

The effect of relaxation and cognitive counseling intervention on blood pressure and quality of life among pregnant women with chronic hypertension – randomized controlled trial

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Abstract

Introduction: Hypertension is one of the most significant chronic diseases in all people, especially pregnant women, which can pose many risks to the mother and fetus. It also reduces the quality of life (QOL) of pregnant women. The aim of this study was to compare the effect of relaxation and cognitive counseling on blood pressure and quality of life among hypertensive pregnant women.

Material and methods: This randomized clinical trial was conducted on 60 hypertensive pregnant women. Subjects were randomly assigned to three groups: cognitive ($n = 20$), relaxation ($n = 20$), and controls ($n = 20$). The blood pressure of the participants was measured using a standard mercury sphygmomanometer, and their quality of life was assessed by using World Health Organization QOL (WHOQOL) scale, before and after the intervention. Data analysis was performed using SPSS version 20.0 with chi-square, one-way ANOVA, Bonferroni post hoc and paired sample t test.

Results: None of the study variables were significantly different between three study groups at baseline. Systolic and diastolic blood pressure showed a decrease in both intervention and control groups. The quality of life score showed an increase in all dimensions of quality of life in the intervention groups. However, there was no significant change in the control group. The increase in quality of life score in the cognitive counseling group was larger than in the relaxation group ($p < 0.01$).

Conclusions: The results of this study showed that cognitive counseling and relaxation can effectively improve quality of life of women with hypertensive disorders of pregnancy.

Key words: blood pressure, quality of life, relaxation, cognitive counseling, pregnant women.

Introduction

High blood pressure is one of the major psychophysiological disorders that can negatively affect the vitality and quality of life (QOL) of individuals (Tarkhan *et al.* 2012). High blood pressure during pregnancy is very important, as it is one of the major causes of both maternal and fetal death, and a main cause of occupation of hospital beds and utilization of antenatal care and facilities (Zare *et al.* 2017). Hypertension has been shown to affect 5-10% of pregnant women (Dodangeh 2016).

The odds of maternal and neonatal morbidity and mortality increase in pregnancies complicated by preeclampsia, imposing an economic burden on disease-affected families and the community (Haghnia 2016). Hypertension as a chronic medical condition can adversely affect QOL of patients (Wong *et al.* 2020). Quality of life is defined as a person's perception of their position in the context of the culture and value systems in which they live and in relation to their goals, standards, expectations and concerns (Fereidouni *et al.* 2021). Nowadays, in addition to traditional health indicators, such

as morbidity, mortality and disease complications, other health indicators, including QOL, which can be an indicator for clinical assessment of interventions, are taken into consideration (Bijani *et al.* 2021; Ghaem *et al.* 2010). Due to possible side effects of chemotherapeutic drugs, non-pharmacological therapies can reduce drug dependence and effectively contribute to disease control (Clark *et al.* 2015). Relaxation and cognitive counseling are interventional methods applied in the treatment and performance improvement of patients with various medical conditions (Akmeşe and Oran 2014; Bakhteh *et al.* 2018; Jafarnejhad *et al.* 2011; Sheu *et al.* 2003).

Relaxation for muscle relaxation is a safe way to control health problems, including anxiety, insomnia, high blood pressure and digestive disorders, and provides a deep state of relaxation (Shobeiri *et al.* 2015). Jacobson's relaxation technique is a relaxation therapy concentrating on tightening and relaxing specific muscle groups so that muscles and muscle groups achieve the desired state of deep relaxation. In this way, the person tightens and then relaxes a group of selected muscles until the whole body or the designated area is relaxed. By daily exercising, the person progressively tends to develop a "relaxed state" (Jafarnejad *et al.* 2011). Another method that improves the relaxation state and reduces stress in pregnant women is cognitive therapy. Cognitive therapy is a progressive therapy that helps patients improve their faulty misconceptions, leading to certain moods and behaviors (Nayeri *et al.* 2014). The number of studies on the effect of these treatments is limited in Iran. Azimian *et al.* (2017) and Jafarnejhad *et al.* (2011) found that muscle relaxation reduced blood pressure in pregnant women. Navabinezhad and Fallahzadeh (2004) also concluded that cognitive counseling and muscle relaxation and the combination of both methods effectively reduced blood pressure in women. However, there have been no studies comparing the effect of these interventions on QOL of pregnant women. Given the limited number of previous studies focusing on the effect of non-pharmacological therapies, such as cognitive counseling and relaxation, on blood pressure as well as the QOL of patients with hypertension in Iran, and the lack of studies comparing the effectiveness of these two interventions, we conducted this study to examine the effect of relaxation and cognitive counseling on QOL and hypertension in hypertensive pregnant women.

Material and methods

Study design and setting

This parallel randomized clinical trial was conducted in Fasa city, Fars province, Iran in May and June 2020. The target group was pregnant women with chronic hypertension (systolic pressure > 135 and diastolic pressure > 85).

Sample size calculation

The sample size was calculated as 9 in each study group with 95% confidence interval, 80% power and mean difference of 14 based on the common standard deviation of blood pressure presented in a study conducted by Jafarnejhad *et al.* (2011). We selected a total of 20 subjects in each group to increase the power of the study and due to probable dropouts.

Inclusion and exclusion criteria

The inclusion criteria were: pregnant women of 24-26 weeks' gestation (second trimester), being literate and have no hearing or speech problems, having no debilitating diseases such as diabetes, endocrine diseases, etc., not starting antihypertensive drugs before the intervention and also lack of dependence on narcotic and psychotropic substances (Jalilian *et al.* 2018; Gharadaghi *et al.* 2015). The exclusion criteria were: failure to attend two or more sessions of counseling sessions, unwillingness to participate, occurrence of any complication affecting the QOL during the intervention, such as severe mood and emotional changes (e.g. death of a close relative), and fetal or maternal complications during the study procedure (e.g. abortion, fetal death). Those who displayed any mental illness requiring medication were also excluded from the study (Shobeiri *et al.* 2015; Jalilian *et al.* 2018; Bakhteh *et al.* 2018).

Patients and random allocation

First, this study was approved by the ethics committee of Kerman University of Medical Sciences (IR.KMU.REC.1398.344) and was registered with No. IRCT20191028045259N1 in the Iranian registry of clinical trials. Then we asked family physicians in Fasa city to introduce cases of chronic hypertension. Written informed consent was obtained from all enrolled participants. Then, they were randomly divided into three groups. For randomization, 60 cards were prepared and divided into 3 categories; the first 20 cards were numbered 1, the sec-

ond 20 cards were numbered 2, and the third 20 cards were numbered 3. All cards were placed in an envelope. Each pregnant woman with hypertensive disorder was asked to choose one of the cards. The number of the selected card pack indicated the group membership. Group categories constituted cognitive counseling (group 1), relaxation (group 2) and controls (group 3). It should be noted that this study had a single-blind design and all members of the study groups were blinded to interventions performed in other groups. Figure 1 presents the consort flow diagram of the participants throughout the study.

Interventions

In the cognitive counseling group, the intervention was delivered in 8-10 one-hour sessions. As such, 8 sessions were held at the group level and 2 sessions at the individual level to express specific topics. During these sessions, cognitive therapy was first defined and its importance was highlighted, the role of the cognitive exploration method in identification of pregnancy-related dysfunctional cognitions was explained, cognitive evaluation of patients regarding the effectiveness of cognitive techniques was done,

and summarized review future thoughts and behavior change program training was provided to the patients. In the relaxation group, the intervention was performed using Jacobson's relaxation method. This method was delivered in 4 90-minute sessions. During these sessions, the effects of relaxation on maternal physical and mental health, sleep improvement, maternal nutrition, as well as its positive effect on the delivery process, postpartum recovery, breast-feeding and postpartum depression prevention were highlighted and explained to the participants. In each session, relaxation techniques were practically trained, and the target group practiced relaxation exercises in groups. In order to ensure that the pregnant women were relaxed and exercised at home, they were given a home recording checklist. Participants were asked to do relaxation exercises at least once a day using manual videos. In the next session, checklists were collected and general questions were answered and learning objectives of the previous week were reviewed and combined with new contents and materials. All patients in both the intervention groups (cognitive counseling and relaxation) and the control group received the medication prescribed by their doctor.

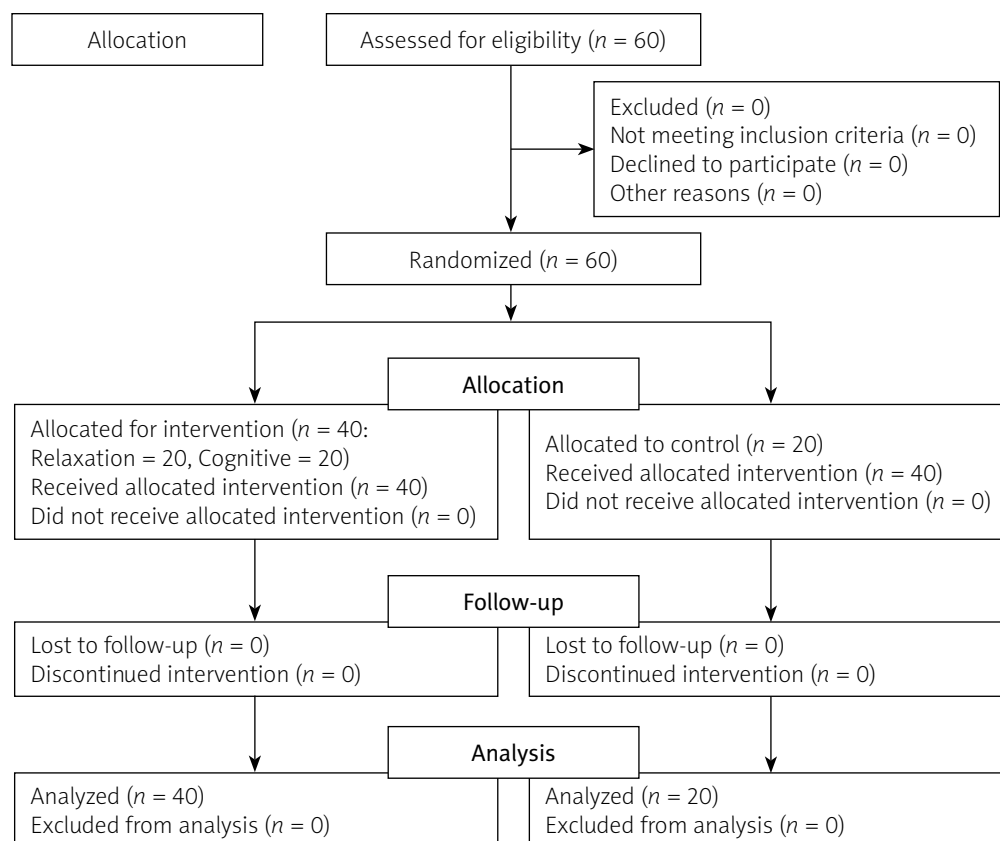


Fig. 1. Consort flow diagram of the participants

Measuring blood pressure and quality of life

Before the intervention at the first visit of the participants, their blood pressure was measured and the participants completed the World Health Organization QOL (WHOQOL-BREF) questionnaire. Blood pressure and quality of life were also measured after the last intervention session. Blood pressure was measured by a nurse using a mercury sphygmomanometer with daily calibration check. First, the pregnant women rested for 10 minutes, then systolic blood pressure/diastolic blood pressure for the 10-min interval was measured, and their average blood pressure level was recorded.

In addition, a questionnaire consisting of demographic variables and the WHOQOL-BREF questionnaire were completed by the study participants.

The WHOQOL-BREF questionnaire is a 26-item questionnaire that measures QOL in four domains: physical activity, psychological, social relationships and environment (Jahanfar *et al.* 2020). Respectively 8, 6, 7 and 3 questions belonged to physical activity, psychological, social relationships and environment domains of the questionnaire. The first two questions of the scale did not belong to any of the domains, and evaluated the overall health state and QOL of respondents. Following necessary calculations in each domain, each domain was separately scored from 4 to 20, where a score of 4 indicated a very poor impression and a score of 20 indicated a very good impression. These scores can also be converted into a score range of 0 to 100, which is well-known form of scoring (Gholami *et al.* 2013; Nejat *et al.* 2006). In this study, we used a 0-100 score range to score domains of the scale. The Persian version of this questionnaire possessed acceptable validity and reliability in Iran (Nejat *et al.* 2006).

Statistical analysis

The chi-square and one-way ANOVA test were used to compare baseline variables. Also,

one-way ANOVA and the Bonferroni post hoc test were used to compare blood pressure and QOL between the three study groups before and after the intervention. Also, the paired sample *t* test was performed to compare blood pressure and QOL scores in all domains. Between before and after the intervention, data analysis was performed using SPSS version 20.0, and $p < 0.05$ was considered to be statistically significant.

Results

In this study, 60 hypertensive pregnant women were recruited and assigned to three groups in May and June 2020: cognitive counseling, relaxation, and controls.

Table 2 presents the comparison of mean systolic and diastolic blood pressure between the three study groups, cognitive counseling, relaxation and control groups, before and after the intervention, as well as the comparison of mean systolic and diastolic blood pressure, before and after the intervention between all study groups. Accordingly, there was no significant difference in the mean systole and diastole levels between the three study groups, before the intervention, whereas the mean systole and diastole levels were significantly different between the study groups, after the intervention. The results of the Bonferroni post hoc test also demonstrated that the mean systolic and diastolic blood pressure were significantly different between cognitive counseling and relaxation groups with controls, after the intervention, while no significant difference was observed between the two intervention groups.

The results of the paired sample *t* test also showed that the mean systolic and diastolic blood pressure significantly decreased in all intervention and control groups, after the intervention. However, the cognitive counseling and relaxation groups as well as the blood pressure control group had a significant reduction. But the decrease in the control group was significantly less than the intervention groups.

Table 1. Comparison of baseline variables between study groups

	Cognitive	Relaxation	Control	P-value*
Age	24.47 ±4.64	24.61 ±3.66	25.15 ±6.04	0.902
Weight	63.32 ±11.64	61.78 ±7.37	62.95 ±9.31	0.952
Height	162.89 ±6.58	163.44 ±8.01	162.74 ±6.78	0.881
BMI	23.74 ±3.51	23.14 ±2.59	23.7 ±2.86	0.794
Gestational age	19.95 ±2.48	19.74 ±2.33	20.53 ±2.48	0.453

*One-way ANOVA test

Table 2. Comparison of the systole and diastole among the cognitive counseling, relaxation and control groups before and after the intervention as well as inter-group comparison (before and after intervention for each group)

		Before		After		Mean difference		P-value*
		Mean	SD	Mean	SD	Mean	SD	
Systole	Cognitive	139.68	4.15	126.84	3.67	12.84	4.58	< 0.001
	Relaxation	138.27	3.28	124.72	5.58	13.55	6.34	< 0.001
	Control	138.94	4.63	132.84	4.68	6.1	5.53	0.0003
	P-value**	0.417		< 0.001		< 0.001		
Diastole	Cognitive	87.89	2.53	81.36	3.05	5.52	3.29	< 0.001
	Relaxation	87.50	2.59	82.47	3.09	4.03	4.53	< 0.001
	Control	86.57	2.91	84.32	3.42	2.25	3.33	0.035
	P-value**	0.308		0.007		< 0.001		

* Paired sample t test, ** One-way ANOVA test

Table 3 demonstrates the comparison of the mean score of domains of the QOL questionnaire, before and after the intervention between the 3 study groups, as well as the comparison of the mean score of the questionnaire domains, before and after the intervention. As such, the QOL score in the two groups of cognitive counseling and relaxation was shown to significantly increase in all domains of the questionnaire. However, there was no significant difference in QOL scores in the controls, after the intervention. Also, Bonferroni post hoc test results showed that the increase in the quality of life score in the cognitive counseling group was more than in the relaxation group ($p < 0.01$).

Discussion

The results of this study suggest that relaxation and cognitive counseling were positively associated with level of systolic and diastolic blood pressure as well as the quality of life of the study participants. I.e. these interventions reduced blood pressure level and increased QOL score. Similar results have been reported by previous studies. For example, Navabnejad *et al.* (2004) conducted a study in Tehran province which showed that cognitive psychotherapy, muscle relaxation and the combination of these two methods effectively reduced the basic blood pressure of women compared with the control group (Navabinezhad and Falahzadeh 2014).

Table 3. Comparison of the mean scores of all domains of quality of life among the cognitive counseling, relaxation and control groups before and after the intervention as well as inter-group comparison (before and after intervention for each group)

		Before		After		Mean difference		P-value*
		Mean	SD	Mean	SD	Mean	SD	
Physical activity	Cognitive	49.47	6.81	69.26	8.87	19.78	12.52	< 0.001
	Relaxation	51.16	8.02	63.11	5.96	11.94	8.57	< 0.001
	Control	48.73	8.81	49.36	8.42	0.63	2.75	0.331
	P-value**	0.638		< 0.001		< 0.001		
Psychological	Cognitive	49.05	10.26	69.84	8.001	20.78	8.91	< 0.001
	Relaxation	52.05	5.92	65.50	5.03	13.44	10.56	< 0.001
	Control	47.58	12.49	48.42	10.56	0.84	5.60	0.519
	P-value**	0.391		0.007		< 0.001		
Social relationships	Cognitive	48.05	11.98	80.21	10.90	32.15	5.72	< 0.001
	Relaxation	52.77	10.55	70.83	12.59	18.05	13.75	< 0.001
	Control	50.10	19.44	51.31	17.39	1.21	6.06	0.881
	P-value**	0.617		< 0.001		< 0.001		
Environmental	Cognitive	59.42	9.67	70.89	4.49	11.47	8.21	< 0.001
	Relaxation	60.56	10.07	64.38	9.29	3.83	4.76	0.003
	Control	56.10	16.06	55.78	15.85	0.31	1.37	0.331
	P-value**	0.523		< 0.001		< 0.001		

* Paired sample t test, ** One-way ANOVA test

Azimian *et al.* (2017) also found that progressive muscle relaxation intervention reduced systolic and diastolic blood pressure in the intervention group compared to the control group. Jafarnejad *et al.* (2011) stated that muscle relaxation reduced systolic and diastolic blood pressure in pregnant women. Also, a study conducted by Sheu *et al.* (2003) in Taiwan showed the decreased blood pressure of pregnant women after implementation of muscle relaxation intervention compared to the control group. Urech *et al.* (2010) also demonstrated that progressive muscle relaxation and mental imagery were not associated with hypertension. The sympathetic system is involved in the onset and persistence of hypertension. Therapies that reduce the activity of the sympathetic system may effectively control high blood pressure. Non-pharmacological methods include various behavioral therapy methods, weight loss, and avoiding intake of certain foods that increase sympathetic activity. Therapies such as meditation, yoga, and cognitive therapies may also lower blood pressure to varying degrees (Najafian and Tabib 2011).

According to the results of the present study, QOL score was shown to increase after the intervention in both cognitive and relaxation groups compared to the controls, which was consistent with previous studies. Accordingly, Akmeşe and Oran (2014) found that muscle relaxation exercises were positively linked with all aspects of patients' QOL, and improved their QOL. Also, the QOL score was higher in the intervention group than in the control group, after the intervention.

A meta-analysis conducted by Hofmann *et al.* in 2014 showed that cognitive-behavioral therapy (CBT) improved QOL of patients with anxiety disorders. Also, the effect of face-to-face cognitive behavioral counseling was more significant than virtual counseling. In another study, Garg *et al.* (2015) found that cognitive-behavioral counseling significantly reduced psychological complaints in women with preeclampsia, indicating the therapeutic effect of cognitive counseling on psychological issues in pregnant women. Hassan *et al.* (2020) proposed that CBT can be used as a treatment option for lowering anxiety, stress and depression in women with preeclampsia, as well as improving coping skills in high-risk pregnant women. Asoudi Kermani *et al.* (2010) also found that progressive muscle relaxation technique had no significant effect on anxiety, depression and QOL in cancer patients undergoing chemotherapy, which may be attributed to the nature of the studied disease.

Limitations of the study

The role of some confounding variables, such as use of herbal medicines in controlling blood pressure, were not evaluated.

Conclusions

The findings of this study showed that interventional methods such as cognitive counseling and sedation can be used along with medication to control blood pressure and increase the quality of life of pregnant women.

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Iranian Registry of Clinical Trials: IRCT registration number: IRCT20190917044802N3.

Disclosure

The authors declare no conflict of interest.

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