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Applicability of quantitative seizure movement analysis technology in a Portuguese Epilepsy Monitoring Unit / Aplicabilidade de tecnologia de análise de movimento de crises epiléticas numa Unidade de Monitorização de Epilepsia portuguesa

MARÇO, 2024

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Trabalho efetuado sob a Orientação de:

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E sob a Coorientação de:

Dr.ª Ana Catarina Oliveira Caldeiras,
Professor Doutor Pedro Miguel Paredes de Abreu

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Applicability of quantitative seizure movement analysis technology in a Portuguese Epilepsy Monitoring Unit

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UC Dissertação - DECLARAÇÃO DE TRANSPARÊNCIA

RELATIVAMENTE À UTILIZAÇÃO DE FERRAMENTAS DE CHATBOT

GENERATIVO BASEADAS EM LARGE LANGUAGE MODELS

Eu, Ana Carvalho Araújo Simão Moreira, abaixo assinado, nº mecanográfico 201807450, estudante do 6º ano do Ciclo de Estudos Integrado em Medicina, na Faculdade de Medicina da Universidade do Porto, declaro que:

☒ Não procedi à utilização de ferramentas de *chatbox* generativo baseadas em *large language models* para nenhuma das tarefas no contexto do meu trabalho de Dissertação ou Monografia

☐ Procedi à utilização de ferramentas de *chatbox* generativo baseadas em *large language models* no contexto do meu trabalho de Dissertação ou Monografia, encontrando-se todas as interacções (*prompts* e respostas) transcritas em anexo bem como a indicação das aplicações utilizadas.

Neste sentido, confirmo que a eventual utilização de ferramentas de *chatbox* generativo baseadas em *large language models* no contexto do meu trabalho de Dissertação ou Monografia foi exclusivamente descrita na sequência de *prompts* e respostas transcritos em anexo e nas aplicações indicadas.

Faculdade de Medicina da Universidade do Porto, 21/03/2024

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Ana Carvalho Araújo Simão Moreira

Dedicatória

Em primeiro lugar, quero agradecer à equipa que trabalhou arduamente comigo para fazer este projeto acontecer. À Dra. Marta Carvalho, por ter prontamente aceitado o convite e por me guiar nesta exigente jornada. À Dra. Catarina Caldeiras, por toda a paciência e apoio imprescindível prestado face aos obstáculos que fomos encontrando. À Rojan Aslani pela colaboração e por me ajudar a entrar neste complexo mundo da biofísica. Ao Dr. Ricardo Rego pela preciosa orientação no decorrer do projeto.

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A todos os que sem saber contribuíram para que eu chegasse aqui e fosse a pessoa que sou hoje. Obrigada. Têm para sempre um lugar especial no meu coração.

Applicability of quantitative seizure movement analysis technology in a Portuguese Epilepsy Monitoring Unit

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Highlights

- DeepInBed is a novel tool that allows automatic motion quantification from 2D videos
- When applied to a Portuguese EMU, it was able to extract motion metrics correctly
- DeepInBed metrics allowed distinction between automotor and hypermotor seizures.
- KiSA is a semi-automated motion tracking software meant to be used by clinicians.
- Enhancing KiSA for clinical use requires user-friendly and workload improvements.

Abstract

Introduction

One third of epilepsies are drug-resistant and potential candidates to surgical treatment. Seizure semiology is essential for determining the epileptogenic zone but it relies on subjective analysis. Quantitative motion analysis during motor seizures can be a more accurate indicator and it has been successfully developed and laboriously implemented in a specific Epilepsy Monitoring Unit (EMU). This study aims to evaluate the feasibility of integrating quantitative seizure movement analysis technology into the routine of a Portuguese EMU, by determining DeepInBed system's ability to extract motion quantification metrics from standard 2D video recordings, its effectiveness in distinguishing between automotor and hypermotor seizures, and the ease of use of seizure analysis software by clinicians.

Methods

A single-center, cross-sectional study was conducted with patients with automotor or hypermotor seizures that underwent non-invasive Video-EEG monitoring between January 2019 and February 2024 in an EMU at a Portuguese refractory epilepsy center not originally involved in the development of the software. Video recordings utilized 1080p HD cameras positioned perpendicularly to the patients' bed. Distinct marking points were established for seizure onset, seizure end and for the beginning and ending of automotor or hypermotor semiology. DeepInBed, based on pre-trained vision transformer pose estimation and Python programming, was employed to analyze motion patterns. Movement extent and maximum and mean velocity metrics from 10 automotor and 10 hypermotor seizures reviewed and classified by two experienced epileptologists were assessed to determine their capability to distinguish between the two types of seizures. To assess if Kinect Seizure Analyzer (KiSA), a software for quantitative movement analysis, is clinician-friendly and easy to use, two experimental tests were performed and qualitatively analyzed.

Results

Twenty-three automotor (seven patients) and twelve hypermotor (five patients) seizures were included. Aggregated metrics from 17 joints showed a higher sum of displacements (hypermotor=17758 pixels vs automotor=13064 pixels, p value=0.001), movement extent (hypermotor=832162 pixels2 vs automotor=499955 pixels2, p value<0.001), mean velocity (hypermotor=627 pixels/s vs automotor=336 pixels/s, p value<0.001), mean acceleration (hypermotor=7137 pixels/s2 vs automotor=3969 pixels/s2, p value<0.001) and mean jerk (hypermotor=129287 pixels/s3 vs automotor=77870 pixels/s3, p value<0.001), in hypermotor than in automotor seizures with a statistically significant difference. Separate analysis of movement extent and maximum and mean velocity of the trunk and the most active wrist key points in 10 automotor and 10 hypermotor seizures demonstrated no statistically significant difference between these metrics, preventing us from yielding distinct cutoff parameters. The experimental tests using KiSA showed that although useful and able to perform semi-automatic motion tracking, the program is time consuming for non-experts and still has a few glitches.

Conclusion

DeepInBed quantitative seizure movement analysis is capable of extracting objective motion metrics from 2D videos routinely recorded in a Portuguese EMU, making it a promising tool in pre-surgical evaluation. Even with a low number of seizures, objective metrics seemed to differ between hypermotor and automotor seizures. We could not, however, find a reliable cutoff value for wrist and trunk, which are usually the most clearly seen key points during seizures, to distinguish between the two seizure types, limiting its application in clinical practice. Additionally, seizure analysis software is useful, but needs to be improved to become clinician-friendly for everyday practice.

Keywords

Seizure semiology; Quantitative movement analysis; Motion tracking technology; Automotor seizure; Hypermotor seizure

1. Introduction

Epilepsy is a common neurological disorder affecting approximately 50 million people worldwide (WHO, 2019). While most patients have a good prognosis, around 30% are considered refractory (Kwan and Brodie, 2000). In such cases, epilepsy surgery can lead to seizure freedom or significant seizure reduction (Tufenkjian and Lüders, 2012).

Video-EEG combines EEG signal with seizure semiology to determine the epileptogenic zone, making it the gold-standard for pre-surgical evaluation (Elwan et al., 2018). Many seizures produce signs and symptoms that strongly suggest the activation of a specific cerebral area, providing seizure semiology with significant lateralizing and localizing value (Foldvary-Schaefer and Unnwongse, 2011). However, seizure semiology predominantly relies on epileptologists' qualitative visual examination of video recordings, rendering it highly subjective and lacking standardization. Consequently, it is susceptible to interobserver bias and poor interobserver reliability, increasing the risk of diagnostic inaccuracy (Noachtar and Peters, 2019; Elwan et al., 2018; Jin et al., 2014). Observer-independent methods for quantifying seizure semiology may help address this issue, since they provide objective data on seizure motion patterns, including information imperceptible on visual inspection (Zhanjian et al., 2002). This is possible for motor seizure semiology, using motion tracking technology, as demonstrated in previous studies that identified objective movement parameters capable of successfully distinguishing hypermotor from automotor seizures (Rémi et al., 2011).

Currently, more advanced three-dimensional (3D) video-EEG systems have been developed, such as NeuroKinect. It is based on a RGB-D sensor (Microsoft Kinect camera) combined with KinecTracker (KiT), a software tool that handles all the data acquisition workflow, and Kinect Seizure Analyzer (KiSA) (Cunha et al., 2016), a custom-made software tool designed for seizure analysis that features a second-generation semi-automatic motion tracking algorithm (Pereira et al., 2018). NeuroKinect has been previously tested in the Epilepsy Monitoring Unit (EMU) of the Ludwig Maximilian University of Munich, proving to be a reliable tool for the quantitative analysis of motion patterns associated with epileptic seizures (Cunha et al., 2016). Nevertheless, NeuroKinect has been laboriously developed and implemented in a specific EMU that has been improving its technical setup for this purpose, meaning most EMUs worldwide do not have this refined environment. Additionally, even though NeuroKinect has lower costs and is easier to set up than other 3D motion quantification alternatives (Cunha et al., 2016), it still entails certain investments and modifications to the typical EMU environment. In response to this issue, the Biomedical Research And Innovation (BRAIN) group is developing a new system named DeepInBed, for motion detection and automatic quantification of seizures based on the use of a vision transformer for pose estimation (Xu et al., 2022). This system is compatible with conventional two-dimensional (2D), high-definition (HD), red, green and blue (RGB) seizure videos, allowing for easy application in a typical EMU setting without the need for any environment

changes. However, it does not have a user-friendly interface suitable for non-tech-savvy users yet. For these reasons, it is relevant to understand if this motion quantification technology can be integrated into the routine of EMUs around the world with standard resources and if the results are accurate.

This study aims to assess the applicability of quantitative seizure movement analysis technology within the EMU of a Surgical Epilepsy Center in Portugal, addressing three questions:

1) Is DeepInBed capable of extracting movement quantification metrics when applied to the EMU's routinely recorded 2D videos?

2) Do the metrics obtained allow the distinction between automotor and hypermotor seizures?

3) Is KiSA an accessible and intuitive tool for clinicians to use?

2. Methods

2.1. Study design

We conducted a single-center, cross-sectional study in the EMU of a Surgical Epilepsy Center in Portugal. It was approved by the Ethics Committee for Health and the Administration Board of the Hospital (approval document CE348/2023, January 18th 2024). All participants provided written informed consent. The research adhered to The Code of Ethics of the World Medical Association (Declaration of Helsinki).

2.2. Participants and data collection

We analyzed data from patients admitted to the EMU for non-invasive Video-EEG monitoring between January 2019 and February 2024.

Patients were selected based on the presence of either automotor or hypermotor seizures on their monitoring report. Only patients with a clear epilepsy classification were included. Seizures were reviewed by two experienced epileptologists and a final classification was reached by consensus in all cases. The distinction between automotor and hypermotor seizures was based on the semiological classification by Lüders et al. (1998). Patients who declined to participate in the study were excluded.

As the amount of seizures was much higher for automotor than hypermotor seizures, videos of all hypermotor seizures were reviewed for inclusion while for automotor seizures only one year was selected. Based on a higher frequency of automotor seizures on reports we chose 2022.

After a preselection, we included seizures in which most of the semiology was clearly seen and with a considerable range of movement. We collected data on the circumstances and environmental factors during seizures, such as lighting conditions (daylight, artificial light, infrared at night) and staff and blanket occlusion. Occlusion was categorized based on its frequency: none, low (<10% of seizure duration), medium (10%-90%), and high (>90%).

We collected sociodemographic data (age and sex), data on epilepsy characterization and seizure types.

2.3. EMU setting

Our EMU is a two-bed ward with continuous supervision by neurophysiology technicians and nurses. Scalp EEG recordings were obtained placing gold cup electrodes (with conductive paste and collodium), according to the 10-20 system and current IFCN recommendations, ranging from 21 to 44 electrodes (the latter in the case of patients admitted for presurgical evaluation). Polygraphic derivations included an EKG channel (as standard on EEG recordings) and two or more symmetrical EMG channels in selected cases. The signal was sampled at 512 Hz and recordings were visually analyzed using standard bipolar and referential montages. Anti-seizure drugs were maintained, reduced, or discontinued, following the EMU protocol (which depends on baseline seizure types and frequency), under the supervision of a team of epileptologists.

Video is continuously acquired using 1080p HD (1920 x 1080 maximum resolution) cameras with night mode functionality, which means all ictal events that occur within camera reach are recorded. The cameras used for recording seizures remained the same from 2019 to 2024. The camera is positioned perpendicular to the trunk facing the camera in an upright position, complying with a geometric model previously defined by Cunha et al. (2003). During seizures patients are tested for motor and cognitive dysfunction. Ictal video-EEG files are reviewed by experienced clinical neurologists and neurophysiologists and classified according to semiology (Lüders et al.,1998) and EEG features, especially the topographical definition of the ictal onset zone.

2.4. Movement quantification

For each seizure selected in section 2.2., we established distinct marking points to identify the seizure's onset (corresponding to either the first clinical manifestation or to the EEG onset), the beginning and ending of the automotor/hypermotor semiology and the seizure's EEG offset. Seizure duration was measured considering the phase of interest, based on semiology features and evolution. Postictal movements were not analyzed. Using these designated intervals, we applied DeepInBed to quantitatively analyze the seizure motion patterns. This system extracts

objective movement parameters, such as maximum and sum of displacements, movement extent, maximum, minimum, mean, median and standard deviation of velocity, acceleration and jerk.

This technology operates in two main phases. In the initial phase, the system automatically estimates key points of the patient using seizure videos with standard parameters found in typical EMUs, i.e. HD, 2D and RGB. This process is accomplished by employing a pre-trained vision transformer human pose estimation architecture following the COCO topology, resulting in metrics from 17 body key points, including nose, left and right eyes, ears, shoulders, elbows, wrists, hips, knees and ankles. In the second phase, the system quantifies motion metrics for each previously estimated keypoint. Both phases utilize the Python programming language. Currently, the system does not have a user-friendly interface suitable for medical professionals and was operated by a team of biomedical engineers.

In order to evaluate the possibility of determining distinct cutoff parameters capable of distinguishing between automotor and hypermotor seizures, we analyzed the metrics obtained with DeepInBed. As previously done in other studies (Rémi et al., 2011), we selected 10 automotor and 10 hypermotor seizures from our dataset to analyze in terms of movement extent, which refers to the area covered by the key point during the seizure, and maximum and mean velocity. We aggregated the shoulder metrics to represent the trunk and evaluated only the most active wrist. Movements were quantified by analyzing all video frames throughout the entire seizure (32 frames per second).

2.5. Experimenting KiSA

KiSA is a specialized software tool designed for seizure analysis. It features a semi-automatic motion tracking algorithm that identifies body parts exhibiting relevant movements. Then, it calculates metrics for quantifying movements of interest (MOI), allowing for labeling, editing, and deleting of these movements. Additionally, KiSA generates a 3D visualization of the tracked MOI, as well as an automatic report for each analyzed seizure, including MOI quantification statistics and tracings (Pereira et al., 2018).

To assess the applicability of tools like KiSA in the routine of an EMU, we conducted two experimental tests trying the KiSA software from a medical perspective. Even though KiSA can provide 3D metrics, to replicate the conditions found in a standard EMU, we only worked with 2D parameters and utilized test seizure videos. These trials took place at the INESC TEC facilities, using a well-equipped computer with the KiSA system.

2.6. Statistical analysis

We conducted statistical analysis using version 29.0.0.0 (241) of the Statistical Package for Social Sciences (SPSS)® software. To analyze quantitative movement parameters, we presented mean and standard deviation for normally distributed data, and median and interquartile range otherwise. Normality of distribution was assessed using the Kolmogorov-Smirnov Test. We compared parameters between groups using the Independent Samples t-test for normally distributed variables and the Mann-Whitney U test for non-normally distributed variables. Significance was set at $P < 0.05$, and multiple testing was adjusted using the Bonferroni–Holm correction.

3. Results

3.1. Participants' demographics and clinical features

Continuous Video-EEG monitoring lasting at least 3 days (mean=4, SD=1) was performed in all included patients.

After patient selection, we assembled a dataset of 36 automotor (8 patients) and 26 hypermotor (8 patients) seizures. Despite our selection criteria, several seizures had to be removed due to inadequate video conditions that were still unsuitable for the system to analyze, such as poor illumination, insufficient range of motion (i.e. difficult to discern with 1920 x 1080 camera resolution), and occlusion from blankets and staff. This resulted in 23 automotor (7 patients) and 12 hypermotor (5 patients) seizures remaining. Patients' demographic and clinical data is summarized in Table 1.

Information about the conditions in which the seizures happened is presented in Table 2. All automotor seizures exhibited manual automatisms, while 75% of hypermotor seizures involved upper limb movements. Conversely, only 4% of automotor seizures showed pedal automatisms. Medium occlusions by staff affected 48% of automotor seizures and 41.7% of hypermotor seizures, while 57% of automotor seizures experienced medium occlusions by blankets. Additionally, 87% of automotor seizures and 83.3% of hypermotor seizures were tested during the ictal phase.

3.2. Quantitative movement analysis

Results of the motion quantification performed by DeepInBed can be found in Table 3. The system allowed for the extraction of 18 metrics from 17 body key points. These values are aggregated to aid in the comprehension of Table 3. Following the application of the Bonferroni-Holm correction, the quantitative analysis of the movement parameters showed higher sum of

displacements, movement extent, minimum, mean, median and standard deviation of velocity, acceleration and jerk, as well as maximum jerk, in hypermotor than in automotor seizures with a statistically significant difference. Therefore, 15 of the extracted metrics were able to differentiate between the two types of seizures.

A separate quantitative analysis of the metrics extracted from the most active wrist and trunk (mean of shoulders) of 10 automotor and 10 hypermotor seizures was performed in an attempt to find cutoff parameters capable of distinction. We chose the trunk and wrist as it was proved in a previous study (Rémi et al., 2011) that those key points were able to distinguish between automotor and hypermotor seizures and in our dataset both seizure types had a high percentage of involvement of the upper limbs during the seizure.The results are displayed in Table 4. After implementing the Bonferroni-Holm correction, the analysis of movement extent and velocity of the trunk and wrist, along with seizure duration, provided no statistically significant differences, failing to distinguish between automotor and hypermotor seizures. Although there was a trend of higher movement extent and mean velocity in hypermotor seizures compared to automotor seizures, the difference was not statistically significant.

3.3. KiSA's user experience

During the two KiSA trials, distinct test patients were analyzed. The initial test focused on learning how to work with the software, tracking the left hand ROI. The second test aimed to simulate clinical use, tracking the head and right hand ROIs. The time spent on each of the following steps of both experimental tests is summarized in Table 5.

To get started, one has to run the KiSA program in MATLAB, which takes only a few seconds. Users have to select the folder containing the seizure videos and remove any videos that do not contain MOI, after confirming the seizure's clinical start and end timestamps. The folder contains 3 files per minute of video, so one entire minute has to be selected, even if the MOI lasts less. The software loads the files and computes optical-flow (OF) estimations, which may take a significant amount of time. Afterwards, the video is displayed on the KiSA main window and users can watch it, but skipping to a specific point using the time bar is not possible. The video can appear rotated 90º, making it challenging to work with.

To initiate tracking, one must select the region of interest (ROI), such as head, trunk, right or left hand (which refers to the entire arms as well) or leg (which refers to the feet as well), by clicking on a small arbitrary spot on the ROI. The semi-automatic system does some of the tracking, but it needs to be clicked every few frames and it must be precise, because if one selects the background and wants to correct it, the tracking must restart from the beginning. Consistently clicking on the same spot can be difficult when the video resolution is low. Tracking the entire minute of video is necessary, even if the MOI lasts less. During tracking, primary source

("Infrared", "OF Tracking" and "Tracings"), current frame and timestamp information can be visualized on the left side of the window. After tracking is complete, a window shows video length, manually tracked frames, percentage of manual tracking and time spent at the same time that large displacement optical flow tracking and tracking labeling are being performed, a process that can take considerable time. Simultaneously, a tracking video is generated with the full path of the ROI movements drawn in green.

Tracking additional MOIs from the same ROI or different ROIs can be done without reloading the video. The user has to load the ROI tracking video into the KiSA Analysis window, which appears in a small section of the window, and zooming in is not possible. To ensure that the background was not tracked, users should confirm if the green line shows a real path of movement and if the white dot, indicating the current tracking location, is moving accordingly. The KiSA Analysis window includes valuable motion quantification data presented in tables, figures and graphs, including the representation of a selected metric, an image with the tracking drawing and a 3D movement graph (which does not have a caption explaining what is being visualized). Users can select specific ROIs and metrics to view data for only the chosen parameters. However, glitches in the window during full-screen or downsizing attempts result in overlap between the video, graphs, and tables, making some unreadable. Maximizing the window size, without making it full-screen, is the only option. Additionally, switching metrics can cause graph lines to overlap with different colors, making it incomprehensible, and the creation of an excessive caption column that overlaps with the tables. The aforementioned technical flaws are depicted in Fig. 1. After reviewing the movement quantification in the KiSA Analysis window, the user must press the "Export Data" button, which automatically creates a folder with Word, csv ROI and csv MOI reports, as well as MATLAB information.

4. Discussion

4.1. Quantitative movement analysis

This study provides evidence that the DeepInBed system is capable of extracting quantitative movement parameters when used with routinely recorded, 2D, HD and RGB seizure video recordings. Moreover, this technical setup does not require the attachment of any reflectors or sensors to the patient's body, which overcomes limitations encountered in previous 2D infrared marker-based approaches, such as instability of the attached reflectors or sensors caused by vigorous movements associated with seizures and repeated occlusions of markers (Cunha et al., 2003; Zhanjian et al., 2002), or the need to have a specific RGB-D camera such as Neurokinect (Cunha et al., 2016). Therefore, our study suggests that DeepInBed is suitable to be implemented in everyday practice, as it does not entail any alterations to a standard EMU. However, our results also showed that in the typical EMU setting a high amount of recordings are taken in low-light environments, with blankets covering relevant movement and EMU personnel or other elements

obstructing the viewing of the patient. These conditions pose challenges for systems like DeepInBed, compromising the quality of motion quantification and potentially resulting in errors, such as incorrect estimation of the patient's key points. Further investigations are needed to evaluate the accuracy of key point identification by such technologies under these conditions.

Working with 2D video recordings presents several constraints. For instance, the lack of precision when movements are not aligned parallel to the image plane can distort the analysis. It would be important to further refine these quantitative movement analysis technologies by addressing the stringent video requirements to be more adequate to the reality of the majority of EMUs worldwide. With such improvements, other studies should focus on motion quantification that encompasses body parts typically concealed, such as the legs and feet. Furthermore, the COCO topology currently used in DeepInBed does not provide mouth and finger key points, making it impossible to detect subtle automatisms, such as oral and digital movements. Future work adding those key points and improving recognition of subtle movements in videos with limited video resolution (1080p HD) could add valuable quantifying information.

Automatisms refer to sequences of involuntary, repetitive behavioral actions that are inappropriate for the situation (Lüders and Noachtar, 2009). These movements provide valuable information regarding lateralization and localization of the epileptogenic zone. For instance, two thirds of temporal lobe seizures manifest manual and oral automatisms and ictal automatisms with preserved awareness point to the non-dominant hemisphere (Chowdhury et al., 2021). However, upon visual examination, each individual automatism may appear intentional, rendering them "complex" movements and challenging to evaluate solely based on inspection (Cunha et al., 2013). Automotor seizures are complex motor seizures characterized by automatisms affecting the distal portions of the hands and feet, or the mouth and tongue. In turn, brisker, faster and higher amplitude complex movements primarily affecting the proximal segments of the limbs and trunk constitute the main manifestations of hypermotor seizures, which are more frequently seen in frontal lobe epilepsies (Luders et al., 1998). Distinguishing between these two seizure types is not always straightforward, as it can be difficult to determine whether the movements predominantly involve proximal or distal limbs (Lüders and Noachtar, 2009) or the degree of amplitude and speed that constitute a cutoff point, making it essential to find objective parameters to better characterize these movements. In fact, other studies have found characteristic differences in motion patterns of automatisms (Cunha et al., 2013; Mirzadjanova et al., 2010; Yang et al., 2009). Moreover, previous works have established movement metrics that distinguish between automotor and hypermotor seizures (Rémi et al., 2011). These considerations support a quantitative approach to movement analysis.

Our study demonstrated that, when applied to the dataset from a Portuguese refractory epilepsy center, DeepInBed obtained objective motion metrics that also differentiated automotor from hypermotor seizures. In fact, hypermotor seizures motion patterns proved to be faster and

have higher levels of sum of displacement, acceleration and jerk than in automotor seizures. For this study, we only included automotor and hypermotor seizures reviewed and classified by a consensus of experienced epileptologists, in order to grant diagnostic accuracy.

In addition to evaluating the ability of extracted metrics to distinguish between automotor and hypermotor seizures, we aimed to assess if the analysis of specific metrics and key points could establish distinct cutoff parameters that could be applied to other datasets. All automotor seizures in our dataset featured manual automatisms, while 75% of hypermotor seizures involved upper limb movements. Conversely, only 17% of automotor seizures showed pedal automatisms. Considering these factors, we focused on the trunk (including aggregated shoulder metrics) and wrist (the most active one), which also are usually the most clearly visible key points during seizures.

When we specifically analyzed movement extent and maximum and mean velocity of the trunk and wrist, as well as seizure duration, from 10 automotor and 10 hypermotor seizures, we could not find statistically significant differences between the two types of seizures. Thus, by using the DeepInBed system with our hospital dataset, we were not able to replicate the findings of Rémi et al. (2011). This may be due to the limited sample size, as well as the stringent video requirements imposed by this motion quantification technology. Different systems were used for measurement of these parameters. Rémi et al. (2011) applied a quantitative analysis of movements previously published (Cunha et al., 2003; Zhanjian et al., 2002).
Moreover, medium levels of occlusion by staff were observed in a considerable proportion of automotor and hypermotor seizures, while many automotor seizures encountered medium occlusion from blankets. Furthermore, a high percentage of seizures were tested during the ictal phase, potentially influencing the results, since these tests involve activities such as asking the patient to raise their upper limbs, which may overestimate movement extent and velocity in patients who comply with such commands during their seizures. We plan to test the effect of the removal of these solicited movements in the quantitative analysis in future studies.

While our study successfully applied the DeepInBed system for quantitative seizure movement analysis, its novelty poses inherent limitations as it has not been previously tested or validated. As with any new technology, there may be unforeseen biases or inaccuracies in the data analysis process that could affect the interpretation of findings. Future work should focus on conducting comprehensive validation tests of DeepInBed as well as explore the system's performance across a broader range of scenarios. Variations in patient demographics, seizure types, and environmental conditions could impact the system's effectiveness and generalizability. Additionally, since DeepInBed has the advantage of providing quantification metrics for several body key points, future research could explore the possibility of using other key points to find better cutoff parameters. By addressing these limitations we can promote the effective integration

of this technology into routine clinical care, ultimately benefiting patients with epilepsy and facilitating more accurate diagnosis and treatment decisions.

4.2. KiSA's user experience

It would have been ideal to evaluate the user experience of the DeepInBed system. However, due to its current lack of a user-friendly interface tailored for non-tech-savvy users, we opted to assess an alternative motion tracking technology: KiSA. Future studies should consider examining the usability of DeepInBed.

KiSA streamlines seizure movement quantification with its semi-automatic tracking, reducing manual effort by up to 94%. Real-time frame and timestamp display aids user control. Post-tracking, KiSA provides information such as seizure length, tracked frames, percentage of manually tracking and time spent. It allows tracking of additional MOIs without video reloading. It generates a tracking video displaying the full path of movements and offers comprehensive analysis via its Analysis window. Users enjoy flexibility with open-close options and video source switching. Automated report generation post data exportation enhances practicality.

Nevertheless, KiSA presents certain constraints that hinder its usability and efficiency. Although it is intended for routine clinical use, the software's user-friendliness could be improved. The MATLAB-based interface is not intuitive for users less familiar with these technical tools. It lacks features like skipping to specific points in the video, suffers occasional rotation issues, and displays the video in a small window without zoom capability. Additionally, glitches during window resizing can interfere with data visualization and interpretation, causing overlapping content. Moreover, using KiSA involves numerous time-consuming steps. Our initial test required 19 times more time than the duration of the seizure video itself. In clinical settings, this timeframe would allow for the visual inspection of the video numerous times over. While KiSA presents a learning curve, we showed that the process tends to become more efficient with practice. However, even with familiarity, our second test still required 9 to 6 times more time than the seizure video's duration and it is important to note that the quickest test was also the one where the system performed better in automated tracking. The inability to input timestamps directly and automatic loading for files matching MOI duration or stop tracking at any desired point, processing delays, reliance on user tracking accuracy, particularly challenging with low-resolution videos, and the need to restart from the beginning to correct tracking errors increasing are all limitations that increase both time and manual workload.

Once these issues are addressed, KiSA can evolve into a more user-friendly tool. Enhancements such as refining ROI tracking to include specific body parts like shoulders, elbows, and feet, allowing the user to return to the previously tracked frames for correction, enabling viewing of tracings for all ROIs within the same video, clarifying data presented during analysis

and resolving the technical flaws encountered, can turn KiSA into a potential tool to be integrated into everyday clinical practice.

5. Conclusion

The DeepInBed system is capable of extracting movement quantification parameters when applied to an EMU's routinely recorded 2D videos, without the need for alterations to the usual EMU settings. The metrics obtained allowed for the distinction between automotor and hypermotor seizures, rendering it a valuable tool that has the potential to be applied in standard EMUs worldwide. KiSA is still not as intuitive, time efficient and accessible as needed for everyday clinical practice. However, it remains a valuable semi-automatic motion tracking algorithm, offering assistance in the quantitative characterization of seizures with potential for integration into the routine of an EMU.

Declarations of interest

None of the authors have conflicts of interest to declare.

Authorship contributions

Conceptualization: João Paulo Cunha, Ricardo Rego, Tamás Karácsony. Data curation: Ana Moreira, Catarina Caldeiras, Rojan Aslani. Investigation: Ana Moreira. Methodology: Ana Moreira, Catarina Caldeiras. Software: Rojan Aslani. Supervision: João Paulo Cunha, Marta Carvalho, Ricardo Rego. Writing - original draft: Ana Moreira. Writing - review & editing: Ana Moreira, Catarina Caldeiras, Marta Carvalho, Ricardo Rego.

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Table 1. Patients' demographic and clinical data.

	Automotor (n patients = 7)	**Hypermotor (n of patients = 5)**
Age (years)	54 (26)*	38 (21)
Sex		
Female, n (%)	5 (71.4%)	2 (40%)
Male, n (%)	2 (28.6%)	3 (60%)
Epilepsy syndrome, n (%)	Temporal lobe epilepsy, 7 (100%) - Mesial, 6 (85.7%)	Frontal lobe epilepsy, 3 (60%) Temporal lobe epilepsy, 1 (20%) Multilobar epilepsy, 1 (20%)
Etiology, n (%)	Hippocampal sclerosis, 5 (71.4%) Cavernous haemangioma, 1 (14.3%) Other, 1 (14.3%)	Indeterminate, 2 (40%) Malformations of cortical development, 1 (20%) Hippocampal sclerosis, 1 (20%) Hypoxic–ischaemic brain injury, 1 (20%)
Laterality, n (%)	Left hemisphere, 5 (71.4%) Right hemisphere, 1 (14.3%) Bilateral, 1 (14.3%)	Bilateral, 3 (60%) Right hemisphere, 2 (40%)
Age of onset (years)	23 (15)	10 (5)
Duration of epilepsy (years)	22 (13)	28 (22)
Refractory to ASD, n (%)	2A, 4 (57.1%) 2B, 2 (28.6%) No, 1 (14.3%)	2A, 3 (60%) 2B, 2 (40%)

ASD – anti-seizure drugs

Note. Values are given as means (standard deviation), except for the value with an *, that is median (interquartile range).

Table 2. Circumstances and environmental factors during seizures.

	Automotor (n seizures = 23)	**Hypermotor (n seizures = 12)**
Body parts involved in seizures, n (%)	Oral automatisms, 22 (92%) Manual automatisms, 23 (100%) Pedal automatisms, 4 (17%)	Upper limbs, 9 (75%) Trunk, 12 (100%) Lower limbs, 11 (91,7%)
Lighting, n (%)	Daylight, 11 (48%) Artificial light, 8 (35%) Infrared and artificial light, 4 (17%)	Daylight, 6 (50%) Artificial light, 3 (25%) Infrared, 1 (8,3%) Infrared and artificial light, 2 (16,7%)
Obstruction		
Staff, n (%)	None, 3 (13%) Low, 9 (39%) Medium, 11 (48%) High, 0 (0%)	None, 5 (41,7%) Low, 2 (16,7%) Medium, 5 (41,7%) High, 0 (0%)
Blanket, n (%)	None, 5 (22%) Low, 4 (17%) Medium, 13 (57%) High, 1 (4%)	None, 7 (58,3%) Low, 1 (8,3%) Medium, 3 (25%) High, 1 (8,3%)
Other, n (%)	None, 23 (100%)	None, 12 (100%)
Test during ictal phase, n (%)	Yes, 20 (87%) No, 3 (13%)	Yes, 10 (83,3%) No, 2 (16,7%)

Table 3. Movement parameters extracted with the DeepInBed system from all the seizures in the dataset.

Movement metrics	Automotor seizures (n = 23)	Hypermotor seizures (n = 12)	*p* value	Bonferroni-Holm Correction
Displacement (pixels)				
Maximum	173 (84)*	194 (86)	0.045†	n.s.
Sum	13064 (15669)	17758 (29316)	0.001†	
Movement extent (pixels^2)	499955 (637623)	832162 (728568)	<0.001†	
Velocity (pixels/s)				
Maximum	5186 (2520)*	5817 (2579)	0.045†	n.s.
Minimum	0.31 (0.37)	0.53 (0.86)	<0.001†	
Mean	336 (332)	627 (398)	<0.001†	
Median	63 (71)	223 (280)	<0.001†	
Standard Deviation	659 (523)	907 (469)	<0.001†	
Acceleration (pixels/s^2)				
Maximum	68316 (49306)	77914 (41053)	0.058†	n.s.
Minimum	0.25 (0.60)	0.92 (3.49)	<0.001†	
Mean	3969 (4629)	7137 (3830)*	<0.001†	
Median	509 (646)	1763 (2610)	<0.001†	
Standard Deviation	8382 (6869)	11216 (5999)	<0.001†	
Jerk (pixels/s^3)				
Maximum	1443109 (737169)*	1619087 (707387)*	0.005‡	
Minimum	4.22 (9.11)	13.40 (49.64)	<0.001†	
Mean	77870 (95964)	129287 (89008)	<0.001†	
Median	8338 (12224)	30569 (46678)	<0.001†	
Standard Deviation	170557 (151376)	217596 (97109)*	<0.001†	

Note. Values are given as median (interquartile range), except for the values with an *, those are means (standard deviation).
n.s. – not significant
† Mann-Whitney U test, ‡ Independent Samples t-test

Table 4. Movement parameters extracted with the DeepInBed system from 10 automotor and 10 hypermotor seizures.

Seizure type	Movement extent (pixels^2)		Movement velocity (pixels/s)				Seizure duration (s)
			Maximum		Mean		
	Trunk	Wrist	Trunk	Wrist	Trunk	Wrist	
Automotor	679648 (523956)	967989 (896823)*	6521 (2845)	7772 (3696)*	414 (243)	413 (212)	54 (28)
Hypermotor	1022840 (467709)	1097370 (452551)	6219 (1202)*	5887 (2942)*	686 (238)	735 (310)	55 (38)
***p* value**	0.140†	0.529‡	0.912‡	1.000‡	0.021†	0.014†	0.979†
Bonferroni-Holm Correction	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.	n.s.

Note. Values are given as means (standard deviation), except for the values with an *, those are median (interquartile range).
n.s. – not significant
† Independent Samples t-test, ‡ Mann-Whitney U test

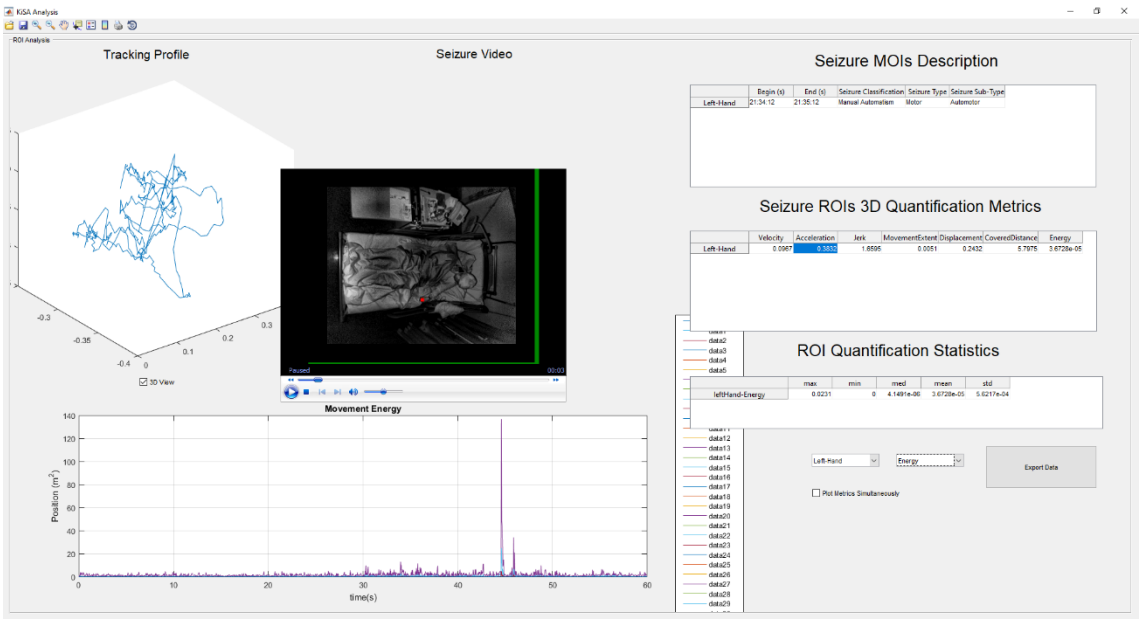

Fig. 1. Technical glitches encountered while using KiSA. The seizure tracking video appears rotated 90º, making it challenging to work with. The "3D View" graph does not have a caption explaining what is being visualized. The full-screen attempt results in overlap between the video and "3D View" graph, making it partially unreadable. Switching metrics can cause graph lines to overlap with different colors, making it incomprehensible, and the creation of an excessive caption column that overlaps with the tables.

Table 5. Time spent and motion tracking details from two experimental tests with KiSA.

	First experiment	**Second experiment**	
Tracked ROI	Left hand	Head	Right hand
Video length	1 min 1800 frames	1 min 1224 frames	1 min 1224 frames
Time spent on loading files and computing optical-flow estimations	4 min	2 min 35 s	
Manually tracked frames	179	168	71
Percentage of manual tracking	10%	14%	6%
Time spent manual tracking	12 min 25 s	4 min 9 s	1 min 40 s
Time spent on LDOF tracking	2 min	1 min 34 s	1 min 3 s
Time spent on tracking labelling	1 min 6 s	39 s	44 s
Total time spent	19 min 31 s	8 min 57 s	6 min 2 s

ROI – region of interest, min – minutes, s – seconds, LDOF - large displacement optical flow

Apêndices

A. STROBE Reporting guidelines
B. Regras de formatação da revista *Epilepsy Research*
C. Parecer da Comissão de Ética para a Saúde da ULS de São João

STROBE Statement—Checklist of items that should be included in reports of ***cross-sectional studies***

	Item No	Recommendation	Page No
Title and abstract	1	(*a*) Indicate the study's design with a commonly used term in the title or the abstract	Page 8
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Pages 8-9
Introduction			
Background/rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 10 Introduction
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 11 Introduction
Methods			
Study design	4	Present key elements of study design early in the paper	Page 11 Study design
Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 12 EMU setting
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Page 11 Participants and data collection
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Pages 11-14 Methods
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group	Pages 11-14 Methods
Bias	9	Describe any efforts to address potential sources of bias	Pages 11-14 Methods

Study size	10	Explain how the study size was arrived at	Page 11 Participants and data collection Pages 12-13 Movement quantification
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Pages 11-14 Methods
Statistical methods	12	(*a*) Describe all statistical methods, including those used to control for confounding	Page 14 Statistical analysis
		(*b*) Describe any methods used to examine subgroups and interactions	Page 14 Statistical analysis
		(*c*) Explain how missing data were addressed	Page 14 Statistical analysis
		(*d*) If applicable, describe analytical methods taking account of sampling strategy	Page 14 Statistical analysis
		(e) Describe any sensitivity analyses	Page 14 Statistical analysis
Results			
Participants	13*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed	Page 11 Participants and data collection Page 14 Participants' demographics and clinical features
		(b) Give reasons for non-participation at each stage	Page 11 Participants and data collection Page 14 Participants' demographics and clinical features
		(c) Consider use of a flow diagram	Page 11

			Participants and data collection Page 14 Participants' demographics and clinical features
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 23 Table 1. Patients' demographic and clinical data Page 24 Table 2. Circumstances and environmental factors during seizures
		(b) Indicate number of participants with missing data for each variable of interest	Page 23 Table 1. Patients' demographic and clinical data Page 24 Table 2. Circumstances and environmental factors during seizures
Outcome data	15*	Report numbers of outcome events or summary measures	Pages 25 Table 3. Movement parameters extracted with the DeepInBed system from all the seizures in the dataset. Page 26 Table 4. Movement parameters extracted with the DeepInBed system from 10 automotor and 10 hypermotor seizures.
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included	Pages 24-26 Tables 2-4

		(*b*) Report category boundaries when continuous variables were categorized	Pages 24-26 Tables 2-4
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Pages 14-15 Results
Discussion			
Key results	18	Summarise key results with reference to study objectives	Pages 16-20 Discussion
Limitations	19	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias	Pages 16-20 Discussion
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Pages 16-20 Discussion
Generalisability	21	Discuss the generalisability (external validity) of the study results	Pages 16-20 Discussion
Other information			
Funding	22	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based	Page 20 Funding

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at http://www.plosmedicine.org/, Annals of Internal Medicine at http://www.annals.org/, and Epidemiology at http://www.epidem.com/). Information on the STROBE Initiative is available at www.strobe-statement.org.

Guide for authors

Before you begin

Preparation

After acceptance

- Online proof correction
- Offprints

Author inquiries

Types of article

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DELIBERAÇÃO DO CONSELHO DE ADMINISTRAÇÃO

Após apreciação e pareceres favoráveis da Comissão de Ética e do Centro de Epidemiologia Hospitalar, considerando que se encontram reunidos os requisitos e demais trâmites previstos no circuito para submissão de projetos de investigação na ULS de São João e em conformidade com as disposições legais em vigor, o Conselho de Administração – ao abrigo das competências previstas no Artigo 71.º dos Estatutos dos hospitais, centros hospitalares, institutos portugueses de oncologia e unidades locais de saúde, aprovados pelo Decreto-Lei n.º 52/2022, de 4 de agosto – delibera:

1. Aprovar a realização do projeto de investigação:
   - "Aplicabilidade do sistema Neurokinect numa Unidade de Monitorização de Epilepsia nacional".
   - Serviço(s) onde decorrerá o projeto de investigação: Neurologia.
   - Investigador(a) principal: Catarina Caldeiras
2. Remeta-se à Comissão de Ética para os procedimentos adequados e demais trâmites convenientes.

CONSELHO DE ADMINISTRAÇÃO DA ULS DE SÃO JOÃO, EPE • REUNIÃO DE 18 DE JANEIRO DE 2024

Presidente do Conselho de Administração

Prof.ª Doutora Maria João Baptista

Diretor Clínico	Enfermeiro Diretor	Vogal Executiva	Vogal Executiva
Prof.º Doutor Roberto Roncon	Enfermeiro Paulo Emílio Mota	Dra. Sofia Leal	Dra. Fernanda Oliveira

› Comissão de Ética
› Centro de Epidemiologia Hospitalar
› Direção Clínica

CE 348/2023

Centro de Epidemiologia Hospitalar

Tomei conhecimento. Nada a opor. À DC.

12 de Janeiro de 2024

A Diretora do Centro de Epidemiologia Hospitalar

(Prof.ª Doutora Ana Azevedo)

n.º 348 / 2023

SÃO JOÃO

DIRECÇÃO CLÍNICA
15 JAN 2024

PEDIDO DE AUTORIZAÇÃO

Realização de Investigação

Exmo. Senhor Presidente do Conselho de Administração
do Centro Hospitalar Universitário de São João

Nome do Investigador Principal:
Catarina Caldeiras

Título da Investigação:
Aplicabilidade do sistema NeuroKinect numa Unidade de Monitorização de Epilepsia nacional

Pretendendo realizar no(s) Serviço(s) de:
Serviço de Neurologia do CHUSJ

a investigação em epígrafe, solicito a V. Exa., na qualidade de Investigador/Promotor, autorização para a sua efetivação.

Para o efeito, anexo toda a documentação referida no dossier da Comissão de Ética do Centro Hospitalar Universitário de São João/ Faculdade de Medicina da Universidade do Porto respeitante à investigação, à qual enderecei pedido de apreciação e parecer.

Com os melhores cumprimentos.

O Investigador/Promotor

Porto, 5 *de* outubro *de* 2023 . Catarina Caldas

assinatura

Centro Hospitalar São João
Centro de Epidemiologia Hospitalar
10 / 1 / 2024

SÃO JOÃO | Encarregado de Proteção de Dados
Data Protection Officer
Entrada 23 / 11 / 2023

CES-IM005-1

Parecer da Comissão de Ética do
Centro Hospitalar Universitário de São João

Título do Projeto: Aplicabilidade do sistema NeuroKinect numa Unidade de Monitorização de Epilepsia nacional

Nome da Investigadora Principal: Dra. Catarina Caldeiras, interna de formação específica em Neurologia no CHUSJ. Serão co-investigadores Ana Moreira (estudante da FMUP) e o Dr. Ricardo Rego.

Onde decorre o Estudo: No Serviço de Neurologia do CHUSJ. Apresentou a declaração da Prof.ª Doutora Elsa Azevedo, diretora do Serviço de Neurologia, que dispõe das condições para a realização.

Objetivos do Estudo:
Perceber se o sistema NeuroKinect é aplicável numa Unidade de Monitorização de Epilepsia (UMEs) com menos recursos. Adicionalmente, pretende-se determinar se a tecnologia de gravação com resolução HD disponível no CHUSJ aumenta a sensibilidade do sistema NeuroKinect.
Estudo realizado no âmbito do Mestrado Integrado em Medicina da FMUP de Ana Moreira, sob orientação da Dra. Marta Carvalho.

Conceção e Pertinência do estudo:
Doentes admitidos na UME do CHUSJ no último trimestre de 2023.
Estão definidos os critérios de inclusão e os dados a ser recolhidos: registos eletrofisiológicos, vídeo e imagem médica, adquiridas no âmbito hospitalar com a equipa de investigadores, bem como dados de natureza clínica e demográfica.

Benefício/risco:
Não são esperados riscos pela participação neste estudo.

Confidencialidade dos dados:
A cada participante será atribuído um código. Todos os dados recolhidos serão guardados num servidor local do INESC TEC/Universidade do Porto (instituição acolhedora do projeto) com acesso restrito e limitado apenas aos membros do grupo de investigação envolvidos. Qualquer vídeo ou fotogramas contendo imagens que possam identificar os participantes serão guardados de forma segura e apenas é permitido o seu acesso a investigadores autorizados. Os vídeos e fotogramas que eventualmente sejam escolhidos para constar de apresentações, publicações e outras atividades de I&D e de educação serão sempre anonimizados e não irão conter imagens da sua cara (e.g. cara será tapada/desfocada), nem qualquer forma de o identificar. Os dados anonimizados podem ser partilhados com investigadores de outros centros de I&D para trabalhos científicos e de educação.
Apresentou um pedido de reutilização de registos clínicos para Investigação e Desenvolvimento ao RAI, e uma 'avaliação sobre o impacto da proteção de dados' para o EPD.

Respeito pela liberdade e autonomia do sujeito de ensaio:
Dispõe de uma adequada informação ao participante e o modelo de CI é o CHUSJ.

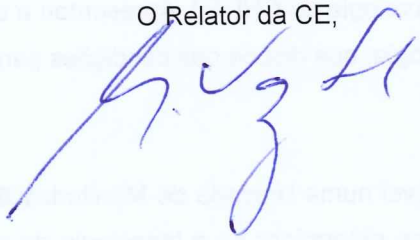
***Curriculum* da investigadora**: Adequado à investigação.

Data previsível da conclusão do estudo: fevereiro de 2024

Conclusão: Proponho um parecer favorável à realização do estudo.

Porto, 20 de outubro de 2023

O Relator da CE,



Questionário eletrónico

n.º 348 / 2023

SÃO JOÃO

SUBMISSÃO DE PROJETO DE INVESTIGAÇÃO PARA PARECER E AUTORIZAÇÃO

Preenchimento em formato digital obrigatório

Caro/a Investigador/a

Este questionário vai ser objeto de apreciação pela Comissão de Ética (CE), que emitirá o competente parecer; pelo Responsável de Acesso à Informação (RAI), que emitirá um despacho de autorização ou indeferimento, relativamente à reutilização da informação a que pretende ter acesso; pelo Encarregado de Proteção de Dados (EPD), que emitirá um parecer, mediante a 'avaliação do impacto sobre a proteção de dados' (que deve anexar a este pedido); pelo Centro de Epidemiologia Hospitalar; sendo enviado, num último momento, para decisão institucional do Conselho de Administração do CHUSJ. Os respetivos despachos de parecer e autorização serão exarados no final deste documento, e enviados posteriormente, de modo a poder iniciar, nesse momento, a investigação a que se propõe.

IDENTIFICAÇÃO DO ESTUDO

Título do projeto:

Aplicabilidade do sistema NeuroKinect numa Unidade de Monitorização de Epilepsia nacional

Data prevista para início: 01 /11 /2023 Data prevista para o término: 29 /02 /2024

EQUIPA DE INVESTIGAÇÃO

1. Investigador principal

Nome: Catarina Caldeiras

Afiliação institucional: ☒ CHUSJ ☒ FMUP Outro:

Serviço/ Departamento: Serviço Neurologia CHUSJ, Departamento Neurociências Clínicas e Saúde Mental

Grupo profissional: Médica Cédula Profissional n.º: 66268

Contacto telefónico: 910967312 Endereço eletrónico institucional: u015773@chsj.min-saude.pt

Formação em Boas Práticas Clínicas (GCP): ☐ Não ☒ Sim

2. Co-investigadores

Nome: Ana Moreira

Afiliação institucional: Departamento de Neurociências Clínicas e Saúde Mental da FMUP

Grupo profissional: Estudante Cédula Profissional n.º:

Contacto telefónico: 915495155 Endereço eletrónico institucional: up201807450@up.pt

Nome: Ricardo Rego

Afiliação institucional: Serviço de Neurologia do CHUSJ

Grupo profissional: Médico Cédula Profissional n.º: 38437

Contacto telefónico: 964255129 Endereço eletrónico institucional: u010498@chsj.min-saude.pt

(acrescentar nº de investigadores, se apropriado ao projeto de investigação)

3. Promotor *(se aplicável)*:

CARACTERIZAÇÃO DA INVESTIGAÇÃO

1. Metodologia da investigação

☐ Qualitativa ☒ Mista (qualitativa+quantitativa) ☐ Outra. Qual?_____

Se quantitativa:

☐ Experimental ☒ Observacional ☒ Sem intervenção ☐ Com intervenção

Se experimental ou observacional com intervenção, qual o tipo de intervenção?

☐ Algoritmo de decisão diagnóstica/terapêutica ☐ Comunicação

☐ Outra. Qual? _____

2. Aleatorização dos braços de intervenção: ☒ Não ☐ Sim

3. Se observacional, qual o desenho?

☐ Coorte prospetivo ☐ Coorte retrospetivo ☐ Caso-controlo

☒ Transversal ☐ Ecológico ☐ Outro. Qual?_____

REALIZAÇÃO DA INVESTIGAÇÃO

Local onde se realiza a investigação: ☒ CHUSJ ☐ FMUP ☐ Outro

Serviço/ Departamento: Serviço de Neurologia do CHUSJ

Existem outros Centros onde se realizará a investigação? ☐ Não ☒ Sim. Quais? INESC TEC

ENTIDADE(S) QUE TUTELA(M) A INVESTIGAÇÃO

1. CHUSJ – Serviço: Neurologia

2. FMUP – Departamento: Departamento de Neurociências Clínicas e Saúde Mental

3. Outra instituição. Qual?_____

ORIENTADOR *(se aplicável)*

Nome: Marta Carvalho

Afiliação:_____ Endereço eletrónico institucional: marta.monteiro@chsj.min-saude.pt

Departamento de Neurociências Clínicas e Saúde Mental da FMUP, Serviço de Neurologia do CHUSJ

PROFISSIONAL DE LIGAÇÃO *(se aplicável - ver anexo)*

Nome:_____ Serviço:_____

ENQUADRAMENTO DA INVESTIGAÇÃO

Em trabalho académico? ☐ Não ☒ Sim Conferidor de grau? ☐ Não ☒ Sim

Síntese dos objetivos:

Ver protocolo em anexo por favor.

Perceber se o sistema NeuroKinect é aplicável numa Unidade de Monitorização de Epilepsia (UMEs) com menos nacional. Adicionalmente, pretende-se determinar se a tecnologia de gravação com resolução HD disponível no CHUSJ aumenta a sensibilidade do sistema NeuroKinect

Fundamentação ética *(incluir informação sumária sobre o estado da arte, ganhos em conhecimento/inovação, ponderação geral sobre benefícios/risco)*:

Ver protocolo em anexo por favor.

Não são previsíveis riscos decorrentes deste trabalho. A participação neste estudo será importante para o progresso que está a ser feito em relação ao tratamento da Epilepsia.

PARTICIPANTES PREVISTOS PARA A INVESTIGAÇÃO

Estão definidos critérios de inclusão / de exclusão de doentes? ☐ Não ☒ Sim

Onde e como serão recrutados os participantes no estudo?
Doentes admitidos na UME do hospital de São João no último trimestre de 2023

Qual é o tamanho amostral? 10

Está prevista a recolha de material biológico específico para a investigação?

☒ Não ☐ Sim. Identifique e justifique:

BENEFÍCIO/RISCO DECORRENTE DA PARTICIPAÇÃO

Descreva os benefícios previsíveis:
Será importante para o progresso que está a ser feito em relação ao tratamento da Epilepsia.

Descreva os riscos/incómodos previsíveis:
Não são esperados riscos pela participação neste estudo.

CONSENTIMENTO INFORMADO, ESCLARECIDO E LIVRE

Prevê a obtenção de consentimento informado? ☒ Sim ☐ Não

Se não, justifique: _____

Prevê informação escrita para os participantes? ☒ Sim. Enviar modelo preenchido.

☐ Não. Justifique: _____

O modelo para obtenção de consentimento é o modelo institucional do CHUSJ? ☒ Sim ☐ Não

PROTEÇÃO DE DADOS PESSOAIS

Necessita consultar registos clínicos? ☐ Não ☒ Sim

Está previsto o tratamento de dados pessoais? ☐ Não ☒ Sim

Se sim, de que forma é garantida a pseudonimização dos dados recolhidos? *(codificação, uso de filtros, siglas...)*

A cada participante será atribuído um código. Todos os dados recolhidos serão guardados num servidor local do INESC TEC/Universidade do Porto (instituição acolhedora do projeto) com acesso restrito e limitado apenas aos membros do grupo de investigação envolvidos. Qualquer vídeo ou fotogramas contendo imagens que possam identificar os participantes serão guardados de forma segura e apenas é permitido o seu acesso a investigadores autorizados. Os vídeos e fotogramas que eventualmente sejam escolhidos para constar de apresentações, publicações e outras atividades de I&D e de educação serão sempre anonimizados e não irão conter imagens da sua cara (e.g. cara será tapada/desfocada), nem qualquer forma de o identificar. Os dados anonimizados podem ser partilhados com investigadores de outros centros de I&D para trabalhos científicos e de educação.

Descreva o património informacional a que pretende ter acesso *(v.g.: nome, idade, data nascimento, idade, morada, diagnóstico, história clínica, tratamento...)*:

Informação médica como registos eletrofisiológicos, vídeo e imagem médica, adquiridas no âmbito hospitalar com a equipa de investigadores, bem como dados de natureza clínica e demográfica.

Está prevista a criação de um Banco de Dados? ☐ Não ☐ Sim

Está previsto o registo de som ou de imagem dos participantes? ☐ Não ☒ Sim

O estudo envolve investigação genética? ☒ Não ☐ Sim

PROPRIEDADE INTELECTUAL

De quem será a propriedade intelectual da investigação e seus resultados?

☐ Investigador ☐ Promotor ☐ Serviço/CHUSJ ☒ Todos

DIVULGAÇÃO DOS RESULTADOS

Está prevista a divulgação dos resultados da investigação? ☐ Não ☒ Sim

Se sim, estão definidos critérios de publicação? ☒ Não ☐ Sim. Quais? _____

CONTRAPARTIDAS PARA OS PARTICIPANTES

Estão previstas contrapartidas para os participantes? ☒ Não ☐ Sim

Pela participação? ☒ Não ☐ Sim

Pelas deslocações? ☒ Não ☐ Sim

Pelas perdas salariais? ☒ Não ☐ Sim

Por outras perdas e/ou danos? ☒ Não ☐ Sim

EXAMES COMPLEMENTARES DE DIAGNÓSTICO

Estão previstos exames complementares de diagnóstico, para além dos inerentes à rotina assistencial?

☒ Não ☐ Sim. Quais? _____

Por quem serão suportados estes custos?

_____

PROTOCOLO FINANCEIRO

Existe protocolo financeiro com o CHUSJ? ☒ Não ☐ Sim

SEGURO

Este estudo prevê intervenção clínica que implique a existência de um seguro para os participantes?

☒ Não ☐ Sim *(se sim, junte cópia da respetiva Apólice)*

Data previsível para fim das credenciais de acesso: ____/____/____

DOCUMENTOS ANEXOS *(em suporte digital)*

- [x] Pedido de autorização ao Presidente do Conselho de Administração do CHUSJ
- [x] Protocolo do estudo
- [ ] Caderno de recolha de dados (CRF)
- [x] Declaração Diretor(es) Serviço(s)
- [x] Informação Orientador
- [ ] Profissional de ligação
- [x] Informação aos participantes
- [x] Modelo de consentimento a utilizar
- [ ] Instrumentos de avaliação (*escalas, inquéritos*)_____
- [x] Curriculum/a vitae *(investigador/es)*
- [ ] Questionário para Encarregado de Proteção de Dados (EPD)
- [ ] Termo de Responsabilidade do Centro Académico Clínico *(para investigadores da FMUP que não pertençam ao CHUSJ)*
- [ ] Protocolo financeiro
- [ ] Outros:_____

TERMO DE RESPONSABILIDADE

Aceitação dos termos e condições de reutilização

Cumulativamente com as obrigações decorrentes da *Lei n.º 26/2016, de 22 de agosto*, maxime dos *n.º 2 e 3 do artigo 21 e o n.º 1 e 2 do artigo 12*, ao submeter o presente pedido, concordo e fico ainda juridicamente vinculado aos seguintes termos e condições:

- Comprometo-me a manter confidencial toda a informação à qual vou ter acesso;
- Após explicação do RAI do CHUSJ, embora a Lei 26/2016, de 22 de agosto, imponha como requisito a anonimização sem possibilidades de reversão, tal desiderato, é não só uma impossibilidade matemática já comprovada, como ainda resulta num prejuízo para a investigação, face à quantidade e à qualidade da informação a retirar à fonte, razão pela qual, concordando com o RAI, assumimos como compromisso a pseudonimização, o que impõe uma avaliação e gestão do risco, num quadro ético-jurídico que aceitamos e nos comprometemos a colaborar e respeitar;
- Não vou elaborar registos, suscetíveis de identificar ou tornar identificável a identidade das pessoas a quem os mesmos dizem respeito;
- Comprometo-me a consultar os processos clínicos nos termos e locais que me forem indicados para o efeito;
- Tomei conhecimento, que a violação de qualquer dos compromissos aqui assumidos, poderá resultar no apuramento de responsabilidades disciplinares, civis e penais, e ainda, à impossibilidade futura de aceder a informação de saúde para fins de investigação.
- Independentemente de requerer a Certidão de Reutilização, DAta REuse Certificate for Research (DARE), comprometo-me a citar as fontes, sempre que publicitar, no todo ou em parte, resultados da presente investigação.

COMPROMISSO DE HONRA E DECLARAÇÃO DE INTERESSES

Eu, Ana Patrícia Queirós Caldeira,

abaixo assinado, na qualidade de Investigador Principal, declaro por minha honra que as informações prestadas neste questionário são verdadeiras. Mais declaro que, durante o estudo, serão respeitadas as recomendações constantes na Declaração de Helsínquia (1960, e sucessivas emendas), da Organização Mundial de Saúde, da Convenção de Oviedo e das 'Boas Práticas Clínicas' (GCP/ICH) no que se refere à experimentação que envolve seres humanos. Aceito, também, a recomendação da CE de que o recrutamento para este estudo se fará junto de doentes que não tenham participado em outro estudo, nos últimos três meses. Comprometo-me a entregar à CE o relatório final da investigação, assim que concluído.

Data: 9 / 10 / 2023 Patrícia Caldeira

assinatura

COMISSÃO DE ÉTICA CHUSJ/FMUP

Parecer da CE, emitido na reunião plenária de 20 / 10 / 2023

A Comissão de Ética para a Saúde APROVA por unanimidade o parecer do Relator, pelo que nada tem a opor à realização deste projecto de investigação.

• Centro Hosp. Univ. São João •
Comissão de Ética
Manuel Vaz Silva
Presidente

RAI 230164/90

RAI - Responsável pelo Acesso à Informação no Centro Hospitalar Universitário de São João (Art. 9º, Lei 26/2016 de 22 de Agosto)

SÃO JOÃO HOSPITAL
Gabinete de Apoio ao RAI
Recebido em 21/11/2023
A funcionária

SÃO JOÃO
AUTORIZO
RAI - Responsável pelo Acesso à Informação do Centro Hospitalar de São João (Art. 9º, Lei 26/2016, de 22/8)
21/11/2023

CENTRO DE EPIDEMIOLOGIA HOSPITALAR

ENCARREGADO DE PROTEÇÃO DE DADOS (EPD)
UNIDADE LOCAL DE SAÚDE SÃO JOÃO, E.P.E.
Paulo Alexandre Mota da Silva
Encarregado de Proteção de Dados do CHUSJ
epd@chsj.min-saude.pt

SÃO JOÃO

Ref.ª CES CHUSJ: **348 / 2023**

Título do Projeto	Aplicabilidade do sistema NeuroKinect numa Unidade de Monitorização de Epilepsia nacional
Responsável pelo tratamento	Ana Catarina Oliveira Caldeiras
Instituição	Centro Hospitalar Universitário São João (CHUSJ)
	Faculdade de Medicina da Universidade do Porto (FMUP)
	Instituto de Engenharia de Sistemas e Computadores, Tecnologia e Ciência (INESTEC)
Investigador	**Interno** Externo
Contacto telefónico	910967312 — Endereço Electrónico 015773@chsj.min-saude.p
Profissional de Ligação	Não aplicável
Amostra	10
Análise de Risco	Tolerável Baixo **Elevado** Muito Elevado

Parecer do EPD:

Data: 08/01/2024

Finalidade: determinar se o sistema NeuroKinect é aplicável numa UME nacional e se a tecnologia de gravação com resolução HD disponível no CHUSJ aumenta a sensibilidade do sistema NeuroKinect.

Licitude: fundamento previsto no artigo **6(1)(a)** e **9(2)(a)** do **RGPD.**

Categorias de dados pessoais: variáveis identificadas com detalhe na AIPD, datada de 23/11/2023, **ponto 13**, tendo presente o **princípio da minimização dos dados.**

Conservação: os dados serão alvo de **pseudonimização**, armazenados em **local seguro**, em área restrita com acesso limitado ao Investigador Principal e Equipa de Investigação, com acesso a ficheiros protegido por **palavra-passe**, efetuando-se a conservação até a conclusão da investigação, durante o prazo máximo de **seis (6) meses**. Os dados recolhidos **serão destruídos** após a finalização do estudo.

Comunicação de Dados: **há partilha** de dados pessoais (pseudonimizados).

Face ao exposto, e observadas as recomendações, entende-se que a presente AIPD apresenta os elementos necessários para assegurar que o **tratamento é realizado em conformidade com o RGPD.**

Recomendações:

1. Sempre que o consentimento do titular for o fundamento de legitimidade adequado para o tratamento de dados, dever-se-á assegurar que o mesmo é válido nas condições legalmente exigíveis: *uma manifestação de vontade livre, específica, informada e inequívoca*. Neste contexto, o consentimento deverá ser objeto de reflexão por parte do participante fora do ambiente hospitalar, devendo para tal, existir a possibilidade de o mesmo remeter o consentimento por correio em envelope RSF.
2. Reforçar as medidas de segurança previstas para a conservação dos documentos em formato de papel que impeçam o acesso à informação a pessoas não autorizadas, bem como o seu manuseamento indevido;
3. Garantir medidas de segurança adicionais no transporte dos dados com recurso a dispositivos electrónicos de armazenamento (Laptop, Disco Externo), nomeadamente através de medidas de cifragem e autenticação;
4. Garantir medidas de segurança adicionais (ex. transformar os dados com recursos a técnicas de generalização, perturbação e/ou como último recurso, a supressão de dados) para os dados que, ainda que pseudonimizados, contém elementos informativos que no seu conjunto possibilitam a re-identificação dos participantes, tendo presente a amostra em estudo (doentes admitidos na UME do HSJ), em particular na fase de disseminação ou publicação dos resultados (incluindo repositórios científicos).
5. A chave de descodificação que permite a re-identificação dos titulares dos dados (CHUSJ) deve ficar sempre na posse do Investigador Principal CHUSJ e protegida de acessos indevidos / terceiros;
6. Em caso de necessidade de extensão de prazo e/ou de qualquer alteração dos pressupostos atinentes ao presente parecer o Investigador Principal deverá solicitar a reapreciação do projeto de investigação junto do EPD.

Revisão AIPD:

☐ Data da próxima revisão: ___ /___ / _____ ☒ Não carece de revisão.

Anexos:

1. Processo CES n.º 348/2023
2. Parecer CES (20/10/2023)
3. AIPD (23/11/2023)
4. Consentimento Informado e Informação ao Participante
5. Protocolo de Investigação

Encarregado de Proteção de Dados
Assinado por: **PAULO ALEXANDRE MOTA DA SILVA**
Data: 2024.01.08 10:58:20+00'00'
Localização: CHUSJ

CARTÃO DE CIDADÃO