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RESEARCH ARTICLE

Artificial intelligence-driven closed-loop devices in sudden unexpected death in epilepsy prediction and prevention: Insights from persons with epilepsy and caregivers

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Abstract

Objective: The absence of strategies for predicting and preventing sudden unexpected death in epilepsy (SUDEP) is intertwined with the lack of studies measuring users' attitudes toward potential innovative interventions. The NEUROSENSE Project (http://www.neurosense-project.eu) aims to evaluate novel SUDEP-predictive neuroendocrine biomarkers in interstitial fluid. The ultimate aim is to develop an artificial intelligence-driven closed loop device (AI-CLD) prototype that can recognize life-threatening seizures and prevent SUDEP through automatic intervention. The current study introduces the potential use of AI-CLDs in SUDEP prediction and prevention, while assessing person with epilepsy (PWE) and caregiver (CG) attitudes toward AI-CLD adoption and implementation.

Methods: A qualitative study was conducted through three focus groups involving PWEs and CGs. Participants were recruited through the NEUROSENSE Patient Advisory Board, with discussions facilitated through a semistructured interview guide. The study followed grounded theory and qualitative content analysis methods. Data were collected between October 2024 and February 2025, with all sessions transcribed and analyzed.

Results: Three main areas emerged from the analysis: expectations of AI-CLDs for SUDEP prediction and prevention, decision-making processes involving AI use in health care, and barriers and facilitators to AI-CLD adoption. PWEs and CGs generally expressed positive attitudes toward AI-CLDs, supporting automatic data sharing with health care providers and real-time alerts. However, concerns

For affiliations refer to page 10.

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about AI accuracy, overreliance on automation, and the need for control over interventions were raised. Both groups preferred wearable devices over implanted solutions, emphasizing comfort and discretion as critical factors for adoption.
Significance: This study highlights the potential of AI-CLDs in improving the prediction and prevention of SUDEP, showing promise for enhancing patient safety through real-time monitoring and interventions. The findings underscore the importance of user-centered design in device development, emphasizing comfort, control over interventions, and integration into daily life. This research provides insights useful for future development aiming to improve PWE and CG confidence in using AI technologies for epilepsy care and risk management.

KEYWORDS
artificial intelligence, automated intervention, closed loop system, epilepsy, medical device, medical device design, sudden death in epilepsy, user involvement

1 | INTRODUCTION

Sudden unexpected death in epilepsy (SUDEP) is the leading cause of epilepsy-related mortality, with an estimated incidence of 1.2 per 1000 person-years in individuals with epilepsy, increasing significantly in drug-resistant epilepsy.[1] The exact mechanisms underlying SUDEP remain unclear, but autonomic dysfunction, seizure-related respiratory depression, and cardiac abnormalities have been implicated.[2] Given the unpredictability and lethality of SUDEP, there is an urgent need for novel risk assessment and prevention strategies.

Existing SUDEP prevention efforts primarily focus on seizure control, nocturnal monitoring, and lifestyle modifications. However, these approaches remain insufficient in mitigating risk, as many cases occur unexpectedly, even in individuals receiving optimal medical treatment.[3] Current monitoring devices, such as wearable seizure detectors, have limitations in sensitivity and specificity, often leading to false alarms and limited real-time intervention capability.[4]

Recent advances in artificial intelligence (AI) have shown promise in improving epilepsy management by enabling seizure prediction, automated detection, and personalized treatment approaches.[5] Machine learning algorithms trained on multimodal physiological data, such as electroencephalographic,[6] electrocardiographic,[7] and respiratory patterns,[8] have demonstrated the potential to identify preseizure states and high-risk conditions.[9] Given these advancements, AI-based solutions could play a pivotal role in SUDEP risk stratification and intervention.[10]

AI-driven closed loop devices (AI-CLDs) are an emerging technology in digital health that integrates real-time data acquisition, AI-based predictive modeling, and automated interventions.[11] In these systems, the computational algorithms analyze real-time physiological data,

Key points

- PWEs and CGs generally support AI-CLDs for SUDEP prevention but emphasize the need for accuracy, reliability, and user control over interventions.
- Enhancing transparency, reducing false alarms, and mitigating the risk of overreliance on AI may be crucial to promoting AI-CLD adoption.
- Future research should focus on improving AI-CLD accuracy, addressing ethical issues, and ensuring seamless integration into epilepsy care through collaboration with health care providers and technology developers.

adjust control variables, and use actuators to deliver energy or materials to maintain the target physiological level.[12] This integration allows AI-CLDs to be successfully applied in neurological disorders, such as Parkinson disease and epilepsy, for optimizing deep brain stimulation and seizure control.[13,14] These emerging devices may have the potential to revolutionize the standard of care by ensuring adequate and timely therapy delivery in an emergency setting, reducing cognitive overload, minimizing human error, and enhancing medical care during surge scenarios such as a life-threatening seizure.[15]

Designed as wearable devices, AI-CLDs for SUDEP prediction and prevention should support continuous use while ensuring practicality and real-time responsiveness and prioritizing user comfort and acceptance.[16] Although AI-CLDs hold significant potential for SUDEP prediction and prevention, this remains an emerging field, and the concept has yet to be thoroughly explored. Moreover, the

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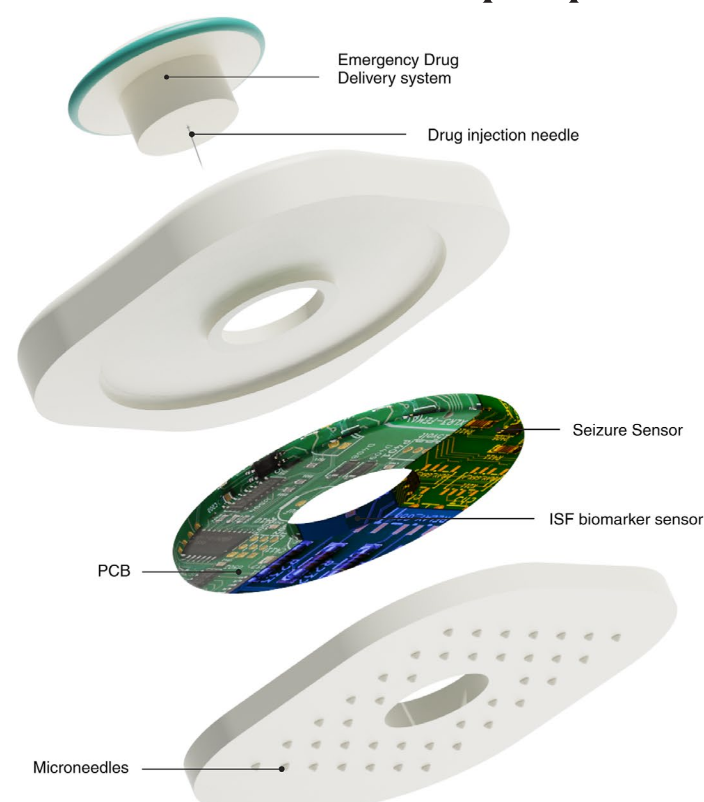

FIGURE 1 Overview of the artificial intelligence-driven closed loop device system, consisting of a continuous seizure detection sensor, a sudden unexpected death in epilepsy biomarker sensor, a processor, and an emergency drug delivery actuator. ISF, interstitial fluid; PCB, printed circuit board.

successful implementation of AI-CLDs in SUDEP prediction and prevention requires the acceptance and trust of users, including persons with epilepsy (PWEs) and their caregivers (CGs). Factors such as integration with daily life, aesthetic and emotional resonance, adaptability to seizure characteristics, and user-centric design must be taken into consideration to promote safe and effective use of these devices.[16] Additionally, the design and development process must address ethical considerations, data privacy concerns, usability challenges, and potential psychological impacts.[17]

This study aims to introduce, for the first time, the potential application of AI-CLDs as a novel approach for SUDEP prediction and prevention, while exploring the perspectives of PWEs and CGs regarding the adoption and use of these technologies.

2 | MATERIALS AND METHODS

2.1 | Description of the NEUROSENSE project and proposed AI-CLD

The NEUROSENSE Project (http://www.neurosense-project.eu) aims to identify novel SUDEP-predictive neuroendocrine biomarkers in interstitial fluid (ISF) and develop an AI-CLD prototype to recognize life-threatening seizures and prevent SUDEP through automatic intervention (Figure 1). By using ISF as a matrix for biomarker detection, the intended prototype consists of a wearable device that can be autonomously applied by the patient to the skin and remain in place for several days. The foreseen AI-CLD system (Figure 1) comprises four key components: (1) a continuous seizure detection sensor, (2) a continuous sensor monitoring the SUDEP biomarker, (3) a processor, and (4) an actuator–emergency drug delivery system.

When the device is applied to the skin (Figure 2, action 1), ISF is sampled continuously through minimally invasive microneedles (Figure 2, action 2) and the SUDEP biomarker is quantified in real time by the device's sensor. When a seizure occurs, the seizure detection sensor activates the AI-CLD processor (Figure 2, action 3), which analyzes the data generated by the biomarker sensor using a built-in algorithm. The algorithm, trained on historical data from the recorded patient's biomarker patterns during seizures, analyzes the data in real time to assess the risk of SUDEP. When a high-risk seizure is identified (Figure 2, action 4), the AI-CLD processor immediately triggers the actuator to deliver a SUDEP preventing intervention, for example,

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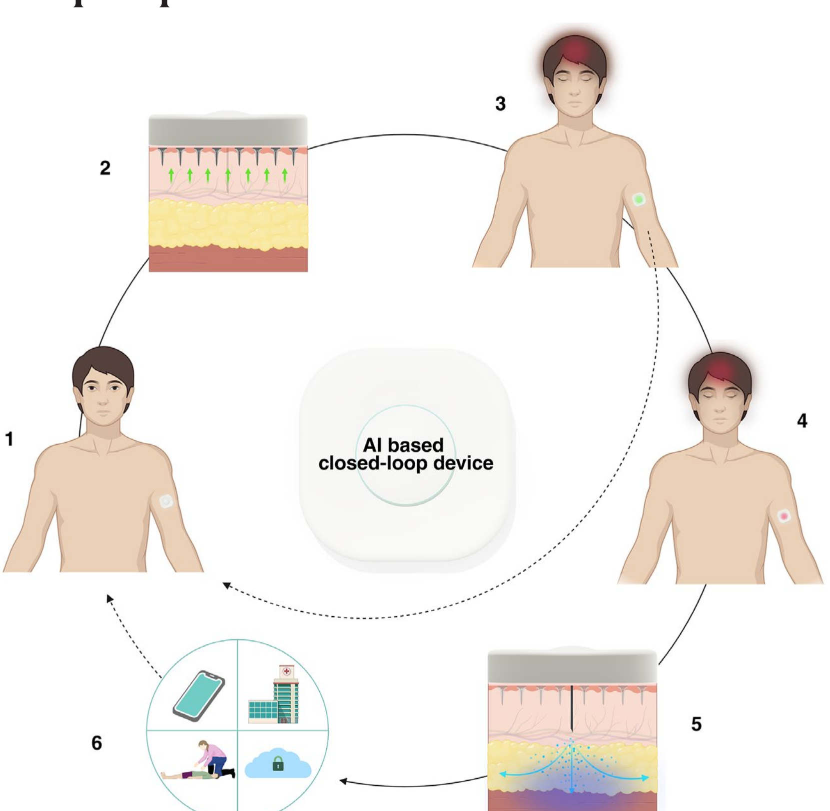

FIGURE 2 Automated prediction and prevention of sudden unexpected death in epilepsy (SUDEP). The artificial intelligence (AI)-driven closed loop device collects interstitial fluid via microneedles, analyses biomarker data in real time, and intervenes automatically to prevent SUDEP while communicating risk assessments to caregivers and health care providers.

an appropriate dose of a SUDEP-preventing medication (Figure 2, action 5). Simultaneously, the AI-CLD communicates with a mobile device (Figure 2, action 6) to alert first responders (CGs and health care providers), thereby enabling a coordinated and timely response. The mobile app continuously displays the current risk score, tracks changes in the score over time, and shows trends in risk (e.g., increasing or decreasing risk) with corresponding timelines. Additionally, a secondary app provides users with detailed information about their risk profile and uploads data to a secure cloud platform for easy access by the medical team (Figure 2, action 6). Through this platform, health care providers can monitor the patient's risk progression and tailor preventive treatments as necessary, ensuring a personalized approach to SUDEP risk management.

2.2 | PWE and CG involvement in the project

Realizing the importance of user-centered design in the AI-CLD development process, the NEUROSENSE Consortium has initiated a structured series of workshops to assess PWE and CG perspectives. The first cross-sectional survey workshop, the results of which have been reported previously,[16] identified key values that were incorporated into the preliminary design of the intended AI-CLD prototype (Figure 1). Building on these findings, we conducted a second workshop to assess how PWEs and CGs perceive these values in the proposed design. A grounded theory methodological orientation composed of semistructured interviews and focus groups was used to inductively describe users' perspectives.

Participants were recruited through the Spanish Dravet Foundation and Epilepsy Sparks, which are key contributors to the NEUROSENSE Patient Advisory Board. Both the methods and reporting followed the Standards for Reporting Qualitative Research guidelines.[18]

2.3 | Focus group methodology

Three focus group meetings (two with PWEs and one with CGs) were conducted between October 2024 and February 2025. Two of the meetings took place at El Centro de Referencia Estatal de Atención a Personas con Enfermedades Raras y sus Familias in Burgos, Spain, and one was organized online (Zoom Video Communications). Each focus group included six to eight PWEs or CGs, in addition to three members of the research team (J.F., M.F., M.R.) and a facilitator. A total of eight PWEs (three males, five females, median age range = 30–39 years) and 15 CGs (six males,

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TABLE 1 Overview of categories, subcategories, and representative quotes based on results from the focus groups of PWEs and CGs.

Categories	Subcategories	Quotes
Expectations of AI-CLD in SUDEP Prediction and Prevention	Attitudes Toward AI-Based Prediction and Prevention of SUDEP	PWE: "If I travel alone, and in case a seizure occurs, a wearable device managed by AI would help with an automatic intervention." PWE: "As long as the AI is strictly set up and controlled correctly, fine." PWE: "Not sure as it is a new concept. I don't really know how safe it would be." PWE: "No, I don't have any concerns with an automated intervention, as the device purpose is the prevention of SUDEP." PWE: "Depends on the risks of the medication if administered as a result of a false positive." CG: "As long as it's something that does not threaten the health of the person under my care." CG: "It might get it wrong once, but as long as it is very well tested and it does not make many mistakes, then it's fine for me." CG: "I would not tolerate a compulsory administration of a drug very easily. If, on the other hand, it just sends a notification, I would be more at ease with the use of the device, because a false positive would be more acceptable. However, if the administration of a drug is compulsory, I wouldn't be very comfortable." CG: "I'm concerned due to the lack of knowledge of this technology. But if I can see it and it proves to be reliable, it would be a good thing."
	Preferred Features and Functions of the AI-CLD	PWE: "It seems to me like a good system would have something like this that could just literally administer standard 'antiepileptic' drugs." PWE: "I think it would be very nice if both me and my wife could get the notification." CG: "The device should be sufficiently intelligent and give parents the power to decide whether or not to administer medication, i.e., it should be configurable." CG: "Give parents the opportunity to configure when the device alerts you that there is a SUDEP event. Allow us a few moments to administer the drug. If that doesn't happen then let the device act."
	Integration with Health Care Professionals	PWE: "So I think if like for instance we had a device that could tell automatically if we'd forgotten our medication and send a message to the doctor, that would be helpful for our communication with our doctors." PWE: "I'm very comfortable in automatically sharing my data with my neurologist over the internet." PWE: "When the doctors ask questions, you know, they always want to know, when did it start? How long was it? You know, it's not always easy to remember that. So, if we have something where you can get that actual data or even if you can decide to send that to the doctor." PWE: "Often the caregivers will say understandably their perception of what happened, but it's not necessarily accurate. And so, if you can provide data that not to say you're wrong, but just, you know, something that's more accurate and then you can affect, treat the patient much more effectively." CG: "Being caregivers, we rely very much on our intuition as parents to act properly when needed. This experience no one else has quite like us." CG: "I think it's perfect, as the doctor is informed at the same time as we are."
AI, SUDEP, and the Decision-Making Process	Trust in AI for SUDEP Risk Monitoring	PWE: "No one worries if there's a false positive. If all it's doing is kind of keeping you breathing really, but if it's like benzodiazepines or something, then that's a big problem." CG: "I don't think AI has developed enough yet." CG: "If in 15 years this device proves to be reliable, then maybe, little by little, I could delegate some of my responsibilities to it." CG: "I always believe that there must be a human making the decision to administer the drug. A parent's intuition and experience cannot be substituted by AI."

(Continues)

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TABLE 1 (Continued)

Categories	Subcategories	Quotes
	Accuracy and Reliability Considerations	PWE: "100% accuracy hopefully or as close as possible. No dangers of medication administered in case of false positives." PWE: "Any risk reduction will be good, but hopefully you can get it to be 100%." CG: "The minimum guarantee is that, for example, there aren't a lot of adverse effects."
	Control Over AI-Driven Interventions	CG: "This way we would retain the power to decide what to do after being notified, just like we have to do now when is our turn to be 'ready.' Of course, we can also fail, just like the device; we are only humans. But I would rather be the one failing than trusting the device and then have the device failing on us." CG: "There should be a protocol that warns us when a SUDEP event is happening, giving us, the caregivers, 3 minutes to act and, for instance, press 'yes' or 'no' on the app notification for drug delivery."
Barriers and Facilitators to the Adoption and Use of an AI-CLD	Wearability and Usability Factors	PWE: "A lot of people probably wouldn't even question it, because they wouldn't know that it's not a device for diabetes." CG: "I would like if the device was a bit thinner. Now that I'm handling it, it feels like you could still see it through the clothes. I'm not saying this for aesthetic reasons, but rather because kids will notice it and might try to remove it." CG: "Could be possible to camouflage the device using an appropriate color, so the user won't even notice it's wearing it." CG: "The size doesn't bother me, I would use it, but of course, uncomfortable for them." CG: "I think it's something that would go very unnoticed because a lot of people already wear something similar."
	System Alerts and Notifications	PWE: "I might not want to see that warning because it might make me feel more stressed or something, I wouldn't really care because SUDEP doesn't scare me at all." CG: "I think the device should also allow the parent to make a decision when notified. Before the decision to administrate is made, could the artificial intelligence automatically ask you if you agree to let them administrate?" CG: "It would be necessary to differentiate when it is a crisis, that is, to somehow know when a crisis is going to happen. That is to say, to differentiate a 'crisis' from SUDEP."

Abbreviations: AI-CLD, artificial intelligence-driven closed loop device; CG, caregiver; PWE, person with epilepsy; SUDEP, sudden unexpected death in epilepsy.

nine females, median age range = 40–49 years) participated in the study (Appendix S1). The CGs were not relatives of the participating PWEs. The composition of each focus group aimed to ensure heterogeneity in terms of age, gender, education, and privacy concerns. The latter dimension was regarded as particularly important because of its potential influence on user's willingness to use wearable AI-CLDs. In accordance with the NEUROSENSE Project's ethical and data protection protocols, which comply with European General Data Protection Regulation standards, only nonidentifiable demographic data (e.g., age ranges and sex) were collected; details such as exact age or epilepsy subtype were not recorded, to ensure participant anonymity and data minimization. A semistructured interview guide (Appendices S2 and S3) shaped by literature review and expert insights steered discussions on seizure detection, current monitoring methods, and perspectives on wearable AI-CLDs for SUDEP prediction and prevention. The interview guide was divided into four parts: Part 1, open questions regarding the progression of the condition and current assessment of epilepsy severity; Part 2, multiple choice questions regarding remote monitoring and AI for SUDEP prediction and prevention; Part 3, multiple choice questions about the AI-CLD prototype; and Part 4, open exploratory questions to address any comments or concerns from participants. During these sessions, PWEs and CGs were offered illustrative materials about the NEUROSENSE project, such as models of the wearable AI-CLD and user instructions (Appendix S3). The concept presented to participants included minimally invasive microneedles for interstitial fluid sampling. Although this feature was implicitly part of the overall device description, it was not explicitly discussed or isolated as a separate topic during the focus group discussions. Participants were actively

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encouraged to provide their thoughts and opinions on the topics presented by the research team. All interactions were audiorecorded, transcribed verbatim, and translated into English as needed. Possible discussion points were formulated surrounding the use of AI-CLDs and categorized into three main themes (Table 1):

1. PWE and CG attitudes and beliefs related to the prediction and prevention of SUDEP.
2. PWE and CG thoughts and feelings related to the use of closed loop technologies and AI for prediction and prevention of SUDEP.
3. PWE and CG perspectives on using a developed SUDEP predictive and preventive AI-CLD prototype as part of their daily life.

2.4 | Data analysis

A qualitative content analysis with an inductive approach was chosen to describe differences in participants' perceptions according to the methodology developed by Graneheim and Lundman.[19] The text from all focus groups was regarded as one text unit and divided into meaning units, focusing on the manifest content close to the text.[19] The meaning units were condensed into codes, which were sorted and abstracted into subcategories based on similarities and differences. The subcategories were then abstracted to categories. The analytic process contained a back and forth movement between the original text and its parts. The trustworthiness of categories and subcategories was strengthened by continued discussions within the full research group. Throughout this process, the group affiliation of the meaning units was kept identifiable to allow description of similarities and differences between groups of participants within each subcategory.

2.5 | Ethical considerations

The study was conducted according to the principles of the Helsinki Declaration and the Medical Research Involving Human Subjects Act. The study protocol was evaluated and approved by the Committee for Ethical and Responsible Conduct of Research of the Instituto de Investigação e Inovação em Saúde da Universidade do Porto. Participation was voluntary, and no material incentives were given. All participants provided written informed consent. Confidentiality was maintained through secure and restricted access to the data to only the research team and immediate destruction of focus group recordings after transcription.

3 | RESULTS

The questions used to assess perspectives of PWEs and CGs are listed in Appendices S2 and S3, respectively. Key findings are summarized in the sections below, whereas representative comments from PWEs and CGs for each of the main theme categories and subcategories are listed in Table 1. Additional details of summary results are provided in Appendix S5.

3.1 | Expectations of AI-CLD in SUDEP prediction and prevention

Both CGs and PWEs demonstrated a generally positive attitude toward an AI-based monitoring system for SUDEP prediction and prevention. Most participants expressed comfort with a wearable device (CG Question 1: $n=11$ comfortable, $n=3$ very comfortable; PWE Question 1: $n=3$ comfortable, $n=3$ very comfortable). However, attitudes toward an implanted version were more variable, with most participants expressing discomfort (Question 3: $n=6$ CGs and $n=4$ PWEs) and fewer reporting high comfort levels (Question 3: $n=4$ CGs and $n=2$ PWEs).

Participants expected the device to provide vital sign information after seizures (Question 17d: $n=14$ CGs and $n=8$ PWEs agreed or strongly agreed) and track SUDEP risk over time (Question 17e: $n=15$ CGs and $n=8$ PWEs agreed or strongly agreed).

Automatic data sharing with health care providers was widely accepted (Question 9), with all CGs and PWEs supporting it in some form. Users cited benefits such as improved medical oversight, increased safety, and real-time medical updates. Participants emphasized that the device should complement health care professionals rather than replace them (Question 17h: $n=15$ CGs, $n=8$ PWEs).

Participants strongly supported features that track SUDEP risk progression over time (Question 17e: $n=15$ CGs, $n=8$ PWEs agreed or strongly agreed) and provide instant feedback before a seizure (Question 16a: $n=15$ CGs, $n=7$ PWEs agreed or strongly agreed) as well as before an automated intervention (Question 16b: $n=14$ CGs, $n=8$ PWEs agreed or strongly agreed).

3.2 | AI, SUDEP, and the decision-making process

Both CGs and PWEs had a positive perspective on AI-based SUDEP monitoring, with 11 of 15 CGs and six of eight PWEs feeling comfortable or very comfortable with AI tracking SUDEP risk (Question 11). However, both

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CGs and PWEs raised some concerns over the limitations of AI-driven monitoring, namely the fear of the potential replacement of the human medical decision. Additionally, both CGs and PWEs emphasized that AI-driven interventions should be transparent and a clear rationale should be provided to enhance trust in the device.

Accuracy was a key consideration. Eight CGs were willing to accept false alarm rates as high as 10%, whereas others were open to rates of up to 40%. In contrast, PWEs were generally more cautious, with most preferring no false alarms or a tolerance of no more than 5% (Question 12c). The introduction of automatic intervention (e.g., drug administration) generated mixed reactions. Whereas most CGs were open to the concept (Question 17a: $n=5$ strongly agreed, $n=8$ agreed), two expressed hesitance. In contrast, all PWEs supported automatic intervention. Control over interventions was another major theme, with all CGs and six of eight PWEs stating they wanted the ability to adjust interventions (Question 12d).

Concerns were also raised about the safety and reliability of interventions, with 11 CGs and five PWEs citing these concerns (Question 12a). Additionally, CGs emphasized the importance of interventions being tied to risk detection of a confirmed SUDEP risk biomarker (Question 17b: $n=13$ agreed or strongly agreed).

3.3 | Barriers and facilitators to the adoption and use of an AI-CLD

Both CGs and PWEs found the wearable prototype acceptable (Question 14a: $n=11$ CGs strongly agreed, $n=4$ agreed; $n=6$ PWEs strongly agreed, $n=2$ agreed). Preferences for device placement varied. Most CCGs preferred the back ($n=10$ voted as first choice), whereas PWEs preferred the arm ($n=5$ voted as first choice). Wearability factors such as comfort (Question 14c: $n=13$ CGs and $n=8$ PWEs agreed or strongly agreed) and discretion (Question 14b: $n=13$ CGs and $n=7$ PWEs agreed or strongly agreed) were largely favored among both groups. Concerns were raised about the device affecting daily routines, particularly among CGs (Question 14d: $n=5$ CGs and $n=2$ PWEs agreed).

Regarding interface preferences, CGs favored mobile phone interaction, whereas PWEs preferred an integrated screen (Question 6: $n=13$ CGs preferred mobile phone interaction; $n=5$ PWEs preferred an integrated screen). A mobile app for notifications was strongly favored (Question 16i–ii: $n=15$ CGs and $n=7$ PWEs agreed or strongly agreed), reinforcing the preference for digital integration.

Regarding device replacement frequency, weekly replacements were considered inadequate by most CGs (Question 15b: $n=7$ disagreed, $n=3$ strongly disagreed), whereas biweekly replacements were seen as more acceptable (Question 15c: $n=5$ strongly agreed, $n=6$ agreed). In contrast, PWEs preferred weekly replacements ($n=8$ agreed or strongly agreed) over biweekly replacements ($n=6$ agreed or strongly agreed).

Most participants preferred the device to alert them in case of any seizure rather than only those leading to SUDEP (Question 8: $n=8$ CGs and $n=7$ PWEs), although some supported alerts for both. Nearly all participants wanted alerts if the device became detached unintentionally (Question 16g: $n=15$ CGs and $n=7$ PWEs agreed or strongly agreed to send alerts to the CG; Question 16h: $n=10$ CGs and $n=6$ PWEs agreed or strongly agreed to send alerts to the medical team).

Real-time alerts for seizures and device interventions were widely supported, reinforcing the need for a robust communication system (Question 17e: $n=15$ CGs, $n=8$ PWEs agreed or strongly agreed).

4 | DISCUSSION

This study is the first to introduce the concept of a wearable AI-CLD for SUDEP prediction and prevention, and to explore the perspectives of PWEs and CGs on its potential implementation. Our findings indicate a shared general positive attitude and willingness to accept a wearable AI-CLD, with key considerations emerging around device usability, comfort, and control over automated interventions.

The participants recognized the complexities involved in accurately predicting and preventing SUDEP and showed interest in the potential advantages of a wearable AI-CLD able to identify a life-threatening seizure and offer an automated immediate intervention. These findings align with the need, highlighted in the literature, to provide a real-time intervention while minimizing human error.[15]

Although AI-CLDs have been widely adopted and hailed as a technological revolution in the treatment of people with type 1 diabetes,[20] their application to predict and prevent SUDEP represents a novel concept. This may explain why participants' positive views were contingent on proactive oversight to mitigate potential harms from an automated intervention. Although participants were able to appreciate the wide-reaching impact of AI in predicting a life-threatening seizure and preventing SUDEP, both PWEs and CGs emphasized the need to retain control over interventions, as well as the need for more information on how AI might result in harm to them personally or to those they care about. Specifically, concerns were raised about potential

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side effects of a preventive intervention, in line with literature reports highlighting unease about AI replacing users' own decision-making in health-related tasks.[21] Compared with PWEs, CGs were more open to automatic interventions. This may be attributed to differences in risk perception, with CGs prioritizing immediate response capabilities and PWEs being more concerned about autonomy, one of the core principles of medical ethics.[22]

Although retaining control over interventions may be challenging in emergency scenarios where immediate action is crucial to save a person's life,[15] developing interventions with minimal side effects and high safety would be crucial to enable broad acceptance of automated solutions for SUDEP prevention. In addition, to foster trust and encourage adoption, AI-CLDs should be integrated into health care in a transparent and informative manner that addresses concerns among PWEs and CGs. A key factor in this integration is the central role of medical teams in medical decision-making, due to broad recognition that physician oversight is essential for patient safety.[23] As part of this oversight, all participants agreed that notifying the medical team upon device detachment is important to ensure patient's safety by minimizing periods of unmonitored risk and to enable early identification of adherence or technical issues that may impact long-term care. Likewise, both CGs and PWEs indicated their willingness to share device-generated data with health care providers, thereby acknowledging the potential benefits of AI-enhanced medical supervision. Previous studies have shown that digital health interventions can improve patient confidence and support clinical decision-making.[24] The strong support for automatic data transmission further underscores AI's potential to bridge gaps in epilepsy care by enabling real-time communication between PWEs, CGs, and health care professionals.

An important finding from this study is that both CGs and PWEs exhibit a strong preference for AI-driven wearable devices over implantable solutions. Whereas the majority of participants were comfortable with wearable technology, the notion of implantable AI monitoring received mixed reactions, with many expressing discomfort. Prior research also suggested that noninvasive monitoring is generally more acceptable in epilepsy management, due to concerns about procedural risks and long-term impacts of implantation.[25] The preference for a wearable device highlights the importance of designing nonintrusive, effective monitoring solutions that ensure adherence and acceptance while integrating seamlessly into daily life. Similar findings emerged from our previous research.[16] User-friendly technology might be particularly beneficial for chronic conditions, as it could help to reduce the stigma burden.

Another important finding relates to users' attitude about device specificity, sensitivity, and accuracy. Compared with PWEs, CGs expressed a higher tolerance for false alarm rates, probably due to CGs prioritizing comprehensive risk detection and PWEs being more concerned with disruptions to daily life. These results suggest that customizable alert settings may be beneficial in optimizing user's experience, allowing individuals to adjust the sensitivity based on personal preferences.

From a practical standpoint, our findings are important for the successful implementation of AI-based SUDEP risk monitoring. Device discretion, comfort, and usability emerged as significant factors influencing acceptance. These preferences are consistent with findings from studies on continuous glucose monitoring and sensor-augmented insulin pumps used by patients with diabetes, where similar concerns regarding comfort, visibility, and ease of integration into daily life have been reported.[26,27] Given that most participants favored mobile phone integration over standalone screens, the ultimate design should emphasize seamless digital integration through smartphone applications. Concerns regarding device placement and replacement frequency indicate that flexible options should be explored to cater to diverse user preferences. Importantly, these insights not only guide the refinement of the NEUROSENSE prototype but also offer a transferable knowledge base for other researchers and developers working to advance user-aligned, AI-driven solutions for SUDEP prevention.

4.1 | Significance for epilepsy understanding and treatment

The results of our study are relevant to ongoing research addressing the unmet need for SUDEP prediction and prevention. Wearable AI-CLDs offer an opportunity to improve early risk detection and enable timely interventions, potentially reducing mortality rates. AI-driven systems may improve clinical decision-making and individualized treatment plans, as indicated by the strong preference for data-sharing with health care providers. Insights into alarm sensitivity, intervention control, and user preferences can guide the refinement of future SUDEP predictive and preventive devices. These devices can be customized to increase PWE and CG confidence by implementing user-centered design principles, which will eventually result in wider adoption and improved outcomes. Overall, AI-driven SUDEP monitoring has the potential to

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revolutionize the treatment of epilepsy by enhancing both patient safety and clinical oversight.

5 | LIMITATIONS

Although this study provides valuable evidence supporting the development of user-friendly AI-based devices for SUDEP risk detection and prevention, some limitations should be acknowledged. The relatively small size of the focus groups may limit the generalizability of the findings. Some caregivers were recruited through an organization dedicated to support research and care for people with Dravet syndrome, which may have resulted in selection of individuals with heightened awareness and familiarity with SUDEP risks and seizure management technologies. As the project progresses and after a first prototype becomes available for testing, additional studies with larger and more diverse populations will be conducted to increase the robustness and generalizability of our findings. At this time, we could not provide participants with a tangible prototype. Lack of direct interaction with an actual device or with simulated AI results might have limited participants' understanding of practical complications. Actual implementation might unearth unanticipated benefits or challenges that could alter their perspectives. After a prototype is available, issues related to long-term usability will also need to be explored.

Of note, the focus group with PWEs was held online, reflecting either participant preferences or logistical constraints. Prior research indicates that, although in-person and video call interviews generally produce similar results, in-person interviews often allow greater depth.[28] Despite this, qualitative interviews performed by video, by telephone, and online are valid alternatives and offer an acceptable solution when logistical or budgetary constraints are present.[29]

6 | CONCLUSIONS AND FUTURE DIRECTIONS

This study provides valuable insights into the perspectives of PWEs and CGs regarding the use of AI-CLDs for the prediction and prevention of SUDEP. Both groups expressed generally positive attitudes toward wearable AI-CLDs, particularly appreciating the potential benefits of real-time monitoring, automatic data sharing with health care providers, and timely intervention. Moreover, our research underscores the need to address key concerns such as accuracy of AI systems, potential automation overreliance, and control over interventions to ensure that these devices are deployed in a way that builds trust and fosters acceptance among both PWEs and CGs.

Long-term studies will be needed to establish the real-world effectiveness and safety of AI-based SUDEP prevention technologies, especially in diverse populations. Moreover, future studies should incorporate negative control groups (i.e., individuals without epilepsy exposed to life-threatening situations where movements occur before cardiac arrest, as in sports or other impact injuries, or intensive care unit mortalities with reflex movements) to further validate the specificity of the AI-CLD approach. In addition, understanding the ethical, privacy, and psychological implications associated with the implementation of AI-powered health technologies will be vital to promote adoption and enhance usability among both PWEs and CGs. Optimizing the collaboration between clinical teams, epilepsy advocacy groups, and technology developers will be essential to ensure AI-CLDs meet both clinical and user needs.

AUTHOR CONTRIBUTIONS

João Ferreira, Miguel França, Carlos Conde, João Claro, and Lígia Lopes were responsible for conceptualization and study design. João Ferreira, Miguel França, and Mariana Cardoso Regalo carried out the focus groups. João Ferreira and Mariana Rei carried out the data analyses. João Ferreira was the main contributor to the original draft and led the review and editing of the writing. João Ferreira, Miguel França, and Mariana Cardoso Regalo drafted the manuscript. All authors critically edited and revised the manuscript, approved its submitted version, and accept responsibility for its content. The article is the original work of the authors and has not been previously published, nor is it currently under consideration by any other journal.

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CONFLICT OF INTEREST STATEMENT

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DATA AVAILABILITY STATEMENT

Aggregate data will be made freely available on NEUROSENSE's data-sharing platform, NEUROSENSE (www.neurosense-project.eu).

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SUPPORTING INFORMATION

Additional supporting information can be found online in the Supporting Information section at the end of this article.

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