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Effect of Hydroalcoholic Extracts of Flaxseed and *Nigella sativa* Herbal Plants on Fatigue Status of Multiple Sclerosis Patients

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ABSTRACT

Introduction: Multiple sclerosis (MS) is a chronic and progressive disease of the central nervous system characterized by chronic inflammation, myelin degradation of nerve cells by the immune system, and the formation of plaques in the nervous system. Fatigue is one of the significant issues for patients with MS, but usually, it gets neglected. This study aimed to determine the effect of hydroalcoholic extract of flaxseed and Nigella sativa herbal plants on the fatigue status of MS patients.

Methods and Materials: In this clinical trial study, relevant questionnaires were completed to select the patients who meet the study criteria. Inclusion criteria required a diagnosis of RRMS, an EDSS score of less than 4, age 18 or older, and informed consent. Exclusion criteria included inability to access health information, recent disease relapse, substance abuse, smoking, alcohol use, recent vitamin D supplements, pregnancy, specific medication use, and dissatisfaction with participation. After the initial assessment, 50 patients were ultimately included in the study. These participants were divided into two groups: one group receiving hydroalcoholic extracts of flaxseed and Nigella sativa herbal plants (25 patients) and the other group receiving the placebo (25 patients). Following the intervention period, patients who did not follow up 3 months after receiving the intervention were excluded from the analysis. This led to a final inclusion of 36 patients, with 17 patients from the intervention group and 19 from the control group. Data were analyzed using SPSS 22, employing descriptive statistics and analytical methods such as t-test, Mann-Whitney U-test, and Chi-square.

Results: The results of the study showed that there was no significant difference in physical function (EDSS before:1.5[2.8] vs. 1[1], p = 0.08 and EDSS after: 1.5[2.9] vs. 1[2], p = 0.22) and cognitive function (SDMT before: 50[38] vs 47[35], p = 0.98 and SDMT after:60[39] vs 51[25], p = 0.42) between the two groups before and after the treatment period, indicating the ineffectiveness of the supplement in improving the fatigue status and overall health of the patients. The only difference between the study groups was the overall fatigue status of the patients (90[40] vs 60[80], p = 0.03), which was also observed before the intervention (90[35] vs 65[70], p = 0.03). The study groups had no significant difference in pain, stress, anxiety, sleep problems, nutrition problems, and walking difficulties (p = 0.05).

Conclusion and Discussion: The results of this study showed that a 3-month consumption of hydroalcoholic extract of flaxseed and Nigella sativa herbal plants did not significantly improve the fatigue status of MS patients.

Keywords: Fatigue, Multiple sclerosis, Nigella sativa

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