ScienceDirect

Clinical Nutrition

Volume 38, Issue 3, June 2019, Pages 1031-1035

Randomized Control Trials

Clinical and metabolic response to probiotic administration in people with Parkinson's disease: A randomized, double-blind, placebo-controlled trial

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https://doi.org/10.1016/j.clnu.2018.05.018

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Summary

Background & aims

The investigation was done to assess the impacts of probiotic supplementation on movement and metabolic parameters in individuals with Parkinson's disease (PD).

Methods

The study is randomized, double-blind, placebo-controlled clinical trial, which was done in sixty people with PD. Individuals were randomly divided into two groups in order to take either 8×10^9CFU/day probiotic or placebo (n=30 each group) that lasted 12 weeks. The Movement Disorders Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) was recorded at pre- and post-intervention.

Results

Compared with the placebo, consuming probiotic decreased MDS-UPDRS (−4.8±12.5 vs.+3.8±13.0, P=0.01). Probiotic supplementation also reduced high-sensitivity C-reactive protein (−1.6±2.5 vs.+0.1±0.3 mg/L, P<0.001) and malondialdehyde (−0.2±0.3 vs.+0.1±0.3 μmol/L, P=0.006), and enhanced glutathione levels (+40.1±81.5 vs.−12.1±41.7 μmol/L, P=0.03) in comparison with the placebo. Additionally, probiotic consumption resulted in a statistically significant reduction in insulin levels (−2.1±3.4 vs.+1.5±5.1 μIU/mL, P=0.002) and insulin resistance (−0.5±0.9 vs.+0.4±1.2, P=0.002), and a statistically significant rise in insulin

sensitivity (+0.01±0.02 vs.−0.006±0.02, P=0.01) in comparison with the placebo. Probiotic intake had no any significant impact on other metabolic profiles.

Conclusions

Our study evidenced that 12 weeks of probiotic consumption by individuals with PD had useful impacts on MDS-UPDRS and few metabolic profiles. Registered under ClinicalTrials.gov↗ Identifier no. http://www.irct.ir↗: IRCT2017082434497N4.

Introduction

Parkinson's disease (PD) is a neuropsychiatric disturbance that influences up to two percent of people older [1] and reported a prevalence of 14 per 100,000 subjects [2]. Approximately, 40% of PD people present cognitive disorders [3]. Various factors such as increased production of free radicals and oxidative damage, mitochondrial dysfunction, excitotoxicity, increased inflammatory cytokines, genetic factors, environmental factors, and apoptosis in neuronal degeneration of PD have been proposed [4]. In addition, data from epidemiological studies reported that more than 50% of people with PD have impaired carbohydrate metabolism [5], however data from prospective studies suggest the association is more modest with type 2 diabetes mellitus subjects having approximately a 40% elevated risk of developing PD [6].

Animal studies have reported a disturbed gut microbiota (GM) in a number of central nervous system disturbances, such as PD and multiple sclerosis (MS); data from human studies is little and controversial [7]. Multiple factors including aging, gut barrier, and functions related to blood–brain barrier may be associated with neurodegenerative disorders [8]. GM can affect various neurological outcomes, such as cognition, learning, and memory [9]. Earlier, some researchers have exhibited that probiotics are benefit on clinical and metabolic parameters in neurodegenerative disorders. The authors have previously demonstrated that 12 weeks of probiotic consumption by individuals with MS had beneficial impacts on clinical signs, mental health, insulin resistance and markers of cardio-metabolic risk [10]. The intake of synbiotic milk was benefit in improving constipation in people with PD [11]. Moreover, a meta-analysis study supported probiotic intake is effective in reducing lipid values and factors related to cardiovascular disease [12].

Considering the antioxidant and anti-inflammatory effects of probiotic, we assumed that probiotic might be useful in patients with PD. Therefore, this investigation was done to define the impacts of probiotic supplementation on clinical and biochemical profiles in people with PD.

Section snippets

Trial design and participants

This study was a 12-week randomized, double-blinded, placebo-controlled clinical trial, which was registered with the website for registration of clinical trials in Iran (http://www.irct.ir↗: IRCT2017082434497N4). Sixty individuals with PD, aged 50–90 years, which were diagnosed in accordance

with the UK PD Society Brain Bank clinical diagnostic criteria [13] were included in this trial. The study was carried out from August to December 2017 and study protocol was confirmed by the Kashan…

Results

Six participants dropped during follow-up, due to personal reasons, four in the supplemented and 2 in the placebo groups (Fig.1). However, using ITT analyses, all sixty individuals were included in the final analysis. Above 90% of capsules were used during intervention in case and control groups leading to high compliance rate in this study. Probiotic supplementation in PD patients did not result in any reported side effects.

Mean age and anthropometric indices at baseline and end of trial were …

Discussion

In this investigation, we determined the effect of consuming probiotic on movement and metabolic parameters in people with PD.We realized that taking probiotic for 12 weeks by people with PDhad favorable impacts on MDS-UPDRS, hs-CRP, GSH, MDA and insulin metabolism, but did not affect other metabolic parameters. This investigation is the first report of the impacts of probiotic consumption on movement and metabolic parameters in people with PD.…

Conflicts of interest

None.…

Author contributions

ZA and MT contributed in conception, design, statistical analysis and drafting of the manuscript. O-RT, RD-K, EK, FB, SB, SO and AM contributed in conception, data collection and manuscript drafting.…

Clinical registration

http://www.irct.ir↗: IRCT2017082434497N4.…

Acknowledgements

The present study was supported by a grant from the Vice-chancellor for Research, KAUMS (no.1396.29), and Iran.…

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