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

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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.

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

METHODS
We designed a randomized, controlled trial.

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.

REFERENCES

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