MONITORING HEALTH-RELATED QUALITY OF LIFE FOLLOWING DIETARY SUPPLEMENTATION WITH FOLIC ACID, VITAMIN B12, AND VITAMIN D3 IN PATIENTS DIAGNOSED WITH PARKINSON DISEASE IN ROMANIA

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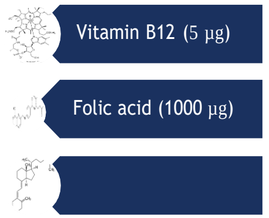
OBJECTIVES: Parkinson's Disease (PD) is a progressive neurodegenerative disorder characterized by worsening symptoms over time. The focus of this study is to analyse changes in the Health-Related Quality of Life (HRQoL) among patients with PD following a 6-month treatment regimen involving supplements containing:



The combined vitamin product PARKOVIT® is utilized for the sustained treatment of nutrient deficiency induced by medicinal treatment in patients with Parkinson's disease. PARKOVIT® is a dietary supplement used for special medical purposes (= balanced diet) and is intended for a defined group of patients who exhibit medically conditioned nutritional requirements.

For individuals with Parkinson's disease, long-term medicinal therapy is often necessary throughout their lives. Medicinal therapy can negatively influence the body's own metabolic processes. For instance, the administration of Levodopa often leads to an increase in blood homocysteine levels. Elevated homocysteine concentrations can promote the development of arteriosclerosis and have a detrimental effect on cognitive functions.

Certain vitamins such as folic acid and vitamin B12 can counteract elevated levels of homocysteine. Since Parkinson's disease is an ailment of advanced age, there is often also a deficiency in vitamin D. Generally, patients with Parkinson's disease often have an increased need for folic acid, vitamin B12, and vitamin D. Keun et al. provided solid evidence through a meta-analysis about the potential of the supplements of vitamin B12, and folic acid, to treat consequent metabolic and clinical complications among patients with Parkinson [1].

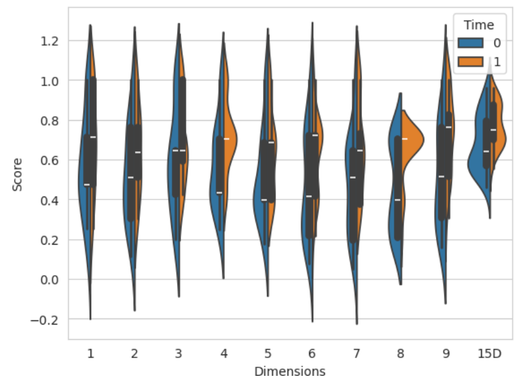
METHODS: The present study was a multicenter, hospital-based observational study conducted in Romania. We assessed the baseline and post-6-month treatment levels of homocysteine. HRQoL was evaluated using the 15D instrument, which explores 15 dimensions, including mobility, vision, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality, and sexual activity [2]. An important clinical improvement in HRQoL, characterized as "much better," is a minimum important difference of 0.035 in the 15D scores from baseline. A "slightly better" clinical improvement is considered for a difference between 0.015 and 0.035, and a "much the same (no change)" for a difference between -0.015 and 0.015. In the case of a difference between -0.035 and -0.015, it is considered a "slightly worse" clinical improvement and a "much worse" clinical improvement for a difference less than -0.035 [3].

CONCLUSIONS: : In the current observational study, the supplementation of vitamin B12, vitamin D, and folic acid proved effective in lowering elevated homocysteine concentrations resulting from levodopa metabolism. The administration of vitamin B12, vitamin D, and folic acid supplements is recommended concurrently with the initiation of levodopa to mitigate hyperhomocysteinemia and improve health-related quality of life (HRQoL), particularly in the aspects of speech, mental function, disconfort, and depression..

RESULTS: A total of 24 patients with PD, treated with levodopa/carbidopa, were recruited. Dietary intake was assessed at baseline and after 6 months of treatment (1 tablet daily). Homocysteine levels showed a significant reduction from a mean±SD of 19.73±5.5 µmol/L at baseline to 15.44±3.8 µmol/L (p=0.0049).

Vitamins	Baseline	After 6 months of treatment	p-value
Homocysteine µmol/L	19.73±5.5 19 (14.3-23.93)	15.44±3.8 15.45(13.38-17.23)	0.0049**
B12 pg/mL	336.79±119.9 313.5(249-384)	361.54±127.41 336.5(279.3-458.3)	0.4964
Vitamin D ng/ml	19.74±7.4 18.4(14.95-25.38)	23.02±7.23 21.51(18.02-30.34)	0.1003

Furthermore, a noteworthy improvement in the HRQoL was observed after 6 months of treatment (p=0.0246), specifically in the dimensions of speech (p=0.0126), mental function (p=0.0230), discomfort and symptoms (p=0.0024), and depression (p=0.0053). Importantly, a "much better" clinical change was noted for all these dimensions and overall HRQoL



References
1. Keun JTB, Arnoldussen IAC, Vriend C, van de Rest O. Dietary Approaches to Improve Efficacy and Control Side Effects of Levodopa Therapy in Parkinson's Disease: A Systematic Review. Adv Nutr 2021, 12(6), 2265-87. doi: 10.1093/advances/nmab060.
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