

Proceeding Paper

Nutritional and Motor Functional Status in Parkinson's Disease: The NutriSPark Protocol [†]

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Abstract: A growing body of evidence suggests that nutritional status may play an important role in the development and course of Parkinson's disease (PD). Nutritional status is known to influence PD motor and non-motor features and is in turn influenced by disease duration and severity. A proper nutritional status assessment and intervention should be incorporated in the management and follow-up of PD patients. This study aims to characterize the impact of nutritional status in multiple domains of PD and to explore the feasibility and the effectiveness of a customized and intensive nutritional intervention compared to standard care.

Keywords: Parkinson's disease; nutritional status; motor function



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1. Introduction

Gastrointestinal impairment, such as constipation and delayed gastric emptying, are commonly observed at all stages of Parkinson's disease (PD) and are often overlooked and under-reported in patient interviews, especially in the early stages of PD [1]. A growing body of evidence suggests that nutrition and nutritional status may play an important role in PD [2]. There is preliminary data suggesting that some nutrients may increase an individual's risk for PD, while others may be neuroprotective. In PD patients the disease-related risk of malnutrition adds to the frequent age-related one, becoming an important contributor to poor quality of life (QoL) [3]. A proper nutritional status assessment and intervention should be incorporated in the management and follow-up of people with Parkinson's disease (PwP). In order to reduce the gaps in this area, this project pretends to characterize the neurological, nutritional, and functional status in PwP to determine the relationship between nutritional status, disease severity, motor and non-motor features, depression, cognition, and QoL, and to explore the feasibility and effectiveness of a three-month intensive, customized nutritional intervention, the "NutriSPark protocol", compared to standard care.

2. Materials and Methods

This study is a multicenter, prospective, interventional, randomized, single-blinded study with an active enrollment extending for 15 months. The inclusion criteria are

adult patients with a confirmed PD diagnosis according to the appropriate clinical criteria followed up by an examination performed by a neurologist specialized in movement disorders and a willingness to participate in the study. The exclusion criteria are PwP unwilling or unable to provide informed consent, unable to fully understand and respond to questionnaires, already following specific diets or taking nutritional supplements, or with other medical conditions likely to cause malnutrition.

Protocol stages: **T0—Baseline:** demographics; clinical data and PD features; neurological evaluation of PD; evaluation of depression; cognitive assessment; evaluation of QoL; physical assessment; nutritional assessment; anthropometric measurements; laboratory data; and grip strength evaluation via dynamometry. **T1—Nutritional Intervention and Follow-up.** The type of nutritional intervention and counseling will be optimized for each subject and will last for three months. The initial nutritional appointment will be similar for all subjects, who will then be randomized into two groups: (1) “intensive/customized nutritional intervention”—“NutriSPark protocol”; (2) “standard care”. In this study, the nutritional goal is 1.2–1.5 g/Kg/day of protein. The protein intake will consider the schedule of the levodopa-containing medications prescribed by the neurologist. Each month the “NutriSPark protocol” group will have nutritional appointments to optimize the nutritional intervention. Halfway between the nutritional appointments, a phone call will be made to monitor and troubleshoot any problems concerning the nutritional care plan. The “standard care” group will receive a generic (but adapted to the clinical setting) flyer/brochure with nutritional information for PwP. **T2—Re-evaluation and End of Intervention Visit:** At the end of the three-month nutritional intervention, all subjects will be re-evaluated (assessment similar to the baseline). Except for the researchers directly involved in the nutritional care, the investigators and raters (e.g., neurologist) will be blinded for the type of nutritional care that the subjects received. Appropriate statistical analysis will be performed.

The NutriSPark project will be conducted in accordance with the Helsinki Declaration and will seek approval by the local Ethics Committee. Data collection and analysis will be conducted in compliance with all ethical principles, including proper protection of the confidentiality of the participants.

3. Results and Discussion

In accordance with the current knowledge in this field, we expect PD patients to underperform in both functional and nutritional assessments. In addition, we expect to confirm that poorer functional/nutritional status in PwP correlates with disease severity, motor and non-motor features, depression, cognition, and QoL. Finally, if the three-month intensive and customized nutritional intervention of NutriSPark proves feasible and effective, it might lead to meaningful changes in the clinical management of PD.

Institutional Review Board Statement: The study was conducted according to the guidelines of the Declaration of Helsinki, and approved by the Institutional Review Board of Instituto Universitário Egas Moniz (protocol code 113/2021; date of approval: 8 July 2021).

Informed Consent Statement: Not applicable.

Data Availability Statement: Not applicable.

Conflicts of Interest: The authors declare no conflict of interest.

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