 (moderate-level), and phase 3 and 4 (high-level evidence) studies were identified.

Most of the phase 3 and 4 studies were conducted in the home-setting or residential-care settings. Because many participants in the phase 4 studies had severe epilepsy and intellectual disabilities and were living in residential-care settings, it is uncertain how well these findings generalise to the broader population of people with tonic-clonic seizures. Most phase 2 studies included in the systematic reviews were conducted in epilepsy monitoring units, which differ from home environments and may inflate apparent effectiveness of the epilepsy alarm compared with real-world use. Experts contacted by HTW researchers suggest that wearable seizure-detection devices are used in the social care setting in Wales and may be used to support independent living as opposed to residential care or a live-in carer, although we did not identify any evidence to support this.

Most of the studies focus on technical-performance metrics (for example, sensitivity and false-alarm rate). Limited evidence was identified for patient-centred outcomes, such as the impact of seizure-detection devices on seizure-related injuries. No evidence was identified for the effect of epilepsy alarms on seizure-related mortality. Most quality-of-life data were reported for caregivers, with one study using a non-validated questionnaire to assess quality of life in patients. A statistically significant reduction in caregiver stress levels was reported, but it is unclear whether the reduction was clinically significant. Usability- and wearability-data often came from surveys completed by caregivers and subject to bias.

Most of the evidence in the systematic reviews were single-arm, observational studies. This absence of comparator-data limits the ability to determine whether observed benefits exceed those of usual care.

The reporting of false-alarm rates varied across studies, with some studies reporting per day, some per night, and some per hour. This made direct comparison between devices difficult. However, we attempted to address this issue by estimating the hourly false-alarm rates (Figure 1). False-alarm burden was not usually linked to user tolerance or response behaviour, and the impact of false alarms on alarm fatigue and night-time disruption was not often reported.

Many studies in the systematic reviews did not report monitoring time or reported relatively short monitoring periods of up to a few weeks. As a result, there is limited evidence of long-term adherence, device durability, alarm fatigue, and how user behaviour adapts over months or years. Most of the studies with short-monitoring periods were conducted in epilepsy monitoring units. Two real-world phase-4 studies had long monitoring durations of 14 to 15 months (Meritam et al. 2018, van Westrhenen et al. 2023).

There is a potential "unit-of-analysis" issue, as some patients in the studies had multiple seizures, and it was not always clear whether sensitivity was calculated per patient or overall for all seizures, which can produce different results depending on which analysis is used.

Some of the included studies pooled data from paediatric and adult populations, despite physiological and behavioural differences that may affect performance. Additionally, some studies pooled data from tonic-clonic seizures and other types of convulsive seizures, which may have different movement and physiological profiles.

6. Cost effectiveness

6.1 Economic literature review

One publication was identified in the economic review (Table 10). Engelgeer et al. (2022) reported the cost-utility and cost-effectiveness of a wearable multimodal seizure-detection device, NightWatch, based on results of the PROMISE trial. The study is partially applicable to the UK perspective; however, we identified some potentially serious limitations that could impact its conclusions.

The PROMISE trial is a pre-post study evaluating the use of NightWatch in children living at home aged four to 16 years who experience at least one major nocturnal motor seizure a week and are treated at a tertiary epilepsy centre. The study collected data during a two-month baseline period, whereby no seizure-detection device was used, and during a two-month intervention period, whereby NightWatch was used at home. Data from 41 participants of the trial were available for the current economic analysis.

Data was collected on caregiver quality of life and stress using the EQ-5D-5L and the CSI, respectively. Questionnaires were completed prior to the baseline period, at the end of the baseline period, and at the end of the intervention period. The analysis took a societal perspective, with societal costs collected using the Institute for Medical Technology Assessment Medical Consumption Questionnaire (iMTA MCQ) and the Institute for Medical Technology Assessment Productivity Costs Questionnaire (iMTA PCQ). Healthcare costs were sourced from national databases. Costs for a homeopathic consultation were sourced from the Society of Homeopathy, and an average cost of respite care was calculated from a range of respite care providers. Informal care costs were calculated using shadow pricing and applying the hourly minimum wage, and productivity losses were estimated using the friction cost method. As NightWatch and all required equipment were provided free of charge from the manufacturer for the purposes of the study, device costs were not included in the economic analysis.

Non-parametric bootstrapping with 1,000 replications was used to test for statistically significant differences in costs between the baseline and intervention period in the base case economic analysis. To calculate the incremental cost-effectiveness ratio (ICER), 5,000 bootstrap replications were performed on base case results using Microsoft Excel.

Base case results of the economic analysis demonstrate that NightWatch is expected to decrease costs by €775 (£681) per patient. No breakdown of costs during the baseline and intervention period is provided, and so it is not clear what is driving cost savings in the intervention period. No differences in caregiver quality adjusted life years (QALYs) were identified between the baseline period and the intervention period, however NightWatch was found to decrease the CSI score by 0.91. The 95% confidence interval (CI) of the ICERs were €19,387 - €28,182 (£17,045 - £24,777) per QALY and €376 - €7,946 (£331 - £6,986) per CSI. There was a 72% probability that NightWatch would be cost-effective at a willingness to pay threshold of €50,000 (£43,959) per QALY.

Three sensitivity analyses tested key assumptions within the economic analysis. The first considered only healthcare costs, and found that NightWatch reduced costs by €675 (£593) compared to usual care from a healthcare perspective. The impact of the imputation method used to handle missing data was also explored. The base case analysis handled missing data with mean imputation, whereby the mean score of the non-missing data was used, however, a sensitivity analysis explored the use of individual mean imputation, where missing data was replaced by the individual mean score of a completed questionnaire at an earlier or later timepoint. This scenario found cost savings of €84 (£74) with NightWatch, but found that QALYs were reduced by 0.01, and that the CSI score was increased by 0.51, suggesting a lower quality of

life and more stress for caregivers under this assumption. The final sensitivity analysis explored excluding all missing data from the analysis. In this case, NightWatch saved €178 (£156), but QALYs were reduced by 0.02 and the CSI score was increased by 0.96. These results highlight that the method used to handle missing data has a significant impact on conclusions of the analysis, as neither of the scenarios which explored assumptions around missing data resulted in a cost-effective ICER.

A general limitation of the study was that quality of life and stress was only measured on caregivers, despite seizure-detection devices being used on children. A measure of their quality of life was not collected within the study.

The study did not include device costs in their economic analysis as devices had been supplied free of charge from the manufacturer. The total cost of NightWatch is provided in the study as around €1,500 (£1,319). If this full cost had been included within the economic analysis, NightWatch would not have been a cost saving intervention. However, assuming a monthly cost of NightWatch of €62.50 (£55), gives a cost of €125 (£110) for the two month study period. If this had been included within the analysis, cost savings would have been reduced to only €650 (£571) per patient with NightWatch.

The economic analysis was performed on results of the PROMISE trial, which is associated with a number of limitations. The study had a pre-post study design, and so any outcomes cannot be assumed to be as a result of intervention due to other confounding factors. There was a short time horizon of only two months in the baseline period, and two months in the intervention period. It is unclear whether the full costs associated with seizures would have been able to be captured in this time frame. There was a small sample size available for inclusion in the economic analysis, with only 41 children included. Finally, a high drop out rate was reported after the intervention period, with 37% of participants being lost to follow up.

Table 10 – Summary of included economic studies: Engelgeer et al. (2022)

Study details	Study population and design	Data sources	Results	Quality assessment
Author and year: Engelgeer et al. (2022) **Country:** The Netherlands **Type of economic analysis:** Cost utility and cost-effectiveness analysis **Perspective:** Societal **Currency:** Euros **Price year:** 2021 **Time horizon:** 2 months **Discounting:** NA **Potential conflict of interest:** One author received research support and fees as a speaker or consultant from pharmaceutical	**Population:** 41 children from a cohort of 60 aged 4 – 16 years with at least one major nocturnal motor seizure per week, living at home and treated at a tertiary epilepsy centre in the Netherlands. **Intervention:** NightWatch – a multimodal wearable combining photoplethysmography and accelerometery to alert for nocturnal major motor seizures. **Comparator:** Usual care – no seizure-detection device **Study design** A pre-post study design whereby patients were followed for a baseline period of two months without a seizure-detection device and an intervention period of two months with a seizure-detection device at home (NightWatch). For the economic analysis, non-parametric bootstrapping (1,000 replications) tested for statistical differences in costs. ICERs were calculated using 5,000 bootstrap	**Source of baseline and effectiveness data:** Data was collected from the PROMISE study – a prospective multicentre home-based implementation study. Caregivers completed questionnaires before the baseline period, after the baseline period and after the intervention period. Caregiver quality of life was measured using EQ-5D-5L and caregiver stress was measured using CSI. **Source of resource use and cost data:** Societal costs were collected during PROMISE study using the iMTA MCQ and iMTA PCQ. Health care costs were extracted from national databases in line with the Dutch costing guidelines. Homeopathic consultation costs were sourced from the Society of Homeopathy. Cost of respite care were calculated by averaging prices of different providers. Informal care costs were calculated using shadow pricing, applying the general hourly minimum wage. Productivity losses were estimated using the friction	**Results** **Total Societal Costs** Usual Care: €3,238 (£2,847) NightWatch: €2,463 (£2,165) NightWatch saves €775 (£681) **Caregiver QALY** Usual Care: 0.90 NightWatch: 0.90 No difference with NightWatch **Caregiver Stress Index** Usual Care: 8.02 NightWatch: 7.11 NightWatch decreases CSI by 0.91 **ICER per QALY** 95% CI: €19,387 - €28,182 (£17,045 - £24,777) 72% probability of being CE at a WTP threshold of €50,000 (£43,959) **ICER per CSI** 95% CI: €376 - €7,946 (£331 - £6,986) **Sensitivity analysis** **Health care perspective only:** Probability of NightWatch being CE decreased by 2% **Health Care Costs** Usual Care: €2,911 (£2,559) NightWatch: €2,236 (£1,966) NightWatch saves €675 (£593) **Caregiver QALY** Usual Care: 0.90 NightWatch: 0.90 No difference with NightWatch **Caregiver Stress Level**	**Applicability** Partially applicable – correct intervention but from a Dutch societal perspective. **Limitations** This study has potentially serious limitations. • Quality of life was measured on caregivers only. Children's quality of life was not considered in the analysis. • No device costs were included in the analysis. Devices and equipment were provided free of charge for the purposes of the study by the manufacturer of NightWatch, LivAsured. The study states that NightWatch costs €1,500 (£1,319), meaning that cost saving conclusions could change had device costs been included. • The PROMISE trial was a pre-post study deign. Therefore, it cannot be assumed that any changes from the baseline period were due to the intervention itself as there could have been confounding factors. • Following the baseline period, there was a 5% drop out rate, which increased to 37% after the intervention period.

Study details	Study population and design	Data sources	Results	Quality assessment
companies and manufacturers. SEIN and Kempenhaeghe are receiving a percentage of revenue from the manufacturer of NightWatch, LivAssured, for the exclusive licence to implement data for commercial purposes. The Dutch Tele-Epilepsy Consortium will receive money if NightWatch is profitable.	replications. Missing data was handled by mean imputation.	cost method, based on a mean added value of the Dutch working population.	Usual Care: 8.02 NightWatch: 7.11 NightWatch decreases CSI by 0.91 **Individual mean imputation:** Probability of NightWatch being CE decreased to 46% **Total Societal Costs** Usual Care: €3,307 (£2,907) NightWatch: €3,223 (£2,834) NightWatch saves €84 (£74) **Caregiver QALY** Usual Care: 0.90 NightWatch: 0.89 NightWatch reduces QALYs by 0.01 **Caregiver Stress Level** Usual Care: 7.51 NightWatch: 8.02 NightWatch increases CSI by 0.51 **Missing data excluded:** Probability of NightWatch being CE decreased to 33% **Total Societal Costs** Usual Care: €2,504 (£2,201) NightWatch: €2,326 (£2,045) NightWatch saves €178 (£156) **Caregiver QALY** Usual Care: 0.92 NightWatch: 0.90 NightWatch reduces QALYs by 0.02 **Caregiver Stress Level** Usual Care: 7.00 NightWatch: 7.96 NightWatch increases CSI by 0.96	• The economic analysis is based on a sample size of only 41 children. • Short time horizon of only two months. It is unclear whether the full costs associated with seizures could have been captured in this time frame. • The study was not able to assess retention rate. • The study didn't measure impacts on SUDEP, visits to the emergency room or alarm fatigue. • The study didn't capture medication up-titration – an increase in seizure detection could impact epilepsy management. • Only used NightWatch and not other seizure-detection devices. • Analysis includes homeopathic consultation costs which are not applicable to a Welsh NHS perspective. • It is not clear where cost savings in the intervention period come from as no cost breakdown is provided.

Abbreviations: CE, cost-effective; CSI, Caregiver Stress Index; EQ-5D-5L, EuroQol five-dimensions questionnaire 5-level; ICER, incremental cost-effectiveness ratio; iMTA MCQ, Institute for Medical Technology Assessment Medical Consumption Questionnaire; iMTA PCQ, Institute for Medical Technology Assessment Productivity Costs Questionnaire; NA, not applicable; QALY, quality-adjusted life year; SUDEP, sudden unexpected death in epilepsy; WTP, willingness to pay.

6.2 HTW cost utility analysis

We considered developing an economic analysis to estimate the costs and outcomes of wearable and bed-based technologies to detect tonic-clonic seizures in people with epilepsy. However, it was deemed that the evidence base was insufficient to be used as the basis for an economic analysis. The following limitations were noted from the effectiveness evidence:

- The evidence consists of observational studies, and no randomised controlled trials were identified in the literature review. This study design introduces confounding bias and so any economic analysis informed by observational studies would be limited by the quality of the evidence.
- Limited evidence was identified which reported statistically significant differences between wearable and bed-based technologies, compared to standard care.
- A wide range of sensitivity was reported for wearable and bed-based technologies, varying from 11 – 100%. This range was reduced when only including wearable technologies.
- No evidence was identified to suggest that wearable and bed-based technologies have an impact on long-term outcomes. One study collected data on quality of life using the EQ-5D-5L, however, no statistically significant differences were identified between epilepsy alarms and standard care.

In lieu of an economic model, the costs of devices that are available in the UK are provided in Table 11. These costs have been identified from a commercial website (Epilepsy Alarms UK 2026), and it is not known whether NHS Wales would benefit from any discount schemes if they were to purchase devices directly. The only device which reports having a monthly subscription fee is the EpiMonitor device (standard and pro version). The standard battery life on devices is two years, with the exception of the Companion Mini and MP5v2, which report a battery life of three years. None of the technologies are rechargeable and so would need replacing at the end of their battery life.

Table 11 – Costs of wearable and bed-based technologies

Health technology	Upfront cost	12-month subscription cost*	Total 2 year cost
EpiMonitor Standard	£359	£258	**£875**
EpiMonitor Pro	£359	£497	**£1,353**
NightWatch+	£1,399	-	**£1,399**
NightWatch+ PRO	£1,499	-	**£1,499**
Epi-Care free	£1,399	-	**£1,399**
Epi-Care mobile	£1,195	-	**£1,195**
Companion Mini	£248	-	**£248**
Emfit Epilepsy Alarms**	£697	-	**£697**
MP5***	£226	-	**£226**
MP5v2***	£231	-	**£231**

All prices exclude VAT.
*Total subscription cost for a 12-month period. Subscriptions can be taken for a 6-month period but this has been excluded here due to a higher cost.
** Cost for Emfit Epilepsy alarm sourced from Care Alarms (2026a) and includes the cost of the bed sensor, PVC mat and pager.
*** Cost for MP5 devices sourced from Care Alarms (2026b)

The standard cost of video-EEG is calculated from the 2024/25 National Cost Collection data as £4,347 per year (NHS England 2026). It is therefore likely that wearable and bed-based technologies are a cheaper alternative to video-EEGs to detect tonic-clonic seizures, but that they may detect fewer seizures.

7. Organisational considerations

There is a higher prevalence of epilepsy in Wales than in England or Scotland (Epilepsy Action Cymru 2025). People with epilepsy can experience reduced access to educational opportunities, a withholding of the opportunity to obtain a driving license, and barriers to enter particular occupations (WHO 2024).

A significant number of patients with epilepsy reside in socially-deprived areas, often facing financial difficulties (Epilepsy Action Cymru 2025). These challenges contribute to poor attendance at scheduled hospital appointments, leading to delayed treatment reviews and reduced access to necessary support (Epilepsy Action Cymru 2025).

There are many devices monitoring physiological signal(s) commercially available in Wales, but most are not regulated for use as medical devices. People with epilepsy are left to explore these technologies themselves, and either self-fund them or seek funding support from their local authority or charities (Epilepsy Action 2026a).

Some experts contacted by HTW suggested that clarification is needed on who would decide which patients were eligible to receive the device. Other experts stated that it would be the patient's local Epilepsy Team, and that they would need to be trained to support the use of seizure-detection devices. Patients and carers would also need to be trained on using the devices, and experts stated that patients would need to be reviewed regularly and informed of up-to-date information on the latest most appropriate devices, as opposed to this information being provided solely by the voluntary sector. They also suggested that consideration would need to be given to digital integration with Welsh systems, and the governance around data use.

Experts noted that the devices may need to be supported by NHS clinical engineering. They reported that introduction of these devices may result in a change in the diagnosis and management of epilepsy, although it's unclear what this would look like. There may be a reduced need for diagnostics such as EEG, but also a possible increase if more seizures were recorded than expected. Hospital admissions for seizure-related injuries may reduce, but there may be increased access to patient-advice lines and patient-initiated follow up. The devices may allow for improved treatment decisions, and may reduce the need for support for carers if their stress levels decrease, but also may result in an increase in the need for support if the device has a high false-alarm rate.

Experts reported that seizure-detection devices are being used in some social care settings in Wales, although it is unclear which device(s) are being used. They noted that there would need to be a more joined-up approach between social care services, epilepsy clinics and the emergency services should these devices be recommended. Experts suggested that this more integrated approach would enable information from the epilepsy alarms to be used by social care services to support independent living as opposed to residential care or a live-in carer; and used by epilepsy clinics to support clinical decisions, and also by the emergency services to support decision making.

For those living in rural parts of Wales, long travel times to specialist services further compound inequities. Remote seizure-detection technologies have the potential to enhance safety for people living far from emergency care and to reduce reliance on frequent in-person reviews.

However, their effectiveness may be limited by rural connectivity challenges, including variable mobile coverage and broadband availability.

Intellectual disability is the most common comorbidity in children with epilepsy (30% to 40%) (WHO 2019). People with learning disabilities, older adults, and individuals with low digital confidence may require additional support to use devices safely. Some individuals with neurodevelopmental conditions may also have sensory sensitivities that make wearing devices difficult or intolerable.

For devices using PPG, signal quality can be affected by a range of physiological and environmental factors. These include lighting conditions, differing levels of skin pigmentation, skin conditions such as eczema, low skin temperature, and the presence of tattoos—all of which may impact device performance.

8. Patient, carer and family considerations

8.1 HTW and Epilepsy Action Patient and Carer Focus Group

HTW collaborated with Epilepsy Action to collect evidence on the views, experiences, perspectives and opinions of people with epilepsy on the use of seizure alarms. Epilepsy Action invited HTW to speak at a focus group. Eight people attended the online focus group on the 20 January 2026. The attendees were a mix of ages and races and were from various parts of Wales, England and Northern Ireland. Seven attendees have epilepsy themselves, and one was a parent of an adult child with epilepsy. Five attendees have tonic-clonic seizures, while the remaining attendees had forms of epilepsy that began with tonic-clonic seizures and progressed on to other forms such as multifocal epilepsy. Attendees were given five questions to consider. These questions were given to them in advance of the focus group date so they could prepare.

The aims of the focus group were:

- to gain an understanding of the needs patients have that push them towards considering epilepsy alarm devices
- the types of alarms they know about and what appeals to them
- their awareness and understanding of regulation of medical devices
- how they are currently funding access to devices

Epilepsy Action also provided a statement on their position regarding the use of epilepsy devices. This statement is included in full in section 8.4.

8.2 Focus group discussions

Two of the eight attendees had experiences of alarm devices aimed at detecting tonic-clonic seizures: one had prior experiences of using a bed/mattress alarm and another type of alarm device, the other of using an undisclosed type of alarm. Six attendees used GPS-tracking smart watches with no seizure detection technology. The remaining attendees had no experiences with devices, epilepsy specific or otherwise.

8.2.1 Quality of life impacts of epilepsy

When asked why they are interested in exploring epilepsy alarms, attendees spoke of the profoundly vulnerable situations they, and the people they care for, encounter when experiencing a seizure.

8.2.1.1 Types of epilepsy

Tonic-clonic seizures can cause a person to fall, lose consciousness and injure themselves. Other types of seizures, such as multifocal or focal impaired awareness seizures, can also cause people to engage in behaviours they are not consciously aware of. Attendees of the focus group spoke about the quickly changing nature of epilepsy, and how tonic-clonic epilepsy can rapidly change to other forms, causing them to experience a wider array of behaviours and symptoms, such as wandering and undressing. While this EAR is concerned with evidence for tonic-clonic seizures, the experiences of the attendees with other forms of epilepsy are included in this section for the following reasons: these attendees began with tonic-clonic seizures before their epilepsy evolved; they attest to the quickly changing nature of epilepsy that means that any devices they could have used while they had tonic-clonic seizures they would have continued to use as their

epilepsy developed; and because many of the benefits they see these devices providing would apply to epilepsy of various forms.

8.2.1.2 Impacts of living with epilepsy

Attendees described what happens to them during a seizure. Seizure related falls and seizures at night were two main areas of concerns discussed, as well as the sense of loss of control and loss of awareness/consciousness. Falls, such as missing a step and falling downstairs, had resulted in injury and hospital admissions for some and seizures at night were described as particularly difficult to keep track of, especially for those who sleep alone, such as children or lone adults. The loss of awareness and/or consciousness means that people with epilepsy do not know what happens to them while they are having a seizure, and this can lead to confusion and concerns such as; not knowing if they have injured themselves, not knowing how long they were seizing and not knowing what, if anything, had happened to them while in the seizure. For those whose epilepsy changed from tonic-clonic to other forms, absences during seizures are not without behaviours. These attendees described taking off their clothes in public settings when seizures hit them, changing from one set of clothes to another and wandering off when in the house and out in public. One attendee described coming out of a seizure to find herself in the back garden shed in an unrelated man's property. This shows how profoundly vulnerable people with epilepsy are when they are experiencing a seizure and contributes to a sense of loss of control that many people with epilepsy struggle with. As well as feeling vulnerable, the sense of loss of control over their own bodies can leave people with epilepsy to experience anxiety over what may happen to them during a seizure and can impact the choices they make, such as whether or not they feel safe to leave the house, to engage in social activities, as well as limiting their daily activities, such as not being safe to drive. This can cut them off from a wide range of otherwise usual life experiences. As well as anxiety, dealing with the intense vulnerability and the limitations imposed on life choices and decisions that comes with living with epilepsy can lead to a deterioration in mental, and physical, wellbeing.

> *"I used to have tonic clonic seizures, but now I have focal impaired awareness seizures. So last night, for example, I was at <redacted> and all of a sudden I took my trousers off randomly, Took my shoes off, wandering about speaking gibberish."*
>
> Attendee quote

8.2.1.3 Challenges to diagnosis and monitoring

Loss of consciousness or awareness also makes it difficult to track seizure activity. As epilepsy is a quickly changing disease with seizures that are often difficult to detect, attendees advised that they are often looking to find ways to evidence that seizures are happening to them, particularly if they have no one to help monitor seizure activity. For example, one attendee described how he would have been completely unaware he was having seizures at night if it wasn't for his wife. A need to understand how often seizures occur, how long they last and what happens to their bodies during a seizure, are a major driver in interest in epilepsy alarm devices.

> *"I used to have tonic clonic epilepsy that it was easier to detect, but I have I now have multifocal epilepsy now with this type of epilepsy, what can happen is I can just all of a sudden stop watching TV. Get up, walk and go up the stairs. And the next thing I know is my clothes have been changed and I'm in bed and I'm thinking to myself, how on Earth did this happen? One time that happened, my wife was out and I fell downstairs."*
>
> Attendee quote

8.2.2 Epilepsy alarm devices

Attendees expressed the opinion - and the hope - that epilepsy alarms have the potential to bring back a sense of control that is taken from them by their illness. They view devices as the way to address fears and anxieties and as a way of regaining access to activities and life choices previously denied to them. One attendee was a university student living away from family in student accommodation, and she spoke of the reassurances that devices can provide that make it possible for her to do something like travel away from home for university.

> *"my interest in it is like it brings back kind of like a sense of control and kind of removes that layer of fear especially because I'm a university student and like I'm away from my family, I think it's quite nice to know that if something were to happen to me that people could be alerted and that I'm not just kind of left by myself. So I think it's quite nice to then not have that fear and know that I can kind of go about and do like everyday kind of tasks without having to shift it because of the epilepsy."*
>
> *"I have a smart watch as well. Just gives me a sort of sense of some kind of control"*
>
> *"I've had seizures where I've not been able to tell people, like, I can't talk, but I'm still kind of like moving around. And you can't say I'm <redacted> and I'm having a seizure like so it could be useful to like communicate information."*
>
> Attendee quotes

Other expressed the hope that devices can provide a sense of security and a sense of being able to function without being reliant of the support and help of other people.

> *"I have recently broken up my partner moved back home. I want to move away again. However, when I have my seizures, I immediately feel like I kind of progressed to some new low and I suddenly feel like an infant and not an adult. And so I just feel like it takes away a lot of my sort of ability to be an adult. And so having some kind of alarm I think, would give me a bit more confidence in still going about and living my life independently."*
>
> Attendee quote

8.2.2.1 Type of alarms and preferred features

Attendees spoke about wanting to understand what is happening to them when in a seizure and identified devices as a possible method of gaining that understanding. They spoke of wanting devices that could record and give them information on their heart rate, bodily movements, sweat, breathing and detecting falls. As well as information for themselves, attendees also spoke of gathering this information as evidence of seizure activity to share with clinicians, who may be able to alter treatment courses, doses or decisions accordingly.

> *"knowing that my heart rate was too high at certain times of night. And then I was able to take that information to the GP and go look, this has happened and I've got something solid and you can't just say oh, it's stress or it's not a big deal, [you can say] look my heart rate was like 90 something and I've just woken up like."*
>
> Attendee quotes

One feature that was discussed at length was the use of GPS or location tracking. Knowing that their location would be accessible to a carer or to emergency services was of huge importance, particularly for people who live alone or who experience wandering behaviours during a seizure.

It would mean that help would be able to reach them, even if they were unconscious or unable to provide a location.

> *"Awareness for others as well as myself. Maybe knowledge of where I'm going because sometimes I'll end up randomly somewhere, not knowing [where]"*
>
> *"I like to see my heart rate and seeing what it's doing when I when I know I've had a seizure, I find that interesting and it kind of gives me a sense of control"*
>
> Attendee quotes

One attendee expressed interest in a devices ability to predict a seizure before it occurs, with the possibility to alert the wearer who would then be able to get themselves to a safe place before the seizure happened. The ability of a device to send alerts – predictively, but also when an event or seizure had occurred - was of significant interest. Sending alerts to a carer or parents was discussed, but there was also interest in alerts that would inform the wearer of events such as an increase in heart rate or other physical indications that a seizure had taken place, such as staying too long in the shower.

> *"Is there any way you could maybe like do things like you know like spatial awareness in the house? You could be like, oh, someone's at the top of the stairs or someone's in a shower. Or you've been there for too long. Things like that."*
>
> Attendee quote

Attendees did not wish to disclose the specific brands of devices they had used but were happy to share the type of device they have tried. Most of them had a smart watch with GPS tracking and other health monitoring. Few had tried epilepsy specific devices, but those who did had tried bed mattress alarms.

Mattress alarms were described as preferable to video monitoring for detecting night-time seizures. This was due to concerns around what activities – other than epileptic activities – would be captured and shared from the video device and concerns for the privacy of bed partners. However, the mattress alarm was described as 'cumbersome' as it would move position or become entrapped by the bed sheets during the night and require re-positioning.

> *"I just want to get clearer evidence of what is what is happening to me at night and someone could say, well, why don't you buy a camera. Obviously. I'm. I'm sleeping with somebody else and they're not happy with that type of thing."*
>
> *"[I purchased a device that] monitors movement, but it's for sleeping. That's what I used to use. But I in the end I actually gave it away, because it was just too, you know, cumbersome to use, you know, because I had to put it under underneath the sheet and sometimes it would just gather by itself, you know, and you have to re spread it and make sure it's that it would be OK. That's one of the reasons why I've moved to a smart watch."*
>
> Attendee quotes

Smart watches were described as a useful tool for GPS and location tracking, but attendees were sceptical of their usefulness in detecting actual seizure activity. Attendees expressed that they like the idea of using a device that is a watch, because watches are a normal accessory and they would be able to wear one without feeling as if they were wearing something that drew attention to them or that would make them feel like they look like someone who is unwell. Smart watches were also viewed as convenient and easy to use. There was also a sense of confusion over the best types of apps to use with smart technology and a feeling that there are a lot of potential devices and apps, but no real guidance on what to use.

"I wear a device on my wrist and again I won't name it, and I wear it all through the night, and if I have a tonic-clonic seizure in the night it doesn't pick up much. But because I it's in the night. I'd like to see something that can pick up bit better with a tonic-clonic seizure at night. At the moment, there doesn't seem to be much."

" What I like about (the) watch and I think a lot of people in terms of what type of alarm you'd like to use is it's something that everyone wears, [you look like] you're going about your everyday life and it looks just like a watch. I would like to have something that had was more epilepsy related or beneficial to me"

"You don't have to remember it as well, so you can just put it on your wrist and you don't have to think about sorting it out in the bed, turning it on, making sure you charge it. You have to remember an awful lot when [you're epileptic] we've got medications and all the rest of it to kind of negotiate, so you can just put it on and sort of leave it for, you know, whatever longer the battery lasts."

"there's so many apps on there now and I don't know which one's the best app to use"

Attendee quotes

8.2.2.2 Sources of information

Attendees spoke with surprise at the lack of information on epilepsy alarms from healthcare services. One expressed that she only 'found out' about such alarms when this focus group was advertised and questioned others on where they got their information from. Most attendees spoke of trusted information sources where they would not question the advice provided and named charities (such as Epilepsy Action) as their main source of information and support. Secondary to charities, the advice of healthcare services and NHS resources were named as a trusted source, although these were criticised as being 'unforthcoming'.

8.2.2.3 Regulation and funding

When questioned, most of the attendees admitted to being unaware of regulatory bodies for health technologies and did not research a devices regulatory status as a feature when conducting their own research into epilepsy alarms. There were conflicting views on the importance of a device's regulatory status. Some attendees expressed that they would not be put-off from a device if it did not have CE (or equivalent) marking, expressing that their need was greater than if a device is CE marked or not. Others expressed the opinion that regulation was important if they are to trust that a device is safe to use and provides reliable help or information and is worth spending their money on. As most of the attendees were using technology that isn't epilepsy specific (ie, smart watches), they expressed the opinion that regulation is less important as the features they were interested in (such as GPS tracking) would not require extensive regulation and as such they would still use them.

"Regulation is important because it gives you a sense of knowing that it's been judged within a context of things. But I think to be honest, because we do [deal with] so much, I think if I found a watch that actually served me better, that wasn't [regulated], I would probably use that."

"financially having to think about purchases and decisions like that, having CE marking I think would make a massive difference if I was going to make a purchase that maybe would seem slightly quite expensive."

"Something that has been recommended and has been checked to make sure that it works would affect whether or not I would purchase something like that, because it's very difficult sometimes to know if things are just made and hiked price wise. So CE for me would make a massive difference for my health, and with whether I purchase something."

"[Better] understanding that CE marking might mean something specific to epilepsy as well, not just like oh, this has been [regulated for] safety. Understanding what it's actually been tested for and what it'll actually do for you rather than it just being like a random [regulation] that is the same with toys. I mean, if it's the same for a toy as it is for a watch and it's not necessarily like specific to epilepsy or to me or my needs [then it wouldn't put me off buying the watch]."

Attendee quotes

Attendees confirmed that all the devices they spoke of during the focus group had been privately bought or financed. There was no indication that they had applied to local authorities to receive funding.

8.2.3 Carer and parent experiences

One attendee was a carer for her adult child and described the fear she constantly lives with surrounding her child's epilepsy. She advised that she views devices that could alarm her to her child's state as positive, as they would also have the effect of improving her own state of mind and protecting her health and her sleep.

"I'm a carer. I'm caring for my son. He's an adult now. [Epilepsy] happened when he was still younger, before he was ten. Then after that, it's been managed by the medication that he is taking. Then neurologist told me that it may come again. Now because he's an adult, he sleeps in his own bedroom, and I'm in my own bedroom [whereas] when he was younger, I never thought of needing an alarm because we were in the same room, every time the seizure was starting I was there, I would just see it at the same time and then call for emergency [help]. But now I always have a fear that it happens to him and he's in his bedroom and I don't see him and they always happen at night. It right in the middle of the night. So now I'm having this fear that if it can happen to him while he's sleeping and I wouldn't know. When I wake up, if I go to the bathroom. I always check, open his room and check if he's still sleeping. Because I'm having this fear."

Attendee quote

8.3 Statement from Epilepsy Action

Epilepsy Action provided the following statement to supplement the discussions of the focus group:

Epilepsy alarms, monitors, and other health technologies can be life saving for people with epilepsy. Epilepsy/seizure devices are one of the most common topics discussed on our helpline, and our device information pages are some of the most popular pages on our website. This is a topic that people living with epilepsy, and their families, carers and loved ones, are very interested in.

However, there is limited evidence as to how effective these devices are. People affected by epilepsy want to be able to trust devices to give an accurate reflection of the number of seizures they are having, and to alert others only when it is necessary. The published literature on this topic gives a varied view of their effectiveness in these regards. The anecdotal evidence we receive through conversations on our helpline, at our talk and support

groups, and through our peer support service, also gives a mixed, but more positive view of the effectiveness of devices. Generally our service users find them helpful and reassuring, however there are complaints of a lack of accuracy, 'false alarms', and a frustration that they generally only detect tonic clonic seizures.

The biggest complaint that we hear by far is a lack of access to these devices. There is almost always a lack of clarity over whether the NHS or social services are responsible for funding the purchase of a device, and when there is clarity, it is usually because neither organisation will fund it. There are some small charities who may provide funding for epilepsy devices in some limited circumstances, but in almost all cases, people with epilepsy have to fund the purchase themselves. Many devices cost hundreds and occasionally thousands of pounds, and sometimes have ongoing subscription costs beyond the initial purchase. This is particularly difficult for people with epilepsy to afford, due to epilepsy having the second lowest rate of employment of any disability in the UK, and a poor success rate for people with epilepsy receiving disability benefits.

People with epilepsy need easy access to reliable epilepsy/seizure devices. They also need clear guidance on how and when these devices should be used, and when other means are needed to ensure safety.

8.4 Qualitative literature

Seven studies were identified during the clinical effectiveness evidence sift as potentially relevant to patient experiences and expectations. Of these, one was based in the UK. The others were based in Europe and Canada and were excluded on this basis.

8.4.1 Patient experiences with epilepsy alarms

Simblett et al. (2020) considered patients' experiences of wearing multimodal sensor devices to detect epileptic seizures in the UK. Five wearable biosensors were given to participants to use alongside EEG and video recordings during an extended hospital stay. The devices used were the E4 devices and Everion, which were CE- or FDA-marked, and the other three were "research sensors" including a bespoke armband, Epilog, and Sensor Dots. The E4 devices are the only relevant ones to this appraisal. Each participant was asked to self-manage their devices (Simblett et al. 2020).

Patients advised that wearables are more convenient and practical than EEG monitoring (Simblett et al. 2020). Patients expressed a preference for discrete wearables. Armband sensors were the more practical and sensors that stuck to the head often fell off, particularly when sleeping. Wearables that required additional wires/electrodes were described as cumbersome and interfered with daily tasks and personal hygiene, but all the wearables were comfortable for sleeping. There was a general preference for wrist and arm devices over flexible position devices. Patients were happy with the data collection and sharing that devices would perform, although one had some concerns over the sharing of information such as location. When asked about wearing these devices at home, patients expressed that the arm and wrist bands would be beneficial, as these look more like other smart tech. They spoke of needing the support of relatives and families to use devices at home, and of the concern that some people may be excluded from the benefits of wearables if they are less tech savvy (Simblett et al. 2020).

8.5 Expert review

Experts contacted by HTW highlighted that many people with epilepsy value seizure-detection devices despite limited evidence of effectiveness. They suggested that this is due to the increased sense of security for those living alone with epilepsy, the potential for a reduction in caregiver concern and stress, and the potential for a reduction in seizure-related injuries. Experts reported that whilst benefits of seizure-detection devices may include increased independence and reassurance for patients and carers, risks may arise from false positives, false negatives, potential over-reliance, and stigma for some users. Some experts reported that devices with a high false-activation rate may reduce carer quality of life by enhancing anxiety about the disorder. Other experts suggested that use of these devices could result in a reduction in the need for medication or additional support for the carer if their levels of stress decreased.

Experts suggested that when considering the value of any seizure-detection device, the carer or person with epilepsy should carefully consider which adverse outcome they wish to avoid and whether the device can plausibly address that concern.

8.6 Equality, diversity and equity considerations

From the focus group discussions and the evidence within the clinical effectiveness sift, epilepsy alarms may show benefit for people who live alone, students, children and people with additional needs (physical and mental).

People with learning disabilities, older adults, and individuals with low digital confidence may require additional support to use devices safely. Some individuals with neurodevelopmental conditions may also have sensory sensitivities that make wearing devices difficult or intolerable. In the literature search for evidence of clinical effectiveness, we identified two studies including adults and children with epilepsy and learning disabilities, who wore a multimodal (ACM and PPG) armband (Arends et al. 2018, van Westrhenen et al. 2023). One of these studies reported a sensitivity of 81% and a false-alarm rate of 0.03 per night, in 34 adults and children in a residential-care setting, similar to studies including people without intellectual disabilities (Arends et al. 2018). However, in the study by van Westrhenen et al. (2023), it was reported that children with learning disabilities were significantly more likely to exhibit higher false-alarm rates than those without (0.05 per hour versus 0.02 per hour), but the sensitivity did not vary.

The study by Arends et al. (2018), of 20 adults and children with major seizures (including GTCS) and intellectual disability, reported that mean user-friendliness of a multimodal armband seizure-detection alarm was rated at 7.3 out of 10 (with lower scores indicating poorer usability). Of the eight people who experienced skin irritation due to the device, or tightness of the device, all cases were resolved by adjusting the strap or sensor (Arends et al. 2018).

No data were identified assessing the impact of skin pigmentation on PPG-based epilepsy alarms. One study reported that they originally defined skin pigmentation as an exclusion criterion, as they assumed that the light-based PPG signal would be less reliable through pigmented skin (van Westrhenen et al. 2023). However, the authors of the study then went on to say that after validating the PPG-based device on pigmented skin, they discovered that the PPG method worked reliably on all types of skin pigmentation, so they abandoned it as an exclusion criterion after 42 included children (a total of 53 children were included in the study). Data were not reported separately for different skin pigmentations (van Westrhenen et al. 2023).

9. Conclusions

This evidence review summarised published evidence on the effectiveness and cost effectiveness of wearable or bed-based technologies for the detection of tonic-clonic seizures in people with epilepsy.

The literature search identified 12 single-arm observational studies in two systematic reviews by Komal et al. (2024) and Meritam Larsen & Beniczky (2023), and an additional single-arm observational study published after the systematic reviews (Jahani et al. 2026).

The evidence included in this review suggests that unimodal- and multimodal-ACM wristbands and armbands, and piezoelectric under-mattress sensors have a high sensitivity and low false-alarm rates. Older under-mattress movement sensors often had lower sensitivity and a higher number of false-alarms. In general, there is a trade-off between sensitivity and the false-positive rate, with false alarms increasing with increasing sensitivity. Estimates of the positive predictive value suggest that around half of the alarms from the multimodal armbands and wristbands are true seizures. The real-world accuracy and long-term effectiveness of these devices is uncertain.

Evidence on patient-centred outcomes was limited: no mortality data were found, and only two caregiver-reported studies suggested a reduction in seizure-related injuries. A multimodal armband significantly reduced caregiver stress, but their stress-levels were assessed as being high even with the device, and caregiver quality of life and sleep did not significantly improve. Limited quality-of-life evidence was found for the patients themselves. Wearability problems, mainly mild skin irritation or tightness, were uncommon and typically resolved with strap or sensor adjustments.

One study was identified that assessed the cost-effectiveness of wearable technologies for the detection of tonic-clonic seizures in people with epilepsy. The analysis was conducted on data from the PROMISE trial, which evaluated the use of Nightwatch in children living at home. Base case results demonstrated that Nightwatch was cost-effective with a 95% confidence interval of the incremental cost effectiveness ratio of €19,387 - €28,182 (£17,045 - £24,777) per QALY. This analysis was associated with potentially serious limitations, being limited mostly by the study design of the PROMISE trial. However, it was deemed that there was an insufficient evidence base to develop an economic model to evaluate the cost-effectiveness of wearable or bed-based technologies from the Welsh perspective. Costs from commercial websites and calculations from the National Schedule of Reference Costs suggest that wearable and bed-based technologies are a cheaper alternative to video-EEGs to detect tonic-clonic seizures, but they may detect fewer seizures.

Experts raised some potential organisational issues to consider, including training requirements; digital integration with Welsh systems and governance around data use; and a more joined-up approach between social care, epilepsy clinics and the emergency services. They suggested that this may result in a change in the diagnosis and management of epilepsy, either increasing or decreasing the need for intervention from epilepsy specialists and diagnostics such as EEG.

Experts contacted by HTW, and a Focus Group conducted by HTW and Epilepsy Action reported that many people with epilepsy value these devices despite limited evidence of effectiveness. This appears to be due to the increased sense of security for those living alone with epilepsy, the potential for a reduction in caregiver concern and stress, and the potential for a reduction in seizure-related injuries.

10. Contributors

This topic was proposed by Dr Joseph Anderson, Consultant Neurologist, Aneurin Bevan University Health Board.

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The HTW Assessment Group advised on methodology throughout the scoping and development of the report.

We are grateful to the following subject experts, who also contributed to this appraisal:

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Subject experts contributed to this appraisal by commenting on a draft of this report, and in some cases providing other advice to HTW's staff and decision-making groups. All contributions from reviewers were considered by HTW's Assessment Group and actioned accordingly. However, subject experts had no role in authorship or editorial control, and the views expressed are those of Health Technology Wales.

We are grateful to Epilepsy Action and the attendees of the PPI Focus Group who provided their views, experiences, perspectives and opinions of epilepsy and the use of seizure alarms, all of which were included in this EAR.

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Appendix 1 – Evidence review methods

We searched for evidence that could be used to answer the review question: What is the clinical and cost effectiveness of wearable or bed-based technologies for the detection of tonic-clonic seizures in people with epilepsy?

The criteria used to select evidence for the appraisal are outlined in Appendix 2. These criteria were developed following comments from the Health Technology Wales (HTW) Assessment Group and UK experts.

The systematic search followed HTW's standard rapid review methodology. A search was undertaken of Medline, Embase, CINAHL, KSR Evidence, Cochrane Library, and the International Network of Agencies for Health Technology Assessment (INAHTA) HTA database. Additionally, searches were conducted of key websites and clinical trials registries. The searches were carried out in November 2025 with an update search of Medline, Embase, CINAHL, KSR Evidence, Cochrane Library, and INAHTA HTA database conducted on 31 March 2026. At the same time as the update search, forward citation searching of the included studies used within this review was conducted in Scopus.

Appendix 3 gives details of the search strategy used for Medline. Search strategies for other databases are available on request.

Appendix 4 (i.e., the PRISMA diagram) summarises the selection of articles for inclusion in the review.

Appendix 2 – Inclusion and exclusion criteria for evidence included in the review

	Inclusion criteria	Exclusion criteria
Population	Adults and children who experience tonic-clonic seizures	• Neonates • Epilepsy Monitoring Units
Intervention	MHRA registered and CE/UKCA marked (e.g. EpiMonitor, Epi-Care, Nightwatch): • Wearable devices used to detect tonic-clonic seizures • Bed/mattress/sheet alarms used to detect tonic-clonic seizures	• Devices that are only available in a hospital setting • Devices that use video/audio alone (e.g. Nelli) • Devices that detect other types of seizures • Wearable EEG devices/devices fitted by specialists in a hospital setting
Comparison/ Comparators	Observation / video-EEG (note: diagnostic accuracy studies may be conducted in in-patient setting with devices that are designed for at-home use). Standard of care	
Outcome measures	Diagnostic accuracy Seizure-related injury Seizure-related mortality Health related quality of life Patient-reported outcomes (e.g. ease of use, comfort, retention rates, patient-reported seizure management) Resource use Economic outcomes	
Study design	We will prioritise the following study types, in the order listed: • Systematic reviews of randomised controlled trials or diagnostic test-accuracy studies. • Randomised controlled trials. • Diagnostic test-accuracy studies • Non-randomised comparative trials. • Single-arm (no control group) trials that report any relevant outcome. We will only include evidence from "lower priority" sources where this is not reported by a "higher priority" source. This could be because higher priority evidence: • Does not cover all relevant populations • Does not compare the technology of interest to all relevant comparators • Does not cover all outcomes of interest • Reports over short-term follow up periods and longer follow up data is required to facilitate decision making.	

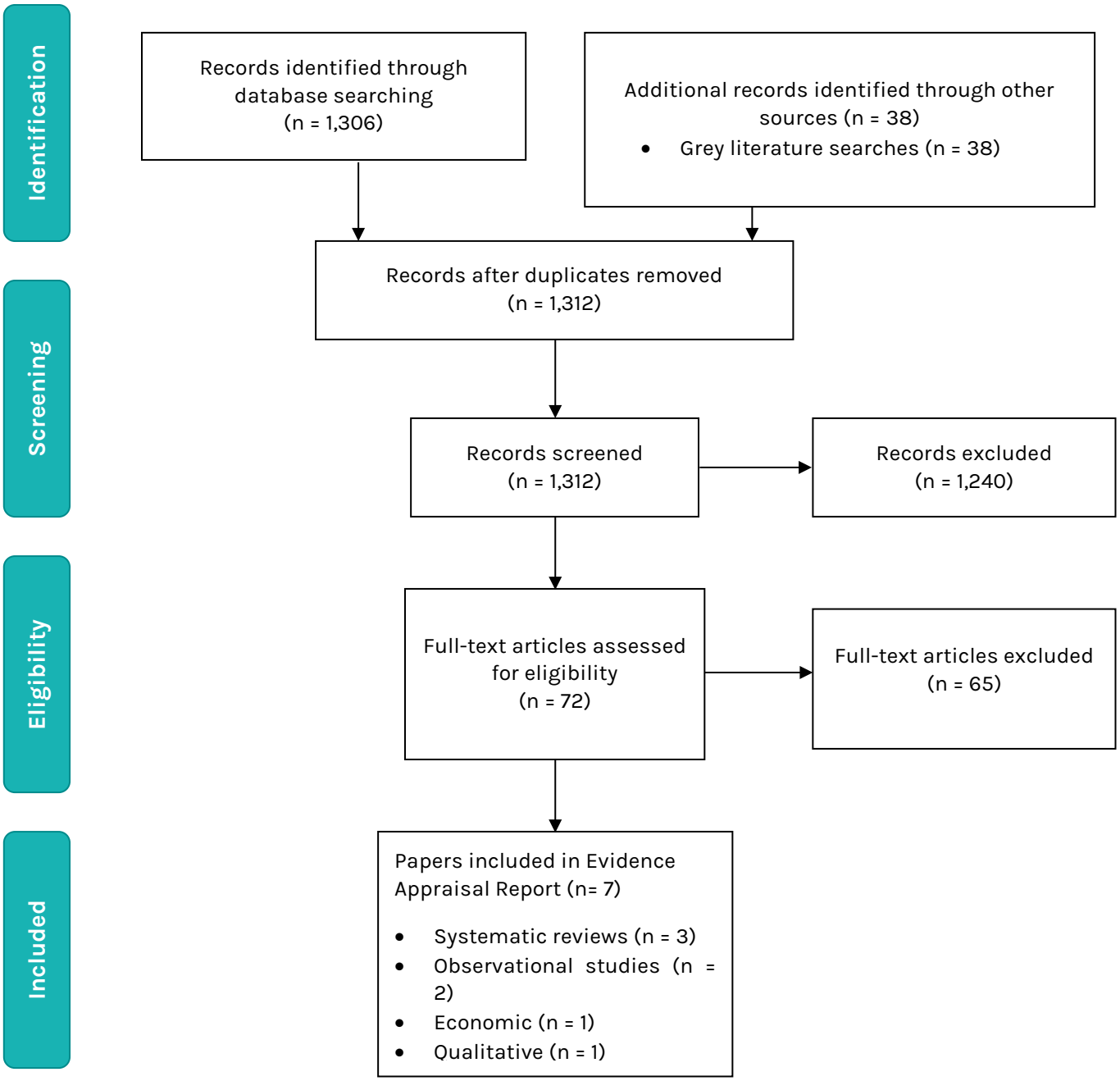
	Inclusion criteria	Exclusion criteria
	Where relevant and well-conducted systematic reviews exist, we will use these by: • Reporting or adapting their reported outcome measures where these are fully relevant to the scope of our review, and appropriate synthesis methods have been used • Using these reviews as a source of potentially relevant studies where the review cannot be used as a source of outcome data We will prioritise systematic reviews in terms of the sources of evidence they include, using the order described above.	
Search limits	No date limits apply English language only	
Subgroup analysis	Where the evidence allows, we will report outcomes separately according to list any factors identified as potentially influential on outcomes such as: • Type of alarm (i.e. wearable technologies or bed/mattress alarms) • Setting (i.e. patients who live alone, sleep alone, or live in a care environment such as a nursing home/sheltered-living accommodation, hospital inpatients) • Patient age (older adults, adults, children)	

Appendix 3 – Medline strategy

Ovid MEDLINE(R) ALL 1946 to March 31, 2026		
Epilepsy		
1	exp Epilepsy/	136814
2	Seizures/	68296
3	exp Status Epilepticus/	10579
4	(epilep* or convuls* or seizure*).tw,kf.	281373
5	1 or 2 or 3 or 4	309596
Monitoring		
6	"Neurophysiological Monitoring"/	691
7	Electromyography/	89932
8	Accelerometry/	9684
9	Biometry/	30045
10	Monitoring, Physiologic/	61611
11	Monitoring, Ambulatory/	8889
12	Telemetry/	10494
13	(electromyogra* or electro-myogra* or EMG* or sEMG* or acceleromet* or biometr* or telemetr* or tele-metr*).tw,kf.	140681
14	(monitoring or tracking).kf.	89180
15	Galvanic Skin Response/	9329
16	((electro-dermal* or electrodermal* or electro dermal* or EDA) adj3 (activit* or conductivit* or device* or measure* or parameter* or response* or sensor*)).tw,kf.	3223
17	Heart Rate/	184717
18	((heart-rate or heart rate) adj3 (varia* or chang* or monitor* or track*)).tw,kf.	48336
19	(biosensor* or bio-sensor* or biosignal* or bio-signal*).tw,kf.	62602
20	6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 or 14 or 15 or 16 or 17 or 18 or 19	616776
Wearables/technology		
21	exp Wearable Electronic Devices/	26255
22	((wearable* or headband or head-band or movement) adj3 (alarm* or application* or detect* or device* or monitor* or record* or sensor* or system* or technolog* or tool*)).tw,kf.	46446
23	wearable*.kf.	14469
24	Wrist/	11633
25	(wrist* adj3 (alarm* or application* or detect* or device* or monitor* or record* or sensor* or system* or technolog* or tool*)).tw,kf.	3930
26	(wrist* adj3 band*).tw,kf.	195
27	Cell Phone/	10677
28	Smartphone/	13032
29	Mobile Applications/	16904
30	Remote Sensing Technology/	5222
31	((phone* or smartphone* or smart-phone* or biosens* or mobile or remote) adj3 (alarm* or application* or detect* or device* or monitor* or record* or sensor* or system* or technolog* or tool*)).tw,kf.	88265
32	(smart-watch* or smartwatch* or smart watch*).tw,kf.	2441
33	((SMS* or short* messag* service*) adj7 (alarm* or notif*)).tw,kf.	112
34	Geographic Information Systems/	10499
35	((global position* system* or GPS*) adj3 (coordinate* or co-ordinate* or device* or locator* or track*)).tw,kf.	2332
36	(global* and GPS*).tw,kf.	4152
37	Wireless Technology/	5638
38	((portable or wireless*) adj3 (alarm* or application* or detect* or device* or monitor* or record* or sensor* or system* or technolog* or tool*)).tw,kf.	33851
39	Beds/ or "Bedding and Linens"/	8487

40	((bed or bedsheet or bed-sheet or mattress or sheet or under-mattress) adj3 (alarm* or application* or detect* or device* or monitor* or record* or sensor* or system* or technolog* or tool*)).tw,kf.	5552
41	*Home Care Services/	28565
42	((at-home or homebased or home-based or in-home) adj3 (alarm* or application* or detect* or device* or monitor* or record* or sensor* or system* or technolog* or tool*)).tw,kf.	6024
43	21 or 22 or 23 or 24 or 25 or 26 or 27 or 28 or 29 or 30 or 31 or 32 or 33 or 34 or 35 or 36 or 37 or 38 or 39 or 40 or 41 or 42	272498
Set combination – epilepsy AND monitoring AND wearables/technology		
44	5 and 20 and 43	488
Seizure detection devices including brand names		
45	(exp *Epilepsy/ or *Seizures/) and wearable*.tw,kf.	312
46	(wearable* adj3 (seizure detect* or seizure monitor*)).tw,kf.	90
47	((tonic* or clonic*) adj3 (seizure detect* or seizure monitor*)).tw,kf.	11
48	(seizure* detect* device* or seizure* monitor* device*).tw,kf.	122
49	(seizure* alarm* or seizure detector* or seizure track*).tw,kf.	155
50	(remote adj2 measure* adj2 technolog*).tw,kf.	52
51	(Emfit or Empatica* or Epi-Care* or Epihunter* or EpiMonitor* or EpiWatch* or Nightwatch* or PulseGuard or SeizAlarm or Seizure Link).mp.	301
52	5 and (50 or 51)	50
Final set combination including limits		
53	44 or 45 or 46 or 47 or 48 or 49 or 52	875
54	limit 53 to english language	858
55	exp Animals/ not Humans/	5441203
56	(baboon*1 or bovine*1 or canine*1 or cat*1 or chimpanzee*1 or cow*1 or dog*1 or feline*1 or goat*1 or hens or macque*1 or mice or monkey*1 or (mouse adj2 model*1) or murine*1 or ovine or pig*1 or porcine or (non-human adj2 primate*1) or sheep or rabbit*1 or rat or rats or rattus or rhesus or rodent*1 or zebrafish).ti.	2303716
57	Disease Models, Animal/	452068
58	55 or 56 or 57	6011597
59	54 not 58	811

Appendix 4 – Flow diagram outlining selection of relevant evidence sources



Appendix 5 – Full sources of evidence and outcome data

Table A1 – Included systematic reviews: design and characteristics

Review	Search period	Eligibility criteria	Trial/patient characteristics	Outcome measures	Comments
Komal et al. (2024)	2015 to 2023	Inclusion criteria: - Seizure-detection device - Non-invasive input modality - Device performance (sensitivity and FAR) - Marketed/commercially available devices - Assessment of remote monitoring device Exclusion criteria: - Invasive methods - Surgery or implanted methods - Comparison between psychogenic non-epileptic seizures and epilepsy - Underdeveloped research-based prototype - Simulation-based research	10 observational studies included: Arends et al. (2018), Beniczky et al. (2013), Carlson et al. (2009), Fulton et al. (2013), Lazeron et al. (2022), Meritam et al. (2018), Narechania et al. (2013), Nouboue et al. (2023), Onorati et al. (2017), van Westrhenen et al. (2023) 364 participants with epilepsy (mainly GTCS and FBTCS) - Adult participants: 2 studies (Narechania et al. 2013, Nouboue et al. 2023) - Children: 4 studies (Carlson et al. 2009, Fulton et al. 2013, Lazeron et al. 2022, van Westrhenen et al. 2023) - Adults and children: (Arends et al. 2018, Beniczky et al. 2013, Meritam et al. 2018, Onorati et al. 2017) - 2 comparative-observational studies: NightWatch vs. Emfit (Arends et al. 2018) MP5 vs. ST-2 (Medpage) (Fulton et al. 2013) - 8 non-comparative observational studies (Beniczky et al. 2021, Carlson et al. 2009, Lazeron et al. 2022, Meritam et al. 2018, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2017, van Westrhenen et al. 2023) - 8 prospective observational studies (Arends et al. 2018, Beniczky et al. 2013, Carlson et al. 2009, Fulton et al. 2013, Lazeron et al. 2022, Meritam et al. 2018, Narechania et al. 2013, van Westrhenen et al. 2023) - 2 retrospective observational studies (Nouboue et al. 2023, Onorati et al. 2017)	- Diagnostic accuracy (sensitivity and FAR) - Patient-reported outcomes (e.g. usability, wearability)	- Using the GRADE method, the SR by Beniczky et al. (2021) assessed the primary studies by Arends et al. (2018) and Beniczky et al. (2013) as high quality. The certainty of the other studies was not assessed. - Some studies in the SR were excluded from this report because the device is not relevant to this appraisal. - The proportion of adults and children in each study NR in the SR, so we reported the proportion by going into the primary studies. - The reference standards were NR in the SR, so we reported it using the primary studies. - Data from the comparative observational studies (Arends et al. 2018, Fulton et al. 2013) NR in the SR - 1 of the studies (Meritam et al. 2018) did not report the number of seizures as it was an infield study. - The study by Fulton et al. (2013) included 2 devices (1 with evidence of regulatory approval [MP5] and 1 without evidence of regulatory approval [ST-2]). The SR reports data from both devices, but we only included data from MP5. Additionally, this study included children with TCS and other types

Review	Search period	Eligibility criteria	Trial/patient characteristics	Outcome measures	Comments
			Range of recording length: 2 months to 15 months (median time) Range of detection latency: 5 seconds to 151 seconds Devices used: - Armband (Nightwatch): 3 studies (Arends et al. 2018, Lazeron et al. 2022, van Westrhenen et al. 2023) - Bed mattress (Emfit): 2 studies (Narechania et al. 2013, Nouboue et al. 2023) - Bed mattress (MP5): 2 studies (Carlson et al. 2009, Fulton et al. 2013) - Wristwatch (Epi-Care): 2 studies (Beniczky et al. 2013, Meritam et al. 2018) - Wristwatch (Embrace): 1 study (Onorati et al. 2017) Modalities of devices: - ACM: 2 studies (Beniczky et al. 2013, Meritam et al. 2018) - ACM and EDA: 1 study (Onorati et al. 2017) - ACM and PPG: 3 studies (Arends et al. 2018, Lazeron et al. 2022, van Westrhenen et al. 2023) - Movement: 4 studies (Fulton et al. 2013, Carlson et al. 2009, Narechania et al. 2013, Nouboue et al. 2023) Reference standard: - Video-EEG: 6 studies (Beniczky et al. 2013, Carlson et al. 2009, Fulton et al. 2013, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2017) - Video recordings without EEG: 3 studies (Arends et al. 2018, Lazeron et al. 2022, van Westrhenen et al. 2023) - Account provided by patients and caregivers: 1 study (Meritam et al. 2018) Setting: - Home: 2 studies (Meritam et al. 2018, van Westrhenen et al. 2023)		of seizures, and all data were reported in the SR. We have only reported data from children with TCS in the study by Fulton et al. (2013). - The number of participants and seizures in the study by Carlson et al. (2009) were NR in the SR, so we included the figures from the primary study. - Device detection latency NR in some studies (Arends et al. 2018, Carlson et al. 2009, Fulton et al. 2013, Meritam et al. 2018, van Westrhenen et al. 2023) - FAR NR in 1 study (Fulton et al. 2013) - It is unclear what cut-offs are considered high/low FARs. - Different studies reported false-alarm rates using different time units (per hour, per night, or per day), which limited direct comparability across studies. - QoL based on self-reported Likert-scale ratings, and non-pre-post analysis was performed using a validated QoL instrument. - The 'overall' results also included 2 patients (0.83%) who used Seizurelink. We were unable to confirm whether this device has appropriate regulatory approval for use in NHS Wales - Outcomes relied on patient and caregiver reporting, introducing potential recall and selection bias

Review	Search period	Eligibility criteria	Trial/patient characteristics	Outcome measures	Comments
			- Residential care: 1 study (Arends et al. 2018) - Residential care or home: 1 study (Lazeron et al. 2022) - EMU: 6 studies (Beniczky et al. 2013, Carlson et al. 2009, Fulton et al. 2013, Narechania et al. 2013, Nouboue et al. 2023, Onorati et al. 2017)		
Meritam Larsen & Beniczky (2023)	October 2019 to August 2023	Inclusion criteria: - Children and adults with epilepsy who are not seizure-free - Patients experiencing GTCS or FBTCS - Use of non-invasive wearable devices providing automated, real-time seizure detection - Devices that have undergone clinical validation using expert-confirmed seizures (e.g. video-EEG or video review) - Use in outpatient or ambulatory settings Exclusion criteria: - Seizure types other than GTCS or FBTCS (e.g. absence, myoclonic without tonic-clonic component, focal aware seizures, PNES) - Seizure-free patients - Use of wearable devices as a stand-alone diagnostic tool	4 observational studies by Hadady et al. (2023), Meritam et al. (2018), Onorati et al. (2021), van Westrhenen et al. (2023) 518 adults and children with TCS 588 TCS seizures occurred Setting: - EMU: 1 study (Onorati et al. 2021) - Home: 3 studies (Hadady et al. 2023, Meritam et al. 2018, Onorati et al. 2021) Device: - Wristwatch (Embrace): 2 studies (Hadady et al. 2023, Onorati et al. 2021) - Wristwatch (Epi-Care): 2 studies (Hadady et al. 2023, Meritam et al. 2018) - Armband (NightWatch): 2 studies (Hadady et al. 2023, van Westrhenen et al. 2023) Modalities of devices: - ACM: 2 studies (Hadady et al. 2023, Meritam et al. 2018) - ACM and EDA: 2 studies (Hadady et al. 2023, Onorati et al. 2021) - ACM and PPG: 2 studies (Hadady et al. 2023, van Westrhenen et al. 2023) Time using device: 2 to 15 months	- Diagnostic accuracy (sensitivity and FAR) - Seizure-related injuries - Quality of life	- This SR was an update of the SR by Beniczky et al. (2021) - According to ILAE and IFCN standards for testing and validation for seizure detection devices, this study was assessed as being high-level evidence - Proportion of adults and children NR in the SR - Recording length NR in the SR, so it was obtained from the primary studies - Number of seizures NR for 2 of the studies - According to ILAE and IFCN standards for testing and validation for seizure detection devices, these studies were assessed as being high-level evidence - Outcomes relied on patient and caregiver report, introducing potential recall and selection bias - In 1 study, the intervention combined NightWatch with video/audio monitoring - Online questionnaires were fully completed by 47% of caregivers in 1 study

Review	Search period	Eligibility criteria	Trial/patient characteristics	Outcome measures	Comments
		- Devices without clinical validation or relying solely on offline analysis - Closed-loop systems triggering therapeutic interventions			

Abbreviations: ACM, accelerometer; EDA, electrodermal activity; EEG, electroencephalography; EMU, epilepsy monitoring unit; FAR, false-alarm rate; FBTCS, focal-to-bilateral tonic-clonic seizures; GRADE, Grading of Recommendations, Assessment, Development and Evaluation; GTCS, generalised tonic-clonic seizures; IFCN, International Federation of Clinical Neurophysiology; ILAE, International League Against Epilepsy; NR, not reported; PPG, photoplethysmography; SR, systematic review; TCS, tonic-clonic seizure; vs, versus

Table A2 – Included primary studies: design and characteristics

Study	Time period	Trial/patient characteristics	Outcome measures	Comments
Jahani et al. (2026)	April 2024 to June 2025	- Prospective observational study over 373 monitoring days - Eligible participants were admitted for continuous video-EEG monitoring at the EMU for at least 48 hours - 72 adults with GTCS, FBTCS or focal seizures (14 people had 15 FBTCS and 1 person had 1 GTCS). - EMU setting in Canada - Female: 57% - Age: 39 years (average); 19 to 81 years (range) - 85% (n = 62) underwent medication withdrawal during their monitoring period - Recording length: 5.1 days per patient (average) with a range of 2 to 16 days - Detection latency for FBTCS: 80 seconds (median) with a range of 45 to 480 seconds - Detection latency for GTCS: 25 seconds - ACM and EDA wristwatch (Embrace2) - Reference standard: Video-EEG	- Diagnostic accuracy (sensitivity and FAR) - Seizure-related injuries - Usability - Resource use	- A total of 18 FBTCS and 1 GTCS seizure occurred: 3 of these occurred when the patient was not wearing the device - 1 patient had a detection latency of 480 seconds due to an initially subtle seizure onset, which was not clinically recognised until secondary generalisation - None of the 510 focal seizures were detected - All seizures recorded during the monitoring period were the patient's typical seizures - Most people had no reported seizures during their time at the EMU

Abbreviations: ACM, accelerometer; EDA, electrodermal activity; EEG, electroencephalography; EMU, epilepsy monitoring unit; FAR, false-alarm rate; FBTCS, focal-to-bilateral tonic-clonic seizures; GTCS, generalised tonic-clonic seizures