



# Performance, impact and experiences of using wearable devices for seizure detection in community-based settings: a mixed methods systematic review

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**Background:** There is growing scientific evidence that wearable devices for seizure detection (WDD) perform well in controlled environments. However, their impact on the health and experience of patients with epilepsy (PWE) in community-based settings is less documented. We aimed to synthesize the scientific evidence about the performance of wearable devices used by PWE in community-based settings, and their impact on health outcomes and patient experience.

**Methods:** We performed a mixed methods systematic review. We performed searches in PubMed, Google Scholar, Web of Science and Embase from inception until December 2022. Independent reviewers checked studies published in English for eligibility based on predefined inclusion and exclusion criteria. We collected information about studies, wearable devices, their performance, and their impact on health outcomes and patient experience. We used a narrative method to synthesize separately data for each question. We assessed the quality of included studies with the QUADAS-C and MMAT tools.

**Results:** On a total of 9,595 publications, 10 studies met our eligibility criteria. Study populations included mostly PWE who were young ( $\leq 18$  years) and/or their caregivers. Participants were living at home in most studies. Accelerometer was the wearable device mostly used for seizure detection. Wearable device performance was high (sensitivity  $\geq 80\%$  and false alarm rate  $\leq 1/\text{day}$ ), but some concerns remained due to false alarms according to qualitative studies. There was no significant effect of wearable device on quality of life (QoL) measures and no study reported quantitatively other health outcomes. Qualitative studies reported positive effect of wearable devices on QoL, seizure management and seizure-related injuries. Overall, patients reported that the device, especially the accelerometer, was suitable, but when the device was too visible, they found it uncomfortable. Study quality was low to medium.

**Conclusions:** There is low quality scientific evidence supporting the performance of WDD in a home environment. Although qualitative findings support the positive impacts of wearable devices for patients and caregivers, more quantitative studies are needed to assess their impact on health outcomes such as QoL and seizure-related injuries.

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**Keywords:** Wearable; technology; epilepsy; community health

Received: 08 February 2024; Accepted: 05 June 2024; Published online: 12 July 2024.

doi: 10.21037/mhealth-24-7

View this article at: <https://dx.doi.org/10.21037/mhealth-24-7>

## Introduction

### Background

More than 50 million people live with epilepsy worldwide (1), with 30% presenting resistance to antiseizure medications (2). Seizures are associated with an increased risk of morbidity (e.g., burns, falls, dislocations, fractures and cerebral sequelae etc.) and mortality (e.g., sudden unexpected death in epilepsy) (3,4). These consequences are exacerbated by uncontrolled seizures and unsupervised environments, especially in home and in workplace settings (5).

Methods based on seizure self-reporting by patients or caregivers are often unreliable to optimize epilepsy management (6-10). Wearable devices for seizure detection (WDD) are mobile technological devices gathering biophysical signals during seizures to trigger alarms for patients or caregivers (11). These devices could improve safety, clinical management, self-management and quality of life (QoL) for patients with epilepsy (PWE). To achieve these outcomes, seizure detection devices should be

accurate. Also, they should be acceptable and efficient for PWE (12).

### Rationale and knowledge gap

There is some evidence that WDD can accurately identify generalized and focal-to-bilateral tonic-clonic seizures with high sensitivity and low false alarm rate (13-17). However, most diagnostic accuracy studies were conducted in inpatient settings (epilepsy monitoring units), limiting the safe transferability of results to outpatient settings (home and workplace). Research orientations from previous reviews suggest a focus on the performance assessment in outpatient settings (12,15,17). Previous reviews also lack report of WDD acceptability for PWE and caregivers, and their impact on health outcomes such as QoL, clinical management and self-management (12,14).

### Objective

This systematic review aims to report the scientific evidence on: (I) performance of WDD to detect seizures in community-based settings (home, workplace and residential care setting); (II) impact of using WDD on health-related outcomes (QoL, seizure management, medication adherence and mortality), and (III) patient experience of using WDD. This review addressed outcomes that could inform evidence-based healthcare on epilepsy management at home for PWE and their informal caregivers, nurses, medical practitioners and policy makers according the FAME (Feasibility, Appropriateness, Meaningfulness and Effectiveness) scale proposed by Pearson *et al.* (18). We present this article in accordance with the PRISMA reporting checklist (available at <https://mhealth.amegroups.com/article/view/10.21037/mhealth-24-7/rc>) (19).

### Methods

This systematic review follows the mixed methods systematic review approach (20,21). This protocol was registered on PROSPERO (Prospective Register of Systematic Reviews)

### Highlight box

#### Key findings

- Accelerometers performed well (sensitivity  $\geq 80\%$  and false alarm rate  $\leq 1/\text{day}$ ), at home among young patients with epilepsy in community-based settings.
- Patients felt uncomfortable and on spotlight when the device was too visible.

#### What is known and what is new?

- Wearable devices for seizure detection have high performance in inpatient settings. There is a gap of evidence on their performance, effect on health outcomes, and acceptability in outpatient and community-based settings.
- This systematic review provides evidence that wearable devices for seizure detection, especially accelerometers, perform well in community-based settings.

#### What is the implication, and what should change now?

- Further research were needed to examine the effect of wearable devices on health outcomes.
- Wearable devices' developers must pay attention to their usability.

before the selection step (CRD42020129787).

### *Eligibility criteria*

#### **Population**

All studies about PWE were included in this review. Patients with acute seizures (i.e., related to an acute brain insult such as encephalitis, toxic-metabolic encephalopathies etc.) were excluded.

#### **Intervention**

WDD was the targeted intervention. The types of WDD were those already available on the market and validated in inpatient settings [accelerometer, electrodermal sensor, electrocardiogram (ECG), electroencephalogram (EEG), electromyogram (EMG), photoplethysmography, sound detection sensors, under-mattress device, blood oxygenation sensors, and multimodal sensors] (13-15).

#### **Comparator**

Patients in comparator group could receive inpatient or outpatient conventional video/EEG or usual care.

#### **Outcomes**

Three domains of outcomes were considered in this review: (I) performance of the device (sensitivity and false alarm rates); (II) impact of the device on health outcomes (QoL, clinical and self-management); and (III) patient experience about the device (perception, opinion and other experiences related to the use of WDD).

#### **Type of studies**

All empirical studies (quantitative, qualitative, mixed methods) performed in community-based settings were considered in this review. Studies from database creation up to 31 December 2022 were included. Only studies published in English were included. Editorials, comments, letters to the editor and technical memo were excluded.

### *Information sources*

We developed a search strategy with a librarian with expertise in systematic reviews, for PubMed and Embase (OVID), Web of Science and Google Scholar. Articles published in the last 10 years (January 2013 to December 2022) were considered. The complete search strategy is available in Supplementary file ([Appendix 1](#)). We checked

the references of eligible studies to retrieve studies that escaped our search strategy. Articles included in other systematic reviews published until 31 December 2022 were also retrieved as other sources of information.

### *Selection process*

All references from databases and secondary sources were imported in Covidence (22), to manage the selection of relevant studies and the data extraction. Two independent reviewers (E.A. and J.M.W.S.) were involved in title and abstract assessment to apply the eligibility criteria on all potential sources. All sources retained were then independently evaluated using the full text to apply the eligibility criteria. When there was discrepancy between the two reviewers, a senior reviewer (M.S. or M.P.G.) made final eligibility decision.

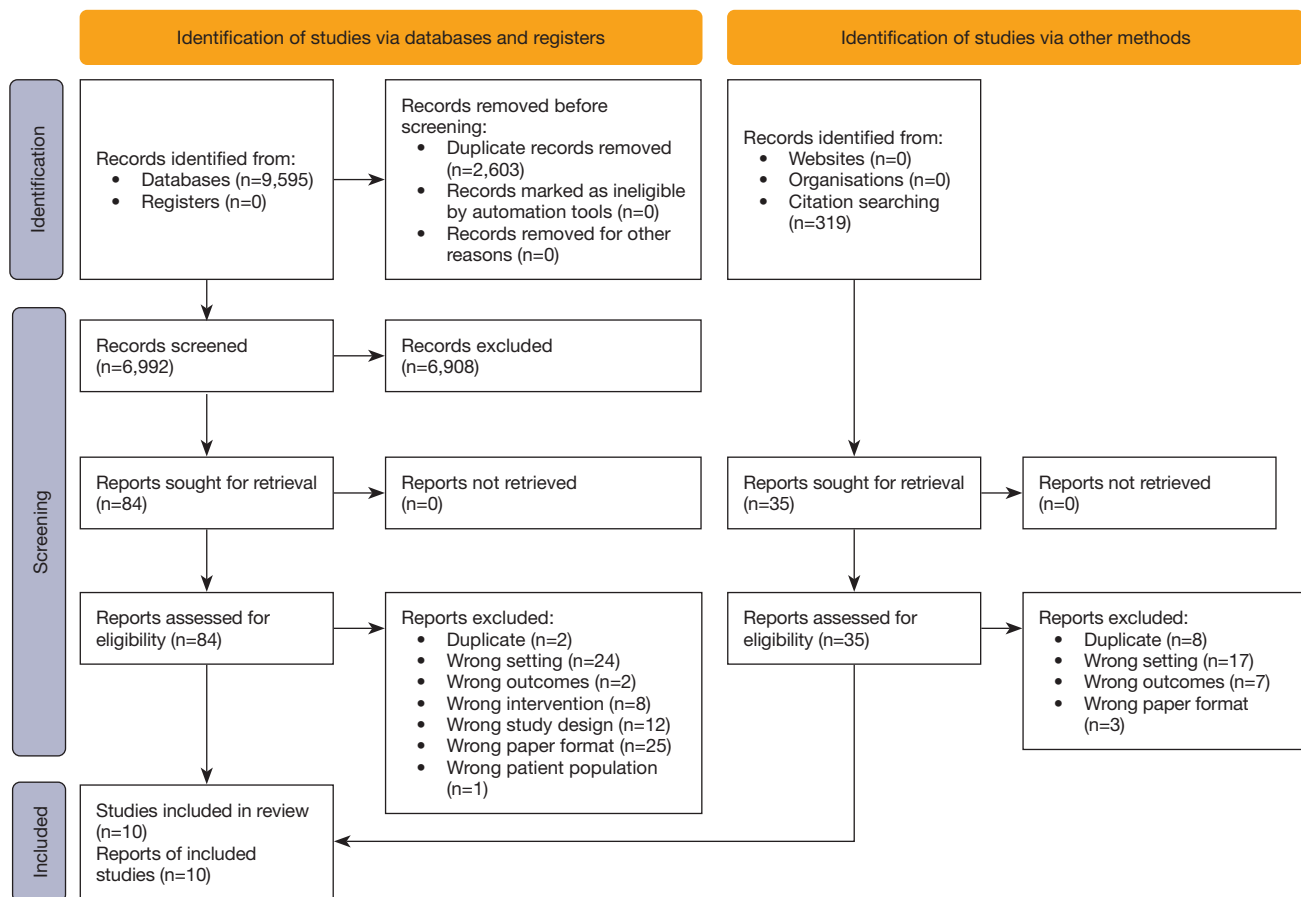
### *Data extraction process*

We developed a data extraction form and pretested it using two sources to ensure reliability. Two reviewers extracted the data using the Covidence online tool (22), and a senior reviewer validated all extractions.

We extracted the following information about studies: year, author, country, design, setting, method, and follow-up. Characteristics of patients were: age (mean or median with standard deviation or interquartile range) and sex (percentage of female). Clinical information collected included: type of seizures and number of seizures. Wearable device characteristics were: type of device, type of sensor, features of the device (place on body or home, remote alarm or monitoring, mode of signal transmission, battery autonomy, and mobility), and performance of the WDD (sensitivity and false alarm rate). We extracted information about health outcomes, including QoL, medication adherence, health professional or patient monitoring of seizures, and death. We operationalized the effects in a qualitative form: yes, no, or unclear. We also extracted information about the value, satisfaction, comfort, visibility, intrusiveness, and perceived utility of the WDD.

### *Data synthesis*

We synthesized all this information separately by question about the performance, effect, and experience in narrative form.



**Figure 1** Flow diagram of studies identification and inclusion.

### Study risk of bias assessment

Studies on WDD performance (diagnostic test accuracy studies) were evaluated by using QUADAS-C (Quality Assessment of Diagnostic Accuracy Studies-Comparative) (23). Other quantitative, qualitative, and mixed methods studies were evaluated by using the Mixed Methods Appraisal Tool (MMAT) (24).

## Results

Overall, 10 studies met the inclusion criteria and were used in the synthesis analysis. The flow diagram describes the selection process (Figure 1). From the 10 retained studies, six studies reported WDD performance in community-based settings (15,25-29). Two studies reported the effects of using WDD on health outcomes (mainly on QoL) in community-based settings (30,31). Finally, eight studies reported the experience of using the WDD in community-

based settings (25-27,29-33) (Table 1).

A majority of studies were conducted in Europe [Belgium (15), Denmark (25,26,33), The Netherlands (29,32), and Germany (31)]. One study was conducted in the US (30) and another one in China (28). The majority of these studies were conducted in a home setting (15,25-28,30-33) (Table 1).

Characteristics of the devices are presented in Table 2. The majority of studies evaluated an accelerometer wearable device (15,25,27,28,30-33).

### Performance of WDD in a community-based setting

Studies that reported about the performance of WDD were cohort studies which compared the WDD with seizure diaries, carers' report, or video. There were two cross-sectional studies which reported performance of WDD without comparison of the device with another tool to detect seizure. The follow up duration ranged from 15 to

**Table 1** Characteristics of studies included in the systematic review

Authors	Country	Title	Setting
van Westrhenen 2021 (32)	The Netherlands	Parental experiences and perspectives on the value of seizure detection while caring for a child with epilepsy: a qualitative study	Home
van Andel 2016 (15)	Belgium	Non-EEG based ambulatory seizure detection designed for home use: what is available and how will it influence epilepsy care	Home
Thompson 2019 (30)	United States	Seizure detection watch improves quality of life for adolescents and their families	Home
Olsen 2021 (33)	Denmark	Wearables in real life: a qualitative study of experiences of people with epilepsy who use home seizure monitoring devices	Home
Meritam 2018 (25)	Denmark	User-based evaluation of applicability and usability of a wearable accelerometer device for detecting bilateral tonic-clonic seizures: a field study	Home and/or residential care
Kjaer 2017 (26)	Denmark	Detection of paroxysms in long-term, single-channel EEG-monitoring of patients with typical absence seizures	Home
Hadady 2023 (27)	Denmark	Real-world user experience with seizure detection wearable devices in the home environment	Home
Dong 2021 (28)	China	Home-based detection of epileptic seizures using a bracelet with motor sensors	Home
Borusiak 2016 (31)	Germany	A longitudinal, randomized, and prospective study of nocturnal monitoring in children and adolescents with epilepsy: effects on quality of life and sleep	Home
Arends 2018 (29)	The Netherlands	Multimodal nocturnal seizure detection in a residential care setting: a long-term prospective trial	Residential care

EEG, electroencephalogram.

450 days. The population were mostly young (children and adolescent) living at home or in residential care setting (intellectual disability) (Table 3). The most common type of seizures was tonic-clonic. Overall, the performance of all devices included in the review was good with high sensitivity ( $\geq 80\%$ ) and low false positive alarm rate ( $\leq 1/\text{day}$ ) (Figure 2). These studies were of low quality according to the QUADAS-C (Table 4). This was mostly due to convenience sample that introduced selection bias and non-representativeness of the target population of the review. Some studies did not use comparator or reference standard to assess the sensitivity and false alarm rate (25,27). Also, it was unclear whether interpretation of the index test had introduced bias in most studies.

### *Impact of WDD on health outcomes*

Studies that addressed the impact of WDD on health outcomes (30,31) were about PWE's QoL, parents' anxiety and quality of sleep, and family support for child with epilepsy. There was no significant effect between groups and within groups on these outcomes in these studies

(Table 5). The studies were of low methodological quality according to the MMAT (Table 6).

### *Experience of using wearable device for seizure detection among PWE*

Eight studies reported patient experience of using WDD in community-based settings (23-25,27-31). Documented attributes included perceived effectiveness, comfort, cost and usability.

PWEs and their caregivers perceived substantial effectiveness of using the WDD (25-27,29-31). Although there was high concern regarding the false alarm rate across studies, good sensitivity overcame this concern (27,30,31). False alarm rates were also reported due to the disconnection of device, difficulty to charge the device, phone intermediation, or other activities that could involve body motion (25,30). The other components of perceived effectiveness of the device were that users reported more freedom and safety (30), improvement in their QoL (25,27,30), improvement in seizure monitoring (27,29), and decrease in seizure related injuries (25,30).

**Table 2** Description of wearable device for seizure detection used in outpatient settings

Authors	Device	Place on body or home	Remote alarm or monitoring	Mobility	Battery autonomy	Mode of transmission
Arends 2018 (29)	Multimodal sensor bracelet	Upper arm	Unclear	Yes	NA	Transmission to a computer
Borusiak 2016 (31)	EpiCare® (ACM)	Under the child's mattress	Yes	No	NA	Transmission to a computer
Borusiak 2016 (31)	Audio baby monitor	NA	NA	NA	NA	NA
Dong 2021 (28)	Bracelet with ACM	Upper arm	Unclear	Yes	More than 24 hours	Storing data on a SD card
Hadady 2023 (27)	NightWatch with a multimodal device based on ACM	Upper arm	NA	NA	NA	NA
Hadady 2023 (27)	Empatica with a wristband with a multimodal seizure detection (ACM and electrodermal activity)	Upper arm	NA	NA	NA	NA
Hadady 2023 (27)	EpiCare with a wrist-band with ACM-based seizure detection	Upper arm	NA	NA	NA	NA
Kjaer 2017 (26)	Portable EEG device	Head	NA	NA	24 hours	NA
Meritam 2018 (25)	EpiCare (ACM)	Upper arm	Yes	Yes	NA	Transmission to portable control unit accessible to parents/caregivers or mobile phone
Olsen 2021 (33)	Portable electroencephalography amplifier with two channels, an electrocardiography device	Sternum	Unclear	No	NA	NA
van Andel 2016 (15)	Video, ACM, and radar-induced activity recording	The camera and radar are attached to a tripod that is placed close to the patient's bed	Unclear	No	10 hours	Transmission to a computer
van Westrhenen 2021 (32)	NightWatch device	NA	NA	NA	NA	NA
Thompson 2019 (30)	Smart Watch with 3D ACM	Wrist	Yes	Unclear	NA	Using Bluetooth to transmission signal to computer

ACM, accelerometer; EEG, electroencephalogram; NA, not available; SD, secure digital.

Discomfort was reported by some users. This outcome was related to the visibility of the device. A highly visible device caused spotlight, vulnerability and social exclusion sensation for some users (33). Some users also expressed discomfort of wearing the device in public places (26,27,33). Some users reported the high workload of using WDD and life privacy invasion (29,32). Only one study reported that

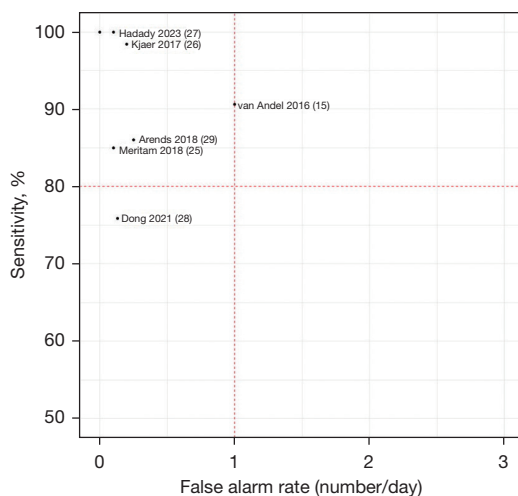
users found the WDD expensive (32).

Overall, studies reported ease of use of WDD, especially watch accelerometers (23,25,27,28). However, users reported that the device was not waterproof so they couldn't wear it everywhere (25,30). Problems with charging or connection with the control unit were also reported (25,27,29,30). Overall, these studies had good quality (Table 7).

**Table 3** Characteristics of studies about the performance of wearable device for seizure detection in community-based settings

Authors, year, country	Design/setting	Follow-up (days)	NS/NP	Population characteristics (age and sex)	Type of seizures	WDD	Sensitivity (%)	False positive alarm rate (per day)
van Andel 2016 (15); Belgium	Cohort study/home	15	32/1	8 years; female (100%)	Tonic-clonic seizures	Accelerometer	90.62	1.00
Meritam 2018 (25); Denmark	Cross sectional study/home and/or residential care	450	NA/71	27 years; female (45%)	Tonic-clonic seizures	Accelerometer	85	0.10
Kjaer 2017 (26); Denmark	Cohort study/home	30	593/6	10 years; female (83.3%)	Absence seizure	Portable EEG	98.4	0.2
Hadady 2023 (27); Denmark	Cross sectional study/home	NA	NA/242	17 years; female (NA)	Tonic-clonic seizures	Accelerometer	100	0.1
Dong 2021 (28); China	Cohort study/home	117	114/5	29 years; female (40%)	Tonic-clonic seizures	Accelerometer	75.91	0.13
Arends 2018 (29); Netherlands	Cohort study/residential care setting	194	809/28	29.1 years; female (35.7%)	Tonic-clonic seizures	Accelerometer and photoplethysmography	86	0.25

NS, number of seizures; NP, number of patients; NA, not available; WDD, wearable device for seizure detection; EEG, electroencephalogram.



**Figure 2** Scatter plot of the studies reporting the performance of the wearable device for seizure detection in community-based settings (15,25-29).

## Discussion

### Key findings

The literature on the use of WDD in community-based settings is scarce despite the potential of this technology to improve the health and well-being of PWE and their caregivers. The WDD most used were accelerometers.

Most studies included child and adolescent patients and focused on tonic-clonic seizures. The overall performance of using the WDD was high with over 80% of sensitivity and less than 1 false alarm per day. This good performance was reflected by users' appreciation in the qualitative material. However, there were some discrepancies in the qualitative findings regarding the perceived false alarm rate which was deemed too high in some studies.

With respect to the second review question, quantitative studies did not report any effect of the use of WDD on QoL, parent child support, parents' fear of seizures, parents' quality of sleep, family life/leisure, condition management, and child autonomy. Qualitative studies reported that the use of WDD positively influenced QoL, condition management and seizure-related injuries. Finally, qualitative studies found that WDD were generally easy to use. However, users perceived more discomfort related to the visibility of the device.

### Strengths and limitations

This review has some limitations. First, there is a possibility of publication bias because we searched publications in English only from two databases (PubMed, Google Scholar, Web of Science and Embase). Although, we could retrieve relevant papers from references of eligible studies and from other systematic reviews, some studies could have been

**Table 4** Risk assessment of studies on performance of wearable device for seizure detection with QUADAS-C

Authors	Patient selection		Index test		Reference standard		Flow and timing	
	Risk of bias	Concerns regarding applicability	Risk of bias	Concerns regarding applicability	Risk of bias	Concerns regarding applicability	Risk of bias	Concerns regarding applicability
van Andel 2016 (15)	Unclear	Unclear	High	High	Unclear	Unclear	Unclear	Unclear
Meritam 2018 (25)	High	Unclear	High	High	High	High	High	High
Kjaer 2017 (26)	Unclear	High	Unclear	Unclear	Unclear	Unclear	Unclear	Unclear
Hadady 2023 (27)	Unclear	Unclear	High	High	High	High	High	High
Dong 2021 (28)	Unclear	High	Unclear	Unclear	Unclear	Low	Unclear	Unclear
Arends 2018 (29)	High	High	Low	Low	Unclear	Unclear	Unclear	Unclear

**Table 5** Characteristics of studies about the effect of wearable device to detect seizure on health outcomes

Author/year/country	Design/setting	Follow-up (days)	Number of participants by group	Population characteristics (age and sex)	Type of seizures	WDD	Health outcomes	Effect (yes/no)
Thompson 2019 (30), United States	Mixed-method research/home (pre-post design)	183	One group (n=10)	17.5; female =70%	Tonic-clonic seizure	Accelerometer	(I) Quality of life in Epilepsy for Adolescent (QOLIE AD-48). (II) Parent-child support. (III) Family life/leisure. (IV) Condition management. (V) Child autonomy. (VI) Child discipline	No for all outcomes
Borusiak 2016 (31), Germany	Mixed-method research/home (pre-post and comparison design)	210	Accelerometer: n=13; control with nothing: n=16	Accelerometer: 8.1 (3.6); female =55%. Control: 9.6 (4.5); female = 69.2%	NA	Accelerometer	(I) Parents' fear of nightly seizures. (II) Change in parents' QoL over time. (III) Frequency of co-sleeping. (IV) Change in parental quality of sleep	No for all outcomes
Borusiak 2016 (31), Germany	Mixed-method research/home	210	Audio baby monitor: n=10; control with nothing: n=16	Audio baby monitor: 9.5 (4.8); female =1%. Control with nothing: n=16	NA	Audio baby monitor	(I) Parents' fear of nightly seizures. (II) Change in parents' QoL over time. (III) Frequency of co-sleeping. (IV) Change in parental quality of sleep	No for all outcomes

NA, not available; WDD, wearable devices for seizure detection; QoL, quality of life.

missed. Second, the studies we synthesized in this review presented several risks of bias so the evidence presented in our review has a high risk of bias. Finally, we used a narrative approach to synthesize our findings, thus our

subjectivity can affect the interpretation of the findings.

The main strength of this review is the systematic approach used to collect and synthesize data. The separate analysis of findings according to specific review questions



**Table 6** Risk of bias assessment of studies reporting about the effect of wearable device on health outcomes

Authors	Are the participants representative of the target population?	Are measurements appropriate regarding both the outcome and intervention (or exposure)?	Are there complete outcome data?	Are the confounders accounted for in the design and analysis?	During the study period, is the intervention administered (or exposure occurred) as intended?
Thompson 2019 (30)	No	Yes	No	No	Can't tell
Borusiak 2016 (31)	No	Yes	No	No	Can't tell

**Table 7** Risk of bias assessment of studies reporting about the experience of using wearable device for seizure detection

Authors	Is the qualitative approach appropriate to answer the research question?	Are the qualitative data collection methods adequate to address the research question?	Are the findings adequately derived from the data?	Is the interpretation of results sufficiently substantiated by data?	Is there coherence between qualitative data sources, collection, analysis and interpretation?
van Westrhenen 2021 (32)	Yes	Yes	Yes	Yes	Yes
Thompson 2019 (30)	Yes	Yes	Yes	Yes	Yes
Olsen 2021 (33)	Yes	Yes	Yes	Yes	Yes
Meritam 2018 (25)	Yes	Yes	Yes	Yes	Yes
Kjaer 2017 (26)	Yes	Yes	Can't tell	Can't tell	Can't tell
Hadady 2023 (27)	Yes	Yes	Yes	Yes	Yes
Borusiak 2016 (31)	Yes	Yes	Yes	Yes	Yes
Arends 2018 (29)	Yes	Yes	Yes	Yes	Yes

is the preferred approach proposed for mixed methods systematic reviews (20).

**Comparison with similar researches**

The results of this mixed methods systematic review are consistent with those of previous reviews about the use of WDD. Previous reviews also reported high performance of WDD in in-patient settings and little concerns about false alarm rate (11,13-15). Previous reviews did not report about the impact of WDD on QoL, comfort, privacy, and impact of false alarms.

**Explanations of findings**

In this review, we reported no effect on QoL in quantitative studies but perceived effect on QoL in qualitative studies. This absence of effect on QoL in quantitative studies may be mainly due to small sample size ( $\leq 30$ ) and perhaps short follow up time ( $\leq 365$  days) used in these studies. Qualitative

studies reported about the positive effect on seizure-related injuries and seizure management, but no quantitative evidence supported these findings. This may result from the difficulty of designing studies with sufficient power to detect these impacts. Our review also reported about comfort and highlighted that WDD, especially accelerometers, were suitable. Other devices which were more visible were less acceptable to users. This is consistent with a study that addressed PWE needs about WDD (34).

**Implications and actions needed**

The findings from this review suggest that WDD have a good performance to detect generalized tonic-clonic seizures and focal seizures in outpatient settings, but some concerns remain about the false alarm rate. More technological developments are needed to improve the performance of these devices, especially to reduce the false alarm rate. There was qualitative evidence that patients perceived improvement of their QoL and seizure

management. Other quantitative studies are needed to support these findings. WDD were deemed comfortable by patients, except when they were too visible. It is thus important that WDD developers consider the visibility aspect to meet users' needs. As such, involving users in the design of WDD is essential.

## Conclusions

This mixed methods systematic review addressed the performance, impact on health outcomes, and patient experience of using WDD in outpatient settings. In general, WDD have a good sensitivity, but their false alarm rate is deemed too high. Qualitative studies reported positive impacts of WDD on QoL and seizure management, but quantitative studies reported no effect. WDD were also acceptable for patients, except when they were too much visible. More quantitative studies are needed to assess the impact of WDD on health outcomes.

## Acknowledgments

We wish to thank Elisabeth Beauchamp-Chalifour (Centre intégré universitaire de santé et services sociaux de la Capitale-Nationale) and Tamara Herrera Fortin (Université de Montréal) for their involvement in the project and their work on the protocol for this systematic review.

*Funding:* This work was supported through the CIHR-NSERC CHRP program funding (No. CPG-163983).

## Footnote

*Reporting Checklist:* The authors have completed the PRISMA reporting checklist. Available at <https://mhealth.amegroups.com/article/view/10.21037/mhealth-24-7/rc>

*Peer Review File:* Available at <https://mhealth.amegroups.com/article/view/10.21037/mhealth-24-7/prf>

*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <https://mhealth.amegroups.com/article/view/10.21037/mhealth-24-7/coif>). M.P.G. serves as an unpaid editorial board member of *mHealth* from April 2024 to March 2026. The other authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related

to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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doi: 10.21037/mhealth-24-7

**Cite this article as:** Sasseville M, Attisso E, Gagnon MP, Supper JMW, Ouellet S, Amil S, Assi EB, Nguyen DK. Performance, impact and experiences of using wearable devices for seizure detection in community-based settings: a mixed methods systematic review. *mHealth* 2024;10:27.