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Tracking generalized tonic-clonic seizures with a wrist accelerometer linked to an online database

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ABSTRACT

Purpose: Clinical management of epilepsy and current epilepsy therapy trials rely on paper or electronic diaries often with inaccurate self-reported seizure frequency as the primary outcome. This is the first study addressing the feasibility of detecting and recording generalized tonic-clonic seizures (GTCS) through a biosensor linked to an online seizure database.
Method: A prospective trial was conducted with video-EEG (vEEG) in an epilepsy monitoring unit. Patients wore a wristwatch accelerometer that detected shaking and transmitted events via Bluetooth® to a bedside electronic tablet and then via Wi-Fi to an online portal. The watch recorded the date, time, audio, duration, frequency and amplitude of events. Events logged by the watch and recorded in a bedside paper diary were measured against vEEG, the "gold standard."
Results: Thirty patients were enrolled and 62 seizures were recorded on vEEG: 31 convulsive and 31 non-convulsive. Twelve patients had a total of 31 convulsive seizures, and of those, 10 patients had 13 GTCS. The watch captured 12/13 (92.3%) GTCS. Watch audio recordings were consistent with seizures in 11/12 (91.6%). Data were successfully transferred to the bedside tablet in 11/12 (91.6%), and to the online database in 10/12 (83.3%) GTCS. The watch recorded 81 false positives, of which 42/81 (51%) were cancelled by the patients. Patients and caregivers verbally reported 15/62 seizures (24.2% sensitivity) but no seizures were recorded on paper logs.
Conclusion: Automatic detection and recording of GTCS to an online database is feasible and may be more informative than seizure logging in a paper diary.

1. Introduction

Logs of seizure counts and characteristics in paper diaries are unreliable, so there is a need for better methods to track seizures [10]. An NINDS-sponsored conference in April 2011 recommended validation studies of epilepsy diaries and linking of electronic diaries to biosensors [1]. This is the first trial assessing the feasibility of detecting and recording generalized tonic-clonic seizures (GTCS) via a biosensor linked to an online electronic seizure diary.

Accurate information about precise timing of seizures, diurnal fluctuation, frequency, intensity and duration could facilitate treatments better tailored to the individual seizure patterns. Data collection with paper diaries presents many inherent difficulties, as it requires moderate intellectual functioning, literacy and adherence. Paper diaries are easily misplaced and cannot compensate for unrecognized seizures or false positive recordings of non-epileptic events [1,21]. Several free electronic web-based epilepsy diaries are available for use by patients and caregivers; however, active entry is still required. Additionally, patients who access these web or computer-based applications tend to be younger and better educated, thereby introducing selection bias into trials [2].

Automatic detection of GTCS based on wristwatch accelerometers is feasible [3,4]. Seizure-detection algorithms validated by patient-initiated and automatic audio recordings of sounds made by patients or bystanders have been reported [5].

The objective of this study was to test the feasibility of detecting and logging GTCS with a wrist accelerometer biosensor and linking the data to an online seizure database. The primary goal of the

Abbreviations: EMU, epilepsy monitoring unit; F, female; GTCS, generalized tonic-clonic seizures; Hz, Hertz; M, male; NINDS, National Institutes of Neurological Diseases and Stroke; vEEG, video electroencephalography.

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study was to achieve at least an 80% sensitivity of accurately capturing GTCS detected and logged by the watch-online interface compared to the gold standard of video-EEG (vEEG). The secondary outcome was to examine the sensitivity and accuracy of detection and documentation of non-seizure events by the watch-online interface compared to vEEG and to patient and caregiver reports of events.

2. Materials/methods

This was a prospective trial conducted in the Stanford Epilepsy Monitoring Unit (EMU), with patients monitored continuously using video, audio, ECG and EEG sensors. The study was performed on patients admitted for usual clinical purposes, not specifically for the study, and to provoke seizures anti-seizure medications were tapered, patients were sleep deprived and performed stationary bike exercises. The protocol and consent documents were approved by the Stanford Institutional Review Board. Adults 18 years and older who were able to give informed consent were recruited upon admission to the EMU. Patients with a seizure semiology that historically included tonic-clonic movements in at least one limb were eligible for the study, while those with a history only of non-tonic-clonic or suspected psychogenic non-epileptic events were not included. Enrolled patients wore a wireless wristwatch accelerometer (SmartWatch developed by SmartMonitor©) (Fig. 1) during their inpatient stay. This watch detects rhythmic, repetitive limb movements. Subjects were told that the watch would vibrate when it detected a seizure-like movement and were instructed to push the right center "cancel" button on the watch if they were having a non-epileptic shake event such as teeth brushing. All patients and/or caregivers were given a paper log and instructed write down all of the seizures that occurred during their inpatient admission and to rate the perceived severity of each on a scale ranging from 1 (mild) to 10 (severe). Patients and caregivers were also instructed to push a bedside button to mark an aura or seizure.

The watch and watch-online interface were programmed to detect shaking events and record the date, start and end times, duration, mean shake frequency and amplitude of abnormal movements, along with associated audio. As a positive control to ensure that the equipment was properly functioning at the time of enrollment, an abnormal test movement was simulated, registered by the watch and instantly uploaded to the watch-online portal.

Fig. 1. Wristwatch accelerometer.

All parameters for each detected event were transmitted via Bluetooth® to a bedside electronic tablet and then via WiFi to an online cloud-based seizure database. Watches were exchanged with fully charged devices every 2 days to prevent battery failures.

Thresholds for shake detections are programmable and, for the purpose of this study, were set to a sensitivity of 4 on a scale of 10, with 10 being the least sensitive, and a requirement for at least 7 s of shaking. When the abnormal motion ended, the watch recorded an additional 30 s to register any recurrent repetitive movements. The entire duration of the abnormal movement was recorded from 7 s before watch detection to 30 s after end of the shaking. Data were automatically transferred to the online portal. Each abnormal motion was recorded as graphical data of shake intensity on a two gravitational (2 g)-force acceleration scale ranging from -2 g to +2 g, corresponding to numerical values -128 to +127 (Fig. 2). The watch recorded shaking frequency as the number of times per second that the accelerometer signal crossed the zero level. The shaking frequency was then reported as low (<5 Hz), medium (5–10 Hz) or high (>10 Hz). Each second of event data was categorized into five levels of peak-to-peak amplitudes where maximum excursion of shake amplitude ranged from 0 to 255 acceleration units. The categories were grouped as low (<120), low-medium (120–160), medium (160–200), medium-high (200–240) or high (>240). Amplitude data then were aggregated for the entire event duration and percentage contributions of each amplitude level were

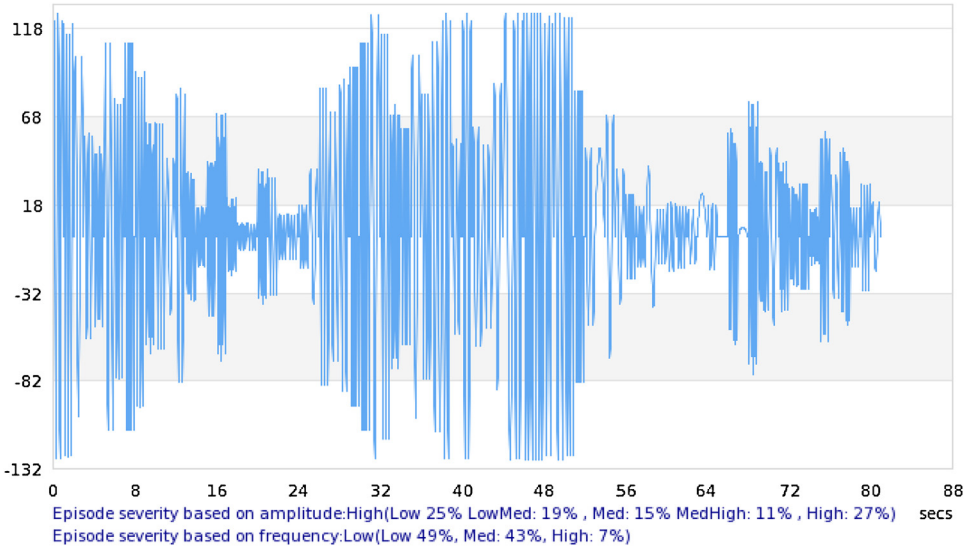

Fig. 2. Case 20 accelerometer data from a GTC. *X*-axis = time in seconds, *Y*-axis = +2 g (+127) to -2 g (-128) force.

computed and labeled according to the dominant amplitude for the event.

A fellowship-trained epileptologist (SL) compared watch detected online entries to vEEG and classified events as tonic-clonic seizures (true positives), non-epileptic events (false positives) including patient-initiated cancellations, and identified seizures not detected by the watch (false negatives). The ILAE seizure classification [22] was used to group events as GTCS or non-GTCS. Convulsive seizures were defined as seizures that had a shaking component in the semiology. Data were used to determine the sensitivity and specificity of the watch's seizure-detection capability and its ability to accurately upload data to the online database. The date, time, behavioral duration, audio and seizure semiology from vEEG were tabulated. Recordings from the vEEG were visually reviewed to determine the intensity, frequency and amplitude of epileptic seizures. The seizure intensity was categorized as mild, moderate or severe. Mild was defined as a myoclonic, tremor, tonic or clonic movement in one limb, moderate as movements in more than one limb but without full body convulsions and severe as full body or generalized tonic-clonic movements. The frequency was estimated as the number of oscillations up and down of the limb divided by the duration in seconds of the tonic-clonic seizure. A predominant frequency was assigned to the convulsion as low (<5 Hz), medium (5–10 Hz) or high (>10 Hz). The predominant amplitude of the abnormal movement was visually categorized into low, medium or high, with the rater blinded as to the watch detection status for the events.

3. Results

Thirty patients were enrolled, but three patients were excluded: one for an early discharge, another because vEEG was not recorded at the time of seizures and a third for losing the watch before recording an event. Table 1 provides baseline patient characteristics, reported seizure types and seizure frequencies about the remaining 27 subjects.

Table 1
Patient baseline characteristics and seizure frequency.

Case	Age	Sex	Reported seizure types	Reported seizure frequency	Watch detected GTC	vEEG detected GTC	Watch detected false positives
1	53	M	Focal with impairment				5
2	41	F	Focal with impairment Focal evolving to convulsive	9 per month	2	2 per 3 days vEEG	0
4	29	F	Generalized (GTCS, absence, myoclonic, myoclonic absence)				1
5	50	F	Focal without impairment Focal evolving to convulsive	1 per 6 months	1	1 per 5 days vEEG	9
6	28	F	Focal with impairment Focal evolving to convulsive	18 per month	0	1 per 4 days vEEG	0
7	66	M	Focal without impairment Focal evolving to convulsive				16
8	54	M	Focal with impairment Focal evolving to convulsive				7
9	56	M	Focal with impairment Focal evolving to convulsive				0
10	62	F	Focal with impairment				6
11	45	F	Focal with impairment Focal evolving to convulsive	1 per month	1	1 per 8 days vEEG	15
12	23	M	Focal with impairment Focal evolving to convulsive	2 per month	1	1 per 2 days vEEG	4
13	46	M	Focal without impairment Focal with impairment Focal evolving to convulsive				2
14	23	F	Focal with impairment Focal evolving to convulsive				0
15	34	F	Focal without impairment Focal evolving to convulsive				0
17	55	M	Focal with impairment Focal evolving to convulsive	1 per 6 months	1	1 per 3 days vEEG	1
18	50	M	Focal with impairment Focal without impairment				1
19	29	M	Focal without impairment Focal with impairment Focal evolving to convulsive				1
20	40	M	Focal with impairment Focal evolving to convulsive	3 per month	2	2 per 6 days vEEG	4
21	29	M	Focal with impairment Focal evolving to convulsive				0
22	47	M	Focal with impairment Focal evolving to convulsive				1
23	44	F	Focal with impairment				0
24	49	M	Focal evolving to convulsive				0
25	21	F	Focal without impairment Focal evolving to convulsive				0
26	62	M	Focal with impairment Focal evolving to convulsive	1 every other month	2	2 per 2 days vEEG	1
28	23	M	Focal with impairment				3
29	19	M	Focal with impairment Focal evolving to convulsive	3 per month	1	1 per 8 days vEEG	0
30	41	M	Focal evolving to convulsive versus GTCS	1 per 3 months	1	1 per 4 days vEEG	4

GTCS = generalized tonic-clonic seizure, M = male, F = female.

Patients wore the watch from 1 to 9 days during vEEG monitoring. A total of 62 seizures were recorded with vEEG: 13 GTCS and 49 non-GTCS. Twelve patients had a total of 31 convulsive seizures. One patient had a 9 s myoclonic seizure, during which the caregiver restrained the arm, so it was not detected by the watch. Another patient with frontal lobe epilepsy had 17 events comprised of hypermotor leg movements and body rocking but no rhythmic arm movements and therefore these were not detected by the wristwatch. The remaining 10 patients had 13 GTCS, of which 12 were captured by the watch – yielding a sensitivity of 92.3% (Table 1). One patient was not physically wearing the watch at the time of a GTCS. The watch did not detect any focal seizures with or without impairment of consciousness if they did not evolve to GTCS. Therefore, seizures were successfully recorded in nine patients.

All events detected by the watch recorded the correct date and time of GTCS. Three out of 13 GTCs occurred out of sleep or at nighttime; whereas, 10/13 GTCs occurred during the day or while the patients were awake. The durations of the events captured by the watch were an underestimate of the total behavioral durations on vEEG because the watch only recorded repetitive shake activity but did not capture low frequency movements such as fumbling or end of seizure clonic jerks (Fig. 3, Table 2).

In Case 12, one GTC seizure was inaccurately reported by the watch to last 746 s, however visual vEEG analysis showed a seizure duration of 121 s and a shake duration of 70 s. The average duration for the GTCS captured by the watch was 38.2 s compared to vEEG duration of 52.9 s, excluding the outlier Case 12. Seizure activity was detected on watch audio recordings in 11/12 (91.7%) and 13/13 (100%) on vEEG including ictal vocalizations, abnormal breathing, repetitive noises or staff assessing the patients. Table 2 shows frequency and amplitude characteristics captured by the watch compared to visual analysis by vEEG in the GTCS.

Event data were successfully uploaded to the bedside tablet in 11/12 (91.7%) and to the online database in 10/12 (83.3%) of the GTCS. One technical failure occurred because the patient was not wearing the watch at the time of the seizure. In patient 17, the watch, bedside tablet and online portal detected the seizure and recorded the date and time of the event but neither the tablet nor the online database recorded the audio, intensity graph, frequency or amplitude parameters. In patient 30, all data were recorded on the bedside tablet, however, the online portal detected the date and time of the seizure but did not record any other parameters. Patients 17 and 30 were wearing the watches and they had sufficient battery power but failure of the data transfer was likely due to interruption of the Bluetooth® or WiFi signal via signal or cross-body interference.

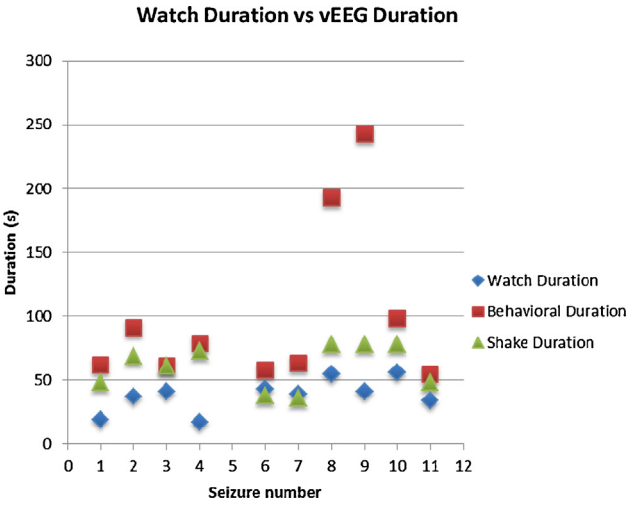

Fig. 3. Watch duration versus vEEG duration of captured events. Case 12 excluded.

The watch recorded 81 false positives (Table 1) and of these 42 (51.8%) were cancelled by the patients. All but one of the false-positive events occurred during wakefulness, the one false-positive event that was not cancelled occurred during sleep when the patient was tossing and turning in bed. On the vEEG, patients were observed to hit the "cancel" button when they were playing with the watch or being examined by staff. False positives that were not cancelled by the patients were explained on vEEG as non-epileptic repetitive movements such as teeth brushing, applying cosmetics, rubbing hands, using the restroom, fiddling with the watching, scratching, shaking a drink, nurse checking an IV, stirring coffee, washing hands, talking on the phone and hand gesturing while talking (Fig. 4). Audio recordings captured by the watch were used to distinguish true positives from uncancelled false positives. For uncancelled false positives, 34/39 had audio recordings with background noise but none had sounds concerning for ictal activity. The background noise was comprised of talking, teeth brushing, TV sounds, or beeping of equipment without nursing staff subsequently rushing into the room. For each the remaining 5/39 uncancelled false positives without audio recordings, the total watch durations were short and lasted 7 s: which is the pre-programmed detection threshold for the watch. In contrast, the average watch duration for the captured GTCS was 38.2 s with a range of 10–49 s.Patients and caregivers verbally reported or pushed the bedside event button for 15/62 (24.2% sensitivity) of all seizures captured on vEEG. Only 3/13 GTCS were verbally reported

Table 2
Data parameters watch versus visual analysis vEEG for captured GTCS.

	Watch			vEEG					
	Shake duration (seconds)	Frequency	Amplitude	Seizure Duration (seconds)	Behavioral Duration (seconds	Shake Duration (seconds)	Intensity	Frequency	Amplitude
Case 2: Seizure 1	12	medium	medium	67	62	48	severe	low	high
Case 2: Seizure 2	30	low	medium	95	91	69	severe	low	high
Case 5: Seizure 3	34	low	medium	97	61	61	severe	low	high
Case 11: Seizure 4	10	high	low-medium	84	79	73	severe	low	high
Case 12: Seizure 12	746	medium	high	121	117	70	severe	low	high
Case 17: Seizure 5	technical fail	technical fail	technical fail	79	73	46	severe	low	high
Case 20: Seizure 6	36	medium	low-medium	58	58	38	severe	low	high
Case 20: Seizure 7	32	high	medium-high	65	63	36	severe	low	high
Case 26: Seizure 8	48	high	low	200	193	78	severe	low	med
Case 26: Seizure 9	34	high	low-medium	246	243	78	severe	low	med
Case 29: Seizure 10	49	high	medium	111	98	78	severe	low	med
Case 30: Seizure 11	27	medium	high	65	55	48	severe	low	med

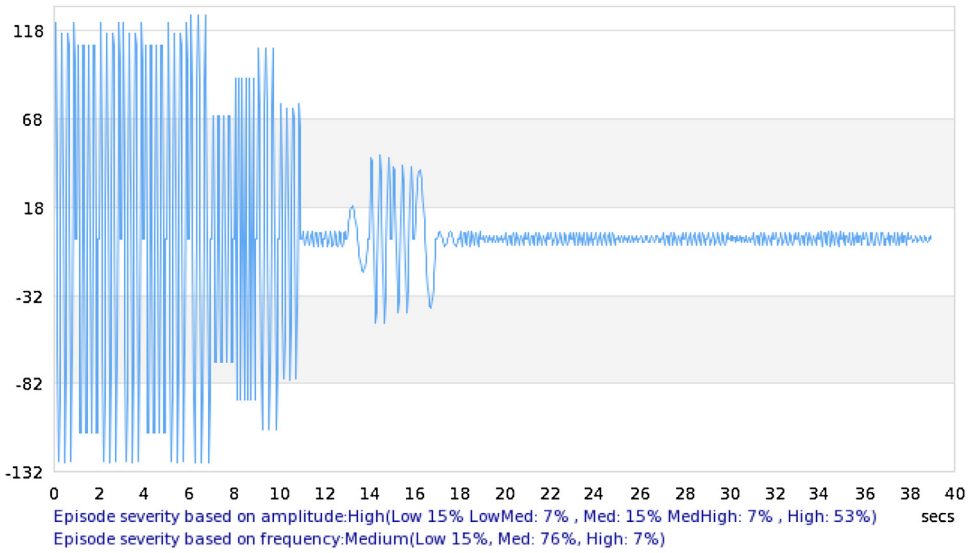

Fig. 4. Case 13 accelerometer data from non-epileptic coffee stirring detected by the watch. *X*-axis = time in seconds, *Y*-axis = +2 g (+127) to -2 g (-128) force.

to the medical staff. Not a single epileptic seizure, including GTCS, was recorded on the bedside paper diary. One patient logged non-epileptic events as epileptic events on the paper diary.

4. Discussion

An accelerometer programmed to detect shaking characteristic of tonic-clonic seizures can generate a record of seizures in an online electronic diary, without need for patient cooperation beyond wearing the watch and recharging the battery (current battery life extends to 5 days when fully charged). Patients need not be literate, technologically sophisticated or even aware of their tonic-clonic seizures. With information uploaded to a web-based diary, accuracy and adherence also becomes less problematic. Selection bias against people with limited literacy, ability to write in a diary or use technology is reduced.

Sensitivity of the watch for detection of GTCS and automatically logging to a diary was 100% provided that the watch was on, the watch battery charged and the relevant limb not restrained. In the inpatient setting, care was taken to ensure that the battery was charged and the watch was on, but such supervision will not necessarily be available in the outpatient setting. In two cases, the data uploaded to the online diary on the bedside tablet, however, it did not upload to the online portal, possibly due to interference with the Bluetooth/WiFi signal when the patients were being held or turned.

The absence of any logged GTCS or epileptic seizures by a paper diary was surprising. Prior studies have suggested that from 23 to 60% of seizures in an epilepsy monitoring unit go unrecognized by the patient [6–12]. For the patients with captured GTCS on vEEG and by watch, the number of seizures captured approximated the verbally reported seizure frequencies on admission though the increase in frequency of seizures during monitoring is mostly explained by withdrawal of anti-seizure medications (Table 1). But even in the EMU setting with specific instructions to log seizures, none of the epileptic seizures, including the GTCS, were recorded in the paper diaries. False-positive detections are a concern for logs documenting benefits of therapies and for clinical trials. One study utilizing ambulatory 16-channel EEG in 502 patients found 87% of log entries to lack concurrent EEG changes [7]. How many of these were false-positive detections versus deep focal seizures not transmitted to scalp EEG is unknown. With an accelerometer watch, an alert patient can cancel false detections, but our study still registered a 48% false-positive detection rate for non-seizure events that the patients did not cancel. However, all but one false positive in our study occurred during wakefulness. Additionally, there were 34/39 uncancelled false positives that had audio recordings with background noise but none had sounds concerning for ictal activity. In 11/12 GTCS, the audio recordings provided sounds consistent with epileptic seizures so we confirmed the observation that a retrospective review of audio recordings during the events can help distinguish true from false-positive seizure detections [5,13].

Accelerometers are useful for detecting shaking [14–17,20], but not activities associated with most tonic, absence, myoclonic or focal seizures without evolution to convulsive generalized tonic-clonic movements. Other detection methods employing electrodermal responses [18], EEG [19] or seizure-associated sounds [5,13] are under investigation to improve the specificity and allow automatic detection of a broad range of seizure types. Seizures that are localized to a body part not wearing the watch will not be detected. Important behavioral components of seizures, including non-motor components and post-ictal phenomena, will not be recorded by an accelerometer; whereby, the true duration of a seizure may be longer than the period of rhythmic shaking, as was seen in our study. Although automatic detection of GTCS underestimated the seizure durations detected on vEEG, it was superior to paper logs and verbal reports by patients and caregivers.

In addition to raw seizure counts, an accelerometer can provide information not easily obtainable with paper or electronic diaries, namely, precise time of day, duration, shake frequency, shake amplitude and accompanying audio. Further study could explore whether this additional information is useful for management or in clinical trials. For example, if the total number of seizures in a patient with medically refractory epilepsy does not decrease but the duration and intensity of events have decreased by 50% with use of a certain medication or device, this could be considered a beneficial change. The quantitative data provided by the accelerometer might allow trials to be designed around continuous numerical data, which could increase the power of a study, reduce required sample size and allow for previously unmeasurable outcome variables, such as seizure severity.

This study was performed in the artificial environment of an EMU, so results may not extend to an outpatient setting. Valid comparisons of accuracy of different methods of seizure detection/logging will require study in a more natural environment, but this study documents feasibility of such a technology.

5. Conclusion

Automatic detection of GTCS and recording on an online database is feasible and can improve accuracy of recorded seizure counts and characteristics. In an inpatient study, data logged to an online database automatically by an accelerometer provided more detailed and accurate data than did caregiver self-reports or a paper diary. The automated diaries generated by accelerometers are subject to occasional technical and user-induced failures, and do not currently detect seizures lacking rhythmical shaking.

Disclosure of conflicts of interest

*Dr. Fisher, who has stock options in SmartMonitor, participated in study design and assisted with writing of the manuscript, but he did not enroll patients, conduct any parts of the study, perform data analysis or formulate conclusions. The remaining authors have no conflicts of interest. This study was approved by the Stanford University Institutional Review Board.

Ethical publication statement

We confirm that all authors have read the Journal's position on issues involved in ethical publication and affirm that this report is consistent with those guidelines.

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