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Letter to the Editor

Challenges on Adherence to Lifestyle Interventions in Integrative Medicine Clinical Trials

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In Persian medicine, as one of the rich medical schools, the preferred approach is to maintain health and prevent diseases by applying codified and classified rules about a healthy lifestyle. Renowned sages of Persian medicine, including Avicenna and Rhazes, have emphasized paying attention to these laws not only for prevention, but also as the first and most important step in the treatment plan of diseases [1-3]. Eating and drinking habits are one of the most important factors in a healthy lifestyle, which in turn has a tremendous effect in preventing or contracting all diseases [1-5].

On the one hand, the physical attributes of food in terms of temperature, concentration, etc., the chemical properties and ingredients of food, the composition and simultaneity of Foodstuffs in a meal; and on the other hand, the individual's personal manners, including the amount of chewing, involvement with mental emotions while eating, etc., are effective on the quality of digestion and ultimately achieving health or illness [1-4].

Considering the prominent role of nutrition in health and treatment, famous Iranian medical scholars emphasize the order of using therapeutic foods as the first line of treatment and have also recommended that if there is a possibility of treatment with nutritional interventions, one should not enter the stage of drug treatment [1,2]. However, after the passage of several centuries and the change of living habits and conditions, today Persian medicine therapists harbor different opinions concerning the measure of patients' adherence to lifestyle interventions and possibility of strictly using food as treatment.

Based on this, we designed a study in the field of improving the symptoms of functional dyspepsia in adults, in which we compared the effect of omeprazole (Group D) with three types of treatment: 1- Sumac and modification of eating and drinking habits (Group A), 2- only modification of eating and drinking habits (Group B), 3- Sumac (Group C). In order to conduct this study, which is part of the thesis of the specialized doctoral degree in Persian medicine, the approval of the Ethics Committee of Golestan University of Medical Sciences with the number IR.GOUMS.REC.1399.298 was obtained and the study was registered in the International Clinical Trial Registration Center of Iran with the number IRCT20200424047192N1.

The group that was treated without medicine (Group B) only received training based on the health maintenance instructions of Persian medicine that are effective on the symptoms of dyspepsia. These instructions include chewing food better, not talking and watching TV and keeping calm while eating, not drinking water or yogurt with food, avoiding the consumption of certain foods at the same time in one meal, for example,

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eggs with dairy products, etc., not consuming some spices and foods that trigger symptoms of dyspepsia, avoiding overeating, and other orders related to eating time.

This study was conducted on 104 patients aged 18-60 with functional dyspepsia. Patients who, while not suffering from *Helicobacter pylori*, if they met Rome IV criteria, were included in the study and in the four groups mentioned, they underwent 4 weeks of treatment and 4 weeks of follow-up.

The level of symptoms and the quality of life of the patients were measured at four points before the start of treatment, the 2nd, the 4th, and the 8th week using standard questionnaires. The data was analyzed by Generalized estimating equations test using SPSS software. The results showed that during the course of the study, there was no significant difference between the improvement of symptoms in the group receiving omeprazole and the group that received only habit modification training (P value = 0.739).

Until the end of the study, one person from the Group A, 15 people from the Group B, 2 people from the Group C, and one people from the Group D were excluded from the study. Most of these people took medicine due to the persistence of symptoms and therefore lost the condition of continuing to participate in the study (Figure 1).

The 11 people who remained in the study from the beginning had a lower average symptom score than all the groups. At the end of the study, which was 4 weeks after stopping the drugs in the other groups, the average symptom score of these people was significantly different from the omeprazole group, which experienced a return of symptoms (P value = 0.011), just as well as the groups receiving sumac (Figure 2).

The patients participating in this study had the criteria of Rome IV, including suffering from 3 days a week with bothersome symptoms. Therefore it seems that it is possible to achieve treatment by making changes in food consumption habits without prescribing drugs only in the patients with milder stages of the disease and not the ones suffering from severe debilitating symptoms. However, patients who are able to follow the treatment by observing the correct eating and drinking habits will benefit from the advantages of drug-free treatment.

In Guadagnoli et al.'s study, the severity of Gastroesophageal reflux disease symptoms was positively correlated with adherence to Proton-pump inhibitor use, but negatively correlated with adherence to dietary guidelines. They stated that the lack of clear and standardized instructions, along with social, cognitive, and financial factors, can impact patients' adherence to lifestyle modification [6]. In the case of our study, it seems that the high level of symptom severity and the initial inadequacy of changing habits for relief

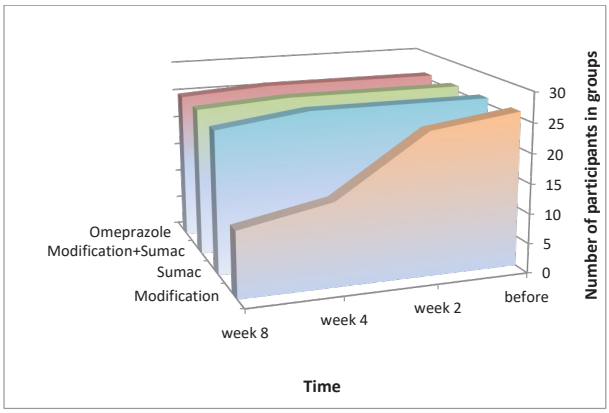

Figure 1. Number of participants in groups by time

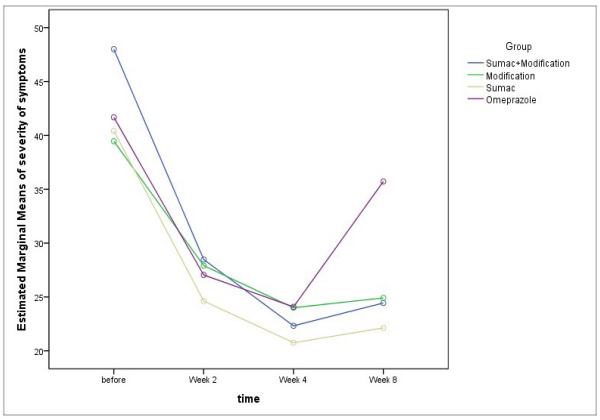

Figure 2. Severity of symptoms by time

were the causes of the low adherence to the lifestyle intervention.

Limited evidence suggests that older age, higher education, and higher stage of recovery at baseline may lead to more adherences [7]. Changing dietary customs requires awareness of bad habits, sufficient motivation to fix the problem, or even fear of symptoms returning [8]. It may also be suitable to refer patients to providers trained in health behavior change, such as health psychologists to aid ameliorate lifestyle modification [6].

Identifying factors affecting adherence in future studies can ultimately improve the successfulness and cost-effectiveness of the lifestyle modification programs.

Conflict of Interests

None.

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