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ORIGINAL RESEARCH

Attitudes and Behaviors of Adults on Interventional (Invasive) Traditional Medicine Methods: A Descriptive Study

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Abstract

Objective: Invasive traditional and complementary medicine (TCM) methods, which are performed with minimal damage to the patient's body integrity, are becoming widespread in order to live healthy and to be treated when necessary. With this study, we aimed to evaluate the attitudes and behaviors of adults towards interventional TCM methods.

Material-Method: The descriptive research was conducted between 30/03/2020 and 06/04/2020. The questionnaire form consists of 20 questions. Percentage, mean ± standard deviation were used in descriptive statistics. Chi-square test was used to evaluate qualitative data; $p < 0.05$ was considered statistically significant.

Results: 542 people participated in the research. 74.9% of the participants are women, 42.8% of them were under the age of 30, 79.3% were university graduates. Interventional TCM methods were applied to 51.7% of the participants. A statistically significant difference was found between age ($p < 0.001$), educational status ($p = 0.006$) and profession ($p < 0.001$) and the application of interventional TCM methods. 56.8% of those who had interventional TCM methods performed the application in a non-clinical environment; It was observed that 39.7% had it done by a physician

Conclusion: It has been observed that TCM applications are increasingly preferred by the society, even if they are invasive, the complication rates are low, and most of them consider to have the same application again, but when evaluated in terms of the person performing the application and the place where it is performed, it is seen that studies on this subject should be planned. It is very important that invasive method applications, which always have complication risks, should be performed under clinical conditions and by the physician.

Keywords: Invasive, Traditional Medicine, Wet Cupping, Acupuncture

INTRODUCTION

Nowadays, interest in TCM methods is increasing. In 2000 report of The World Health Organization (WHO), it was announced that approximately 50% of the people living in Europe, Australia and North America use one of the TCM methods and herbal products are the mostly used one of them[1-3].

In our country; Department of Traditional, Complementary and Alternative Medicine Practices was established in 2012 under the roof of the Ministry of Health and the "Traditional and Complementary Medicine Practices Regulation" was published in the Official Gazette and put into effect dated October 27, 2014 [4]. According to this regulation, physicians are authorized by the ministry, as well as dentists to apply only in their own field. The place of application must have a permit issued by the ministry, and the physician who will perform the application must have a certificate signed and approved by the relevant ministry [5,6].

All interventions performed with minimal damage to the patient's body integrity are called "minimally invasive interventions" [7]. Acupuncture, leech therapy (hirudotherapy), wet cupping, larval therapy, mesotherapy, prolotherapy, osteopathy and ozone treatments, which are under the title of Traditional and Complementary Medicine, are applications with infection risk because they are invasive procedures. There are many publications in the literature about infections that develop as a result of such applications [8,9]. Pyogenic infections such as skin and soft tissue infections, cellulitis, abscess, septic arthritis, cartilage tissue inflammations, osteomyelitis, caused by bacteria in the skin flora or colonizing the skin due to the deterioration of skin integrity during treatments can often be seen. There is also a risk of developing bacteremia and

endocarditis. In addition, by not paying attention to the sterilization of the materials used during the interventions or by using the same materials to more than one person, hepatitis B, hepatitis C and HIV infection can be transmitted from blood-borne diseases [10].

According to the literature review, there are various studies specific to TCM applications [11-34]. It is seen that these studies are related to general TCM methods or to a specific method [11-15]. There has been no study evaluating the general approach to interventional TCM methods, which are methods that need particular attention for their complications and application methods. Evaluating the experience and attitudes of adult individuals on this issue may give an idea about the measures and controls that should be taken against these new methods in our country. For these reasons, we aimed to evaluate the attitudes and behaviors of adult individuals against interventional TCM methods with this research.

MATERIALS AND METHODS

The descriptive research was conducted in the organization of Hacettepe University Faculty of Medicine, Department of Family Medicine between 30/03/2020 and 30/04/2020. The population of the study consists of individuals who applied to the outpatient clinics of Hacettepe University Faculty of Medicine, Department of Family Medicine. The people included in the study are those over the age of 18 who have applied to our polyclinics for any reason and who do not have a psychiatric disease. Epi Info 7 StatCalc was used to calculate the minimum sample size and the sample size was estimated as 384 adults, assuming 95% confidence interval and 5% sampling error.

A questionnaire form consisting of 20 questions, prepared by the researchers and piloted on 20 adults, was applied to adults over the age of 18 who applied to our Hacettepe University Family Medicine Polyclinics and accepted to participate in our study. The questionnaire consist of four questions (gender, age, occupation, education level) for sociodemographic characteristics answered by all participants; nine questions about interventional traditional medicine methods; seven questions prepared for people who use only interventional traditional medicine methods.

The questionnaires were administered by giving the questionnaire form to the participants and collecting it again by the researcher after obtaining written consent. During the data collection process, the socio-demographic information of the individuals, social attitudes and behaviors towards traditional and complementary medicine methods, and the opinions of the individuals affected by the application were collected with the questionnaire form prepared by the researchers. The questionnaires were filled by the participants in an average of 5-10 minutes. The study was conducted in accordance with principles of the Declaration of Helsinki.

In the evaluation of the data, mean ± standard deviation was used for continuous variables and the frequency table was used for qualitative data. Chi-square test was used to investigate the relationship between qualitative data. A value of $\alpha = 0.05$ was accepted as the level of error. Data were analyzed with IBM SPSS V23.

Permissions

Ethics committee approval of the research was obtained from Hacettepe University Non-Interventional Clinical Research Ethics Committee with the number GO20 / 745.

RESULTS

542 people participated in the research. Of the participants 74.9% (n = 406) were women; 42.8% (n = 232) were under 30 years old; 17.7% (n = 96) were 51 years old and above and 79.3% (n = 429) were university graduates. The profession of 69.5% (n = 376) is not related to the field of health. 51.7% (n = 281) of the participants applied invasive traditional medicine methods at some stage of their lives. The distribution of the participants according to their general characteristics and the application of interventional traditional medicine methods are given in Table 1. A statistically significant difference was found between age ($p < 0.001$), educational status ($p=0.006$) and profession ($p<0.001$) and the application of interventional traditional medicine methods. Interventional traditional medicine methods are used more frequently in those who are over the age of 41 and who do not have a health-related profession; It was observed that the frequency of applying interventional traditional medicine methods decreased with the increasing education level.

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Table 1. Distribution of the general characteristics of the participants according to their interventional TCM methods use

	Application of interventional traditional medicine methods						
	Total (N = 542)		Yes (n=281)		No (n=261)		p
	n	%	n	%	n	%	
Age							
30>	232	42.8	84	36.2	148	63.8	
31-40	118	21.8	62	52.5	56	47.5	0.000
41-50	96	17.7	71	74.0	25	26.0	
51<	96	17.7	64	66.7	32	33.3	
Gender							
Woman	406	74.9	212	52.2	194	47.8	0.765
Man	136	25.1	69	50.7	67	49.3	
Education status							
Primary education	41	7.6	30	73.2	11	26.8	
High school	71	13.1	43	60.6	28	39.4	0.006
University	310	57.3	153	49.4	157	50.6	
Master / doctorate	119	22.0	54	45.4	65	54.6	
Profession							
Health Related	165	30.5	63	38.2	102	61.8	0.000
Non-Health Related	376	69.5	217	57.7	159	42.3	

Chi-square test, p <0.05 statistically significant

It was observed that 45.5% (n = 128) of the participants had wet cupping application, 20.1% (n = 56) had leech application and 10.1% (n = 284) had acupuncture application among the interventional TCM methods. The distributions of the interventional traditional medicine methods applied are given in Figure 1.

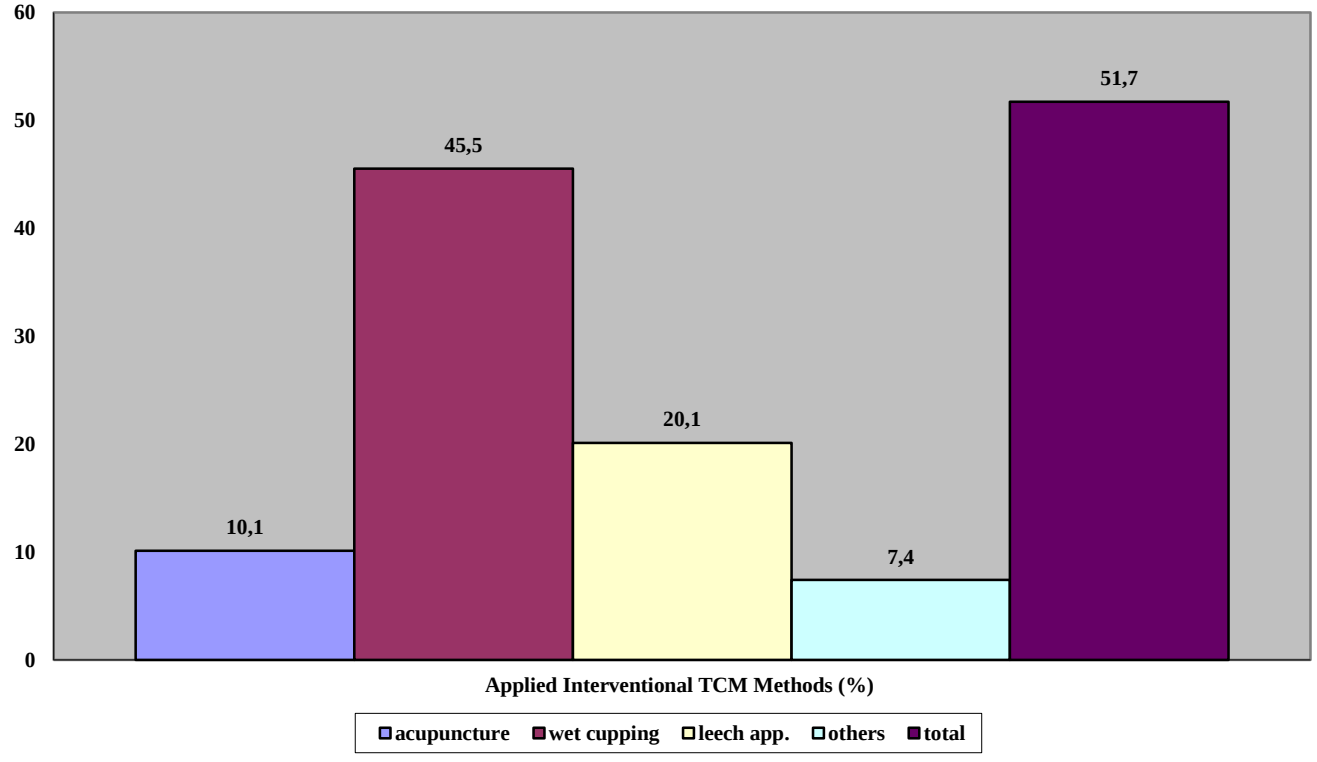

Figure 1. Distribution of interventional TCM methods applied

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The most common reasons for those who do not have the interventional TCM application are given in Table 2. Lack of health problem and not having sufficient knowledge about the subject were reported as the most common reasons.

Table 2. Reasons for not applying interventional TCM methods.

	Number (n)	Percentage (%)
Not having a health problem to require	138	25.4
Not knowing enough about the subject	59	10.9
Not finding it safe, hygienic	24	4.4
Thinking it is not useful or not effective	23	4.2
Negative opinions of people who have previously applied	3	0.6

While 86.2% of the participants (n = 468) had acquaintances who used TCM methods in their close environment; 76.8% (n = 417) of them had positive opinions about the application. 73.7% of the participants (n = 400) thought that TCM methods were effective in the treatment of health problems.

The distribution of interventional TCM methods that participants will prefer when there is a need for implementation is given in Figure 2.

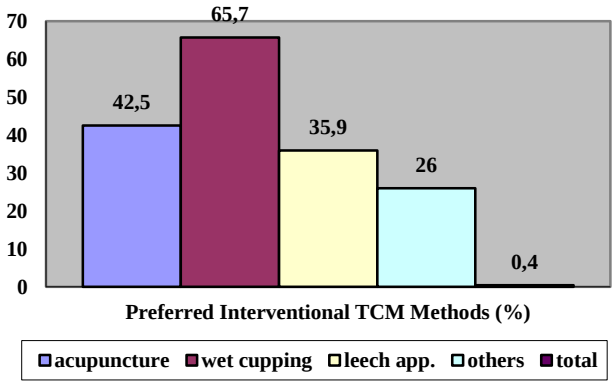

Figure 2. Distribution of interventional TCM methods to be preferred in case of need for implementation

It was found that 56.8% (n = 158) of those who applied interventional traditional medicine methods had the application done in a non-clinical environment, 34.9% (n = 96) in a private clinic, 8.2% (n = 22) in a hospital; It was observed that 39.7% (n = 77) had it done by a physician, 38.8% (n = 97) by a healthcare worker, and 20.7% (n = 44) to other people. 89.7% (n = 251) of the participants who had the interventional TCM application stated that they did not experience complications, 82.2% (n = 232) of them were observed the infection control measures / hygiene rules during the application, 4.1% did not, 13.7% of them stated that they were partially paid attention, 75% (n = 202) of them knew that the practitioner had a certificate. Of those who had the application, 78.9% (n = 210) stated that their complaints decreased after the application, 14.1% (n = 35) had no effect, 7% (n = 25) stated that their complaints completely disappeared and 83,7% of them reported that they might consider getting the same practice done again.

DISCUSSION

In the study aiming to evaluate the attitudes and behaviors of adults against interventional TCM methods, approximately half of the participants had the interventional TCM method applied, the most frequent application of wet cupping, followed by leech application and acupuncture application; It was observed that interventional TCM methods were used more in people aged 41 and over, those who did not have a health-related profession, and as the level of education decreased. About half of those who have these methods done in a non-clinical environment; It was observed that approximately one third of them had it done by physicians and one fifth by non-medical people.

When examined the researches done in Turkey and the world, seems to be on the research of all TCM methods or specific methods. In the literature, there is no study focusing on interventional TCM methods. Using TCM method frequencies in studies in Turkey be differentiated between 30-65% [16-21], this frequency varies between 24-90% in international studies [22-25]. In our study, 51.7% (n = 281) of the participants had interventional TCM methods applied at some stage of their lives. We saw that the people participating in our study preferred wet cupping among the interventional TCM methods, followed by leech application and acupuncture application. When looking at the studies questioning the use of all TCM methods in our country; in a study conducted with family health center applicants, 39.7% of the most common was wet cupping; 17.7% used leech, 16.1% acupuncture, 13.7% phytotherapy; in a study conducted in Kayseri, 37.2% of them used phytotherapy, 19.5% of them used bottle drawing, 6.8% of them used wet cupping [26]; in a study conducted with medical faculty students, 33.3% of them used phytotherapy, 11.5% of them used wet

cupping, 6% of them used acupuncture [27]; in another study conducted in Nevşehir, it was observed that 70.1% of them frequently preferred herbal treatment methods [28]. Phytotherapy is one of the most frequently used methods in international studies, followed by practices such as massage, yoga, and acupuncture [23,24,30]. In studies conducted in our country, all TCM methods were questioned and it was seen that interventional TCM methods were among the most common methods. Therefore, although our study evaluates the frequency of use of a particular group of methods; The fact that interventional TCM methods are among the most commonly used methods among general methods may explain the high frequency of interventional TCM use in our study. In international studies, interventional TCM methods are not among the most frequently used methods, it is thought that this is related to the application conditions, permits and the regulations applied in the countries.

In our study, when the factors related to the use of interventional TCM methods of the participants were examined, it was found that more interventional traditional medicine methods were used in those aged 41 and over and those who did not have a health-related profession; It was observed that the frequency of application of interventional traditional medicine methods decreased with the increasing education level. When the factors affecting the use of TCM methods in the literature are investigated; In a study conducted in Kayseri, those who are over 50 years old, married, and have not completed any school use TCM methods more [26]; In a study conducted in Nevşehir, TCM methods were preferred more frequently in the 70-79 age group and in the illiterate [28]; According to a study conducted in Isparta, it was determined that those who were married and graduated from primary school and below preferred TCM methods more [29]. In international studies, the effect of factors such as gender, educational status and social level on the tendency to TCM methods has been shown [30], and it is stated that the use of TCM increases with the decreasing education level in general. In line with the results of our study, it was emphasized in other studies that the use of TCM increased with increasing age. The relationship between educational status and use of TCM has resulted differently in various studies; Although it is seen in some studies that as the education level increases, the use of TCM decreases in accordance with our study [26,28,29]; In some, contrary to our study, it was stated that TCM methods are used more as the education level increases [23,31-33].

In our study, the reasons for not having the interventional TCM application were evaluated. The most common reasons for not having it done are; They were reported as not having a necessary health condition and not having sufficient information about the subject. Similar to our study, it has been observed in national studies that those who do not prefer TCM applications do not prefer these applications because they do not need it or because they do not believe it is useful [17,18]. In international studies, it is seen that the rate of those who do not use it because they find scientific evidence insufficient is high [34].

In our study, most of our participants (86.2%) had acquaintances in their close environment who used the interventional TCM method; Most of them (73.7%) had positive opinions about the implementation. As the interventional TCM methods to be preferred in a situation where application is required, we saw that wet cupping is the most preferred method, followed by acupuncture and leech applications.

In our study, approximately half of the participants applied interventional TCM methods; However, it was observed that most of them had the application done in a non-clinical environment, the number of people who had this done by a physician was quite low (39.7%) and 75% knew that the person who performed the application had a certificate. As stated in the regulation, it is reported that all TCM methods can only be applied by certified physicians and dentists to apply only in their own field, and the place of application must have a permit issued by the ministry [4]. This result shows that the applicants do not have complete information about the conditions of these applications. Lack of knowledge about the person performing the application and the place, especially in interventional applications with risk of complications and making applications in wrong people and environments are very risky situations in terms of public health. In this respect, inspections should be carried out more frequently and the public should be informed about these frequently used methods by the right people.

In our study on interventional TCM applications with a risk of complications, the number of people who had complications among those who had the application were found to be quite low. In many studies, similar to our study, it was stated that there were few complications. While the complications

faced by our participants were bleeding, skin and soft tissue infection-abscess, palpitations-fainting and other complications; When we look at the literature, we see that the most common side effects and complications with leech application are local skin lesions, bleeding, anemia, allergies, and infection [8], and there are case reports such as lymphangitis after leech application [9]. Complications caused by acupuncture are reported to be associated with not paying attention to sterility at the intervention site or systemic infections during the application [8].

Limitations

The most important limitation of our study is that it is a descriptive study and it was conducted only with people who applied to the outpatient clinic. Due to the fact that the study was conducted during the COVID 19 pandemic, which affected the whole world, the variety of patients according to the age groups of the people who applied to our clinic decreased. For these reasons, the results of the study cannot be generalized to the entire adult population.

Superior aspects

Studies conducted in Turkey and in the world, is on the general TCM methods or specific methods. There is no study focusing on interventional TCM methods. We think that this study, which evaluates the usage frequency, satisfaction, complication status and application conditions of these applications, which always carry the risk of complications, will shed light on the literature.

CONCLUSION

Based on these results; In the sample of our study, it was observed that TCM applications were increasingly preferred by the society, even if they were invasive, the complication rates were low and most of them thought to have the same application again, but the results were not very pleasant when evaluated in terms of the person who performed the application and the place where it was performed. In particular, it is very important that invasive methods, which always have a risk of complications, are performed under clinical conditions and by the physician. Public trainings, public service announcements and information brochures on this subject are of great importance.

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During this study, any pharmaceutical company that has a direct connection with the subject of the research, a company that provides and / or produces medical tools, equipment and materials, or any commercial company, during the evaluation process of the study, financial and / or no moral support was received.

Conflict of Interest

Regarding this study, the authors and / or their family members do not have a scientific and medical committee membership or relationship with their members, consultancy, expertise, working status in any company, shareholding or similar situations that may have a potential conflict of interest.

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ORIGINAL RESEARCH

Physiatrists' Perspective on Traditional and Complementary Medicine

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Abstract
Objective: Traditional and complementary medicine (TCM) is becoming more common worldwide. In this study, we aimed to evaluate the perspectives of physiatrists' in Turkey regarding TCM methods.
Methods: A 24-question survey form was prepared which physiatrists were asked to fill out on a voluntary basis via the internet.
Results: A total of 150 physicians participated in the study 53.3% of which had TCM training. We found that specialist physicians attended TCM courses significantly more than professors or associate professors. The most preferred TCM courses were prolotherapy, ozone, and mesotherapy. 19.3% of the participants stated that they do not recommend TCM methods to their patients. The lack of scientific evidence was the main reason for not recommending it. A positive response to the inclusion of TCM in the PMR residency curriculum was supported by 90% of the participants.
Conclusion: Concerning the use of TCM methods, scientific basis is important to physicians. The efficiency and reliability of TCM methods must be proven with quality studies to be conducted on this subject.
Keywords: Traditional Medicine, Complementary Medicine, Physical Medicine and Rehabilitation, Residency Curriculum

INTRODUCTION

In recent years, traditional and complementary medicine (TCM) methods have become popular among both doctors and patients worldwide. The World Health Organization (WHO) defined traditional medicine as "the sum total of knowledge, skill, and practices based on the theories, beliefs, and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness" . Complementary medicine was defined as "a broad set of health care practices that are not part of that country's own tradition or conventional medicine and are not fully integrated into the dominant health care system" .

For a treatment or a procedure to be used in Western medicine, a serious scientific background is required. Lack of adequate scientific evidence for TCM methods causes many doctors to not take these practices seriously resulting in TCM being performed by non-physicians. The fact that these treatment methods are taught to physicians under the supervision of the Ministry of Health in Turkey is important from two aspects. The first point is to prevent the use of TCM practices by those other than physicians and the second is to seek evidence of TCM effectiveness through scientific studies.

One of the most common uses of TCM practices is for chronic pain treatment. This study aimed to evaluate the perspectives of physiatrists' who are most concerned with chronic pain, on TCM practices.

MATERIALS AND METHODS

Study design

The survey includes three parts. The first part of the questionnaire asked about the socio-demographic characteristics of the participants: gender, age, years of experience as a physiatrits, and participant's title. The second part of the questionnaire asked whether the participant had any TCM training, if the participant received training what training they received, whether they recommended TCM to patients, and where they followed up-to-date information on the subject. We also asked about the participant's most trusted TCM methods and the contribution of these methods to patient satisfaction. If the participant did not receive TCM training and did not recommend it to patients, the reason why was asked. In the third part of the survey, the participant

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was asked if they would like to receive more training and their opinion on including TCM in the PMR resident training program. We also asked about security concerns regarding TCM methods.

Ethical consideration

Approval for the study was obtained from the local ethical committee.

Statistical analysis

Statistical analysis was performed using MedCalc software (version 16.2.1; MedCalc Software, Ostend, Belgium). Descriptive statistics (mean, standard deviation, and frequency) were reported. Categorical data were given as counts (n) and percentages (%). Categorical variables were compared using the Chi-square test. Results were evaluated at a significance level of $p < 0.05$.

RESULTS

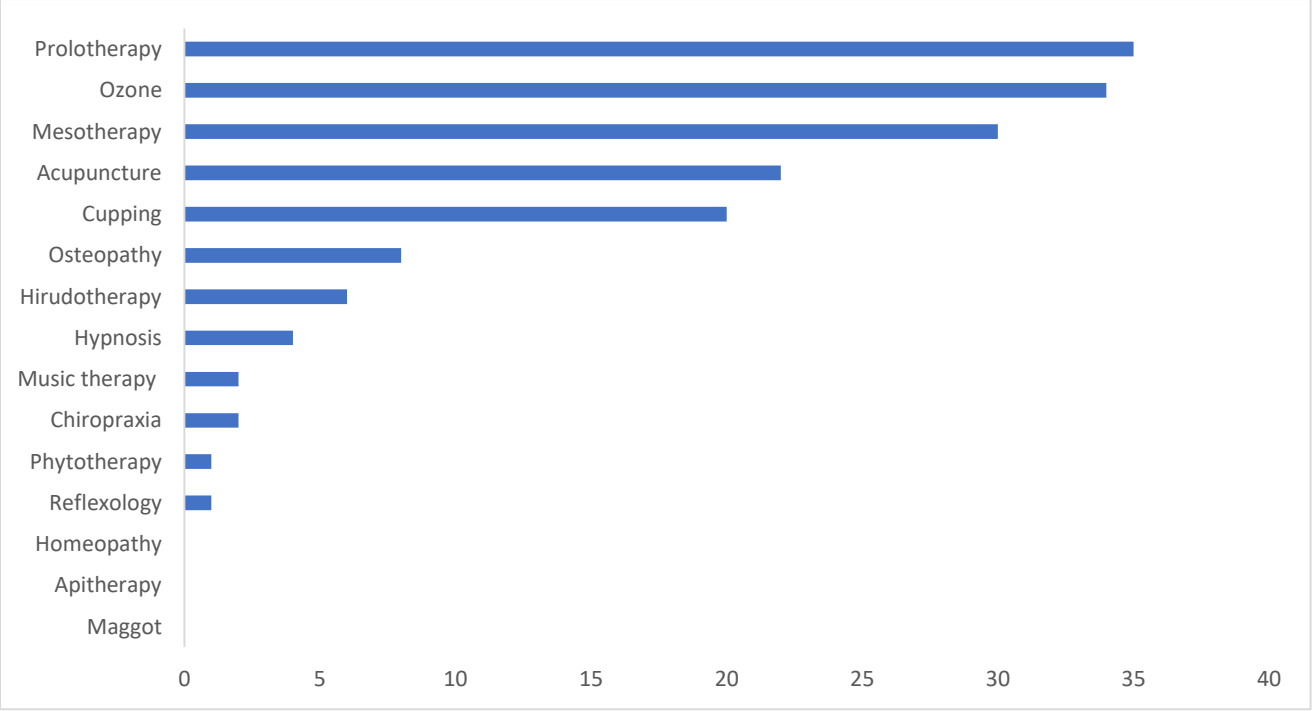
Between November 1-30, 2020, 150 physicians participated in our survey. The demographic data and characteristics of participants are shown in Table 1.

Table 1. The demographic data and characteristics of participants

Gender	Female: 80% Male : 20%
Age	Under 30 :16.7% Between 30-35: 18.7% Between 35-45: 50% Between 45-55: 10% Over 55: 4.7%
Title of participants	Residency: 16% Specialist: 55.3% Assistant professor :5.3% Associate professor:16% Professor: 7.3%

Of the total participants, 53.3% had TCM training and most (78.2%) had taken this training through private courses. It was found that specialist physicians (63.8%) attended these courses significantly more than associate professors (45.8%) and professors (36.6%) ($p = 0.0172$). The five most preferred TCM courses were prolotherapy (46.7%), ozone (45.3%), mesotherapy (40%), acupuncture (29.3%), and cupping (26.7%) (Table 2).

Table 2. Percentage of participants who received traditional and complementary medicine trainings



Of the participants, 25.3% stated that they were not interested in TCM and they had not received information from any source on the subject. Of the participants who were interested in TCM, 54.7% stated that they obtained information from scientific publications and 56.7% from healthcare team members. Of the participants who recommended TCM methods to their patients, 72% defined the contribution of TCM practices to patient satisfaction as effective or very effective.

A total of 37.3% of the physicians recommend TCM methods after physical therapy sessions, 39.3% during physical therapy sessions, and 4% before physical therapy sessions, while 19.3% stated that

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they never recommended TCM methods to their patients. The most common reason for not recommending TCM methods was the lack of sufficient scientific evidence regarding the efficacy and safety of TCM methods (Table 3). No participant who received TCM training thought it ineffective and did not recommend it to their patients.

Table 3. The reasons for not recommending traditional and complementary medicine (TCM) methods

Reasons for not recommending TCM methods to patients	Lack of sufficient scientific evidence on the effectiveness and reliability of TCM methods 78.8 % Lack of knowledge 42.4 % Disbelief in TCM methods 33.3% Finding it risky for health 39.4% concern about substitution of conventional therapy 27.3%

However, 70% of the participants stated that they would like to be able to do TCM applications with more training, 12% did not want it, and 18% were undecided. While only one of the residents (4%) stated that they did not want to be educated in TCM methods, this rate was found to be 54.5% for professors.

When asked whether physiatrists should have TCM practices in the residency training program, 90% of the participants expressed a positive opinion. When asked if TCM practices performed by physicians threaten public health, 91% of the participants expressed a negative opinion, while 14% of the participants stated that TCM practices are a placebo. A total of 39% of respondents agreed with our suggestion that TCM practices are natural, safe, and have very few side effects, while 46% partially agreed, and 15% disagreed. While 19% of the participants stated that they do not intend to perform TCM practices on their patients, 33% stated that they would not like it if patients had TCM practices without asking their physician.

DISCUSSION

The Turkish Ministry of Health published the "Traditional and Complementary Medicine Practices Regulation" in 2014 [1]. According to this regulation, acupuncture, ozone, osteopathy, mesotherapy, prolotherapy, hypnosis, hirudotherapy, reflexology, homeopathy, phytotherapy, chiropractic treatment, maggot therapy, apitherapy, cupping, and music therapy were accepted as TCM practices. After 2014, TCM training for physicians started in centers affiliated with the Ministry of Health. TCM practices are used all over the world. According to the WHO, the frequency of TCM practices for any reason is 80% in Africa, 70% in Canada, 49% in France, and 42% in the USA , In Turkey, the most common reason for using TCM practices is for pain, at a usage frequency of 42%-70% [2]. According to our study, 78% of physiatrists recommend TCM methods to their patients. The most recommended methods are acupuncture, prolotherapy, ozone, mesotherapy, and cupping. It is not surprising that prolotherapy and mesotherapy are among the most recommended methods because these two methods are very similar to the soft tissue injections frequently performed by physiatrists and cupping therapy has similarities to vacuum devices that are used with interferential current. In a study conducted with anesthesiologists, it was reported that the most reliable methods were acupuncture, ozone and hypnosis, respectively [3].

In a study conducted in a physical therapy clinic, ıt was found that 12% of patients tried TCM at least once [4]. In this study, the most preferred methods were found to be cupping, acupuncture, and hirudotherapy. In another study conducted in Turkey, in which 219 patients with degenerative osteoarthritis were included, it was found that 35.6% of the patients sought TCM applications [5]. In a study conducted with 839 patients, in which the traditional and complementary methods used were questioned, balneotherapy and herbal supplements were the most common while cupping, hirudotherapy, and acupuncture were determined as the most preferred TCM methods [6]. In this study, it was determined that 68% of cupping was performed by non-educated people.

Although TCM practices have been used by patients for years, they have only recently become popular among physicians. The biggest advantage of having these practices performed by physicians is that it allows patients to seek treatment at hospitals. Thus, these treatments can be applied by professionals with the method most appropriate for the patient/condition. We found in our study that the main reason TCM applications were not recommended by physicians was due to the lack of scientific evidence on this subject. The fact that more physicians are starting to be involved in this practice and participate in training will result in an increase in quality scientific studies. Of the participants in our

survey, 70% stated that they want to get more training on TCM methods. We found that specialist physicians, who examined the most patients, attended TCM training more than other groups. This may be due to the fact that physicians seek alternatives for drug-dependent patients with chronic pain that do not respond to modern medical methods. Also, 90% of the participants stated that TCM training should be included in the PMR resident training curriculum, which was surprisingly high. In a study, 94.2 % of medical faculty students stated that sufficient training was not given about TCM methods at the medical school [7].

The emergence of PMR expertise in the world was developed on the ideas of "wholeness", "functionality", and "quality of life". Learning the art of medicine implementation should be one of the focal points of residency training. Current medicine and residency training are mainly for isolated pathologies and specific treatment methods. Perhaps the most important point we can teach residents is to "think globally, act locally" [8,9]. In this framework, it would be beneficial to include TCM methods in the residency curriculum.

CONCLUSION

Patients in our country have been using TCM methods for a long time. With the increasing popularity of this method among healthcare professionals, it will pave the way for advances in evidence-based medicine.

Study limitations

A limitation of this study is the small number of participants. There are estimated to be about 3500 PMR residents and specialists in Turkey. A larger survey with more participants would be beneficial. The fact that the survey was related to TCM methods may have negatively affected the participation rate. While TCM methods are highly praised by some physicians despite the lack of scientific evidence, this situation also causes negative reactions in some physicians. In this regard, we think that physiatrists have two important duties: first of all, and perhaps most importantly, they should learn about this subject and ensure that this work is done by trained physicians in hospitals or health institutions, and secondly, quality studies should be conducted on this subject to allow for TCM evaluation in the presence of scientific evidence.

The importance of this work lies in the fact that to our knowledge, this is the first study that investigated the perspective of physiatrists on TCM methods.

Declarations

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Conflict of interest: The authors declare that they have no conflict of interest.

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ORIGINAL RESEARCH

Impact of Music Listening and Information Training Provided Prior to Coronary Angiography on Physiological Parameters and Anxiety

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Abstract:
Objective: Individuals often experience anxiety prior to the coronary angiography procedure (CAG) and this condition affects physiological parameters negatively. The purpose of this study was to determine the impact of music listening and information training provided prior to CAG on anxiety level and physiological parameters.
Materials-Methods: The study was conducted as a randomized controlled intervention study. The sample number was randomized to the intervention 1 (music listening), intervention 2 (information training) and control group (routine care). Each group had 34 individuals. The study assessed the data via the Introductory Characteristics Form, Spielberg's State-Trait Anxiety Inventory, blood pressure, heart rate, respiratory rate and pain level in the SPSS (25.00) program.
Findings: The mean state anxiety scores had the highest decrease in the music listening group ($\bar{X}$=57.59, $\bar{X}$=38.93) and the lowest decrease in the control group ($\bar{X}$=52.57, $\bar{X}$=52.43) compared to before the CAG procedure (p<0.05). Comparing the groups; the lowest anxiety score was in the music listening group ($\bar{X}$=32.7) and then respectively in the information training group ($\bar{X}$=38.93) and the control group ($\bar{X}$=52.43) after the CAG procedure. The physiological parameters created a significant difference (p=0.001) in the music listening and information training group before and after the CAG procedure. However, the parameters created no difference in the control group (p>0.05). There was no difference between the groups in terms of the physiological parameters (P>0.05).
Conclusion: Listening to music and information training provided prior to coronary angiography significantly reduced the blood pressure, heart rate, respiratory rate and anxiety level after the procedure.
Keywords: Coronary Angiography, Training, Music Theraphy, Anxiety, Physiological Parameters

INTRODUCTION

Cardiovascular diseases (CVD) are common and non-contagious diseases involving blood vessels and heart-related diseases[1]. It is the leading cause of death worldwide. 17.9 million people lose their lives each year due to these diseases and this figure constitutes 31% of all deaths[1]. CVDs are also the leading cause of death in our country. The number of deaths due to circulatory system diseases as of 2018 was reported as 161,920. Of this figure, 39,629 were mainly due to Ischemic Heart Disease whereas 26,777 were mainly due to Acute Myocardial Infarction (AMI)[2,3,4]. Coronary artery disease (CAD), on the other hand, is one of the most common encountered CVDs in both men and women in the world and in our country[5,6.] The main cause of Coronary Artery Disease is the decreased coronary arterial blood flow due to atherosclerosis in the coronary arteries[6]. The incidence of CAD is gradually increasing and a delay in the diagnosis causes many problems for the individual such as feeling different from others, anxiety, depression, recurrent stress, fear of surgical intervention and death, work-related problems as well as financial and family-related problems[7]. This is an indication that CAD affects individuals in many ways and its diagnosis is crucial.

Coronary angiography (CAG) is one of the most commonly used methods in diagnosing the disease. CAG procedure also has some complications, as with any invasive procedure. The patient may also suffer accompanying mental problems such as anxiety, depression and stress in addition to physiological complications such as myocardial infarction, stroke, injury to the artery where the

catheter is located, arrhythmia, allergy to opaque material, kidney damage, excessive bleeding and infection[8,9]. Anxiety, one of the most common problems encountered before and during coronary angiography, may cause an increase in blood pressure and heart rate and subsequently increase the risk of complications during the procedure[10]. Research have revealed that high anxiety level before CAG and waiting time further increase pre-procedural anxiety[11,12].

Individuals who will undergo CAG procedure may encounter psychological symptoms such as anxiety, irritability, difficulty in concentration as well as physical effects such as dry mouth, difficulty in swallowing, tenderness in the epigastric region, tachypnea, tachycardia, pain or discomfort on the heart [16]. Anxiety is also known to increase the risk of myocardial infarction[14,15]. Changes in physiological parameters may further cause complications such as rhythm changes during CAG procedure. It may cause respiratory distress in the patient before the procedure and delay the initiation of the CAG procedure and prolong the withdrawal of the femoral catheter after the procedure due to bleeding[16].

Physiological problems that may be experienced by the patients after the procedure, in addition to the possible problems that are likely to be encountered before the CAG procedure, include arrhythmia, retroperitoneal bleeding, hematoma, thrombus, stroke, excessive bleeding, kidney problems, pseudo aneurysm and vascular occlusion. It is therefore recommended to monitor and manage the patient's vital signs such as blood pressure, heart rate, pain level and respiratory rate before and after the CAG procedure in order to detect all these possible complications in advance[16].

Literature review revealed that listening to music, reflexology[17], massage[18] and informative trainings[19] are among the methods applied to reduce the anxiety experienced by individuals. Studies revealed that the visual and auditory trainings to be provided in advance about the intervention to be applied reduces the psychological and physiological problems that may be experienced after the procedure[20,21,22]. These results indicate that the nurses, responsible for preparing individuals for CAG intervention, should not only be limited to this technical step alone but also provide education about the procedure and its results in order to reduce patient's level of anxiety. Nurses are recommended to inform patients and their relatives about the procedure and support them in reducing their fear and anxiety[20]. A study evaluating nurses' ability to understand patients' fears associated with CAG states that nurses should be more careful when assessing patients' fears before CAG intervention and consider the fear-inducing situations[23]. Another study emphasizes that the anxiety levels of individuals who will undergo CAG intervention should be evaluated by nurses with reliable and valid scales, and care protocols should be established to reduce the anxiety levels of individuals[24].

In line with all this information, it is obvious that CAG intervention is likely to trigger psychological and physiological effects on individuals. Individuals, therefore, are likely to experience anxiety before the procedure and to encounter physiological changes in blood pressure, heart rate, respiratory rate and pain level both due to this anxiety and the effect of the procedure. For this reason, non-pharmacological methods such as providing informative training, massage, music listening, reflexology techniques and relaxation exercises are used to reduce the anxiety that may be experienced before the CAG intervention. Music therapy is an effective method on many conditions such as blood pressure, heart rate, oxygen saturation, pain and anxiety levels of patients. Literature review revealed that music therapy is the most frequently preferred method due to relatively shorter period of application, being applicable in accordance with patient preferences and ease of application by nurses to reduce pain and anxiety. Informative trainings, on the other hand, have been determined to provide improvement in physiological parameters[25,26-28]. Based on this information, it is essential to scientifically determine the effects of music therapy and informative training on anxiety and physiological parameters of individuals who will undergo CAG procedure. Furthermore, this study is anticipated to contribute to evidence-based practices on music therapy.

MATERIAL AND METHODS

Study design

This is a randomized controlled intervention study. This study was registered in the archive of the Databases of the National Thesis Center of the Council of Higher Education (No. 578947).

Setting and sample

The study was conducted in a 320-bed, urban, non-profit training and research hospital. More than 3200 cardiac catheterization procedures are performed annually in the CAG laboratory. Two separate 20-bed units working together to implement the procedure and provide post-procedure care are also included in the study.

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Inclusion criteria are 1) electively participating in the femoral CAG procedure, (2) participating in CAG for the first time, (3) performing CAG for diagnostic purposes, (4) not having received training on CAG application, (5) participating in the study voluntarily, no problems in verbal communication, (6) not having hearing loss, (7) being literate, (8) not have been previously diagnosed with a psychiatric illness, (9) being conscious and being 18 years of age or older. Termination criteria are declaring a desire to leave the study, beginning the CAG procedure for diagnostic purposes, however having been decided for a stent and/or balloon intervention during the procedure, being admitted to the intensive care unit, unlike routine follow-up, due to an unexpected complication (arrhythmia, MI, bleeding etc.) during the CAG intervention. Sample size was determined as 28 for each group at the end of the "power analysis" for an 80% power and α=0.05 significance level. 20% more participants were included in the study considering possible losses in the implementation phase. A total of 102 individuals were divided into intervention group 1 (I1), intervention group 2 (I2) and control group (C), with 34 individuals in each group, following a randomization conducted with a computer program[29] (Figure 1). Numbers between 1 and 102 were assigned to the participants in the randomization list. Individuals undergoing elective CAG were assigned to the groups in the randomization list according to their order of submission.

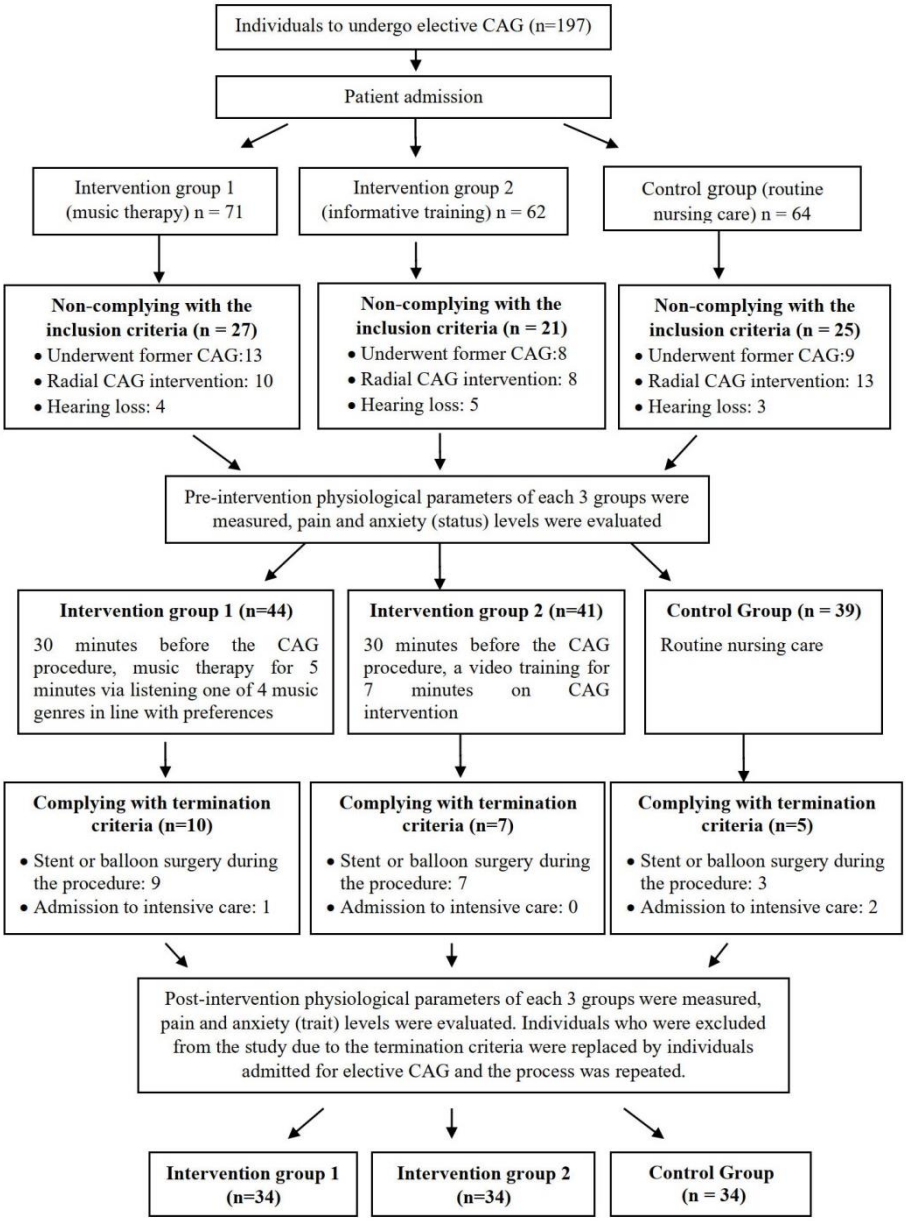

Figure 1. Assignment of Groups and Sampling Diagram

Measures

Introductory Characteristics: It consisted of questions about sociodemographic characteristics, habits, presence and type of chronic diseases and CAG procedure determined by the researchers at the end of the literature review[20, 26, 30].

Physiological Parameters: Blood pressure, heart rate, respiratory rate and pain level were evaluated.

Pain: Pain level was evaluated with visual analog scale (VAS). It is referred to a horizontal straight line with endpoints defined as "I have no pain" and "as bad pain as possible". The patient was then asked to indicate the level of pain by marking on the line between the two endpoints. This tool was first used by Freyd in 1923[31]. Kersten et al.[32] have proven VAS as a valid tool for assessing the level of pain. Ünsal and Ergül[33], in their research, determined that VAS has been used in studies conducted in Turkey.

Anxiety: Anxiety level was evaluated with State-Trait Anxiety Inventory/STAI. Scale was developed by Spielberger et al.[34]. It was adapted into Turkish by Öner and Le Compte[35]. It consists of two sections as State and Trait Anxiety. State Anxiety Inventory evaluates how individuals feel at the moment while Trait Anxiety Inventory measures how the person feels throughout a certain process, regardless of the situation and circumstances. Total score that can be obtained from the scale varies between 20 and 80, where a high score indicates a high level of anxiety[35]. Cronbach alpha value in the study was found to be 0.85 for Stait Anxiety Inventory and 0.80 for Trait Anxiety Inventory.

Procedure

State Anxiety Inventory was applied to the participants the day before the CAG procedure, following their outpatient controls. Introductory Characteristics Form and Trait Anxiety Inventory was applied to the individuals 30-45 minutes before the CAG procedure and their physiological parameters were evaluated. Physiological parameters and anxiety levels were re-evaluated with Trait Anxiety Inventory 15 minutes after the CAG procedure.

Interventions

Intervention group 1: 30 minutes before the CAG procedure, participants were allowed to listen one of 4 music genres (Turkish Folk, Classical, Turkish Classical Music and Sufi Music) determined with expert opinion, in accordance with their preferences via headphones for 5 minutes. Each type of music is instrumental, non-verbal, at 70 decibels, with the same characteristics in terms of rhythm and duration.

Intervention group 2: After the outpatient controls and before AG procedure, the participants were provided visual, auditory and written informative training about CAG for 30 minutes[36-38]. The training prepared in line with literature review and taking expert opinion beforehand included watching a 7-minute video, followed by a question-and-answer discussion and the delivery of a written training booklet.

Control group: The participants in this group were provided routine nursing care and did not receive any intervention. Routine nursing care services performed in the clinic involved preparation for the CAG procedure, which includes vascular access and dressing up with surgical gown, measuring blood pressure, heart rate and oxygen saturation once before and after the procedure and/or more frequently when there are deviations from the normal, and providing answers if the patient asks questions about the procedure.

Statistical analysis

The data were analyzed with the SPSS (25.00) software, and the significance level was considered as $p<0.05$. In addition to descriptive statistical methods (frequency, percentage and mean etc.), Independent Samples t-test was used for intergroup comparisons of parameters with normal distribution and related samples t-test was used for in-group comparisons. Kruskall Wallis was used to detect the significant difference between the variables with more than three sub-categories in the intergroup comparison of parameters without normal distribution, Mann Whitney U was used to determine the group that caused the difference whereas Wilcoxon signed-rank test (for the same group data) was used for in-group comparisons of parameters that did not show normal distribution. The effect sizes of the findings were calculated. Effect sizes were defined as "small, d = 0.1", " medium, d = 0.3", and "large, d = 0.5"[39].

Hypothesis

H_{1-1}: The music played to the patient before coronary angiography has an effect on the patient's anxiety level.

H_{1-2}: The music played to the patient before coronary angiography has an effect on the patient's physiological parameters.

H_{1-3}: The informative training provided to the patient before coronary angiography has an effect on the patient's anxiety level.

H_{1-4}: The informative training provided to the patient before coronary angiography has an effect on the patient's physiological parameters.

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Ethical aspect of research

The study was conducted in accordance with the Declaration of Helsinki and was approved by the institutional ethics committee (ID: 2017/174). Written permission was obtained from the institution where the study was conducted, and informed written consents were duly obtained from the participants.

Limitations of research

The fact that the study was conducted in a single center with patients who firstly in their lives had CAG and with only femoral interventions, independent of the researcher, constituted the limitations of the study.

RESULTS

For the purpose of this research conducted to determine the effects of the music therapy and the informative training provided to individuals before the coronary angiography procedure on their anxiety level and physiological parameters, it was determined that there was no statistically significant difference in the distribution of the introductory characteristics of all three groups included in the study and that the groups were homogeneously distributed. There was no significant difference between the trait anxiety mean scores of the groups (p>0.05) (Table 1).

Table 1. Comparison of trait anxiety scores before coronary angiography intervention (n=102)

Groups	Mean Ranks	DoF	x^2	***p***	Significant Difference
I1 (n=34)	43.83	2	4.41	0.011	None
I2 (n=34)	58.76				
C (n=34)	50.19				

p<0.05, Kruscal Wallis testi

Examining the intergroup state anxiety scores before and after the intervention; no significant difference was determined between the groups before the intervention (p>0.05). After the intervention, however, a significant difference was determined between the groups in terms of their mean scores of state anxiety (p<0.05). It was further determined that mean scores of state anxiety of the intervention 1 and intervention 2 groups exhibited different results both among themselves and with respect to the control group. From which group the differences originated was also examined. Considering the mean rank, the mean anxiety score of the control group ($\bar{X}$ =52.43) was found out to be higher than that of the intervention 1 and intervention 2 groups. When evaluating the mean rank of both intervention groups, among themselves, it was determined that mean post-intervention anxiety score of the intervention 1 group ($\bar{X}$ =32.70), was significantly lower than intervention 2 ($\bar{X}$ =38.93) (Table 2).

Table 2. Inter groups comparison of pre- and post-coronary angiography intervention state anxiety scores (n=102)

Pre-CAG State anxiety score						Post-CAG State anxiety score					
Groups	Mean Rank	DoF	x^2	p	Signif. Diffe.	Groups	Mean Ranks	DoF	x^2	p	Significant Difference
I1 (n=34)	42.59	2	4.564	0.102	None	I1 (n=34)	32.70	2	0.298	0.028	1-2, 1-3
I2 (n=34)	57.59					I2 (n=34)	38.93				2-1, 2-3
C (n=34)	52.57					C (n=34)	52.43				3-1, 3-2
p<0.05, Kruscal Wallis test						*p<0.05, Kruscal Wallis test, Mann Whitney U test post hoc*					

1: Intervention Group, 2: Intervention Group 2, 3: Control Group

$H_{1\text{-}1}$ and $H_{1\text{-}3}$ hypotheses were accepted based on these findings; it was concluded that providing music therapy to the patient before the CAG intervention was more effective in reducing the level of anxiety with respect to providing informative training. The study revealed that post-test anxiety scores of Intervention 1, which received music therapy, and Intervention 2, which received informative training, were significantly lower than their pre-test anxiety scores (p=0.001). On the other hand, there was no significant difference between the pre-test and post-test anxiety scores of the control group (p>0.05) (Table 3).

Table 3. In-Group Comparison of Pre-Test Post-Test anxiety scores (n=102)

Groups	Pre-Test Post-Test	n	Mean Ranks	Rank Sum	Z	p
I1	Negative rank	34	16.85	522.5		0.001
	Positive rank	0	0	0		
	Equal	0			-4.839	
I2	Negative rank	34	17.5	595		0.001
	Positive rank	0	0	0		
	Equal	0			-5.099	
C	Negative rank	34	18.34	587		0.102
	Positive rank	0	0	0		
	Equal	0			-4.954	

p<0.05, Wilcoxon Signed-rank test

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Post-test blood pressure, heart rate and respiratory rate scores of Intervention 1, which received music therapy, and Intervention 2, which received informative training before CAG, were significantly lower than their pre-test scores (p=0.001). There was no significant difference between the pre-test and post-test blood pressure, heart rate and respiratory rate scores of the control group, who received routine care and follow-up before CAG (p>0.05). Post-test and pre-test scores in the control group were similar (Table 4). H1-2 and H1-4 hypotheses were accepted based on these findings.

Table 4. In-Group Comparison of Pre-Test Post-Test Physiologic Parameters (n=102)

Groups	Physiologic Parameters	Pre-Test Post-Test	n	Mean Ranks	Rank Sum	Z	*p*
I1	Blood Pressure	Negative rank	34	16.75	402	-3.507	0.001
		Positive rank	0				
		Equal	0				
	Heart Rate	Negative rank	34	16.52	347	-3.319	0.001
		Positive rank	0				
		Equal	0				
	Respiratory Rate	Negative rank	34	11.75	395	-1.296	0.001
		Positive rank	0				
		Equal	0				
I2	Blood Pressure	Negative rank	34	14.71	250	-3.507	0.001
		Positive rank	0				
		Equal	0				
	Heart Rate	Negative rank	34	14.89	208.5	-3.319	0.001
		Positive rank	0				
		Equal	0				
	Respiratory Rate	Negative rank	34	4.5	36	-1.296	0.001
		Positive rank	0				
		Equal	0				
C	Blood Pressure	Negative rank	34	15.33	233	-1.936	0.053
		Positive rank	0				
		Equal	0				
	Heart Rate	Negative rank	0	0	0	-2.377	0.067
		Positive rank	34	16.83	305		
		Equal	0				
	Respiratory Rate	Negative rank	0	0	0	-2.42	0.006
		Positive rank	34	4.93	34.5		
		Equal	0				

p<0.05, Wilcoxon Signed-rank test

There was no significant difference between the groups in terms of blood pressure, heart rate and respiratory rate before coronary angiography (p>0.05). A decrease was observed after coronary angiography in terms of blood pressure, heart rate and respiratory rate, however this difference was not considered as significant (p>0.05) (Table 5).

The pain level of the patients was also planned to be evaluated in the study, however this parameter could not be evaluated statistically as the participants who underwent elective CAG reported that they did not experience any pain neither before nor after the procedure.

Table 5. Inter-Groups Comparison of Pre- and Post-Coronary Angiography Intervention Physiologic Parameters (n=102)

Pre CAG							Post CAG						
Physiologic Parameters	Groups	Mean Ranks	DoF	x^2	*p*	Signif Differ	Physiologic Parameters	Groups	Mean Ranks	DoF	x^2	*p*	Signif Differ
Blood Pressure	I1 (n=34)	60.06	2	5.643	0.060	Yok	Blood Pressure	I1 (n=34)	56.39	2	5.971	0.052	Yok
	I2 (n=34)	43.41						I2 (n=34)	41.19				
	C (n=34)	49.79						C (n=34))	55.57				
Heart Rate	I1 (n=34)	53.33	2	1.375	0.503	Yok	Heart Rate	I1 (n=34)	51.39	2	0.411	0.814	Yok
	I2 (n=34)	53.33						I2 (n=34)	53.06				
	C (n=34)	46.21						C (n=34)	48.56				
Respiratory Rate	I1 (n=34)	48.38	2	0.509	0.775	Yok	Respiratory Rate	I1 (n=34)	49.59	2	0.604	0.739	Yok
	I2 (n=34)	51.71						I2 (n=34)	49.62				
	C (n=34)	52.84						C (n=34)	53.75				

p<0.05, Kruscal Wallis Testi, Sd: Degree of Freedom, I1: Intervention Group 1, I2: Intervention Group 2, C: Control Group

When examining the effect size in terms of post-test scores of the state anxiety scale; it was determined that the effect size was the highest between the Intervention 1 group and the control group (0.60),

and secondly between the Intervention 2 group and the control group with a close value (0.58). The lowest effect size (0.32) was found among the intervention groups (Table 6). These results indicated that while music therapy was more effective in reducing the state anxiety score, informative training was also effective.

Table 6. The Effect Size Calculated for Post-test State Anxiety Scale Scores

Groups compared	Calculated effect sizes	Comment
Intervention 1- Intervention 2	0.32	Moderate effect
Intervention 1- Control	0.60	High effect
Intervention 2- Control	0.58	High effect

DISCUSSION

Within the scope of the study, patients were either provided music therapy, informative training or routine nursing care without any intervention before coronary angiography. Anxiety levels, blood pressure, heart rate and respiratory rate of the participants, who were randomly divided into three groups, were evaluated. There was no statistically significant difference between the three groups in terms of introductory characteristics and mean trait anxiety scores, which determine how the individual feels regardless of the situation and circumstances. Therefore, the groups were homogeneously distributed. With this result, which is an assumption that should be provided for the intervention study, the effect of different interventions was determined more clearly for groups with the same baseline level. Thus, except for the interventions, the features that could affect the dependent variables of the study were similar in all three groups. The results of the study indicated that both music therapy and informative trainings provided before coronary angiography were effective on the level of anxiety and physiological parameters.

While the state anxiety scores were similar between the groups before coronary angiography intervention (p>0.05), they were different after the intervention (p<0.05). Although this difference is valid for both intervention groups; state anxiety score was significantly lower in the I1 group ($\bar{X}$ =32.70), who were provided music therapy, compared to that of I2 group ($\bar{X}$ =38.93) who were provided informative trainings. On the other hand, no significant difference was observed in the control group (p>0.05) (Table 2). The findings of the research indicated that post-test anxiety scores of Intervention 1, which received music therapy, and Intervention 2, which received informative training, were significantly lower than their pre-test anxiety scores (p=0.001). On the other hand, there was no significant difference between the pre-test and post-test anxiety scores of the control group (p>0.05) (Table 3).

Literature review indicated that; the results of other studies evaluating the anxiety levels of the participants who were provided music therapy for different durations before CAG intervention, similar to the results of the study, revealed a decrease in post-intervention anxiety scores[15,35,36-38,40,41]. Unlike the results derived at the end of this study, a research conducted by Çürük et al.[43] revealed decreasing anxiety scores with respect to pre-test scores. However, this decrease was not considered to be statistically significant (p>0.05). In another study where music therapy was not limited to the pre-intervention stage but was also provided during and after the intervention, post intervention anxiety scores decreased significantly compared to the control group[41]. A study whose sample consisted of women suffering high anxiety levels before the CAG intervention, the participants were provided music therapy only during the procedure and the anxiety level was found to be lower in the intervention group[15]. A review study discussed the effect and significance of music therapy on the anxiety and stress levels experienced by individuals undergoing CAG[25].

Considering patients who will undergo coronary angiography; state anxiety scores of the patients who did not have a previous CAG was found to be significantly higher than the patients who formerly underwent a CAG intervention and state anxiety scores of the patients who received inpatient treatment and care was found to be significantly higher compared to the outpatient angiography patients. Anxiety scores of the patients who had the opportunity to get information about the procedure from their doctor and nurse were significantly lower than those who did not; it was further determined that the majority of the patients were willing to get information about CAG[43]. In another study, patients were asked to express their levels of anxiety and the control group were observed to have experienced the highest anxiety. The reasons underlying this anxiety were found to be feeling pain and suffering

and fear of harm to the heart and body[30].

This study, which aims to reduce the level of anxiety that is frequently observed in individuals who will undergo CAG, revealed that the anxiety score of the group provided informative training was significantly lower than the control group. Similar to these findings, it was determined that the informative training provided before the CAG intervention significantly decreased mean anxiety scores[19,20,30,44]. In a similar study, patients were asked to watch a 12-minute educational video before the KAG initiative; a significant decrease in the anxiety scores of the intervention group has been observed when anxiety and stress levels are evaluated immediately after and one week after KAG initiative[18]. As an informative training is provided to the patients within the scope of our study and individuals had the opportunity to find answers to their questions on KAG, the decrease in their anxiety levels is thought to be more effective.

Post-test blood pressure, heart rate and respiratory rate scores of Intervention 1, who received music therapy, and Intervention 2, who received informative training before CAG, were significantly lower than their pre-test scores (p=0.001). There was no significant difference between the pre-test and post-test blood pressure, heart rate and respiratory rate scores of the control group (p>0.05). (Table 4). There was no significant difference between the groups in terms of blood pressure, heart rate and respiratory rate before and after coronary angiography intervention (p>0.05) (Table 5). Considering another research study where patients who will undergo a CAG intervention are provided music therapy by listening sounds from nature and thereupon their physiological parameters are evaluated, significant reduction in the blood pressure of patients has been determined[45]. Yen et al[46], in their study, evaluated heart rates of the patients who will undergo a CAG intervention and who were provided music therapy via listening relaxing music in advance and concluded that the heart rate of the group receiving music therapy was lower. Forooghy et al.[47] provided their participants music therapy during the KAG intervention; they concluded that the heart rate, blood pressure and respiration of the intervention group decreased significantly with respect to the levels before the intervention. Çürük et al.[42], on the other hand, concluded that post intervention heart rate, blood pressure and respiration rate of the intervention group receiving music therapy decreased however such a decrease was not statistically significant. Studies, where physiological parameters of the patients were evaluated after they were provided informative training on CAG intervention, revealed a significant decrease in the heart rates, blood pressure and respiration rates of the intervention group compared to the control group, similar to the findings of this study[20,48,49]. Another study where participants watched informative videos, post intervention physiological parameters of the patients decreased however such a decrease was not statistically significant [50].

Conclusions and Recommendations

It was determined that the music therapy and informative training provided to patients prior to coronary angiography intervention caused significant subsequent decrease in post intervention blood pressure, heart rate, respiratory rates and anxiety levels of the participants. In line with these results, it may be suggested that patients who will undergo CAG intervention may be provided music therapy and informative training before the process. It is possible to provide music therapy both before and during the CAG intervention. Furthermore, different types of music in different decibels and different rhythms may also be preferred. This study was carried out on the individuals who will undergo femoral CAG intervention. Further research studies may address individuals who will undergo radial CAG, as radial CAG intervention has recently been a preferred method for the patients with indications. In addition, the anxiety levels and physiological parameters of the individuals who will undergo femoral and radial CAG may be compared. Randomized controlled studies may be repeated in different sampling groups to increase the level of evidence of the study.

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ORIGINAL RESEARCH

The Effects of Ginger Kidney Compress on Severity of Pain and Physical Functions of Individuals with Knee Osteoarthritis: A Randomized Controlled Trial

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Abstract:
Objective: This study was conducted in order to determine the effect of ginger kidney compress applied to the waist region for 30 minutes for seven days on the severity of pain and physical functions of individuals with knee osteoarthritis.
Material-Method: This is a randomized controlled trial study. The sample included 124 patients; 43 ginger kidney compresses, 41 hot compresses, and 40 control groups. The data were collected using Patient Information Form, Visual Analog Scale (VAS)–Pain, and WOMAC Osteoarthritis Index. The forms were administered at the beginning (first follow-up) and at the end (7th day, second follow-up) of intervention. The intervention-I group received a ginger kidney compress while intervention-II group received a hot compress and the control group received no intervention.
Results: In the first follow-up, there was no difference between the scores of the groups included in the study ($p > 0.05$), which were obtained from the VAS-Pain and WOMAC Osteoarthritis Index. In the second follow-up, a significant difference between the scores of the groups obtained from the VAS-Pain and WOMAC Osteoarthritis Indexes ($p<0.001$) was detected. According to the initial follow-ups, the scores of the individuals in the ginger kidney compress group at the final follow-up decreased significantly from the VAS-Pain and WOMAC Osteoarthritis Index compared to the individuals in the hot compress and the control group ($p<0.001$).
Conclusion: It has been determined that the application of ginger kidney compress is more effective than hot compress application and that it decreases the VAS-Pain and WOMAC Osteoarthritis Index scores.
Keywords: Knee Osteoarthritis, Pain, Physical Function, Ginger Kidney Compress, Nursing.

INTRODUCTION

Osteoarthritis (OA) is one of the most common rheumatic diseases in the world and Turkey. It is a degenerative joint disease that primarily affects the elderly population and has a high rate of morbidity and mortality. The knee joint is the most affected area by osteoarthritis (OA), which leads to impaired quality of life and economic loss as a result of the loss of function due to the disease [1-3]. Studies have shown that the prevalence of knee OA varies between 12.1% and 43.7% [4-7]. In Turkey, a study on individuals aged 50 and older with knee OA has determined the prevalence of symptomatic knee OA to be 14.8%, reporting it as 22.5% in women, and men as 8% [8]. The Turkey Health Research study conducted by the Turkey Statistical Institute (TSI) in 2019 on the other hand has expressed that OA is seen in 11.2% of the general population [9].

While the most common symptoms in individuals with osteoarthritis are the pain of different severity levels, stiffness in the morning, reduced mobility, tenderness in the affected joint, and atrophy and crepitation in muscles, the most common symptom in the world and the one that causes the most distress is the pain [10,11]. Pain caused by knee OA results in individuals not being able to perform physical functions such as walking on an even ground, going up or down the stairs, getting in or off the car, and standing up, preventing them from participating in daily life and social activities, and causing both physical and psychosocial inabilities. Therefore, pain is presented as the most important symptom that needs to be prioritized in the treatment of individuals with knee OA [10,12].

The aims of the treatment of knee OA are reducing pain, increasing joint mobilization and the functional capacity of the knee, preventing contractures, preserving and improving muscle strength, preventing injuries, treating concomitant diseases, preventing treatment complications, and improving the quality of life and reducing

dependency by educating the patient and his/her family [13-15]. Since only one treatment method is not sufficient in the treatment of knee OA, important clinical guidelines for treatment management generally recommend the use of non-pharmacological and pharmacological treatment methods together, therefore integrative methods [16-19].

Ginger, which is one of the methods used in the complementary treatment of osteoarthritis, has been an important ingredient in traditional Asian, Indian, and Arab treatments since ancient times and in many areas of traditional Chinese Medicine since the fourth century BC [20,21]. Ginger is reported to have been used internally and externally, usually as part of compresses, patches, or plasters, particularly for illnesses and complaints such as abdominal pain, headache, toothache, nausea, vomiting, diarrhoea, cholera, heart diseases, asthma, baldness, snake bites, rheumatic complaints, and seasonal colds, as well as to regulate bleeding [22-27].

One of the methods included in complementary and integrative nursing practices for pain management in osteoarthritis is ginger kidney compress application [26]. Ginger kidney compress application, which is based on the principle of putting ginger powder compresses on individuals' waist region in order to warm up the body, relieve pain, relieve physical and mental tension and fatigue, and to provide relief [26-28]. Studies conducted also indicate that ginger kidney compress application, as part of the management of pain caused by OA, creates heat, stimulation, anti-inflammatory and analgesic effects, and that with this application, gradual relaxation in pain, more comfortable and flexible joint mobility occurs, the patients' quality of life. As a result relaxation and stagnation in thoughts increase, and psychological disorders decrease [26,29-31]. While there is a limited number of studies on the use of ginger kidney compress in reducing the pain of individuals with OA abroad [26,29-31], there are no studies demonstrating the effects of ginger kidney compress in reducing the pain of individuals with OA in Turkey. In this study, which was planned on the basis of this fact, was aimed to determine the effect of ginger kidney compress application on the pain severity and physical functions of individuals with knee OA when applied to the waist for 7 days, 30 minutes (min) per day.

MATERIALS AND METHODS

Study design

This study is a randomized controlled study conducted to determine the effect of ginger kidney compress application on pain severity and physical functions of individuals with knee OA when applied to the waist region for 7 days, 30 minutes per day. It was registered at the archive of the Databases of the National Thesis Center of the Council of Higher Education (No: 390830).

Participants and setting

The population of the research consists of all the individuals who have been diagnosed with OA and subsequently been admitted to the Physical Therapy and Rehabilitation Center after seeking medical care at the Physical Therapy and Rehabilitation Clinic at the State Hospital of a city in Turkey. The collection of data was carried out between 11.03.-11.08.2013 with patients who met the inclusion criteria and was based on the Consolidated Standards of Reporting Trials (CONSORT) guideline.

Inclusion criteria: The scope of the study consists of individuals (a) aged 38 years and older, (b) who have been diagnosed with knee OA by a physician according to the American College of Rheumatology (ACR) criteria, (c) who have had knee pain for at least 6 months, (d) who have received at least 3 points or more from the Visual Analogue Scale (VAS), (e) are not using pain relieving drugs during treatment, (f) have no communication problems, (g) who have the cognitive abilities to be able to answer questions and (h) who have agreed to participate in the research.

Exclusion criteria: Considering that it may affect the results of the research, (a) patients who are pregnant, (b) have a large scar tissue in the lumbar region, (c) have any peripheral vascular disease, (d) a cardiac pacemaker, (e) have a predisposition to bleeding, (f) a history of malignancy, (g) appendicitis or pneumonia, (h) have a heat sensitivity or allergy, (ı) who have undergone physical therapy in the last 6 months, (j) who suffer from an inflammatory joint disease (Rheumatoid arthritis, Ankylosing spondylitis etc.), (k) who have undergone an operation on the abdominal region, and (l) whose VKI ≥ are over 30, were not included in the study.

Termination criteria: (a) Patients whose physical therapy program was changed, (b) who did not wish to continue applying compresses at any stage of the study, (c) who could not adapt to the treatment hours, (d) who could not be reached by phone during follow-ups, (e) who decided to continue treatment outside the city, and (f) who for various reasons, wanted be discharged early, were removed from the study.

Sample size and randomization

Since there is no study in the literature that fully corresponds to our study, there was no sample

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calculation. In the study, biostatistics consultation was obtained and the sample size was planned to be at least 30 people in order to perform parametric tests in each group. Individuals, who were admitted to the Physical Therapy and Rehabilitation Center after being diagnosed with OA according to ACR criteria by the Physical Therapy and Rehabilitation Specialist, were assigned to study groups according to the chart prepared independently from the researcher, by a University's biostatistics unit using the Minitab 16.0 statistical package program, with a randomization method. Considering that there may be separations from the research group during the application process, a total of 135 people were included in the sample, consisting of 45 people in the ginger kidney compress group, 45 in the hot compress group, and 45 in the control group. The study was completed, as a result of two individuals being discharged early, with 43 individuals in the ginger kidney compress group, since one individual had difficulty lying on her back, one individual wanted to quit treatment at their own discretion, and two individuals could not comply with treatment, with 41 individuals in the group where hot compress was applied, and as a result of the fact that 4 individuals could not reached by phone, and that one person left the study voluntarily, with 40 individuals in the control group. At the end of the study, in the intervention, placebo and control groups, in all of the VAS Pain Scale and WOMAC scales, the first type error margin being 0.05, and the power was determined to be 100% (Figure 1).

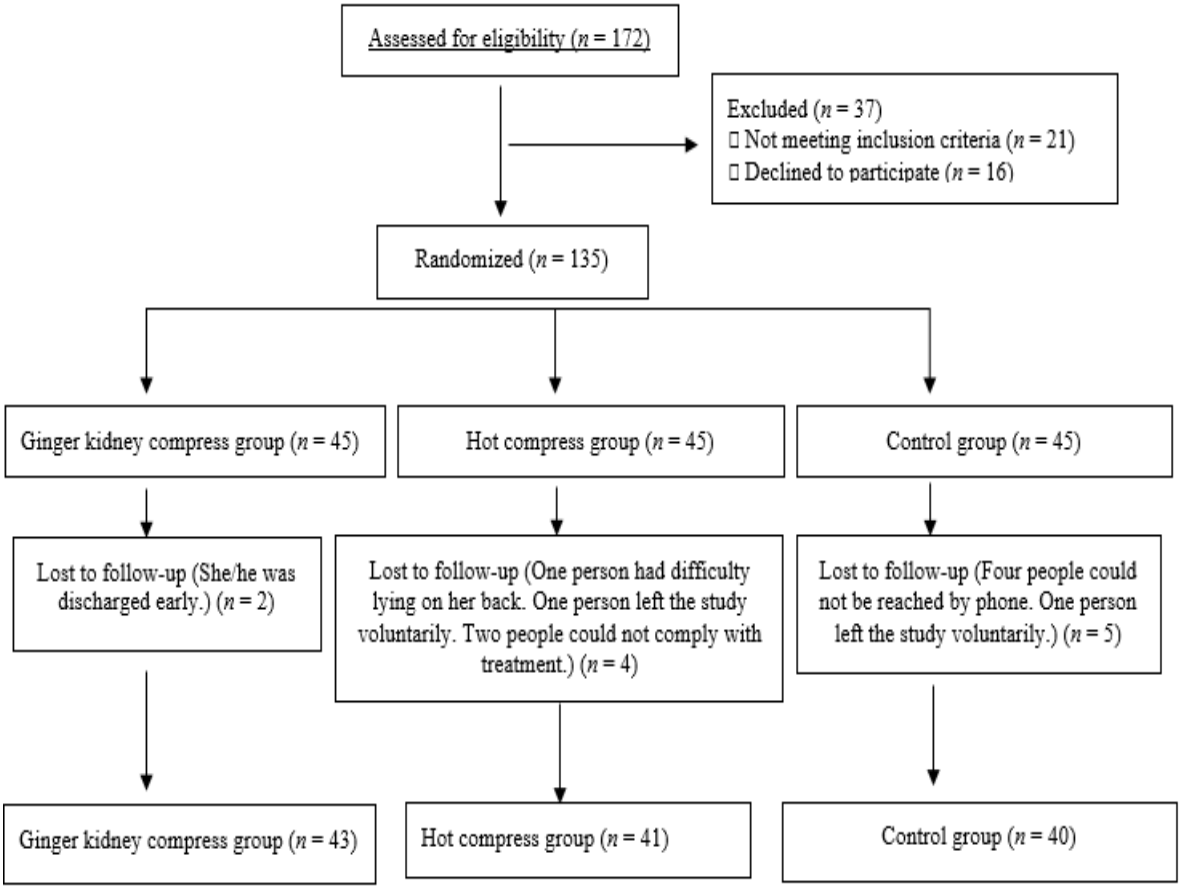

Figure 1. The CONSORT chart of the study.

Outcome measurement tools

In the study, data was collected using Patient Information Form, Visual Analogue Scale (VAS), WOMAC Osteoarthritis Index, Ginger Kidney Compress Application Protocol, Hot Compress Application Protocol, Ginger Kidney Compress Application Chart and Hot Compress Application Chart.

Patient information form

The patient information form, prepared by the responsible researcher by examining the related literature [19,26,27,29,30,32,33] consists of 'socio-demographic characteristics', 'information about the disease' and 'height and weight measurements' with which BMI calculations were made. The MBI was calculated with the following formula: BMI = Body

Weight (kg) / Height (m^2), and was evaluated according to the World Health Organization (WHO) BMI classification [34].

Visual Analogue Scale (VAS), developed by Price et al [35] in 1983, is a scale the beginning of which is -0- "no pain" and the end is -10- "very severe pain" and a scale where a numerical value is given to each cm at intervals of one centimeter (cm). It was explained to the individuals participating in the study that the number "0 " meant "I don't feel any pain at all," that as the numbers got bigger, the intensity of pain increased and that the number "10 " meant "I feel the most severe pain," and they were asked to mark the level of the severity of the pain they were feeling at the moment. The pain experienced by individuals was evaluated twice, once immediately before the procedure and once within the day following the end of the procedure.

WOMAC osteoarthritis index

Various revisions and changes were made in the WOMAC index, which was originally developed in 1982. The latest version is WOMAC 3.1 The validity and reliability study of the Turkish version of the WOMAC Osteoarthritis Index was made by Tüzün et al[36,37]. The index consists of three sub-scales and 24 questions in total: pain (5 questions), stiffness (2 questions), difficulties faced while doing daily physical activities (17 questions). The Turkish version of the WOMAC OA Index is evaluated on a 5-point Likert scale. These are as following: 0 = none, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe. The highest score on the Likert scale is 20 points for pain, 8 points for stiffness and 68 points for difficulties faced during daily activities.

A high score in the index indicates worse or more symptoms, and the highest level of physical limitation [37]. In this study, WOMAC OA Index pain, stiffness and physical function sub-scales cronbach alpha values were respectively 0.85, 0.59 and 0.95 before application and 0.96, 0.87 and 0.98 after application

Ginger kidney compress application protocol

It is the protocol created with the revision of the relevant literature by the responsible researcher [27,38,39] and formed based on the instructions for application of the ginger kidney compress used in the ginger kidney compress training at The Filderklinik Community Hospital in Stuttgart, Germany and at the Ita Wegman Clinic in Basel, Switzerland. It is the protocol applied to the ginger kidney compress group. The protocol includes information about the pre-application preparation phase, materials used, application procedure and the frequency of application.

Hot compress application protocol

It is the protocol created to be applied to the placebo control group, adhering to the ginger compress application protocol prepared by the researcher. The protocol includes information about the pre-application preparation phase, materials used, application procedure and the frequency of application.

Ginger kidney compress application schedule

In the application chart prepared by the researcher, the information about the name and surname of the individuals who were included in the ginger kidney compress group, the starting date of the application, time of the application, duration of the application and the positive/negative effects developed are included.

Hot compress application schedule

In the schedule prepared by the researcher, the information given includes the names and surnames of the individuals included in the hot compress group, the starting date of the application, the time of the application and the positive / negative effects that develop during the application.

Data collection

The responsible researcher in this study has received theoretical and practical training and a certificate on ginger kidney compress at the ARCIM Institute, in collaboration with the Filderklinik Community Hospital and Tübingen University in Stuttgart, Germany for three days, at the Ita Wegman Clinic in Basel, Switzerland for five days. In order to carry out the research on a regular basis, how the patients were to be admitted and where the application was to be made were discussed with physicians of the Physiotherapy and Rehabilitation Center, where the study was to be conducted, as well as with the other healthcare team. Moreover, the staffs were informed about the purpose, scope and method of application, and a physical arrangement was made regarding the place of application. During the study, there was no interference with the routine treatment of patients in the ginger kidney compress, hot compress, and control groups. The individuals were randomized according to the schedule prepared by the University's Biostatistics Unit and were assigned to three groups as ginger kidney compress group, hot compress group and control group. Randomized patients were taken to the physical therapy room between 08.00-12.00, and ginger or hot compresses were applied.

Procedures applied to the ginger kidney compress group

In the first follow-up of the patients in the ginger kidney compress group (first interview - before

starting ginger compress application) Patient Information Form, VAS Pain Scale, and WOMAC Index information were collected by the researcher through the face-to-face interview technique. While calculating the BMI, one of the criteria for inclusion, the tape measure was used for the height measurement of the individuals, and scale was used for the weight measurement.

Afterwards, ginger kidney compress application was applied to each patient in the ginger kidney compress group for 30 minutes per day (7 days) at the same time, in line with the application protocol prepared by the researcher. After one week of application, VAS Pain Scale and WOMAC OA Index were applied again during the day (during the second follow-up of individuals) by meeting face to face with the patients. Patients were informed about the application of the VAS Pain Scale, and were asked to mark the VAS Pain Scale themselves before and after the application. During the course of the study, patients were advised by their doctors not to use any drugs with analgesic properties, and none of the patients used drugs with analgesic properties.

Procedures applied to hot compress group

In the first follow-up of the patients in the hot compress group (first interview - before starting hot compress application) Patient Information Form, VAS Pain Scale, and WOMAC Index information were collected by the researcher through the face-to-face interview technique. While calculating the BMI, one of the criteria for inclusion, tape measure was used for the height measurement of the individuals and scale was used for the weight measurement.

Afterwards, hot compress application was applied to each patient in the hot compress group for 30 minutes per day (7 days) at the same time, in line with the application protocol prepared by the researcher. After one week of application, VAS Pain Scale and WOMAC OA Index were applied again during the day (during the second follow-up of individuals) by meeting face to face with the patients. Patients in the placebo group were informed about the application of the VAS Pain Scale, and were asked to mark the VAS Pain Scale themselves before and after the application. None of the patients used any drugs with analgesic properties during the study.

Procedures applied to the control group

In the first follow-up of the patients included in the control group (first interview - patients coming to make a physical therapy appointment) Patient Information Form, VAS Pain Scale and WOMAC OA Index information were collected by the researcher through the face-to-face interview technique. During the first interview, the patients in the control group were informed about the application of the VAS Pain Scale, and it was ensured that they marked the VAS Pain Scale themselves. While calculating the BMI, tape measure was used for the height measurement of the individuals and scale was used for the weight measurement. On the day (in the second follow-up of the patients) at the end of a week (seven days), the VAS Pain Scale and WOMAC OA Index were re-applied and recorded by the researcher by interviewing the patients via phone. During the first follow-up, the VAS Pain Scale, which was to be used during the second follow-up, was given to the patients, and they were asked during the phone call as well to disclose the value they marked. During the study period, the patients were advised not to use any drugs with analgesic properties and they did not use drugs.

Statistical analysis

The data were evaluated using IBM SPSS Statistics 21.0 and SigmaStat 3.5 statistical software. Independent variables of the study are socio-demographic characteristics of the patients such as age, gender and education level. Dependent variables of the study are the VAS Pain Scale and the WOMAC Index scores. Summary statistics were given as unit number (n), percent (%), mean ± standard deviation, median, 25th and 75th percentile value [(M (Q_1-Q_3)]. The distribution of numerical variables was evaluated by the Shapiro-Wilk normality test. Since the data did not show normal distribution, comparisons between groups were made with the Kruskal-Wallis Variance Analysis, and the Dunn test was used as multiple comparison test.

The Wilcoxon test was used to evaluate the consecutive measurements. Exact method of the Chi-square analysis was used to compare categorical variables and p value <0.05 was considered statistically significant.

Ethical considerations

Before starting the application, Ethics Committee Approval from the University Clinical Research Ethics Committee **(Decision Number: 2012/460),** and written permission from the Chief Physician State Hospital, where the research was conducted (**Number: 97396145/1554**) were taken. After the volunteers were informed about the research and it was stated that their identity would not be disclosed in any way, verbal and written consents were taken, and the informed consent form was signed.

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Limitations of the study

In the research, the blanking method was planned. However, this could not be achieved because of the difficulties in finding suitable working conditions and practitioners for the blanking. In addition, evaluation of individuals over a period of more than 7 days was not possible since in the routine treatment of the clinic, spending more than 7 days without physical therapy and medication was not allowed.

RESULTS

The descriptive features of the participants in the ginger kidney compress, hot compress, and control groups are presented in Table 1. Individuals in the ginger kidney compress, hot compress, and control groups are similar in terms of identifying features except for marital status and smoking status ($p > 0.05$) (Table 1)

The disease features of the participants in the ginger kidney compress, hot compress, and control groups are presented in Table 2. It was observed that individuals in the ginger kidney compress, hot compress, and control groups were similar, except for the presence of OA in the family, in terms of other disease characteristics ($p > 0.05$) (Table 2).

Table 1. Descriptive features of the participants in ginger kidney compress, hot compress and control groups

	Groups						*p*
	Ginger kidney compress group (*n*=43)		**Hot compress group** (*n*=41)		**Control group** (*n*=40)		
	n	**%**	***n***	**%**	***n***	**%**	
Sex							
Female	34	79.1	32	78.0	32	80.0	1.000*
Male	9	20.9	9	22.0	8	20.0	
Age							
50-70 age	25	58.1	28	68.3	25	62.5	0.628*
71 age and above	18	41.9	13	31.7	15	37.5	
Median of Age (25% - 75%)	67.0 (60.5-76.75)		65.0 (60.0-73.0)		67.0 (58.5-78.0)		0.725**
Marital status							
Married	32	74.4	36	87.8	25	62.5	0.034*
Single	11	25.6	5	12.2	15	37.5	
Education							
Not literate	19	44.2	22	53.7	21	52.5	
Literate	17	39.5	13	31.7	11	27.5	0.781*
Primary school	7	16.3	6	14.6	8	20.0	
VKI Average ($\boldsymbol{Mean \pm SD}$)	27.5 ± 3.02		27.57 ± 2.45		27.69 ± 2.38		0.576***
Economic Status							
Good	8	18.6	10	24.4	12	30.0	0.480*
Middle	35	81.4	31	75.6	28	70.0	
Profession							
Housewife	30	69.8	28	68.3	29	72.5	
Retired	8	18.6	7	17.1	6	15.0	0.985*
Farmer	5	11.6	6	14.6	5	12.5	
Residence place of family							
City center	17	39.5	15	36.6	18	45.0	
Countryside	12	27.9	10	24.4	14	35.0	0.463*
Village	14	32.6	16	39.0	8	20.0	
Cigarette							
Never smoked	27	62.8	26	63.4	35	87.5	
He/she smoked, quit smoking	16	37.2	15	36.6	5	12.5	0.020*

Note. SD. Standard deviation. * Fisher chi-square exact test for rxc tables ,** Kruskal-Wallis Analysis, *** One way analysis of variance

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Table 2 . Disease features of the participants in ginger kidney compress, hot compress and control groups

	Ginger kidney compress group (*n*=43)		Hot compress group (*n*=41)		Control group (*n*=40)		p
	n	%	*n*	%	*n*	%	
Duration of disease (years)($Mean \pm SD$)	6.25 ± 5.63		6.41 ± 6.08		5.32 ± 4.35		0.748*
Presence of OA in the family							
Yes	13	30.2	23	56.1	13	32.5	0.031**
No	30	69.8	18	43.9	27	67.5	
Additional disease							
Yes	37	86.0	32	78.0	29	72.5	0.312**
No	6	14.0	9	22.0	11	27.5	
Control Frequency							
The complaint is quite	43	100.0	41	100.0	40	100.0	-
Regular Use of Drugs							
Yes	33	76.7	34	82.9	31	77.5	0.753**
No	10	23.3	7	17.1	9	22.5	
Regular Use of Exercise							
Yes	7	16.3	5	12.2	6	15.0	0.864**
No	36	83.7	36	87.8	34	85.0	
Hospitalization in the Last One Year							
Yes	13	30.2	12	29.3	15	37.5	0.687**
No	30	69.8	29	70.7	25	62.5	
Number of Hospitalizations	(*n*=13)		(*n*=12)		(*n*=15)		
One time	8	61.5	7	58.3	9	60.0	0.987**
Twice	5	38.5	5	41.7	6	40.0	
Perform Prayer							
Yes	37	86.0	35	85.4	33	82.5	0.894
No	6	14.0	6	14.6	7	17.5	
How to Pray	(*n*=37)		(*n*=35)		(*n*=33)		
Standing	16	43.2	16	45.7	14	42.4	0.960
Seated	21	56.8	19	54.3	19	57.6	
Using Auxiliary Tools							
Yes	12	27.9	7	17.1	10	25.0	0.501
No	31	72.1	34	82.9	30	75.0	
Heating Type of the House							
Heater	23	53.5	13	31.7	19	47.5	0.117
Stove	20	46.5	28	68.3	21	52.5	
Wearing of Heels Shoes	(n=34)		(*n*=32)		(*n*=32)		
No	34	100.0	32	100.0	32	100.0	-

Note. **One way analysis of variance, ** Fisher chi-square exact test for rxc tables*

Before the application, the VAS score of the individuals in the ginger kidney compress group was determined as 8.0, the VAS score of the individuals in the hot compress group was determined as 8.0 and the VAS score of the individuals in the control group was determined as 7.0. This difference between the groups in terms of pre-application VAS scores is not significant ($p > 0.05$). It was found that compared to pre-application, there was a significant difference between the VAS scores of the ginger kidney compress group, the hot compress group, and the control group after the application ($p<0.001$). In the analysis, it was determined that the VAS pain score of individuals in the ginger kidney compress group decreased more than the individuals in the hot compress and control groups, that there was an increase in pain in the individuals in the control group and that the difference between the groups was significant ($p<0.001$) (Table 3).

Table 3. VAS Pain Points Pretest and Post-test Application of Groups

	Groups			
VAS	**Ginger kidney compress group** (*n*=43) *M(Q1-Q3)*	**Hot compress group** (*n*=41) *M(Q1-Q3)*	**Control group** (*n*=40) *M(Q1-Q3)*	***p****
Pretest	8.0 (7.0-8.75)	8.0 (7.0-9.0)	7.0 (6.0-8.0)	0.064
Post-test	3.0 (3.0-4.0)^a	7.0 (6.0-8.0)^b	8.0 (7.0-9.0)^b	**<0.001**
Odds	4.0 (3.0-5.0)^a	1.0 (0-1.0)^b	-1 (-1-0)^c	**<0.001**
p**	**<0.001**	**<0.001**	**<0.001**	

Note. ^{a,b,c}*: It shows the difference between the groups in the study groups. There are different characters in different groups. *Kruskal-Wallis Analysis, **Wilcoxon test*

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Comparison of the WOMAC OA scale sub-scales scores before and after the application of the groups included in the research are included. The WOMAC-Pain sub-scale score of individuals in the ginger kidney compress group before the application was determined as 15.0 (12.0-17.0), the WOMAC-Stiff sub-dimension score as 5.0 (4.0-7.0), the WOMAC-Physical Function sub-dimension score as 52.0 (48.25-61.0); the WOMAC-Pain sub-scale score was determined as 16.0 (13.75-18.0), the WOMAC-Stiffness sub-scale score as 6.0 (5.0-6.0), the WOMAC-Physical function sub-scale score as 58.0 (44.0-61.0) and the WOMAC-Pain of control group sub-scale score as 14.0 (13.0-16.5), the WOMAC-stiffness score as 5.0 (4.0-5.5), and the WOMAC-Physical Function sub-scale score as 51.0 (46.5-59.5). While there was a significance in the WOMAC-Stiffness sub-scale between the groups before the application (p<0.05), this difference between the groups was not significant in terms of the WOMAC-Pain sub-scale and the WOMAC-Physical Function sub-scale scores (p> 0.05). On the other hand, compared to pre-application, in the individuals the ginger kidney compress group, the hot compress group, and the control group, there was a highly significant difference between the WOMAC-Pain sub-scale, WOMAC-Stiffness sub-scale and the WOMAC-Physical Function sub-scale after the application p<0.001). In the analysis, it was determined that the WOMAC-Pain sub-dimension, WOMAC-Stiffness sub-dimension, and WOMAC-Physical function sub-dimension scores of individuals in the ginger kidney compress group decreased more than the individuals in the hot compress and control groups, and that there was an increase in pain in the control group and that the difference between the groups was significant. (p<0.001) (Table 4).

Table 4. WOMAC OA index sub-dimensions points pretest and post-test application of groups

WOMAC OA Index Sub-Dimensions	**Groups**			***p****
PAIN	**Ginger kidney compress group** (n=43) *M(Q1-Q3)*	**Hot compress group** (n=41) *M(Q1-Q3)*	**Control group** (n=40) *M(Q1-Q3)*	
Pretest	15.0 (12.0-17.0)	16.0 (13.75-18.0)	14.0 (13.0-16.5)	0.155
Posttest	7.0 (4.25-8.0)[a]	15.0 (13.0-17.0)[b]	16.0 (15.0-17.0)[b]	<0.001
Odds	9.0 (6.0-10.0)[a]	1.0 (0-2.0)[b]	-1.5 (-2-0)[c]	<0.001
p**	<0.001	<0.001	<0.001	
STIFFNESS				
Pretest	5.0 (4.0-7.0)	6.0 (5.0-6.0)	5.0 (4.0-5.5)	0.021
Posttest	3.0 (2.0-3.0)[a]	5.0 (4.0-6.0)[a,b]	6.0 (5.0-6.0)[a]	<0.001
Odds	2.0 (2.0-4.0)[a]	1.0 (0-1.0)[b]	-0.5 (-1-0)[c]	<0.001
p**	<0.001	<0.001	<0.001	
PHYSICAL FUNCTION				
Pretest	52.0 (48.25-61.0)	58.0 (44.0-61.0)	51 (46.5-59.5)	0.413
Posttest	29.0 (24.0-31.0)[a]	53.0 (44.0-59.25)[b]	57.5 (53.0-61.0)[b]	<0.001
Odds	29.0 (20.0-34.0)[a]	3.0 (0-4.0)[b]	-4 (-6-0)[c]	<0.001
p**	<0.001	<0.001	<0.001	

Note .[a,b,c]: *It shows the difference between the groups in the study groups. There are different characters in different groups. *Kruskal-Wallis Analysis, **Wilcoxon test*

DISCUSSION

In our study in which we examined the effect of ginger kidney compress application applied on the waist region of individuals with knee OA for 7 days, 30 minutes a day, on the pain severity and physical functions of individuals. Ginger kidney compress application was aimed to be evaluated with the hot compress and control groups. As a result of the study, it has been determined that the application of ginger kidney compress on individuals with knee OA is effective in reducing the severity of pain and that it increases the physical function capacity of individuals.

In our study, it was observed that the VAS-pain score and the WOMAC-Pain sub-scale, the WOMAC-Stiffness sub-scale, and the WOMAC-Physical function sub-scale scores of individuals knee OA were high in all groups before the application and that after the application, the VAS-Pain score, the WOMAC-Pain sub-scale, WOMAC-Stiffness sub-scale and WOMAC-Physical function

sub-scale scores of the individuals in the ginger kidney compress group decreased after 7 days of application more than those of the individuals in the hot compress and control groups. It is stated that the application of ginger kidney compress causes increased circulation with vasodilation in the region where it is applied and that it helps to remove from the region the metabolic residues that increase the pain by joining blood circulation, that it blocks the sensation of pain by stimulating the afferent and efferent nerves, that it reduces the stiffness and stimulates the organs. In addition, it has effects such as relaxing, heating the body, relieving fatigue, and improving fitness in the individuals treated [26,27,29-31,38,39]. The findings of a limited number of studies in the literature evaluating the effect of ginger kidney compress application applied on individuals with knee OA on the waist region on pain severity and physical functions of individuals are similar to the findings of this study [26,29,30,40].

In the pilot study evaluating the effectiveness of ginger kidney compress and ginger patch product by Therkleson, it was observed that there was a decrease in the pain levels of both ginger compress and ginger patch group in patients' 21-day pain scores (30% decrease in VAS-Pain scale), and that in the Modified Health Assessment Survey results in the score before the application was 1.85, and it was reduced 0.95 in the ginger patch group, and in the ginger group, it decreased from 1.75 to 1.1. After twenty-four weeks, a 73% reduction in pain, 76% in fatigue, 72% in global impact, and 63% in the functional state were achieved [31]. In parallel with the results obtained from our study, it was determined that ginger kidney compress was effective in decreasing the level of pain and increasing functional capacity, but that comparisons with other methods were needed. In our study, in order to compare the effectiveness of ginger kidney compress application, a hot compress group was also included, and therefore it was compared with another method. Furthermore, in our study, the patients informed the practitioner that they felt increasing warmth that spread throughout the body during and after the application of ginger kidney compress, creating a pleasant comfort, loosening their muscles, that from the first application their pain began to decrease and they sleeping more comfortably at night. About WOMAC-Pain sub-scale components, they expressed having less difficulty walking, waking up fewer times due to pain while sleeping at night, not feeling pain while resting, and being able to stand up longer. About the WOMAC-stiffness sub-scale components, they expressed that they experienced less rigidness and stiffness during the first walk in the morning and while lying down during the day. About the WOMAC-Physical function sub-scale, they stated that they had less difficulty especially when climbing and going down the stairs, putting on and taking off socks and that it created a more flexible joint mobility.

Hot applications, by activating the gate control mechanism, stimulating the touch receptors, reducing ischemic pain with vasodilation, removing metabolic residues, increasing the release of endorphins, eliminating muscle spasm, reducing the effects of the changes in the viscoelastic properties of tissues such as pressure, strain, and hypoxia, increasing pain tolerance, and by sedating and creating relief for the patient, reduces or relieves pain [41-43]. In our study, the reason for the decrease, albeit small, in the VAS-Pain score and WOMAC-Pain sub-scale, WOMAC-Stiffness sub-scale, and WOMAC-Physical function sub-scale scores of the individuals in the hot compress group at the end of the 7-day application, is thought to be conditions such as increased circulation by vasodilation due to the effect of the temperature in the area where heat was applied, decreased pressure and tension on nerve endings, reduced pain, and relaxed muscles as a result of removing metabolic residues that cause pain from the region. No studies conducted on the waist region as an application area for reducing pain in knee OA were encountered in the literature, only studies on the application on the knee region have been identified [33,44-48].

In our study, it was found that the VAS-Pain and the WOMAC-Pain sub-scale, the WOMAC-Stiffness sub-scale, and the WOMAC-Physical function sub-scale scores of the individuals in the control group increased even more after 7 days. It should not be ignored that pharmacological methods also play an important role in the treatment of knee OA. However, since the average age of the individuals included in our study is 65 years old and above, it is required to be careful in the use of drugs in OA. The increase in the number of drugs used by elderly individuals causes an increase in drug-related side effects. Therefore, along with changes that occur with aging in the elderly and that may affect drug metabolism in the organism, drugs that are inconvenient or risky to use in this age group, drug interactions, and non-pharmacological methods that can be used should also be known [49-52]..

CONCLUSION

The results of this research have determined that the ginger kidney compress application when applied to

pain compared to hot compress application, and the waist region of individuals with knee OA for 30 minutes a day for 7 days reduces the severity of knee decreases the symptoms caused by pain, and thus making it less difficult for individuals to fulfil their physical functions, and that ginger kidney compress can be an independent integrative nursing practice that can be used easily by nurses in reducing pain symptoms of individuals with knee OA. In order to increase the level of evidence in line with these results, repeating the study as a double-blind randomized controlled study, applying the study to groups of patients who use drugs in order to establish whether it decreases the rate of drug use in reducing pain, that complementary methods such as ginger kidney compress which reduce the severity of pain and increase the quality of life of individuals with knee OA being included in physical therapy programs and their use with pharmacological methods in clinics being extended may be suggested.

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Note: This study was presented in 16th National Congress of Internal Medicine at 15-19 October 2014 and verbal paper received the second prize.

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ORIGINAL RESEARCH

Investigation of Antagonistic Effect of Probiotic Food Supplement against Different Strains of Bacteria

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Abstract

Objective: Probiotics are an important part of the microbiota associated with many diseases. The production of food and food supplements containing probiotic products has increased considerably in recent years, due to their protective effect on health and antagonistic effect against some pathogenic microorganisms. However, it is unknown whether the content of these products has the expected effect. In this study was aimed to investigate the antagonistic effect of Probiotics & Prebiotics® commercial product.

Material-Method: The probiotic food supplement was obtained from Aym-Net®. Antagonistic effect of the product on 10 different test bacteria was investigated by the agar spot assay method. Also lyophilized probiotics were cultured in MRS broth medium and centrifuged at 3500 rpm for 25 minutes in order to obtain metabolites that the probiotic microorganisms provide their effectiveness. Effect of probiotic supernatant on test bacteria were determined to disk diffusion test by CLSI. Each test bacteria combined with the probiotic product incubated at 37 ^{0}C for 24 hours to determine the bacterial inhibition rate of product which analyzed using the Mann Whitney U test.

Results: Probiotic product inhibited growth of *L. monocytogenes* by (86 %), *Y. pseudotuberculosis* (82%), *S. aureus* (76%), *E. coli* (74%), *S. typhimurium* (73%), *P. aeruginosa* (69%) and *S. epidermidis* (67%) respectively. The lowest antagonistic effect was detected against *E. faecalis* 44%. While probiotic product provided significant growth inhibition on 8 strains ($p<0.05$), there were not statistically significant growth inhibition for *P. vulgaris* and *E. cloacae* ($p>0.05$).

Conclusion: It was concluded that antagonistic effect of probiotic food supplement on test bacteria. Therefore it may be beneficial to use in bacterial infections.

Keywords: Antimicrobial Effect, Food Supplement, *Lactobacillus*, Probiotics

INTRODUCTION

The gastrointestinal system hosts a microbial community called microbiota which is so important for health[1]. Studies show a correlation between microbiota changes with mental disorders, obesity, metabolic diseases, autoimmune diseases, allergies, irritable bowel syndrome (IBS), acute chronic bowel inflammation and gastroenteritis[2-4]. There could be a cycle in which various natural biological functions affect the composition of the microbiota or, due to developing health problems, the composition and function of the microbiota are affected and impaired, hence the emergence of other health problems. Therefore, the preservation of the natural structure of the microbiota is considered to be very important for human health[5]. Microbiota with dysbiosis, aside from the metabolic diseases it causes, directly leads to serious health problems such as constipation, diarrhea, other intestinal disorders and even colitis[6]. One of the important issues in preserving the natural structure of the microbiota is the presence of probiotics. Living microorganisms that live in the microbiota and are resistant to stomach acids and bile, which have significant beneficial effects on the host, are generally called probiotics[7]. Studies shows that probiotics have many important roles in the body: They play role in preventing some infections, preventing cancer, preventing allergies, boost to the immune system, and daily digestion[8, 9]. In addition, they colonize throughout the intestinal system and prevent pathogens from outside from settling into the intestine. Also probiotic bacterial proteins have an antagonistic effect on some pathogens[10, 11]. Therefore, it is frequently used as a supplementary food in the treatment of various infectious diseases. So returning to nature and naturalness appears in many areas worldwide[12]. Moreover, antibiotic resistance, which manifested itself as a serious crisis especially in recent years, and increased treatment costs have also led to an increase in the consumption of probiotic

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supplements[13]. However, not all probiotics work for all. Therefore, commercial probiotics have come into the agenda in recent years. This is because it is known which health outcomes are supported by identified probiotics. For instance a probiotic bacterium used for constipation does not work for digestive problems caused by antibiotics[14-16]. Probiotic market has grown rapidly in recent years. The efficacy of probiotics is specific to some strains and should not be generalized[17]. In this study, it was aimed to investigate the antagonistic effect of a commercial probiotic food supplement on some microorganisms.

MATERIALS AND METHODS

Probiotic food supplement

The probiotic food supplement used in this study was obtained from Aym-Net®. It contains mixed probiotic microorganism. Product content is given in Table 1.

Table 1. Content of Probiotics & Prebiotics®

Ingredients	Composition
Fibrous (from oat) (Avenasative L.)	700 mg
Lactobacillus acidophilus	$2x10^9$ CFU/gr
Saccharomyces boulardii:	$2x10^9$ CFU/gr
Bifidobacterium infantis	$1x10^9$ CFU/gr
Lactobacillus plantarum	$1x10^9$ CFU/gr
Bifidobacterium bifidum	$1x10^9$ CFU/gr
Bifidobacterium longum	$1x10^9$ CFU/gr
Lactobacillus paracasei	$5x10^8$ CFU/gr
Lactobacillus reuteri	$5x10^8$ CFU/gr
Lactobacillus bulgaricus	$5x10^8$ CFU/gr
Lactobacillus rhamnosus	$2,5x10^8$ CFU/gr
Lactobacillus brevis	$2,5x10^8$ CFU/gr

Test bacteria

Yersinia pseudotuberculosis ATCC 911, *Salmonella Salmonella enterica subsp. enterica typhimurium* ATCC 14028, *Pseudomonas aeruginosa* ATCC 27853, *Listeria monocytogenes* ATCC 7644, *Escherichia coli* ATCC 25922, *Staphylococcus epidermidis* 12228, *Staphylococcus aureus* ATCC 25923, *Enterococcus faecalis* ATCC 29212, *P. vulgaris* ATCC 29905, *Enterobacter cloacae* ATCC 13047 strains were used in the study and was obtained from the Microbiology Laboratory culture collection of Duzce University Traditional and Complementary Medicine Application and Research Center.

Agar spot assay

The capsule containing lyophilized probiotic microorganisms was dissolved in 10 ml of distilled water and kept at 37 ^{0}C for 1 hour. Afterwards, it was inoculated in MHA medium as a point with a sterile needle-tipped swab (Mueller Hinton Agar, Merck) and incubated at 37 ^{0}C for 24 hours. Test bacterial cultures prepared 24 hours ago in Mueller Hinton Broth (MHB, Merck) were mixed into 5ml soft agar media (MHB containing 0.7% agar) to contain $1x10^8$ cells and poured over probiotic culture. It was evaluated for the presence of inhibition zones after the incubating 24 h at 37 ^{0}C[7, 11]. All experiments were carried out three times.

Disk diffusion method

Supernatant of probiotics was obtained and inhibition zones formed on test bacteria were measured[18]. Test bacteria were prepared 24 h before the experiment on NA (Nutrient Agar, Merck). Then 2 -3 colonies were added in sterile physiological serum at a density of $1\text{-}1,5x10^8$ CFU / ml (McFarland 0.5) and inoculated on MHA. On the other hand of lyophilized probiotic food supplement dissolved in 10 ml distilled water and 1 ml of it inoculated into 9 ml of MRS broth (e man, Rogosa and Sharpe, Merck) incubated at 37 ^{0}C to 24 h. Bacterial supernatant after centrifuging the liquid medium containing the probiotic product for 25 minutes at 3500 rpm was absorbed on blank disks (Bioanalyase, blank disk 6mm). Gentamicin (Bioanalyase, CN 10µg disk) was used as positive control13. All experiment performed in triplicate in different days.

Growth inhibition rate

The inhibitory effect of the probiotic product on the growth of test bacteria was calculated separately in the form of a combination with probiotic product and each test bacterium. One hundred fifty µl of test bacteria culture (prepared $1x10^8$ CFU / ml) and 50 µl of probiotic food supplement were added to each well in 96 well plates. Each test bacterium and probiotic supplement were also put into the well alone. Accordingly, the growth turbidity of tested bacteria alone is considered 100%. The OD_{630} was recorded (Plate Reader, Biotek 800TS, USA) after the microplate was incubated at 37 ^{0}C for 24 h[19, 20]. All experiment performed in triplicate.

Statistical analysis

Whole experiments were performed in triplicate. All data have been given as mean (± SD) and SPSS 15.0 has been used to evaluate the data. Inhibition ratio of the probiotic product between control have been analyzed using the Mann Whitney U test.

RESULTS

Test product containing a mixture of probiotic bacteria did not form an inhibition zone in two different bacterial strains, while an inhibition zone was found in others. Accordingly, the highest inhibition was seen in *Y. pseudotuberculosis* and *L.*

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monocytogenes, while the lowest inhibition was seen in *E. faecalis*. The zones determined according to both methods are given in Tables 2 and 3.

Table 2. Antagonistic effect of product by agar spot assay

Test Bacteria	Inhibition Zone
Y. pseudotuberculosis	+
S. typhimurium	+
S. epidermidis	+
E. faecalis	+
P. aeruginosa	+
L. monocytogenes	+
E. coli	+
P. vulgaris	-
E. cloacae	-
S. aureus	+

Table 3. Zone diameters to the disk diffusion method

Test Bacteria	Zone Diameter (mm)± SD	
	Probiotic Product	Gentamicin
Y. pseudotuberculosis	18 (±1)	20
S. typhimurium	16 (±0)	20
S. epidermidis	13 (±0.57)	18 (±0.57)
E. faecalis	9 (±0,57)	20
P. aeruginosa	15 (±0)	20
L. monocytogenes	18 (±0.57)	25
E. coli	14(±1.15)	25
P. vulgaris	R	15
E. cloacae	R	20
S. aureus	14(±0.57)	20

R: Resistant, no inhibition zone.

The inhibition rate of probiotic food supplement on test bacteria is given in Figure 1. Probiotic product inhibited growth of *L. monocytogenes* by 86 %. Similarly, it was shown that 82% antagonistic effect against *Y. pseudotuberculosis* while it was determined against to *S. aureus (*76%), *E. coli (*74%), *S. typhimurium (*73%), *P. aeruginosa (*69%) and *S. epidermidis* (67%) respectively. The lowest antagonistic effect was detected against *E. faecalis* 44%.

DISCUSSION

Lifestyle and nutrition play an important role in the pathogen of infections. Hence, healthy nutrition and natural product preference is increasingly important in preventing disease. On the other hand, antimicrobial agent resistance caused by the consumption too much antibiotics and synthetic products leads to the need for natural products to protect against infectious diseases. In addition, probiotic food supplement intake is recommended in some cases, such as diarrhea caused by a decrease in probiotic bacteria in gut due to antibiotic consumption[13,21,22]. It is a known fact that probiotics are recommended for a number of indications in relation to this and such health[23]. They are often seen as part of the immune system and are reported to play an important role in preventing infectious diseases. It is frequently used in intestinal infections. *Lactobacillus* and *Bifidobacterium* species are also associated with obesity, anxiety, diabetes and brain function, as well as bowel disorders[24]. Therefore, commercial products containing probiotics are increasing day by day[25]. In particular, the lack of milk and dairy products as a source of probiotics suitable for consumption by some individuals due to lactose intolerance has led to an increase in alternative probiotic foods and food supplements[16].

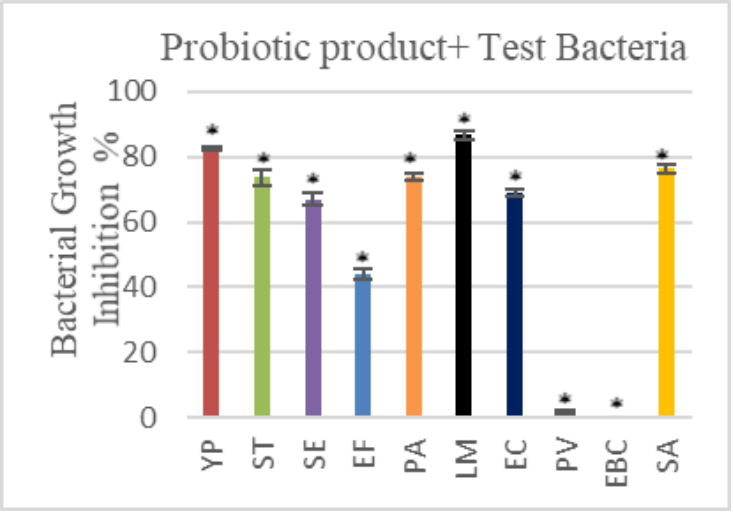

Figure 1. Growth inhibition of test bacteria. * p<0.05. Growth inhibition rates of test bacteria observed as a result of combined incubation of each test bacteria with probiotic food supplement were given. YP: *Y. pseudotuberculosis*, ST: *S. typhimurium*, SE: *S. epidermidis*, EF: *E. faecalis*, PA: *P. aeruginosa*, LM: *L. monocytogenes*, EC: *E. coli*, PV: *P. vulgaris*, EBC: *E. cloacae*, SA: *S. aureus*.

Currently, food supplements containing dried probiotics have a fairly large market in this sense. This situation brings about some problems. Some of these problems are that products do not show the expected functional properties[23,26]. In this study, the content of commercial food supplements containing probiotic microorganisms was evaluated in total without being defined separately. Antagonistic effect of the product was tested in 10 different bacterial strains and the ratio of its possible inhibitory effect was investigated. Accordingly, it was observed that it formed an inhibition zone in 8 different bacterial strains. Edalati et al.[7] found that different species of *Leuconostoc*, *Lactobacillus* and *Weissella* formed an inhibition zone on *E. coli.* Iglesias et al.[27] reported that *L. acidophilus* has antagonistic effects on food-borne *Salmonella* and *L. monocytogenes* and that probiotics can be used to control the growth of pathogens in foods. Karimi et al.[13] investigated the effectiveness of lactobacilli on *E. coli*, a common agent of diarrhea, and reported that the highest inhibitory effect had *L. plantorum*. Corr et al.[28] have shown that various probiotics have a significant antagonistic effect in *Listeria* infections. In parallel, the highest antagonistic effect was determined against *L. monocytogenes* in this study. The Test product inhibited the growth of *L. monocytogenes* by 86%. Also it has been shown in studies that *S. boulardii* has antimicrobial activity against various intestinal pathogens[9]. Therefore, it can be said that this study has expected results. In another study, the inhibition zone diameters of pineapple juice containing *Pediococcus pentosaceus and L. rhamnosus* were detected on *Klebsiella* 10mm, *P.aureus* 11 mm, *Bacillus* spp. 13 mm, *E.coli* 14 mm, *Pseudomonas* 14 mm, similar to this study[16]. The zone diameters in this study were determined as 14 mm for *E. coli* and 15 mm for *P. aeruginosa*. But the inhibition ratio detected for *P. aeruginosa* (69%) was lower than the inhibition ratio of *E. coli* (74%). This may be due to the abduction of some antagonistic metabolites in obtaining the probiotic upper phase used in disc diffusion testing. Because the product tested contains many probiotic microorganisms. The effectiveness of the product containing multiple probiotic microorganisms was evaluated as a whole in this study. In general, there are many studies that probiotics contained in the test product show antagonistic effects on different strains of bacteria and yeast[29-31]. Studies are mostly on the antagonistic effect of the probiotic microorganism alone. Although the combination of probiotics is expected to be a synergistic effect in basically it is also possible that it will lead to a decrease in the effect[19]. Therefore, it has been evaluated totally in terms of whether the product is effective or not. In addition, it is a current problem that the content of probiotic products, which has increased frequently in recent years, must be controlled[26]. Therefore, it was important to demonstrate the effectiveness of commercial probiotic food supplements tested in this sense.

In his study, Valdez et al.[19] investigated the antagonistic effect of *B. infantis*, *B. lactis* and *B. longum* species on periodontal pathogens alone or in various combinations and reported an antagonistic effect in both cases. Probiotic microorganisms have an antagonistic effect on pathogens via various metabolites (bacteriocin etc.). Acid organics such as lactic acid, which produced by probiotics are highly effective in the Gram negative bacterial cell membrane[19,32,33]. In this study, antagonistic effect against gram negative bacteria was found to be higher. There are two bacterial strains (*P. vulgaris* and *E. cloacae*) that do not show growth inhibition ($p>0.05$). These bacteria probably showed resistance to the metabolites produced by probiotic microorganisms.

CONCLUSION

Evaluating the effectiveness of probiotic food supplements is a problem today. This study was investigated the antimicrobial efficacy of the commercial probiotic food supplement Probiotics & Prebiotics®.

It was concluded that antagonistic effect of probiotic food supplement was detected on a variety of test bacteria. Therefore, its use as a supplement in these bacterial infections can provide a beneficial effect.

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REVIEW

Complementary and Alternative Therapies for Pregnant Women Suffering from Constipation: A Systematic Review

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Abstract
Background: Constipation is one of the most common gastrointestinal symptoms in pregnant women.
Purpose: This study was aimed at determining the effects of complementary and alternative therapy methods on the symptoms of pregnancy-related constipation.
Search strategy: The authors performed a systematic search according to PRISMA guidelines. The database Web of Science, Scopus, EMBASE, CENTRAL, national databases were screened to reach studies published from January 2010 to March 2020 with restriction to human studies in English or Turkish language**.** The quality of the studies included in the study was assessed with the measurement tool proposed in the JADAD, JBI, and Observational Open-Label Studies scales.
Inclusion criteria: Electronic searches were conducted in PubMed using the keywords constipation "pregnancy" or pregnant woman and "acupuncture" or "acupressure" or "massage" or "herbal medicine" or "aromatherapy" or "music therapy" or "homeopathy" or "hypnosis" or "meditation" or "reflexology" or "moxibustion" or "ayurvedic Medicine" or "ayurveda" or "Traditional Iranian Medicine
Data extraction and analysis: Selection of included articles, data extraction and methodological quality assessments were respectively conducted by two review authors.
Findings: 14536 studies were selected and 706 studies were screened based on their titles and abstracts. Seventy-three studies were analyzed in detail to assess whether they were suitable. In order to find a larger number of original articles, of the studies in the reference lists of these studies, those found in the electronical environment were screened, but no studies were found to meet the inclusion criteria. Finally, 3 studies were included in the study.
Conclusions: The results demonstrated that herbal medicine and foot reflexology reduced constipation complaints during pregnancy without any side effects. Because the number of studies conducted to investigate the efficacy and safety of different types of complementary and alternative medicine methods in pregnant women with constipation is very few, more studies should be carried out on the issue.
Key words: Complementary and Alternative Medicine, Pregnancy Care, Constipation

What is already known about the topic: One of the leading complaints during pregnancy is constipation. In recent years, the use of complementary and alternative medicine instead of pharmacological drugs for the alleviation of such complaints has drawn more attention.
What do the results of this study add: Performing a larger number of randomized controlled studies to assess the effects of Complementary and Alternative Therapy methods on pregnancy-related constipation may be effective in reducing the need for pharmacological methods to be used during pregnancy.
What are the implications of these findings for clinical practice and or further research:
Complementary and Alternative Therapies are easy to apply and cost-effective methods and play a significant role in reducing constipation. Performing more studies on the use of CAM methods will provide an alternative option for pregnant women who do not want to resort topharmacological methods.

INTRODUCTION

Constipation is one of the most common symptoms of gastrointestinal complaints in pregnant women.[1,2] Pregnancy-related constipation affects the daily life of women negatively.[1] In Rungsiprakan et al.'s systematic review (2015), the rate of constipation during pregnancy ranges between 11% and 44%.[3] According to the results of studies conducted in Turkey, the rate of constipation in pregnant women varies between 38.8% and 47%.[4,5] The etiology of constipation that occurs during pregnancy is

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multifactorial. One of these factors is that the pelvic organs and the structures supporting the urethra (levator ani muscle and anal sphincters) that are primarily responsible for the defecation process undergo changes due to the increase in the internal abdominal pressure during pregnancy.[2] Another factor is the decrease in bowel movements caused by the increase in the hormone progesterone level during pregnancy. In addition, the enlargement of the uterus, a decrease in the activities of daily living of the mother, stress, taking iron and calcium preparations, inadequate fluid consumption and changes in diet cause constipation more frequently during pregnancy.[1,6-8] The review of the literature demonstrated that pregnancy-related constipation (both difficult defecation and the feeling of not being able to empty fully) is common in every trimester of pregnancy.[9-11]

Among the pharmacological methods used for constipation are the use of stool softeners, prokinetic agents, osmotic agents and stimulant laxatives.[1,12] These pharmacological methods used during pregnancy can negatively affect the health of both the mother and the fetus.[1, 13-15] According to clinical guidelines, no clinical recommendations have been made for the treatment of constipation during pregnancy.[1,12] Today, the choice of treatment for the pregnancy-related constipation remains a challenging clinical problem. The National Center for Complementary and Integrative Health (NCCIH) defines the Complementary and Alternative Medicine (CAM) as a healthcare approach not considered as a part of the general Western or traditional medicine.[16] While the term 'complementary medicine' refers to treatments used together with conventional medical treatments, the term 'alternative medicine' refers to treatments used instead of conventional medical treatments.[16] In many parts of the world, the use of CAM to reduce such problems as nausea, vomiting, labor pain, low back pain, pelvic pain, anxiety etc. occurring during pregnancy is very common. Among the most widely used CAM methods are herbal medicine, acupuncture, acupressure, relaxation therapies, aromatherapy, moxibustion, massage, reflexology and homeopathy.[17-22] Although data in the literature on the rates of using CAM in reducing constipation during pregnancy is very limited, the rates of CAM use in pregnancy-related problems are reported to be quite common in developed countries such as America (69%), the United Kingdom (57%) and Germany (51%).[23-25] Performing research to reveal the efficacy and safety of CAM methods in reducing the symptoms of pregnancy-related constipation is a realistic and urgent need.

Many women experience constipation during their pregnancy. Nowadays, interest in non-pharmacological methods has increased, rather than pharmacological methods, in reducing this constipation that develops due to pregnancy. Especially, it is very important for midwives in every period of women's life to know what CAM methods are. That's why in this systematic review, it was aimed to focus on articles analyzing the effectiveness of CAM methods used to reduce symptoms pregnancy-related constipation.

MATERIALS AND METHODS

Design

This study is a quantitative systematic review in which the PRISMA guidelines were used for the analysis of the studies.[25] These guidelines ensure a clear and transparent review of the articles included in the study in terms of their integrity. This study focused on articles analyzing the effectiveness of CAM methods used to reduce symptoms pregnancy-related constipation.

After the duplicate articles were removed, the study was carried out through a three-stage inclusion process:

1. Screening relevant articles according to their titles and abstracts,
2. Selection of articles based on the reading of the entire text,
3. Analysis of the texts

These 3 stages were analysis by at least two of the three referees independently of each other, one of whom not included in the study (AŞK, SD, NÇD)

Search methods

The study was carried out between January 2010 and March 2020 by retrospectively screening the publications that analyzed the effectiveness of CAM methods used to reduce pregnancy-related constipation. For this purpose, the databases were screened over the internet access networks of Kocaeli University and Kırklareli University using the following keywords: constipation [MeSH Terms and free text terms] and (pregnancy [MeSH Terms and free text terms] or pregnant woman [MeSH Terms and free text terms] and ("Acupuncture" or "Acupressure" or "Massage" or "Herbal medicine" or "Aromatherapy" or "Music therapy" or "Homeopathy" or "Hypnosis" or "Meditation" or "Reflexology" or "Moxibustion" or "Ayurvedic Medicine" or "Ayurveda" or "Traditional Iranian Medicine") .

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Search outcomes

Original studies which met the following inclusion criteria were included in the study:

1- Randomized design, quasi-randomized trial, non-controlled and non-randomized prospective studies

2- Published in English or Turkish

3- Published between January 2010 and March 2020

4-Interventions pregnancy-related constipation associated with one of the aforementioned CAM methods

5- Outcome measure which was focused on changes in constipation with one of the aforementioned CAM methods

Quality appraisal

The quality appraisal of the studies was performed in accordance with the Cochrane Handbook for Systematic Reviews of Interventions (Higgins and Green, version 5.1.0, updated in March 2011).[27]. Therefore, after the selection of each study, the quality of the studies was rated using different methods to evaluate different study designs.

Assessment of the risk of bias is part of conducting and reporting of any systematic review. In this context, the JADAD checklist was used to assess the risk of bias and the quality of randomized controlled trials in each study.[28] This scale consists of 3 items: describing randomization, blinding and accountability (dropouts and withdrawals).

Scoring: If randomization was mentioned in the study, it was given 1 point and if the study was consistent with the randomization method, it was given 1 point. However, if the study was not consistent with the randomization method, 1 point was subtracted.

Blinding: One point was given if blinding was mentioned. Another 1 point was given if it was consistent with the blinding method. If not, 1 point was subtracted.

Finally, we assigned 1 point if the accountability was known; if there were no data, the reason should have been stated. In the Jadad rating, scoring ranges between 0 and 5 points. If the Jadad score was ≥3points, the study was considered a high-quality study, and if it was ≤2 points, the study was considered a low-quality study.[28-31]

Similarly, the CONSORT checklist was used to assess the quality of study report. This quality assessment includes the following: identification of the structured abstract and title to find out whether the study was a randomized study, the rational and scientific background and description of the goals or hypothesis, the definition of research design and important changes, the criteria for the compliance with participants and the study environment, interventions including replication details for each group, results and changes in the results, sample size and interim analysis and stop guides, explanation of randomization, blindness and similarity of interventions, statistical methods and additional analyses, participant flow, losses and exclusions, recruitment and reasons for stopped trial, basic data, numbers analyzed, results, estimation and binary outcomes, subsidiary analysis, losses, limitations, generalization and interpretation. Studies that did not meet at least 70% of the items included in the CONSORT checklist were considered to contain significant methodological flaws.

In this systematic review, the quality of quasi-randomized trial was assessed using the JBI Checklist.[43] This measuring tool consists of 10 items. The JBI checklist is used to assess whether the following criteria are met in studies: cause and effect relationship, presence of a control group, whether the treatment and control groups undergo the same application, the number of variables examined before and after the intervention, exact definition of the follow-up process, whether the variables in the two groups are evaluated with the same measurement method, same measurement methods for the variables in the two groups, whether the appropriate statistical tests are used and whether the overall assessment is made. Whether the criteria are met or not is determined with the following options: "Yes", "no", "unclear" and "not applicable".

In addition, because there is no quality assessment scale to rate non-randomized, non-controlled and prospective observational studies, a scale was developed to assess the quality of the studies based on the criteria list proposed by the Observational Open-Label Studies scale. The scale consists of 12 items. Whether the criteria were met or not was assessed with the “yes”, “no” or “unclear” options. If a study met 9 or more of the 12 criteria, the study was considered to have a low risk of bias (RoB) and to be a high-quality study. If 6 to 8 of the 12 criteria were met, the study was considered to have a moderate RoB and to be a medium quality study. If only 5 or fewer of the criteria were met, the study was considered to have a high RoB and to be a low quality study.

Data extraction

The document included the following data: type of the CAM, name of the study, authors / publication year of the study, country where the study was conducted, type of study, place of study, inclusion criteria for the study and participants’ age and gestational age,

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sample size, data collection tools, details of the intervention, and results.

RESULTS

Study selection

For the review, 14536 studies were selected. Of hem, 706 were excluded because they were not in English or Turkish, or they were duplicates. As a result, 706 studies were screened based on their titles and abstracts. Seventy-three studies were analyzed in detail to assess whether they were suitable by two of the authors. They determined whether the title and abstract met the inclusion criteria.

In order to find a larger number of original articles, of the studies in the reference lists of these studies, those found in the electronical environment were screened, but no studies were found to meet the inclusion criteria. In case of disagreement between the authors, the referees reached a decision after discussing the matter. In case they did not reach a decision, the opinion of the third referee who was not involved in the study was asked.

Finally, 3 studies were included in the study. The process was illustrated in a flow diagram in Figure 1. Detailed information of these 3 studies was summarized in Table 1.

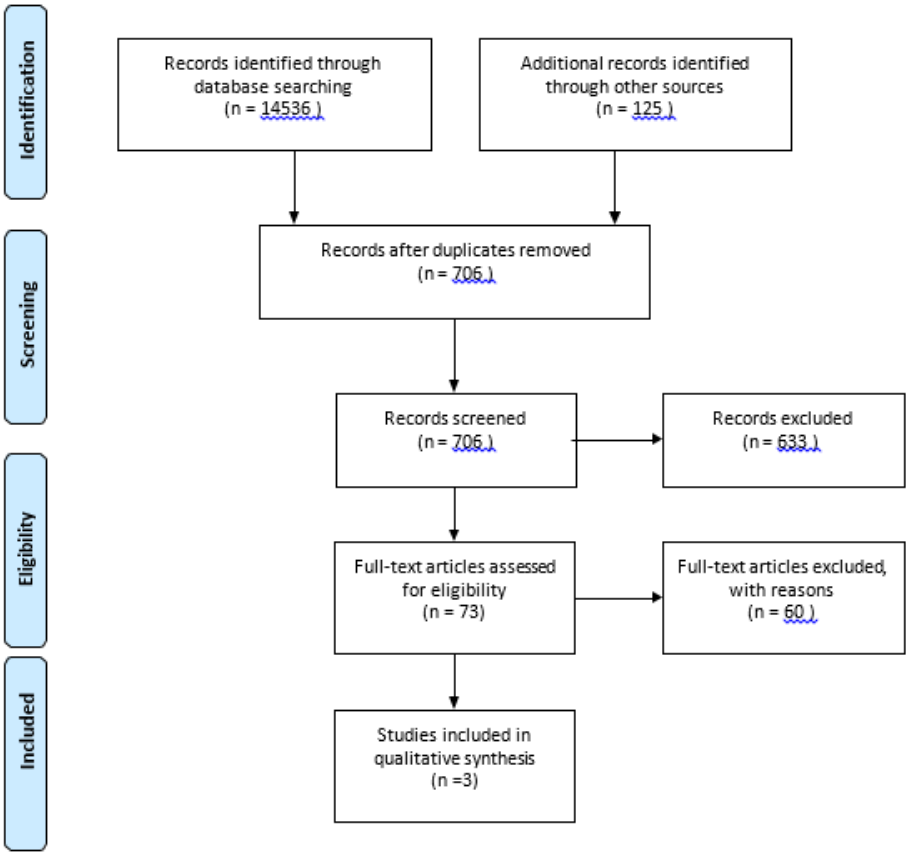

Figure 1. Study selection process.

Study characteristics

We reached the final stage on these 3 studies conducted between January 2010 and March 2020 to investigate the effects of CAM methods on women suffering from constipation during pregnancy. These studies were a randomized controlled trial (RTC), a quasi-experimental studies and non-randomized, non-controlled and prospective observational study conducted on herbal medicine (n = 2) and reflexology (n = 1). The number of the participants in the samples of the studies varied between 20 and 74. The ages of the pregnant women participating in them ranged between 16 and 45.

One of the 3 studies was a RTC whose quality was assessed using the JADAD checklist. The score range of this study was ≥3. One of the remaining 2 studies was a quasi-experimental study. Its quality was assessed using the JBI checklist. The third study was a non-randomized, non-controlled and prospective observational study. Its quality was assessed using the Observational Open-Label Studies Scale. The study met 11 of the 12 criteria. Therefore, it was considered a high quality study because its RoB was low. All the 3 studies were included in the study according to the items studied.

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Table 1. Complementary and alternative therapies for pregnant women suffer from constipation: a systematic review.

Complementary and alternative therapies for pregnant women suffer from constipation: results of a systematic review of randomized trials													
Type of CAM	**Title of manuscript**	**First Author Year**	**Country**	**Type of study**	**Place**	**Gestational weeks/ İncluded criterias**	**Age**	**Sample size**	**Tools of data**	**Treatment arm**	**Control arm**	**Primary outcome**	**Quality**
Herbal Medicine (Daikenchuto)	Efficacy and safety of daikenchuto (TJ-100) in pregnant women with constipation	Tsuda et al., 2016 [31]	Japon	Prospective Observational Open-label trial (A prospective interventional one-arm study)	Hospital	-14-28 w - Suffering with constipation during pregnancy period.	-Unclear	20	Constipation assessment scale (CAS)	The patients received 7.5 g/day of daikenchuto for 28 days from the day of registration.	No	Daikenchuto is reliable and effective in the treatment of pregnancy-related constipation	Observational Open-Label Studies scale: 11/12 yes 1/12 no
Herbal Medicine (Glucomana)	The effect of glucomannan on pregnancy constipation	Janani and Changaee, 2018 [32]	Iran	Non randomized control study	Hospital	- Unclear gestational weeks - Suffering with constipation during pregnancy period.	-Unclear	64	Questionnaire (demographi, reproductive characteristic, information about constipation).	-4 g of powdered glucomannan in two divided doses of morning and night with a glass of water.	-The magnesium hydroxide was been asked to take a tablespoon of the drug each night.	The use of glucomannan in the treatment of pregnancy-related constipation is very effective and it does not lead to serious complications	JBI: 5/9 yes 1/9 no 3/9 unclear
Foot Reflexology	The effect of short-term foot reflexology in improving constipation symptoms during pregnancy: A two-armed, randomized controlled trial	Sehhatti et al.,2020 [33]	Iran	Randomized blinded control trial study	Health care centers	-23-28 w -Having a score of 9 to 16 based on a CAS	16–45 years of age	74	-Constipation Assessment Scale (CAS). - State-Trait Anxiety Inventory (STAI)	-Foot reflexology was performed for a short period of time for 6 weeks for 12 minutes.	-Standard care	Short-term foot reflexology reduces the symptoms of constipation and anxiety during pregnancy	JADAD: 4/5

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Interventions characteristics

Of the CAM methods, herbal medicine was used in two of the 3 studies included in the study, and reflexology was used in the third one.

Herbal medicine Intervention

Two of the 3 studies included in our review were on herbal medicine interventions. One of them was a Prospective Observational Open-label trial (A prospective interventional one-arm study) conducted by Tsuda et al. (2016), in which Daikenchuto (TJ-100), a traditional Japanese herbal medicine, was used.[32] The sample of this study performed in Japan comprised 20 pregnant women whose gestational age ranged between 14 and 28 weeks. The "Constipation assessment scale" (CAS) was used to assess constipation in the participating women. Daikenchuto (7.5 g / day) was administered to the participating pregnant women for 28 days. At the end of the study, Daikenchuto was determined to be effective and reliable in reducing the symptoms of constipation during pregnancy. The study was rated using the Observational Open-Label Studies scale and was given 11 points out of 12.

The other 2 studies in which herbal medicine interventions were used was a non-randomized control study conducted by Janani and Changaee (2018).[33] They administered a plant called Glucomannan used in various diseases to the patients. In this study conducted with 64 pregnant women in Iran, the questionnaire (demographic and reproductive characteristics of the participants, information about constipation) created by the researchers was used to assess constipation in pregnant women. In the study, the participants in the experimental group drank a glass of water including glucomannan. The total dose (4 g / day) of glucomannan was divided into two and administered twice a day in the morning and in the evening for one month days. The participants in the control group were given 1 tablespoon of magnesium hydroxide every night for one month. At the end of the study, it was stated that glucomannan was quite effective in the treatment of pregnancy-related constipation with no serious complications. The study was rated using the JBI checklist and was given 5 points out of 9.

Reflexology intervention

The third of the 3 studies reviewed was a study of foot reflexology. The study conducted by Sehhatti et al. (2020) is a randomized blinded control trial study.[34] The study sample comprised 74 Iranian pregnant women aged between 16 and 45 year. Their gestational age ranged between 23 and 28 weeks. In the study, the Constipation Assessment Scale (CAS) and State-Trait Anxiety Inventory (STAI) were used to assess constipation and other symptoms suffered by the participants. Those with a CAS score of 9-16 were especially included in the study. The participants in the experimental group underwent a 12-minute foot reflexology session per week for 6 weeks. The participants in the control group were given standard care. At the end of the study, foot reflexology was determined to decrease pregnancy-related constipation and anxiety. The study was rated using the JADAD checklist and was given 4 points out of 5.

DISCUSSION

This systematic review was conducted to determine the effects of CAM methods such as herbal medicine and reflexology on reducing constipation during pregnancy. Our review included 3 studies conducted in 2 countries between January 2010 and March 2020 with 158 pregnant women suffering from constipation. Of the 3 studies, 1 was about the use of foot reflexology and 2 were about the use of herbal medicines.

In one of the 2 studies about the use of herbal medicines, Daikenchuto (TJ-100), a traditional Japanese herbal medicine, was administered. This herbal extract consists of four active ingredients, including processed ginger, ginseng, Japanese zanthoxylum bark and koi (maltose powder). In the literature, Daikenchuto plant is known to affect gastrointestinal motility and microcirculation and to have anti-inflammatory effect.[35,36] In a prospective randomized controlled study conducted with 39 patients with esophageal cancer in Japan, treatment with Daikenchuto was found to improve gastrointestinal motility after esophageal cancer resection.[36] According to Hosaka et al.' meta-analysis (2019), daikenchuto, administered to patients with gastrointestinal system cancer in the postoperative period, was determined to improve intestinal dysfunction.[37] In a study conducted with 22 patients with chronic constipation, daikenchuto reduced constipation-related bloating and abdominal pain.[38] The results of another study conducted with 34 patients with stroke suffering from constipation problems revealed that daikenchuto could treat functional constipation, improved clinical constipation scores and decreased the intestinal gas volume.[39]

While there are no domestic (Turkish) studies on the use of CAM methods to reduce the symptoms of pregnancy-related constipation, there are many studies conducted abroad, but these studies included small sample sizes. In order for the applications to

have evidence-based value, randomized controlled experimental studies to be conducted in the future should have larger samples.

Glucomannan is one of the medicinal herbs widely used in the treatment of various diseases. This plant prevents stool from hardening, prevents the retention of feces in the rectum, and thus increases bowel movements.[33,40] In the literature, although there are several studies indicating the effect of glucomannan on the symptoms of constipation especially in children,[41,42,44] there is only one study investigating its effect on pregnant women.[33] In Staiano et al.'s randomized controlled study conducted with 20 pediatric patients with a brain injury (2004), glucomannan increased the frequency of defecation (stool frequency), but had no effect on the colon motility.[42] In their experimental study conducted with 31 children suffering from chronic constipation (2004), Loening-Baucke et al. found that glucomannan was effective in the treatment of constipation.[41] In their systematic review including 8 studies conducted with children (2017), Han et al. reported that glucomannan moderately increased the frequency of defecation in children with constipation, but did not decrease stool consistency or did not lead to a general improvement in the treatment success.[44] Although the results of these studies indicate that glucomannan had positive effects, side effects of glucomannan remain unknown due to the small sizes of the samples. Therefore, given the small sample size and the risk status of the side effects, the results of these studies should be interpreted more carefully.

The third study included in our review was a study of foot reflexology. Reflexology is a massage technique applied to the hands, soles of the feet and ears under certain rules.[45] Reflexology is a non-invasive and safe intervention method. The review of the literature demonstrated that reflexology reduced pain, anxiety, depression, fatigue, symptoms related to gastrointestinal tract and constipation, and improved immune functions, and quality of sleep and life.[46,47] In Sajadi et al.'s randomized controlled study conducted with 63 patients with multiple sclerosis (MS) who underwent foot reflexology (2020), this method was found to reduce the symptoms of constipation.[47] Similarly, in another study performed with 40 children with cerebral palsy suffering from constipation, foot reflexology helped relieve constipation.[45] In their study (2017), Canbulat and Demirgoz reported that foot reflexology did not make a statistically significant difference in stool consistency and the number of defecation in 37 children with functional constipation.[46] The number of studies investigating the effect of foot reflexology on constipation is rather limited, and what is more, these studies included small sample sizes. In addition, in the literature, there is no systematic review or meta-analysis investigating the effect of foot reflexology on constipation

Limitations

The main problem encountered during our review was that the studies were very few. There was no study conducted on each CAM therapy. The studies available differed from each other in terms of the method investigated and sample sizes. In addition, due to language limitation, not all studies were reached. Therefore, the review was completed with 3 clinical studies.

Strengths

This study evaluating CAM methods for reducing the symptoms of pregnancy-related constipation is the first high-degree systematic review in terms of the period in which the articles were published, the number of studies examined and the number of databases. The most noteworthy strength of the study was that it revealed that the number of studies on the effects of CAM on the reduction of the symptoms of pregnancy-related constipation was very few, and that in the future, on this issue, more studies with larger samples should be conducted.

CONCLUSION

Diagnosis and treatment in CAM is often complicated. Although the duration of interventions for each CAM method was determined in some studies, this cannot be generalized to all CAM treatments. Today, in the medical literature, more studies should be carried out to provide evidence of molecular biology for the use of CAM methods in individual diagnosis and intervention within the framework of the concept of "Individualized Medicine".[7] CAM methods used in reducing the symptoms of pregnancy-related constipation differ from one study to another, in terms of the type of the study, and the application method, measurement tools and assessment methods used in the study. This systematic review of 3 studies (2 on the use of herbal medicine and 1 on the use of foot reflexology) demonstrated that the methods used in these 3 studies were effective in reducing the symptoms of pregnancy-related constipation. In order to provide valid evidence on the long-term safety of CAM applications, a large number of well-designed randomized controlled trials with larger samples should be performed in the future.

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REVIEW

Trditional Chinese Medicine: The Effect on the Human Therapy

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Abstract
Traditional Chinese Medicine (TCM) is an ancient system of health that has been used in China for thousands of years. TCM has played an essential role in treating disease and enhancing human health. This Traditional Medicine used 2500 years ago is based on some ancestral concepts and many medical approaches. This review aimed firstly to show you an overview about the history of Chinese medicine. In the second part, it will be focused to present a few pillars which influence human therapy and are still used in clinical today to treat modern diseases.
Keywords: Traditional Chinese Medicine, Human Therapy, Chinese Herbal Medicine, Acupuncture

INTRODUCTION

Traditional Chinese Medicine (TCM) is an old health and wellness system that has been used in China for thousands of years. TCM is based on balance, harmony, and energy. There are two central ideas behind TCM:

a) Qi: Also called energy or vital force. According to Chinese Medicine, Qi circulates throughout the body and is constantly changing. Treatments for TCM often focus on ways to maintain the flow of qi [(1)].

b) Yin and Yang: These are opposites that describe the qualities of Qi. Yin is associated with the cold, the night, the feminine and the negative. Yang is associated with daylight, warmth, positivity, and masculinity.

According to traditional Chinese medicine, when you balance the yin and yang of Qi, you feel good and healthy. So when they are out of control, you feel sick. Chinese medicine focus to create a healthy flow of qi.

In this review, the essential principles and concepts used in this medicine will be clarified by presenting an overview on the history of TCM. In the second part, a few pillars and strategies used in this medicine as a human therapy to treat some dangerous diseases will be explained [(2)].

History of traditional chinese medicine:

TCM is largely used in the Sinosphere [(3) (4) (5)], and has evolved a long history since the first traces of practice dates to 1000 BCE (Before the common Era). Since then, it has continued to develop and evolved by a successive dynasty in China.

Traces of therapeutic approaches in China dates from the **Shang dynasty** (1850- 1122 BCE) and **Zhou** (1121-771 BCE). According to these dynasties, Epigraphic data investigated the existence of primitive Chinese medicine related to natural and spiritual concepts. Because of furious desires expressed by ancestors, Therapy then consisted of satisfying them by giving earthly gifts such as clothing, food, tea, and other offerings [(6)].

Before the 19th century, to design all forms of medicine in China, the term Yi was generally used(醫) which means "medicine", and the variant is the character (毉). When compared these two ideograms, we notice that the lower part of "Yi" (醫) turns into (巫) which means the "magic". This allows us to suggest that, during antiquity in China, Medicine and Magic were related disciplines for treating disease [(7)]. The artifacts that better represent the history of the Shang Dynasty are oracle bones.

In the oracle inscriptions bone, it was found some characters refer to diseases that affected the Shang royal family such as: "nose illness, head illness, eye illness", etc. This proves that Shang people had a concept of illness and on the specificity and localization of illness [(8)].

Han Dynasty (206 BCE- 220 CE) is the first dynasty of unified China. Developed TCM continued and evoluted. During this period, three books were written that still considered today as fundamental classics:

a) Shén Nóng Běn Ca Jīng (神农本草经) **:** It is composed of 365 medical substances (including 252

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vegetables, 67 animals, 46 minerals) that are classified into three major groups according to their utility and toxicity level.

b) Shāng Hán Zá Bìng Lùn 伤寒 杂 **病** 论 which constitutes an essential role, both clinical pathology and Chinese pharmacology.

c) "Nan Jing" which clarifies knowledge about pulse diagnosis and acupuncture. The Nan Jing was the first Chinese work in which the medicine was no longer associated with magic and demonism [(7)].

During the period of **Sui** (590-617) and **Tang** (618-907) dynasties, Chinese civilization lives in political stability that promotes cultural and economic development. The main figure of this period is Sūn Sī Miao who wrote books on acupuncture and national pharmacopoeia [(8) (9)].

In another part, around 900-1000 AD (Anno Domini), the first precursor to a modern vaccination occurred in China. The Chinese were the first to explore and develop a primitive form of a vaccine around the 10th century. Known as inoculation or variolation, this method was developed to prevent smallpox- a dangerous disease that frequently plagued Asia and Europe in the Middle Ages [(10)].

The followed dynasties **Song and Yuan** (960-1368) were marked by a huge exploration in the field of chemistry, mainly that of distillation on aromatherapy and phytotherapy. From 1368 to 1643, the **Ming dynasty** came. This period was considered as a boom in acupuncture. Yáng Jì Zhōu displayed a synthesis of all knowledge concerning acupuncture and presented mainly around 670 acupuncture points [(11)]

During the Qing dynasty (1644-1911), new TCM works appeared, but under the influence of western ideologies, this ancestral and traditional medicine was more and more criticized [(12)]. Then came the Cultural revolution (1966-1978). During this period, the Chinese government performed large investments in traditional medicine and tried to develop public health facilities and inexpensive medical care. This movement started to define a new and modern China [(13)]. In the 19th century, Western doctors began to practice acupuncture. It was the diplomats who played an efficient role to import this discipline [(14)].

Today in China, TCM and Western medicine are associated and go hand in hand. Although there are hospitals dedicated to Chinese medicine and others to Western medicine, all Chinese medicine doctors are entitled to prescribe western medicines [(15)].

Tcm : Effect on the human therapy

While in the West, medicine seeks to cure diseases, in China, TCM focuses on caring for a human health. In this part, an essential pillar that can be developed to bring TCM more interesting will be discussed and how TCM can promote healthy people and the planet will be displayed. The essential therapeutic means used in traditional Chinese medicine for restoring and maintaining the harmony of the body in its environment are:

• Chinese Herbal Medicine
• Acupuncture

1) Chinese herbal medicine (CHM)

CHM is part of a vast healing system called Traditional Chinese Medicine (TCM), which also includes massage therapy, acupuncture, and exercise. The main principles of TCM differ from traditional Western notions about illness, the workings of the body and health [(16)]. Chinese herbs are prescribed to stabilize imbalanced energy that runs through invisible meridians in our bodies. The TCM concepts suggests that everything including body organs - is formed of the five elements: earth, fire, metal, water, and wood. The herbs are also classified into the five tastes - salty, sweet, bitter, sour, and pungent - which correspond to these five elements, for example (the skin is a metal element organ, it could be treated with a pungent herb) [(16) (17)].

Normally, CHM is mainly plant - based, but some preparations contain animal products or minerals. They can be packaged as pastes, powder, tablets, or lotions, depending on the herb and its previewed use. In this traditional Chinese medicine, herbs are used simply, somewhat in the manner of Western herbal medicine. Herbs most used include **Schisandra, lyceum, licorice, astragalus and astragalus** (Figure 1). Besides herbs, some substances considered as supplements are utilized in CHM such as glandular extracts, human placenta, and a variety of minerals [(18) (19)].

,Figure 1. *Examples of Herbal Chinese Medicine (https://acupuncturenutrition.com/therapies/chinese-herbal-medicine/)*

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For today, CHM can be used to treat any virtual condition including liver disease (cirrhosis and hepatitis), colds and flus, menstrual pain menopause, and cancer treatment support [(19) (20)].

2) Acupuncture:

a) Principles of acupuncture therapy:

The term acupuncture comes from the Latin acus, which means "needle" and pungere, which means "to prick". Today, according to the World Health Organization (WHO), it is used in more than 78 countries around the world. Traditional acupuncture is a therapeutic practice that involves stimulating specific points on the body called acupuncture points to relieve, prevent or cure a disease [(21)]. These points are mainly found at the level of the nerve endings: feet, hands, head, ears… The needles then promote nervous stimulation which will make it possible to restore the good circulation of vital energies in the body. Acupuncture uses the meridian system where energy flows. The needles are planted on some of the 361 acupuncture points, and act on the energy present in this point and which reflects the energy circulating in the meridian and the viscera that it serves**Hata! Başvuru kaynağı bulunamadı.**).

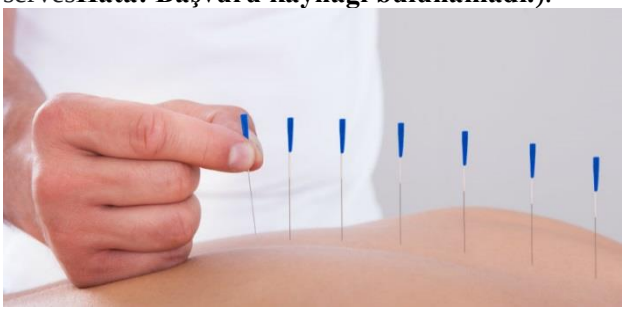

Figure 2. Principle of Acupuncture (https://www.sante-sur-le-net.com/acupuncture-place-urgences/

The points to be stimulated are defined by the therapist, after a complete examination of the person based on the taking the pulse in different parts of the body thus making it possible to assess the circulation of energy in the body [(22)]. Two old techniques derived from acupuncture are also to be mentioned: acupressure and moxibustion. Stimulation of the acupuncture points is then done by the pressure of fingers in acupressure or by a heat source in moxibustion [(23)] (Figure 3).

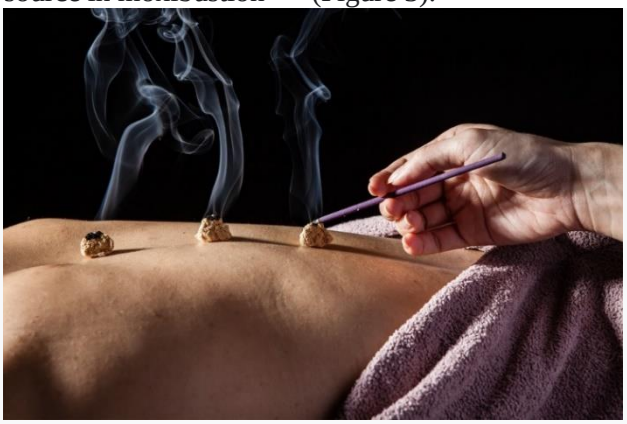

Figure 3. Principle of Moxibustion (https://www.britannica.com/science/moxa-treatment

Today, Electro-Acupuncture also show a development. It is an acupuncture technique in which small electrical impulses are applied to fine needles inserted at specific points [(24)].

CONCLUSION

The history of Chinese Medicine is constantly evolving. The "tradition invented" by Mao seems to be more than a transformation, a mutation of Chinese medicine into an "integrative" Chinese medicine as has been achieved already over the centuries. Chinese acupuncturists have always been careful not to reject previous concepts and have preferred to integrate them into the initial corpus. In China, even if acupuncture has been gradually rejected in favor of Western medicine, many different models persist where Western acupuncture and traditional acupuncture based on the great Classics coexist to unify and modernize the practice, which the West has called Traditional Chinese Medicine (TCM), but which for the Chinese is simply Chinese Medicine. The advantages of Chinese Medicine are numerous: Besides its preventive aspect, TCM benefits from a long history and continuous evolution. Therefore, it accumulates a knowledge which allows it a very wide field of application. Today, the main inconvenience of TCM that it is often compared and opposed to conventional Western medicine. In fact, these are mostly two visions and systems that can be mutually beneficia[6].

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REVIEW

Use of Aromatherapy in Diabetes Management

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Abstract
Diabetes has become a global health issue on a worldwide scale in our present day. In addition to long-term treatment, diabetes is a chronic disease with the participation of individuals in the disease and treatment processes, the self-care and self-efficacy of individuals. Individuals include complementary and supportive practices, along with medical treatments such as medication, nutrition, and exercise, into disease management processes. Complementary and supportive practices are among the practices frequently preferred by individuals in the management of chronic diseases. Complementary and supportive practices are preferred due to the side effects of the treatment protocols used in diabetes, which is one of the common chronic diseases, problems in the process of adherence with drug treatment and the need for long-term medical treatment, as well as the cost-effectiveness of complementary and supportive applications, easy accessibility and applicability. Aromatherapy, which is one of these practices, is preferred because it is effective, reliable, and can be easily applied by the patient. Aromatherapy is known as the use of essential oils obtained from plants for therapeutic purposes. Although aromatherapy has different methods of application, inhalation and massage often come to the fore. Positive effects of the application on anxiety, fatigue, sleep problems, and neuropathic pain were reported by many studies. In line with the results of the study, it should be supported with more sample groups and randomized controlled studies in this field. This review was planned to emphasize aromatherapy usage areas, methods of application, and their effectiveness in diabetes management.
Keywords: Diabetes Mellitus, Complementary Therapies, Aromatherapy, Nursing.

INTRODUCTION

Diabetes is an important healthcare problem at alarming levels with nearly half a billion people diagnosed on a worldwide scale. Although diabetic individuals were known to be 463 million in 2019, it is estimated to reach 578 million in 2030, and approximately 700 million with a 51% increase in 2045[1]. According to the International Diabetes Federation (IDF), Turkey has the highest comparative prevalence (11.1%) corrected according to age among countries in the European region. The biggest number of diabetic individuals is in Germany (9.5 million), in Russian Federation (8.3 million), and in Turkey (6.6 million)[1].

Diabetes, which is one of the most common chronic diseases, increases direct medical costs causing early mortality with complications, such as cardiovascular system diseases, renal failure, extremity amputations, vision loss, and nerve damage and great economic losses for individuals, families, healthcare systems, and national economies[2]. It was reported that approximately 4.2 million people between the ages of 20 and 79 died, which corresponded to a mortality level of every eight seconds because of complications associated with diabetes[1]. Diabetes-related complications are among the most important reasons for increased diabetes expenses in Turkey, and it is considered that complications make up three-quarters of the expenses [3]. As well as the drug treatment, medical nutrition treatment and exercise treatment[4], managing the disease processes for diabetic individuals includes maintaining ideal body weight, self-monitoring of blood sugar, and lifestyle changes, which leads to difficult and complex processes, complicating the adaptation processes because such self-management behaviors cause behavioral changes in diabetic individuals[5,6].

Since the disease management of diabetic individuals is difficult and complex, medical treatment, lifestyle changes, and complementary and supportive practices are used to improve the management of the process and quality of life[7]. It was reported that such practices

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are preferred for decreasing or balancing blood glucose[8,9], for avoiding complications[9] since they are cost effective and applied easily[10].

According to the results of the study, it was found that the frequency of using complementary and supportive practices in diabetic individuals varied by 27.6 - 75.3%[8-15]. Among the complementary and supportive practices used by diabetic individuals, there are cognitive-behavioral approaches, manipulative approaches, energy approaches, alternative medical systems, and biological approaches[10].

One of the most frequently used and most popular practices in biological approaches of complementary and supportive practices is aromatherapy, which is a non-pharmacological application that can be safely applied by nurses and transferred to clinic with different application methods, such as topical, internal, inhalation and oral routes[7]. Aromatherapy helps to alleviate health problems and improve quality of life[16] as an inexpensive and non-invasive method[17].

Aromatherapy

Although aromatherapy is known as the therapeutic use of essential oils that are extracted and distilled from flowers, barks, stems, roots or leaves of plants, its main purpose is to provide symptom control instead of treatment[18,19]. Essential oils, which are also defined as “etheric oils” or "essence", are called in this way as they evaporate at room temperature[20]. Aromatherapy, which means odor molecules and healing in literal terms [21,22] is used as a natural method to improve physical and psychological health[23]. It is known in our present day that there are approximately 150 essential oils[24]. Although more than 40 plant derivatives were identified for therapeutic usage, lavender, eucalyptus, rosemary, chamomile, and mint are the most commonly used ones[25].

Essential oils constitute a mixture of saturated and unsaturated hydrocarbons, alcohols, aldehydes, esters, ethers, ketones, oxides, phenols, and terpenes, which can produce characteristic odor. In this respect, they are colorless and fragrant liquids[22]. Essential oils are used after they are diluted with vegetable oils, which are also known as carrier oils because of their high concentrations[26,27]. Essential oils of plants are 100 times denser compared to the plant itself; and are stored in the veins, sacs, and glands of the plant revealing the aroma of essential oils when they are crushed or rubbed[28]. The parts of the plants some essential oils that are employed in aromatherapy are obtained from are given in Table 1.

Table 1. Plants producing essential oils[22]

Essential oils	Parts of the plant
Bergamot, lemon, lime, sweet orange, tangerine, mandarin	Fruit peel
Cinnamon	Bark
Citronella, lemongrass, petitgrain, palmarosa, patchouli	Leaves
Geranium, lavender, rosemary, spike lavender	Entire plant
Ginger, vetiver	Roots
Jasmine, neroli (orange blossom), rose, ylang ylang	Flowers

Usage areas of aromatherapy

Aromatherapy has a wide range of therapeutic usage areas in physical, emotional, and mental conditions.[20] Many essential oils employed in aromatherapy are known to have antimicrobial, anti-inflammatory, anti-stress, anti-depressive, and immune-enhancing effects[29].

There are many studies in the literature on different usage areas of aromatherapy[16,18,19,23,29-34]. When studies on aromatherapy were examined, aromatherapy was shown to be employed as an effective application to decrease fistula pain[30], and itching problems in individuals who receive hemodialysis treatment[31]. It was reported in previous studies that with their anti-inflammatory, antiseptic, analgesic and sedative effects, they can reduce pain caused by rheumatoid arthritis [19], the aromatherapy applied by using orange essential oil reduced pain and anxiety levels in individuals with extremity fractures[23], and can help to increase positive effects on fatigue and sleep quality in individuals[32]. Studies on the effects of aromatherapy on students reported that aromatherapy has positive effects on test anxiety in students[18] and the use of aromatherapy in tests may be a good option to help students[33].

It was also shown that aromatherapy provides better sleep quality[29], has positive effects on blood glucose levels[16] and decrease pregnancy-related lower back pain[34] result in lower perceived stress and depression levels. Some commonly used essential oils and their usage areas are given in Table 2.

Aromatherapy application methods

The oils used in aromatherapy are used as topically (it can be applied by touch, through compress to the skin, or baths), internally (application as mouthwash, vaginal or by rectal route to the mucosa), inhalation (directly or indirectly, with steam, or by non-vapor inhalation), and orally (by applying with gelatin capsules or by watering in honey, alcohol or any other diluents)[19,28,35].

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Table 2. Some essential oils and their properties[28]

Oils	Properties
Lavender (Lavandula angustifolia)	Skin regenerative: For burns, wound healing, insect bites, mild eczema. Calming, good for insomnia and depression, good for stress. Reduces agitation in dementia. Enhances sense of well-being. Effective against ticks. Fungistatic, not fungicidal.
Peppermint (Mentha piperita)	Analgesic, migraine, postherpetic neuralgia. Antinausea, opiate detoxification. Useful in treatment of irritable bowel syndrome (antispasmodic). Antibacterial; useful in sinusitis.
Tea Tree (Melaleuca alternifolia)	Bacterial infections, acne. Fungal infections including athlete's foot, tinea. Most skin infections, including impetigo, cold sores, herpes, and warts. Mouth infections. Antiviral, including influenza, antitumoral. Vaginal infections, especially Candida albicans. Tea tree can be diluted and used as a vaginal douche for infections, or it can be diluted in carrier oil and used on tampon: put 2 drops of tea tree oil in 1 teaspoonful of carrier oil, roll tampon in mixture, and insert into vagina. Repeat with fresh tampon every 4 hours and leave in overnight. Relief should occur within 48 hours. Vaginal thrush should not reoccur
Blue Gum (Eucalyptus globulus)	Respiratory complaints, Effective against pneumonia in ventilated patients. Effective against head lice. Antibacterial.

Although inhalation is a method used commonly to apply in aromatherapy[36], it shows its effect faster[37]. Fats enter the body via the nasal mucosa and lungs, reach the bloodstream and have systemic effects[36]. The sense of smell plays important roles in the physiological functions in individuals. The olfactory molecules of essential oils are transmitted to the brain via olfactory sensory neurons in the nasal cavity. Even a small amount of odor molecules in breath cause indirect physical effects by activating the olfactory memory or via absorption of it in the bloodstream[38]. Steam, aroma stones, strips of oil-scented fabrics (cloth soaked in oil solution), or diffuser aromatherapy inhalation are also used in this respect[39].

Topical application of aromatherapy can be in the form of essential oils absorbed by the skin via diffusion and since they are lipophilic with the ability to be stored in fatty areas of the body and cross the blood brain barrier. It was also reported in previous studies that there is some evidence showing that massage and hot water increase absorption[28]. Each massage type can be employed in aromatherapy, and the key in aromatherapy massage is selecting the proper oil. The effects of aromatherapy massages appear with the massage itself and the oil used[19,36]. Oils circulate in about 30 minutes during aromatherapy massage and are then excreted from the body in a few hours[26,27].

Another option for the topical application of aromatherapy is aromatherapy bath. The therapeutic substances in essential oils pass through the oil and sweat glands, and via the airway into the bloodstream during aroma therapeutic bathing. It is recommended that the temperature of the water is approximately 40°C, and the bath lasts about 15-30 minutes. It is also important not to use soaps and foaming agents. After the bath, the body should be rinsed with water and dried completely. Aromatherapy bath can be supported with hydro massages or underwater massages[36].

The oral use of essential oils is applied with gelatin capsules[39] after being prepared by mixing alcohol, honey water, and vegetable oils[35]. Oral use of essential oils is reported to be safe when the appropriate dosage guidelines are followed[40].

The application of essential oils via internal absorption includes fragrant mouthwash, fragrant suppository, and vaginal shower[39]. Vaginal application is considered to be effective in cystitis and fungal infections[28].

Use of aromatherapy in diabetes management

Aromatherapy is used for the solution of many problems in diabetic individuals. Studies conducted show that aromatherapy was related with the management of anxiety in individuals with diabetes [41,42] fatigue[32,42], sleep quality[16,32,43], and neuropathic pain[44,45].

Diabetic individuals face many accompanying problems, which include anxiety and fatigue[42,46,47]. Factors, such as a chronic disease, hospitalization process, problems in adapting to the disease and treatment processes, complications that might develop because of diabetes, emotional stress, and the long-term treatment process cause more anxiety with the diagnosis of diabetes in diabetic individuals[42,48]. It was reported in studies which examined the effects of aromatherapy on anxiety that orange and bitter orange oil were preferred frequently, and aromatherapy applied with inhalation was a useful application in anxiety management[41,42].

In diabetes, fatigue is a common condition in diabetic individuals, and is associated with physiological conditions caused by the changes in blood glucose levels. The course of the disease, blood glucose levels, sleep disorders, decreased physical activity, and diabetes-related complications are considered to be among the factors causing fatigue[49,50]. Fatigue has adverse impacts on the ability of diabetic individuals to perform self-management behaviors[46]. There are also several studies reporting that aromatherapy has effects on fatigue. Aromatherapy was reported as an

application that may have positive impacts on fatigue in individuals[32,42].

One of the problems diabetic individuals often face is sleep disorders, which are considered to affect glucose metabolism[43]. Problems such as diabetes-related nocturia, polyuria, diabetic neuropathy, and neuropathy-related pain cause sleep problems in individuals[51]. It was reported that aromatherapy has effects on sleep quality in diabetic individuals[32], and improves sleep duration and overall sleep quality[16,43]. For this reason, it is considered that aromatherapy may be a safe, non-invasive, and effective approach for clinical nurses in routine care to improve the sleep quality of diabetic individuals[16].

Both microvascular and macrovascular complications develop because of diabetes, and neuropathy is common among microvascular complications[2]. Peripheral distal neuropathy, mononeuropathy, and autonomic neuropathy are among the types of neuropathy[52]. The reported prevalence of peripheral neuropathy related to diabetes ranges between 16% and 87%, and the rate of painful neuropathy was reported as approximately 26%[1].

Aromatherapy is applied in diabetic individuals who have neuropathic pain, and it was reported that combining aromatherapy with different massage techniques increased its effectiveness on neuropathic pain management[45]. The study that examined the effects of aromatherapy massage on neuropathic pain was conducted with 46 diabetic individuals and 5 different essential oils (e.g. coconut oil as the carrier oil, and rosemary, geranium, lavender, eucalyptus, and chamomile oil) were used as essential oils in aromatherapy massage. The patients who underwent aromatherapy massage received 12 aromatherapy massage sessions throughout 4 weeks with each massage lasting 30 minutes. Aromatherapy massage was determined to be a simple, effective, and non-pharmacological nursing intervention that could be used to manage neuropathic pain and to improve quality of life in diabetic individuals with painful neuropathy[44]. Another study that examined the effect of aromatherapy massage on neuropathic pain in individuals with type 2 diabetes was conducted with 60 diabetic individuals, and rosemary, eucalyptus, and lavender oil were preferred as essential oils; and sunflower oil was used as the carrier oil for one month 3 times a week for each patient with each session lasting about 30 minutes. It was concluded that aromatherapy massage is an effective nursing initiative in decreasing neuropathic pain in individuals with type 2 diabetes[45].

CONCLUSION

Although diabetes has become a global epidemic, complications related to diabetes increase mortality and morbidity in individuals affecting their quality of life, self-care, and self-sufficiency levels. As well as drug therapy, nutritional therapy, and exercise therapy, non-pharmacological treatment methods are also used in diabetes. Aromatherapy, which is among the complementary and supportive practices, is applied in many areas, such as anxiety, fatigue, quality of life, sleep problems, and neuropathic pain, which are common in diabetic individuals. It was determined that inhalation and aromatherapy massage method are used most commonly in aromatherapy. It is considered that the quality of life increases after applying aromatherapy on sleep problems, neuropathic pain, anxiety, and fatigue, which are associated with diabetes, by decreasing these effects in individuals. Aromatherapy is considered a holistic nursing initiative, which can be applied by nurses to the problems experienced by individuals. Nurses must pay attention to the effects, contents, appropriate way, appropriate oil, appropriate frequency of aromatherapy oils used during aromatherapy. They are expected to have the necessary knowledge and skills to perform these practices. Studies are needed with larger sample groups and different disease groups to determine the efficacy of aromatherapy and increase evidence levels.

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