

# REHABILITATION PROGRAM WITH OR WITHOUT A MUSCLE-TARGETED NUTRITIONAL SUPPORT IN PATIENTS WITH PARKINSON'S DISEASE OR PARKINSONISM: STUDY DESIGN OF A RANDOMIZED, CONTROLLED TRIAL

Barichella M.<sup>a</sup>, Cereda E.<sup>b</sup>, Pinelli G.<sup>ac</sup>, Caroli D.<sup>a</sup>, Masiero I.<sup>a</sup>, Negri S.J.<sup>a</sup>, Ferri V.<sup>a</sup>, Iorio L.<sup>ad</sup>, Cassani E.<sup>a</sup>, Riboldazzi G.<sup>d</sup>, Frazzitta G.<sup>c</sup>, Pezzoli G.<sup>a</sup>

<sup>a</sup> ASST G. Pini-CTO, ex-ICP, Parkinson Institute, Milano, Italy

<sup>b</sup> Fondazione IRCCS Policlinico San Matteo, Pavia, Italy,

<sup>c</sup> Dipartimento Riabilitazione Malattia di Parkinson e Disturbi del Movimento, Ospedale Classificato Moriggia Pelascini di Gravedona, Gravedona, Italy

<sup>d</sup> U.S. Riabilitazione Parkinson, Fondazione Gaetano e Piera Borghi di Brebbia, Brebbia, Italy

## INTRODUCTION

Physical rehabilitation is an important strategy for treating motor disability in patients suffering from Parkinson's disease (PD) or parkinsonism. Muscle dysfunction is highly prevalent in this patient population and previous studies in old adults have shown that the outcome of exercise-based treatments may be positively influenced by concomitant nutritional support.

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## OBJECTIVE

To evaluate whether the use of a whey protein-based nutritional formula enriched with essential aminoacids – particularly leucine - and vitamin D have a beneficial effect on functional exercise-based rehabilitation.

## METHODS

 We designed a randomized, controlled trial.

SELECTION

ASSESSMENT

END POINTS

### PARKINSON OR PARKINSONISM PATIENTS SCHEDULED FOR A MULTIDISCIPLINARY INTENSIVE REHABILITATION TREATMENT

Inclusion criteria	Exclusion criteria
All patients were potentially eligible if they were deemed cognitively appropriate to perform tests and provide informed consent. (based on the Mini-Mental State Examination (MMSE) > 24)	Stadium Hoehn-Yahr > 4 DBS intervention - Infusion of dopamine Renal or hepatic impairment Lactose intolerance Endocrine disorders associated with calcium metabolism disorders (excluding osteoporosis) Additional calcium intake over 500 mg / day or Supplementation of Vit D over 40 iug / day

WHEY PROTEIN	21 G
ESSENTIAL AMINOACIDS	11 G
LEUCINE	3 G
VITAMIN D	800 IU
CALCIUM	500 MG

Adequate intake of protein (>1 g/kg/d), energy and vitamin D along with adequate physical activities may help prevent sarcopenia

Leucine/HMB exercise Leucine/HMB and exercise should be considered as + interventions in the management of sarcopenia

Evidence Base Importance of continuity of nutritional care following discharge from hospital and during rehabilitation

**NUTRITIONAL SUPPLEMENT**  
twice daily for 30 days

STANDARD HOSPITAL DIET

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**NEUROLOGICAL**

Disease duration, regular practice of physical therapy during the past 6 months.

Clinical rating of activities of daily living and motor symptoms (by means of the Unified PD Rating Scale [UPDRS] part II and part III, respectively; the higher the value, the lower the performance).

Disease severity (Hoehn-Yahr stage).

Type of parkinsonism.

Pharmacological treatment.

**NUTRITIONAL**

Body weight, height, body mass index (BMI), calf circumference.

Adherence to a protein-redistribution dietary regimen.

Whole-body muscle mass from impedance.

Maximal isometric contraction handgrip strength (HS) in the dominant hand.

25(OH)vitD.

Presence of dysphagia (Swallowing Disturbance Questionnaire score).

**REHABILITATION**

Evaluation of functional recovery measures.

(6 minute walk test, chair-stand test, timed up and go test, Berg balance scale, speed of 4 meters).

Evaluated perceived functional recovery.

(Self-assessment Parkinson's Disease Disability Scale [SPDDS]).

## PRIMARY EFFICACY END POINT

THE INCREASE IN THE DISTANCE WALKED DURING A 6-MINUTE WALKING TEST.

## SECONDARY OUTCOME VARIABLES

Evaluate effectiveness on other functional recovery and functional recovery measures perceived - Assess the effectiveness of body composition (bioimpedentimeter analysis) - Assess the effectiveness of body weight - Assess the effectiveness of nutrition - Assess the effectiveness of muscle strength (handgrip strength) - Evaluate the safety of the treatment - Evaluate the desire to continue treatment

## RESULTS

In absence of preliminary data on this topic, considering an effect size of 0.5 (clinically meaningful according to Cohen), the sample size sufficient to have a power of 80% to detect a significant difference in the primary outcome measure with a two-tailed type-I error of 5%, we would need at least 64 patients per group. After assuming 10% withdrawal, we planned to enroll 140 patients (70 per treatment group).

## CONCLUSION

Positive data from this trial would offer an effective adjuvant treatment options for patients with PD or parkinsonism undergoing a multidisciplinary intensive rehabilitation treatment.