Chronic Diseases

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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)

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The effects of healthy lifestyle promoting behaviors on general health of the employees working in Isfahan University of Medical Sciences, Iran

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3 Department of Biostatistics and Epidemiology, School of Health, Isfahan University of Medical Sciences, Isfahan, Iran

Original Article

Abstract

BACKGROUND: The objective of this investigation was to assess the effects of health promotion behaviors on general health, which is one of the main determinants of health, preventing many diseases.

METHODS: This cross-sectional descriptive analytic study was performed in Isfahan University of Medical Sciences, Isfahan, Iran. A total of 175 employees working in Isfahan University of Medical Sciences were enrolled into the study via random sampling. In this study, Health Promoting Lifestyle Profile II (HPLP-II) questionnaire, General Health Questionnaire (GHQ), and a demographic questionnaire were used. The collected data were entered into SPSS software and analyzed using descriptive statistics and multiple regression tests.

RESULTS: Based on the results of multiple regression analysis, at a significance level of 5%, health promotion behaviors had a significant effect on mental health (P = 0.003). Considering the calculated coefficient (0.283), every one unit of increase in health promotion score increased the mean mental health score by 0.24 units.

CONCLUSION: Protecting the psychic health of the staff is one of the critical issues which plays a role in increasing the efficiency of the organization. Thus, it is of great importance to take steps to promote healthy lifestyle behaviors among employees and implement various interventions in this field.

KEYWORDS: Healthy Lifestyle; Health Status; Occupational Groups

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Introduction

The Ottawa Charter for Health Promotion declares that equal opportunities and resources to secure "access to information, life skills, and opportunities for making healthy choices" are some of the prerequisites for health improvements.[1] Health promotion programs put emphasis on behaviors such as regular exercise, eating nutritious foods, overcoming challenges, avoiding smoking, alcohol, and drugs, living in clean air, and having a goal in life.[2] Health problems, such as insulin resistance, cardiovascular disease (CVD), osteoporosis, and cancer share some common risk factors, including unhealthy and excessive nutrition, a lack of physical activity, smoking, and heavy drinking.[3] According to a report by the Statistical Centre of Iran published in 2011, of a total of 380 thousand cases of death, at least 180 thousand deaths are associated with seven

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major causes (smoking/hookah, unhealthy eating, sedentary lifestyle, obesity, high blood pressure, high blood sugar, and high blood cholesterol), and by the year 2025, about 70% of diseases in the country will be associated with non-communicable diseases (NCDs), and the rest will be related to infectious diseases such as acquired immunodeficiency syndrome (AIDS).[4,5] Healthy lifestyles contain an array of likely flexible behaviors that can prevent a wide dimension of diseases, such as some cancers, congestive heart failure (CHF), stroke, dementia, mental illness, and diabetes.[6] Rastegar et al. conducted a study in Mashhad, Iran; they found that the volunteer healthcare providers had a moderate to low level of health promoting lifestyle.[7] Moreover, the results of previous research show that a large number of deaths among young people and people of working age are due to suicide and murder, which are more or less associated with the mental health of people.[8] Mental health problems are inseparable from the environment[9] that is an essential factor for maintaining and sustaining social, occupational, and educational performance of the community.[10] Sadeghpour et al. conducted a study on relationship between physical activity and psychic health among the staff working in Isfahan University of Medical Sciences, Isfahan, Iran, and found that the level of physical activity was lower than the mean level and the sample group had a good psychic health status.[11] Undoubtedly, in a healthy organization, the organization's management not only puts emphasis on production and productivity but also has an interest in physical and mental health of its employees. In a healthy society, the responsibility of organizations is not solely limited to generating more profitable goods and services, and managers in such organizations know that more productive outputs can be achieved through effective management; furthermore, effective management cannot be achieved without considering and addressing the mental health of the employees.[12] Surely, the intelligent and expert staff in every country play a vital role in the progress of their country. They can largely affect different aspects of their life in the community. Therefore, the measurement of the level of mental health and physical health promotion behaviors as well as determining the relationship between them in staff working in Isfahan University of Medical Sciences can help authorities improve the provision of health services and address the needs of the staff.

Materials and Methods

This study was a cross-sectional descriptive analytic study which was conducted among 175 employees (non-faculty members). The subjects were selected via random sampling method. Only the staffs who had declared full consent for participation were enrolled into the study. After obtaining permission from the Ethics Committee of Isfahan University of Medical Sciences (No. IR.MUI.REC.2017.1.216), the data were collected with informed consent from the target group.

In order to collect the required data, we used Health Promoting Lifestyle Profile II (HPLP-II) questionnaire, General Health Questionnaire (GHQ), and a demographic questionnaire. The questionnaires had been localized and the validity and reliability of the questionnaires had been confirmed by previous studies.[13] The first questionnaire is related to the variables of health promoting behaviors in employees; its original English version, i.e., HPLP-II, is a 52-item tool. As reported, the reliability of the questionnaire measured by Cronbach's alpha coefficient is 0.82 and the reliability of its various areas has been reported between 0.64 and 0.91.[14] This questionnaire contains 52 items in six domains including: nutrition, physical activity, health responsibility, stress management, interpersonal relationships, and spiritual growth. The second questionnaire was Goldberg and Hillier's GHQ with 28 items

(GHQ-28). The questions were based on the Likert scale and were scored from one to four. The questions in this questionnaire were classified in four domains: physical impairment, anxiety, performance, and depression, with seven questions in each domain.

The collected data were entered into SPSS software (version 19, SPSS Inc., Chicago, IL, USA) and analyzed using descriptive statistics and multiple regression tests.

Results

A whole of 175 employees were engaged in this study. The mean age of the participants was 39.60 ± 8.29 years. Based on the self-reports, 14.4% of employees had a monthly income of less than 50 USD and 4.2% earned more than 200 USD per month. Moreover, 57.2% of the staff owned a personal home. Table 1 presents the demographic characteristics of the participants.

Based on the outcome of multiple regression analysis at a significance level of 5%, health promotion behaviors had a significant effect on mental health (P = 0.003). Taking into account the calculated coefficient (0.283), every one unit increase in health promotion score increased the mean mental health score by 0.24 units. Since after the control of the confounders, the adjusted R-squared was equal to 0.242, health promotion behaviors accounted for 24% of the variability in mental health.

Considering the P-values obtained in multiple regression analysis, we observed significant effects in the following cases: stress management on functional disorders, physical activity on physical impairment, nutrition on anxiety disorders, physical disorders, and functional disorders, and interpersonal relationships on functional disorders and depression disorders.

The percentage of variability in anxiety disorders, functional disorders, depression disorders, and physical impairment explained by health promotion dimensions was 95%, 91%, 92%, and 82%, respectively, which indicates the strength of these factors in explaining factors affecting mental health.

Table 1. Frequency distribution of the participants in terms of demographic characteristics

Demographic characteristics	Demographic levels	n (%)
Age (year)	Younger than 30	33 (15.3)
	31 to 40	106 (49.3)
	41 to 50	52 (24.2)
	Older than 50	24 (11.2)
Sex	Female	88 (50.3)
	Male	87 (49.7)
Marital status	Married	45 (82.9)
	Single	25 (14.3)
	Divorced	5 (2.9)
Employment status	Official	68 (31.6)
	Contractual	109 (50.7)
	Newly graduated staffs	6 (2.8)
	Short period employment	15 (7.0)
	Other	17 (7.9)
Family size	One to two people	51 (29.1)
	Three to four people	108 (61.7)
	Five to six people	13 (7.4)
	More than six people	1 (0.6)
Educational status	High school diploma	45 (25.7)
	Associate diploma	15 (8.6)
	Bachelor	68 (38.9)
	Master	45 (25.7)
	PhD	1 (0.6)
	Other	1 (0.6)
Work experience (year)	Less than 10	51 (33.1)
	10-15	46 (26.3)
	16-20	27 (15.4)
	21-25	20 (11.4)
	More than 25	24 (13.7)

The table below presents the magnitude of the significant effects as shown by the coefficients. For example, one unit increase in the mean nutrition score improved the mean score of anxiety disorders by 0.299 units. One unit increase in stress management score improved the mean score of functional disorders by 0.432 units. In addition, one unit increase in the mean nutrition improved the mean functional disorders by 0.350 units, one unit increase in the mean interpersonal relationship improved the mean functional

disorder by 0.203 units, one unit increase in the mean interpersonal relationship improved the mean score of depression disorders by 0.410 units, one unit increase in the mean score of nutrition improved the mean score of physical disorder by 0.397 units, and one unit enhancement in the mean score of physical activity improved the mean score of physical impairments by 0.208 units (Table 2).

Discussion

The objective of this study was to investigate the effect of healthy lifestyle promotion behaviors on general health. We analyzed the effect of different dimensions of health promotion behaviors on different dimensions of general health and the outcomes of this survey showed that nutrition had an effect on anxiety disorders, physical disorders, and functional disorders; in addition, the improvement in nutrition improved the status of the mentioned general health dimensions. Anxiety disorders are one of the most frequent types of psychiatric disorders that affect one quarter of world population throughout their life. On the other hand, obesity is perhaps one of the risk factors for anxiety disorders. Obesity causes anxiety disorders in a variety of ways, for instance, the discrimination and stigma due to overweight can deeply perplex obese people. In addition, the negative impact of obesity on health and quality of life can be particularly stressful. Both of them can eventually lead to anxiety disorder.[15]

The results of the study show that stress management is effective on functional disorders and the ability to manage stress improves the performance of the staff. In addition, improvement in interpersonal relationships improves people's performance and reduces their depression. When people are stressed, they must develop the necessary coping skills to be able to reduce stress. If stress is managed and effective coping skills are provided, one will be able to better address the needs and challenges in his/her life.[16]

Table 2. Parameter estimates

Dependent variable	Parameter	B	t	P
Anxiety disorder	Health responsibility	-0.062	-0.458	0.648
	Spiritual growth	0.117	0.927	0.355
	Stress management	0.288	1.543	0.125
	Physical activity	-0.056	-0.544	0.587
	Nutrition	0.299	2.441	0.016
	Interpersonal relationship	0.231	1.891	0.060
Functional disorder	Health responsibility	-0.082	-0.779	0.437
	Spiritual growth	0.046	0.467	0.641
	Stress management	0.432	2.987	0.003
	Physical activity	-0.106	-1.318	0.189
	Nutrition	0.350	3.676	< 0.001
	Interpersonal relationship	0.203	2.146	0.033
Depression disorder	Health responsibility	-0.115	-0.547	0.585
	Spiritual growth	0.200	1.025	0.307
	Stress management	0.277	0.963	0.337
	Physical activity	0.044	0.278	0.781
	Nutrition	0.018	0.095	0.924
	Interpersonal relationship	0.410	2.179	0.031
Physical disorder	Health responsibility	-0.012	-0.093	0.926
	Spiritual growth	0.219	1.762	0.080
	Stress management	0.304	1.656	0.100
	Physical activity	0.208	-2.038	0.043
	Nutrition	0.397	3.285	0.001
	Interpersonal relationship	0.099	0.822	0.412

As reported by World Health Organization (WHO), there are 10 coping skills including effective communication, effective interpersonal communication, confrontation with emotions (failure, anxiety, depression, etc.), and coping with stress.[17] The important thing is that all of these skills can be learned; these skills help the person control problems such as depression, anxiety, loneliness, rejection, shyness, anger, conflict in interpersonal relationships, failure, and lack of support.[18]

The results also showed that increased physical activity was effective in reducing physical disorders. Physical activity is one of the most critical behaviors that can affect NCDs. There are numerous physical, mental, and social health benefits of sport but unhealthy food in sports settings competes with these health benefits.[19] Physical inactivity doubles the risk of CVD, type 2 diabetes, and obesity. It also increases the risk of breast and bowel cancer, hypertension (HTN), lipid disorders, osteoporosis, depression, and anxiety. Daily physical activity is one of the ways to strengthen the immune system which prevents more than 20 diseases.[14] As reported by WHO, lack of awareness about the advantage of physical activity, lack of adequate information on the level and the range of physical activity, lack of supportive commitments, insufficient co-operation, lack of community access to sports facilities, economic pressure, time constraints, cultural problems hindering women's physical activity, population density, lack of security, air pollution, lack of parks, and lack of sports and simple recreational activities and walking make it difficult for people to choose their favorite type of physical activity.[19]

One of the limitations of this research is non-cooperation of employees in filling out the questionnaire. It is of great importance to take steps to promote healthy lifestyle behaviors among employees and implement various interventions in this field.

Conclusion

Considering the results of this study, it was found that different dimensions of health promotion had an impact on mental health; it was also found that psychic health of the staff was one of the most critical issues in increasing the efficiency of an organization. Thus, it is of great importance to conduct studies and adopt measures to improve healthy lifestyle promotion behaviors and carry out related interventions among the staffs.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

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Comparison of alpha–theta neurofeedback versus sensorimotor rhythm neurofeedback in the treatment of patients with fibromyalgia: A randomized, double-blind, controlled clinical trial

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Original Article

Abstract

BACKGROUND: Fibromyalgia (FM) is a chronic disease with widespread musculoskeletal pain. In this study, we used neurofeedback to reduce pain and enhance the quality of life (QOL).

METHODS: We conducted a double-blind randomized controlled trial (RCT) in 40 patients referred to Tuba Specialized Clinic and Clinic of Imam Khomeini Hospital in Sari, Iran, between December 2013 and July 2015. Group 1 underwent sensorimotor rhythm (SMR) neurofeedback training and group 2 underwent neurofeedback training for alpha-theta training. The primary outcomes were pain reduction and increasing QOL, which were measured using Visual Analog Scale (VAS), Numeric Pain Scale, Fibromyalgia Impact Questionnaire (FIQ), and Medical Outcomes Study (MOS) Sleep Scale, respectively, within the first day, 4 weeks, and 8 weeks post-randomization.

RESULTS: A total of 46 patients were screened for eligibility and 40 patients completed the trial. In both groups, the differences between FIQ scores before and after the study were statistically significant ($P < 0.05$).

CONCLUSION: Neurofeedback training could be applied to reduce pain and improve the QOL of patients with FM.

KEYWORDS: Neurofeedback; Fibromyalgia; Pain

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Introduction

Fibromyalgia (FM) is one of the most common musculoskeletal syndromes in adults. It also encompasses symptoms such as fatigue and sleep disturbances, morning stiffness, paresthesia, headache, and mood and cognitive disorders.[1] The exact cause of the disease is unknown; however, some evidence indicates that FM is a non-inflammatory syndrome.[1,2] Onset of symptoms may be followed by a viral infection, psychological or physical damages, or may be slow and gradual with no clear cause.[1,2] Several factors have been reported to be responsible for the pathogenesis of this syndrome including autonomic nervous system (ANS) disorders, peripheral decrease in cortisol response to stress, increased levels of neurotransmitters in cerebrospinal fluid (CSF), low levels of growth hormone (GH), low levels of metabolites of serotonin in CSF, and sleep disturbances.[2] FM, after osteoarthritis (OA), is the most common diagnosis in rheumatology clinics.[3] The prevalence of this syndrome is 2 to

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7 percent and in various studies, the prevalence rate among women and men has been reported 0.7% to 13.0% and 0.2% to 3.9%, respectively.[2] FM is a multifaceted and complicated syndrome with relatively unpredictable process. Since the tolerance and response to treatment methods differs among patients, hence, choosing the most appropriate treatment for both the physician and the patient is difficult.[3] The main goals of treatment are reducing pain and improving sleep in patients.[1] Neurofeedback is one of the new methods introduced in the treatment of these patients, which is in fact operant conditioning of electrical activity of the brain.[4,5]

Over the past decade, neurofeedback has been used to treat a wide range of psychiatric disorders. One of the neurofeedback protocols is "sensorimotor rhythm (SMR) reinforcement" that its effectiveness in reducing the symptoms of FM has been reported.[6-8] Another protocols is "alpha-theta reinforcement" that is used to increase optimal and innovative performance, reinforce working memory, improve sleep quality, and treat anxiety disorders including generalized anxiety disorder (GAD), post-traumatic stress disorder (PTSD), anxiety and depression associated with alcohol use disorders, and insomnia.[9-12] However, based on the available resources, this protocol has not been used in the treatment of FM so far.

New criteria mainly emphasize on the clinical symptoms of widespread pain (diffuse) and neuropsychological symptoms.[13] Patients, in addition to widespread pain, also complain about fatigue, stiffness, sleep disturbance [difficulty falling asleep, difficulty maintaining sleep, restless legs syndrome (RLS), and impaired breathing during sleep]. Analysis of genetic predisposing factors indicates the presence of neuropsychological routes shared with mood disorders and the role of the central mediators.[14] Feeling of pain in patients with FM is affected by emotional and cognitive aspects that provide a solid foundation for the use of cognitive, therapeutic, and behavioral strategies.[15,16]

Materials and Methods

In two referral centers, Tuba Specialized Clinic and Imam Khomeini Hospital in Sari, Iran, we randomized patients in a double-blind, randomized controlled trial (RCT) comparing the clinical consequences of alpha–theta reinforcement neurofeedback therapy versus SMR reinforcement neurofeedback therapy between December 2013 and July 2015. All of the patients were under treatment with 50 to 150 mg of pregabalin per day. Participants gave written informed consent at screening and were not paid for participating.

The study was approved by the Ethics Committee of Mazandaran University of Medical Sciences, Sari (Reference Number: IR.MAZUMS.REC.94-907). This trial was registered at the Iranian Registry of Clinical Trials (IRCT) (code: IRCT2015022111885N4).

We assessed the eligibility of all women with FM who referred to each of the two referral centers and were 18-50 years old. FM was diagnosed by a rheumatologist and based on American College of Rheumatology preliminary diagnostic criteria.[1] The exclusion criteria were being younger than 18 years and older than 50 years, the presence of infectious diseases, chronic diseases such as cancer, diabetes, history of cardiovascular disease (CVD), rheumatologic diseases [such as lupus, rheumatoid arthritis (RA), etc.], history of neck and spine surgery, psychological disorders [including psychotic disorders, major depressive disorder (MDD), bipolar disorder, substance abuse disorders], use of psychiatric drugs (antidepressants, anti-anxiety, hypnotic, etc.), the incidence of unbearable side effects caused by intervention during the study, or unwillingness to participate in the study.

A total of 46 patients were screened for eligibility and were randomized between December 2013 and July 2015 (Figure 1).

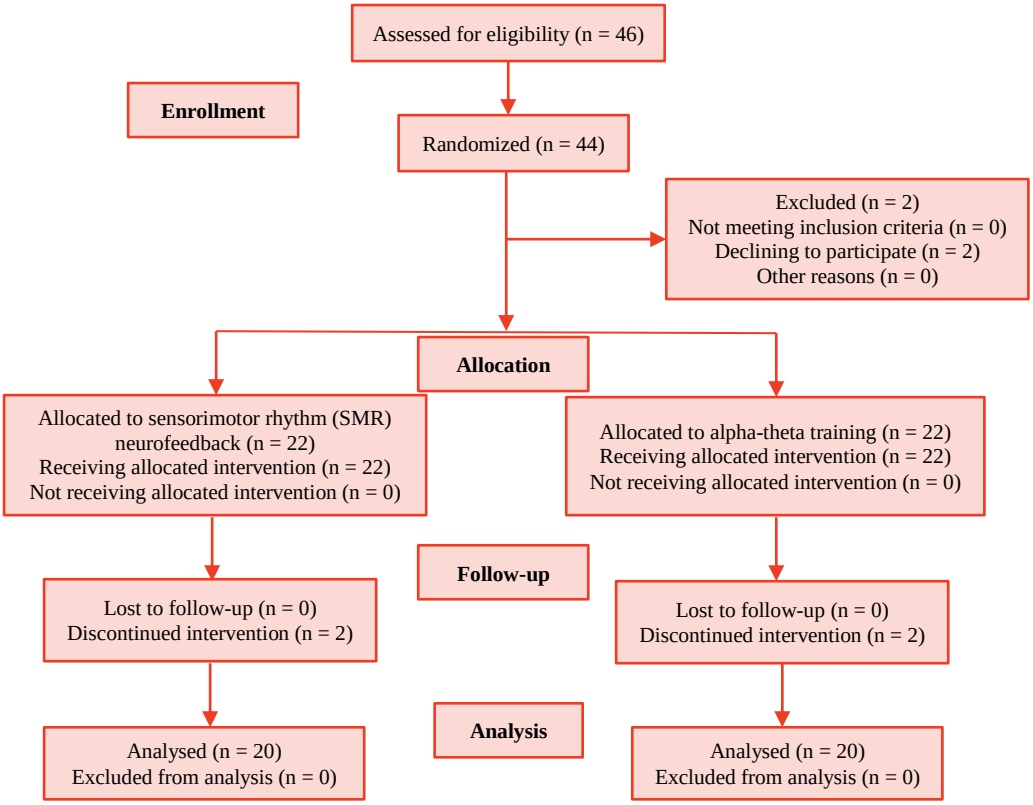

Figure 1. Participation consort flow diagram

Two patients declined to participate in study and four patients refused to continue the trial. The ineffectiveness of treatment on the symptoms of illness and lack of adequate time for follow-up were mentioned as the reason for treatment refusal. Forty randomized patients completed the trial.

At the beginning of the study, all eligible patients were assessed using Visual Analog Scale (VAS), Multiple Outcomes Study (MOS) Sleep Scale, and Fibromyalgia Impact Questionnaire (FIQ). The validity and reliability of FIQ have been approved by other studies.[17] The Persian translation of this questionnaire is a valid and reliable tool for assessing the health status of Persian-speaking patients with FM.[18] The validity and reliability of MOS Sleep Scale have also been demonstrated in previous studies.[19-21]

MOS Sleep Scale measures 12 items in 6 dimensions of sleep including sleep disorder, sleep efficiency, amount of sleep, sleepiness, snoring, and shortness of breath or headache. The sessions were twice a week (each for 30 minutes) for a period of 4 weeks. Group 1 underwent SMR neurofeedback training or training on Cz sensorimotor area and group 2 underwent neurofeedback training for alpha-theta training on Pz area. Neurofeedback was performed using ProComp 2 devices and Thought Technology software in the neurofeedback unit of Imam Khomeini Hospital.

In total, 40 patients were selected and randomly assigned to two groups (block randomization). First, a number was allocated to each patient, then they were assigned into blocks of 4 patients, and finally the blocks were studied using RANDBETWEEN function of Microsoft Excel software. Study investigators, research coordinators, attending care teams, and the patients were blinded to

treatment allocation.

The primary outcomes were pain and quality of life (QOL), which were measured using VAS, Numeric Pain Scale, FIQ, and MOS Sleep Scale, respectively, at the beginning of study and at the end of eight sessions of neurofeedback (after four weeks); and four weeks after the last session of neurofeedback training were filled by patients. We estimated that a total of 40 patients would be needed to detect a difference between groups, with a two-tailed α of 0.05 and a (1-β) of 0.80, for a comparison of 2 independent proportions. Repeated measures analysis of variance (ANOVA) was used to compare the results between the two groups. P-values of less than 0.050 were regarded as statistically significant. All analyses were conducted using SPSS software (version 16, SPSS Inc., Chicago, IL, USA).

Results

Baseline demographic and clinical characteristics were similar in both groups.

The mean age of patients in group 1 (SMR neurofeedback training) was 41.64 ± 5.70 years and in group 2 (alpha-theta neurofeedback training) was 39.75 ± 5.06 years, that the difference was not statistically significant (P = 0.319). In both groups, there was statistically significant differences between the scores of VAS (pain severity) at the beginning of study, end of the fourth week, and end of the eighth week (P = 0.001). Nevertheless, using repeated measures ANOVA, there was not a statistically significant difference between the two groups (P > 0.050) (Figure 2).

The FIQ: In group 1, there was a statistically significant difference in the mean scores of FIQ at the beginning (60.07 ± 12.08) and at the end of study (44.66 ± 14.09) (P < 0.001). In group 2, there was a statistically significant difference in the mean scores of FIQ at the beginning (56.77 ± 17.24) and at the end of study (38.30 ± 17.06) (P = 0.001).

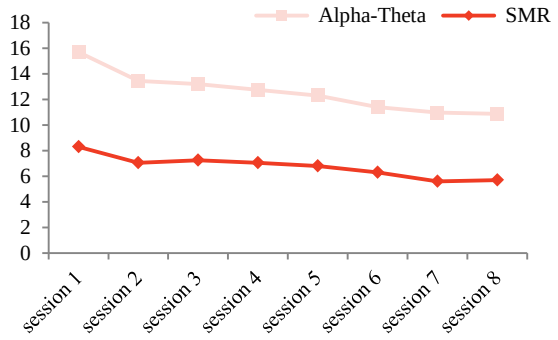

Figure 2. Visual Analog Scale (VAS) of pain during 8 sessions of neurofeedback treatment in alpha-theta and sensorimotor rhythm (SMR) neurofeedback groups

The follow-up of patients showed a higher FIQ score after eighth week compared to the fourth week; nevertheless, the difference between initial and final (8 weeks) FIQ scores was still statistically significant (P < 0.050) (Figure 3).

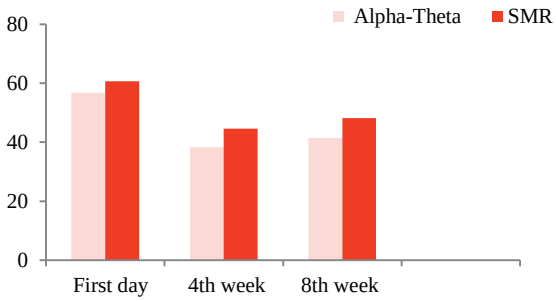

Figure 3. The Fibromyalgia Impact Questionnaire (FIQ) in alpha-theta and sensorimotor rhythm (SMR) neurofeedback groups

MOS Sleep Scale: In group 1 patients, there was a statistically significant difference between MOS scores in the beginning and at the end of the study (P < 0.050). In group 2 patients, there was a statistically significant difference between MOS scores in the beginning and end of the forth week (P < 0.050). But the difference between the two methods was not statistically significant (P > 0.050). In this study, no statistically significant difference was observed between the two treatment protocols after the eighth week (P > 0.050) (Table 1).

Table 1. Mean and standard deviation (SD) of Medical Outcomes Study (MOS) Sleep Scale in both groups

Neurofeedback protocol	1st day (mean ± SD)	4th week (mean ± SD)	8th week (mean ± SD)	P (1^{st} day/4^{th} week)	P (1^{st} day/8^{th} week)
SMR	32.05 ± 6.45	34.78 ± 5.44	32.20 ± 5.01	0.042	0.370
Alpha-theta	33.26 ± 4.02	35.68 ± 5.41	33.80 ± 4.30	0.045	0.040
P (SMR/alpha-theta)	0.590	0.580	0.682	-	-

SMR: Sensorimotor rhythm; SD: Standard deviation

Discussion

Neurofeedback facilitates inhibitory mechanisms in thalamus and can reconstruct the pain pathways in patients with FM.[22] Some studies have also supported the hypothesis that neurofeedback can increase the amplitude of the delayed P300, that this triggers the inhibitory mechanism of the thalamus. The facilitation of inhibitory mechanisms may play a positive role in the central regulation of pain and changing the central reinforcement.[23] This theory was the basis of this study for the use of neurofeedback in reducing pain in patients with FM.

Few studies have been conducted to reduce pain by neurofeedback. These studies have shown that chronic pain is reduced by this method.[24] For instance, the decrease in complex regional pain syndrome type I (CRPS-I) associated with migraine has been noted using neurofeedback method.[16] Furthermore, it has been shown that neurofeedback compared with escitalopram further improves the disease symptoms and QOL.[6] All patients in our study during a 4-week treatment with the two neurofeedback protocols, SMR and alpha-theta, sequentially mentioned lower pain intensity. As neurofeedback cannot affect the severity of symptoms immediately especially the pain, therefore, this led to the discouragement of patients to follow the treatment. The strength of our study compared to previous studies was the evaluation of two neurofeedback protocols at the same time and the comparison of the effectiveness of the two protocols including SMR reinforcement, which its effects on FM has been shown in previous studies and alpha-theta reinforcement protocol that its effect on patients with FM has not been investigated so far.[25] Kayiran et al. conducted a randomized study but only the evaluator was blind to the intervention.[6] None of the three other studies conducted in this context had randomized double-blind design with control groups.[7,8,25] Similar to other studies, all participants in this study were women, which indicates very high prevalence of the disease among women.

In the study by Kayiran et al.,[6] patients who received neurofeedback and were not allowed to take any type of medication were compared with patients who received escitalopram. In the studies by Kravitz et al.[5] and Nelson et al.,[26] patients were allowed to take medications such as morphine, benzodiazepines, and serotonin reuptake inhibitors at the same time. But in our study, except taking pregabalin, the patients were not under treatment with any medication.

The results of this study were consistent with the results of other studies. According to our results, both neurofeedback protocols were equally effective in reducing pain and this effect was maintained for up to 4 weeks after the treatment termination. In the study by Kayiran et al., patients were treated with neurofeedback for 4 weeks. VAS tool was used to measure the pain of patients. In this study, the patients' pain was evaluated until week 24 and according to the data, pain reduction process was clearly observed until week 8 and afterwards the treatment method showed no further beneficial effect in reducing pain.[6]

In the present study, there was a statistically significant difference between FIQ scores of all patients at the beginning of the study and at

the end of the eight weeks of treatment. Similar to our results, in the study by Kayiran et al.[6], which was conducted on a smaller number of patients in a shorter period of time, the FIQ scores significantly progressed during the study.

In another study by Nelson et al., conducted on 32 patients with FM, MOS Sleep Scale and FIQ were used to assess the effect of treatment on patients. In this study, patients were divided into two groups; one group was placebo feedback group and another group was treated actively with Low Energy Neurofeedback System (LENS) neurofeedback method. In this study, the amount of MOS significantly reduced during the study, which is in line with our results. Moreover, in this study, patients were followed up twice within 3 months and 6 months after treatment.[26]

On the other hand, Kravitz et al. conducted a study on 58 patients with FM. The FIQ questionnaires were completed by the patients before and after treatment. The results showed no statistically significant difference.[5]

The results of the present study indicated that the use of alpha-theta neurofeedback, similar to SMR neurofeedback could be a suitable method in reducing pain in patients with FM and improving sleep quality and FIQ index in these patients. This result is consistent with the results of previous studies on the impact of relaxation techniques (relaxation) on decreasing pain.[25] SMR neurofeedback training methods by strengthening amplitude of waves from 12 to 15 Hz can increase attention and concentration, cognitive processing, and sleep quality and can reduce fatigue.[26] Unlike SMR training that is performed in the area of sensorimotor with open eyes, alpha-theta neurofeedback is performed with eyes closed and in a different location behind the head, and through 7 to 8 Hz reinforcement of the waves helps to induce relaxation and meditation and reduce stress and anxiety levels, and hence, demonstrates therapeutic effect.[9,26]

Conclusion

It can be said that performing any neurofeedback training protocol finally through instructing self-regulation can be effective in reducing the pain sensation and pain perception. Taken together, further studies with larger sample size and longer follow-up are recommended. In addition, the utilization of methods such as functional magnetic resonance imaging (fMRI) during the treatment is suggested to be able to more precisely examine the main mechanism of the disease and the effectiveness of treatment in patients.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

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The effect of training of information processing approach on self-confidence in girl students in vocational schools in Isfahan, Iran

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Original Article

Abstract

BACKGROUND: Self-confidence is one of the main aspects of mental health during adolescence, which is essential for achieving goals. The purpose of this study is to investigate the effectiveness of training information processing approach on self-confidence in female students of vocational schools in Isfahan, Iran.

METHODS: This randomized control trial study was conducted on 50 adolescent female students in Isfahan in academic year 2016-2017. The Eysenck self-esteem scale (ESES) was used to assess self-esteem among the students. Training the information processing approach was performed on the experimental group. Data were analyzed by SPSS software using paired sample t-test, independent t- test, and Kolmogorov-Smirnov (K-S) test.

RESULTS: The scores of the students' self-confidence in the experimental group increased compared to the control group ($P \leq 0.050$).

CONCLUSION: According to the results of this study, training information processing approach is effective on self-confidence in female students of vocational schools in Isfahan. It is suggested to consider the training information processing approach along with other approaches.

KEYWORDS: Information Processing; Self-confidence; Students

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Introduction

Adolescence is one of the most important stages in the life of individuals which is considered as a critical period in terms of physical, social, and psychological changes.[1] One of the main aspects of the psychological performance in this period is self-confidence.[2] Self-confidence includes what we think and the emotion about ourselves, which is the outcome of self-assurance and self-respect.[3] However, self-confidence depends on the extent to which a person feels he/she is acceptable from the point of view of others, as well as his overall sense of self-worth. Basically, self-confidence is a gradual process rather than a sudden one, in the sense that it develops over time and is essential to achieve goals.[4] Self-confidence affects the quality of life (QOL) of individuals and how they feel about themselves.[5,6] People who feel they are lovable and pleasant to others, have definitely better social relationships, help and support friends and family when they need, and supporting others make them believe that they can overcome the problems and realize their goals.[7] Therefore, there must be some degree of trust in every human being, the trust that its

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absence is unacceptable for a healthy person. Higher quality and quantity levels of self-confidence guarantee the greater mental health of the individual and a person with high level of self-confidence will have more independency and creativity, and he thinks differently towards failures and control of desires.[8] Nevertheless, helping the adolescents to restore these cognitive structures and judgments and to carefully investigate the abilities and positive features, one can contribute to develope their self-confidence.[9]

With the advent of cognitive psychology, which emphasizes the information processing models, a new approach emerged. Its basic point is to recognize intelligence based on the cognitive processes performed during intelligence activities.[10] According to this theory, learning opportunities should be provided to improve the process abilities of individuals. In this way, the authorities are the solvers of the problems and develop their capabilities both for immediate satisfaction and for resolving future problems.[11] The information processing dimensions begin with screening, transferring, and encryption of data in the short-term memory. It is then stored in the long-term memory and when needed, it is activated and transferred to the active memory to reach the solution.[12] In the cognitive information processing (CIP) theory, problem solving is a chain of intellectual processing that ultimately ends up to solving problems and removing or reducing the gap between the present position and the ideal position of the individual. Achieving this goal depends on the dimensions of information processing such as self-awareness, knowledge, and decision-making skills. In the decision-making process, by talking to themselves, the individuals focus on increasing self-awareness and, by identifying the appropriate time for the next step in the decision-making process, develop their ability to monitor and control the information process.[13] Moreover, for skills in the field of implementation, teaching the metacognitive skills to people can be helpful. Therefore, in the cognitive psychology and data processing theory, the relationship between intelligence with learning, thinking, problem solving, and other cognitive processes has been considered.[12] Through efficient control processes (focusing, attention, monitoring, and reviewing) and metacognition (deep thinking or retrieval, tracking, and wonder), new solutions develop.

So far, several studies have been accomplished to enhance self-confidence in students, but the effectiveness of the information processing approach has not been studied in this regard. In this study, it has been attempted to investigate the effectiveness of training the pyramid of information processing approach to students in order to increase self-confidence among them. Since adolescence is a period of struggle and growth that is typically accompanied by a reduction in reliance and dependency on parents and family, developing self-leadership, finding worthiness and beliefs, paying attention to self-confidence in the adolescents seems to be an important problem. Accordingly, this study aims to investigate the effect of training the information processing approach on self-confidence of students of the vocational schools in Isfahan, Iran.

Materials and Methods

The present study was a quasi-experimental design with pre-test and post-test evaluations to compare the experimental group with a control group. The population of the study consisted of adolescent girl students in Isfahan in the academic year 2016-2017. The study including criteria were willingness to participate in the study, students aged 16 to 18 years old, non-attendance in other educational programs, and living with parents, and the exclusion criteria were disinclination to participate in the study. A total of 50 students who had inclusion criteria were randomly

selected and randomly assigned to one of the experimental (25 students) or control groups (25 students). In the pre-test, the study variables were measured simultaneously in both groups. Training the information processing approach was performed in the experimental group, but the control group did not receive any intervention. Finally, the effect of the intervention on the post test scores of the experimental group was compared to that of the control group. The stages of the information processing approach were carried out in 8 sessions of 90 minutes.

Information Processing Approach Protocol: This protocol was intended to teach the information processing approach in 8 sessions as follows, and in each session the therapist set up an assignment after training (Table 1).

Evaluation Tools

Eysenck Self-esteem Scale (ESES): To measure self-confidence, ESES was used which includes 30 items with yes-no options aiming to measure self-confidence. The scores of the items are combined to obtain the total score of the questionnaire. The total score ranges from 0 to 30, with scores above 21, 11-21, and below 11 representing higher levels of self-confidence, moderate self-confidence, and lower self-confidence level, respectively. The reliability coefficient of the questionnaire was obtained as 0.88 and 0.87 using the Cronbach's alpha coefficient and halving methods, respectively.[14]

The pre-test and post-test were performed by ESES respectively during the first session and after completion of training of the information processing approach protocol. The data were analyzed using SPSS software (version 23, IBM Corporation, Armonk, NY, USA) using paired sample t-test, independent t-test, and Kolmogorov-Smirnov (K-S) test. The minimum significance level in the study assumptions was considered to be 0.050.

Results

The findings of this study showed that the mean self-confidence score before the intervention in the experimental group was 16.36 ± 1.99, and the mean confidence score before the intervention in the control group was 16.94 ± 3.90 (P = 0.440). There was no significant difference in the self-confidence scores before the intervention between the experimental and control groups. The mean self-confidence score after the intervention in the experimental group was 18.60 ± 3.29 and the mean confidence score after the intervention in the control group was 16.28 ± 2.00 (P = 0.004). There was a significant difference in the self-confidence scores after the intervention between the intervention and control groups (Table 2).

Furthermore, the mean score of self-confidence before the intervention in the experimental group was 16.36 ± 1.99. The mean confidence score after the intervention in the experimental group was 18.60 ± 3.29 (P ≤ 0.007). The difference in the self- confidence score before and after the intervention in the experimental group was statistically significant (Table 3).

Table 1. General content of training sessions of information processing approach protocol

Sessions	Educational content of the information processing approach
First	Introduction, expressing the purpose of the session, the concept of the information processing approach, and the history of this theory
Second	Determining the necessity, investigating and teaching self-awareness in adolescents (knowledge field)
Third	Determining the necessity, investigating and teaching how to understand the environment (knowledge field)
Fourth	Training the skill of communication with problems and their analysis (Decision making field)
Fifth	Training solution combination skill (Decision making field)
Sixth	Training solution evaluation skill (Decision making field)
Seventh	Training the skill of better implementation of solutions (field of execution skills)
Eighth	Concluding and providing feedback from participants and taking post-tests

Table 2. Comparison of mean self-confidence score of students in the experimental and control groups before and after the intervention

Variables	Mean ± SD	P
Self-confidence score before intervention in experimental group	16.360 ± 1.992	0.440
Self-confidence score before intervention in control group	16.940 ± 3.196	
Self-confidence score after intervention in experimental group	18.602 ± 3.298	0.004
Self-confidence score after intervention in control group	16.280 ± 2.002	

SD: Standard deviation

Table 3. Comparison of mean self-confidence score of students in the experimental group before and after training

Variables	Mean ± SD	P
Self-confidence score before intervention	16.362 ± 1.998	0.007
Self-confidence score after intervention	18.608 ± 3.298	

SD: Standard deviation

Discussion

The aim of this study was to investigate the effect of training the CIP approach to adolescents. The results of the study showed that training the CIP approach is effective on self-confidence in adolescents.

Self-confidence means believing in one's abilities and talents and his proud and positive feelings towards himself.[15] Self-confidence is distinct in facial expression, behaviour, speech, and movement. Individuals with high self-confidence openly face others, are criticisable, and easily accept their mistakes, in addition to believing in their abilities. They have a sense of worthiness both to themselves and to others.[9,16] It seems that self-confidence increases among the teenagers when they feel that they can solve the problems in their lives using their own capabilities. It should be noted that in the CIP theory, problem solving is a chain of intellectual processing that ultimately ends up to solving problems and removing or reducing the gap between the present position and the ideal position of the individual.[17] Achieving this goal depend on the dimensions of information processing such as self-awareness, Job knowledge, and decision-making skills. In the decision-making process, by talking to themselves, the individuals focus on increasing self-awareness and, by identifying the appropriate time for the next step in the decision-making process, develop their ability to monitor and control the information process. The first step in the self-confidence development, after clairvoyance, is self-awareness. Self-reliance, narcissism, positive thinking of individuals or positive self-reflection, confrontation with difficulties, reinforcement of will, patience, experiential learning, and self-respect are other factors that can improve self-confidence.[18,19] The results of this study indicated that training the information processing approach can increase the power of individual analysis and lead to better communication with others in adolescents. These findings are consistent with the results of other studies with different protocols.[20-22]

Conclusion

As this study had some limitations, and among them, the subjects were selected from girls and in city of Isfahan, and long follow-up of the effectiveness of the treatment course was not performed. Therefore, it is recommended that in addition to the girl students, therapeutic efficacy should be performed in two different gender groups in different cities and after the intervention, follow-up of the effectiveness is required.

Conflict of Interests

Authors have no conflict of interests.

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Pain and depression in women with rheumatoid arthritis: The effect of cognitive behavioral therapy

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Original Article

Abstract

BACKGROUND: Pain is the main symptom of the disease in patients with rheumatoid arthritis (RA). This disease is the most common arthritis identified in women. Many studies have stated that there is a relationship between chronic pain and depression. The aim of this study was to examine the efficacy of the cognitive behavioral therapy (CBT) on reducing pain and depression in women with RA.

METHODS: Four patients with RA were included in a single-subject study with multiple baseline design conducted in Tabriz, Iran, in 2017. Scores were measured with Beck Depression Inventory (BDI) and McGill Pain Questionnaire (MPQ) before and during treatment periods.

RESULTS: The effect sizes according to the results of the BDI for the first, second, third, and fourth subject were 5.00, 0.66, 5.00, and 6.00, respectively. The effect sizes of the MPQ for the first, second, third, and fourth subject were 2.24, 3.44, 5.74, and 2.79, respectively.

CONCLUSION: The symptoms of depression are high among patients with RA due to chronic pain. CBT significantly reduced pain and depression in patients with RA. CBT is a great help in reducing the physical and mental problems of patients with RA.

KEYWORDS: Cognitive Behavioral Therapy; Pain; Depression; Rheumatoid Arthritis

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Introduction

1-5 percent of the adult population has rheumatoid arthritis (RA) and this disease is known as an autoimmune disease.[1] The most common symptoms are pain, stiffness, swelling, and loss of motion in the affected joint. Other common symptoms are fever, weakness, and loss of appetite.[2] In most cases, RA involves disability, pain, limitation of activity, and limitation of social participation, which greatly affects the physical, psychological, and social level of the individual and requires multi-dimensional assessment.[3] The biopsychosocial model of diseases shows that although biologic factors affect chronic pain, psychological and social factors are also considered to be effective.[1]

The pain is multidimensional, defined by the International Association for the Study of Pain (IASP) as "unpleasant sensation and emotional experience associated with actual or potential tissue damage, or described in terms of such damage".[4] Pain with psychosocial distress can interfere with social and physical function and increase the need for health care. The prognosis of pain in this disease is poor; even when inflammatory disease is well controlled, pain control is the best treatment.[5]

Symptoms of depression are known as a major problem in one-fourth of the patients with RA.[6] These patients have poor mental

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health. There are high levels of depression and anxiety in these patients compared to healthy people. Depression is a mediator between the pain and the impaired cognitive function in both early and late RA.[5] In particular, depression in patients with RA is an independent risk factor for cardiovascular disease (CVD) and myocardial infarction (MI), suicide, and death, even after a period of control for RA disease, illness, activity, disability, and pain. In addition to negative health outcomes, depression can help unemployment, loss of labor productivity, and increased health care costs in people with arthritis.[7]

Cognitive behavioral therapy (CBT) is known as an effective treatment and is known to treat chronic pain and mood disorders. It is helpful as an effective treatment combined with medical treatment in RA.[8] Despite the significant impact of CBT on health promotion, few studies have been conducted on the effect of CBT on pain relief and depression in patients. The results are also contradictory; a meta-analysis showed that treatment of chronic back pain had a positive effect on tolerance, dependence on pain, involvement in activities, quality of life, and depression.[9] In another study, no superiority was observed with respect to control conditions and CBT was not useful.[10]

Given that the research background on CBT studies is limited in patients with RA, considering the elimination of this conflict which simultaneously reduces depression and pain, and given the importance of the stated cases, the main question of this study is whether CBT is effective in reducing pain and depression in women with RA.

The hypotheses of this study were:

1) Women with RA suffer from depression.

2) Depression symptoms in women with RA decrease after CBT.

3) Pain in women with RA decreases after CBT.

Materials and Methods

In this research, with regard to the aim and limitations available for conducting the research, a single-subject experimental test with a multiple baseline design has been used, in which observation has been performed with repeated measures. The study population consisted of all women with RA that were referred to Sina Hospital, Tabriz, Iran, in 2017, among whom, 4 women were randomly selected. Subjects were also interviewed by a specialist physician to ensure that they had chronic pain criteria. Then, these subjects received cognitive therapy for eight sessions of 90 minutes. At the end of the sessions, they were evaluated by Beck Depression Inventory (BDI) and McGill Pain Questionnaire (MPQ).

In this study, graphic charts, tables, calculation of the effect size by Cohen's d, and reduction percentages were used to analyze the results. The summary of the items discussed at the psychotherapy sessions included:

Session 1: Basic familiarization and introduction, discussion on the effect of pain, the conceptualization of pain, familiarity with the symptoms of depression and psychosocial issues of pain and depression, the presentation of the treatment process, the goals of treatment.

Session 2: Reviewing the task of the previous session, introducing the cycle, expressing the theory of pain control, what causes the closure of the pain gate and what causes it to open, teaching planning activities and training and programming for enjoyable activities, presenting the new task.

Session 3: Reviewing the task of the previous session, explaining your thoughts, explaining how the thoughts lead to excitement, understanding the relationship between excitement and pain, detection of the relationship between depression and pain, muscle relaxation, and giving a task.

Session 4: Reviewing the task of the previous session, evaluating inappropriate thoughts, reviewing the subjects' thoughts,

cognitive error, thinking patterns based on wrong assumptions or misconceptions, presenting the new task.

Session 5: Reviewing the task of the previous session, identifying the evidence and indicating the negative aspects of subjects' thoughts, diverting attention through pleasurable activities, presenting the assignment.

Session 6: Reviewing the task of the previous session, stress and controlling it, replacing the right rationale instead of uncorrected thoughts, muscle relaxation, presentation of the new task.

Session 7: Reviewing the task of the previous session, explaining about anger and wrath, social skills training, concluding and summarizing sessions.

Session 8: Sleep hygiene and ways to improve sleep, an overview of previous sessions.

Measurements

BDI: The BDI is a 21-item tool. Each item is ranked based on a 4 point Likert scale from 0 to 3 based on severity over the past two weeks. The overall score is between 0 and 63, with higher scores indicating severe symptoms of depression. The overall score of BDI of 0-13 was considered as minimum depression, 14-19 mild depression, 20-28 moderate depression, and 29-63 severe depression. The validity and reliability of this test is high, so that the Cronbach's alpha is 0.80 and it has the ability to separate patients from normal people.[11]

MPQ: The MPQ is one of the most common pain assessment questionnaires. This test has high validity and reliability.[12,13]

Ethical issues: Participants were satisfied and informed consent was obtained from all participants included in the study. The written informed consent was obtained from the patients for publication of this study. This study was approved by the local ethics committee.

Results

Participants included four married housewives with an average age of 40 years, often having high school education. The effect size was calculated using a method based on the standard mean and standard deviation (SD) (Cohen's d). The effect size above 0.8 shows that the therapeutic effect is high, the values between 0.5 and 0.8 represent a medium effect size, and between 0.2 and 0.5 represent a low effect size. Quantities less than 0.2 also indicate that treatment has not been effective.[14]

The results of changes in the subjects' scores in the pre-test and post-test of the BDI are presented in table 1.

The results of changes in the subjects' scores during the pre-test and post-test of MPQ are presented in table 2.

Figures 1 and 2 of the subject's scores are drawn based on the BDI and the MPQ.

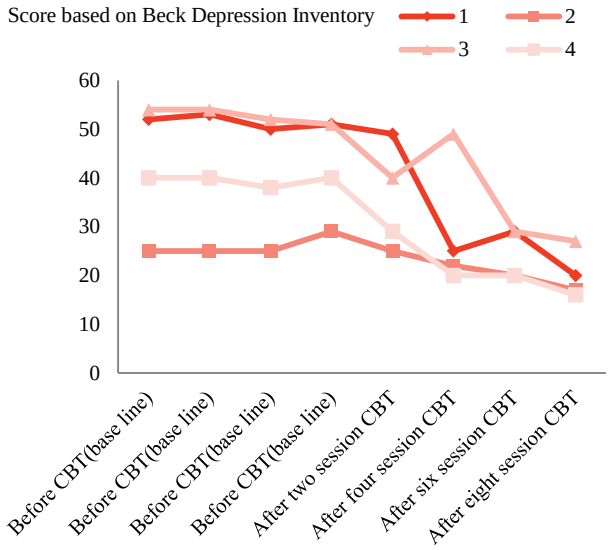

Figure 1. Subjects' scores based on the Beck Depression Inventory (BDI)

Discussion

The purpose of this study was to investigate the effect of CBT on decrease of pain and depression in women with RA. According to the first hypothesis of this study, women with pain in RA suffer from depression, which according to table 1, in all subjects with a history of RA, depression was high in pre-CBT, which is consistent with other research done in this area.[3,5,7,15]

Table 1. The results of changes in the subjects' scores in the pre-test and post-test of the Beck Depression Inventory (BDI)

Subject	Before CBT (baseline)				After two sessions of CBT	After four sessions of CBT	After six sessions of CBT	After eight sessions of CBT	Mean ± SD (baseline)	Mean ± SD (therapy stage)	Effect size (baseline-therapy stage)	Reduction percent
1	52	53	50	51	40	29	25	20	51.50 ± 1.29	28.50 ± 8.50	5.00	60
2	25	25	25	29	25	22	20	17	26.00 ± 2.00	21.00 ± 3.36	0.66	41
3	54	54	52	51	40	40	29	27	52.75 ± 1.50	34.00 ± 6.97	5.00	47
4	40	40	38	40	29	20	20	16	39.50 ± 1.00	21.25 ± 5.50	6.00	60

CBT: Cognitive behavioral therapy; SD: Standard deviation

Table 2. The results of changes in the subjects' scores during the pre-test and post-test of McGill Pain Questionnaire (MPQ)

Subject	Before CBT (baseline)				After two sessions of CBT	After four sessions of CBT	After six sessions of CBT	After eight sessions of CBT	Mean ± SD (baseline)	Mean ± SD (therapy stage)	Effect size (baseline-therapy stage)	Reduction percent
1	92	90	92	91	85	80	70	60	91.25 ± 0.95	73.75 ± 11.00	2.24	19
2	70	70	71	71	65	60	55	55	70.50 ± 0.60	58.75 ± 4.78	3.44	16
3	95	95	94	95	75	75	65	60	94.75 ± 0.50	66.25 ± 7.00	5.74	30
4	80	81	82	82	75	65	65	55	81.25 ± 0.95	65.00 ± 8.16	2.79	20

CBT: Cognitive behavioral therapy; SD: Standard deviation

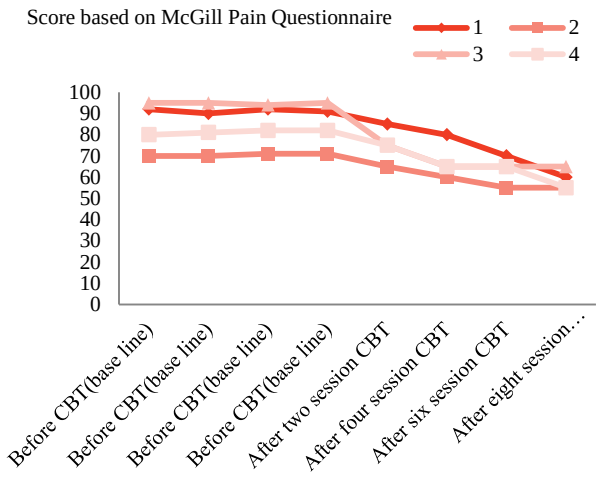

Figure 2. Subjects' scores based on the McGill Pain Questionnaire (MPQ)

Patients with RA, as a result of motor limitation and reduced daily activity, suffer from physical, psychological, and social impairment and become depressed. The study found that patients with RA suffer from depression. Depression and stress play a role in the incidence and continuity of the disease. Patients who are in the off stage of the disease will be relapsed if they cannot control their depression and loneliness. Pain in RA predicts depression. Patients with a history of depression are more likely to have worse RA pain than those who do not have such a history.[16,17]

According to the second hypothesis, depression symptoms in women with RA decrease after CBT. According to the data from table 1, based on the results of BDI, for three subjects who received CBT, the effect size was high and for the other subject, the effect size was calculated medium and the second hypothesis of the study was confirmed. The effectiveness of CBT has been studied in several groups and the findings of this study are in line with these results[2,18] and are not consistent with Parker et al.'s findings.[6] In explaining this finding, it can be said that CBT helps the patients control problems by changing the irrational beliefs, emotions, and behaviors and increase in alternative activities and sense of self-efficacy. The core of CBT for reducing depression is that people's mood is directly related to their mental patterns, and the negative thinking and application of it leads to the mood and behavior and even the physical state of individuals, so the mood of people with RA has a relationship with their unpleasant and negative thoughts. Consequently, CBT helps these individuals rebuild their thinking patterns and replace them with positive thinking practices which reduce the symptoms of depression. In eight sessions of the CBT, the patient is assisted in identifying the automatic thoughts and distinguishing between her thoughts and her feelings. The behavioral vagaries and even the physiological response can be understood.[2]

According to the data obtained from table 2, based on the MPQ, for four subjects who received CBT, a high effect size was achieved and the third hypothesis of this study was confirmed. The results showed that CBT could be used as a suitable therapeutic approach in these patients, which is consistent with previous findings showing the effect of CBT on the reduction of pain in patients with chronic pain.[19,20]

In explaining this, care should be taken to reduce physical pain alone and it should be noted that chronic pain is more than a physical cause, and the continuation of this pain leads to widespread and painful problems such as weakening of the mood, emotional disturbance, limitation of social and professional activities, increased use of medications, frequent referral to the health department, and the development of the role of the disease in other parts of the life of the individual. Since cognitive processes such as attention, attributes, and emotional processes such as pain-related fears and safety-seeking behaviors affect pain behaviors and disability levels, teaching cognitive-emotional components in CBT can lead to correction of

these processes and as a result, key components to increasing effective coping.[21] Providing information related to pain in its cognitive processing as well as educating distraction techniques can lead to reduced pain, and also CBT and its application causes patients to worry less about pain and to engage in active encounter with it control over.[22] The limitations of this research include low number of subjects, female subjects, and use of self-reporting tests. It is recommended that studies on chronic pain in men and women with other chronic diseases such as chronic back pain be performed. Therefore, further research in this area leads to the discovery of the relationship between pain and depression in other chronic diseases and more about the effectiveness of this treatment in reducing pain and other psychological disorders in other diseases.

Conclusion

According to the findings, high effectiveness of CBT has been achieved in reducing pain intensity and depression. CBT seems to be a very suitable approach for patients with health problems and medical treatment issues. The effectiveness of this treatment can be used to increase the quality of life of patients. Physicians, nurses, and health psychologists should measure mental health of patients in diagnostic priorities. CBT is a great help in reducing the physical and mental problems of patients with RA. Psychological training emphasizes that the patient can have better choices even in the condition of the disease.

Conflict of Interests

Authors have no conflict of interests.

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Frequency and characteristics of Brucellosis in Golestan Province, Iran

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Original Article

Abstract

BACKGROUND: Brucellosis is a common widespread zoonotic disease between humans and livestock with significant economic and health problems caused by various species of Brucella. The disease is a significant public health issue throughout the world and one of the most socioeconomic problems in many developing countries. This study aimed to report the information available at the Provincial Health Center about the frequency and characteristics of patients with Brucellosis in Golestan Province, Iran.

METHODS: This study was analytic-descriptive cross-sectional. The study population included all patients with Brucellosis diagnosed from 2011 to 2015 in the health center of Golestan Province, based on the serological method. The data gathering tool was a questionnaire that included demographic information, clinical presentation and examinations, history of exposure, laboratory findings, and treatment protocols. Descriptive statistics were reported as frequency and mean ± standard deviation (SD) and analyzed by SPSS software.

RESULTS: In this study, a total of 1788 cases of Brucellosis were reported. The number of male cases was 1163 (65.04%) and female cases were 625 (34.95%). People who had a history of contact with infected animals were younger than the others. Musculoskeletal pain (79.69%) and fever (76.45%) were the most commonly reported clinical symptoms.

CONCLUSION: Overall, the results indicate that Brucellosis is still a health problem in the province. The high incidence of Brucellosis in villages, the lack of full coverage of animal vaccination, and the link between the disease and livestock businesses are significant.

KEYWORDS: Brucellosis; Brucella Infection; Iran

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Introduction

Brucellosis is a common widespread zoonotic disease between humans and livestock with significant economic and health problems caused by various species of Brucella.[1,2] All cases of Brucellosis infection in humans are directly or indirectly contaminated with animal or animal products, and the incidence of disease is directly related to the prevalence of animal disease, socioeconomic status, food habits, poor health, and occupations that cause exposure to humans or infected animals.[3] Person-to-person transmission of Brucellosis is infrequent, and animals and their products are the primary sources of human Brucellosis.[4] The Brucellosis

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disease in humans is followed by consuming raw milk, its products, and cooked meat.[5]

The disease is a significant public health issue throughout the world and one of the most socioeconomic problems in many developing countries, especially in the Mediterranean Basin, North and East Africa, the Middle East, the Arabian Peninsula, the Indian Subcontinent, and parts of South America and Central Asia.[6] According to the World Health Organization (WHO) reports, annually, more than 500000 new cases are found in different parts of the world.[7,8] About 50000 cases of Brucellosis are reported annually. In different countries, contamination varies from 3.5 to 10.5 per thousand varieties.[9] Human Brucellosis is endemic in Iran and is continuously reported from different parts of the country.[10] In a study conducted in Gonbad-e Kavus County in Golestan Province, Iran, 13.2% of the studied population were infected with Brucellosis.[11] In another study, patients referred to the 5th Azar Hospital in Gorgan, Golestan Province, Iran, had the highest Brucellosis in these areas in men and residents of villages.[5]

This disease is a multi-system disease and clinical signs generally include fever, weight loss, arthritis, spondylitis, hepatosplenomegaly, and neurological symptoms.[12] The most common clinical manifestation is fever (83.1%), followed by arthralgia and back pain, and the most common complication of this disease is spondylitis (10.4%).[5] Clinical signs of human Brucellosis are non-specific and very different.[13] Since the symptoms of human Brucellosis are not specific, it can be clinically confused with the febrile disease, especially malaria.[4] Endocarditis and aortic valve infection as well as other valves are reported with Brucellosis, which can be up to 5% of mortality in humans.[14]

Despite extensive studies on zoonotic diseases, few studies have been done on Brucellosis.[15-17] According to the prevalence of Brucellosis and the importance of diagnosing and treating the disease, the study of the condition of Brucellosis in the Golestan Province can provide valuable information about the condition and its risk factors as a febrile illness and a major zoonotic disease. Employees of the health system will be able to benefit from the results of our study in preventing, controlling, and treating illnesses. This study aimed to report the information available at the Provincial Health Center about the frequency and characteristics of patients with Brucellosis in Golestan Province.

Materials and Methods

This was an analytic-descriptive cross-sectional study. The study population included all patients with Brucellosis diagnosed from April 2011 to March 2015 in the Provincial Health Center of Golestan based on the serological method. The serum of patients was examined by Standard Agglutination Test (SAT) and 2-Mercaptoethanol (2-ME) method. The titers of SAT over 1/80 and 2-ME over 1/40 were considered as the definitive diagnosis of Brucellosis.

The data gathering tool was a questionnaire that included demographic information, clinical presentation and examinations, history of exposure, laboratory findings, and treatment protocols. The infectious disease specialist and epidemiologist evaluated the content validity of the questionnaire. Sampling was started after taking the required permission for the research from the Ethics Committee in the Research and Technology Deputy of Golestan University of Medical Sciences, Gorgan. Since the information was recorded with the code, and the name of the patients was excluded in the research, the confidentiality of the data was fully respected. No one had the right to access information other than study performers. Data extracted from the records of patients who were admitted with Brucellosis diagnosis in Golestan Province Health Center during 2011-2015 were collected. Finally, descriptive statistics were reported as frequency and mean ± standard deviation (SD)

and analyzed by SPSS software (version 22, IBM Corporation, Armonk, NY, USA).

Results

A total of 1788 cases were evaluated. The lowest rate of Brucellosis was reported in 2011 with 11.12% and the highest rate in 2014 with 29.97% (Figure 1). A total of 1788 cases of Brucellosis were detected, and the mean ± SD of subjects' age was 34.17 ± 17.10 years. The age range of patients was from 1 to 20 years, and the last age range was 87-61 years. The highest number of patients was in the age group of 21-40 years (40.65%).

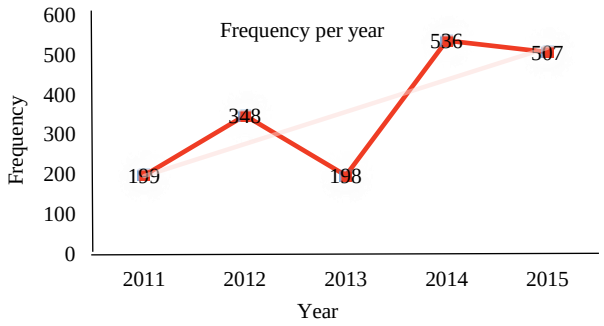

Figure 1. Frequency distribution of Brucellosis during 2011-2015

The youngest patient was 1 year old, and the oldest was 87 years old (Figure 2). Among the patients with Brucellosis, 547 (30.59%) were Turkmen.

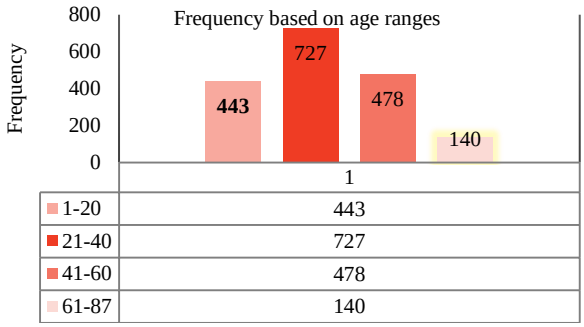

Figure 2. Frequency distribution of Brucellosis based on the age ranges

The frequency of cases was 1163 (65.04%) in men and 625 (34.95%) in women. Of these, 1473 (82.38%) lived in the village and 293 (16.38%) lived in the city. The two cities of Marwa Tappeh with 213 cases (11.91%) and Agh Qala with 55 cases (3.07%) had the highest and lowest incidence, respectively. Stockbreeder (35.91%) included the most among different occupations (Table 1).

Table 1. Demographic characteristics of patients with Brucellosis

Variables	n (%)
Gender	
Male	1163 (65.05)
Female	625 (34.95)
Living place	
Village	1473 (82.38)
City	293 (16.38)
Nomads	22 (1.24)
Job	
Stockbreeder	642 (35.91)
Housekeeper	505 (28.24)
Butcher	6 (0.33)
Farmer	56 (3.13)
Workman	119 (6.65)
Others	460 (25.71)

In 2014 and 2015, two and four pregnant women were reported with Brucellosis, respectively. The mean age of men with Brucellosis was significantly lower than that of women. Villagers with Brucellosis also had a significantly lower age than urban residents. Those who had a history of contact with infected animals were significantly younger than the others (Table 2).

The frequency of clinical features in patients was very different, but muscle pain and fever were the most common ones (Figure 3). Considering that, in most cases, a patient with multiple clinical manifestations has been contacted simultaneously, the total percentages were reported to be higher than 100%. Contact with infected animals was reported in 1426 people (79.75%). Vaccination of livestock was registered in 833 (46.58%) cases. In 1521 (85.66%) cases, consumption of non-pasteurized dairy products was reported, and 271 (15.15%) cases had a positive family history.

Table 2. Comparison of the mean and standard deviation (SD) of age of people with Brucellosis in terms of gender, location, and history of contact with infected animals

Variables		Age (year) (mean ± SD)	n (%)
Gender	Male	31.76 ± 16.55	0.004
	Female	37.50 ± 16.70	
Location	Village	33.08 ± 16.71	< 0.001
	City	37.15 ± 17.01	
The history of contact with an infected animal	Yes	33.08 ± 16.54	0.001
	No	37.16 ± 17.75	

SD: Standard deviation

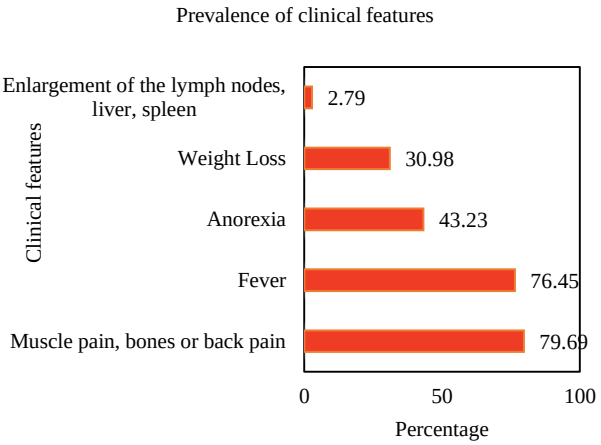

Figure 3. Frequency of clinical manifestations

As shown in table 3, 26 patients (1.45%) complained of complications. Arthritis was the most common complication of the disease, which was observed in 20 cases (1.11%) and spondylitis and orchitis occurred in 4 (0.22%) and 2 (0.11%) cases, respectively.

Table 3. Frequency distribution of complications

Complication	n (%)
Arthritis	20 (1.12)
Spondylitis	4 (0.22)
Orchitis	2 (0.11)
Total	26 (1.45)

Totally, 1313 (73.44%) cases were treated with two drugs, and 475 (26.56%) were treated with three drugs. In patients treated with three drugs, in almost all cases, streptomycin or gentamicin was prescribed in the first 7-10 days, and the continued treatment of patients was two drugs (Table 4).

Table 4. Frequency of patients with Brucellosis based on the type of treatment performed

Type of treatment	n (%)
Double drugs*	1313 (73.44)
Triple drugs**	475 (26.56)

* Double drugs include: Tetracycline + rifampin/streptomycin + rifampin/streptomycin + doxycycline/cotrimoxazole + rifampin/doxycycline + rifampin/cotrimoxazole + doxycycline/streptomycin + cotrimoxazole

** Triple drugs include: Rifampin + streptomycin + doxycycline/streptomycin + cotrimoxazole + rifampin/cotrimoxazole + streptomycin + doxycycline/doxycycline + rifampin + gentamicin

Discussion

In our study, with the review of records of patients with a definite diagnosis of Brucellosis in Golestan Province during the years 2011 to 2015, the prevalence of Brucellosis was 1788 cases. In a study by Ebrahimpour et al. in Babol, Iran, 377 patients with Brucellosis were reported during 2010.[18] According to the WHO, the incidence of the disease is half of a million every year, and the prevalence in our region varies from 0.5 per 100 to 10.9 per 100 people in different provinces.[19] In this study, in terms of age distribution, the mean age of the cases was 34.17 years, and the SD of the age was 17.17. The youngest person was 1 year old, and the oldest was 87 years old. The highest number of patients was in the age group of 21-40 years (40.65%).

According to a study done in Gonbad-e Kavus by Poorhajibagher et al. between 2009 and 2011, the highest prevalence of Brucellosis in the patients referred to the Gonbad-e Kavus Health Center belonged to the age group of 20-29 years (26.20%), and the highest prevalence

of the disease was in the age group under 40 years old.[11] In a study by Hasanjani Roushan et al. in Babol, the mean age of patients was 34.0 ± 16.9 years, 44.10% of patients were between 21-40 years old, and 24.90% of them were < 20 years old.[20]

Brucellosis has been observed at all ages, but it is more prevalent in younger age groups than in the older ones, as in the study by Zeinalian et al. in 2012. The mean age of the infected patients was 31.30 years, which is probably due to the high chance of dealing with infected animals and their products.[19] In terms of the gender of the patients, 67.20% of men and 32.80% of women were ill. As a result, in our study, the outbreak in men was more than women. According to a study by Hosseini et al. between 2011 and 2013 in Amol, Iran, 104 cases (60.12%) were men, and 69 (39.88%) cases were women.[21] Also, in Hasanjani Roushan et al.'s study in Babol, 957 patients with Brucellosis were observed, of whom, 55.9% were men,[20] which is matched with our study. This increase in the men prevalence can be due to several factors, such as the slaughtering job of these individuals.

In this study, the prevalence of Brucellosis in rural areas (82.38%) was significantly higher than in urban areas (16.38%). Also, in a study by Hosseini et al., 68.21% of people with Brucellosis lived in village and 31.79% of them lived in city.[21] This can be due to job and direct contact with livestock and non-pasteurized dairy products in villagers, and less access to pasteurized dairy products in villages.

In our study, the mean age of men (31.76 years) with Brucellosis was lower than women (37.50 years). The villagers (33.08 years) with Brucellosis also had a higher incidence of Brucellosis than urban residents (37.18 years). Those who had a history of contact with infected animals (33.08 years) were younger than the others (37.16 years). However, in other studies that we examined, the relationship between these variables and age was not studied. In terms of job, livestock jobs (35.99%) had the highest incidence among different occupations in our study. A study by Mosavi et al. showed that the most prevalent disease was in livestock, agriculture, and housekeeping occupations.[22] The similar study conducted by Earhart et al. also showed that most of the patients had livestock jobs,[23] but a study by Ebrahimpour et al. showed that the most frequent illness was in homemakers.[24]

In our study, muscle, bone, and back pain (79.69%) and fever (76.45%) were the most common clinical manifestations of the disease. The enlargement of lymph nodes, liver, and spleen had the lowest incidence (2.79%). In a study by Hasanjani Roushan et al. in Babol, the most common clinical manifestations were arthralgia (71.00%), sweating (66.70%), fever (57.20%), and backache (39.30%).[20] As a result, Brucellosis disease can occur as unusual clinical manifestations and the simultaneous involvement of various organs. For this reason, endemic areas should be considered.

Also, 547 (30.55%) Turkmen were among the patients with Brucellosis. In this study, 1313 people (73.44%) were treated with two drugs, and 475 people (26.56%) were treated with three drugs. However, in other studies that we reviewed, these were not mentioned. In this study, in general, 26 patients (1.45%) had complications that arthritis was the most common complication of the disease, which was observed in 1.11% of patients and orchitis (0.11%) had lowest outbreak. In the study of Hasanjani Roushan et al., the most common complication was arthralgia (71.00%).[20] A study by Taheri Soodejani et al. also showed that fever was the most frequent clinical symptom among patients.[25]

Contact with infected animals was found in 75.79% of cases. In this study, non-pasteurized dairy products were present in 85.06% of cases. The results of the study by Mosavi et al. showed that more than 85.00% of patients had a history of non-pasteurized milk consumption

and 90.00% of them reported a history of contact with an infected animal.[22] The study by Taheri Soodejani et al. also found that contact with infected animals had the highest frequency of risk factors among patients.[25] Ebrahimpour et al. also found that the consumption of cheese and non-pasteurized milk was the most common among risk factors.[24] Vaccination of livestock in the area of Brucellosis residence was recorded in 46.58%. However, in other studies we reviewed, these were not mentioned. The family history of Brucellosis was 15.15% in our study.

Although spondylitis was reported in only four cases in our study (2011-2015), Ghasemian et al.[26] in Mazandaran Province (2013-2017) reported 14 cases. As the duration of both studies is similar (5 years), the higher frequency can be resulted that their study has been performed in Infectious Diseases Center of Mazandaran Province.

Conclusion

In general, the results indicate that Brucellosis is still a health problem in the province. The high incidence of Brucellosis in villages, the lack of animal vaccine coverage, and the link between disease and occupations associated with livestock are significant.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

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Patient adherence to tyrosine kinase inhibitor therapy in chronic myeloid leukemia: influence of coping strategies and psychological factors

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Original Article

Abstract

BACKGROUND: Medication non-adherence is associated with poor health outcomes and increased healthcare costs. Although the use of tyrosine kinase inhibitor (TKI) for chronic myeloid leukemia (CML) treatment is satisfactory in clinical results, it is subject to non-adherence. In this study, we intend to verify if there are psychological factors, such as anxiety, depression, and coping style that can influence medication adherence.

METHODS: The study was conducted on 120 patients with CML receiving long-term TKI therapy. The sample was collected in the years 2016-2017 at Department of Oncology-Hematology in Pescara, Italy. Adherence behaviour was measured with the eight-item Morisky Medication Adherence Scale (MMAS-8) and psychological factors investigated included: anxiety and depression symptoms [Hospital Anxiety and Depression Scale (HADS)] and coping strategies [abbreviated version of the Coping Orientation to Problems Experienced (Brief-COPE)]. T-test and logistic regression analyses were performed to investigate factors associated with medication adherence.

RESULTS: The participants, 74 men and 46 women, reported a mean age of 56.65 ± 15.80 years. The results showed that 71.67% of the patients were adherent while 28.33% were non-adherent. Furthermore, adherence was positively associated with active coping ($P < 0.050$) and instrumental support ($P < 0.001$). Also, depression symptoms were risk factor for non-adherence ($P < 0.050$).

CONCLUSION: This study suggests that active coping strategies with a good level of instrumental support are factors associated with greater adherence to long-term therapy. The results of this study support paying attention to factors identified as being helpful in monitoring patients with a risk of non-adherence. There is a need to provide increased psychosocial support for patients with chronic disease by planning effective client-focused interventions.

KEYWORDS: Adherence; Chronic Myeloid Leukemia; Coping Strategies; Anxiety; Depression

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Introduction

The use of the new tyrosine kinase inhibitor (TKI) has revolutionized the treatment of chronic myeloid leukemia (CML). Since the advent of TKI, patients with CML had significantly improved prognosis. Although most patients treated with TKI have durable responses, resistance and side effects occur in some patients. This induces the patient to postpone or refuse the treatment. This is the reason why today there is a great difficulty in achieving an adequate therapeutic compliance.[1] According to the World Health Organization (WHO), approximately 50% of chronically ill patients who undergo long-term treatment are non-adherent to their

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medication and non-adherence is related with poor health outcomes and increased healthcare costs.[2] A systematic review about adherence in patients with hematological malignancies reports adherence rates between 20%-53% in patients with CML and non-adherence rates of 6%-35% in patients with acute lymphoid leukemia (ALL).[3] In addition, socio-economic factors are found to be associated to medication non-adherence.[4,5] A recent study shows how in patients with CML treated with imatinib (IM) for some years, poor adherence may be the predominant reason for inability to obtain adequate molecular responses. In addition, optimal drug adherence was associated with positive health outcomes.[6] Another study shows that the higher the adherence, the lower the level of breakpoint cluster region gene (BCR) at chromosome 22q11 to the Abelson gene (ABL1) (BCR-ABL1), but there are not many studies that investigate the influence of psychological factors on adherence.[7]

Coping strategies influence non-adherence and comorbidities in patients with chronic disease.[8] Exploration of these influencers has important implications for health education. Coping refers to the way an individual engages, both behaviourally and cognitively, to attenuate the impact of a stressor.[9] Coping is most commonly divided into two patterns: active (or problem-focused) and passive (or emotion-focused). Preceding studies have shown that people who respond with acceptance, positive reinterpretation, and problem-focused coping appear to be correlated to better psychological condition and better illness outcome, whereas a passive coping style is correlated with worse illness outcome.[10]

Other psychological factors associated with poor adherence are depressive and anxiety symptoms. A recent study shows the depressive trait as independent predictor of medication adherence.[11] Also, the results indicate that patients with psychological distress are at increased risk of non-adherence, and could therefore benefit from extra attention from the healthcare professionals. Patients with symptoms of anxiety and/or depression should be identified and monitored in order to improve adherence to medication regimens. The assessment of anxiety and depression in patients with acute leukemia since hospital admission is substantial for the adherence to treatment.[12]

Therefore, this cross-sectional study looked at patients with CML hospitalized in the Department of Oncology-Hematology, UOC Clinical Hematology, Regional Authority of Abruzzo, Pescara, Italy. The hypothesis is that non-adherent patients manifested more depression and anxiety symptoms compared to adherent patients, and that some coping strategies can be predictors of a good adherence. Therefore, the aim of this study is to determine the relationship of coping styles, anxiety, and depression with adherence in patients with TKIs treatment.

Materials and Methods

The study was submitted and approved by the Ethical Committee with the name of "Observational study of psychological factors: Adherence in treatment with TKI in CML". The research protocol was also authorized by the Ethics Committee (code: LMC-QoL01 of 28/09/2015) of ASL of the General Hospital in Pescara. The research was conducted with respect for the rights of all participants and the data were analysed entirely anonymously. Thus, all 120 participants were volunteers who filled out the questionnaires in a confidential setting.

A consecutive and unselected sample of 122 patients in the Department of Oncology-Hematology of the Civil Hospital, in Pescara was recruited in the years 2016-2017. Of the 122 recruited patients, 120 (98.3%) accepted to be enrolled. There are no missing data. Therefore, the sample consisted of 120 patients of both genders with a medically-documented diagnosis of CML, in the first line of treatment with TKIs, according to the diagnostic criteria of the WHO. Patients taking part in this study were

hospitalized in the UOC Clinical Hematology and all patients were contacted by clinical psychologists in collaboration with medical hematologists. We included patients of both sexes who met the following inclusion criteria: a) adult patients with an age ranging from 18 to 75 years, b) diagnosis of CML, and c) patients in treatment with TKI for at least six months. By contrast, patients with severe addictions and neurological or psychiatric disorders were excluded from the study. Moreover, patients suffering from CML previously submitted to bone marrow transplantation (BMT) and patients with CML who had undergone TKI for less than 6 months were excluded from the study. All participants completed the following self-rating scales: Hospital Anxiety and Depression Scale (HADS), abbreviated version of the Coping Orientation to Problems Experienced (Brief-COPE), and eight-item Morisky Medication Adherence Scale (MMAS-8).

The demographic and social factors such as age, gender, and housing situation were collected at baseline (i.e., at the time of diagnosis) (Patient Advocacy and Research Ethics). The clinical outcomes including the years of therapy, monitor, report, respond, and remedy ate (MR3), anxiety, and depression were obtained from the patients' medical records.

The presence of depressive and anxiety symptoms was assessed using clinical interview and self-report HADS.[13] HADS scale was used to measure anxiety and depression levels and consisted of two subscales. Both of them were structured of seven items scored from 0 to 3. Out of a possible 21 points, 0-7 points were considered normal, scores ranging between 8 to 10 were considered borderline, and > 11 points indicate severe symptoms of anxiety and depression.

The MMAS-8,[14] a standardised test, was used to measure adherence. Patients who scored 8 points, < 8 to > 6 points, and ≤ 6 points on the scale were considered to have high, medium, and low adherence, respectively. This test has been developed from the well-validated Morisky-Green Test and The eight-item Morisky Medication Adherence Scale (MMAS-8). The internal consistency reliability of the Italian version of 8-item MMAS, measured by the Crohnbach's α, had a value of 0.89. The MMAS is composed of 8 questions that explore adherence behaviour based on forgetfulness, negligence, interruption of drug intake, and restart when symptoms worsen. This definition of adherence is based on how patients theoretically would have completed the MMAS if they had taken at least 95% of prescribed doses.

The Brief-COPE[15] is a self-report, validated, 28-item questionnaire that evaluates state coping, which is the manner in which an individual copes in response to a specific situation (i.e., the cancer diagnosis). It consist of 14 subscales (2 items per subscale) measuring the following: self-distraction, active coping, denial, substance use, use of emotional support, use of instrumental support, behavioural disengagement, venting, positive reframing, planning, humour, acceptance, religion, and self-blame. Cronbach's α ranges from 0.50 to 0.90 for the Brief-COPE subscales. Each single item is scored along a 4-point scale with the following options: 1) I usually do not do this at all, 2) I usually do this a little bit, 3) I usually do this a medium amount, and 4) I usually do this a lot. The following 8 subscales are classified as adaptive strategies: active coping, planning, positive re-framing, acceptance, humour, religion, use of emotional support, and use of instrumental support. The remaining 6 subscales are considered to be maladaptive and include self-distraction, denial, venting, substance use, behavioural disengagement, and self-blame. The maximum score for the 14 subscales is 8 points, with a higher score indicating greater use of a specific coping strategy.

A 3-step strategy was used for data analysis. First, socio-demographic and clinical variables

between adherent and non-adherent patients were compared using Student's t-test or chi-square test, and effect sizes were expressed as standardized mean differences. A standardized effect size (Cohen's d) of 0.20-0.50 is considered small, 0.50-0.80 moderate, and > 0.80 is considered large. The reliability of the applied scales was assessed using Cronbach's α coefficient. Second, binary logistic regression analysis was performed to identify major determinants that best predict the adherence; the letter as a dependent variable (dummy coded: 0 = low adherence, 1 = adherence) and the independent variables were age, sex, years of therapy, depression, and anxiety symptoms and coping strategies. Four regression models were processed and regression coefficients, the related confidence intervals (CIs), odds ratios (ORs), and P-values were estimated. We also calculated the R^2 coefficient value for each of the adjusted models. Third, direct maximum likelihood (ML) confirmatory factor analysis (CFA) was used to examine the construct validity of the Italian MMAS-8 scale. Data were analysed using Stata software (version 13, Stata Corporation, College Station, TX, USA) at the statistical significance level of $P < 0.050$.

Results

120 participants reported a mean age of 56.65 ± 15.80 years, with ages between 23 and 75 years and were predominantly men (n = 74). Most of the participants resulted to be currently married (n = 104) and the participants of the study were assessed for years of therapy that showed an average of 6.30 [standard deviation (SD) = 4.6] years. Table 1 reports the comparisons between adherent and non-adherent patients. According to our results, 71.67% of patients were considered as adherers; therefore, they regularly followed the recommended drug therapy, while 28.33% of the patients presented non-adherence to the drug therapy. To check the reliability of the factors (psychological dimensions), Cronbach's α coefficients were computed. The results showed that Cronbach's α resulted greater than 0.70 for all the factors, meaning that each factor scale had consistency. No between-group significant differences were found in socio-demographic and clinical (years of therapy) characteristics. The two subgroups of patients, adherent and non-adherent, were markedly different when they were evaluated for active coping, emotional and instrumental support, with low effect sizes in the small range. Adherent patients reported significantly higher active coping and emotional and instrumental support scores than non-adherent patients (5.64 ± 1.73 vs. 5.27 ± 1.94, 4.40 ± 1.88 vs. 3.97 ± 1.74, 4.97 ± 1.97 vs. 4.27 ± 1.97, respectively) with effect size of d = 20, d = 23, and d = 35, respectively. Same significant between-group differences were found for the depression symptoms but not the anxiety trait. Moreover, non-adherent patients had significantly higher depressive (9.63 ± 6.03) scores than the adherent group (5.31 ± 4.56) (d = 0.32). A significant difference was found between groups for MR3 clinical variable ($P < 0.001$) (Table 1).

4 regression models with adherence score as binary outcome were explained. The first model with age and sex, as principal predictors, explained a small part of the adherence variance ($R^2 = 0.04$). The second model was adjusted with years of therapy and MR3 variables adding 17% to the explained variance (OR = 1.03). The third model adjusted for depressive and anxiety scale explained a major part of the variance ($R^2 = 0.19$). The final model, adjusted for emotional support, active coping, and instrumental support scores predicted 22% of the explained variance (OR = 0.95, OR = 1.02, OR = 1.32, respectively). The results showed that depression symptoms ($P \leq 0.050$) were risk factors of non-adherence, but active coping ($P \leq 0.050$) and instrumental support ($P \leq 0.001$) were significant predictors of adherence. No significant results were found for age, gender, years of therapy, anxiety symptoms, and emotional support variables (Table 2).

Table 1. Socio-demographic and clinical characteristics of the study sample: Comparison with adherence (n = 120)

Variable		Total sample (n = 120)	Adherence (n = 86)	Non-Adherence (n = 34)	t/χ^2	P	Cohen's d
Gender	Men	74	52 (60.47)	22 (64.71)	-0.42	0.670	0.08
	Women	46	34 (39.53)	12 (35.29)			
Housing situation	Living alone	16	12 (13.95)	4 (11.77)	0.31	0.750	0.18
	Living with others	104	74 (86.05)	30 (88.23)			
MR3	Yes	107	84 (97.67)	23 (67.64)	5.25	< 0.001	0.80
	No	13	2 (2.33)	11 (32.36)			
Age (year)		56.65 ± 15.80	57.49 ± 15.42	54.61 ± 16.98	-0.88	0.370	0.18
Brief-COPE	Active coping	5.38 ± 1.88	5.64 ± 1.73	5.27 ± 1.94	1.96	< 0.001	0.20
	Planning	5.45 ± 2.10	5.47 ± 2.17	5.38 ± 1.93	-0.22	0.820	0.04
	Positive refraining	5.63 ± 1.99	5.60 ± 2.11	5.70 ± 1.67	0.24	0.800	0.05
	Acceptance	7.15 ± 1.40	7.17 ± 1.48	7.08 ± 1.21	-0.30	0.760	0.06
	Humour	3.92 ± 1.76	7.89 ± 1.77	4.00 ± 1.75	0.29	0.750	0.05
	Religion	5.15 ± 2.26	5.24 ± 2.26	4.94 ± 2.29	-0.66	0.500	0.13
	Emotional support	4.28 ± 1.85	4.40 ± 1.88	3.97 ± 1.74	1.16	< 0.001	0.23
	Instrument support	4.78 ± 1.99	4.97 ± 1.97	4.27 ± 1.97	-1.74	< 0.001	0.35
	Self-distraction	5.00 ± 1.98	5.10 ± 2.02	4.76 ± 1.89	-0.84	0.400	0.17
	Denial	2.90 ± 1.66	2.93 ± 1.74	2.85 ± 1.45	0.22	0.810	0.04
	Venting	4.11 ± 1.86	4.77 ± 1.89	3.73 ± 1.78	-1.42	0.100	0.28
	Substance use	2.12 ± 0.64	2.16 ± 0.74	2.03 ± 0.17	-1.01	0.310	0.20
	Behavioural disengagement	3.11 ± 1.68	3.19 ± 1.67	2.91 ± 1.71	-0.83	0.400	0.16
	Self-blame	3.88 ± 1.49	3.86 ± 1.59	3.96 ± 1.21	0.32	0.740	0.07
Years of therapy		6.30 ± 4.64	6.46 ± 4.67	5.86 ± 2.01	0.59	0.550	0.12
HADS-D		6.56 ± 5.26	5.31 ± 4.56	9.63 ± 6.03	-5.21	< 0.001	0.32
HADS-A		6.61 ± 3.80	6.45 ± 3.84	7.02 ± 3.74	0.74	0.450	0.15

Data are presented as mean ± standard deviation (SD) or number and percentage
MR3: monitor, report, respond, and remediate; COPE: Coping Orientation to Problems Experienced; HADS-A: Hospital Anxiety and Depression Scale-Anxiety subscale; HADS-D: Hospital Anxiety and Depression Scale-Depression subscale

At last, the CFA showed satisfactory construct and results pointed to a one-factor solution in all the items contributed to the final index of adherence. Accordingly, the Italian version of the MMAS-8 is a reliable and valid measure of medication adherence (Table 3).

Table 2. Predictors of adherence, results of binary regression models (n = 120)

Variables	β	OR (95% CI)	P	R^2
Model 1				0.04
Age	0.01	1.01 (0.98-1.03)	0.950	
Gender	0.28	0.64 (0.28-1.46)	0.290	
Model 2				0.17
+ Years of therapy	0.03	1.03 (0.93-1.13)	0.640	
+ MR3	0.73	1.11 (0.95-1.19)	< 0.001	
Model 3				0.19
+ HADS-A	0.05	0.95 (0.83-1.11)	0.440	
+ HADS-D	-0.11	1.02 (0.85-1.13)	< 0.050	
Model 4				0.22
+ Emotional support	0.04	0.95 (0.78-1.35)	0.790	
+ Active coping	0.15	1.02 (1.05-1.09)	< 0.050	
+ Instrumental support	0.30	1.32 (0.94-1.85)	< 0.001	

HADS-A: Hospital Anxiety and Depression Scale-Anxiety subscale; HADS-D: Hospital Anxiety and Depression Scale-Depression subscale; OR: Odds ratio; CI: Confidence interval

Table 3. Factor loading patterns of the Italian eight-item Morisky Medication Adherence Scale (MMAS-8) (n = 120)

Item as numbered in the original MMAS-8	Items loading
1. Do you sometimes forget to take your medications?	0.61
2. People sometimes miss taking their medications for reasons other than forgetting. Thinking over the past two weeks, were there any days when you did not take your medicine?	0.73
3. Have you ever cut back or stopped taking your medication without telling your doctor, because you felt worse when you took it?	0.44
4. When you travel or leave home, do you sometimes forget to bring along your medication?	0.59
5. Did you take your medicine yesterday?	0.32
6. When you feel like you are under control, do you sometimes stop taking your medicine?	0.62
7. Taking medication every day is a real inconvenience for some people. Do you ever feel hassled about sticking to your treatment plan?	0.40
8. How often do you have difficulty remembering to take all your medications?	0.28

Values in bold are those with a loading at 0.32 or higher on a factor which means that they pertain to this factor
MMAS-8: Eight-item Morisky Medication Adherence Scale

Discussion

Patients with chronic disease could have different elapses and evolutions, not always explainable with organic factors or with objective differences of environmental or social contexts. The way in which the patient can give a meaning to the drug, which is both slavation (Patient Advocacy and Research Ethics) and limit, will have great importance for the whole run of his/her own illness. In psychology, adherence is a process by which individuals create their own balance or at least, an absence of conflict, with the environmental conditions. The adherence of patients with chronic illness is a mediator among the psychological, social, environmental, and physical characteristics that plays a crucial role. A complete adherence is the moment when the patient is included in his/her life medicine and the disease.[16]

Given the paucity of data in the CML literature, we selected possible factors associated with adherence behaviour based on previous studies in other chronic medical conditions. Evidence from other studies on adherence in chronic patient populations showed that younger age was associated with lower adherence as well.[17]

There are a number of studies which focused on anxiety and depression in cancer; however, the same interest is not observed in the field of hematologic malignancies. This study was to test the prevalence of adherence to TKI treatment in patients with CML and evaluate psychological factors (anxiety and depression traits) associated with adherence. The second step was to explore the association between coping styles as predictors of adherence. The results confirm that patients with a good level of adherence are 71.67% of the observed group. Furthermore, the results confirm that in CML therapy, a good adherence is essential for a successful treatment. However, this element decreases with the increase of the years of treatment for both sexes, but in our study, it is not statistically significant.

Psychological and medical supports at the time of diagnosis and during treatment are essential to revitalize the patient's desire to live and increase the adherence to treatment.[12] The study of psychological dimensions in patients with CML showed that some coping strategies were potentially significant for the definition of adherence. A recent study by Conti et al. shows that increasing the depression levels decreases the medication adherence;[18] and also from our results, it is observed that depression is a risk factor for low adherence.

As for the coping behaviour, it has been shown that the use of the active coping strategies (positive reappraisal, self-

controlling) helps patients with cancer to significantly reduce the level of anxiety and depression caused by the uncontrollable threat to life and the high uncertainty of the disease situation. It has been indicated that excessive use of an avoidance coping style can easily produce negative emotions and then affect treatment adherence.[19] The use of passive emotional-oriented coping strategies such as avoidance is often associated with low adherence to treatment in patients with chronic disease. In a recent study, even a negative effect of the avoiding coping on outcome of cancer was found.[20] As well, in this study, we found a positive relationship between adherence and patient's coping strategies; patients showing greater adherence frequently use coping strategy as: active coping and instrumental support. Binary regression analysis reflected the need for developing strategies to strengthen instrumental support and active coping as a factor in promoting adherence to treatment, but it shows that patients with high levels of depression have low adherence to therapy. Therefore, depression symptoms can be risk factors for health outcomes.

This study contributes to the growing literature on the effect of depression symptoms and coping style on adherence. Our results imply that interventions that improve coping style and better adherence may lead to improved health outcomes and should thus be explored. Hence, to prevent negative emotions and treatment non-adherence in the future, psychological interventions should be conducted to improve the coping style of haematological patients. We can say that psychological support improves adherence.

Another limitation of the study was that due to its cross-sectional nature, it only explains the relationship between the variables affecting adherence and is not capable of showing the sequence. Longitudinal studies could provide more insight into the underlying mechanism of the relationships found in this study.

Conclusion

Patients with symptoms of anxiety and/or depression should be identified and monitored in order to improve adherence to medication regimens. In conclusion, the regression models explained less than 22% of the variance of the study outcome. Therefore, further research is required to explore which additional factors can determine coping styles and adherence among patients with CML.

Limitations: This study is not without limitations. First, because it was conducted in a relatively small group of inpatients treated in a single health facility, its results are applicable only to the patients surveyed, and thus, they cannot be generalized to other patients. Second, we relied exclusively upon self-report measures for assessing our constructs and the use of self-reporting for data selection, so the participants' answers might be subject to social desirability bias.

Conflict of Interests

Authors have no conflict of interests.

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The relationship between childhood emotional maltreatment and disordered eating behaviors among students: Mediating role of emotion dysregulation: A cross-sectional study

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Original Article

Abstract

BACKGROUND: Previous studies have shown that childhood emotional maltreatment (CEM) plays a role in development of disordered eating behaviors (DEBs). Difficulty in emotion regulation is another factor influencing disordered eating. This study was directed to examine the association between CEM and DEB among students, by considering the emotion dysregulation as a mediator.

METHODS: This correlational study was conducted in form of a cross-sectional design, using structural equation modeling (SEM) to analyze the data collected from 401 non-native undergraduate students through convenience sampling method. Childhood Trauma Questionnaire (CTQ) was used to assess childhood emotional abuse and neglect. Emotion dysregulation and DEB were respectively measured using the Difficulties in Emotion Regulation Scale (DERS) and Eating Attitude Test (EAT).

RESULTS: The partial mediation model of difficulties in emotion regulation in the association between CEM and DEB among male and female students had a good fit to the data. The outcomes of the gender specificity of structural relations in the model confirmed gender invariance of the structural model. All regression weights in the model were statistically significant and the CEM and emotion dysregulation variables accounted for 22%, 17%, and 35% of the variance of DEB among the entire sample, female students, and male students, respectively.

CONCLUSION: The outcomes are in line with research findings suggesting a relationship between CEM and DEB, and confirm the role of emotion dysregulation as a mediator. This highlights the importance of assessment of childhood experiences in treatment of eating disorders and introduce emotion regulation as a significant target for intervention.

KEYWORDS: Eating Disorders; Emotional Regulation; Emotions

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Introduction

Eating and feeding behaviors are changing dramatically around the world. Along with the change in the beauty ideals, the concept of eating behavior patterns has also undergone a change. Significant shift in beauty standards of society toward a leaner body has led to obsession with dietary restraint and weight loss, as well as an increasing prevalence of disordered eating behaviors (DEBs). Epidemiological studies report that the prevalence rate of eating disorders among female students lies within a range of 11%-17%[1] and among male students is about 4%.[2] DEBs are defined as problematic eating behaviors, compulsive overeating, restricted

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eating, meal skipping, and inappropriate weight loss or weight control methods including purging behaviors (e.g., self-induced vomiting and/or misuse of laxatives/diuretics) that due to inadequate frequency and/or severity do not satisfy the diagnostic criteria for a feeding or eating disorder namely anorexia nervosa, bulimia nervosa, binge-eating disorder (BED), or other specified/unspecified feeding or eating disorder. DEBs, although less severe, are more prevalent than eating disorders, and negatively impact the affected individuals' health and quality of life;[3] they have become one of the health challenges worldwide in recent years.[4]

Childhood maltreatment, as a multidimensional construct, consists of various types of abuse and neglect, including physical abuse, sexual abuse, emotional abuse, physical neglect, and emotional neglect. The experience of childhood maltreatment has played a role as a risk factor in development of eating disorders.[5,6] Emotional maltreatment has been defined as a construct including emotional abuse and emotional neglect. Emotional abuse has been defined as "verbal assaults on a child's sense of worth or well-being, or any humiliating, demeaning, or threatening behavior directed toward a child by an older person"; and emotional neglect has been described as "the failure of caretakers to provide a child's basic psychological and emotional needs, such as love, encouragement, belonging, and support".[7] The association between childhood emotional abuse and DEBs has been supported by research findings.[8-10]

Emotion regulation refers to the ability to recognize emotions as well as control how emotions are felt, experienced, and expressed[8,11] and is an attempt to influence which emotions are experienced, and when and how the emotions are experienced or expressed. Gratz and Roemer[12] conceptualized emotion regulation/dysregulation as a multidimensional construct which involves the ability to modulate emotional arousal, to have an awareness and understanding of emotional experience, to accept emotional response, and to function purposively regardless of emotional state. Among all forms of childhood maltreatment, emotional maltreatment showed stronger associations with emotion dysregulation.[8,9]

Since DEBs are often associated with negative consequences in the areas of physical and mental health, disordered eating has the potential to become a clinical eating disorder if no measures are taken to prevent and treat it. The role of "childhood emotional maltreatment (CEM)" and "emotion dysregulation" as risk factors in the development of eating psychopathology reflects the need to formulate preventive measures for childhood traumatic events. Given that no similar research has been directed in this population, this study's purpose was to examine the association between CEM and DEBs among undergraduate male and female students, considering emotion dysregulation as a mediator.

Materials and Methods

The present correlational study was carried out in a cross-sectional design using structural equation modeling (SEM). The study population consisted of all non-native undergraduate male and female students of Shahid Beheshti University, Tehran, Iran. The research sample was selected through convenience non-probability sampling method due to executive constraints, including failure to access the population members list. The data were collected from 401 participants (aged 18-23 years), of whom 54.1% were women, at Shahid Beheshti University from February to June 2018. Given the research sample size and the number of parameters included in the hypothesized model, the ratio of 16 to 1 was achieved. Inclusion criteria were: 1) being 18 to 24 years old, 2) enrolment in the second semester of 2017-2018 academic years at Shahid Beheshti University and residency in

the dormitories of the university, and 3) obtaining informed consent. The research data were collected by demographic questionnaire, Childhood Trauma Questionnaire (CTQ), Difficulties in Emotion Regulation Scale (DERS), and Eating Attitude Test (EAT). The data were analyzed using SEM by SPSS Amos software (version 26.0, IBM Corporation, Armonk, NY, USA). To examine the gender invariance of the hypothesized model, the multi-group SEM was used. Firstly, the baseline unconstrained model (the hypothesized model without parameter constraints) was tested. Subsequently, the gender-based equivalence of the hypothesized model was analyzed through imposing equality constraints on measurement residuals, structural residuals, structural covariances, structural weights, and measurement weights in the two groups of male and female participants. In this study, the researcher emphasized on the theoretical and empirical evidence and hypothesized that some of the common dispersions between the conceptual circles of emotional maltreatment and DEBs in male and female students were explained by emotion dysregulation. The assumptions of SEM were examined. To handle the missing values which were less than 5% of the entire dataset for each variable, the Expectation-Maximization (EM) imputation method was used. The distribution of data was also found to be normal. The assumption of linear relationships was verified by examining the scatterplots. Further, the assumption of multicollinearity was examined by tolerance and variance inflation factor (VIF) and the criterion was confirmed. All stages of the study were conducted based on the latest version of the Declaration of Helsinki.

Demographic questionnaire, CTQ, DERS, and EAT were utilized for data collection in this study.

Demographic checklist: This checklist was designed and used by the researcher to collect data including the participants' age, sex, education, weight, and height.

CTQ: CTQ[7] was used to assess childhood maltreatment experience. This instrument consists of 28 items and measures childhood maltreatment in five dimensions of physical abuse, sexual abuse, emotional abuse, physical neglect, and emotional neglect and provides a score from 5 to 25 for each of subscales. CTQ also provides a total score for childhood maltreatment scale. The internal reliability of this tool has been reported to be acceptable in the study of Khosravani et al.[13] This research study used the emotional abuse and the emotional neglect subscales to measure CEM. The internal consistency of the emotional abuse subscale and the emotional neglect subscale was reported to be 0.82 and 080, respectively, in this study.

EAT-26: This questionnaire was developed as a self-assessment screening tool for eating-related disordered attitudes and behaviors. The tool has 26 items, using a six-point Likert scale, and consists of three subscales of dieting, bulimia and food preoccupation, and oral control. This scale provides a total score and three proprietary scores for the named subscales. The higher scores on each subscale and the whole scale indicate more abnormalities in eating attitudes and behaviors. The psychometric properties of this measure were reported to be optimal in Iranian sample. The internal consistency of this tool was reported to be 0.76-0.92, its test-retest reliability was 0.26-0.64, and the discriminant validity of the tool was reported acceptable. In this research, internal consistency coefficients of overall score and dieting, bulimia and food preoccupation, and oral control were estimated to be 0.80, 0.81, 0.72, and 0.67, respectively.

DERS: DERS is a self-report measure, consisting of 36 items, developed by Gratz and Roemer[12] to assess the difficulty in emotion regulation in six dimensions. Responses are measured using a five-point Likert scale from 1

(almost never) to 5 (almost always). This tool has six subscales of non-acceptance of emotional responses, difficulty engaging in goal-directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity. The outcomes of the research conducted by Cancian et al.[14] showed that this tool had acceptable simultaneous factor analysis, validity, and reliability. In this research, the internal consistency coefficients of the total score and subscales of non-acceptance of emotional responses, difficulty engaging in goal-directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity were estimated as 0.90, 0.84, 0.85, 0.84, 0.77, 0.86, and 0.75, respectively.

Results

Descriptive indices of the research variables for male and female participants are presented in table 1.

Descriptive findings showed that the sample consisted of 184 male and 217 female students. Test results of the correlation between aspects of CEM including emotional abuse and emotional neglect with dimensions of emotion dysregulation, including non-acceptance of emotional responses, difficulty engaging in goal-directed behavior, impulse control difficulties, lack of emotional awareness, limited access to emotion regulation strategies, and lack of emotional clarity, and facets of DEBs, including dieting, bulimia and food preoccupation, and oral control showed that there were positive and significant relationships between childhood emotional abuse and childhood emotional neglect and the dimensions of emotion dysregulation and DEBs in the two groups of male and female students ($P < 0.05$). Furthermore, the correlations between the dimensions of emotion dysregulation and the facets of DEBs were all positive and significant in both male and female students samples ($P < 0.05$).

Table 1. Descriptive indices of research variables in male and female students (sample size = 401)

Overall factor	Subscales	Group	Mean ± SD
CEM	Childhood emotional abuse	Male (n = 184)	7.47 ± 3.32
	Childhood emotional neglect		10.16 ± 3.72
Emotion dysregulation	Non-acceptance of emotional responses		14.42 ± 5.19
	Difficulty engaging in goal-directed behavior		14.59 ± 4.22
	Impulse control difficulties		15.11 ± 4.59
	Lack of emotional awareness		16.35 ± 3.92
	Limited access to emotion regulation strategies		19.55 ± 6.26
	Lack of emotional clarity		12.56 ± 3.77
DEBs	Dieting		2.65 ± 2.30
	Bulimia and food preoccupation		1.04 ± 1.11
	Oral control		2.62 ± 2.70
CEM	Childhood emotional abuse	Female (n = 217)	7.28 ± 2.93
	Childhood emotional neglect		10.11 ± 4.24
Emotion dysregulation	Non-acceptance of emotional responses		13.17 ± 5.16
	Difficulty engaging in goal-directed behavior		14.73 ± 4.64
	Impulse control difficulties		14.82 ± 4.96
	Lack of emotional awareness		15.61 ± 4.77
	Limited access to emotion regulation strategies		19.62 ± 6.10
	Lack of emotional clarity		11.90 ± 3.67
DEBs	Dieting		3.67 ± 3.27
	Bulimia and food preoccupation		1.12 ± 1.83
	Oral control		2.47 ± 2.61

CEM: Childhood emotional maltreatment; DEB: Disordered eating behavior; SD: Standard deviation

In order to explain the statistical dispersion of the distribution of DEBs by CEM and the mediation of emotion dysregulation in the samples of male students, female students, and the entire students, SEM was used, as presented in figure 1. The hypothesized model of the structural relationships between CEM and DEBs through mediation of difficulty in emotion regulation was tested in the entire sample of male and female students, the sample of female students, and the sample of male students and the results are presented, respectively.

The fit indices of the hypothesized model in the entire sample of students including chi-square (χ^2), the ratio of chi-square to degree of freedom (df) index (χ^2/df), comparative fit index (CFI), goodness of fit index (GFI), adjusted GFI (AGFI), and root mean square error of approximation (RMSEA) were computed as 151.05, 3.68, 0.87, 0.88, 0.85, and 0.09, respectively. The values greater than 3 for the ratio of chi-square to df index (χ^2/df), values greater than 0.08 for RMSEA, and values less than 0.90 for CFI, GFI, and AGFI stress the necessity of modifying the hypothesized model in order to improve its fit to the data.

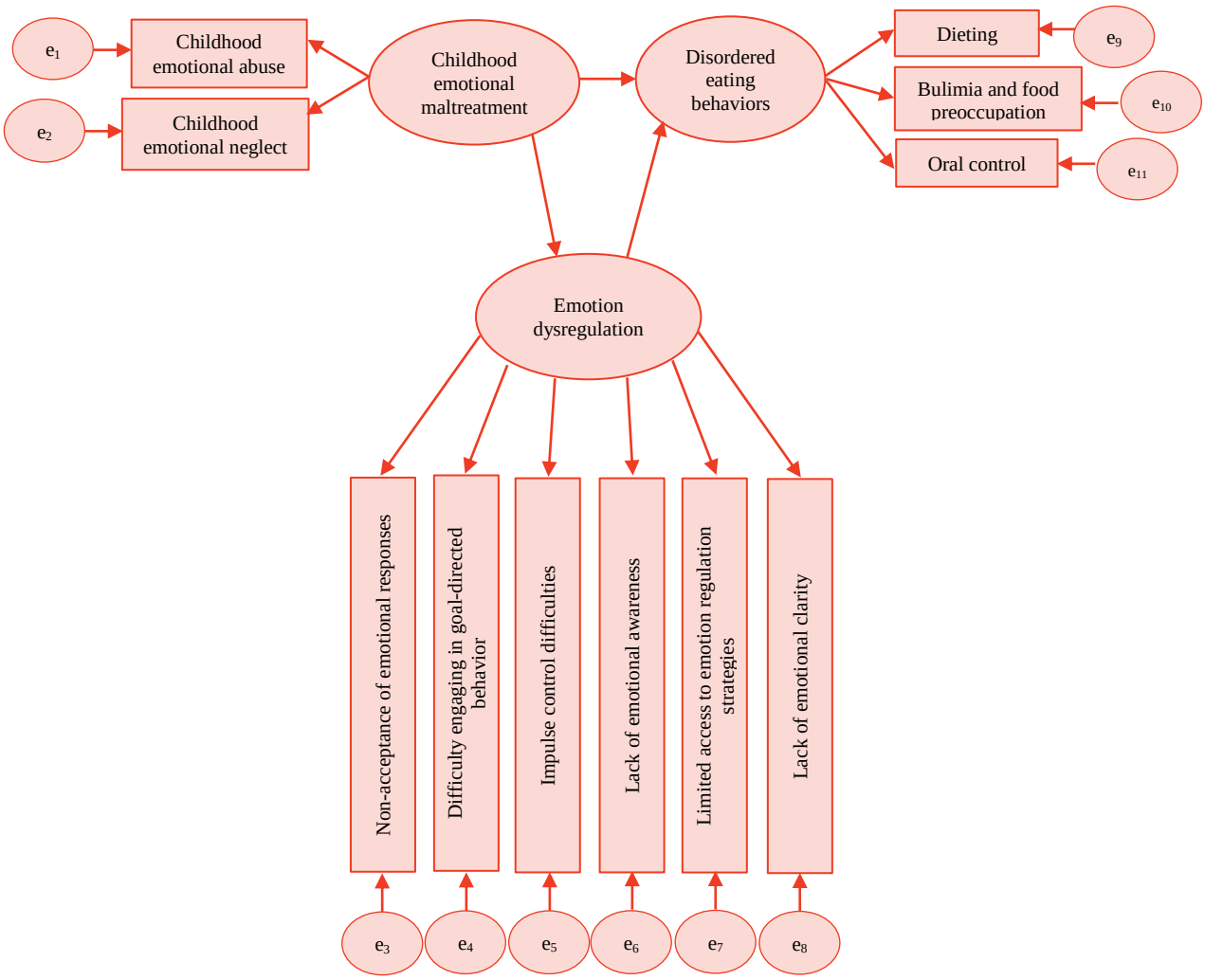

Figure 1. The hypothesized model of mediating role of emotion dysregulation in relationship between childhood emotional maltreatment (CEM) and disordered eating behaviors (DEBs)

In order to improve the model fitness to the sample data, a covariance was considered between error residuals of emotional abuse and emotional neglect indicators of CEM latent variable. For emotion dysregulation latent variable, the covariances were considered between the error residuals of difficulty engaging in goal-directed behavior and impulse control difficulties, difficulty engaging in goal-directed behavior and lack of emotional awareness, as well as lack of emotional awareness and lack of emotional clarity indicators. Another covariance was taken into account between the error residuals of dieting and bulimia and food preoccupation indicators of DEBs latent variable, as presented in figure 2. Given the applied modifications and a 5-unit decrease of the df in the modified model, the numerical value of χ^2 in the model was dropped by 65.38 units and the values of other fit indices were improved, satisfying Meyers et al. rule, as provided in table 2.

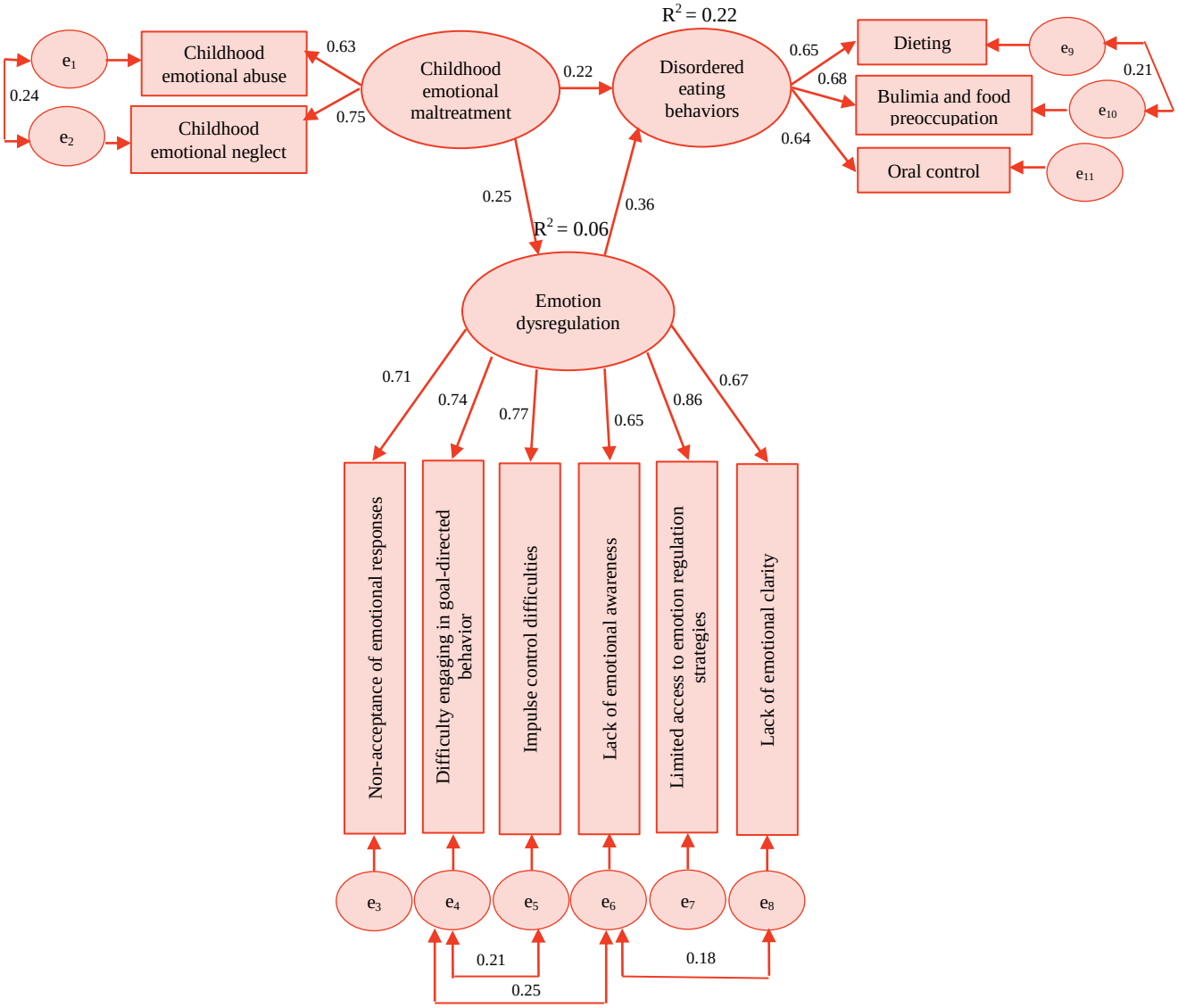

Figure 2. The modified model of mediating role of emotion dysregulation in relationship between childhood emotional maltreatment (CEM) and disordered eating behaviors (DEBs) among the entire sample of female and male undergraduate students

Table 2. Goodness of fit indices (GFIs) for the hypothesized model in the entire sample of students

Model	χ^2	df	χ^2/df	GFI	AGFI	CFI	RMSEA
Before modification	151.05	41	3.68	0.88	0.85	0.87	0.09
After modification	86.68	36	2.41	0.96	0.93	0.96	0.05

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

On the basis of findings presented in figure 2, in the hypothesized partial mediation model of emotion dysregulation in association between CEM and DEBs in the entire sample of male and female students, all path coefficients between the latent variables were statistically significant ($P < 0.05$). Moreover, 6% of emotion dysregulation distribution variance was explained by CEM. CEM and emotion dysregulation together accounted for 22% of the DEB scores variance.

In this research, bootstrap method was utilized to determine the statistical significance of the indirect effect of CEM on DEBs through emotion dysregulation. In this model, the indirect effect of CEM on DEBs through emotion dysregulation in the entire sample of male and female students was found to be 0.10 which was statistically significant ($P < 0.05$).

The hypothesized model of the structural relationships between CEM and DEBs through mediation of emotion dysregulation in the sample of female students was subsequently tested. The results of the fit indices of the hypothesized model in female students including chi-square (χ^2), the ratio of chi-square to df index (χ^2/df), CFI, GFI, AGFI, and RMSEA were computed as 158.56, 3.86, 0.85, 0.86, 0.82, and 0.10, respectively. Given the values of the fit indices, Meyers et al. stressed the necessity of modifying the hypothesized model in order to improve its fit to the sample data. After applying the modifications presented in figure 3 and a 5-unit decrease in the df in the modified model, χ^2 of the model dropped by 72.79 units and the values of other fit indices were improved, as provided in table 3.

On the basis of findings presented in figure 3, in the hypothesized partial mediation model of emotion dysregulation in relationship between CEM and DEBs in the sample of female students, all path coefficients between the latent variables were statistically significant ($P < 0.05$). Moreover, 8% of emotion dysregulation distribution variance was explained by CEM. CEM and emotion dysregulation together explained 17% of the DEB scores variance.

Bootstrap method was used to determine the statistical significance of the indirect effect of CEM on DEBs through emotion dysregulation in the sample of female students. In this model, effect of CEM on DEBs through emotion dysregulation in the sample of female students was found to be 0.08 which was statistically significant ($P < 0.05$).

The hypothesized model of the structural relationships between CEM and DEBs through mediation of emotion dysregulation in the sample of male students was tested in the next step. The fit indices of the hypothesized model in the sample of male students including chi-square (χ^2), the ratio of chi-square to df index (χ^2/df), CFI, GFI, AGFI, and RMSEA were computed as 121.79, 2.97, 0.86, 0.90, 0.85, and 0.09, respectively.

Table 3. Goodness of fit indices (GFIs) for the hypothesized model in the sample of female students

Model	χ^2	df	χ^2/df	GFI	AGFI	CFI	RMSEA
Before modification	158.56	41	3.86	0.86	0.85	0.87	0.10
After modification	85.77	36	2.38	0.94	0.90	0.94	0.06

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

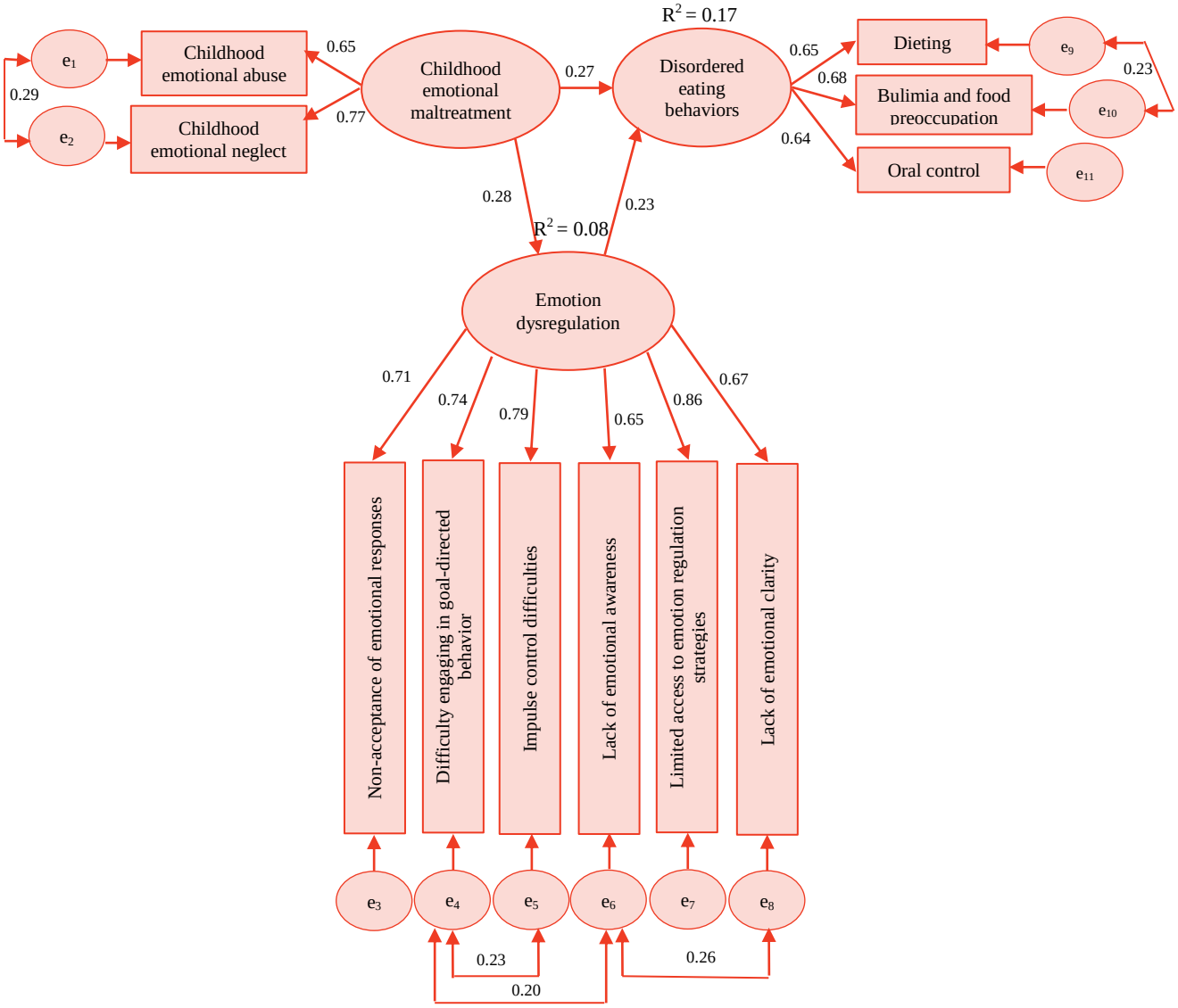

Figure 3. The modified model of mediating role of emotion dysregulation in relationship between childhood emotional maltreatment (CEM) and disordered eating behaviors (DEBs) among female undergraduate students

The fit indices of the hypothesized model in the sample of male students including chi-square (χ^2), the ratio of chi-square to df index (χ^2/df), CFI, GFI, AGFI, and RMSEA were computed as 121.79, 2.97, 0.86, 0.90, 0.85, and 0.09, respectively. Consequently, the necessity of modifying the hypothesized model to improve its fit to the sample data are steressed. After applying the modifications presented in figure 4 and a 3-unit decrease of the df in the modified model, χ^2 of the model dropped by 72.79 units and the values of other fit indices were improved as provided in table 4.

On the basis of findings presented in figure 4, in the hypothesized partial mediation model of difficulty in emotion regulation in the relationship between CEM and DEBs in the sample of male students, all path coefficients between the latent variables were statistically significant ($P < 0.05$).

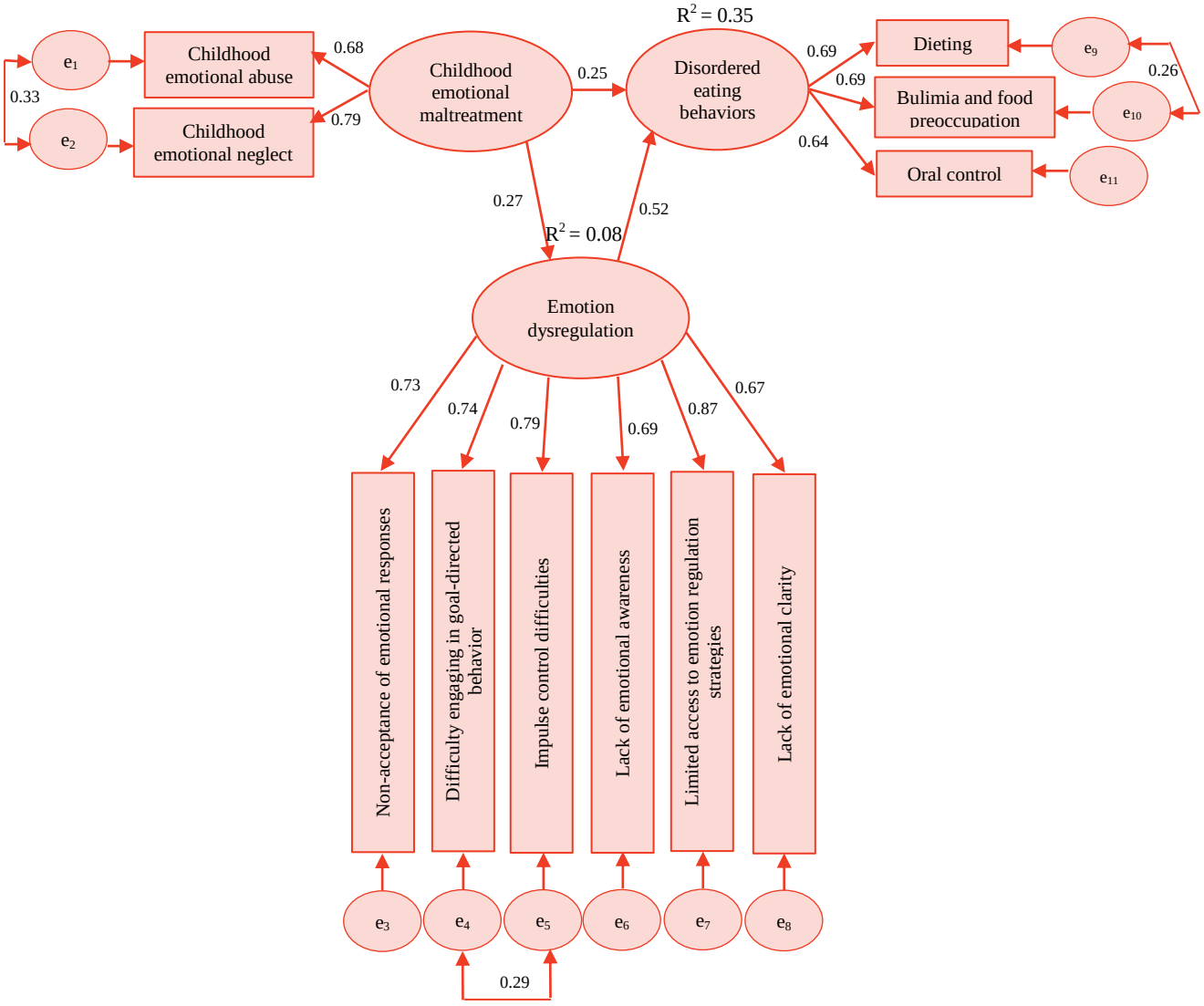

Figure 4. The modified model of mediating role of emotion dysregulation in relationship between childhood emotional maltreatment (CEM) and disordered eating behaviors (DEBs) among male undergraduate students

Moreover, 8% of emotion dysregulation distribution variance was explained by CEM. CEM and emotion dysregulation together accounted for 35% of the DEB score variance. Bootstrap method was used to determine the statistical significance of the indirect effect of the CEM on DEBs through emotion dysregulation in the sample of male students.

Table 4. Goodness of fit indices (GFIs) for the hypothesized model in the sample of male students

Model	χ^2	df	χ^2/df	GFI	AGFI	CFI	RMSEA
Before modification	121.79	41	2.97	0.90	0.85	0.86	0.09
After modification	40.04	38	1.05	0.96	0.93	0.99	0.01

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

Table 5. Gender invariance of the hypothesized partial mediation model of emotion dysregulation

Model	Constrained/ unconstrained	χ^2	χ^2/df	CFI	GFI	AGFI	RMSEA	$\Delta\chi^2$	Δdf	P
Unconstrained	Unconstrained model	120.620	1.680	0.962	0.948	0.904	0.041	-	-	-
Constrained	Measurement residuals	141.980	1.690	0.945	0.927	0.905	0.041	20.350	19	0.25
	Structural residuals	132.240	1.540	0.964	0.943	0.912	0.037	11.620	14	0.64
	Structural covariance	132.230	1.570	0.962	0.943	0.910	0.038	11.610	12	0.48
	Structural weights	132.210	1.590	0.961	0.943	0.909	0.039	11.590	11	0.40
	Measurement weights	127.040	1.590	0.963	0.945	0.909	0.038	6.410	8	0.60

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

In this model, indirect effect of CEM on DEBs through emotion dysregulation was found to be 0.15 in the sample of male students which was statistically significant ($P < 0.05$).

In order to analyze the gender invariance of the structural relationships in the hypothesized partial mediation model of emotion dysregulation in association between CEM and DEBs, the equivalence of structural relationships in the model was tested for male and female students groups. Accordingly, firstly, a baseline unconstrained model was developed and tested in two groups of male and female students. Subsequently, gender-based equivalence of the hypothesized model was tested by imposing equality constraint on measurement residuals, structural residuals, structural covariances, structural weights, and measurement weights in the two groups of female and male students. As the results provided in table 5 reflect, the gender invariance of the structural model in male and female students groups were confirmed.

Discussion

The study was directed to examine the association between the experiences of CEM and DEBs among undergraduate students, by considering emotion dysregulation as a mediator. The findings confirmed that the hypothesized partial mediating model of emotion dysregulation in association between CEM and DEBs had a good fit to the sample data. The outcomes of the gender specificity of structural relations in the hypothesized model were equivalent for both groups of male and female undergraduate students. Furthermore, a significant part of the dispersion of DEB scores was explained by CEM and emotion dysregulation in the hypothesized model for the entire sample of students, the sample of female students, and the sample of male students.

This study's findings support the hypothesized model of the relationship between CEM experience and DEBs through mediation of emotion dysregulation in line with previous studies[8,10] although some researches have studied this relationship in clinical communities.[10]

On the basis of findings of previous studies, there is a positive and significant relationship between childhood emotional abuse and DEBs through mediation of alexithymia and general distress (as a component of depression and anxiety) among female students.[15] The study's results also supported a positive and significant relationship between childhood emotional abuse and alexithymia and a weak though significant complex association between childhood emotional abuse and DEBs.

Further, Mills et al.[8] showed that disordered eating was associated with childhood emotional abuse, dysfunctional strategies of emotion regulation, and female gender among

adolescents (14 to 18 years). Further, an indirect relationship between childhood emotional abuse and eating psychopathology through dysfunctional strategies of emotion regulation was revealed. In this study, emotional neglect predicted lower levels of effective emotion regulation. This study's findings confirmed emotion regulation's role as the mediator of the association between childhood emotional abuse and DEBs and revealed that experience of emotional abuse and emotional neglect had distinguishing effects on emotion regulation. The research study by Corstorphine indicated that dysfunctional emotion regulation, rather than lack of effective emotion regulation, was associated with disordered eating; as some researchers have argued, DEBs are a form of dysfunctional emotion regulation strategy.[16] Accordingly, there are some overlaps between the criterion variable (symptoms of eating disorders) and the mediating variable (dysfunctional emotion regulation).

The study by Moulton et al.[10] provides further evidence to support an indirect link between childhood traumatic events and eating psychopathology. This research evaluated a wide range of childhood traumatic events. Child emotional abuse, physical abuse, emotional neglect, and physical neglect but not child sexual abuse showed a significant association with disordered eating. All types of childhood maltreatment significantly predicted difficulty in emotion regulation (and dissociation) although child emotional abuse was recognized as the only type of childhood maltreatment that independently predicted emotion dysregulation.

Bakalar et al.[6] research findings indicated that experience of childhood adversity was associated with high body mass index (BMI) and eating disorders. Kimber et al.[17] research study showed that individuals with childhood emotional abuse and neglect experiences were more likely to develop eating disorders in adulthood. In this regard, Ergang et al.[18] also revealed a significant negative association between the quality of maternal care and emotional eating in adulthood, reflecting the effects of the primary environment in development of eating disorders and DEBs.

Consistent with this study's findings, results of Mallorqui-Bague et al.[19] research showed that deficit in emotion regulation was the core of all eating disorders and improved emotion regulation, especially in individuals affected by bulimia nervosa, was associated with desired therapeutic outcomes. In line with results of this study, Aguera et al.[20] research study indicated that difficulty in emotion regulation was observable in men with eating disorders, similar to women. The findings of Anderson et al.[21] study revealed the importance of employing therapies focused on development of adaptive emotion regulation strategies in the treatment of eating psychopathology.

Emotional maltreatment, where the child's emotions or the importance and validity of the child's emotions are ignored, can lead to difficulties in identifying, expressing, and managing emotions. The caregiver's inappropriate reaction to emotional experiences of the child may result in the child's confusion about his or her emotion, which may negatively affect one's capacity to tolerate and regulate emotions in long term.

Deficit in emotion management ability exposes the individual to experience more general distress and in the absence of more adaptive strategies, DEBs may be a way to cope with severe psychological distress and unpleasant experiences associated with these distresses.

Given that the experience of childhood emotional abuse and neglect will have consequences as difficulty in managing and regulating emotions, individuals who are considered victims of CEM will profit from the interventions which train and develop adaptive strategies to manage psychological

distresses and negative emotions.

This research study was conducted with some limitations. Since eating disorders are still widely considered as a feminine issue, men affected by eating disorders face challenges to attend clinical settings for diagnosis and treatment or even to express their symptoms. Reliance on self-report instruments to collect data should be cautious since such measuring tools rely on the accuracy, precision, and integrity of participants about their experiences and behaviors, and thus, the provided data may be biased. It is suggested that biological evaluations be also used in future studies along with paper and pen tools. Finally, retrospective studies and evaluation of childhood experiences can be biased.

Conclusion

In summary, this study provides a theoretically useful and economical model integrating the experience of CEM, emotion dysregulation, and DEBs in adulthood that fits the data collected from undergraduate students residing in dormitories of Shahid Beheshti University. The findings of this research study confirm the relationship between the experience of emotional abuse and emotional neglect in childhood and DEBs in adulthood directly and indirectly through mediating role of emotion dysregulation among male and female undergraduate students. The findings of this research study provide further empirical evidence for the stress-vulnerability model and the trauma theory indicating that traumatic experiences lead to deficits in emotion processes.

Conflict of Interests

Authors have no conflict of interests.

Acknowledgments

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Is parent-child interaction therapy effective on aggression and biological indices in pre-school children with parents who use high-potency cannabis? A double-blind randomized controlled trial study in an Iranian sample

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Short Communication

Abstract

BACKGROUND: Improving interpersonal interactions between parents and the child can indirectly reduce the extrapolation behavioral problems, including aggression in children.

METHODS: Among parents who used high-potency cannabis (marijuana or 'gol' as it is called in Iran) and lived in Tehran, Iran, sixty four caregivers and an Iranian child were selected through respondent-driven sampling and studied in the form of a double-blind randomized controlled trial (RCT) (TCTR20180804001) with repeated measurements method and a 6-month follow-up. The changes in the aggression and cortisol levels were repeatedly evaluated during 12 weeks of interactive treatment and analyzed by Monte Carlo test, repeated measures correlation (rmcorr), and generalized estimating equation (GEE) via SPSS software. Statistical significance was accepted on the level of $P < 0.010$.

RESULTS: 12 weeks of Parent-Child Interaction Therapy (PCIT) had a significant effect on the reduction of aggression and the salivary cortisol level in children ($P < 0.010$). However, the results did not remain stable till the 6-month follow-up stage ($P = 0.067$). Also, results revealed a significant relationship between aggression index and the level of cortisol ($P < 0.010$).

CONCLUSION: Since the core of the damage resulted from illicit drug abuse is reflected in interactive activities, improving social interactions can be considered as the key to the treatment of addiction.

KEYWORDS: Aggression; Tetrahydrocannabinol; Addiction; Problem Behavior; Child; Preschool

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Introduction

The appearance of anxiety and depression syndrome in children may have extraversion problems for the children, such as family functioning disruption, school absenteeism, difficulty in academic performance, aggression, and social interaction deficit in youth period.[1]

High-potency cannabis (marijuana or 'gol' as it is called in Iran) is a type of tetrahydrocannabinol (THC), and using 'gol' has significantly been increased in Iran during

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the past few years. The use of cannabis (acute and chronic use) is associated with adverse damages for psychological health.[2]

On the other hand, the cortisol secretion is increased due to stressors stimuli. Some research has shown that a significant correlation exists between the cortisol level and mood and behavioral indices, and cortisol could be used as a biomarker in evaluating psychological indices.[3]

Parent-Child Interaction Therapy (PCIT) is an evidence-based and short-term therapy which is based on interest and social learning theory; this theory is used in children with age of 2 to 8 years who have a history of disruptive behavior disorders. This treatment could be effective in developing relationships between the child and parents through active listening, empathy, eye contact, refinement, and summarizing instead of criticism.[4] Several studies have shown that PCIT is effective in reducing the extraversion problems.[5-7]

Many studies have been carried out on the use of PCIT in children's extraversion problems, but there are a few studies in the sample of THC users. Therefore, in this study, we intend to explore the effectiveness of PCIT in reducing aggression and the cortisol level in pre-school children with parents who use high-potency cannabis.

Materials and Methods

The current study was a double-blind randomized controlled trial (RCT) with repeated measures and a 6-month follow-up that was done during March 2015 to October 2016. The participants were 64 Iranian caregivers who were selected through respondent-driven sampling method and by Office software, they were assigned to treatment group (n = 33) of parent-child interaction (main protocol) or placebo group (n = 31) (Figure 1).

The criteria for entry into the study were: 1) children with age of 5 to 7 years, 2) the recognition of dependence to 'gol' with a specific dose for at least one of the parents, 3) the diagnosis of aggression and behavior disorder in both clinical domains and evaluation of questionnaires, 4) age range of 20-45 years for parents, and 5) the ability to read and write.

The exclusion criteria for the mother and the child were as follows: 1) having natural intelligence less than 70 and 2) use of psychiatric medications more than three months due to the likely effects on psychological syndrome.

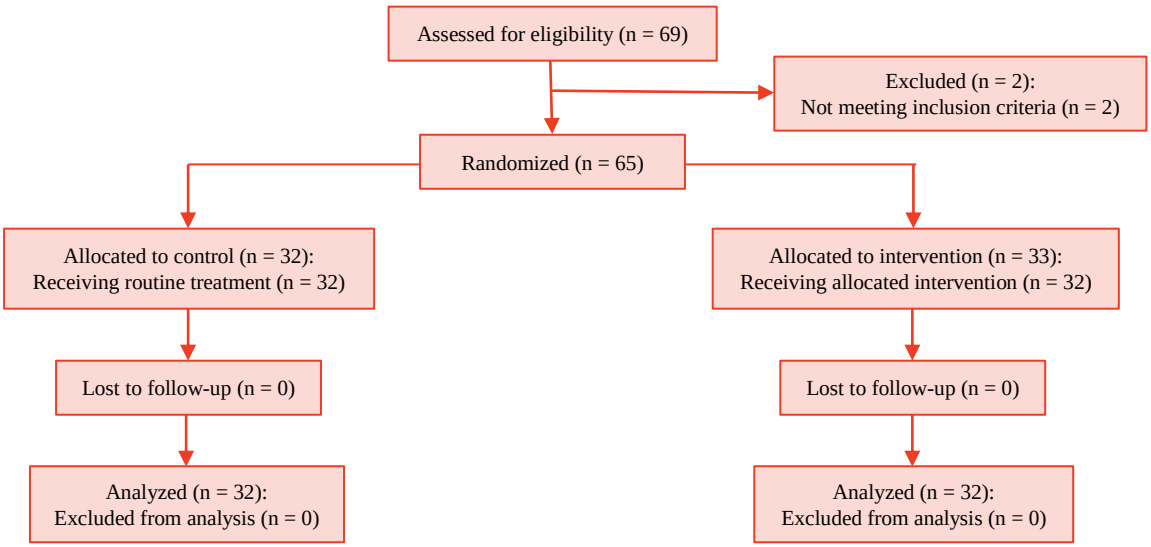

Figure 1. Flow diagram of the progress through the phases of a parallel randomized trial of two groups

The PCIT was conducted in two phases of child-directed interaction (to develop communication) and parent-directed interaction (to improve interactive discipline) in 12 sessions.

Saliva samples (2 milliliters) were collected in three intervals by a synthetic cotton swab. The synthetic cotton swab was placed in the baby's mouth for a time of sixty seconds; the samples were stored at -80 °C and in home freezer and then the samples were centrifuged at room temperature at a rate of 3000 rpm for 15 minutes and tested with a highly-sensitive enzyme-linked immunosorbent assay (ELISA). This assay uses a solid-phase enzyme immunoassay (EIA) to detect the existence of a ligand (usually a protein) in a liquid sample using antibodies directed against the protein to be measured. In the present study, a structured clinical interview, a demographic questionnaire that was made by the researcher, Aggression Questionnaire, and an immunoassay method were used. ELISA has been used as a diagnostic tool in medicine, plant pathology, and biotechnology, as well as a quality control check in various industries.

The present study was part of a research project approved by the Ethics Committee of Shahid Beheshti University of Medical Sciences, Tehran, Iran (TCTR20180804001). The stages of the study were carried out after obtaining informed written consent from the parents (and the verbal consent of the child) and according to the latest version of Declaration of Helsinki.

Results

The coded disorders in children were as follows: separation anxiety (27%), generalized anxiety disorder (GAD) (24%), specific phobia (16%), social phobia/agoraphobia (13%), injury phobia (11%), and obsessive-compulsive disorder (OCD) (9%). The caregiver's relationship with the child was as parent caregivers (81%), foster mother (8%), grandparents and grandmothers (5%), aunt (4%), and kinship careers (2%).

In order to evaluate the changes in the anxiety and the levels of salivary cortisol in children, generalized estimating equation (GEE) was used via SPSS software (version 20, IBM Corporation, Armonk, NY, USA). Statistical significance was accepted on the level of $P < 0.010$. GEE is an approach to fit a marginal model for longitudinal/clustered data analysis, and it has been increasingly used in clinical trials and biomedical studies.

The changes of the two indices were significant. To determine the relationship between anxiety and level of cortisol, repeated measures correlation (rmcorr) was used. The results revealed that a significant relationship existed between anxiety index and cortisol level ($P < 0.010$).

Discussion

The findings of the study showed that PCIT reduced both anxiety and cortisol indices. However, the changes were not constant till the follow-up stage. In line with the results of this study, the results of a study by Pirnia et al.[8] that investigated the effectiveness of PCIT on the anxiety index of pre-school children showed that this therapy was effective in reducing the anxiety index. The results of another study carried out by Thomas et al.[6] also showed that PCIT significantly reduced the children's externalizing behaviors. In addition, the results of Herschell et al.[7] and Pirnia et al.[9] studies showed that PCIT was effective in reducing child maladaptive behaviors, parenting style, and psychological syndrome.

However, the results of this study revealed that the effectiveness of this therapy on anxiety and cortisol level indices was not stable till 6-month follow-up stage. In contrast with our results, the study of Graziano et al.[5] showed that the effectiveness of PCIT was maintained in 6-9-month follow-up.

The findings of this study also showed that a

direct relationship existed between the level of cortisol and aggression. These results, in line with the findings of Pirnia et al.,[3] showed that a significant relationship existed between the cortisol level and mood index. In contrast with the results of this study, Pirnia et al.[10] showed that there was no significant relationship between the cortisol level and psychological indices.

This study had some limitations. The most important limitation was that evaluating the dose and concentration of the consumed THC was not possible. It is suggested that the relationship between the concentration of cannabis and the cortisol level be investigated in future studies. Also, evaluating the mediating role of mother's cortisol in the relationship between the psychological problems of mothers and children can be a suitable route for future studies.

Conclusion

This study was conducted to examine the effectiveness of PCIT on aggression and the cortisol level in pre-school children with parents who use THC. The findings showed that twelve weeks of PCIT significantly reduced children's aggression and salivary cortisol level. Also results revealed that there was a significant relationship between aggression index and cortisol level. These results showed that improving social interactions could be considered as the key to the treatment of addiction.

Conflict of Interests

Authors have no conflict of interests.

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