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FACULDADE DE MEDICINA
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MESTRADO INTEGRADO EM MEDICINA

2023/2024

Miguel Português Rodrigues

Internal tremor: characterization and quantification in a cohort of neurological patients

MARÇO, 2024

Miguel Português Rodrigues

Internal tremor: characterization and quantification in a cohort of neurological patients

Mestrado Integrado em Medicina

Área: Neurologia

Tipologia: Dissertação

Trabalho efetuado sob a Orientação de:

Professor Doutor Rui Manuel Moreira Araújo

E sob a Coorientação de:

Doutor André Daniel Aires Fernandes

Trabalho organizado de acordo com as normas da revista:
Movement Disorders Clinical Practice

MARÇO, 2024

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DESIGNAÇÃO DA ÁREA DO PROJECTO

Medicina clínica

TÍTULO DISSERTAÇÃO/~~MONOGRAFIA~~ (riscar o que não interessa)

Internal tremor: characterization and quantification in a cohort of neurological patients

ORIENTADOR

Rui Manuel Moreira Araújo

COORIENTADOR (se aplicável)

André Daniel Aires Fernandes

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UC Dissertação - DECLARAÇÃO DE TRANSPARÊNCIA RELATIVAMENTE À UTILIZAÇÃO DE FERRAMENTAS DE CHATBOT GENERATIVO BASEADAS EM LARGE LANGUAGE MODELS

Eu, Miguel Português Rodrigues, abaixo assinado, nº mecanográfico 201807390, 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

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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.

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Assinatura conforme cartão de identificação:

Miguel Rodrigues

Ao Prof. Dr. Rui Araújo e ao Dr. André Fernandes, pela orientação, dedicação e disponibilidade,

Aos meus pais, pelo apoio inabalável e pelo incentivo constante,

Aos que sempre me acompanharam e tornaram o percurso possível,

Obrigado

Internal tremor: characterization and quantification in a cohort of neurological patients

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Word count:

Abstract: 250 words

Main Text: 1870 words

Running title: Internal Tremor in Neurological Patients

Key words: Internal tremor; Parkinson´s disease; Essential tremor

Abstract

Background: Internal tremor (IT) is an underexplored symptom. It may be present in up to 44% of patients with Parkinson's Disease (PD) and 55% of patients with essential tremor (ET). Some authors suggest a possible association with anxiety.

Objectives: We aimed to ascertain the presence of IT in a cohort of patients with PD and ET. Secondly, we intended to characterize its phenomenological features (specifically tremor frequency), to study its correlation with postural and resting tremors, and to analyze its association with anxiety.

Methods: This observational cross-sectional study enrolled 50 patients diagnosed with PD or ET. Patients reporting IT completed a questionnaire regarding its characteristics, and their postural and resting tremors were quantified using a smartphone application. We further inquired whether they could mimic this sensation orally, and then recorded and analyzed their vocal imitations with acoustic analysis software. Internal tremor frequency was subsequentially calculated and compared with the patients' postural and resting tremors.

Results: IT was reported in seven patients (14%). Five patients (71.4%) noted a correlation with anxiety. Five patients (71.4%) were able to characterize IT through sound, with frequencies generally falling within the range of 4-6 Hz.

Conclusions: IT appears to be an infrequent phenomenon in patients with overt tremor syndromes. It could be associated with anxiety, and it can also reflect a subclinical tremor. Our study is compatible with the possibility of a central pattern generator driving the tremor observed (and felt) in patients with PD and ET. Larger studies are required to better understand IT.

Tremor is the most prevalent hyperkinetic movement disorder. It manifests as a rhythmic and sinusoidal movement pattern and affects a substantial portion of patients diagnosed with Parkinson's disease (PD) and all individuals with essential tremor (ET). This condition can essentially be classified as resting, postural, and kinetic tremors[1]. Additionally, there is another type, "internal tremor," which is a poorly comprehended and underexplored symptom in neurology, specifically in the field of movement disorders. Internal tremor (IT) can be described as a feeling of tremor, shaking, or vibration in the body that is not associated with an actual movement[2]. The underlying pathophysiological mechanism and anatomical origin of IT remain unclear. Nevertheless, it has been suggested a possible association with anxiety [2-4]. In some patients, IT may underpin a subclinical “physical tremor” [2-5] which may go unnoticed during the neurological evaluation. The detection and characterization of IT presents unique challenges due to its subjective nature. As a result, this condition may be prone to underdiagnosis, particularly when paired with a "normal" neurological exam. Despite being an understudied phenomenon, some authors report internal tremor to be present in up to 44% of PD patients and 55% of ET patients. While it is perceived as benign and often clinically dismissed, some patients may perceive it as very bothersome[3].

The present study aims to ascertain the presence or absence of internal tremor in a cohort of patients with PD and ET followed in the Outpatient Neurology Department – Movement Disorders at Unidade Local de Saúde de São João. Secondly, we aimed to characterize its phenomenological features (specifically tremor frequency), to study its correlation with postural and resting tremors, and to analyze its association with anxiety features.

Methods

Study design

We conducted an observational cross-sectional study comprising patients diagnosed with PD or ET, followed in the Outpatient Neurology Department – Movement Disorders Movement Disorders at Unidade Local de Saúde de São João, between June 2023 and September 2023. The diagnosis of PD and ET was made according to the Clinical Diagnostic Criteria for Parkinson's disease[6] and the Consensus Statement on the classification of tremors proposed by the International Parkinson and Movement Disorder Society (MDS)[1].

Inclusion criteria: All willing participants with a diagnosis of Parkinson's disease or Essential Tremor, and whose clinical records are available for consultation at Centro Hospitalar Universitário São João.

Exclusion criteria: not applicable.

The study was approved by the Ethical Committee of the Faculty of Medicine of Porto University, with the process number CE-284-23.

Data collection

Participants were asked about the presence of internal tremor (either currently active or previously experienced), which was defined as "a feeling of tremor, shaking, or vibration in the body that is not associated with an actual movement". This description was read ipsis verbis to the participants.

The following information was collected: gender, age, diagnosis (Parkinson's disease or Essential Tremor), disease duration, and pharmacological history.

In patients who reported internal tremor, we collected the following data:

For individuals with Parkinson's disease: Hoehn-Yahr stage, dominant hand and MDS-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) part III[7].

For individuals with essential tremor: dominant hand and clinical rating scale for total tremor (Clinical Rating Scale for Tremor)[8].

Patients with IT were required to answer a questionnaire (see Supplemental information), which included a set of questions to assess the presence and location of IT; if the IT was perceived the same or differently than the "external" visible tremors; when IT began in relation to the other symptoms and signs of the condition; how many days per week it occurred and how long it lasted for; if there are potential factors that may be associated with the episodes; if they experienced any burning, tingling or aching along with IT, and their general level of anxiety (scale from 1 to 10). The presence of anxiety symptoms was further evaluated by the Anxiety, Depression, and Stress Scale (EADS-21)[9].

Postural and resting tremors were quantified using a commercially available smartphone application (Studymytremor® for iPhone®). In patients who reported the presence of "internal tremor", we further inquired whether they could mimic this sensation orally. The patients' vocal imitations were recorded and analyzed using an acoustic analysis software (Goldwave®). Internal tremor frequency was subsequentially calculated visually (in hertz – sound oscillations / second) and compared with the patients' resting and postural tremors.

Statistical analysis

Statistical analysis was conducted using IBM SPSS® Statistics for MacOS, version 29. For continuous variables, with normal distribution, mean and standard deviation (SD) were used, for non-normal distributed variables, median, maximum, and minimum values are presented. To describe categorical variables absolute and relative frequencies were used (n, %).

Results

Baseline characteristics

A total of 50 patients were included, of which 28 (56%) were male. The majority of the patients included (90%) had a diagnosis of PD and the remaining patients had a diagnosis of ET. Concerning PD patients, the current mean age was 71±14 years, and the median disease duration was 6 years (maximum: 76, minimum: 1). Resting tremor was observed in 32 patients and the median stage according to the Hoehn and Yahr classification was 2 (maximum: 5, minimum: 1). Patients diagnosed with ET had a current mean age of 72±12 years, with a median disease duration of 11 years (maximum: 16, minimum: 3). 25 (55.6%) of PD patients and 3 (60.0%) of ET patients were under treatment with anxiolytic or anti-depressant medication. Table 1 summarizes the main demographic and clinical characteristics of the patients.

Internal tremor

IT was reported in seven patients (14.0%) – five with PD, and two with ET, of which six (85.6%) were female. Regarding IT patients, the current mean age was 70±16 years, with a median disease duration of 6 years (maximum: 12, minimum: 1).

The median score of MDS-UPDRS part III was 26 (maximum: 51, minimum: 14). On the Clinical Rating Scale for Tremor, one patient obtained a score of 20, while another patient scored 27.

The mean score of the Anxiety, Depression, and Stress Scale (EADS-21) was 31±14. The anxiety subscale of the EADS-21 revealed that, only one patient did not exhibit elevated levels of anxiety, whereas one showed moderate anxiety, two were labeled severe anxiety, and three were classified with extreme anxiety.

Patients with IT were asked to answer a questionnaire regarding its characteristics and additional features (table 2). Regarding the anatomic localization, one patient reported IT in the hand(s) and another patient experienced IT in the neck and head. IT was confined to hand(s)

and the chest, neck or head in one patient. Three patients experienced IT simultaneously in hand(s), feet or legs and in the chest, neck or head. One patient localized the sensation to the lumbar region. Four patients (57.1%) were currently under anxiolytic or anti-depressant therapy. The majority (71.4%) reported an association with anxiety. IT was experienced at least two days per week by two patients and daily by one patient.

One patient revealed that the onset of IT appeared before the formal diagnosis of ET was made, four patients indicated it occurred sometime after the diagnosis was performed, and one patient reported it occurred alongside other clinical features that led to the establishment of the diagnosis.

Internal tremor evaluation

Concerning patients who reported experiencing internal tremor (n=7, 14.0%), we asked if they could mimic their sensation orally. The patients' vocal imitations were recorded and analyzed using acoustic analysis software (Goldwave®). Internal tremor frequency was subsequentially calculated visually (in hertz – sound oscillations / second) and compared with the patients' resting and postural tremors (as shown below and further in Table 3).

Patient 1: Female, 77 years old, Parkinson's disease, 6.0 Hz left postural tremor and 5.1 Hz left rest tremor, internal tremor estimated at 5.0 Hz (figure 1).

Patient 2: Female, 75 years old, Parkinson's disease, 5.5 Hz right rest tremor, internal tremor estimated at 3.0 Hz (figure 2).

Patient 3: Female, 85 years old, Parkinson's disease, 6.6 Hz right postural tremor and 7.1 Hz right rest tremor, internal tremor estimated at 4.0 Hz (figure 3).

Patient 4: Female, 85 years old, Parkinson's disease, 2.5 Hz right postural tremor and 4.2 Hz right rest tremor, internal tremor estimated at 5.5 Hz (figure 4).

Patient 5: Male, 56 years old, essential tremor, 5.5 Hz right postural tremor, internal tremor estimated at 4.0 Hz (figure 5).

Discussion

Internal tremor remains an understudied symptom that may be present in diverse neurologic disorders, including PD and ET. To the best of our knowledge, we were the first to attempt to objectively characterize the internal tremor's frequency.

IT is associated with marked clinical heterogeneity, mainly regarding patient experience. Internal tremor seems to be associated with anxious symptomology, as documented by a direct question and EADS-21 results, which aligns with existing literature [2–4]. However, whether anxiety acts as a trigger and/or as an aggravating factor is still unknown.

In our cohort, only a minority of patients was able to mimic their internal tremor. We speculate this happens because it is an inherently difficult task to reproduce exactly what someone feels internally. Obviously, we acknowledge this imitation may not entirely overlap with the "real" internal tremor (assuming it really exists), but we considered it to be an apt attempt. The measurement of frequencies of tremors that are "heard" in addition to being seen has been done before[10]. A second and important limitation of this method is the impossibility of orally mimicking very high-frequency tremors, which may, in theory, explain why certain individuals experience IT but cannot imitate them orally. An interesting analysis for the future would be to study whether people who experience IT but cannot orally reproduce them have high-frequency "external" tremors.

Even though the number of analyzed internal tremors is low to make any substantial considerations, we find it interesting that the frequencies of IT were within the "parkinsonian range" (4-6 Hz). This discovery is compatible with the idea of a pacemaker or central pattern generator.

We acknowledge additional limitations in our study. Firstly, we used a convenience sampling method. Patients included in the study were those who presented at a specific healthcare center during the study period, which may not represent the broader population of

neurological patients and thus contributing to a selection bias. Additionally, we considered the hypothesis that patients with internal tremor who did not meet the definition used were inadvertently excluded. The reduced sample size and the absence of a control group interfere negatively with the ability to assess the prevalence of internal tremor in patients with PD and ET compared to the general population. Furthermore, the IT questionnaire applied was not formally validated in our population,

In conclusion, our study expands the knowledge about internal tremor. It is an infrequent phenomenon, which is likely associated with the underlying tremor disorder, and possibly associated with anxiety. While further studies are required, it is possible that these tremors fall within 3-6 Hz. Large-scale and prospective longitudinal studies evaluating the response of internal tremor to dopaminergic and/or "anti-tremor therapy" could further enhance our understanding of its pathophysiology and management. No specific funding was received for this work.

Author Roles:

1. Research project: A. Conception, B. Organization, C. Execution;
2. Statistical Analysis: A. Design, B. Execution, C. Review and Critique;
3. Manuscript Preparation: A. Writing of the first draft, B. Review and Critique;

M.R. 1B, 1C, 2A, 2B, 3A

A.F. 1A, 1B, 1C, 2A, 2B, 3B

R.A. 1A, 1B, 1C, 2C, 3B

Funding Sources and Conflict of Interest:

No specific funding was received for this work.

The authors declare that there are no conflicts of interest relevant to this work.

Financial Disclosures for the previous 12 months:

The authors declare that there are no additional disclosures to report.

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Tables

Table 1: Main demographic and clinical characteristics of the patients.

	PD (n=45)	**ET** (n=5)
Gender		
Male	25 (55.6%)	3 (60.0%)
Female	20 (44.4%)	2 (40.0%)
Age (years)		
Mean ± SD	71 ± 14	72 ± 12
Years Since Diagnosis		
Median	6	11
Max	76	16
Min	1	3
Internal Tremor		
No	40 (88.9%)	3 (60.0%)
Yes	5 (11.1%)	2 (40.0%)
Anxiolytic or Anti-depressant Medication		
No	20 (44.4%)	2 (40.0%)
Yes	25 (55.6%)	3 (60.0%)
Hoehn and Yahr Scale		
Median	2	-
Max	5	-
Min	1	-

PD: Parkinson´s disease; ET: Essential tremor; SD: Standard deviation; Max: maximum value; Min: minimum value

Table 2: Characteristics and additional features of internal tremor.

		n (%)	Mean ± SD	Median	Max	Min
Gender	Male	1 (14.3)				
	Female	6 (85.7)				
Age			70 ± 16			
Dominant hand	Right	7 (100.0)				
	Left	0 (0.0)				
Diagnosis	PD	5 (71.4)				
	ET	2 (28.6)				
Years Since Diagnosis				6	12	1
Anxiolytic or anti-depressant medication	No	3 (42.9)				
	Yes	4 (57.1)				
IT in the hand(s)	No	2 (28.6)				
	Yes	5 (71.4)				
IT in feet or legs	No	4 (57.1)				
	Yes	3 (42.9)				
IT in chest, neck or head	No	2 (28.6)				
	Yes	5 (71.4)				
IT feel the same as the visible tremors	No	4 (57.1)				
	Yes	3 (42.9)				
Onset of IT in relation to PD/ET	Before	1 (14.3)				
	Simultaneously	2 (28.6)				
	After	4 (57.1)				
Days per week experiencing IT	<=1	4 (57.1)				
	2-4	2 (28.6)				
	>5	1 (14.3)				
Association with anxiety (patient´s perception)	No	1 (14.3)				
	Don´t know	1 (14.3)				
	Yes	5 (71.4)				
EADS-21			31 ± 14			

PD: Parkinson´s disease; ET: Essential tremor; IT: Internal tremor; SD: Standard deviation; Max: maximum value; Min: minimum value

Table 3: Frequency of postural, rest and internal tremors.

	Postural tremor		Rest tremor		Internal tremor
Patient	**Right**	**Left**	**Right**	**Left**	
1	-	6.0 Hz	-	5.1 Hz	5.0 Hz
2	-	-	5.5 Hz	5.1 Hz	3.0 Hz
3	6.6 Hz	6.5 Hz	7.1 Hz	6.9 Hz	4.0 Hz
4	2.5 Hz	2.3 Hz	4.2 Hz	4.8 Hz	5.5 Hz
5	5.5 Hz	9.6 Hz	-	-	4.0 Hz
6	5.8 Hz	6.5 Hz	5.8 Hz	6.1 Hz	NA
7	9.0 Hz	8.4 Hz	4.1 Hz	7.6 Hz	NA

NA, not available; -, absent

Supplemental information

Figures

Figure 1: Patient 1, internal tremor estimated at 5.0 Hz.

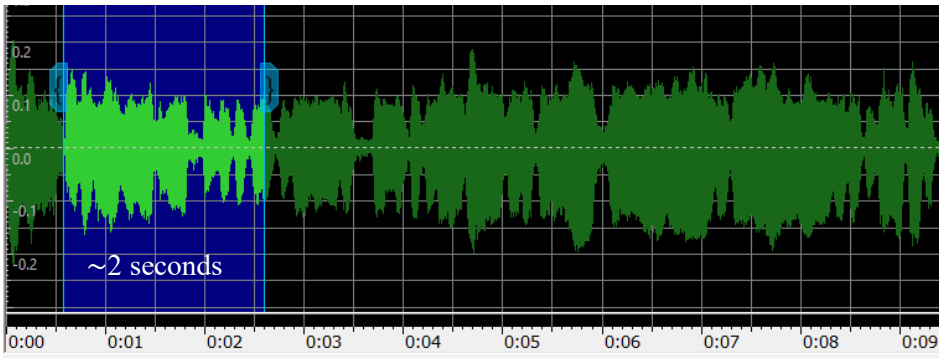


Figure 2: Patient 2, internal tremor estimated at 3.0 Hz.

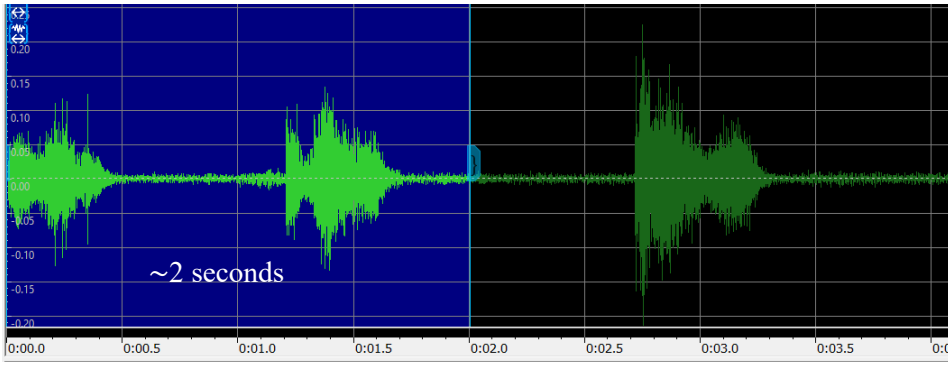


Figure 3: Patient 3, internal tremor estimated at 4.0 Hz.

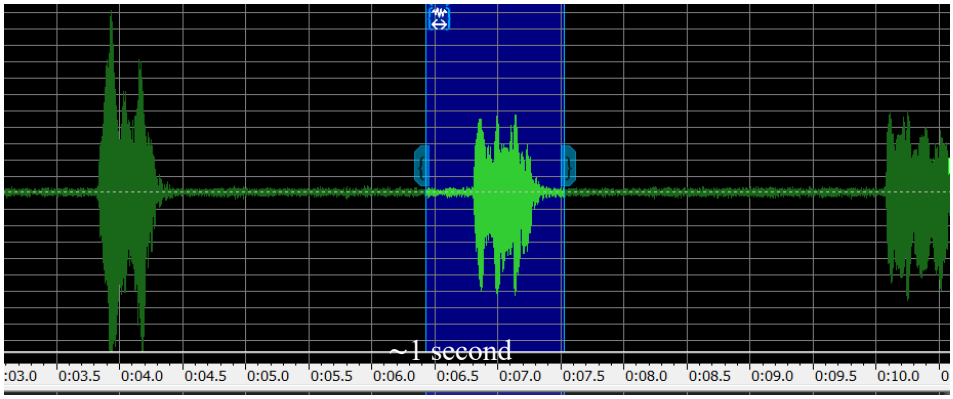


Figure 4: Patient 4, internal tremor estimated at 5.5 Hz.

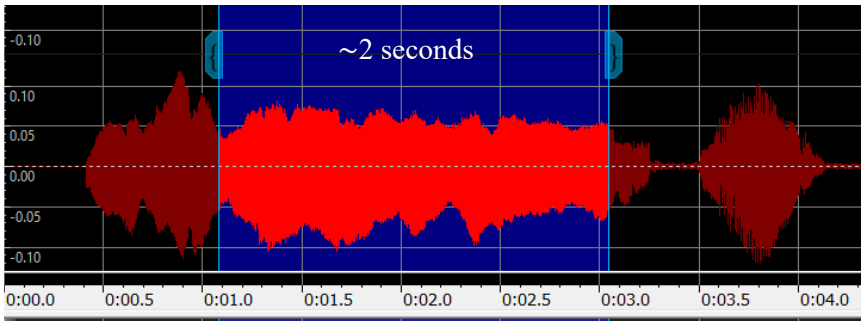
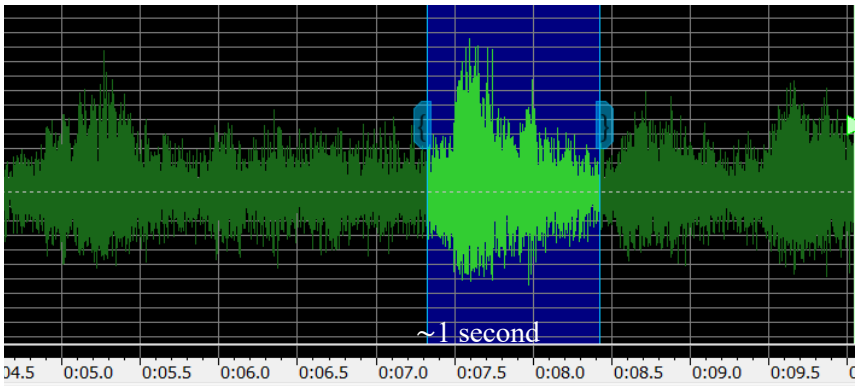


Figure 5: Patient 5, internal tremor estimated at 4.0 Hz.



Questionário Tremor interno

1. Identificação e dados demográficos

   Nome:

   Contacto:

   a. Código:

   b. Idade atual

   c. Sexo M ☐ F ☐

2. Mão dominante E ☐ D ☐

3. Diagnóstico

   Tremor essencial ☐ Doença de Parkinson ☐

4. Tempo em anos de evolução DP/ET:____

5. Medicação atual

   _____
   _____
   _____

Já sentiu tremores, agitação ou vibração no seu corpo, mesmo na ausência de movimento aparente? S__N__

Se sim:

Às vezes sente a sua mão(s) a tremer quando não o está objetivamente? S__N__

Às vezes sente o(s) seu(s) pé(s) ou perna(s) a tremer quando não o está objetivamente? S__N__

Sente tremores ou vibração no seu peito, pescoço ou cabeça? S N__

A sensação de tremor interno é semelhante ao tremor visível? Se diferente, quais as diferenças?

_____

A sensação de tremor interno começou antes, ao mesmo tempo ou após os sinais ou sintomas de doença de Parkinson/tremor essencial? (estimar em anos)_____

Quantos dias por semana, em média, sente o tremor interno? _____

Quanto tempo dura a sensação de tremor interno (minutos-horas)? _____

Existe algo que precipite/torne mais frequente a sensação de tremor interno?

_____

Existe algo que pare a sensação de tremor interno?

_____

Acha que a sensação de tremor interno está associada a ansiedade?

Sim ☐ Não ☐ Não sei ☐

Se sim, acha que agrava quando está ansiosa(o)?

Sim ☐ Não ☐ Não sei ☐

Sente sensação de queimor, formigueiro ou um desconforto?

Sim ☐ Não ☐

Numa escala de 0-10, quão ansiosa(o) acha que é (em média)? _____

Reporting Guidelines

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 2, para. 2: "**Methods:** This observational cross-sectional study (…)."
		(*b*) Provide in the abstract an informative and balanced summary of what was done and what was found	Page 2, para. 2, 3: "**Methods:** This observational cross-sectional study enrolled 50 patients (…) frequencies generally falling within the range of 4-6 Hz"
Introduction			
Background/ rationale	2	Explain the scientific background and rationale for the investigation being reported	Page 3, para. 1: ""internal tremor," which is a poorly comprehended and underexplored symptom in neurology (…) some patients may perceive it as very bothersome."
Objectives	3	State specific objectives, including any prespecified hypotheses	Page 3, para. 2: "The present study aims to (…) association with anxiety features."
Methods			
Study design	4	Present key elements of study design early in the paper	Page 4, para 1: "We conducted an observational cross-sectional study (…) Movement Disorder Society (MDS)[1]"

Setting	5	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection	Page 4, para 1: "We conducted an observational cross-sectional study comprising patients diagnosed with PD or ET, followed in the Outpatient Neurology Department – Movement Disorders Movement Disorders at Unidade Local de Saúde de São João, between June 2023 and September 2023."
Participants	6	(*a*) Give the eligibility criteria, and the sources and methods of selection of participants	Page 4, para 2,3: "Inclusion criteria: All willing participants with a diagnosis of Parkinson's disease or Essential Tremor, and whose clinical records are available for consultation at Centro Hospitalar Universitário São João. Exclusion criteria: not applicable."
Variables	7	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable	Page 4, para 5-11: "internal tremor (either currently active or previously experienced), which was defined as (…) and compared with the patients' resting and postural tremors."
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	Page 4, para 5-11: "internal tremor (either currently active or previously experienced), which was defined as (…) and compared with the patients' resting and postural tremors."
Bias	9	Describe any efforts to address potential sources of bias	No specific measures were implemented
Study size	10	Explain how the study size was arrived at	Page 4, para 1-3: "patients diagnosed with PD or ET, followed in the Outpatient Neurology Department (…) Exclusion criteria: not applicable."
Quantitative variables	11	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why	Page 4, para 5-11: "For continuous variables (…) frequencies were used (n, %)."
Statistical methods	12	(a) Describe all statistical methods, including those used to control for confounding	Page 5, para 3: "For continuous variables (…) frequencies were used (n, %)."

		(b) Describe any methods used to examine subgroups and interactions	Not applicable, we didn´t perform an examination of subgroups and interactions.
		(c) Explain how missing data were addressed	Not applicable, there was no missing data.
		If applicable, describe analytical methods taking account of sampling strategy	Not applicable, we did not perform inferential statistics, only descriptive analysis.
		(e) Describe any sensitivity analyses	Not applicable, we did not perform any sensitivity analyses
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 6, para 1, 2: A total of 50 patients were included, of which 28 (56%) were male. The majority of the patients included (90%) had a diagnosis of PD and the remaining patients had essential tremor (…) (85.6%) were female."
		(b) Give reasons for non-participation at each stage	Not applicable, there was no non-participation
		(c) Consider use of a flow diagram	Not applicable
Descriptive data	14*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders	Page 6, 7: "50 patients were included, of which (…) clinical characteristics of the patients."
		(b) Indicate number of participants with missing data for each variable of interest	Not applicable, there was no missing data.
Outcome data	15*	Report numbers of outcome events or summary measures	Page 6, para 2 – page 7: "IT was reported in seven patients (…) internal tremor estimated at 4.0 Hz (figure 5)."
Main results	16	(*a*) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders	Not applicable, we did not perform inferential statistics, only descriptive analysis.

		were adjusted for and why they were included	
		(*b*) Report category boundaries when continuous variables were categorized	Not applicable, continuous variables were not categorized.
		(*c*) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period	Not relevant for our study.
Other analyses	17	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses	Not applicable, the were no other analyses done

Discussion

Key results	18	Summarise key results with reference to study objectives	Page 8, para 2-4: "internal tremor seems to be associated (…) central pattern generator."
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	Page 8, para 3, 5: "Obviously, we acknowledge (…) was not formally validated in our population."
Interpretation	20	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence	Page 8, para 2-4: "However, whether anxiety acts (…) was not formally validated in our population."
Generalisability	21	Discuss the generalisability (external validity) of the study results	Page 8, para 5: "We acknowledge additional limitations (…) was not formally validated in our population."

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 9: "No specific funding was received (…) no additional disclosures to report."

Movement Disorders Clinical Practice (MDCP)

MANUSCRIPT PRE-SUBMISSION AND ETHICAL PUBLICATION GUIDELINES

Movement Disorders Clinical Practice (MDCP) complies with recommendations of the International Committee of Medical Journal Editors. The journal is a member of the Committee on Publication Ethics (COPE) and adheres to its principles.

Manuscripts that do not conform to the Journal's Ethical Publication guidelines will not be considered for publication. Discovery of or failure to comply will result in rejection of the manuscript, retraction of the published article, and/or a ban on future submissions by the author(s).

The Editors reserve the right to require authors to submit their original data for comparison with the manuscript's illustrations, tables, and results.

Authors are welcome to post a preliminary version of their manuscript on a preprint server (e.g. bioRxiv, medRxiv), but once the manuscript has been accepted, the final version must not be posted. Rather, the original preprint server posting should be updated with a link to the digital object identifier (doi) for the final version that appears in *MDCP*. Authors should not assign copyright during the preprint process; authors should retain copyright in their work when posting to a preprint server.

Preferably, authors should only grant "no re-use" licenses to their preprints. However, *MDCP* will consider for publication submissions that have previously been assigned CC-BY (-NC/-NC-ND) as preprints. If a preprint has been posted under a CC license, it is still possible to publish in the journal under the *MDCP* Copyright Transfer Agreement (CTA).

Requirements for Experimental Investigation of Human and Animal Subjects

For experimental investigation of human or animal subjects, please state in the Ethical Compliance Statement section that an appropriate institutional review board approved the project in accordance with all applicable national and/or international guidelines/laws. The authors should also provide their allowance number for performing animal experiments when available and should add a statement indicating that the principles outlined in the ARRIVE guidelines and the Basel declaration including the 3R concept have been considered when planning the experiments.

For those investigators who do not have formal ethics review committees, the principles outlined in the "Declaration of Helsinki" should be followed. For investigations in human subjects, state in the Ethical Compliance Statement section the manner in which informed consent was obtained from the subjects. Ethical conduct of research should be explicitly disclosed in all submission types that appear in *MDCP*.

Patient Confidentiality and Consent

Authors are responsible for ensuring anonymity when required in photographs, patient descriptions, and pedigrees in which a possibility of identification exists. When submitting a patient video or photograph in which a patient can be identified, the corresponding author must provide the journal with written confirmation (via the author copyright form, Section H) that permission has been obtained from the patient, patient's guardian or, in the event of the patient being deceased, next of kin, that stipulates that authorization has been obtained in compliance with any laws regarding patient authorizations relating to the use or disclosure of protected health information of the jurisdiction(s) to which the patient and the physician are subject including, if applicable, the United States Health Insurance Portability and Accountability Act of 1996 ("HIPAA"). Section H of the copyright form indicates that patient consent forms have been obtained and can be provided to the journal or its readers if requested. Authors will not be required to upload consent forms during submission, but if a paper is accepted for publication, all copyright forms must be signed and collected before the production process will begin.

According to HIPAA, the following core elements must be included in a patient consent form:

1. A specific and meaningful description of the information to be used
2. The name of the Physician and/or Hospital allowed to disclose the information
3. That the video clip and/or photograph will be submitted for publication in a peer-reviewed medical journal
4. That the video clip and/or photograph will eventually be used by the readers of a peer-reviewed medical journal for educational purposes
5. An expiration date that relates to the individual or the purpose of the use or disclosure
6. The individual's signature and the date the authorization is signed.

In addition, the patient's consent form should include the following:

- A statement that the Patient has the right to revoke his or her consent in writing
- A statement regarding whether the Physician has the ability to condition medical treatment on the Patient's giving such consent
- A statement that information, once disclosed, may be subject to further disclosure by the recipient journal, in which case confidentiality would no longer be assured. The consenting party must understand, additionally, that in some cases the video might be re-presented elsewhere because the journal has policies that allow permissions and/or use copyrighted materials with other educational organizations. The consenting party must understand that in such a case the signed author's consent form may be shared with this third party and the consenting party consents to this sharing of information for educational purposes.

Reporting Guidelines

Data reporting should follow appropriate checklists and guidelines (e.g., STROBE for observational trials; CONSORT for clinical trials), and other checklists should be consulted for other reports including diagnostic accuracy (STARD) or meta-analyses (PRISMA). Additional guidance on checklists and guidelines can be found here: http://www.equator-network.org/

Checklists can be downloaded from the following:

- STROBE: http://strobe-statement.org
- CONSORT: http://www.consort-statement.org/consortstatement/
- STARD: http://www.stard-statement.org/
- PRISMA: http://www.prisma-statement.org/

Redundant and Duplicate Publication

The editors, members of the editorial board, and publisher's staff at *MDCP* take their responsibility seriously to assure that the highest ethical publishing standards are maintained by assisting in safeguarding the medical scientific literature against fraudulent publications. Please note that all manuscripts are run through plagiarism-detection software as part of the submission process.

Examples of fraud in scientific research include (but are not limited to):

1) The submission of duplicate publications using similar data (i.e., attesting that work submitted is original when, in fact, it was submitted to or accepted by another journal);
2) Falsification of data, copyright, or information regarding conflict of interest;
3) Submission of work from other sources that was not done by the author and is presented as a new and original (plagiarism);
4) Authorship (allowing one's name to appear as an author or adding an author to a manuscript) without

substantial input or without having agreed to submission of the manuscript. (Please see "Authorship" section below; all authors must meet all authors must meet ICMJE criteria for authorship.)

The above examples are not meant to be a comprehensive list of fraudulent publication practices, rather, they should provide adequate basis for careful consideration of avoidable conflicts and editorial scrutiny regarding inappropriate preparation and submission of manuscripts. Manuscripts that have appeared in publications that are not peer-reviewed, are not registered in Pub Med, or are available only on the internet, will be considered for publication in *MDCP* as long as the Editors are informed and grant approval prior to submission of the manuscript for review. If there are questions as to any issues regarding inappropriate submission, the Editors should be consulted prior to the submission. If a submitted or published manuscript is discovered or suspected to be inappropriate, the authors will be asked for a written explanation. If the rationale provided by the authors remains unsatisfactory in the judgment of the editors, the manuscript will be rejected or retracted. The provost (or equivalent) of the authors' academic institutions will be informed of inappropriate submissions or publications, and the authors will not be allowed to subsequently submit their research to *MDCP*. The journal leadership will also inform the editors and publishers of other journals which have published manuscripts judged to be inappropriately submitted to *MDCP*.

Use of Drug Names

Use generic names only in referring to drugs, followed in parentheses after first mention by any commonly used generic variant.

Jurisdictional Neutrality

In alignment with our publisher's policy on jurisdictional neutrality, *MDCP* recognizes that the global research community includes diverse perspectives on many issues, including the legal status of certain countries/regions. We believe the best way to respect those diverse views is for authors to be able to identify their own institutional and country/region affiliations. We achieve this by being neutral on any jurisdictional claims. This means that the geographical designations and institutional affiliations in published materials do not represent the journal's, the editors', or MDS' opinion about the legal status of any country or region.

ARTICLE TYPES AND LENGTH REQUIREMENTS

If a submitted manuscript has merit but does not meet the requirements for novelty and impact, the editors may suggest resubmitting the manuscript in a different format (which offer the author may of course choose to either accept or decline).

Clinical Research Articles

Description: Clinical Research Articles must present important and substantial new material. Articles can be clinical material, electrophysiology, genetics, clinico-pathological or therapeutics with a direct relevance to clinical practice.

Abstract: 250 words with headings: Background, Objectives, Methods, Results, Conclusions

Text: 3700 words

Text format: Introductory paragraph (no heading), Methods, Results, Discussion

References: 80

Graphics (Tables/Figures): 8

Clinical Assessment Articles
All requirements for Clinical Research Articles listed above apply to Clinical Assessment Articles, which present a validation or other research study on a new or revised clinical outcome assessment or rating scale. The term

"Clinical Assessment" includes rating scales, measurement tools, questionnaires, patient or clinician reported assessments, outcome measures, and other instruments used to measure, rate, qualify, quantify or evaluate a disease state. The copyright to the scales featured in Clinical Assessment Articles published in *Movement Disorders Clinical Practice* will transfer to MDS upon acceptance and publication of the article. Prior to submitting a Clinical Assessment Article to *MDCP*, please contact the International Parkinson and Movement Disorder Society at ratingscales@movementdisorders.org to discuss publication requirements. Please confirm in the Cover Letter that authors have contacted the Society prior to submitting.

Brief Reports

Description: Brief reports of clinical or translational research related to any aspect of movement disorders. Important but negative results are best considered as Brief Reports.

*Abstract: 1*50 words with headings: Background, Objectives, Methods, Results, Conclusions

*Text: 1*700 words

Text format: Introductory paragraph (no heading), Methods, Results, Discussion

References: 40

Graphics (Tables/Figures): 2

Review Articles

Description: There are three different types of reviews, and authors must identify the appropriate category at the time of submission: 1) Systematic – Uses appropriate methods (PRISMA, SCOPUS), includes meta-analyses; 2) Educational – Descriptive, pragmatic review with the aim of medical education for the reader; 3) Historical – Provides history/evolution of a condition. NOTE: For Educational/Historical Reviews, the structure outlined here may not be strictly applicable.

Abstract: 250 words with headings: Background, Objectives, Methods, Results, Conclusions

Text: 5,000 words

Text format: Methods, Results, Conclusion

References: No limit

Graphics (Tables/Figures): 5

Case Series with Literature Review

Description: Case Series may sometimes have a literature review, in which case this submission type should be used. Description of individual cases up to 4 are allowed. If it's more than 4 cases, authors are encouraged to group data with a table and summary of demography and clinical characteristics rather than describe the cases individually. The title may contain "Review of the Literature".

Abstract: 200 words with headings: Background, Cases, Literature Review, Conclusions

Text: 2,500 words

Text format: Case Series (with subheadings Case 1, Case 2, etc), Literature Review, Discussion

References: 40

Graphics (Tables/Figures): 5

Clinico-Pathological Cases

Description: These are cases with pathological diagnosis. The article should have an illustrative clinical report and post-mortem or other diagnostic pathology with good illustration. Authors will prepare the case including the pathological findings.

Abstract: 250 words with headings: Background, Objectives, Methods, Results, Conclusions

Text: 2,000 words

Text format: Case Report (or Series), Pathological Findings, Discussion

References: 15

Graphics (Tables/Figures): 3

Case Series

Description: Topics suitable for presentation for short reports include case series which illustrate new phenomena, or original clinical research. Authors must have a minimum of 3 cases, from different families, in order to use the "Case Series" article type. If there are more than 4 cases, authors are encouraged to group data with a table and summary of demography and clinical characteristics rather than describe the cases individually.

Abstract: 150 words with headings: Background, Cases, Conclusions

Text: 1,500 words

Text format: Introduction, Case Series (with subheadings Case 1, Case 2, etc), Discussion

References: 10

Graphics (Tables/Figures): 3

Case Report

Description: Topics suitable for presentation as Case Reports include one or two cases that illustrates new phenomena or original clinical research. A brief introduction to the case should be included without a heading. At least one video is required for this type of submission.

Abstract: No Abstract

Text: 800 words

Text format: Introductory paragraph (no heading), Case Report, Discussion

References: 10

Graphics (Tables/Figures): 2

Clinical Vignette

Description: These are interesting cases that are not necessarily original but highlight differential diagnosis, imaging or a treatment aspect (i.e. postural tremor in a patient with absent reflexes). At least one video is

required for this type of submission. Clinical Vignettes that are mainly based in a video segment may have a Commentary by an expert in the area.

Abstract: No Abstract

Text: 500 words

Text format: No headings

References: 5

Graphics (Tables/Figures): 1

Phenomenology Video

Description: These submissions include videos illustrating phenomenology of movement disorders (i.e. different forms of myoclonus) with an educational multiple-choice question. Four options should be listed with numbers and then the correct answer and explanation to be provided (with references). Format the text using the headings: Question and Answer. This may be solicited by the editors or non-solicited.

Abstract: No Abstract

Text: 300 words

Text format: First heading should be the question, then another heading “Answer”

References: 2

Graphics (Tables/Figures): 1

Drug Trials

Description: Drug Trials (including negative drug trials) will be considered.

Abstract: 250 words with headings: Background, Objectives, Methods, Results, Conclusions

Text: 3,700 words

Text format: Introductory paragraph (no heading), Methods, Results, Discussion

References: 80

Graphics (Tables/Figures): 8

Viewpoint

Description: Viewpoints related to any aspect of movement disorders may be submitted without solicitation. These submissions present a pragmatic or contrary view based on the author's opinion. NOTE: Special concessions may be requested for official task forces.

Abstract: No Abstract

Text: 2,000 words

Text format: Headings are flexible and at author/editor discretion

References: 40

Graphics (Tables/Figures): 1

In Focus

Description: In Focus submissions are reports of breakthrough findings published elsewhere which deserve a comment in the journal. Please send a proposal to the Editorial Office prior to submitting.

Abstract: No Abstract

Text: 500 words

Text format: No headings

References: 5

Graphics (Tables/Figures): 1

Revealing Images

Description: Revealing Images can be any form of visual graphic of some clinical feature or investigation. For example, a picture of a clinical sign or unique imaging including MRI, DAT Scans, DTI or other, and also EMG video recording or video of microrecordings from functional surgery. These should be accompanied by a paragraph of explanation. Authors may choose to include one multiple choice question along with a list of possible answers, including an indication and explanation of the correct answer.

Abstract: No Abstract

Text: 200 words

Text format: No headings

References: 2

Graphics (Tables/Figures): 2 figures

Historical Perspectives

Description: Interesting old tapes/videos, sound recordings, photographs or seminal historical papers, or previously published commentary by the author.

Abstract: No Abstract

Text: 500 words

Text format: No headings

References: 5

Graphics (Tables/Figures): 3

Letters to the Editor: New Observations

Description: Letters containing original research which is not covered by any of the topics mentioned above will also be considered.

Abstract: No Abstract

Text: 500 words

Text format: No headings

References: 5

Graphics (Tables/Figures): 1

Letters to the Editor: Published Article

Description: Letters in response to articles published in MDCP are welcome.

Abstract: No Abstract

Text: 500 words

Text format: No headings

References: 5

Graphics (Tables/Figures): 1

Letters to the Editor: Genotype & Phenotype

Description: Cases with genetic description of a new phenotype or expansion of a previously described phenotype.

Abstract: No Abstract

Text: 800 words

Text format: No headings

References: 10

Graphics (Tables/Figures): 1

Letters to the Editor: Neuromodulation

Description: We encourage submissions from researchers and clinicians in the field of DBS, ablative surgery, transcranial magnetic stimulation and any other form of incisionless neuromodulation.

Abstract: No Abstract

Text: 800 words

Text format: No headings

References: 10

Graphics (Tables/Figures): 1

Editorial Commentary (Invited)

Description: Editorials will generally be solicited by the editors and are subjected to a review process. Authors wishing to submit an editorial should seek the advice of the editors in advance.

Abstract: No Abstract

Text: 1,500 words

Text format: No headings

References: 25

Graphics (Tables/Figures): 1

How Do I? (Invited)

Description: Authors wishing to submit a "How Do I" video must seek the advice of the editors in advance.

Abstract: 250 words, no headings

Text: 200 words

Text format: No headings

References: 5

Graphics (Tables/Figures): No limit

MANUSCRIPT SUBMISSION PROCESS

All manuscripts will be initially evaluated by one of the editors in chief. If the paper does not meet the journal's standards for peer review, both editors will discuss prior to making an editorial rejection decision. If an editor has a conflict of interest, the other will handle the process without consultation. If peer review is deemed appropriate, the paper will be sent out with the intention of securing one or more reviewers as needed. Authors may indicate the names of potential referees as well as those whom they wish not to review the paper, but the editor(s) will make the final reviewer decision. Reviewers are asked to provide their comments within two weeks, and the editors aim to return decisions on all papers within four weeks of their submission.

This journal operates under a single-blind peer review model. Manuscripts are peer reviewed generally by two or more anonymous reviewers and there is an oversight review by the two Editors-in-Chief, as outlined above. Papers will only be sent to review if the Editor-in-Chief determines that the paper meets the appropriate quality and relevance requirements. As with all papers, when an Editorial Board member has authored a submission, the paper will be sent to reviewers who are not affiliated with the author or their institution and monitored carefully to ensure there is no peer review bias.

Authors will be given a *maximum of 60 days* for major revisions and *30 days* for minor revisions. Authors who plan to resubmit but cannot meet their deadline can contact the editorial office to request an extension; otherwise, the online system will prevent you from uploading the manuscript in the system.

Revisions may receive an immediate decision, may be sent back to the original reviewers, or, in rare cases, sent to new reviewers for additional comments. This decision is at the discretion of the editors in chief.

ScholarOne Submission System:

Authors may submit manuscripts and all supplementary material online at http://mc.manuscriptcentral.com/mdcp.

- Click on the "Check for Existing Account" button at the bottom of the opening page.
- If you do not already have an account, then create one by clicking on the "Create an Account" button.
- Click on “Author Center.” Follow the on-screen instructions carefully.
- At the end of a successful submission, you will see a confirmation screen with your manuscript number, and you will receive a separate e-mail confirming receipt.
- If these two messages do not appear, then go into your Author Center and make sure that you have clicked on the “Submit” button or contact the editorial office.

PRE-SUBMISSION INQUIRIES

Generally, MDCP does not respond to pre-submission author inquiries. This applies to requests for feedback about the suitability of a manuscript for MDCP based on a brief description of the objective, a copy of the abstract, or a copy of the full draft manuscript.

Please review the journal’s Aims and Scope and the guidelines on this page to determine the suitability for the journal and to choose the best article type for your submission.

The editors will only respond to inquiries about submission types that require prior communication: How Do I videos and In Focus pieces.

PREPARING THE SUBMISSION

Cover Letter

The cover letter should be entered into the submission form, on Step 6. Briefly describe the scientific or clinical importance of the manuscript. The cover letter must confirm that a) all co-authors have been substantially involved in the study and/or preparation of the manuscript; b) no undisclosed groups or personal have had a primary role in the study and/or in the manuscript preparation (i.e., there are no “ghost writers”); and c) all co-authors have read and approved the submitted manuscript. Also, a statement that no ghost writing by anyone not named on the author list must be included (see Editorial in Movement Disorders 2005;20:1536).

File Format

The manuscript file should be double-spaced, with page numbers and continuous line numbering. The file should be in .doc, .docx. or .tex* format, with 1” margins and 12pt font size. **Please see further instructions on LaTex (.tex) submissions at the end of this section.**

Order of Manuscript Elements

(1) Title Page:

This should be the first page of the manuscript file, not uploaded separately. Include ALL the following:

- *Video note:* If an article includes a video, the upper right corner of the title page of the manuscript file must be marked “Video is part of ms.”
- *Article title:* Titles should be short, specific, and clear. They should not exceed 100 characters. Do not use abbreviations/acronyms in the title.
- *Authors' names and affiliations:* Provide author names as they should be published, including academic degrees. Indicate the specific affiliation of each author with footnotes (superscripted, Arabic numerals). If appropriate, see “Group Authorship” section for instructions on how to acknowledge members of a group author.

- *Correspondence information:* Name, address, telephone and email address of the corresponding author
- *Word counts:* For the Abstract (if applicable) and the main text. The word count *excludes* the title page, abstract, tables, acknowledgements and contributions, and references.
- *Running title:* A short title not to exceed 45 letters and spaces
- *Key words:* Up to 5

(2) Abstract:

If the chosen submission type requires an Abstract, it must be structured with subheadings. Authors are required to spell out all abbreviations/acronyms in the structured abstract unless this has become accepted in the standard scientific literature (e.g. DNA, MPTP).

(3) Main Text:

See instructions for the chosen submission type for specific formatting notes.

(4) Acknowledgment:

Do not include funding information in this section. Authors may include, as needed, (consistent with requirements of courtesy and disclosure) participation of contributors to the study who are not included in the author list.

(5) Author Roles:

At the end of the manuscript, list the itemized contributions in number/letter format, as below. These should include but are not restricted to:

1. Research project: A. Conception, B. Organization, C. Execution;
2. Statistical Analysis: A. Design, B. Execution, C. Review and Critique;
3. Manuscript Preparation: A. Writing of the first draft, B. Review and Critique;

Author 1: 1A, 2B, 3B
Author 2: 2A, 3C

List each author (by their initials) beneath the numbered list information and refer to their specific roles in the project and manuscript preparations by number and letter. For example: ECH: 1A, 2B, 2C, 3B

(6) Disclosures:

All submissions require a "Disclosures" section that covers the financial disclosures and conflicts of interest for all authors. This should be presented in complete sentences and organized under the headings below:

- ***Funding Sources and Conflict of Interest:***

  Document all funding sources and potential conflicts of interest from each author that relate to the research covered in the article, regardless of date. If there are none, please state: "No specific funding was received for this work." And "The authors declare that there are no conflicts of interest relevant to this work."

- ***Financial Disclosures for the previous 12 months:***

  Document all funding sources, not related to the current research in the article, for each author. If there are none, please state: "The authors declare that there are no additional disclosures to report."

NOTE: The copyright form that each author is required to sign also states that both of these entries are documented in the submitted material.

(7) Ethical Compliance Statement

All submissions, regardless of type, require an Ethical Compliance Statement at the end of the manuscript. This must include all three of the following:

- Name of the institutional review board or ethics committee that approved the study. Alternatively, if certain ethical guidelines were followed in the absence of an IRB, that should be stated.
- Declaration of patient consent — Detail what type (written, verbal) and how it was obtained and documented, etc. If this was not required, include a statement affirming that "Informed patient consent was not necessary for this work."
- Affirmation that all authors have read and complied with the Journal's Ethical Publication Guidelines. "We confirm that we have read the Journal's position on issues involved in ethical publication and affirm that this work is consistent with those guidelines."

(8) References:

Cite references sequentially in the text by number and include a References section at the end of the manuscript that lists all references in the order of appearance. *MDCP* complies with the reference style given in "Uniform Requirements for Manuscripts Submitted to Biomedical Journals." (See Annals of Internal Medicine 1982;96:766-771, or British Medical Journal 1982:284:1766-1770.) The reference section should be double-spaced at the end of the text, following the sample formats given below. Provide all authors' names when fewer than seven; when seven or more, list the first three and add 'et al'. Provide article titles and inclusive pages. Accuracy of reference data is the responsibility of the author. For abbreviations of journal names, refer to List of Journals Indexed in Index Medicus (available from the Superintendent of Documents, U.S. Government Printing Office, Washington DC 20402, USA, DHEW Publication No. (NIH) 83-267; ISSN 0093-3821).

Sample References

Journal article

1. Krack P, Benzzzouz A, Pollak P, et al. Treatment of tremor in Parkinson's disease by Subthalamic nucleus stimulation. Mov Disord 1998; 13: 907-914.

Book

1. Fahn S, Jankovic J, editors. Principles and Practice of Movement Disorders, Philadelphia, Churchill Livingstone, 2010, pp 96.

Book Chapter

1. Olanow CW. Hyperkinetic Movement Disorders. In: Fauci A, Braunwald E, Kasper D, Hauser S, Longo D, Jameson JL, Loscalzo J. Eds. Harrison's Textbook of Medicine 17th edition. 2008; p2560-2565.

(9) Legends for Figures and Supplemental files:

Figure legends should be double-spaced and fewer than 40 words each. Refer to panels by capital letters (A, B, etc). For photomicrographs, please include the type of specimen, original magnification, and stain type. Include internal scale-markers on photomicrographs when appropriate. Where applicable, indicate the method used to digitally enhance images. Every supplemental file should have a corresponding legend in the manuscript file.

(10) Tables

Tables should be included at the end of the manuscript file and each table should begin on a new page. Number tables with Arabic numerals and provide the title above the table and list any footnotes must be listed beneath it.

Do not include color elements or split tables into multiple parts (1a and 1b). Define all abbreviations and special formatting using footnotes. Do not repeat the same information in tables and figures that is present in the text. IMPORTANT: Each table must be limited to 2 pages in PORTRAIT (vertical) orientation, with at least 11pt font. Overly wide or long tables will have to be rotated during typesetting and should be presented as supplemental information instead.

Other Files

Color figures are encouraged, when appropriate. Each figure should be uploaded as an individual file. Do not include figures in your manuscript file. Label each panel with one capital letter (A, B, etc.) and ensure that all necessary axes are labeled. Font in figures should be at least 11pt. Identifying information such as dates, names, and hospital locations should be removed or obscured before submission. Any illustration or figure from another publication must be acknowledged in the figure legend and the copyright holder's written permission to (re)use any image online in *MDCP* must be submitted to the editorial office.

Digital Artwork Preparation

1. Check your software options to see if you can 'save as' or 'export' using one of the robust, industry-standard formats. These are:

- Encapsulated PostScript (EPS)
- Tagged Image File Format (TIFF)
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- Portable Document Format (PDF)

2. As a general rule of thumb, images that contain text and line art (graphs, charts, maps, etc.) will reproduce best if saved as EPS or PDF. If you choose this option, it is important to remember to embed fonts. This ensures that any text reproduces exactly as you intend.

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4. If you are not sure which format would be the best option, it is always best to default to EPS or PDF as these are more likely to preserve the high-quality characteristics of the original.

5. Microsoft Office. If you have generated your images in Microsoft Office software (Word, Excel, PowerPoint), please convert the image to a PDF and ensure that all text is clear and legible at 100% zoom. Note that you might be asked to send us the files in their native file formats.

6. Please ensure all images are a minimum of 600 dpi

Video Files

As of 2021, videos will be embedded in the published article in a similar way to which we currently embed figures and tables. These files should be uploaded as "Embedded Video" files during the submission process.

In the manuscript:

- Every video must be cited in the main text.
- Please upload a placeholder image for each of your video files as an "Image" file in the submission system. The file name should be "Video1_Image" and "Video2_Image", etc. If your paper is accepted, this image will be typeset as close to the first video citation as possible, similar to tables and figures. This static image must come from the video itself and will preferably correlate to the first frame of the video file.

- A legend must be included at the end of the article for each video, labeled “Video 1, Video 2,” etc. This should concisely and sequentially describe what is seen in the video so that it can be readily understood. Do not repeat explanatory material that is already in text. If there are multiple segments in a video, please identify what happens in each segment (Segment 1, Segment 2, etc.)

File Requirements:

- Video must be submitted with manuscripts online in one of the following digital formats: MP4, MKV, MOV, AVI, FLV, MPEG-2 TS, MPEG-2 PS, MXF, LXF, GXF, 3GP, WebM, MPG, QuickTime.
- Video file names must be “Video1_Image” and “Video2_Image”.
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- Please limit file size to 100 MB, if possible. The combined manuscript files, including video, audio, tables, figures, and text must not exceed 350 MB.
- The aspect ratio for videos should be 16:9. Aspect ratios other than 16:9 will still play within the player. However, black bars above and below or to the side of the video will appear.
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Content:

- Video content should be edited to illustrate the key findings in a concise and informative manner. The video should be of high quality (both in content and visibility). The video should be edited to ensure maximal efficiency and make the specific point; particularly, it should demonstrate the features described in the text of the manuscript.
- The use of text and/or special transition effects between the titles, subtitles and video segments is permitted. The video you submit should be the final product that will be published with the article.
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Patient Consent:

- It is the responsibility of the corresponding author to seek informed consent from any identifiable participant in the rich media files. Masking a participant’s eyes, or excluded head and shoulders is not sufficient.
- Authors are restricted from submitting video and audio that they do not have a license to.
- The corresponding author must confirm in the author copyright form (Section H) that he or she has received a signed release form from each patient videotaped authorizing the offline and/or online distribution of this video material.
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- Electronic graphics files for the illustrations in Encapsulated PostScript (EPS), PDF or TIFF format. Authors are requested not to create figures using LaTeX codes.

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SÃO JOÃO

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 no Centro Hospitalar Universitário de S. 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:
   - "Internal tremor: characterization and quantification in a cohort of neurological patients".
   - Serviço(s) onde decorrerá o projeto de investigação: Neurologia.
   - Investigador(a) principal: André Aires Fernandes
2. Remeta-se à Comissão de Ética para os procedimentos adequados e demais trâmites convenientes.

CONSELHO DE ADMINISTRAÇÃO DO CENTRO HOSPITALAR UNIVERSITÁRIO DE S. JOÃO, EPE • REUNIÃO DE 14 DE DEZEMBRO DE 2023

Presidente do Conselho de Administração

Prof.ª Doutora Maria João Baptista

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

CE 284/2023

Centro de Epidemiologia Hospitalar

Tomei conhecimento. Nada a opor. À DC.

13 de Dezembro de 2023

A Diretora do Centro de Epidemiologia Hospitalar

(Prof.ª Doutora Ana Azevedo)

n.º 284 / 2023

SÃO JOÃO

DIRECÇÃO CLÍNICA
14 DEZ. 2023

PEDIDO DE AUTORIZAÇÃO

Realização de Investigação

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

Nome do Investigador Principal:
André Aires Fernandes

Título da Investigação:
Internal tremor: characterization and quantification in a cohort of neurological patients

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

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, 25 *de* Junho *de* 2023.

assinatura

Centro Hospitalar São João
Centro de Epidemiologia Hospitalar
13, 12, 2023

SÃO JOÃO | Encarregado de Proteção de Dados / Data Protection Officer

Entrada 16/10/2023

CES-IM005-1

Parecer da Comissão de Ética do

Centro Hospitalar Universitário de São João / Faculdade de Medicina da Universidade do Porto

Título do Projeto: Internal tremor: characterization and quantification in a cohort of neurological patients

Nome do Investigador Principal: Dr. André Aires Fernandes, interno de formação específica em Neurologia no CHUSJ.

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

Objetivos do Estudo:

Estudo observacional, com intervenção, que pretende identificar e caracterizar o tremor interno enquanto sintoma neurológico, numa coorte prospetiva de doentes seguidos em consulta externa de Neurologia/Doenças do movimento.

Como objetivos secundários pretende-se quantificar de forma objetiva o ritmo e frequência da sensação de tremor e compará-la com a frequência do tremor avaliado em indivíduos com tremor manual visível (postural e de repouso). A frequência do tremor interna será avaliada usando uma análise acústica formal enquanto os doentes exemplificam por som as características do tremor interno. Será usado o software GoldWave® Inc. A frequência de tremor postural e de repouso será avaliado por aplicação de smartphone (StudyMyTremor®).

Conceção e Pertinência do estudo:

O tremor interno é um sintoma ainda pouco reconhecido, mas que tem sido descrito em doente com Doença de Parkinson. É descrito como uma sensação de tremor nas extremidades ou tronco sem se manifestar com um movimento objetivável. Apesar de aparentemente não incapacitante, é descrito por alguns doentes como incomodativo. Desconhece-se o mecanismo fisiopatológico e origem anatómica inerente ao tremor, sendo que é sugerido que possa associar-se a outras doenças neurológicas, como tremor essencial ou esclerose múltipla. Estudos prévios sugerem a presença de ansiedade como potencial fator de risco. Dada a natureza não objetiva inerente ao tremor interno, esta condição pode ser subdiagnosticada, mesmo aos olhos de neurologistas.

Doentes da consulta de Neurologia/Doenças do movimento. Tamanho da amostra: 100 participantes.

Estão definidos os critérios de inclusão e os dados a recolher.

Benefício/risco:

Conhecimento de um sintoma incapacitante e abordagem sintomática.

Confidencialidade dos dados:

A cada participante será atribuído um código único. Todos os dados serão anonimizados.

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 modelo de CI do CHUSJ.

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

Data previsível da conclusão do estudo: dezembro de 2023

Conclusão: Proponho um parecer favorável à realização do estudo.

Porto, 15 de setembro de 2023

O Relator da CE, Prof. Doutor Manuel Vaz da Silva

Questionário eletrónico

n.º 284 / 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:

Internal tremor: characterization and quantification in a cohort of neurological patients

Data prevista para início: 01 /09 /2023 Data prevista para o término: 01 /12 /2023

EQUIPA DE INVESTIGAÇÃO

1. Investigador principal

Nome: Andre Aires Fernandes

Afiliação institucional: ☒ CHUSJ ☒ FMUP Outro: _____

Serviço/ Departamento: Neurologia

Grupo profissional: Medico Cédula Profissional n.º: 67855

Contacto telefónico: X Endereço eletrónico institucional: andre.aires.fernandes@chsj.min-saude.pt

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

2. Co-investigadores

Nome: _____

Afiliação institucional: _____

Grupo profissional: _____ Cédula Profissional n.º: _____

Contacto telefónico: _____ Endereço eletrónico institucional: _____

Nome: _____

Afiliação institucional: _____

Grupo profissional: _____ Cédula Profissional n.º: _____

Contacto telefónico: _____ Endereço eletrónico institucional: _____

(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? medição do tremor por aplica(

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: Neurologia

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

ENTIDADE(S) QUE TUTELA(M) A INVESTIGAÇÃO

1. CHUSJ – Serviço: Neurologia

2. FMUP – Departamento: Neurociencias

3. Outra instituição. Qual? _____

ORIENTADOR *(se aplicável)*

Nome: _____

Afiliação: _____ Endereço eletrónico institucional: _____

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:

O presente estudo pretende identificar e caracterizar o tremor interno enquanto sintoma neurológico, numa coorte prospetiva de doentes seguidos em consulta externa de Neurologia-Doenças do movimento. Como objetivos secundários pretende-se quantificar de forma objetiva o ritmo e frequência da sensação de tremor e compará-la com a frequência do tremor avaliado em indivíduos com tremor manual visível (postural e de repouso). A frequência do tremor interno será avaliada usando uma análise acústica formal enquanto os doentes exemplificam por som as características do tremor interno. Será usado o software GoldWave® Inc. A frequência de tremor postural e de repouso será avaliado por aplicação de smartphone (StudyMyTremor®).

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

O tremor interno é um sintoma um sintoma ainda pouco reconhecido, mas que tem sido descrito em doente com Doença de Parkinson. É descrito como uma sensação de tremor nas extremidades ou tronco sem se manifestar com um movimento objetivável. Apesar de aparentemente não incapacitante, é descrito por alguns doentes como incomodativo. Á data desconhece-se o mecanismo fisiopatológico e origem anatómico inerente ao tremor, sendo que é sugerido que possa associar-se a outras doenças neurológicos, como tremor essencial ou esclerose múltipla. Estudos prévios sugerem a presença de ansiedade como potencial fator de risco. Dado a natureza não objetiva inerente ao tremor interno, esta condição poderá ser subdiagnosticada, mesmo aos olhos de Neurologistas, especialmente quando associado a um exame neurológico "normal

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?

De forma oportunistica na consulta de Neurologia

Qual é o tamanho amostral? 100

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:

Conhecimento de um sintoma incapacitante e abordagem sintomática

Descreva os riscos/incómodos previsíveis:

não aplicável

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...)*

codificação, uso de siglas

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

número de processo, idade, história clínica, resultados de MCDTs.

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: 01 /12 /2023

DOCUMENTOS ANEXOS *(em suporte digital)*

- [x] Pedido de autorização ao Presidente do Conselho de Administração do CHUSJ
- [ ] Protocolo do estudo
- [ ] Caderno de recolha de dados (CRF)
- [x] Declaração Diretor(es) Serviço(s)
- [ ] Informação Orientador
- [ ] Profissional de ligação
- [x] Informação aos participantes
- [x] Modelo de consentimento a utilizar
- [x] Instrumentos de avaliação *(escalas, inquéritos)* escala de ansiedade
- [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, André Aires Fernandes ,

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: 10 /08 /2023

assinatura

COMISSÃO DE ÉTICA CHUSJ/FMUP

Parecer da CE, emitido na reunião plenária de 15 / 09 / 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.

RAI 23014464

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 13/10/2023
A funcionária

SÃO JOÃO
AUTORIZADO
RAI - Responsável pelo Acesso à Informação no Centro Hospitalar de São João (Art. 9º, Lei 26/2016, de 22/8)
16/10/2023

CENTRO DE EPIDEMIOLOGIA HOSPITALAR

ENCARREGADO DE PROTEÇÃO DE DADOS (EPD)
CENTRO HOSPITALAR UNIVERSITÁRIO DE S. JOÃO, EPE
Paulo Alexandre Mota da Silva
Encarregado de Proteção de Dados do CHUSJ
epd@chsj.min-saude.pt

Ref.ª CES CHUSJ: **284 / 2023**

Título do Projeto Tremor interno: caracterização e quantificação de uma coorte de doentes neurológicos

Responsável pelo tratamento	André Aires Fernandes
Instituição	Centro Hospitalar Universitário São João (CHUSJ)
	Faculdade de Medicina da Universidade do Porto (FMUP)
Investigador	**Interno** Externo
Contacto telefónico	964829620
Endereço Electrónico	u016820@chsj.min-saude.pt
Profissional de Ligação	Não aplicável
Amostra	100

Análise de Risco: Tolerável | **Baixo** | Elevado | Muito Elevado

Parecer do EPD: Data: 12/12/2023

Finalidade: identificar e caracterizar o tremor interno enquanto sintoma neurológico, numa coorte prospetiva de doentes seguidos em consulta externa de Neurologia- Doenças do movimento. Como objetivos secundários pretende-se quantificar de forma objetiva o ritmo e frequência da sensação de tremor e compará-la com a frequência do tremor avaliado em indivíduos com tremor manual visível (postural e de repouso). A frequência do tremor interno será avaliada usando uma análise acústica formal enquanto os doentes exemplificam por som as características do tremor interno. Será usado o software GoldWave® Inc. A frequência de tremor postural e de repouso será avaliado por aplicação de smartphone (StudyMyTremor®).

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 26/10/2023, **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, com acesso a ficheiros protegido por **palavra-passe**, efetuando-se a conservação até a conclusão da investigação, durante o prazo máximo de **quatro (4) meses**. Os dados recolhidos **serão destruídos** após a finalização do estudo.

Comunicação de Dados: **não há partilha** de dados pessoais.

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), 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 seguidos na consulta de Neurologia / Doenças do movimento), em particular na fase de disseminação ou publicação dos resultados (incluindo repositórios científicos).

5. 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 284/2023
2. Parecer CES (15/09/2023)
3. AIPD (26/10/2023)
4. Consentimento Informado e Informação ao Participante
5. Protocolo de Investigação

Encarregado de Proteção de Dados
Assinado por: **PAULO ALEXANDRE MOTA DA SILVA**
Data: 2023.12.12 12:45:05+00'00'
Localização: CHUSJ

CARTÃO DE CIDADÃO