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# THE EFFECT OF AVICENNA'S SELF-CARE RECOMMENDATION IN THE MIGRAINEURS: A SINGLE ARM CLINICAL TRIAL STUDY

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**Abstract:**

***Background:*** *Migraine is a prevalent neurologic disorder that affects a lot of people in the world. Current Classical treatments of Migraine are not effective and getting help from the complementary and alternative medicines such as Persian medicine is Necessity.*

***Objective:*** *Avicenna (Ibn Sina) and other physicians of Traditional Persian Medicine, believe that avoiding flatulent foods that improves headaches. This study with aim of the evaluation the effect of a Persian medicine-based diet on monthly bouts of headache in migraineurs has been done.*

***Patients and Methods:*** *This study was a single arm clinical trial study. We enrolled 50 eligible migraines patients 2016-11-28 to 2017-02-26 in Tehran, Iran. Patients, prohibited and recommended food including avoiding Special foods including 6 groups: 1) bread and cereals, 2) fruits and vegetables, 3) meat and Eggs, 4) milk and dairy products, 5) cereals, seeds and beans, and 6) Other according to the Persian medicine recommendation.*

***Results:*** *This study conducted on 50 migraine patients with Age (yrs.) Mean ± SD, 42.52±10.70. The study showed frequency (9.74 vs. 5.98, P<0.001), duration (93:30 vs. 42:19 P<0.001), severity (66.78 vs. 27.24 P<0.001) of headaches, Analgesics intake (7.86 vs. 2.38 P<0.001) and Disability (63.18 vs. 54.26 P<0.001) in migraine patient's significance decrease during study*

***Conclusion:*** *According to the results of this study, dietary Based on Persian Medicine are effective for the managing and cure of migraine.*

**Keywords**: *Iranian Traditional Medicine; Persian Medicine; Migraine; Headache; Diet; Flatulence;*

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## INTRODUCTION:

"Headache disorders are third cause of disability worldwide"(1). Headache is an important public health problem and is a great burden health care system. Headache is a common symptom that all people almost suffer at a time of their life. The previous study estimated that nearly half of the adult population in the world has got headache (2, 3). International headache society classification committee, classified headache disorders into three main divisions (4). " Classifying headaches as primary, secondary, and cranial neuropathy can facilitate evaluation and management". 90% of all headaches are primary headaches. Migraine is the most common in primary headaches (5). The one year prevalence of migraine was 27.6% (6). "Migraine is a highly prevalent and largely familial disorder characterized by periodic, commonly unilateral, often pulsatile headaches that begin in childhood, adolescence, or early adult life and recur with diminishing frequency during advancing years" (7). Migraines have a high direct and indirect personal, socio-economic consequences (8, 9). Chronic migraine costs are nearly three times more expensive than an episodic migraine. Therapeutic interventions that reduce the frequency of headaches can be important ways to steady or reduce medical expenses for migraine headaches (10). According to the World Health Organization's ten-year Strategic Plan, from 2014 to 2023, use of Complementary Medicine like Traditional Medicine in each countries recommended (11). We decided to carry out this study to find out a new solution from Persian medicine for managing and treating migraine. Physicians in medieval Persia by collecting ancient knowledge from other cultures and adding them to their own knowledge provided solutions for diseases (12, 13). They used clinical approaches for diagnosing, classifying, and cope with headaches, and these observations provide a comprehensive explanation of a headache (13-15). In Iranian medicine, lifestyle modification has priority over other treatments (16, 17). Self-care and lifestyle modification like nutritional modifications in migraine can also be effective (18, 19). Paying attention to modification of patient's diet to treat migraine headaches is preferable to taking preventive medications that have side effects (20). The feeling of abdominal fullness, bloating and moving of gas in the abdomen is a very unpleasant sensation called flatulence. According to the Persian medicine references, bloating is known as Nafkh and Rih (21). Some foods can produce flatulence in gastrointestinal tract (22), and one of the main principle treatments for all headaches, in Persian medicine is the elimination of flatulent foods or Nafakhat in headache sufferers nutrition. Avicenna and other physicians of Persian Medicine, believe in avoiding flatulent foods that improve the headaches (17, 23).

**Objective:**

The aim of this study is evolution of Persian medicine-based diet effect, on monthly bouts of headache in migraines has been done.

## PATIENTS AND METHODS:

This single arm clinical trial study conducted on man or women migraine patients from 2016-11-28 to 2017-02-26 in Tehran, Iran. Inclusion criteria: 1-Age 18 to 60 years; 2-confirm the presence of migraine according to the ICHD-III respected by neurologist; 3-No Other Neurological diseases and systemic diseases such as diabetes, hypertension, liver failure, renal failure; 4-Non-pregnant patient. Exclusion criteria: 1-patient's unwillingness to continue to participate in the research, 2-detect any incidence of systemic diseases. The intervention is to avoid eating the flatulent foods for four weeks. Food ban, contains a list of flatulent foods that as a list (Table-2) is available to patients. At the beginning of the four-week monitoring period, then at the beginning of the intervention and at the end of the fourth week intervention, patients visited by researcher and study in terms severity, duration, frequency of headaches, number of analgesic use, quality of life and nutritional status by questionnaires that will be evaluated. Primary outcome in this study were frequency of headaches, duration of headaches, severity of headaches, pain and secondary outcome was disability and number of analgesic use. In this study after permission from the Ethics Committee of Shahed University (Code No: Shahed.REC.1395.134) and registration on the Iranian registry of clinical trials website (Code No: IRCT2016120331210N1), Neurology Clinic of Shahid Mostafa Khomeini Hospital of Tehran (A general governmental hospital) The referred patients were chosen by simple random sampling. After explaining the study included its objectives, probable risks, the benefits of participating in the study, and also stating the voluntary nature of participation in the study, informed consent was obtained and the patients was administered. In this study, 65 patients were assessed in terms of eligibility criteria but 15 were excluded. Finally, 50 patients participated in this study.

**Intervention**

For intervention, initially a systematic review in Iranian traditional medicine references like Mansuri-fi-Teb (24), Canon-fi-Teb (17) Tohfatol-Momenin (25), Makhzan- Al' Advieh (26), Exir-e Azam (23), to determine the flatulent foods and Table-1 were obtained after collection and summarization. Local

and international search engines like Pro Quest, PubMed, Scopus Data Base Science, Iran Medex, SID and Elsevier searched then after review and finding flatulent foods in conventional medicine researches, identified new flatulent foods, such as carbonated beverages, they have been also added to food Avoidance List (27-29) and overall, Table 2 was achieved. When List was identified, then the nutrition education program was designed as an initial prototype to aid in the prevention of headache in Migraineurs. In this study firstly, subjects were evaluated basically four weeks before the intervention. In this period, frequency, duration, severity of headaches, number of analgesic use and disability of patients were evaluated then after the initial monitoring, in second visit, after two days to remove the effects of previous used foods, necessary explanation for the intervention presented to patients.

In this section researchers reminded patient that the type of previous treatment does not change during the study, and they educated to use Persian Medicine-based Avoiding Diet Program (PMADP). In PMADP some prohibited (flatulent foods) and recommended foods advised to patients according to the Table 2. PMADP contain six categories 1) bread and cereals, 2) fruits and vegetables, 3) meat and Eggs, 4) milk and dairy products, 5) cereals, seeds and beans, and 6) Other. The accuracy of the intervention was evaluated by the patients through regular visits, reminder form as well as telephone contacts. Patients should comply at least with 80% of the diet. Again, patient's frequency, duration and severity of headaches and in addition number of analgesic use, and disability were evaluated in end of study (after 4 weeks) and the final result of data has been analyzed.

**Table 1: The list of Prohibited and Recommended Food**

| Food Group | Prohibited |
|---|---|
| **Bread and Cereals** | Barley bread |
| **Fruits and Vegetables** | Grapes, Melons, Figs, Pears, Toes, Apples, Dates, Bananas Cucumber, Lettuce, Pumpkin, Cabbage, Lime Cabbage, Raw Garlic, Raw Onion, Eggplant, Mushroom, Turnip, Horse, Zardak Puree, basil, turkey, fenugreek, dill, celery, spinach, persimmon, chicory |
| **Meat and Eggs** | Beef, buffalo, camel |
| **Milk and Dairy products** | Yogurt, Cheese, Ice Cream, Dough |
| **Cereals, Seeds and beans** | Bean, Lentil, Beans, Chickpea, Leeks, Cobra, Sesame Walnuts, Pistachios Mustard, pepper, cannabis |
| **Other** | Chili sauce and mustard sauce Carbonated beverages |

**Table 2: The list of Prohibited and Recommended Food**

| Food Group | Contain | Prohibited | Recommended |
|---|---|---|---|
| **Bread and Cereals** | Traditional Bread, Local Bread, Whole Bread Cereals (rice, wheat, barley) Types of pasta | Barley bread | Sangak Baked Sour Cream Fried rice |
| **Fruits and Vegetables** | Fruits Dried Fruit Raisins, dates Cooked vegetables or vegetable juices Raw Vegetables | Melons, Figs, Pears, Toes, Apples, Dates, Bananas Cucumber, Lettuce, Pumpkin, Cabbage, Lime Cabbage, Raw Garlic, Raw Onion, Eggplant, Mushroom, Turnip, Horse, Zardak Puree, basil, turkey, fenugreek, dill, celery, spinach, persimmon, chicory | Olives, figs, sweet pomegranate Cooked vegetables, Carrot juice, Apple juice Raisins, currants |
| **Meat and Eggs** | White meat (fish and birds) egg Red meat (sheep, calf) Processed Meat Feather and viscera (liver, heart, throat, tongue, brain, peppermint, drinking water) | Beef, buffalo, camel | Chicken and birds Honey egg yolk lamb meat |

| | | | | |
|---|---|---|---|---|
| **Milk and Dairy products** | | Milk, Yogurt, Ice Cream, Whey, Cheese, Cream and Sour, Doog Calcium Supplements Vitamin D | Yogurt, Cheese, Ice Cream, Dough | Milk a little candy or honey Pasteurized Cheese |
| **Cereals, Seeds and beans** | | Walnuts, Almonds, hazelnuts, Pistachios and ... Seeds of Seeds Chickpea, Beans, Lentils, Bean, Leeks, Mushrooms Coffee, cocoa | Bean, Lentil, Beans, Chickpea, Leeks, Cobra, Sesame Walnuts, Pistachios Mustard, pepper, cannabis | Rice |
| | **Other** | Fats: Solid and liquid oils, Fat, Fat, Butter, Cream, Cucumber, Fatty Sauce Sweets: Types of Jams, Syrups, Sugar, Sweets, Varieties of Desserts, Candy and Chocolate Pickles, salads and seasonings: spices, peppers, salt, turmeric, cinnamon, pickles and salty Drinks: carbonated beverages, tea, coffee, all kinds of industrial juices and ready-made powders | Chili sauce and mustard sauce | Olive oil or sesame oil<br>Honey, Sugar, Homemade Jam<br>Salt and turmeric in a small amount |
| | | | Carbonated beverages | Few teas at a low rate and at a distance from the food |

**Visual Analogue Scale (VAS)**

The pain Visual Analogue Scale is an assessment tool that clinically evaluates pain that a patient feels in a range from none to a sever amount of pain (30, 31), which has been widely used in diverse adult populations, including those with Migraines Diseases (32).

**Persian HIT-6 Questionnaire in Migraine**

Six-item Headache Impact Text (HIT-6™) provide a global measure of adverse headache impact. This questioner evaluates the headache pain severity. It is validated in several countries (33). Translation, Convergent Validity and reliability (Cronbach α =0.8) of Iranian version of this questionnaire approved by Zandifar et al (34).

**Data analysis and sample size**

All statistical analyses carried out with SPSS18 (SPSS Inc., Chicago IL). Data for continuous variables expressed as mean ± SD if they distributed normal or median (25-75 percentiles) with non-normal distribution. Categorical variables were showed as frequency (percent). Normality distributions of numeric variables were assessed with Kolmogorov-Smirnov test.

In this study paired sample t test or Wilcoxon test and McNemar test were applied to compare before and after variable. A P value less than 0.05 was regarded to be significant. Sample size considering Cohen effect size [$\alpha$=0.05, $\beta$=0.1, r = 0.5, use formula $n=2\times(1-r)\ (Z_{(\alpha/2)}+Z_{(\beta)})^2/d^2$ and d=0.5] was calculated as 35 patients, also considering the possible drop-out (40%) , 15 subjects added so finally 50 case considered in this study.

**RESULTS:**

This study conducted on 50 migraine patients with Age (yrs.) Mean ± SD, 42.52±10.70. Demographical information variables of patients are presented in Table 3. According to this table, most patients were female, married, Academic Degree with normal age. The Mean and SD of variable before and after of intervention are reported in table 4. As the result of this table showed frequency, duration, severity of headaches, Number of Analgesic and Disability in migraine patient's significance decrease during study.

**Table 3: frequency and percent of demographical variable**

| | | Number | Percent |
|---|---|---|---|
| **Sex** | **Male** | 1 | 2.0% |
| | **Female** | 49 | 98.0% |
| **Marriage** | **Single** | 5 | 10.0% |
| | **Married** | 45 | 90.0% |
| **Education** | **literate** | 10 | 20.0% |
| | **Diploma** | 12 | 24.0% |
| | **Academic Degree** | 28 | 56.0% |
| **Age** | **Under 30** | 9 | 18.0% |
| | **30-40** | 12 | 24.0% |
| | **40-50** | 16 | 32.0% |
| | **Upper 50** | 13 | 26.0% |
| **Weight** | **Normal** | 24 | 48.0% |
| | Overweight | 18 | 36.0% |
| | Obese | 8 | 16.0% |

**Table 4: The Mean and SD of variable before and after of intervention**

| | Before | | After | | P-value |
|---|---|---|---|---|---|
| | Mean | SD | Mean | SD | |
| Frequency of headaches | 9.74 | 3.66 | 5.98 | 2.31 | <0.001 |
| Duration of headaches | 93:30 | 42:19 | 34:22 | 16:33 | <0.001 |
| Severity of headaches | 66.78 | 26.24 | 27.24 | 11.61 | <0.001 |
| Number of Analgesic | 7.86 | 2.96 | 2.38 | 1.34 | <0.001 |
| Disability | 63.18 | 4.01 | 54.26 | 3.26 | <0.001 |

## DISCUSSION:

The clinical manifestations of migraine are significantly related to dietetic and gastrointestinal aspects (35). The result of this study showed frequency (9.74 vs. 5.98, P<0.001), duration (93:30 vs. 42:19 P<0.001), severity (66.78 vs. 27.24 P<0.001) of headaches, Number of Analgesic (7.86 vs. 2.38 P<0.001) and Disability (63.18 vs. 54.26 P<0.001) in migraine patient's significance decrease during study.

The result of this study is similar to the previous studies. The reason for supporting our results is Gastrointestinal complaints accompanying with primary headache, particularly migraine (36-42). Human gut microbes effect on gut-brain axis, through inflammatory cytokines and formation of antimicrobial peptides that influence on the epigenome and enteric nervous system (43). Diet and infections can change human gut microbiota that associated with producing short-chain fatty acids and vitamins, nutrient absorption and production of common neurotransmitters (44). Researchers have suggested, studied and discussed several causes and factors associated with migraine such as allergy (45) or food-allergic disease (46), Oxidative Stress (47), genetic metabolic sensitivity (44), disorder in the bidirectional axis of the Brain-Gut Connection (45), Inflammation (44, 48), T cell-mediated immunity (46). We found that the symptoms of functional disorders (FGIDs) of the digestive tract were very common in patients with migraine based on Rome III criteria. Treatment of FGIDs symptoms may be potential for amelioration of migraine (40). There may be a clinical relationship between gastrointestinal complaints, and chronic headaches. For efficacious treatment of cases, patient's problems should be considered together. The patient's prognosis not only is it related to the treatment of headaches, but also to the treatment of accompanying diseases (41). Eradication treatment of Helicobacter pylori infection can significantly reduce or treat the severity of migraine headache (49, 50).

Diet may play a role in triggering migraine, but available evidence on migraine and diet is limited (20, 35, 46, 51-56). Identifying the dietary factors that constantly trigger a migraine in some people is helpful in reducing the frequency of attacks (57-60).

Bunner et al showed that nutritional approach may be a useful part of migraine treatment (61). Previous studies also showed that food elimination based on immunoglobulin G antibodies in migraine patients who suffer from concomitant irritable bowel syndrome may effectively reduce symptoms from migraine and irritable bowel syndrome (46, 62, 63).

When advising patients on dietary changes to improve migraine, it is important to acknowledge the limits in evidence and the larger role that diet may play in lifestyle changes (51). Food behaviors should be considered in managing headaches. Just as regular eating habits can reduce headaches (64). Persian Medicine Hakim Esmail Jorjani (65) believed that Stomach disorders cause brain disorders such as headaches. He named these diseases coorporative diseases (66). The main point of nutritional aspects of lifestyle correction in traditional Persian medicine for preventing and treatment of all kind of headaches is the elimination of flatulent nutrients (17). It is recommended that, while eliminating of flatulent nutrients from migraineurs diet, additional lifestyle modifications for treating flatulence like the accurate selection of the nutrients based on their ingredients and properties also a proper combination of nutrients and the correct method of preparing the meals and healthy eating manner also to be used (22).

## CONCLUSIONS:

According to the result of this study, it seems Persian Medicine-Based Diet that Includes avoiding flatulent foods can be effective method for managing and treatment of headache in Migraineurs.

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