Manual Therapy, Posturology & Rehabilitation Journal
ISSN: 2236-5435

STUDY PROTOCOL

Progression of Parkinson's Disease and its relationship with sleep quality and functionality: Cross-sectional observational studies

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Abstract

Background: Parkinson's disease (PD) is a progressive neurodegenerative condition that predominantly affects older individuals , with significant impacts on quality of life. It is characterized by motor symptoms, such as tremors and bradykinesia, and non-motor symptoms, such as sleep disorders. Given the complexity of PD, it is essential to deepen the analysis of the factors that interfere with quality of life, contributing to the development of integrated therapeutic strategies. **Objective:** To evaluate the relationship between PD progression and sleep quality and performance in activities of daily living. **Methods:** This is a cross-sectional observational study, conducted at the State University of Minas Gerais, involving individuals with a clinical diagnosis of PD. Participants will be recruited through a search in the Electronic Citizen Record system, in Public Health Centers of Primary Health Care in the city of Divinópolis - MG. To assess PD progression, the following tests will be conducted: the Modified Hoehn and Yahr Scale and parts I, II, and III of the Movement Disorder Society Unified PD Rating Scale (MDS-UPDRS). Sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI) and the Parkinson's Disease Sleep Scale (PDSS) and functionality will be assessed using the Five-Repetition Sit-to-Stand Test and the Coin Rotation Test. **Discussion:** The increased prevalence of PD and gaps in the literature on sleep quality and impact on ADLs may aggravate functional impairments and quality of life of these patients.

Keywords: Parkinson disease; sleep; activities of daily living.

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Received: 21 Ago, 2025
Accepted: 02 Mar, 2026
Published: 27 Mai, 2026

BACKGROUND

Parkinson's disease (PD) is a chronic, progressive, and incurable neurodegenerative disease that predominantly affects individuals over 50 years of age, with symptoms such as persistent movement disorders such as tremors, rigidity, elements of bradykinesia, hypokinesia, akinesia, and postural abnormalities[1].

Worldwide, PD is the second most common neurodegenerative disease, surpassed only by Alzheimer's disease[2]. Furthermore, it is the fastest growing disease associated with aging, with an expected 12 million cases worldwide by 2040[3]. In Brazil, according to the Ministry of Health (MS), in 2017[4], a prevalence of 100 to 200 cases per 100.000 inhabitants is estimated.

The first characteristic of PD is the progressive degeneration of dopaminergic neurons in the substantia nigra of the midbrain, an area of the brain crucial for motor control[5]. With the death of these cells, dopamine levels decrease, impairing communication between the brain regions that regulate movement, generating a reduction in dopamine release in the striatum and resulting in motor (MS) and non-motor (NMS) symptoms[6].

As PD progresses, symptoms become more intense and increasingly interfere with patients' activities of daily living (ADLs), even impacting their autonomy[7]. Thus, disease management requires specific instructions at different stages, focusing both on relieving MS and supporting non-motor aspects, allowing for a more comprehensive and patient - centered approach[8].

According to the Brazilian version of the European Physiotherapy Guideline for PD[9], the cardinal MS of PD are bradykinesia (affecting between 77% and 98% of patients), resting tremor (occurs in approximately 70% of cases at the time of diagnosis and can appear in up to 100% of individuals throughout the progression of the disease), muscle stiffness (observed in 89% to 99% of patients) and balance impairment (can appear in the first three years after diagnosis, influencing mobility and increasing the risk of falls).

In addition to these MS, the disease frequently presents with NMS, such as autonomic dysfunctions, neuropsychiatric symptoms (depression, anxiety), bowel problems, cognitive disorders, and sleep disturbances[10]. Among the NMS, sleep disorders (SD) deserve to be highlighted, with an estimated prevalence of 60 to 90%, including changes in sleep structure and specific disorders[11]. Among the possible changes and specific sleep disorders, insomnia, sleep-disordered breathing (SDB), excessive daytime sleepiness (EDS), REM sleep behavior disorder (RBD), and restless legs syndrome stand out[12].

Sleep is an essential physiological state for the organism, characterized by the reduction of motor and perceptive activity, being regulated by a complex system of neurotransmitters and structures. During sleep, component processes for the homeostasis of the body and brain occur, such as memory consolidation, mood regulation and strengthening of the immune system[13]. It is composed of two phases, non-rapid eye movement (NREM) and rapid eye movement (REM) sleep, and each of them performs specific functions[14].

The NREM sleep comprises about 75% of the sleep cycle and is divided into three progressive stages: Stage 1 is falling asleep, Stage 2 is light sleep, and Stage 3 is deep sleep (which is crucial for physical recovery and strengthening the immune system). The REM sleep, which accounts for approximately 25% of the cycle, is characterized by intense brain activity. This stage is where memory consolidation and emotional processing occur, and it plays an important role in adaptation and mood regulation[15].

Sleep disorders, such as those that occur in patients with PD, result in cognitive impairment, daytime fatigue, and impaired motor functions, not only impairing the ability to perform ADLs, but also hindering clinical management, making the therapeutic approach more complex and multidimensional[16].

ADLs encompass essential tasks such as eating, dressing , and locomotion, and are crucial for independence and quality of life. In people with PD, these activities become progressively more limited as the disease progresses due to MetS and NMS, leading to a cycle of gradual disability that profoundly impacts performance[17]. Therefore, the aim of this study is to evaluate the relationship between PD progression and sleep quality and ADL performance.

METHODS

Study design and ethical consideration

This is a cross-sectional observational study conducted by faculty and students at the State University of Minas Gerais (UEMG). The study design will follow the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) statement[18,19] and is in accordance with the ethical standards established in the 1961 Declaration of Helsinki and the Guidelines and Regulatory Norms for research involving human beings of the National Health Council of the Ministry of Health of Brazil, resolutions 466/2012, 510/2016 and 580/2018 (Figure 1).

The project was submitted to and approved by the Human Research Ethics Committee of UEMG, Passos Unit, under opinion number 6.796.312/2025.

All patients involved will be required to sign an Informed Consent Form (ICF), allowing withdrawal at any time without any cost and ensuring that participants are fully informed about the objectives, procedures and potential risks and benefits of the research before agreeing to participate.

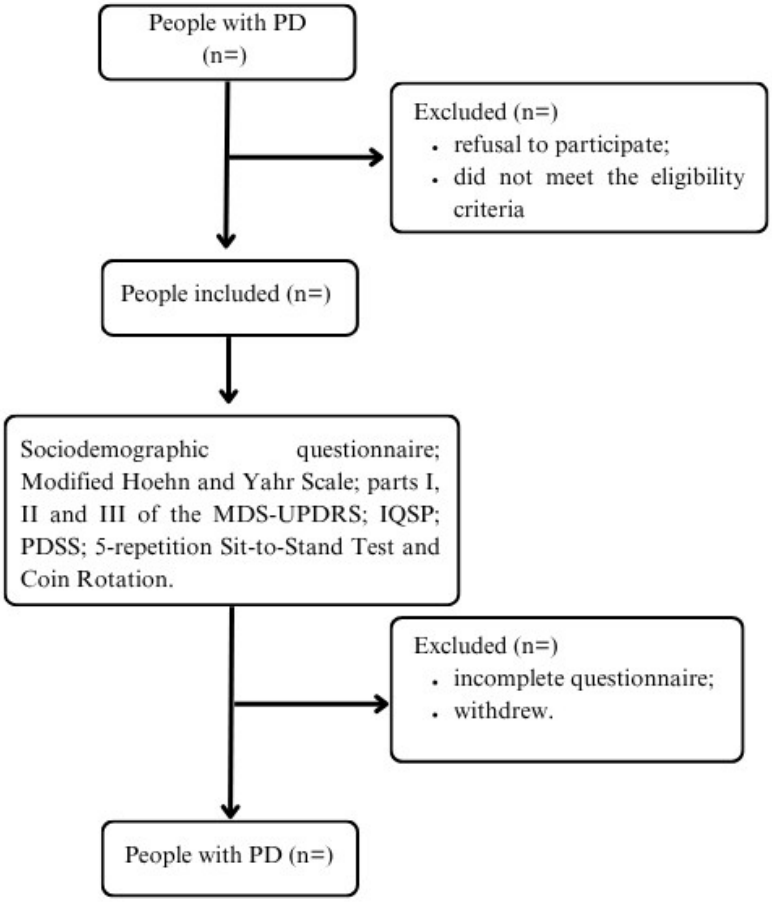

Figure 1: Flowchart of participant selection and assessment procedures in individuals with Parkinson's disease. IQSP = Pittsburgh Sleep Quality Index; MDS-UPDRS = Movement Disorder Society – Unified Parkinson's Disease Rating Scale; PD = Parkinson's disease; PDSS = Parkinson's Disease Sleep Scale.

Participants in this study will be recruited through a search of the Citizen's Electronic Medical Record (PEC) system, which will be conducted at the Primary Health Care Public Health Centers in Divinópolis, Minas Gerais. This system allows for the filtering of patients diagnosed with PD and is accessible to Public Health Center professionals. Furthermore, the system offers electronic support to facilitate this filtering and personal data collection, enabling patient engagement.

With the assistance of these professionals, it will be possible to identify potential volunteers. After identification, they will be contacted by phone or a home visit to explain the study and invite them to participate. This approach will respect ethical principles, ensuring that patients are informed of the research objectives and their rights before formalizing their participation.

The sample size calculation was performed using the G*Power 3.1.9.7 program. Considering an effect size of 0.5, an α (alpha) type error of 5%, and a statistical power (1-β) of 80%, using the Exact Tests with Correlation method (bivariate normal model), it was determined that a sample size of 67 volunteers is sufficient to meet the statistical criteria of the study. Furthermore, studies with similar proposals use a similar or smaller sample[20,21].

Inclusion Criteria

Patients with a clinical diagnosis of PD, over 18 years of age, who are regularly and stably using antiparkinsonian medication, who reside in the city of Divinópolis-MG and who agree to participate in the study by signing the TCLE will be included in the study.

Exclusion Criteria

Those who present cognitive impairment, identified by the Mini Mental State Examination (MMSE)[22], who are unable to answer questions or perform tests and who answer questionnaires incompletely will be excluded from the study.

Procedures and Assessments

Participation will be formalized with the signing of the Informed Consent Form (ICF), which will provide expected information about the objectives, procedures, possible risks and benefits of the research. The Informed Consent Form (ICF) will be obtained from all patients involved, allowing withdrawal at any time without any cost and ensuring that participants are fully informed about the objectives, procedures and potential risks and benefits of the research before agreeing to participate.

Data collection will be structured in four consecutive stages. Initially, the study objectives will be presented, followed by the signing of the informed consent form. Subsequently, the MMSE and a sociodemographic questionnaire will be administered to characterize the sample. In the second stage, PD progression will be assessed using the Modified Hoehn and Yahr Scale (HY)[23] and parts I, II, and III of the Movement Disorder Society Unified Health Scale (MSS). PD Rating Scale (MDS-UPDRS)[24]. Subsequently, sleep quality will be assessed using the Pittsburgh Sleep Quality Index (PSQI)[25] and the PD Sleep Disturbance Scale (PDSS)[26]. Finally, functionality will be assessed using the 5-Repetition Sit-to-Stand Test and Coin Rotation Test[27].

EVOLUTION PROTOCOL

Sociodemographic Questionnaire

A sociodemographic questionnaire will be administered to collect information about the study participants' profiles. This questionnaire will assess data such as age, gender, education level, marital status, and basic health information.

Modified Hoehn and Yahr Scale

Hoehn and Yahr Scale was developed in 1967 to classify the severity of PD, considering the severity of motor symptoms and disease progression[23]. It categorizes the progression of PD into five stages, ranging from mild unilateral symptoms in stage 1 to total immobility in stage 5.

Subsequently, the scale was modified, with subdivisions added to measures 1 and 2 (1.5 and 2.5), providing greater sensitivity in the evaluation of patients with mild to moderate PD[28].

Therefore, the current scale used in the study is divided into stage 0, which corresponds to no signs of the disease; stage 1 (unilateral disease); stage 1.5 (unilateral and axial involvement); stage 2 (disease progression with bilateral involvement but no balance deficit); stage 2.5 (mild bilateral disease, with recovery in the "push test"); stage 3 (mild to moderate bilateral disease, some postural instability, ability to live independently); stage 4 (severe disability, unable to walk or stand without assistance); stage 5 (confined to bed or wheelchair unless helped).

Movement Disorder Society Unified PD Rating Scale (MDS UPDRS)

The MDS-UPDRS, developed in 1987 by Fahn and Elton[29], is widely used to assess PD progression. This scale is administered at various stages of the disease and is an essential clinical and research tool for monitoring these patients. The test contains four parts: Part I (non-motor aspects of daily living), Part II (motor aspects of daily living), Part III (motor assessment), and Part IV (motor complications). The modified version currently used in this study was revised in 2007 to improve the instrument 's accuracy and sensitivity[24].

Each section consists of items with scores ranging from 0 to 4, with 0 indicating no impairment and 4 representing maximum severity. The overall score reflects the degree of disease progression and is used to monitor both progression and therapeutic response. Only parts I, II, and III will be included in this study, as they are directly related to the research objectives. Part I addresses symptoms such as SD, mood, and cognition, key aspects for understanding the impact of sleep quality. Part II analyzes the individual's ability to perform daily activities, allowing for a correlation between sleep quality and ADL performance . Part III focuses on assessing the motor symptoms of PD.

Pittsburgh Sleep Quality Index (PSQI)

The PSQI is a widely used questionnaire to assess sleep quality and detect possible disorders over the past month. Developed by Buysse et al.[30] and later validated for the Brazilian population[25], the instrument offers a reliable and standardized measure for identifying individuals with sleep-related problems.

The questionnaire consists of 19 self-report questions and 5 additional questions for the companion, organized into seven components: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disorders, use of sleeping medications, and daytime dysfunction. At the end of the test, the scores obtained are summed, with a higher number indicating worse sleep quality, with the sum ranging from 0 to 21 points. A total score greater than 5 indicates poor sleep quality.

PD Sleep Disturbance Scale (PDSS)

PDSS was developed by Chadhui[26], as a specific instrument to assess patterns and severity of sleep disorders in patients with PD. It was later translated and adapted into Brazilian Portuguese in 2009 by Margis et al.,[31] maintaining its validity and reliability in the local context.

It covers questions that assess different aspects of sleep, including difficulty falling asleep, overall sleep quality, motor problems during the night, pain, and symptoms related to paralysis or discomfort. The PDSS consists of 15 items, with options ranging from 0 to 10 for each item, resulting in a maximum score of 150; lower scores indicate more severe sleep-related problems.

Sit-to-Stand Test 5 Repetitions

The 5-Repetition Sit-to-Stand Test was created to assess muscle strength and lower limb functionality and is a reliable indicator of functional mobility[32] . The test consists of measuring the time required for the participant to stand up and sit down completely five times consecutively from a standard chair (approximately 43-45 cm high) without the aid of the upper arms. The test should be performed with the upper arms crossed over the chest, and the timer is started upon verbal command and stopped when the individual completes the fifth repetition.

Coin Rotation

The coin rotation test is a simple functional assessment used to measure manual dexterity, coordination, and movement of the hands and fingers. Participants are instructed to use only the thumb, index, and middle fingers of their dominant hand. The task is timed, and the time required to complete the rotation movement can be used as an indicator of fine motor function. The longer the individual takes to complete the task, the greater the difficulty in performing coordinated and rapid movements, which is common in cases of rigidity and tremors associated with PD[27].

STATISTICAL ANALYSIS

For data processing, a spreadsheet will be created in Microsoft Excel. After input and validation, the data will be exported to Statistical software . The Software Package for Social Sciences (SPSS) version 23.0® (Chicago, IL, USA) was used to perform all statistical analyses.

The level of statistical significance was set at 5% for all tests ($p<0.05$), with a 95% confidence interval. Initially, the Kolmogorov -Smirnov normality test was performed to determine whether the data were normal. Numerical data were expressed as mean and standard deviation for normally distributed variables and as median and interquartile range for asymmetrically distributed variables.

Categorical data were presented as total percentages and absolute numbers. When paired samples needed to be compared, the Student 's t-test was performed to stratify the samples.

For comparisons between quantitative variables, the Student 's t-test or the non-parametric Mann-Whitney test was used . For qualitative variables, the chi- square test or Fisher's exact test were used, as appropriate. The correlation between continuous variables will be performed using Pearson's correlation test or Spearman 's correlation test .

DISCUSSION

The increased prevalence of PD, coupled with gaps in the literature on the relationship between disease progression and sleep quality and its impact on ADLs , may contribute to worsening functional impairments and the quality of life of these individuals. Therefore, we hope to understand the relationship between PD progression and sleep quality and identify the relationship between sleep quality and ADL performance at different stages of the disease. Thus, the objective of this study will be to evaluate the relationship between PD progression and sleep quality and performance in ADLs.

Acknowledgments: C.E.V.: Receives grant from the Institutional Program for Research Support of UEMG (acronym PAPq /UEMG).

Author Contributions: All authors contributed to the conception and design of the study. C.E.V.: Provided the idea for the research or article, created the hypothesi, wrote the original proposal, and is the guarantor of the article. C.E.V., N.S.F.J. and J.B.V.: Contributed significantly to the writing of this article, while N.S.F.J. participated in the critical review of the manuscript. This protocol was written by C.E.V., N.S.F.J., P.A.Y.B. and J.B.V. with input from all coauthors. All authors read and approved the final manuscript.

Financial Support: The authors have no relevant financial or non-financial interests to disclose.

Conflict of interest: The authors declare no conflict of interest in this study.

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