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Chronic Diseases Journal

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1. Perlman AI, Sabina A, Williams AL, Njike VY, Katz DL. Massage therapy for osteoarthritis of the knee: a randomized controlled trial. Arch Intern Med 2006; 166(22): 2533-8.

2. Buckwalter JA, Marsh JL, Brown T, Amendola A, Martin JA. Articular cartilage injury. In: Robert L, Robert L, Joseph V, editors. Principles of Tissue Engineering. 3rd ed. Burlington, MA: Academic Press; 2007. p. 897-907.

3. Kuczmarski RJ, Ogden CL, Grammer-Strawn LM, Flegal KM, Guo SS, Wei R, et al. CDC growth charts: United States. Advance data from vital and health statistics. No. 314. Hyattsville, Md: National Center for Health Statistics, 2000. (DHHS publication no. (PHS) 2000-1250 0-0431)

4. World Health organization. Strategic directions for strengthening nursing and midwifery services [online]. Available from: URL:http://www.wpro.who.int/themesfocuses/theme3/focus2/nursingmidwifery.pdf2002

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Original Article(S)

Letter to the Editor(S)

Chronic Diseases Journal

DOI: 10.22122/cdj.v3i2.65 Published by Vesnu Publications

Stress and its related factors in families of patients with cancer

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Original Article

Abstract

BACKGROUND: Cancer is one of the most common kinds of chronic diseases. In addition, it is a cause of stress in the family members of the patient. Therefore, the aim of this study was to determine the amount of stress and its related factors in families of patients with cancer.

METHODS: In this descriptive study, 96 family members of cancer patients admitted to 3 hospitals in Ahvaz, Iran, were recruited in the study. Data gathering tools consisted of the Perceived Stress Scale (PSS-14), and a researcher-made questionnaire for demographic data and factors associated with caregiver stress. Collected data were analyzed using SPSS software.

RESULTS: A total of 55 (57.3%) subjects showed moderate stress levels and 20 subjects (20.8%) showed severe stress levels. There was a significant relationship between the levels of stress and age of less than 30 years and female gender. Moreover, a significant relationship was observed between the level of stress and factors such as uncomfortable treatment environment, feeling dissatisfied with staff, fear of recurrence, difficulties in everyday life, no spiritual practice, negative attitudes toward treatment outcome, refusing to participate in favorite activities, changes in interactions with others, lack of leisure time, imbalance between daily responsibilities and care, inadequate income, and lack of appropriate facilities ($P < 0.05$).

CONCLUSION: There were several factors causing stress in patients' families. It is recommended that nurses and the medical team be informed of these factors in order to manage stress in patients and their families.

KEYWORDS: Traumatic Stress Disorders, Family, Cancer, Chronic Disease

Date of submission: 18 Nov 2014, *Date of acceptance:* 25 Jan 2015

Citation: Rasouli-Ghahfarkhi SM, Molahosseini Sh. **Stress and its related factors in families of patients with cancer.** Chron Dis J 2015; 3(2): 45-54.

Introduction

Unlike 100 years ago, today, the main cause of death in the United States is not communicable diseases, but chronic diseases.[1] Chronic disease is attributed to any condition of prolonged illness such as cancer.[2] They include diseases that occur in every age group or every economic, social, and cultural group. It is anticipated that by 2050, about 167 million people will suffer from chronic diseases worldwide and the estimated cost for this number is about $797 billion.[3] Cancer does not only involve the patient, but it is a cause of stress in family members as well.[4] The annual incidence of cancer and mortality due to cancer in Iran is about 70,000 and 30,000 cases, respectively.

In view of the increase in life expectancy and increasing percentage of elderly population in Iran, a considerable increase in the incidence of cancer is expected in coming decades.[5] Due to the interdependence among family members, the health of each family member is affected by the health and wellbeing of other members. Family caregivers are an essential component of health services in the community.[6] The role of patient care in

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the family can cause burnout and psychiatric disorders for caregivers.[7]

Families with a patient could be considered as vulnerable families.[8] Vulnerable families should be examined in terms of stress, driving force, and the dynamics of health or functional impairment.[2] Several studies have shown that families of cancer patients have high levels of stress, bearing in mind that various factors may play a role in its incidence and severity. Tang et al. conducted a study in Taiwan in 2007 to determine the factors associated with stress among families of patients with cancer.[9] Their results showed that more than three quarters (75.9%) of the caregivers were at high risk of stress. Caregivers who were also the patient's spouse had negative views on the costs, lifestyle, and financial position, and were more prone to stress. Other researchers believed that stress is significantly related to age, gender and, care of patients with chronic diseases.[9-13]

Therefore, care and support for family members of patients is of great importance. However, the study by Takman and Severinsson indicated that not enough attention is paid to these individuals and they are not supported well.[14] Regardless of the type of cancer treatment or prediction of the disease course, patients and their families are prone to various problems. An important role of nurse is to examine the patient and his/her family to determine their problems and to resolve them.[15] In Iran, there are a limited number of studies that have examined the impact of cancer on family members; thus, further investigation is required. Therefore, this study was performed to determine the level of stress and its related factors in families of patients with cancer.

Materials and Methods

The research population of this descriptive study consisted of family members of cancer patients (including spouse, father, mother, sister, and brother who were the main care provider and patient's companion in the hospital) who were referred to Golestan and Shafa Hospitals of Ahvaz, Iran, in 2011. The sample size was determined as 96 people through convenience sampling and consideration of 5% error (P = 0.5 and d = 0.1). The inclusion criteria were consenting to participate in the study and being an immediate family member of the patient, being responsible for the patient's home care, and accompanying the patient in the hospital. Exclusion criteria were being relatives of patients who expired after admission to the clinic, 2-not being a fixed care provider of the patient (confirmed by the researcher), and having a diagnosed mental problem.

Selected subjects for the present study were examined in terms of having the necessary criteria through interviews. Moreover, the objectives of the study were explained to the study subjects and their informed consent to participate in the study was obtained within 4 months. Data gathering tools consisted of the Perceived Stress Scale (PSS-14) and a researcher-made questionnaire for demographic data and factors associated with caregiver stress on personal, psychological, social, economic, and cultural aspects. The PSS-14 contains 14 items that measure general stress based on a 5-point Likert scale. Total level of stress was classified, based on the acquired score, as low (5-19), medium (20-35), and high stress (> 35). The PSS-14 was prepared in 1983 by Cohen et al.[16] The validity of the scale was confirmed in a study conducted by Fliege et al. in Germany.[17] This questionnaire has been used frequently in the Iranian society and its validity has been confirmed.[18,19]

In this study, the reliability of the tool was determined as 0.85 using test-retest. The second tool was a researcher-made questionnaire with 59 questions. Content validity and test-retest were used to determine

its validity and reliability. A questionnaire was prepared after a study of up to date books and articles related to the topic and views of professors and counselors.[3,10,20-31] Then, opinions of 10 nursing and midwifery specialists of the Islamic Azad University, Tehran Medical Branch, Iran, and 2 physicians of the oncology wards were obtained. After gathering their comments and revisions, the final version of the questionnaire was adjusted. Its Cronbach's alpha was calculated as 0.84 that indicates its appropriate reliability. The questionnaires were completed through face-to-face interviews with participants in privacy in order to avoid the influence of other factors. Data were analyzed using SPSS software (version 16, SPSS Inc., Chicago, IL, USA) and applied and descriptive statistical analysis including t-test, ANOVA, and regression analysis.

Results

In the present study, 63 cancer patients were female (65.6%), their mean age was 43.27 ± 20.38, and 60 cases were married (62.5%). The majority of them had a high school diploma (24%). Among the patients, 58 cases were unemployed (67.7%), 65 cases had insurance (67.7%), and 33 cases suffered from breast cancer (34.3%). Most cases were under therapy for less than 6 months (42.7%) (Table 1). Among the subjects, 64 cases (67%) were female and 32 cases (33%) were male, and their average age was 38 years. In relation to stress level, 55 of the subjects (57.3%) had a moderate stress level and 20 (20.8%) of them had a high stress level (Table 2). In relation to stress related factors of family members, results of t-test and ANOVA indicated that there was a statistically significant relationship between stress and the mentioned factors.

Table 1. Demographic characteristics of cancer patients

Variables		n (%)
Age (year)	<_19	20 (20.80)
	20-39	9 (9.40)
	40-59	48 (50.00)
	≥ 60	19 (19.80)
Gender	Male	33 (34.40)
	Female	63 (65.60)
Marital status	Married	60 (62.50)
	Single	27 (28.10)
	Separated	0
	Expired spouse	9 (9.40)
Employment status	Unemployed	58 (60.40)
	Employee and workers	11 (11.40)
	Retired	18 (18.80)
	Housekeeper	5 (5.20)
	Student	4 (4.20)
Insurance status	Yes	65 (67.70)
	NO	31 (32.30)
Type of cancer	Blood	14 (14.50)
	Lung	10 (10.40)
	Breast	33 (34.30)
	Colon	5 (5.20)
	Prostate	2 (2.08)
	Others	32 (33.30)

Table 2. Distribution of absolute and relative frequency of subjects in terms of stress level

Stress level	n (%)
Low	21.9 (21)
Moderate	57.3 (55)
Severe	20.8 (20)
Sum	100 (96)

There was a statistically significant relationship between stress and age of less than 30 years (P = 0.002), being female (P = 0.030), lack of comfort in the working environment (P = 0.010), dissatisfaction with the staff of health centers (P = 0.010), and fear of recurrence (P = 0.002). There was also a statistically significant relationship between stress and occurrence of health care problems (P = 0.003), lack of spiritual belief (P = 0.040), and negative attitude towards success of the treatment (P = 0.010). Moreover, a statistically significant relationship was observed between stress and non-participation in favorite activities (P = 0.001), a change in interaction with others (P = 0.005), not having time for fun (P = 0.03). There was a statistically significant relationship between stress and not establishing a balance between the responsibilities of everyday patient care (P = 0.001), low economic status (P = 0.04), and lack of appropriate facilities (P = 0.030) (Table 3).

There was no statistically significant relationship between stress and demographic variables, including education level (P =0.240), marital status (P = 0.280), caregiver relation to the patient (P = 0.06), parental responsibility (P = 0.150), employment status (P = 0.330), duration and hours of patient care (P = 0.260), hours of care per day (P = 0.290), history of patient care (P = 0.440), physical disease (P = 0.810), and history of drug abuse (P = 0.720). Furthermore, no statistically significant relationship was observed between stress and other psychological variables, including right to decision making in respect to care (P = 0.620), and concerns about themselves (P = 0.620). There was no statistically significant relationship between stress and cultural variables, including type of religion (P = 0.900), knowledge about the disease and patient care (P = 0.310), source of information (P = 0.600), and supporting and encouraging other family members to care for the patient (P = 0.670). There was also no statistically significant relationship between stress and economic variables, including housing status (P = 0.080).

In addition, the result of regression analysis indicated a statistically significant correlation between stress and many factors, and a significant association between stress and problems in life, comfort in the working environment, and fear of recurrence of the disease (Table 4).

Discussion

Results of this study showed that the majority of family members of patients with cancer had a moderate stress level (57.3%). The results indicate that many factors affected perceived stress in family members of patients. In relation to personal factors, the results of t-test and ANOVA indicated that family members of less than 30 years of age, and female family members were more prone to stress. However, regression analysis results did not show this. Kim et al., in their study, concluded that demographic and psychosocial characteristics, such as being young, were associated with caregiver distress.[32] Moreover, Yousafzai et al., in their study, concluded that there was a statistically significant relationship between stress levels and gender.[11]

Nevertheless, the results of the study by Kim and Schulz showed that there was a significant relationship between stress and higher ages.[10] The reason for this difference could be the fact that the participants in the present study

Table 3. Distribution of mean stress and its related factors in families of patients with cancer

Variable			Mean ± SD	Result
Personal factors	Age	> 30	3.33 ± 8.60	F = 5.45
		30-39	27.85 ± 7.13	P = 0.002
		40-49	31.28 ± 9.11	
		≥ 50	25.45 ± 7.71	
	Sex	Male	24.34 ± 8.56	t = 2.18
		Female	28.40 ± 8.90	P = 0.030
Psychological factors	Convenience in the medical environment	Never	31.72 ± 8.81	F = 6.21
		Rarely	30.46 ± 7.60	P = 0.010
		Often	27.87 ± 7.54	
		Frequently	22.39 ± 8.90	
		Always	19.75 ± 8.77	
	Satisfaction with health care workers	Never	33.00 ± 9.89	F = 3.54
		Rarely	34.28 ± 5.73	P = 0.010
		Often	29.41 ± 9.00	
		Frequently	25.85 ± 7.72	
		Always	23.75 ± 8.70	
	Fear of Recurrence	Never	20.66 ± 11.09	F = 4.69
		Rarely	16.16 ± 6.52	P = 0.020
		Often	25.00 ± 7.87	
		Frequently	27.73 ±5. 72	
		Always	29.26 ± 8.92	
	Creating problems in life	Never	22.25 ± 7.71	F = 4.41
		Rarely	22.15 ± 8.82	P = 0.003
		Often	26.50 ± 8.40	
		Frequently	28.45 ± 8.25	
		Always	31.34 ± 8.14	
Social factors	Participating in favorite activities	Yes	23.15 ± 9.10	t = 3.38
		No	29.05 ± 7.83	P = 0.001
	Changes in interactions with others	Yes	28.72 ±7.63	t=2.86
		No	23.65 ± 9.60	P =0.005
	Having a fun time	Yes	24.25 ± 9.30	t=2.17
		No	28.20 ± 8.21	P =0.030
	balance between the responsibilities of everyday life and patient care	Yes	25.17 ± 8.44	t=3.43
		No	32.23 ± 7.94	P =0.001
Cultural factors	Prayer	never	24.00 ± 7.93	F = 2.48
		rarely	34.18 ± 8.47	P = 0.040
		often	26.03 ± 8.30	
		frequently	25.23 ± 7.83	
		always	26.47 ± 9.93	
	Belief in the success of treatment	yes	25.86 ± 8.41	t = 2.57
		no	32.66 ± 9.54	P = 0.010
Economic factors	Adequacy of income	yes	24.20 ± 8.68	t = 2.43
		no	28.51 ± 8.51	P = 0.010
	Appropriate facilities	yes	25.51 ± 8.47	t = 2.12
		no	29.64 ± 9.05	P = 0.030

SD: Standard deviation

Table 4. Distribution of mean stress and its correlation with many factors

	Unstandardized Coefficients		Standardized Coefficients	P	95.0% CI for B	
	B	StandardError	Beta		Lower Bound	Upper Bound
Constant	27.222	4.912		< 0.001	17.454	36.989
Age	-0.015	0.040	-0.036	0.699	-0.095	0.064
Gender	0.588	1.668	0.032	0.725	-2.730	3.906
Difficulties in daily life program	1.332	0.667	0.205	0.049	0.006	2.658
Being comfortable in treatment environment	-2.515	0.680	-0.334	< 0.001	-3.868	-1.162
Fear of recurrence	1.722	0.674	0.240	0.012	0.382	3.061
Belief in the result of treatment	-1.441	2.399	-0.054	0.550	-6.212	3.329
Participate in favorite activities	-2.257	1.773	-0.126	0.207	-5.782	1.269
Changes in interactions with others	0.501	1.735	0.028	0.774	-2.950	3.951
Having leisure time	1.472	2.001	0.081	0.464	-2.508	5.452
Balance between daily responsibilities and patient car	-2.583	2.048	-0.122	0.211	-6.655	1.490
Adequacy of income	-1.440	1.742	-.0810	0.411	-4.904	2.024

CI: Confidence interval

were relatively young and their average age was low. They often cared for someone who was older than themselves. Furthermore, in our country, the majority of parents and children live together and due to their patients' disease, children may be faced with a change in roles or decision making in critical condition. A significant relationship was not found between stress and other personal factors.

Yousafzai et al., in their study in Pakistan, concluded that there was a significant relationship between stress and caregiver relationship.[11] Bainbridge et al. found a significant relationship between the amount of stress experienced by the family members and the amount of time caring for the patient during the day.[33] However, the by Park also showed that there was a significant relationship between the level of stress in the family caregivers and the availability of second caregiver.[13]

All these cases may be related to cultural issues governing the study population and the dependency among family members in the society. In relation to psychological factors, people who were uncomfortable with medical care facilities, were not satisfied with medical staff, and were always concerned about their patients' recurrence, and who were faced with problems were more stressed than others. The results of a survey conducted by Mellon et al. showed that fear of recurrence and lack of social support was related to the amount of stress experienced by patients and their families during the course of the disease.[34]

According to these results, family members needed direct support from the medical staff. Paying more attention to family members of patients, answering their questions, and educating them on diseases and their process could have a significant impact on stress reduction. It is recommended to consider strategies by which family members of these patients who are often their caregivers can be provided with better conditions to perform their duties. No significant relationship was found between stress and decision making right in respect to care and concerns about self-suffering. Winter et al. found that in subjects who did not have the right of decision making for care, the amount of stress was three times that of those who did.[35] This may be because of the high interdependence among family members in our society, and that, in critical cases, caring for an individual and performing health care tasks is a major family role. Many

researchers have emphasized this issue, especially in Asian countries.[2,7,36,37]

In relation to cultural factors, no significant relationship was found. However, Sayegh and Knight, in their study, concluded that family and cultural background have an indirect role in mental health.[38] No significant correlation was found between stress levels and type of religion, awareness about the disease and patient care, source of information, supporting and encouraging other family members to care for the patient. The results of this study are not consistent with the results of the study by Tang et al.[9] They concluded that families who have confidence in their knowledge of patient home care or have adequate awareness about the patients' experience and signs of disease rarely suffer from stress and distress.[9] This issue may be associated with subjects' education or cultural factors governing the statistical population and requires more investigation. Based on the study by Gaugler et al., caregiver optimism toward the result of treatment has a powerful impact on various aspects of stress.[39] In a study conducted in 2009 by Hasson-Ohayon et al., it was found that religious beliefs and practices play an important role in the outcomes of psychological adaptation to cancer.[40]

Nevertheless, results of t-test and ANOVA indicate that people who rarely performed spiritual practices and did not believe in the results of treatment were more likely to suffer from stress. A large number of studies on the relationship between spirituality and health are rooted in measurement of beliefs and religious activities. Some benefits of spirituality are increased sense of well-being and reduced stress.[22] In relation to social factors, those family members who could not participate in their favorite activities were suffering more from stress than others.

The results of this study were consistent with that of previous findings. Chimeh et al. stated that caregivers had no time to spend with friends, for social life, holidays, retreats, and fun, and this restriction of social life can threaten the mental state of a person.[7] Furthermore, in the research by Kim and Given, family members identified many problems of their care giving experience including conflict in the social role.[21]

No significant correlation was found between stress levels and family members who could not participate in their favorite activities, whose relationship with others had changed, and who had no time for leisure and had failed to establish a balance between daily responsibilities and patient care. However, the results of t-test and ANOVA were consistent with this finding. These results imply that family members of patients need time for rest and personal activities and continuing this process can jeopardize an individual's mental health. Thus, extensive planning is necessary to perform appropriate care.

No significant correlation was found between stress and economic factors. Nevertheless, in many studies, low income family members who did not have appropriate facilities experienced more stress than others. In their study, Kim et al. noted that psycho-social and demographic characteristics, including lower socioeconomic status, are associated with distress in caregivers.[32] In addition, the results of studies by Taylor et al.[41] and Craven and Hirnle[42] and results of t-test and ANOVA are consistent with this finding; therefore, this topic requires further investigation. Particular attention should be paid to the economic problems of family members of cancer patients and careful planning in this respect is required.

Today, social workers and insurance departments are present in most of our hospitals, but given the high cost of chronic disease treatment, a particular program should be adopted for all of them. From this study, it can be concluded that several factors are associated with perceived stress levels of

family members of patients with cancer. Therefore, the results of this study can be used in the clinical field by clinical, community, and mental health nurses to identify vulnerable families, provide more appropriate services, play a supporting role in stress management, and to consider this important issue in their nursing care planning. Moreover, in terms of education, the findings of this study and similar studies can be used by educational planners to train nursing students (theoretical and practical training) to recognize factors associated with stress in patients' family members and perform appropriate care. The findings of this study can be considered by nursing service managers in the provision of in-service training courses for nurses, particularly those in oncology wards, to provide them with required, new, and accurate information in the field of care and stress management of family members of patients with cancer. In the field of research, the results of this study can help researchers identify psychosocial problems more precisely and in terms of stress management of patients' family members. Further researches on the relationship between stress-related factors in families of patients with a particular type of cancer are also recommended. In addition, comparative studies should be undertaken to understand the problems and stressors of family members.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

This article was sponsored by the nursing and Midwifery School of Islamic Azad University, Tehran Medical Branch. We would like to thank the Deputy of Research of the School of Nursing and Midwifery and staff of Golestan, Naft, and Shafa Hospitals of Ahvaz for their cooperation.

We would also like thank all families who participated in this study despite their problems related to patient care.

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Chronic Diseases Journal

DOI: 10.22122/cdj.v3i2.139 Published by Vesnu Publications

The effects of Tranquival tablet on some heroin withdrawal symptoms

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Original Article

Abstract

BACKGROUND: Individuals, during opioid withdrawal period, experience symptoms such as dysphoria, insomnia, anxiety, irritability, nausea, agitation, tachycardia, and hypertension which may trigger drug seeking behavior and relapse. This study was conducted with the aim of determining the effect of Tranquival tablets on some heroin withdrawal symptoms in addicted patients referred to an outpatient clinic.

METHODS: In this single-blind quasi-experimental study, 69 patients (37 patients in intervention group and 32 in control group) suffering from heroin withdrawal syndrome were allocated randomly to study groups. In the intervention group, 1 Tranquival tablet was administered 1 hour before sleeping each night for 6 weeks. In the control group, 1 tablet of clonazepam (1 mg) was administered at the same time. The Pittsburgh Sleep Quality Index (PSQI), Hamilton Anxiety Rating Scale (HAM-A), and visual analogue scale (VAS) were completed at the beginning, 3 weeks later, and the end of the study. Data were analyzed using Student's t-test, repeated measures analysis, and chi-square test.

RESULTS: During the study period in both groups, withdrawal symptoms significantly decreased ($P < 0.001$); however, this difference was insignificant between the 3 assessment steps ($P > 0.050$). Furthermore, the Bonferroni correction showed an relationship between Tranquival and clonazepam groups in terms of mean anxiety at the begining and the end stage of assessment ($P = 0.012$). However, these relationships were insignificant in terms of mean sleep and muscular pain ($P = 0.153$ and $P = 0.267$, respectively).

CONCLUSION: Tranquival was as effective as clonazepam in the reduction of muscular pain and anxiety, and improvement of sleep quality in patients suffering from heroin withdrawal syndrome.

KEYWORDS: Clonazepam, Heroin Dependence, Substance Withdrawal Syndrome

Date of submission: 27 Nov 2014, ***Date of acceptance:*** 21 Jan 2015

Citation: Nikfarjam M, Sadeghi M, Parvin N, Deris F. **The effects of Tranquival tablet on some heroin withdrawal symptoms.** Chron Dis J 2015; 3(2): 55-63.

Introduction

Heroin is one of the most commonly used drugs among drug users in both developed and developing countries. Methadone maintenance treatment (MMT) has been found to be an effective harm reduction program for drug users.[1] Methadone is a long-acting synthetic opioid with high attraction to various opioid receptors and has been used as a successful pharmacologic treatment for patients with heroin dependency, and acute and chronic pain.[2] However, there are few studies which comparatively examined the development and course of withdrawal symptoms in opiate addicts in response to such detoxification procedures.[3] Individuals, during the opioid withdrawal period, experience symptoms such

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as dysphoria, insomnia, anxiety, irritability, nausea, agitation, tachycardia, and hypertension which may trigger drug-seeking behavior and relapse.[4]

Drugs such as benzodiazepines are administered in the treatment of heroin withdrawal symptoms.[5] In MMT programs, patients who are addicted to benzodiazepine are at risk for polydrug abuse.[6] Most patients relapse to opioids within one month of opioid agonist detoxification; therefore, there is low rate of completion of detoxification.[7] Some evidence indicates that drugs which are often used to treat anxiety and insomnia have adverse effects that are related to acquired tolerance and withdrawal from the drug.[8,9]

Today, herbal remedies are a popular form of therapy and have been developed as alternative methods of inducing calming effects.[10] Tranquival is an herbal product which consists of valerian, Passiflora, Melissa officinalis, and Humulus lupulus. The efficacy of its ingredients in different disorders has been previously demonstrated. Passiflora is effective on treating nervous restlessness, sleep disorders, nervous stress, generalized anxiety disorder (GAD), symptoms of opiate withdrawal, insomnia, neuralgia, convulsion, spasmodic asthma, attention deficit hyperactivity disorder (ADHD), palpitations, cardiac arrhythmia, hypertension, sexual dysfunction, and menopause.[11-16] Valeriana officinalis L. is a member of the Valerianaceae family with hypnotic,[17] anxiolytic,[18] antidepressant, and myorelaxant properties.[19] Melissa officinalis L. (lemon balm) is used in traditional medicine to treat insomnia, anxiety, gastric conditions, psychiatric conditions, migraine, hypertension, mild to moderate bronchial conditions, and sleep disturbances.[20,21] Humulus lupulus L. (hop) is well known throughout the world, and is used as a mild sedative and activator of gastric function.[22]

Despite the increasing interest in natural and complementary therapies for substance use disorders, clinical studies in this area are limited and there are insufficient documents to support the use of these therapies for opiate withdrawal symptoms. The present study was conducted with the aim of determining the effect of Tranquival on some opiate withdrawal symptoms in heroin addicted patients in the detoxification phase.

Materials and Methods

This study was conducted in an addiction treatment clinic, in Shahrekord, Iran (from June 2012 until October 2012). The Ethics Committee of Shahrekord Univeristy of Medical Sciences, Shahrekord, approved the study protocol and the study was registered in the Iranian Clinical Trial Center (IRCT) by IRCT201306222085N10.

Written informed consents were obtained from all patients before entering the study. A psychiatrist visited all patients and carried out the diagnosis of opioid withdrawal. This psychiatrist prescribed Tranquival or clonazepam for the patients in different study groups.

In this quasi-experimental study, the participants consisted of 80 males with a history of heroin addiction. The participants fulfilled the criteria for opioid dependency and withdrawal syndrome of the Diagnostic and Statistical Manual of Mental Disorders, 4th Edition, Text Revision (DSM-IV-TR). All subjects were outpatients who referred to an addiction treatment clinic. Inclusion criteria consisted of age of 20 to 50 years, a history of heroin use of at least 2 years (0.5 to 1 gr/day), suffering from withdrawal syndrome, receiving methadone treatment (30 to 60 mg/day), lack of allergy to Passiflora, Valeriana officinalis, Humulus lupulus, and Melissa officinalis, and referring to an addiction treatment clinic. Exclusion criteria consisted of psychiatric disorders or history of hospitalization in a psychiatric ward, unwillingness to participation in the study, and occurrence of any side effects related to

Tranquival consumption. In addition, patients who used opioids or drugs without the prescription of a psychiatrist were excluded from the study.

A number was given to each patient, then, according to their odd or even numbers, they were randomly assigned to Tranquival (n = 40) or clonazpam (n = 40) groups.

In the present study, a general physician who was not aware of the patients' groups completed the study questionnaires; thus, this study was a single-blind study. In addition, regarding to the different shapes of Tranquival and clonazepam tablets, the patients were aware of their medication type.

In the Tranquival (intervention) group, the patients took 1 tablet of Tranquival (Dineh Iran Co., Iran) orally an hour before sleep every night for 6 weeks. The ingredients of the Tranquival tablet are 150 mg Valeriana officinalis, 100 mg Passiflora incarnata, 50 mg Humulus lupulus, and 50 mg Melissa officinalis. In the clonazepam (control) group, the patients took 1 mg of clonazepam (Arya Co., Iran) orally an hour before sleep every night for 6 weeks.

The data collection tools consisted of the Pittsburgh Sleep Quality Index (PSQI), Hamilton Anxiety Rating Scale (HAM-A), and visual analogue scale (VAS) for muscular pain assessment. The questionnaires were completed in 3 steps; at the beginning of the study (T1), and 3 (T2) and 6 weeks later (T3). The PSQI is a standardized self-administered questionnaire. Its reliability and validity have been approved for patients with psychiatric disorders, sleep disturbance, and other somatic diseases.[23] The PSQI consists of 7 clinically derived components that assess sleep difficulty, and the sum of these component scores yields a global score of subjective sleep quality (range: 0–21). The reliability and validity of the Persian version of the PSQI (PSQI-P) were assessed by Farrahi et al.[24] In the study by Farrahi et al., the sensitivity and specificity of discrimination of patients with insomnia from control subjects was 94% and 72% for a PSQI cut-off value of 5, and 85% and 84% for a PSQI cut-off value of 6, respectively. The psychometric properties of the PSQI-P are acceptable.[24]

The HAM-A is one of the first rating scales developed to measure the severity of anxiety symptoms, and is widely used in both clinical and research setting. The scale consists of 14 items, each defined by a series of symptoms, and measures of both psychic and somatic anxiety. The HAM-A is widely used as an outcome measure in clinical trials. The reported levels of reliability for the scale are acceptable. Each item is scored on a scale of 0 (not present) to 4 (severe), with a total score range of 0–56. A score of lower than 17 indicates mild severity, 18–24 mild to moderate severity, and 25–30 moderate to severe.[25] This scale was used in an Iranian study.[13] HAM-A consists of 14 factors. A validity of 75% and reliability of 85% has been reported for this scale by Divsalar et al.[26]

The reliability of the VAS for acute pain measurement is high and the VAS is sufficiently reliable in the assessment of acute pain.[27] The VAS is a self-report questionnaire. The respondent is asked to place a line perpendicular to the VAS line at the point that represents their pain intensity. In clinical practice, the percentage of pain relief which is assessed by VAS is considered as a measure of the efficacy of treatment. A higher score indicates greater pain intensity. The reliability and validity of the VAS for disability in patients with chronic musculoskeletal pain has been evaluated by Boonstra et al.[27]

In the present study, data were statistically analyzed using SPSS software (version 16, SPSS Inc., Chicago, IL, USA) and Student's t-test, repeated measures analysis (Bonferroni correction), and chi-square test.

Results

There were no significant differences between the two study groups in terms of the history of addiction in close family members, educational level, economic status, occupation, marital status, age, and heroin dependency period (Table 1). Over the course of the trial, 3 subjects dropped out from the Tranquival group and 8 from the clonazepam group. Therefore, 37 patients in the Tranquival group and 32 in the clonazepam group completed the trial (Figure 1).

Table 1. Demographic characteristics of patients in the two study groups

Variables		Tranquival group	Clonazepam group	P
Occupation	Employed	20	20	0.62
	Unemployed	17	12	
Marital status	Single	13	8	0.43
	Married	24	24	
History of addiction in family	No	24	16	0.23
	Yes	13	16	
Education	Illiterate	16	10	0.28
	Primary school	16	13	
	Middle and high school	5	9	
Economic status	Sufficient	16	10	0.33
	Insufficient	21	22	
Age (year)		31.40 ± 8.30	34.80 ± 8.00	0.09
Heroin dependency period (year)		3.62 ± 1.44	3.25 ± 0.95	0.20

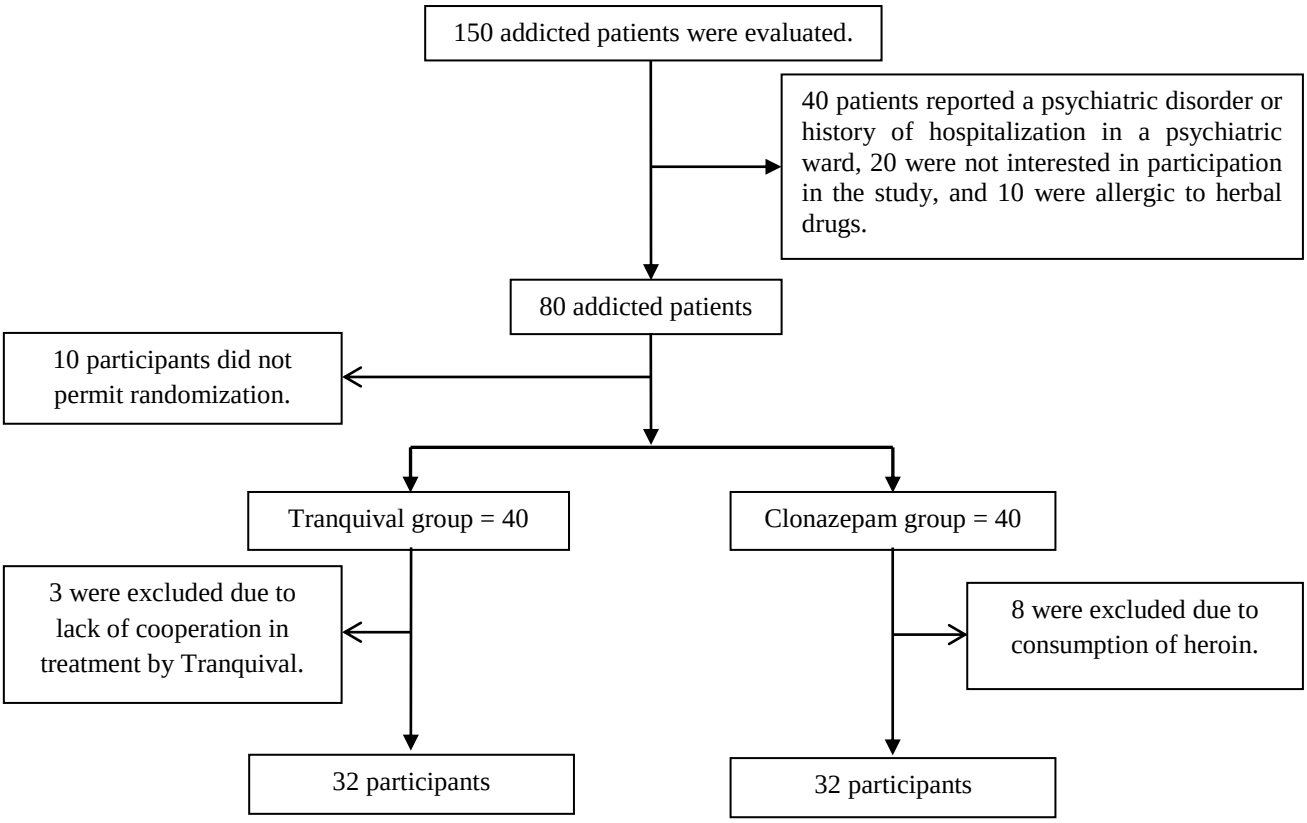

Figure 1. Flow chart of study participants

Table 2. Comparison of the anxiety, quality of sleep, and muscular pain scores in different stages of the study among the two groups

Symptom	Stage of assessment	Tranquival group (mean ± SD)	Clonazepam group (mean ± SD)
Anxiety	Before	23.9 ± 8.2	23.8 ± 8.1
	3 Weeks later	15.4 ± 6.6	17.0 ± 7.9
	6 Weeks later	13.0 ± 7.4	15.8 ± 7.7
Sleep	Before	14.2 ± 3.3	14.5 ± 3.3
	3 Weeks later	8.2 ± 3.1	9.7 ± 4.0
	6 Weeks later	7.4 ± 3.5	9.1 ± 4.5
Muscular pain	Before	51.0 ± 31.0	47.1 ± 30.7
	3 Weeks later	38.0± 28.8	34.3 ± 27.0
	6 Weeks later	28.4 ± 25.5	31.0 ± 25.4

Mean anxiety, sleep disorder, and muscular pain in both groups showed a descending trend (P < 0.001)
There was no significant differences between the two groups in the 3 assessment stages in terms of mean anxiety, sleep disorder, and muscular pain (P > 0.05); SD: Standard deviation

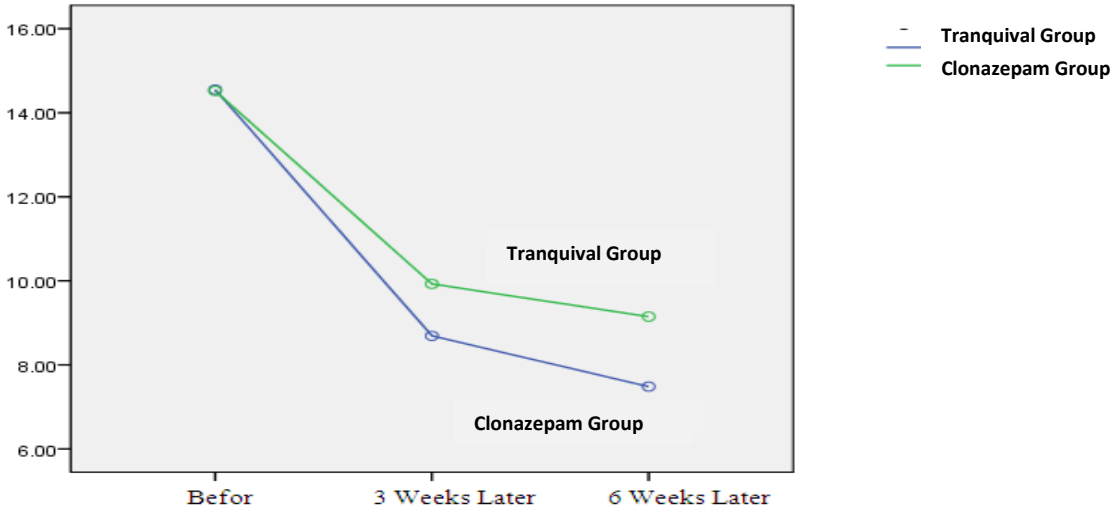

Figure 2. Comparison of the quality of sleep score in different stages of the study among the two groups

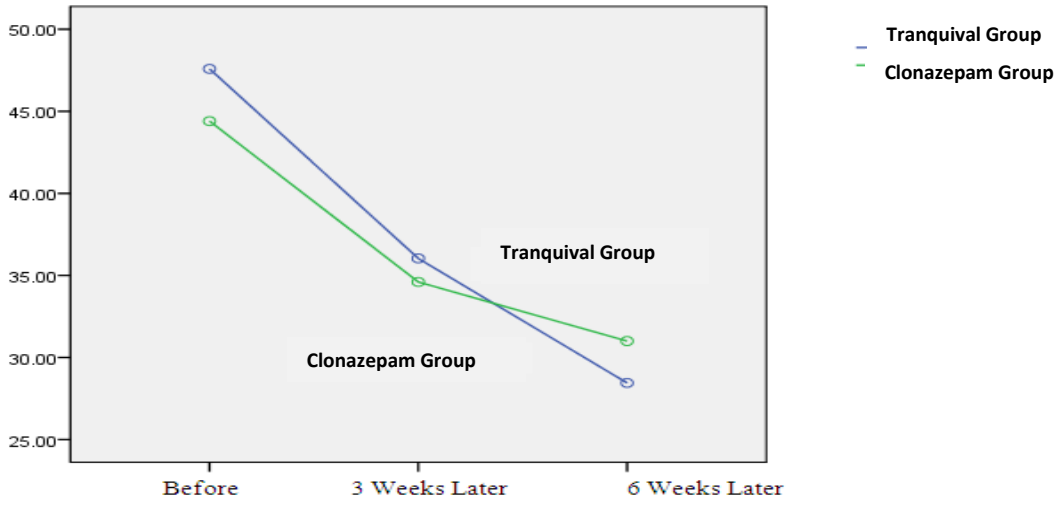

Figure 3. Comparison of muscular pain score in different stages of the study among the two groups

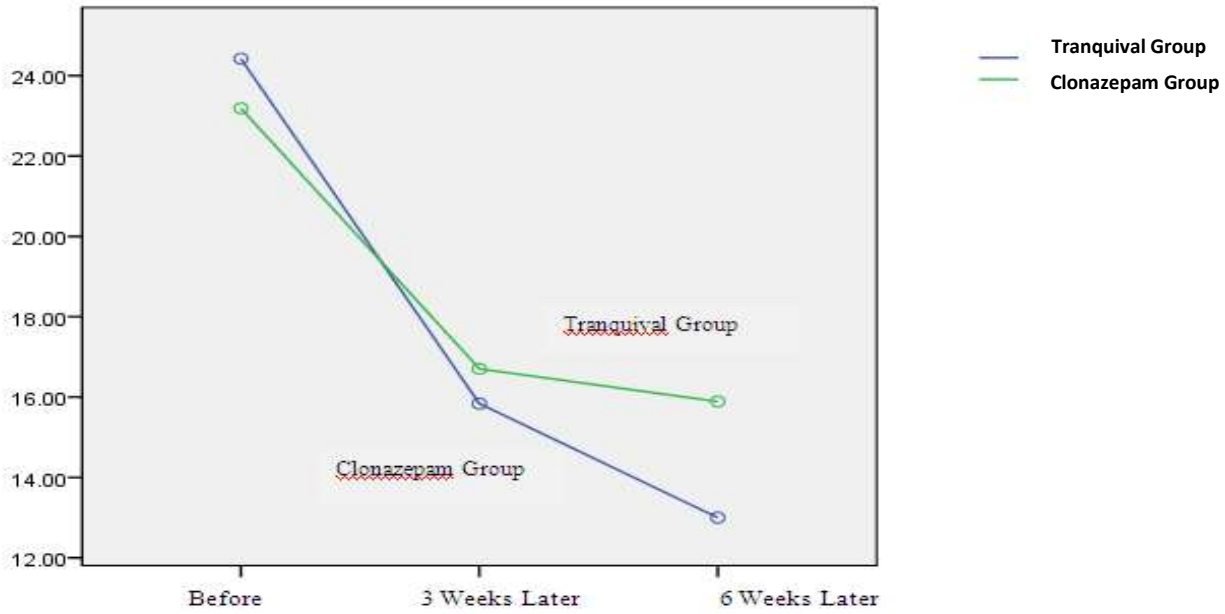

Figure 4. Comparison of the anxiety score in different stages of the study among the two groups

During the study period, in both groups, withdrawal symptoms (sleep, anxiety, and muscular pain) significantly decreased ($P < 0.001$) (Table 2); however, this difference was insignificant in the 3 assessment steps ($P > 0.050$). Furthermore, Bonferroni correction showed a relationship between Tranquival and clonazepam groups in mean anxiety at the beginning and the end stage of assessment ($P = 0.012$). Nevertheless, these relationships were insignificant in terms of mean sleep and muscular pain ($P = 0.153$ and $P = 0.267$, respectively) (Figures 2-4).

In both groups, patients reported drowsiness, but the rate of this side effect was higher in the clonazepam group (3 in Tranquival vs. 9 in clonazepam group). In addition, 3 patients in the clonazepam group had amnesia.

Discussion

This study showed that Tranquival was as effective as clonazepam in the treatment of some withdrawal symptoms in patients with heroin addiction in the detoxification phase. In addition, patients in the Tranquival group reported fewer side effects and greater compliance in comparison to the clonazepam group.

Treatment with benzodiazepines may reduce complaints of pain, but this seems to be an indirect effect related to their psychotropic properties, such as alleviation of anxiety and, in selected cases, depression. Clinical experience has shown benzodiazepines to be effective in the treatment of acute muscle spasm, concomitant chronic pain and anxiety, and lancinating neropathic pain, in which case clonazepam and alprazolam may be the agents of choice.[28]

Although a limited number of clinical studies have been performed on the effectiveness of Tranquival in treatment of opiate detoxification and withdrawal syndrome, each ingredient of Tranquival has anxiolytic effects. Melissa officinalis, Humulus lupulus (hops), valerian, and Passiflora incarnata inhibit γ-aminobutyric acid (GABA) catabolism.[12,29,30]

Miroddi et al., in a bibliographic investigation, found that the genus Passiflora incarnata has been used to cure subjects affected by opiate dependence in India.[31] b

and Conduit, suggested that the consumption of a low dose of Passiflora incarnata is effective in the treatment of mild sleep fluctuations in healthy adults.[15] Akhondzadeh et al. found Passiflora to be effective in the treatment of physical symptoms related to opiates withdrawal syndrome.[13] The numerous pharmacological effects of Passiflora incarnata are mediated via modulation of the GABA system, including affinity to GABAA and GABAB receptors and effects on GABA uptake.[14] In addition, valerian extract (valepotriates) has a potential anxiolytic effect on the psychic symptoms of anxiety. Andreatini et al. suggested that valepotriates have a potential anxiolytic effect on the psychic symptoms of anxiety.[32]

On the other hand, Melissa officinalis is effective on the treatment of anxiety and sleep disturbances. Guginski et al. found that Melissa officinalis (lemon balm) extract produced dose-related antinociceptive effect in several models of chemical pain with cholinergic mechanisms and the L-arginine-nitric oxide pathway. The rosmarinic acid in this plant contributes to its antinociceptive effect.[33]

The sedative effects of Humulus lupulus L. (hops) extract result mainly from its bitter acids, and in particular their oxidative degradation products such as that resulting from the α-acid content (2-methyl-3-buten-2-ol).[34] The main mechanism of action of hops is increasing the activity of the GABA neurotransmitter through modulation of brain GABA (A) receptors. The sedative effect of hops on the nervous system has been widely reported in animal research, as also has its narcotic effect at high concentrations due to 2-methyl-3.[35] Park et al., in their study, suggested that hop extract has an antinociceptive property in various pain models. Furthermore, the antinociceptive effect of hop extract may be mediated by opioidergic receptors.[35]

Furthermore, studies have shown that the combination of these herbs are effective in the treatment of anxiety and sleep disturbance. Kennedy et al. approved the anxiolytic effect of the combination of Melissa officinalis and valerian.[36] In addition, Wahling et al. showed that the combination of valerian, hops, and passion flower can increase sleep quality.[37].

Conclusion

Regarding the effectiveness of Tranquival in reduction of some withdrawal symptoms in heroin addicted patients in the detoxification phase and its fewer side effects in comparison to clonazepam, researchers suggested that this tablet be used in the treatment of heroin withdrawal symptoms. The efficacy of Tranquival may be related to different properties of its ingredients. However, further studies should be undertaken to determine the efficacy and the mechanism of action of Tranquival on withdrawal syndrome.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

We would like to thank the patients who participated in this study. This study was financially supported by Shahrekord University of Medical Sciences.

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Chronic Diseases Journal

DOI: 10.22122/cdj.v3i2.134 Published by Vesnu Publications

Using leprosy elimination campaign on leprosy case finding: Case series study in Kurdistan, Iran

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Original Article

Abstract

BACKGROUND: Because of the long incubation period of leprosy and disability caused by it, even mother to fetus transmission has been reported. Thus, this disease causes much alarm. Kurdistan Province, which is located in the Western part of Iran, is one of the regions that have previously suffered from endemic leprosy. The aim of the present study was to investigate the effects of the leprosy elimination campaign (LEC) on leprosy case finding in Baneh, Iran, in 2012.

METHODS: This case series study was conducted in Baneh District. Case finding was performed via LEC method, which is a recommended method for leprosy case finding in endemic areas. The performed steps included public education, and screening families of ex-patients through careful examination, identification of suspected cases, and diagnosis based on specialist's examination.

RESULTS: The families of ex-patients were assessed and 76 people who had prolonged exposure to ex-patients were invited to be examined by a trained general physician. Subsequently, 50 people were referred to a dermatologist for further examinations, 5 of whom and 1 unexposed person underwent bacteriological test for further evaluation. The results of all the tests were negative.

CONCLUSION: Active leprosy case finding and use of LEC method require a great deal of money and efforts to identify a small number of patients. Because a district like Baneh is in the process of eliminating leprosy and since the economic and social situation has changed greatly over the past two decades, LEC method is no longer cost effective.

KEYWORDS: Leprosy, Case Series, Iran

Date of submission: 13 Nov 2014, ***Date of acceptance:*** 15 Jan 2015

Citation: Nili S, Rahimi A, Rasouli A, Karimi M, Hasanzadeh J, Moradi Gh. **Using leprosy elimination campaign on leprosy case finding: Case series study in Kurdistan, Iran.** Chron Dis J 2015; 3(2): 64-70.

Introduction

Leprosy is a chronic disease with a long incubation period of about 5 years. The disease symptoms can appear about 20 years post-exposure. The disease pattern shows the global registered prevalence of leprosy to be at 180,618 at the end of 2013. Moreover, during the same year, 215,656 new cases were reported.[1] In 1985, 122 countries worldwide had a leprosy incidence of greater than 1 in 10,000 in 2000. This incidence increased to 24 in 10,000 in 2001, and 15 in 10,000 in 2002, but reduced to 12 countries. Currently, the highest numbers of leprosy patients are reported in India, Brazil, Madagascar, Nepal, and Mozambique Tanzania".[2] In the 44th Assembly

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of the World Health Organization (WHO), the elimination of leprosy by the year 2000 was proposed,[3] elimination meaning a prevalence of less than 1 in 10,000. However, due to the long incubation period of between 6 to 20 years, it does not seem logical. As can be seen in the case of South Africa which had achieved the elimination of leprosy in 1924, but recently new cases have been detected in Northern Transvaal.[4]

Appropriate planning for case detection and periodic examination should be regarded necessary to prevent disability.[5] The leprosy elimination campaign (LEC) is one of the strategies recommended for areas where leprosy is endemic and where there are weaknesses in detecting new cases of leprosy,[6] and thus, there is a need for its elimination. According to the WHO, "Iran is among the countries that have achieved leprosy elimination, and has less than one case per 10000".[7] Although Iran has achieved national, provincial, and district elimination of leprosy in 1992, 1996, and 1997, respectively, the disease is still reported in some endemic parts of the country. According to the Ministry of Health and Medical Education's report in 2011, Kermanshah, Kurdistan, and Azerbaijan, Iran, have the highest prevalence rates in the country.[8] Moreover, the prevalence of leprosy in Iran is now only 0.12 cases per 10,000 in the general population.[9]

Thus, leprosy is endemic in Iran.[10,11] Kurdistan province, with a population of 1598440 in 2011, is one of the Western provinces of Iran. Leprosy has always been an endemic disease in Kurdistan. Since the identification of the first cases in 1932 until the end of 2012, 693 cases were registered in Kurdistan. Baneh, Iran, with a population of 139003, is a district in Kurdistan Province. Since the beginning of the registration of leprosy cases until the present moment, 78 cases have been reported in Baneh. It has had the highest prevalence rate in the province.[12]

Considering the abovementioned facts, the importance of finding new cases, and achieving elimination, a case finding intervention program was conducted in 2012 to find hidden cases of leprosy in Baneh. Hence, in this study we tried to not only detect new leprosy cases via LEC method, but also assess the effects of LEC method on the effectiveness of leprosy case detection in Baneh as an endemic area in 2012.

Materials and Methods

This case series study, as a health system research (HSR), was conducted during a period of 3 months from September to November 2012 in Baneh.

The study population included all residents of Baneh. In this study, case finding was performed via LEC method, which is a well-known method. LEC method was introduced for leprosy case detection in endemic areas by the WHO in 1995.

Case finding and multi-drug treatment of patients are the main objectives of LEC. The main components of LEC are capacity building for health workers to improve multiple drug resistance (MDR) services, promoting participation in leprosy-related activities at a peripheral level in the community, and diagnosis and treatment of patients, particularly those who influence the community.[13] In order to assess the impact of public education on LEC, the case finding program was conducted in India and it was found that 50% of people have enough information. Specificity and sensitivity of LEC were 85.7 and 79.2%, respectively.[14]

Executive Team: The research executive team consisted of all doctors and specialists working in health centers and active in public education, a specialized team that consisted of general physicians, and 2 public health undergraduates of leprosy therapeutic centers.

Cost: Elimination of leprosy services have been carried out for 3 months and integrated

with primary health care (PHC) services. Since this area is endemic, many people should be checked and individuals with a history of leprosy or history of leprocy in their close contacts are in the high risk group. The results showed that this method is not a cost-effective method of identifying new cases.

To conduct LEC, two different methods of public education and direct examination of families of ex-patients were used. This study consisted of the following stages:

1. Forming the research and training teams: In this study, research planning and training of teams were performed in Baneh district. As the first step, a workshop was held for staff working in urban and rural health care centers.

2. Public training: In the next stage, public training programs were implemented in the district for 2 weeks. The training programs included training classes at rural health centers and health houses, installation of billboards and banners, and distribution of educational tracts in the city and rural areas.

3. Reception and examination of suspected individuals: At this stage, the examination of suspected cases was coordinated.

4. Visiting the families of ex-patients: The team consisting of 1 general physician and 2 public health undergraduates of leprosy therapeutic centers located in Baneh were trained to detect clinical manifestations (signs and symptoms) and complications of leprosy. First, a list was prepared of names and addresses of all leprosy patients in the district. Then, ex-patients' families were visited and assessed by the research team. All individuals suspected of having leprosy were referred to a dermatology center for further assessment.

5. Examination of suspected cases by a dermatologist: In the next step, leprosy and tuberculosis (TB) coordinator physician referred the suspected cases to a dermatologist for further examinations.

6. Microbiological tests: Because hyperpigmentation is not a specific leprosy lesion, smear test was performed for those individuals who were diagnosed as a suspected case by the dermatologist.

7- All biopsy specimens were sent to the pathology laboratory.

The research process is presented in figure 1.

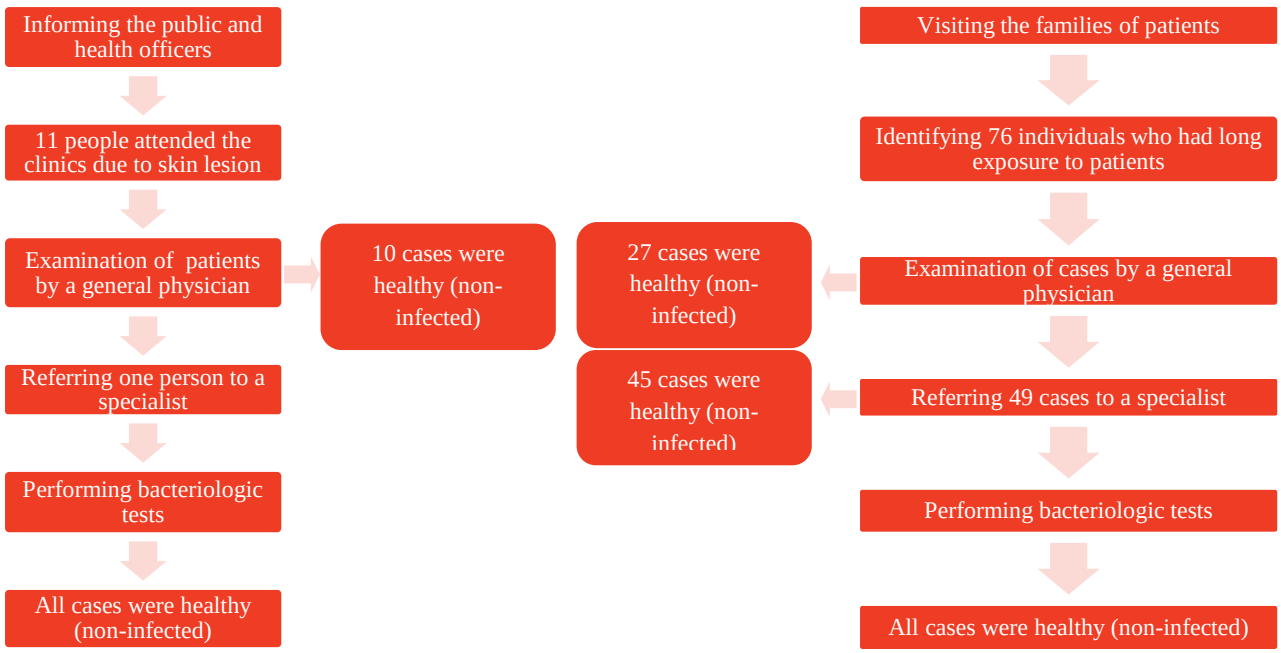

Figure 1. The study process and stages

Results

After informing the public and training health staff, 11 patients referred to the general physician because of skin lesions. After examination and approval, 2 patients who had the symptoms were referred to a general physician; 1 was referred as a probable case. The families of ex-patients were assessed and 76 people who had long exposure to ex-patients were invited to be examined by trained general physicians.

Hyperpigmentation is not regarded as a specific lesion for the diagnosis of leprosy. Thus, all 50 suspected cases (in active and passive case finding) were examined by the dermatologist, and based on the examination, 5 of them were assessed and examined as the final suspects, and skin smear test was performed for them (Table 1). The main characteristics of these 5 people are as follow:

First Person: He is the son of an ex-patient with a history of 11 years of exposure (from 1998 to 2009, died in 2009) is 58 years old, a laborer, and illiterate, and lives in a rural area. He was identified and referred due to physical weakness (Figure 2 a).

Second person: She is the wife of an ex-patient, is 57 years old, a homemaker, and illiterate and lives in an urban area. She was identified and referred due to hyperpigmentation in hand and problems in eyelids (Figure 2 b).

Third Person: He is the son of a leprosy patient, is 40 years old and a laborer, has a primary school degree, and lives in an urban area. He was identified and referred due to multiple wounds that did not improve (Figure 2 c).

Fourth Person: The fourth individual is a male tailor of 25 years of age, lives in an urban area, and has a high school diploma. Following public training and inactive case detection he referred for examination due to spots on the skin that did not improve (Figure 2 d).

Fifth person: She is the wife of a leprosy patient with a history of 11 years of exposure, is a 60 year-old illiterate, housewife, and lives in an urban area. She was identified and referred due to severe hyperpigmentation in the whole body (did not allow to take photos).

Table 1. Distribution and characteristics of suspected cases who were referred to a dermatologist

Variables	Groups	n (%)
Sex	Male	22 (44)
	Female	28 (66)
Age group	0-20	15 (30)
	21-40	11 (22)
	41-60	13 (26)
	61 and older	11 (22)
The place of lesion	Foot	5 (10)
	Hand	13 (26)
	Body (Trunk)	6 (12)
	Head	2 (4)
	Whole body	4 (8)
	Others or mixed	20 (40)
Lesions	Hyperpigmentation	9 (18)
	Hypopigmentation	4 (8)
	Deformity	8 (16)
	Other symptoms or a mix of them	29 (58)
Residential area	Urban	17 (34)
	Rural	33 (66)

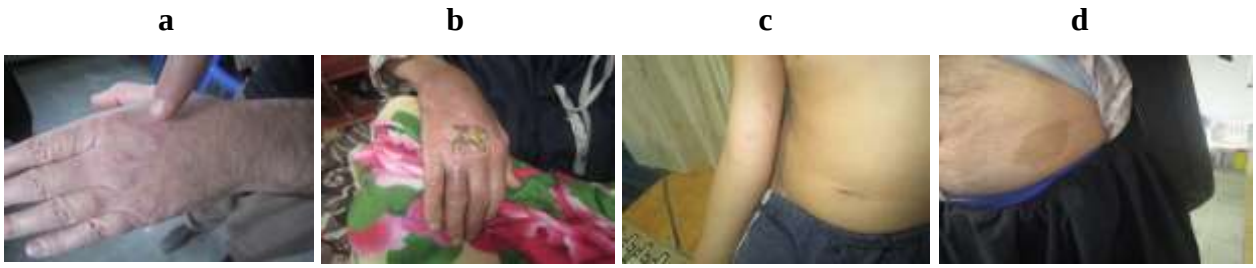

Figure 2. The main skin characteristics of 5 individuals in the second step of the leprosy elimination campaign (LEC) in Baneh

Smear samples were taken from all cases. Reviewing the smear samples showed that none of them were infected with leprosy. Based on the differential diagnosis, appropriate treatment was prescribed.

Discussion

Following the implementation of LEC in Baneh, we detected and examined 76 people in the first phase, 50 people in the second phase, and 5 people in the third phase. The results showed that none of them were infected with leprosy.

In a study that was conducted in Bandar Abbas, elderly patients (based on the leprosy registration system) and their families and close contacts were included (collectively 1861 people). Finally, 509 patients were evaluated; 15 people were willing to do a biopsy, among whom 20 suspected cases and 3 confirmed cases were identified.[15] In a LEC study in Kermanshah Province in the West of Iran in 2012, which coincided with our study, 4 cities with the highest rate of leprosy cases during recent years were studied.[16] Case detection was performed for the families of 90 ex-patients, which covered 178 people. As a result, 32 suspected cases were found. After referral to a specialist for further examinations, only 2 cases with minor injuries were confirmed.[16] In a study by Qasemi-Barqi et al. which was conducted in Qazvin in Central Iran from 2006 to 2007, a total of 1987 people (1379 exposed cases, 319 patients, and 608 cases living in 3 endemic villages with a high prevalence of leprosy) were examined for the diagnosis of leprosy. Accordingly, 256 suspected cases were identified, from which a total of 13 cases were diagnosed as definite new cases.[17] Active case finding requires a great deal of money and efforts to identify a small number of patients and it might cause some problems, for instance it might increase the risk of over-diagnosis up to 25%.[17-19] The rate of over-diagnosis was much more significant in our study. Hence, it seems that LEC is not cost-effective in areas with a low prevalence of leprosy. In a study by Ebenso et al., which was conducted from 13 August to 30 November 1998, the effects of LEC and its treatment outcome were assessed in 37 provinces of Sokoto and Zamfara states in Nigeria. First, health personnel were trained and a total of 353 unknown cases of leprosy were detected.[19] In a study entitled LEC Technical Report, which was carried out in 3 districts in the West of Hunan Province in China in 2001, 249 suspected cases of leprosy and 34 definite new cases of leprosy were identified.[20] A limitation of our study was the lack of a dedicated and pervasive media to educate people in the area. Hence, the training programs might not have covered all the people who were living in the area.

Burden of the disease would have been evaluated if a number of patients had been diagnosed with it. Nevertheless, since no cases of leprosy were discovered in this program, the burden of disease is 0. When the burden of disease in a population is 0, the cost of public education and screening against that disease is high. This strategy was compared with the sensitivity of passive surveillance performed 2

years prior to the implementation of this method. As a result of which, 7 confirmed patients were identified in the province (1 of them was from Baneh). However, in the LEC study, no patients were identified. In India, in areas with high prevalence of leprosy, modified leprosy elimination campaign (MLEC) has led to the identification of 0.99 million new cases.[2] The above studies show that LEC has led to different results in different countries. LEC has some advantages, for instance it increases public and professional awareness on the disease and it leads to the treatment of hundreds of thousands of detected cases of leprosy. In some countries, LEC has had an important role in the integration of services.[20,21] This program has led to the identification of areas with high incidence in certain cases, treatment, reduction of deformity, reduction of transmission, and increasing of cases to be treated.[22]

However, in many countries, it is necessary to reevaluate the effectiveness of LEC in active case detection.[13] According to the WHO, this strategy has some weaknesses. Patients detected via active case detection are less motivated to complete MDR than self-reported patients. Additionally, active case detection could jeopardize the effectiveness of integrated health services, so that sometimes patients with other symptoms may become suspected of leprosy and may be referred to specialized services and be examined and treated wrongly.[13] Additionally, home visits may increase stigma. The term "leprosy elimination campaign" may lead to an incomplete understanding of the leprosy elimination program among administrators and motivate them to spend more resources and make specific planning for health services that are not necessary.[18]

Conclusion

The implementation of LEC in places like Baneh, which is close to eliminating leprosy, is not cost-effectiveness. In areas where the social and economic situation of the people have changed and people have increased level of literacy and education, the authorities should not insist on implementing LEC.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

This study was the result of a research project which was approved and financially supported by the Research Deputy of Kurdistan University of Medical Sciences. The authors would like to thank Elahe Mahmmodi-Moghadam and other colleagues who have participated in this project.

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Chronic Diseases Journal

DOI: 10.22122/cdj.v3i2.153 Published by Vesnu Publications

Predicting dietary behavior of type 2 diabetics: Application of the theory of planned behavior and perceived risk of diabetes complications construct

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Original Article

Abstract

BACKGROUND: Diabetes mellitus (DM) is considered a major health problem due to its complications. However, it could be prevented or delayed by modifications in the patients' behavior and diets. The objective of this study was to explore the utility of the theory of planned behavior (TPB) and complications of diabetes perceived risk to find modifiable diabetes-related beliefs in order to make behavioral changes feasible.

METHODS: The present descriptive-analytical cross-sectional study was conducted in diabetes clinics in Semirom, Iran, based on TPB and complications of diabetes perceived risk using a self-administered questionnaire. A total of 154 patients with diabetes without complications of diabetes participated in the study. Measured variables were patients' attitude, subjective norm, perceived behavioral control, complications of diabetes perceived risk, intention to maintain a healthful diet and nutritional style. Structural equation modeling was used to analyze data.

RESULTS: The results revealed that the TPB and perceived risk of diabetes complications fitted the data acceptably well among patients with type 2 diabetes and within dietary behavior. Perceived behavioral control, subjective norm, perceived risk of diabetes complications, and intention to maintain a healthy diet were related to healthy diet behavior. No relation was found between attitude and intention to follow a healthy diet.

CONCLUSION: The TPB and perceived risk of diabetes complications is a useful theory in determining intentions of patients with diabetes and their adherence to a healthy diet.

KEYWORDS: Type 2 Diabetes, Diet, Theory of Planned Behavior

Date of submission: 18 Jan 2015, *Date of acceptance:* 25 Mar 2015

Citation: Rohani H, Malekahmadi M, Eslami AA, Ghaderi A, Bidkhori M, Raei M, et al. **Predicting dietary behavior of type 2 diabetics: Application of the theory of planned behavior and perceived risk of diabetes complications construct.** Chron Dis J 2015; 3(2): 71-8.

Introduction

Despite the many efforts, the percentage of people with complications of diabetes mellitus (DM) has increased not only in Iran[1], but also around the world.[2] Experts predict that the

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diabetic population will have increased to 9 million by 2021.[3] The World Health Organization (WHO) estimates an annual incidence of 4 million deaths due to diabetes, in other words, 7 diabetic patients die per minute due to its complications.[4] This issue imposes high costs on countries especially their health systems.

According Harris, DM management is the best method to preclude and delay its complications.[5] It can reduce the burden of the complications of this disease in society. Patients with DM should choose a suitable diet that permanently changes their beliefs, and dietary habits and patterns, but these patients rarely comply with a suitable diet as a habitual behavior.

Some studies report low adherence to healthy diets such as eating micronutrients, fruits, and vegetables among patients with DM.[6-8] According to a study conducted in Greece, most type 2 diabetics scarcely use a Mediterranean diet that is rich in vegetables, fruits, fish, cereals, and olive oil.[9] Diabetics try to improve their diet, but often inappropriately. This may be due to the contradictory recommendations derived from various sources such as health personnel, the national media, and social community.[10]

Presently, there are many diabetic clinics around the world that offer recommendations to improve preconception of health and health-care, without considering the patients' beliefs and attitudes, and help them to select a suitable diet pattern. Anderson and Funnel reported that health improvement of patients who suffer from chronic diseases such as diabetes, unlike acute diseases, is likely obtained by themselves, not by physicians or other health care providers.[11] Therefore, recognition of intrapersonal factors related to appropriate diet behavior may lead to increased effectiveness of controlling disease education and decreased complications.

The aim of this study was to use the theory of planned behavior (TPB)[12] as a type 2 diabetic's perceptual and belief framework that measures and empirically assesses behavior toward a healthy diet. According to this theory, health-related behaviors can be predicted through the structure of intention to perform the behavior. This structure is affected by attitude, subjective norm, and controlling perceptual behavior.[13] Many studies have been performed through applying the TPB on diabetics' healthy behavior.[14-16] However, it is necessary to test theoretical frameworks in the target population to identify factors that can be handled in order to achieve optimal behavioral change.[17] The objective of this study was surveying the efficiency of TPB in terms of the perception of suitable dietary behavior among type 2 diabetics in Iran.

Materials and Methods

This cross-sectional study was conducted in 2014. The target population consisted of 154 diabetics without complication who referred to diabetic clinics in the health network of Semirom, Iran. The inclusion criteria were patients with type 2 diabetes who were registered in primary health-care centers and were willing to participate in the study. The exclusion criteria were patients with complications such as foot ulcer and blurred vision according to their physician and incomplete questionnaires. The amount of ratio of studied character was considered 50% in the society, so maximum sample size was obtained. A sample size of 150 was determined in the present study based on 95% confidence level and error limit of 8%, and using the following formula:

$$\left(\frac{z^2_{1-\frac{\alpha}{2}} \times p(1-p)}{d^2}\right)$$

To obtain this number of participants, random sampling was performed among patients referred to diabetic clinics of primary

health-care centers in Semirom. To assess the structure of the TPB in relation to a suitable diet in diabetics, the standardized questionnaire validated and approved by Rohani et al. was employed.[18] Variables of this questionnaire were defined based on the structure of TPB.[12] This questionnaire includes 5 questions on demographic characteristics, 2 questions comprising 8 items on indirect measurement of attitude structure (behavioral belief and outcome evaluation) (each question consists of), 2 questions comprising 6 items on structure of indirect subjective norm (normative belief and motivation to follow) (each question has), 2 questions comprising 8 items on structure of indirect measurement of perceived behavioral control (perceived power and belief's control), 1 question with 3 items for measurement of structure of treatment intention, and 1 question with 3 items for measuring the structure of perceived risk of diabetes complications. Answers in all items were scored on a 5-point scale ranging from 1 (totally agree, very unlikely), to 5 (totally agree and very likely). It should be noted that to obtain participants' scores in structures of attitude, subjective norm, and perceived behavioral control which had two subscales, the scores of relative questions in each subscale were multiplied and added. For other structures, the total score obtained from items was considered as a participant's score. To assess healthy dietary behavior, the Nutritional Style Scale designed by Lippke and Ziegelmann in 2006 was used.[19] This scale includes 19 questions scored based on a 4-point scale ranging from 1 (totally false) to 4 (totally true). Higher total scores obtained from this scale illustrate participants' healthier nutritional style. To localize the Nutritional Style Scale, first, two experts translated it from English to Persian. Then, four nutritionists checked its content and determined which questions were necessary, which were useful but unnecessary, and which questions should be deleted. Subsequently, they determined whether these questions could show studied concepts (heeding healthy diet) or not. Moreover, the clarity, briefness, and cultural appropriateness of each question were checked and some recommendations were considered. Based on the experts' suggestions, one question about nutritional style that was unclear was deleted. To assess the validity of this questionnaire, some participants completed it and provided suggestions for simplicity and comprehensibility. To assess the interior and exterior reliability of this questionnaire, 15 participants of the target group completed it twice with a 2-week interval. Results showed that this questionnaire is reliable (Cronbach's alpha was equal to 0.71 and correlation from the test-retest was equal to 0.730). After obtaining permission and coordinating with the related authorities, interviewers distributed the questionnaires among the participants. The participants received face-to-face training and pamphlets about a healthy diet and followed the training. Then, the participants completed the questionnaires. If they had any disabilities, the questionnaire was completed through interviews by the clinic's health care personnel. Data was analyzed using SPSS software (version 16, SPSS Inc., Chicago, IL, USA) to obtain descriptive information. Then, we used IBM SPSS AMOS software (version 21, IBM Corp., North Castle, NY, USA) to analyze the structural equation.

Results

According to obtained demographic information, the mean age of participants was 46.25 ± 16.08 years. Most of them were women and in terms of marital status were married. The demographic characteristics of type 2 diabetics are presented in table 1.

Results of structural equation modeling (SEM) showed that, in general, data from this study had enough fitting for the model used. Measures of

goodness of fit are presented in table 2.

To determine the relationship between the structures examined in this study and predictive power of following a suitable diet we used the statistical analysis shown in figure 1. Generally, 42% of changes in behavioral intention were expressed by the model. Perceived behavioral control, perceived risk, and subjective norm with impact factors of 0.3, 0.22, and 0.2, respectively, had significant statistical correlation. This means that patients, who better controlled their nutritional behavior, gave more thought to the risk of developing diabetic complications, and were also affected by their relatives, had greater behavioral intention to adhere to a healthy diet. Behavioral intention expressed 16% of behavioral changes. The only structure which had no significant statistical correlation with behavioral intention was attitude. According to the results, the strongest predictor for behavioral intention to follow a healthy diet was the structure of perceived behavioral control.

Discussion

Based on medical literature, there is no absolute cure for diabetes.[20] Thus, controlling and preventing complications of diabetes is important.[21] The best way to control diabetes is by keeping the blood sugar level in the normal range.[22] This depends on maintaining a healthy diet which is suitable for these patients.[21] The aim of this study was to detect psychological factors effective on maintaining a healthy diet for diabetes and effective behavioral intervention using TPB and perceived risk structure.

Table 1. Demographic characteristics of patients

Variables	n (%)	Mean ± SD
Sex		
Men	63 (40.8)	
Women	91 (59.2)	
Marital status		
Single	18 (11.8)	
Married	111 (72.1)	
Divorced	7 (4.4)	
Widowed	18 (11.8)	
Education		
Illiterate	5 (3.3)	
Primary school education	25 (16.4)	
Pre-diploma education	25 (16.4)	
Diploma	43 (27.9)	
Above diploma education	33 (21.3)	
Bachelor's degree or higher	33 (14.8)	
Structure		
Perceived attitude		93.62 ±36.7
Perceived behavioral control		77.54 ± 29.8
Perceived Subjective norm		55.96 ± 24.3
Perceived risk		8.32 ± 2.2
intention		7.22 ± 0.9
Behavior toward a healthy diet		22.40 ± 4.5

SD: Standard division

Table 2. Measures of goodness of fit

Chi-square	DF	CFI	GFI	AGFI	RMSEA
3.22	77.00	0.85	0.92	0.90	0.07

DF: Degree of freedom; CFI: Comparative fitness index; GFI: Goodness of fit index; AGFI: Adjusted goodness of fit index; RMSEA: Root mean square error of approximation

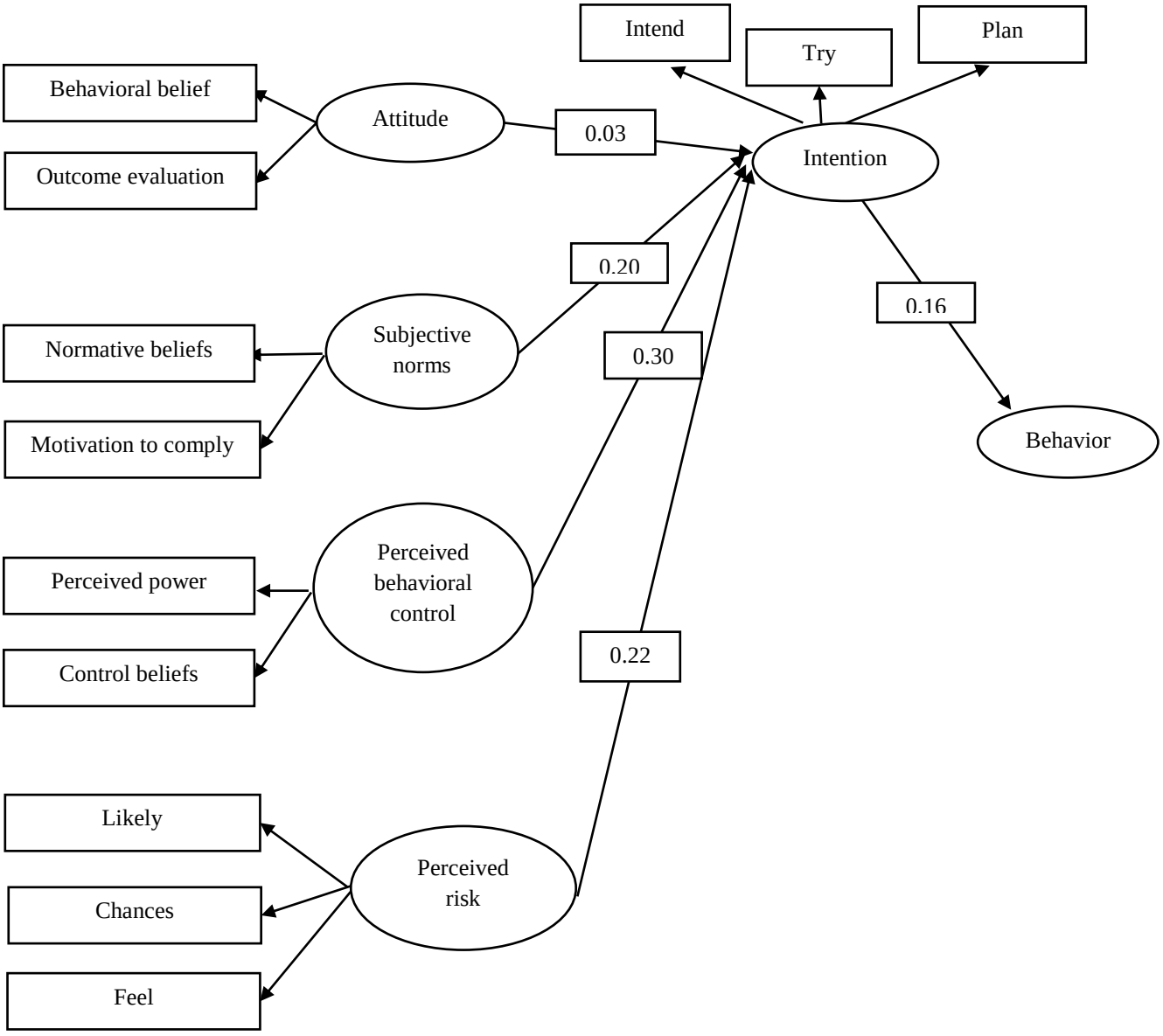

Figure 1. Structural equation modeling

Based on the mean score obtained in this study and its comparison with previous studies in Iran and other countries[22-25], we can conclude that diabetics followed unhealthy diets. This was a predictable issue. Based on this matter, nutritional behaviors of diabetics can be improved by TPB.[26,27]

According to concepts of planned behavior, the best predictor variable for behavior is behavioral intention. We can identify factors effective on behavior by identifying factors affective on behavioral intention. Based on this study, perceived behavioral control structure had the greatest impact on behavioral intention. This result is in agreement with that of some previous studies. For example, the results of the study by Blue on beliefs associated with a healthy diet conducted on 106 diabetics in the USA in 2006 were in agreement with those of the present study.[2] Recent studies conducted on nutritional behavior among healthy subjects using TPB

showed contradictory results. For example, the results of the study by Dehdari et al.[28] that was performed in 2012 to assess nutritional behaviors in female students showed that the structure of perceived behavioral control was not the strongest predictor for behavioral intention. The reason for this inconsistency with previous studies on healthy subjects may have been the experience of regular behaviors in diabetics such as timely use of drugs or diabetic foot examination. By the continuation of these behaviors, patients' power, control, and confidence increased.

Based on our results, attitude toward a healthy diet had minimal impact on behavioral intention in patients. This finding is contradictory to that of some other studies. For example, Omondi et al. conducted a study in Kenia in 2010 to detect beliefs related to healthy diet with the developmental approach using TPB.[26] They concluded that attitude toward a healthy diet was the strongest predictor for behavioral intention. One reason for this inconsistency was weakness and lack of attractiveness of our health messages about healthy diet that was weak in terms of the ability to become behavioral intention in the society especially among diabetics. Another reason may be the influence of the patients' relatives on them that is our cultural characteristic. The findings of our study indicated that subjective norms had more effect on changes in behavioral intention than attitude; thus, politicians and health care personnel can use this to change attitudes and behaviors of individuals especially diabetics.

Various studies have successfully used structure of perceived risk to create behavioral intention related to nutritional behaviors.[2,28-30] Therefore, in this study, we added this structure to the model to increase its predictive power. Our findings showed that the structure of perceived risk of diabetic complication affected patients' behavioral intention. This was in agreement with the results of other studies.[2,31] Accordingly, perceived risk can be replaced by attitude in educational and behavioral interventions.

In our study, the studied structures were good predictors for patients' intention and behavior. Based on the study by Armitage and Conner,[32] behavioral intention was the main cause of behavior. In recent studies, researchers have suggested adding other variables to behavioral intention to increase its predictive power. For example, Schwarzer et al. reported that planning for action and self-overcoming of obstacles decreased the gap between intention and real behavior.[33] Accordingly, additional studies are needed to detect mediator variables. The limitations of the present study were that we did not measure behavioral intention and behavior at two distinct time points because of administrative constraints, which are recommended to be considered in future studies.

Conclusion

The TPB and perceived risk structure can be used as a good model to conduct an effective intervention in providing a healthy diet for diabetes. Perceived behavioral control structure had more effect on behavior than other structures in diabetics. Therefore, it should be taken into consideration in nutritional behavior interventions in diabetics. On the other hand, researchers should consider other structures such as perceived risk which can increase predictive power of the models applied in the health intervention.

Recommendations

There is a lack of an integrated and systematic training program at the national level in the field of prevention of diabetes and its complications. Due to this and the positive results obtained in this study, we recommend more researches to identify beliefs about diet in diabetic patients in Iran and the world. It is hoped that through these studies a better

vision can be achieved in this respect in the country and more effective interventions at a national level can be implemented.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

This research has been supported by the Vice-chancellor for Research, Isfahan University of Medical Sciences, Iran, under the Grant No. 292176.

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Chronic Diseases Journal

DOI: 10.22122/cdj.v3i2.155 Published by Vesnu Publications

A clinical study of the effect of Glycyrrhiza glabra plant and exercise on the quality of life of menopausal women

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Original Article

Abstract

BACKGROUND: Most women experience significant changes during and after menopause which causes various complications of menopause and the changes in quality of their life. The aim of this study was to evaluate the effect of Glycyrrhiza glabra plant and exercise on quality of life (QOL) of menopausal women.

METHODS: This clinical experiment was performed in Arak, Iran. The study subjects consisted of 120 menopausal women. The participants were selected through convenience method and randomly divided into 4 groups of 30 subjects. Group 1 participants were administered 3 Glycyrrhiza glabra tablets daily. Group 2 participants had a regular exercise program. Group 3 participants were simultaneously administered Glycyrrhiza glabr tablets like group 1 and had an exercise program like group 2. Group 4 received no intervention. The participants' QOL was investigated before and 1 month after the intervention using the Menopause-Specific Quality of Life (MENQOL) Questionnaire. Data analysis was performed in SPSS software using Mann-Whitney, Wilcoxon, Kruskal-Wallis, and chi-square tests, and variance analysis.

RESULTS: No significant difference between the four groups in terms of vasomotor, psychosocial, physical, and sexual health, and QOL based on the Kruskal-Wallis test before the intervention. However, a significant difference was observed between the groups in terms of vasomotor, psychosocial, physical, and sexual health and QOL after the intervention.

CONCLUSION: The results of this study showed the efficacy of Glycyrrhiza glabra and exercise programs in controlling the symptoms of menopause. It is recommended that postmenopausal women use exercise programs and Glycyrrhiza glabra to control menopausal symptoms.

KEYWORDS: Glycyrrhiza Glabra, Exercise, Quality of Life, Menopause

Date of submission: 25 Jan 2015, ***Date of acceptance:*** 19 Mar 2015

Citation: Asgari P, Bahramnezhad F, Narenji F, Golitaleb M, Askari M. **A clinical study of the effect of Glycyrrhiza glabra plant and exercise on the quality of life of menopausal women.** Chron Dis J 2015; 3(2): 79-86.

Introduction

Menopause is a natural and inevitable process in women's lives., In addition to the positive aspects (contraceptive care and menstruation) of menopause, women experience different symptoms such as urinary disorders, depression and isolation[1], sexual dysfunction, hot flashes[2], and osteoporosis.[3] These

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symptoms affect women's occupational and social activities, mood, sexual activity, and quality of life (QOL).[4] Previous studies have indicated the negative impact of menopause on QOL of menopausal women.[5,6]

Thus, consideration of QOL during menopause is very important in terms of public health.[7] Factors such as education, medication, and regular exercise moderate menopausal symptoms and improve QOL.[8] Due to the side effects of hormone therapy such as endometrial and breast cancer, nausea, and headache in menopausal women,[1,9] researchers have applied aromatherapy[4] and behavioral approaches such as participation in aerobic and anaerobic sports to control the side effects of menopause treatment.[10]

In addition to its psychological effect due to increased fibrinolysis system activity, exercise improves menopausal symptoms such as hot flashes, fatigue, libido, and the treatment and prevention of diseases such as osteoporosis, arthritis, and cardiovascular diseases.[11] Glycyrrhiza glabra is a medicinal plant containing phytoestrogens.[12] This plant has varied benefits such as its effect on sleep disturbance, fatigue, depression, hot flashes, gastric intestinal disorders, and menopause.[13] Due to its advantages, its use leads to a reduction in menopausal symptoms and side effects, and thus, improvement in physical and mental health of menopausal women.[14.]

Due to increased life expectancy, menopause comprises a long period of women's life (about one third).[15] Because of the importance of QOL in postmenopausal women and the lack of studies on the impact of interventions on the QOL in menopausal women, the present study was conducted. This study was conducted with the aim to evaluate the clinical efficacy of Glycyrrhiza glabra and regular aerobic exercise on QOL of menopausal women.

Materials and Methods

Randomized controlled trials (RCT) were used to evaluate the effects of Glycyrrhiza glabra plant and regular aerobic exercise on QOL of menopausal women. Figure 1 shows the conceptual framework of this study.

In the article by Yazdkhasti et al.,[16] S = 0.01 and a 10% drop in the sample was predicted with 95% confidence and 80% test power = 85%, $\alpha = 0.05$, $\mu_1 = 113.30 \pm 34.45$, and $\mu_2 = 138.35 \pm 1$. Written informed consent forms were completed by all study participants.

After receiving permission from the Ethics Committee of the Arak University of Medical Sciences with the code IRCT2015031117873N4.NO and introducing themselves and explaining the purpose and methodology of this research, the researchers collected data from October to March 2013. The participants consisted of 120 menopausal women. The subjects were selected using convenience method and randomly divided into 4 groups of 30 subjects. After determining the target population, the samples were randomly divided into two groups.

The first group received 3 Glycyrrhiza glabra tablets (manufactured by Razak Pharmaceutical, containing 380 mg Glycyrrhiza glabra extract) three times daily; in the morning, afternoon, and evening. The tablets were administered before meals, due to favorable side effects, such as elimination of gastrointestinal dyspepsia, flatulence, heartburn, and constipation, according to the manufacturer's instructions[4] for 4 weeks. Group 2 participants took part in a regular aerobic exercise program like regular walking 3 sessions (even days) per week at 9 am for 4 weeks. This means that each session included a 5 minute warm up, 30 minute walking, or 5 minute cool-down routine.[17] Group 3 took Glycyrrhiza glabra like group 1 and took part in an exercise program like group 2. Group 4 did not receive any intervention and only completed the questionnaires. After the study, the control group participants were informed that they could use other methods if they wished. The

inclusion criteria consisted of women aged 48-52 years with a minimum of 1 year and a maximum of 3 years since their last menstrual cycle, the lack of chronic diseases such as diabetes, hypertension, hypothyroidism and hyperthyroidism, lack of surgical removal of the ovaries and uterus, having a spouse, no history of depression and psychiatric disorders, non-smokers, lack of use of hormone replacements therapy (HRT). Patients who reported physical and mental illnesses, the incidence of adverse events, and accidents or illness during the study, were prescribed and administered a new drug, or were at risk of musculoskeletal disorders (fractures, and etc.), and thus were unable to perform the exercise program, were excluded. Before the end of the 4th week after the intervention, the questionnaires were distributed among the subjects and completed through self-report. In this study, blinding method was not applied.

The questionnaire included a demographic questionnaire and the Menopause-Specific Quality of Life (MENQOL) Questionnaire. The MENQOL questionnaire contains 26 questions and its validity and reliability have been confirmed by Arian (r = 0.92).[18] The MENQOL questionnaire consists of 4 vasomotor, psychomotor, physical, and sexual aspects and the questions are scored based on 4-point scale ranging from 0 to 3 (0: lack of presence

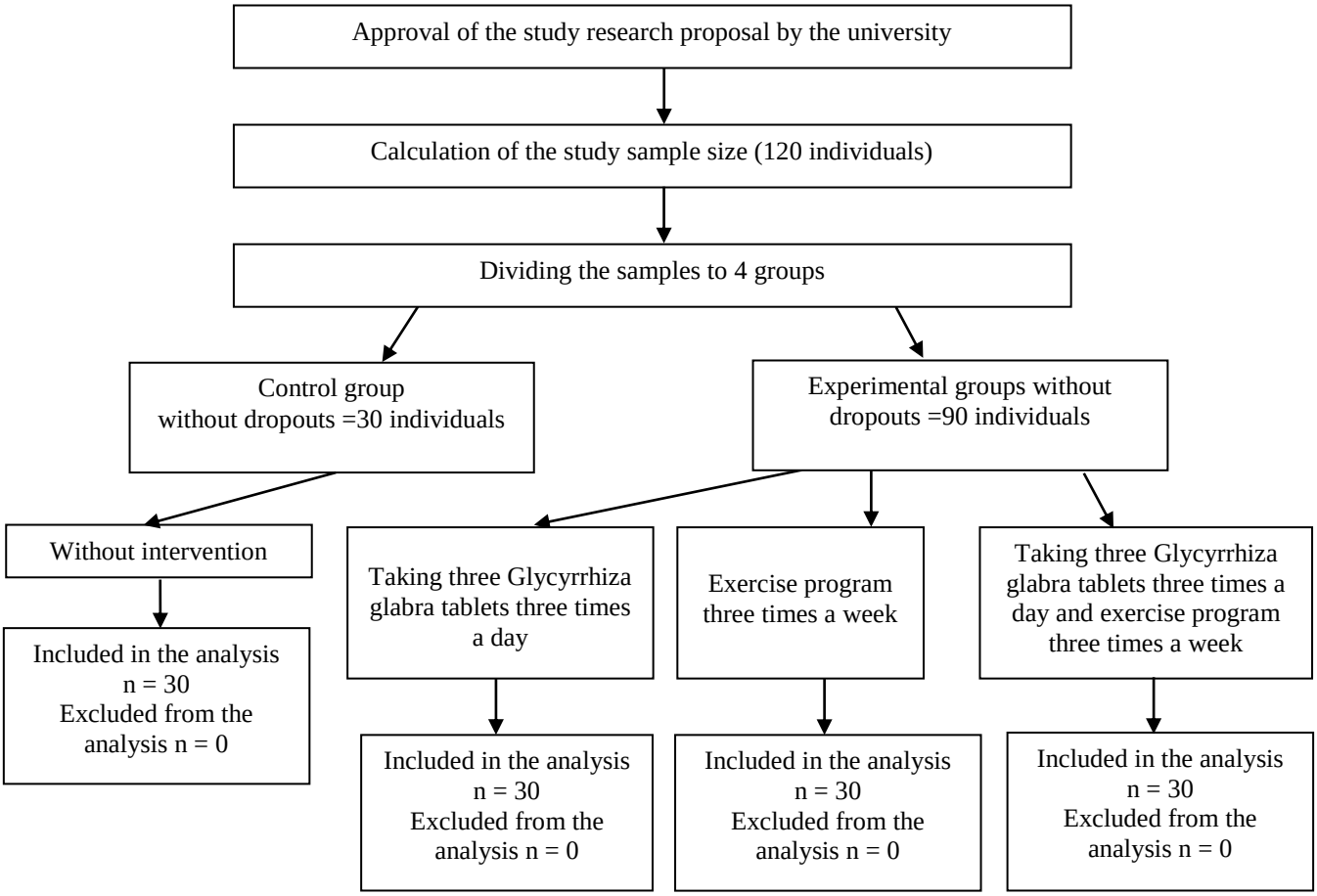

Figure 1. Diagram plan

of that aspect, 1: low presence, 2: average presence, and 3: extreme presence. Then, subjects were classified into 3 groups on the basis of their response to the questionnaire. Scores in the range of 0-26, 26-52, and 52-78 illustrate poor, moderate, and favorable QOL, respectively (higher scores indicate lower QOL). Data was analyzed in SPSS software (version 16, SPSS Inc., Chicago, IL, USA) using chi-square, Wilcoxon, Kruskal-Wallis, and Mann-Whitney tests.

Results

Demographic characteristic

In the present study, 30 menopausal women in each of the 4 groups were studied, and none were excluded. The groups were similar in terms of mean age, age at menopause, body mass index (BMI), number of deceased and living children, education, occupation, and income levels before and after the intervention and were not significantly different (Table 1).

Baseline analyses

QOL and its aspects are presented in table 2 before and after the intervention in the four groups. Due to the lack of difference in the groups' interventions using the Kruskal-Wallis test, Mann-Whitney test was applied to compare the mean scores of the groups. To reduce the Type I error, the amount of alpha was determined (0.05 ÷ 4 = 0.0125) according to the Bonferroni correction. According to Mann-Whitney test results, the comparison of the mean and standard deviation of QOL showed no significant difference between groups 1 and 2 in terms of vasomotor (P = 0.15), emotional, social, physical, and sexual aspects, and total QOL. Significant differences were observed between groups 1 and 3 after the intervention in terms of the sexual dimension (P = 0.004) and QOL (P = 0.001). The results showed a significant difference between Glycyrrhiza glabra and controls after the intervention in terms of vasomotor (P = 0.001), emotional-social (P = 0.001), and physical dimensions (P = 0.001), and QOL (P = 0.001). Moreover, the results showed a significant difference between groups 2 and 3 after the intervention in terms of vasomotor dimension (P = 0.001), and QOL (P = 0.001). A significant difference was observed between group 2 and the control group in exercise and vasomotor control (P = 0.005), psychosocial (P = 0.001), physical (P = 0.001), and QOL (P = 0.001) scores. Furthermore, in group 2 and the control group, a significant difference was observed in vasomotor (P = 0.001), psychosocial (P = 0.001), physical (P = 0.001), and QOL (P = 0.001) scores.

Discussion

The present study aimed to evaluate the effect of Glycyrrhiza glabra plant and a regular exercise program on improvement of QOL and its aspects such as vasomotor, psychosocial, physical, and sexual aspects in menopausal women. The results indicated the positive impact of Glycyrrhiza glabra on improvement of QOL and its aspects. The present study confirms the findings of Nahidi et al.[19] They concluded that the Glycyrrhiza glabra plant can reduce hot flashes at night and improve the level of physical and mental health in menopausal women.[19] The researchers believed that this herb may cause a reduction in hot flashes, especially at night, and thus, improve sleep and as a result QOL. Hajirahimkhan et al. conducted a study on the effects of estrogenic activity of licorice species as compared to hops on symptoms and side effects of menopause.[20] They recommended this plant for the controlling of menopausal symptoms due to having higher estrogenic activity, yet being safer than other plants.[20] The present study has explained the positive impact and effectiveness of Glycyrrhiza glabra. A study was conducted by Abdollahi et al. to investigate the effect of the aqueous extract of Glycyrrhiza glabra on menopausal symptoms.[21] The results showed a significant and meaningful difference in the average number of hot flashes (vasomotor aspect) at the end of the treatment compared to

Table 1. Demographic characteristics of menopausal women in four groups (n = 120)

Characteristics	Group	Group 1	Group 2	Group 3	Group 4	Total	Result
Age at time of study (mean ± SD)		51.90 ± 2.02	51.8 ± 1.76	51.90 ± 1.98	51.9 ± 1.65	51.9 ± 1.84	F = 0.02 P = 0.993
Age at menopause (mean ± SD)		49.60 ± 1.09	50.4 ± 1.43	50.50 ± 1.16	50.2 ± 1.16	50.2 ± 1.33	F = 2.88 P = 0.039
Body mass index (BMI) (mean ± SD)		24.91 ± 20.06	25.02 ± 2.55	25.06 ± 2.20	25.26 ± 2.53	25.06 ± 2.32	F = 0.11 P = 0.953
Number of living children (mean ± SD)		4.23 ± 1.73	3.46 ± 1.63	0.64 ± 1.52	4.56 ± 1.51	4.08 ± 1.68	F = 2.32 P = 0.079
Number of deceased children (mean ± SD)		0.33 ± 0.55	0.40 ± 0.56	0.20 ± 0.48	0.166 ± 0.46	0.517 ± 0.27	F = 1.36 P = 0.256
Educational level [n (%)]	Illiterate	4 (13.4)	2 (6.6)	4 (13.3)	5 (16.6)	15 (12.5)	X^2 = 10.5
	Under Diploma	13 (43.3)	9 (30.0)	14 (46.6)	17 (56.6)	53 (44.9)	df = 1
	Diploma	10 (33.3)	14 (46.6)	9 (30.0)	7 (23.3)	40 (33.3)	P = 0.572
	University Degree	3 (10.0)	5 (16.6)	3(10.0)	1(3.3)	12 (10.0)	
Occupation [n (%)]	House keeper	27 (90.0)	25 (83.3)	27 (90.0)	29 (96.6)	108 (90.0)	X^2 = 2.96
	Retired	3 (10.0)	5 (16.6)	3 (10.0)	1 (3.3)	12 (10.0)	df = 1
							P = 0.397
Income Rate [n (%)]	Sufficient	3 (10.0)	3 (10.0)	2 (6.7)	1 (3.3)	9 (7.5)	X^2 = 6.92
	Partially Sufficient	11 (36.6)	19 (63.3)	13 (43.3)	17 (56.6)	60 (50.0)	df = 1
	Insufficient	16 (53.3)	8 (26.6)	15 (50.0)	12 (40.0)	51 (42.5)	P = 0.328

SD: Standard deviation

Table 2. Comparison of the mean and standard deviation of quality of life and its dimensions before and 1 month after the intervention in four groups (n = 120)

Groups	Group 1		Group 2		Group 3		Group 4		Kruskal-Wallis test Result between the four group	
	Mean ± SD		Mean ± SD		Mean ± SD		Mean ± SD			
Dimensions	Before	After	Before	After	Before	After	Before	After	Before	After
Vasomotor	3.33 ± 1.88	1.23 ± 1.07	2.53 ± 1.81	1.63 ± 1.21	2.63 ± 1.77	0.70 ± 1.05	2.70 ± 1.82	2.80 ± 1.82	P = 0.317	P = 0.0001
	Z = -3.797 P = 0.001		Z = -2.178 P = 0.290		Z = -4.200 P = 0.0001		Z = -0.130 P = 0.897			
Psychosocial	8.93 ± 3.56	3.80 ± 1.90	8.36 ± 3.01	3.76 ± 2.29	9.20± 2.99	2.90 ± 1.42	7.60 ± 2.72	8.52 ± 3.11	P = 0.160	P = 0.0001
	Z = -4.513 P = 0.0001		Z = -4/390 P = 0.0001		Z = -4.720 P = 0.0001		Z = -0.487 P = 0.629			
Physical	13.96 ± 3.31	7.60 ± 3.91	13.96 ± 4.39	7.16 ± 3.09	14.86 ± 5.7	14.8 ± 4.7	14.40 ± 4.71	8.80 ± 5.03	P = 0.953	P = 0.0001
	Z = -4.344 P = 0.0001		Z = -4.670 P = 0.0001		Z = -4.446 P = 0.0001		Z = -0.108 P = 0.014			
Sexual	3.46 ± 2.16	7.29 ± 6.15	2.83 ± 1.82	1.13 ± 1.19	2.43 ± 1.9	0.87 ± 1.04	2.26 ± 1.92	1.36 ± 1.21	P = 0.153	P = 0.0001
	Z = -2.350 P = 0.0001		Z = -3.237 P = 0.001		Z = -3.051 P = 0.001		Z = -0.170 P = 0.300			
Overall QOL	29.70 ± 6.15	14.76 ± 5.43	27.70 ± 4.85	13.70 ± 5.38	29.10 ± 6.66	10.13 ± 2.94	27.43 ± 7.23	26.30 ± 6.02	P = 0.215	P = 0.0001
	Z = -4.733 P = 0.0001		Z = -4.789 P < 0.001		Z = -4.786 P = 0.0001		Z = -0.788 P = 0.431			

SD: Standard deviation; QOL: Quality of life

the beginning. In this case the symptoms improved and the number of hot flashes was reduced.[21]

In the present study, we examined the Glycyrrhiza glabra plant with the difference that Glycyrrhiza glabra tablets were used instead of its aqueous extract and its impact was measured on other aspects of QOL in addition to the vasomotor aspect. Menati et al. conducted a study on the effect of Glycyrrhiza glabra plant on hot flashes of menopausal women and its comparison with with hormone therapy.[4] They concluded that Glycyrrhiza glabra effective in the treatment of menopausal symptoms such as a hormone and can be used as a replacement treatment without the side effects of hormone therapy.[4] Considering the results of the abovementioned studies and the present research for the prevention of hormone replacement therapy, it seems that consumption of the Glycyrrhiza glabra plant can control inappropriate symptoms and improve QOL in menopausal women. The results also showed that a regular aerobic exercise program improves QOL in menopausal women. These results are in line with the study by Tartibian et al. on the effect of regular aerobic exercise on vasomotor symptoms in menopausal women, which indicated a reduction in vasomotor symptoms (hot flashes) through a regular aerobic exercise.[17] Thus, they recommend the modification of a sedentary lifestyle to an active lifestyle with regular exercise to improve health and physical fitness. Lee et al.[22] in a cross-sectional study titled "relationships between menopausal symptoms, depression, and exercise in middle-aged women" found that more symptoms and side effects of menopause were observed in depressed women than non-depressed women. Women who exercise regularly have fewer depression and menopause symptoms than women who do not exercise. These results are in line with the current research, with the only difference that the effectiveness of regular exercise was analyzed on other aspects of QOL beside the emotional aspect. Results of the study by Madureira et al., on the effect of exercise on QOL in postmenopausal women with osteoporosis is also in line with that of the current research.[7] They demonstrated that regular exercise caused a considerable and significant increase in QOL in menopausal women.[7] A review by Daley et al. on the effect of exercise on reducing vasomotor symptoms and other symptoms of menopause confirmed the effectiveness of exercise in improving vasomotor symptoms, psychological status, and QOL in menopausal women.[23] Agil et al. in a study on short-term effects of exercise on symptoms of menopause, mental health, and QOL in menopausal women have compared the two types of aerobic and resistance exercise.[24] They concluded that both types of exercise had positive effects on menopausal symptoms, depression, and QOL.[24] The researcher believes that exercise may reduce the risk of heart disease and osteoporosis. This leads to improved physical symptoms and QOL in menopausal women. Regular exercise leads to the release of endorphins, which relax individuals, and thus, improve their QOL in the emotional aspect and consequently increase QOL. Sunsern have examined the effect of exercise on psychological stress factors in menopausal women in their study and concluded that exercise leads to a significant reduction in stress in menopausal women.[25] They also found that regular physical exercise can improve QOL in menopausal women.[25] However, the results of the study by Aiello et al. on the long-term effects of exercise interventions on the severity of menopause symptoms indicated no reduction in menopausal symptoms due to exercise.[26] In this study, the type of exercise performed in these women is not mentioned, the researcher believes that this finding may be the result of the type of exercise used or the

time of day the exercise was performed in this study. These findings indicate that aerobic exercise in combination with Glycyrrhiza glabra tablets can improve QOL in postmenopausal women. An extensive review of literature by the researcher showed that no study had been performed to evaluate the effect of exercise and herbal methods to control menopausal symptoms and improve QOL in menopausal women. The researcher believes that the simultaneous use of Glycyrrhiza glabra tablets and aerobic exercise may lead to the strengthening of the effect of each, and thus, improvement of QOL. It should also be noted that further research is required in this regard.

It seems that through methods such as changing a sedentary lifestyle to an active lifestyle and eliminating the side effects of hormone therapy by means of aromatherapy, we can promote health and subsequently improve QOL in menopausal women. Due to time limitation, the intervention was performed in a month. Thus, it is recommended that future studies be conducted with a larger sample size and for a longer time period and its impact be studied on the long-term side effects of menopause, such as osteoporosis, cardiovascular problems, and other cases. Furthermore, since the incidence of diseases such as hypertension and depression is higher in this age group, many women did not participate in the study. Therefore, it is recommended that the effect of herbal medicine be measured in women with the abovementioned diseases through collaboration with other expert groups and the incidence of side effects be compared with healthy subjects.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

The authors would like to thank the Nursing and Midwifery Research Center of Arak University of Medical Sciences (contract NO.1155) and patients and families who participated in this trial.

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Chronic Diseases Journal

DOI: 10.22122/cdj.v3i2.152 Published by Vesnu Publications

The costs of disease burden in Iran

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Date of submission: 18 Nov 2014, *Date of acceptance:* 25 Jan 2015

Editor in Chief

Indicators which help us evaluate the burden of a disease and its related health interventions include financial cost, mortality, and morbidity.[1] Quality-adjusted life year (QALY) and disability-adjusted life year (DALY) are two indicators that quantify the total number of years lost because of illness.[2] One DALY is equal to one year of healthy life lost, and disease burden is a measure of the gap between current health status and the ideal health status.[3] These indicators help us compare disease burdens, and have also been used to forecast the possible impacts of health interventions.[3]

However, as a limitation, DALY is a generalization of a multifaceted reality, and consequently, provides a rough indication of health impact.[4] The consideration of only DALY is not enough for policy makers to base health care plans upon. Policy makers pay the greatest attention to the highest DALYs; however, the presence of lower DALYs, as the major contributing factors of disease burden, should not be ignored. For instance, maternal death maintains a high disease burden, and prevention of coughs in infants does not receive enough financial support.[4]

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The Iranian healthcare system is effective in countering temporary problems, like treating infections. However, a chronic disease should be considered as an epidemic, and as the population ages, health care policy makers should be more efficient in countering chronic diseases. Chronic conditions, like malignancies, heart disease, lung disease, and diabetes, have the highest cost for the health care system.[4]

In Iran's health care system, chronic diseases obtain less attention compared to infectious diseases.[5] A complete action plan should begin with a comprehensive study and end in a multifaceted intervention, linking the whole health system in Iran.[5] Iran has a well-built primary health care system that has been very efficient in decreasing the burden of infectious diseases, infant mortality, and maternal mortality, and increasing the well-being of mother and child. However, this system is not intended to reduce the burden of chronic diseases.[6,7]

Chronic diseases affect national economies in a negative way. Medical charges drain investments in economic fields which in turn worsen the national economy.[8] The direct costs of chronic diseases are huge and their estimates vary in different regions or years. This may cause inequality in access to healthcare benefits, investment systems, and

other related issues.[8] Evidently, health expenditures are services that are used to prevent disease.[9]

In Iran and other countries, chronic diseases are responsible for the majority of mortalities and morbidities. This issue is the major causative factor in failures in economic development. Therefore, interventions should be made in a comprehensive way to reach the global goal of chronic diseases prevention in order to reduce the burden of disease and its related financial costs.

Citation: Abbasian E, Poormohammadi A. **The costs of disease burden in Iran.** Chron Dis J 2015; 3(2): 87-8.

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