RESEARCH ARTICLE



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Investigating the Effect of Cinnamon Edible Drop on Balance and Fear of Falling in MS Patients Referred to MS Association in Isfahan Province

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ABSTRACT

Introduction: Imbalance and fear of falling are common symptoms in multiple sclerosis (MS) patients. Drug therapy and complementary and alternative medicine and the use of medicinal plants are considered treatment options in this regard. Accordingly, the present study was conducted to investigate the effect of cinnamon edible drop on balance and fear of falling in MS patients.

Materials and Methods: This experimental study was a controlled clinical trial with a parallel design. It was conducted using convenience sampling method. Accordingly, 62 MS patients were randomly divided into control and intervention groups, so that 31 patients were placed in the control group and 31 patients were placed in the intervention group. Data collection tools included the Berg balance scale and Falls Efficiency Scale (international form). The data were analyzed at 5% error level through SPSS version 22 software.

Results: The balance scores of the patients in the control and intervention groups at the end of the first and second months were not significantly different than those before the intervention (p >0.05), but the patients' fear of falling score was significantly higher at the end of the third month compared to that before the intervention (p <0.05). There was no significant difference between falling scores in control and intervention groups before and after the intervention (p >0.05).

Conclusion: Based on the results of the present study, it can be concluded that daily consumption of cinnamon in MS patients can improve their balance status after 3 months, while its effect on fear of falling in these patients was not proven.

ARTICLE HISTORY

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KEYWORDS

Multiple Sclerosis (MS), Balance, Fear of Falling, Cinnamon.

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INTRODUCTION

In the present century, the prevalence of chronic diseases is rapidly increasing and these diseases impose a high burden on the healthcare system. Most chronic diseases involve difficult treatment and a long recovery period [1]. Multiple sclerosis (MS) is a complex chronic disease of the central nervous system in which the myelin of the brain and spinal cord is degraded and inflamed [2]. It is considered as the most common cause of the neurological disorder because it can affect a wide range of systems with varying degrees and cause many neurological symptoms [3]. Symptoms of this disease vary depending on where the plaques are in the nervous system [4]. MS patients often show symptoms such as balance disorder, muscle weakness, muscle stiffness, ataxia, tremor, attention deficit, and executive dysfunction, and fatigue [5].

Balance is the state of maintaining the body's position on the surface. Balance is assessed both statically and dynamically. The ability of a person to maintain the body in a static state is called static balance. In dynamic balance, one has to maintain balance during movement [6].

Several factors such as weakness, muscle cramps, cerebellar ataxia, slow somatosensory direction, central integration disorder, fatigue, and attention deficit affect balance and walking [7]. An imbalance is seen in 87% to 94% of MS people. 41% of these patients fall and it causes injury in people aged over 55 years [8]. World Health Organization (WHO) considers falling as the third cause of chronic disability around the world. Falling in MS patients can cause fracture, scratch, compromised mobility, decreased self-esteem and fear of falling [9]. Frequent fallings can have psychological consequences, including restricted motor activity due to fear of falling, restricted social interaction, and reduced quality of life [8]. Falling and fear of falling have a significant effect on the person and lead to reduced activity, social isolation, chronic depression, and disability accumulation. MS imposes high economic and social costs associated with imbalances and fallings, and the social and health care costs increase with increasing severity of disease and immobility [10].

In this regard, it should be stated that there is currently no effective drug treatment for this chronic disease. However, some methods are used to relieve and prevent disease progression and control MS symptoms [11]. Drug therapy (such as beta-interferon) and complementary and alternative medicine are among the treatment options [12]. The conducted studies have led to the discovery of many therapeutic interventions in MS, including interferon, copaxone, tysabri, statin, glucocorticoid, mitoxantrone, cyclophosphamide, and so on [13]. The drugs prescribed to reduce the rate of relapse of the disease are often associated with many side effects. Many conventional MS drugs have significant harmful effects and increase the use of complementary and alternative drugs in MS patients. Most patients turn to complementary and alternative medicine after experiencing adverse effects of traditional and medical medicine [14].

Nowadays, the use of complementary and alternative therapies is increasing and more people are using this type of treatment. Choosing the right lifestyle and the right complementary and alternative therapy can reduce some of the symptoms and improve the quality of life [15]. In the complementary and alternative medicine, "complementary" refers to the use of a secondary approach along with the conventional medicine and "alternative" refers to the use of a secondary approach instead of conventional medicine.

According to the National Institutes of Health theory, one of the complementary medicine options is the use of herbs. Herbs are divided into medicinal, food and spice herbs. One of the oldest popular spices is cinnamon, which was used in ancient Egypt as a flavoring for drinks and medical medicine. The popularity of cinnamon was so that it was more valuable than gold. Cinnamon has been mentioned in the first Chinese medical books, about 2700 BC, indicating the value of this spice in China [16]. Cinnamon is used in traditional medicine as an analgesic, anti-arthritic, antifungal, antimicrobial, antioxidant, and anti-inflammatory. It is also used in reducing severe dental pains and problems. According to studies conducted by the US National Library, cinnamon is effective in treating diarrhea, muscle cramps, insomnia, fungal infections, influenza, and erectile dysfunction. This spice can be effective against multiple sclerosis, Alzheimer and human immunodeficiency virus infections. It has also been suggested for a variety of neurodegenerative diseases such as Alzheimer's, Parkinson's, brain tumor, meningitis, and multiple sclerosis [17]. The objective of this study is to evaluate the effect of cinnamon edible drops on balance and fear of falling in MA patients referred to the MS Association of Isfahan province.

METHODOLOGY

This quasi-experimental study was a controlled clinical trial with a parallel design in which subjects were randomly assigned to control and intervention groups. The statistical population of this study consisted of MS patients referred to the MS Association of Isfahan province. In this study, convenience sampling was used. The sample size was determined 28 people in each group using two-way test at the significant level of 5% ($\alpha = 0.05$), with 80% test power ($\beta = 0.2$) and standard

deviation of $\delta = 0.75 \sigma$ according to the following formula. Considering 10% of dropout in samples, 31 people were considered in each experimental group.

$$n = \frac{2\sigma^2 (z_{1-\alpha/2} + z_{1-\beta})^2}{\delta^2}$$

Fear and concern of falling in these patients were measured using the Yardley et al International Falling Efficacy Scale, which has 16 items scored on a 4-point Likert scale ranging from "I am not concerned" to "I am completely concerned". Scores ranged from 16 to 64. A higher score means more fear of falling or lower self-efficacy [18]. Factor analysis by varimax rotation was used to determine the construct validity. The construct validity of this scale was confirmed in this study. Pearson's correlation coefficient was used to determine temporal reliability and Cronbach's alpha was used to calculate internal reliability. Pearson's correlation coefficients of 0.70 indicated desirable temporal reliability and Cronbach's alpha coefficients of 0.98 showed very good internal reliability for this scale [19]. In this study, the Berg balance scale was used to measure the balance. It is a 14-step test, in which the patient's performance is rated on a scale ranging from zero (unable to perform a sub-test) to 4 (normal performing of sub-test). The range of scores is from zero to 56. In a study entitled "Validity and reliability of the Persian version of the Berg Balance Scale ", Davtegaran Taghipour (2005) reported the reliability of each section of the scale at 0.98. Also, the reliability between each section was reported at 0.99 and its internal consistency was reported at 0.96 [20]. Mann-Whitney test was used for data analysis through SPSS 16 software.

The researcher obtained ethical approval from the Ethics Committee of the Islamic Azad University of Isfahan (Khorasgan Branch) under the code of IR.IAU.KHUISF.1397.151. A total of 160 glass containers containing cinnamon drop were prepared. To make the placebo, it was necessary to prepare a 15 ml glass container. As the container lid was labeled Zardband Company logo, they were purchased twice than needed to replace the lids. Mineral water was used for making a placebo and the containers were matched and coded by that company without the presence of a researcher. Before conducting the study, informed consent was obtained from the samples and those who were not willing to participate in the study were not included in the study, and written consent was obtained from willing samples. By communicating effectively with clients, the researcher explained the whole process for samples in simple words and asked questions about the sensitivity and pregnancy conditions of the women. Then, demographic questionnaire and fear of falling were read by the researcher to the patient, regardless of their education level. Then, the Berg Balance Scale was performed. Drug glasses were coded as X and Y and the way of using the drugs and date of referring along with a checklist on their consumption were included in the cover and they were submitted along with a pencil and a gift to motivate the samples. In the checklist, the sidebar indicated 31 days for summer months and 30 days for autumn months and the upper bar indicated time of consumption in the form of morning, noon, and night, and the client was asked to take 4 drops in each meal along with a glass of tea, water or milk and insert a positive sign, if they consumed, and a negative sign, if they did not consume. Due to long period of time, patients were contacted once every 3 to 4 days to ensure that they were consuming the drugs regularly and they were asked to bring the checklist with themselves to determine if they had consumed it or not. In the case of lack of regular consumption, the person will be excluded from the study.

RESULTS

The results of this study are presented in (Tables 1 and 2).

Based on the results of (Table 1), the mean balance score in the intervention group was higher than that of the control group in all stages of measurement, but the results of Mann-Whitney test did not show a significant difference between the two groups in terms of mean changes in balance after consumption of cinnamon ($p \ge 0.05$). Based on the results of (Table 2), at all stages of

measurement, the mean score of fear of falling in the control group was higher than that of the intervention group. Comparison of fear of falling scores in patients at the stage of before intervention with those of after intervention (p = 0.003), comparison of fear of falling score one month after intervention with total score after the intervention (p=0.012), and comparison of fear of falling score two months after intervention with total score after the intervention (p=0.033) showed a significant difference control and intervention groups.

DISCUSSION

Based on the results, the balance scores of the patients in the intervention group were higher than those of the control group at all stages, but the Mann-Whitney test did not show a significant difference between the two groups in terms of changes in the balance of patients before and after the intervention (p>0.05). The results of the study conducted by Ghanavati et al (2013) entitled "Investigating the effect of standardized cinnamon capsule on quality of life and fatigue in MS patients referred to MS Association of Khuzestan" showed that the quality of physical life increased from 5.29

at the end of the first month to 14.63% at the end of the third month [21]. As balance is one of the most important factors in the quality of physical life, it can be stated that this study is not in line with that of the present study. Thus, it is suggested to conduct further studies on the effects of cinnamon on the balance of MS patients to evaluate the effects of its consumption. The score of fear of falling after the intervention compared to before intervention increased by 1.83 units on average in the control group and decreased by 1.67 units on average in the intervention group. Mann-Whitney test showed a significant difference between the two groups regarding the level of changes in fear of falling before and after the intervention (p < 0.05) and the fear of falling in the intervention group was significantly lower. No study was found on the effect of cinnamon or any other medication on fear of falling in MS patients. However, the study conducted by Caloron et al under the title of "Concerns and fear of falling and length of steps in MS patients reported that with increasing the fear of falling of the patients, the patients will take shorter steps and walk slowly, so they need more supports during walking [22].

CONCLUSION

The results of this study showed that there was no significant difference between the level of balance of MS patients referred to the MS Association of Isfahan province before and after using cinnamon (p < 0.05). Thus, it can be concluded that consuming cinnamon daily in MS patients does not improve their balance status. The results also showed that there was a significant difference between the fear of falling in MS patients before and after using cinnamon (p < 0.05) since in comparing different measurement stages, this difference was significant after 3 months. Hence, it can be concluded that consuming cinnamon daily by MS patients can improve their fear of feeling status after three months.

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| | Measurement time | | Control | Intervention | | Statistic | Significance | | | | | |
|--------------------------|---------------------|-------|---------|--------------|------|-----------|--------------|--|--|--|--|--|
| | | Mean | SD | Mean | SD | | level | | | | | |
| Before | intervention-first | 0.40 | 2.21 | 0.70 | 2.63 | 411.00 | 0.533 | | | | | |
| | month | | | | | | | | | | | |
| Before | intervention-second | 0.50 | 2.65 | 1.40 | 3.84 | 396.00 | 0.414 | | | | | |
| | month | | | | | | | | | | | |
| Before | intervention-after | 0.17 | 3.86 | 2.10 | 5.01 | 370.50 | 0.233 | | | | | |
| | intervention | | | | | | | | | | | |
| First month-second month | | 0.10 | 1.09 | 0.70 | 2.22 | 367.50 | 0.197 | | | | | |
| First | month-before | -0.23 | 2.64 | 1.40 | 3.72 | 333.50 | 0.077 | | | | | |
| | intervention | | | | | | | | | | | |
| Second | month-after | -0.33 | 2.04 | 0.70 | 1.76 | 341.50 | 0.077 | | | | | |
| | intervention | | | | | | | | | | | |

Table 1. Comparison of mean scores of patients' balance at different measurement stages in control and intervention groups

Table 2. Comparison of mean scores of fear of falling in different measurement stages between control and intervention groups

| Measurement time | Control | | Intervention | | Statistic | Significance level |
|---------------------------------|---------|------|--------------|------|-----------|--------------------|
| | Mean | SD | Mean | SD | | |
| Before intervention-first month | 0.17 | 3.35 | -0.23 | 3.08 | 393.00 | 0.395 |
| Before intervention-second | 0.63 | 4.27 | -0.83 | 5.72 | 353.50 | 0.150 |
| month | | | | | | |
| Before intervention-after | 1.83 | 5.75 | -1.67 | 7.02 | 253.00 | 0.003 |
| intervention | | | | | | |
| First month-second month | 0.47 | 2.50 | -0.60 | 4.71 | 403.00 | 0.483 |
| First month-before intervention | 1.67 | 4.10 | -1.43 | 6.45 | 281.00 | 0.012 |
| Second month-after intervention | 1.20 | 4.32 | -0.83 | 2.46 | 308.00 | 0.033 |