Effects of Auriculotherapy on Gestational Hypertension: Randomized Controlled Trial Study

Abstract

Background: This study aims to observe how auriculotherapy acts as a nonpharmacological treatment for pregnant women's gestational hypertension. **Materials and Methods:** This study was a randomized controlled trial. Eighty patients were with gestational hypertension recruited and divided into control (n = 40) and intervention (n = 40) groups. The control group just received the usual perinatal care. The intervention group received one month of auriculotherapy in addition to the usual care. Blood pressure was measured before and 15 minutes after rest in both groups twice a week. The data were analyzed using descriptive statistics and inferential tests. **Results:** The mean systolic blood pressure, based on the Mann-Whitney test, was not statistically significant between the two groups before the intervention and in the first two weeks after the intervention (p >0.05); however, after the third week of intervention, the mean systolic blood pressure in the intervention group was significantly lower than that in the control group (p <0.001). As per the Mann-Whitney test, the mean diastolic blood pressure was not statistically significant between the two groups before the intervention and the first week after the intervention (p <0.05). However, after the second week of intervention, the mean diastolic blood pressure in the intervention group was significantly lower than that in the control group, and this decrease was highest in the fourth week of the intervention (p <0.001). **Conclusions:** This study demonstrated that auriculotherapy would reduce blood pressure in pregnant women suffering from hypertension.

Keywords: *Auriculotherapy, hypertension pregnancy-induced, pregnancy*

Ladan Keshtkar[1], Fatemeh Ranjkesh[2], Mohammad Habibi[3], Farnoosh Rashvand[4,5]

[1]Student Research Committee, Qazvin University of Medical Sciences, Qazvin, Iran, [2]Children Growth Research Center, Research Institute for Prevention of Non-Communicable Diseases, Qazvin University of Medical Sciences, Qazvin Iran, [3]Iranian Scientific Acupuncture Association, [4]Social Determinants of Health Research Center, Research Institute for Prevention of Non Communicable Diseases, Qazvin University of Medical Sciences, Qazvin, Iran, [5]Department of Nursing, Qazvin School of Nursing and Midwifery, Qazvin University of Medical Science, Qazvin, Iran

Address for correspondence:
Dr. Farnoosh Rashvand, Social Determinants of Health Research Center, Research Institute for prevention of Non-Communicable Diseases, Qazvin University of Medical Sciences, Qazvin, Iran.
Department of Nursing, Qazvin School of Nursing and Midwifery, Qazvin University of Medical Science, Qazvin, Iran.
E-mail: f.rashvand@qums.ac.ir

Introduction

Gestational hypertensive disorders are among the most common pregnancy complications that increase fetal and maternal mortality.[1,2] These complications have a global prevalence of 5%-10%[3] rising from 57.3 to 86.5 per thousand births in the hospital.[4] The prevalence of this disorder in Iran has been reported at 6.5%.[5] Today, many studies have shown a relation between gestational hypertension and chronic hypertension, cardiovascular disease, future metabolic disease, thromboembolism, and death.[1,4,6] Despite the problem of hypertension in pregnancy and its numerous complications, no preventive action has been noticed.[7] Applied standard therapies include pharmacological and nonpharmacological therapies, the most common of which are pharmacological therapies (such as hydralazine, labetalol, and nifedipine).[8] Common nonpharmacological treatments encompass absolute or partial bed rest, diet change, and limiting weight gain.[2,7] The nonpharmacologic methods have the advantage of low price and availability and limited side effects, increasing the patients' activity and adaptability, reducing care costs, and the number of bed occupancy in hospitals.[7,9] Nonpharmacological methods that have been considered in recent years include massage, music therapy, hypnosis, herbal medicines, aromatherapy, reflexology, and auricular therapy.[10,11] Auriculotherapy is one of the complementary medicine methods.[12] It is very similar to hand and foot reflexology and means stimulation of the orifice or outer ear. Auriculotherapy is a branch of acupuncture in traditional Chinese medicine[13,14] performed in a variety of ways including electrical stimulation, the use of needles or granular labels including magnetic seeds, and plant

How to cite this article: Keshtkar L, Ranjkesh F, Habibi M, Rashvand F. Effects of auriculotherapy on gestational hypertension: Randomized controlled trial study. Iran J Nurs Midwifery Res 2024;29:40-5.

Submitted: 10-Feb-2021. **Revised:** 12-Sep-2021. **Accepted:** 17-Apr-2023. **Published:** 09-Jan-2024.

Access this article online

Website: https://journals.lww.com/jnmr

DOI: 10.4103/ijnmr.ijnmr_403_20

Quick Response Code:

seeds such as Vaccaria and hand pressure in the outer ear is stimulated.[11,15] Recently, it has become common to use a seed to stimulate the outer ear, which is usually made of steel or Vaccaria beads, which are fixed with a little glue on the ear, which can stay on the ear for 3 to 6 days, and its essential advantage is not inflicting an injury to the skin of the ear.[16]

It is believed that the outer part of the ear is identical to an inverted fetus and is a view of the internal organs and organs of the body so that with the help of the ear, one can reach all anatomical parts of the body and different parts of the brain, spinal cord, and central and peripheral nerves.[17,18] In general, the three main meridians or energy channels that carry energy throughout the body pass through the ear, and by stimulating these points on the ear, one can produce and regulate the flow of energy throughout the body.[9,14,17] This method creates balance in the body and increases the sense of health in humans. Numerous studies on the effect of acupressure on various components such as vital signs, pain, and anxiety have been performed separately.[19-23] Considering the study conducted by Suen *et al*.,[18] which aimed to evaluate the effect of auricular therapy with two different methods of using acupressure and magnetic beads on high blood pressure, the results showed that auricle therapy using magnetic beads had positive results on moderate blood pressure, but there was no significant difference between the two methods in reducing blood pressure.

As per the study carried out by Li *et al*.,[19] auriculotherapy is effective in anxiety and quality of patients' lives, but again there was no difference in blood pressure. In the study of Ferreira *et al*.,[21] auriculotherapy was not effective in heart rate and diastolic blood pressure before and after intervention, but it caused a significant decrease in systolic blood pressure after the intervention. Auricular therapy is a simple, inexpensive, and noninvasive procedure, but there are conflicting results in its effectiveness. Despite the importance of hypertension in pregnancy and considering the side effects of antihypertensive drugs and their inability to prevent preeclampsia, limited studies have been conducted on using acupressure or acupuncture to control blood pressure. Moreover, we did not find any researches that assessed the effects of acupressure on gestational hypertension. Therefore, considering acupressure's safety, we studied acupressure's impacts on gestational hypertension in pregnant women by referring to Kowsar Medical Center in Qazvin.

Materials and Methods

This study is a randomized controlled trial study (IRCT20190402043156N1) in the Obstetrics and Gynecology Center of Kowsar Hospital (Iran) in 2020. We obtained the informed written agreement of every single participant to observe the principles of ethics in the research. Inclusion criteria included hypertension equal to 140/90 mm Hg after 20 weeks of gestation without any specific previous disease history and proteinuria, singleton pregnancy, literate, and not having external ear diseases. Exclusion criteria included pre-eclampsia, eclampsia, and Hemolysis, Elevated Liver Enzymes, and Low Platelets syndrome (HELLP syndrome), systolic blood pressure equal to or more than 160 mm Hg, diastolic blood pressure equal to or more than 110 mm Hg, having uterine contractions and vaginal bleeding, using psychotropic substances, cigarettes, and alcohol, and using other methods of complementary medicine concurrent with our study and premature delivery, dissatisfaction with the continuation of the study, and diagnosis of a new disease during the study. Available sampling was performed on all women with gestational hypertension referring to Kowsar Educational and Medical Center. To estimate the sample volume, considering the first type error, $\alpha = 0.05$, and the second type error, $\beta = 0.20$, and taking into account a 15% drop rate, we estimated 80 people sample size for random allocation, and a quadruple block method was used. There are six different modes for the quadruple block (AaaA, aaAA, AaAa, aAaA, AaaA, and aAAa). These modes were written on six cards and placed in a bag, and by selecting 20 blocks from the six possible blocks, the process of assigning 80 patients to two groups was obtained before the study began. The selected samples were randomly assigned to the intervention group "A" (ear acupressure) and the control group "B" (conventional care).

Before the intervention, the researcher underwent acupuncture medicine training and obtained a valid certificate. After the random allocation of samples to the intervention and control groups, the intervention was started. In the first step, a nurse, other than the researcher, with 15 years of nursing experience and holding a Master's Degree in nursing with established skill in avital signed measurement was selected to complete the study. She measured the blood pressure of the participants and was blind to which group they were in. Moreover, an ABN mercury sphygmomanometer, made in Germany, was used to measure blood pressure. To confirm the validity of the sphygmomanometer, blood pressure was taken twice with a 30-minute interval from several patients, and the constant numbers in these two times confirmed the validity of the tool. In group "A", in addition to routine care such as fetal health, fetal heart rate control, and fundal height measurement to determine fetal growth, mothers received acupressure for one month. In eight sessions (twice a week), the researcher installed a label containing six seeds on the hypertension line behind the ear to perform acupressure in this group. Mothers were asked to apply pressure on the seeds six times a day for at least 1 minute to reach the pain

threshold. Moreover, they were invited to attend the center twice a week to change the seed tags and control their blood pressure. Their blood pressure was measured and recorded at each visit to change the adhesive containing seeds after 15 minutes of rest.[17] Mothers were told that if the seeds caused any unpleasantness such as pain, insomnia, and any change in the conditions following its use, they could remove the label containing the seeds and leave the study. Group B, like group A, visited the center twice a week for routine medical care such as fetal health, fetal heart rate control, and fundal height for fetal growth. At the same time, this group's blood pressure was measured and recorded twice a week after 15 minutes of rest.

Data were analyzed using SPSS software version 19 and descriptive statistics (mean, standard deviation, frequency, and percentage) and inferential tests (Shapiro, Chi-square, Mann-Whitney, and Friedman's tests) were conducted. To check the normality of systolic and diastolic blood pressure, Shapiro-Vick test was used. Due to the non-normality of the variables, the Mann-Whitney test was used to compare the averages in two groups, and Friedman's repeated measurement test was used to compare the averages before and after the intervention; and in each group, p value less than. 05 (p <0.05) was considered significant.

Ethical considerations

This study was approved by the Research Ethics Committee of Qazvin University of Medical Sciences, Iran (IR.QUMS.REC.1397.370). Before the intervention, oral and written consents were obtained from the participants; all participants were informed of the study goal, method, and the voluntary nature of the research; besides, all were assured of the confidentiality of their information.

Result

There were 80 pregnant women in our study. Unfortunately, five participants dropped out of our research. In the intervention group, three patients left the study due to dissatisfaction to continue and one patient left due to hypertension. In the control group, two patients left the study due to hypertension. The data of the 75 remaining cases (37 in the experimental group and 38 in the control group) were analyzed [Figure 1]. The results showed there was no significant difference between the two groups in terms of individual social and pregnancy variables [Table 1].

As per the obtained results, based on the Mann-Whitney test, the mean systolic blood pressure was not statistically significant between two groups before the intervention and in the first two weeks after that (p <0.05). However, after the third week of the intervention, the mean systolic blood pressure in the intervention group was significantly lower than that in the control group (p <0.001). Using Friedman's statistical test, the mean diastolic blood pressure after the intervention in both groups showed a significant decrease (p <0.001). As per the effects' size, the calculated difference in the two groups was an average effect size [Table 2].

As per the Mann-Whitney test, there was no statistically significant mean in diastolic blood pressure between the two groups before the intervention and the first week postintervention (p <0.05). However, after the second week of intervention, the mean diastolic blood pressure in the intervention group was significantly lower than that in the control group, and this decrease reached its peak in the fourth week (p <0.001). Using Friedman's

Table 1: Comparison of demographic information in control group and intervention

	n (%)/Mean (SD)		*p**
	Intervention group "A*" (*n*=37)	Control group "B*" (*n*=38)	
Qualitative variables			
Women's education level			
Guidance school	21 (54.76)	25 (65.79)	0.340
High school	14 (37.84)	10 (26.32)	
Academic	2 (7.40)	3 (7.89)	
Women's job			
Unemployed	37 (100.00)	37 (97.40)	0.780
Employee	0 (0)	1 (2.60)	
Hypertension history			
Yes	1 (2.70)	3 (7.90)	0.285
No	36 (97.30)	35 (92.10)	
Diabetes history			
Yes	3 (8.10)	3 (7.90)	0.200
No	34 (91.90)	35 (92.10)	
Drug history (methyldopa)			
Yes	3 (8.10)	1 (2.63)	0.495
No	34 (91.90)	37 (97.37)	
Quantitative variables			
Women's age (year)	26.56 (4.91)	27.46 (5.03)	0.281
Gestational age (week)	26.21 (3.18)	25.56 (2.90)	0.204
Weight gain (Kg)	8.02 (1.67)	8.44 (1.70)	0.206

*Based on Chi-square or independent *t*-test, A: Intervention group; giving auriculotherapy, B: Control group; giving routine care

Table 2: Comparison of systolic blood pressure in two groups

	Intervention [Mean (SD)] "A"	Control [Mean (SD)] "B"	*p*	Cohen's effect size
Before intervention	143.24 (4.44)	142.24 (4.63)	0.545	
After 1 weeks	135.94 (5.24)	136.44 (6.86)	0.766	
After 2 weeks	133.91 (6.02)	135.38 (5.97)	0.095	
After 3 weeks	132.21 (2.73)	136.05 (6.27)	<0.001	0.37
After 4 weeks	130.81 (3.99)	136.31 (5.02)	<0.001	0.52
p	<0.001	<0.001		

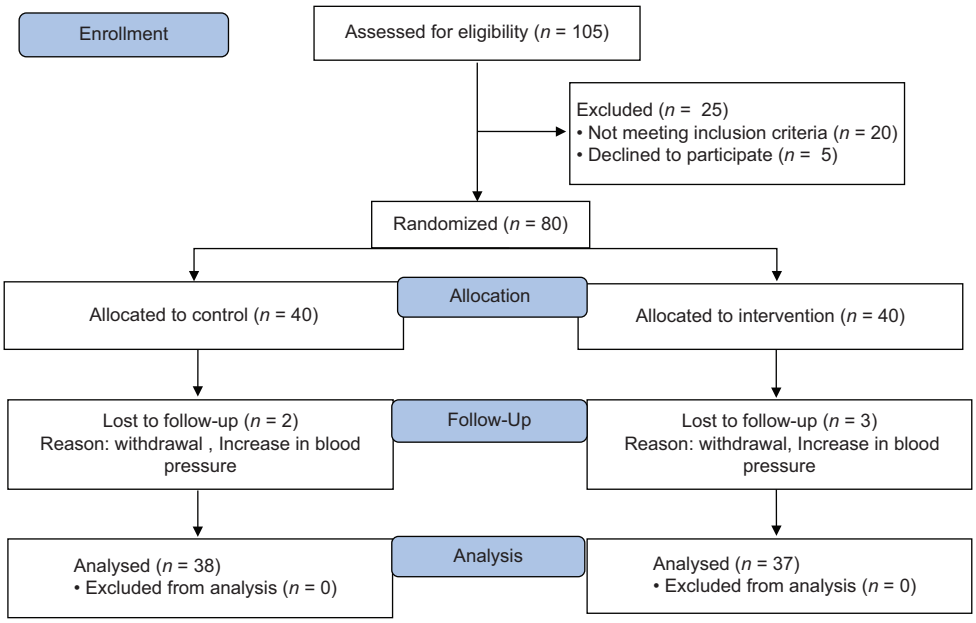

Figure 1: Consort diagram

statistical test, the mean diastolic blood pressure before and after the intervention in both groups showed a significant decrease (p <0.001). Apart from that, as per the effects' size, the difference between the two groups with high effect size has been obtained [Table 3].

Table 3: Comparison of diastolic blood pressure in two groups

	Intervention [Mean (SD)] "A"	Control [Mean (SD)] "B"	*p*	Cohen's effect size
Before intervention	88.10 (6.16)	87.76 (6.22)	0.774	
After 1 weeks	82.16 (4.17)	83.15 (4.71)	0.333	
After 2 weeks	80.81 (2.20)	84.07 (4.91)	0.002	0.39
After 3 weeks	80.54 (1.57)	82.36 (4.14)	0.05	0.28
After 4 weeks	79.67 (1.17)	84.07 (4.91)	<0.001	0.74
p	<0.001	<0.001		

Discussion

This study aimed to evaluate the effect of ear acupressure on systolic and diastolic blood pressure in women with gestational hypertension. The results of this study showed that acupressure in the ear caused a significant reduction in blood pressure in the intervention group two weeks after the intervention.

Studies on the effectiveness of ear acupressure on gestational hypertension are restricted. Kocher and Hobbs[24] conducted a similar study, and the effect of ear acupressure on lowering blood pressure in a pregnant woman with preeclampsia has been reported; a nulliparous pregnant woman with pre-eclampsia was treated with auriculotherapy for 5 weeks in this case study. The result of so-called study, similar to the present study, was a reduction in blood pressure. However, this study is a case report, and there are not a significant number of samples. Furthermore, the subject of the study has pre-eclampsia, which has a significant difference from the present study, and the findings are unreliable. As per Suen LK, the effect of ear acupressure caused a slight decrease in blood pressure in women with moderate hypertension. How long the blood pressure–lowering impact lasted was not noted.[18] Patients were nonpregnant and included both sexes and received acupressure at 6 points and blood pressure medications, as per their findings, although the result is not statistically significant in this study. Kim *et al*.[25] also evaluated ear acupuncture to lower the first stage–hypertension and prehypertension. This finding is consistent with the present study, but our results cannot be interpreted in the same way as Kim's finding because in pregnant women the hypertension mechanism differs from other hypertensive cases.

In a meta-analysis of 44 studies, Gao *et al*.[26] concluded that using ear acupressure combined with antihypertensive medications significantly reduced blood pressure and stabilized blood pressure compared to the time the medicines were just used. However, the role of ear acupressure alone in the persistent blood pressure reduction is still unknown. This study, too, did not analyze the same patients' setting, and further studies are necessary to prove the effectiveness of acupressure. Song *et al*.[27] and Zhao *et al*.[28] evaluated the effect of acupressure on lowering blood pressure, but its persistence is still questionable.

Similar to our research results, the findings of Suen *et al*.[18] also revealed that auriculotherapy with magnetic beads

had positive effects on uncontrolled medium hypertension. In a research by Li *et al*.,[19] they also found out that blood pressure decrease was considerably higher in the intervention group. However, the acupressure techniques employed by Yeh *et al*.[20] could not reduce the blood pressure in patients with chronic hypertension. In this study, nonpregnant people underwent ear acupressure for 10 weeks and in terms of methodology, it is different from the present study and cannot be completed.

Ferreira *et al*.[21] also found out that acupressure had no effect on heart rate nor on the diastolic pressure; nonetheless, there was a significant decline in systolic blood pressure after the intervention.

The results of the present study similar to those of other studies reveal that auriculotherapy can be an influential and effective method to control blood pressure, but further studies in pregnant women with hypertension are mandatory to prove this hypothesis strongly. One of the limitations of this study was the dissatisfaction of participants because some pregnant mothers were not sufficiently willing to use the labels due to the importance of hypertension in pregnancy. To solve this problem, the researcher talked to the patients and assured them that this intervention would not have a negative effect on them and convinced them to participate. Another limitation was the uncertainty of the correct use of the labels. Hence, the researcher was in regular contact with the participants during the study and ensured the correct use of the labels.

Conclusion

It is concluded in this study that as a nonpharmacological intervention, auriculotherapy reduced blood pressure in pregnant women's gestational hypertension.

Acknowledgments

The authors would like to thank the women for their willingness to participate to this study. This research has been supported by Qazvin University of Medical Sciences (Grant No: IR.QUMS.REC.1397.370).

Financial support and sponsorship

Qazvin University of Medical Sciences

Conflicts of interest

Nothing to declare.

References

1. Huang C, Wei K, Lee PMY, Qin G, Yu Y, Li J, *et al*. Maternal hypertensive disorder of pregnancy and mortality in offspring from birth to young adulthood: National population-based cohort study. BMJ 2022:379:e072157.
2. Azimian J, Alipour Heidary M, Ranjkesh F. The effects of Progressive Muscle Relaxation and Guided Imagery on gestational hypertension. Complement Med J Fac Nurs Midwifery 2017;7:1906-17.
3. Welters SM, de Boer M, Teunissen PW, Hermes W, Ravelli ACJ, Mol BW, *et al*. Cardiovascular mortality in women in their forties after hypertensive disorders of pregnancy in the Netherlands: A national cohort study. Lancet Healthy Longev 2023;4:e34-42.
4. Mengistu MD, Kuma T. Feto-maternal outcomes of hypertensive disorders of pregnancy in Yekatit-12 Teaching Hospital, Addis Ababa: A retrospective study. BMC Cardiovasc Disord 2020;20:173.
5. Khani H, Aazam N, Ozgoli G, Pour Ebrahim T, Hamzeh Gardeshi Z. The relationship between mental stress and hypertensive disorders during pregnancy: A review article. Iran J Obstet Gynecol Infertil 2017;20:61-70.
6. Poon LC, Nguyen-Hoang L, Smith GN, Bergman L, O'Brien P, Hod M, *et al*. Hypertensive disorders of pregnancy and long-term cardiovascular health: FIGO best practice advice. Int J Gynecol Obstet 2023;160(Suppl 1):22-34.
7. Brown MA, Magee LA, Kenny LC, Karumanchi SA, McCarthy FP, Saito S, *et al*.; International Society for the Study of Hypertension in Pregnancy (ISSHP). Hypertensive disorders of pregnancy: ISSHP classification, diagnosis, and management recommendations for international practice. Hypertension 2018;72:24-43.
8. Awaludin A, Rahayu C, Daud NAA, Zakiyah N. Antihypertensive medications for severe hypertension in pregnancy: A systematic review and meta-analysis. Healthcare (Basel) 2022;10:325.
9. Verma N, Rastogi S, Chia YC, Siddique S, Turana Y, Cheng HM, *et al*. Non-pharmacological management of hypertension. J Clin Hypertens (Greenwich) 2021;23:1275-83.
10. Saif-Ur-Rahman KM, Shariful Islam S, Hasan M, Hossain S, Mamun R, Shafique S, *et al*. Nonpharmacological interventions for the prevention of hypertension in low- and middle-income countries: A systematic review and meta-analysis. J Hum Hypertens 2019;33:786-94.
11. Mousavi FS, Golmakani N, Taghanaki B, Reza H, Saki A, Akhlaghi F. Effects of auriculotherapy on post cesarean anxiety. Iran J Obstet Gynecol Infertil 2017;20:50-60.
12. Alimoradi Z, Kazemi F, Valiani M, Gorji M. Comparing the effect of auricular acupressure and body acupressure on pain and duration of the first stage of labor: Study protocol for a randomized controlled trial. Trials 2019;20:766.
13. Valiani M, Azimi M, Dehnavi ZM, Mohammadi S, Pirhadi M. The effect of auriculotherapy on the severity and duration of labor pain. J Educ Health Promot 2018;7:101.
14. Tesser CD, Moré AOO, Santos MC, da Silva EDC, Farias FTP, Botelho LJ. Auriculotherapy in primary health care: A large-scale educational experience in Brazil. J Integr Med 2019;17:302-9.
15. Suen LKP, Yeh CH, Yeung SKW. Using auriculotherapy for osteoarthritic knee among elders: A double-blinded randomised feasibility study. BMC Complement Altern Med 2016;16:257.
16. Jouya S, Golmakani N, Mazloum SR, Abdi H, Yousefi Z. Effect of auriculotherapy with vaccaria seeds on the anxiety of female colposcopy candidates. Iran J Obstet Gynecol Infertil. 2018;21:70-9.
17. Suen LKP, Molassiotis A, Yueng SKW, Yeh CH. Comparison of magnetic auriculotherapy, laser auriculotherapy and their combination for treatment of insomnia in the elderly: A double-blinded randomised trial. Evid Based Complement Alternat Med 2019;23:1-19.
18. Suen LKP, Chair SY, Thompson DR, Yu CM, Lin ZX, Lee PW, *et al*. Traditional auriculotherapy for hypertension: A pilot randomized trial. J Cardiovasc Dis 2014;2:19-24.
19. Li L, Zhang K, Shi N. Effects of the traditional Chinese auricular point therapy combined with relaxation training on patients with hypertension and anxiety. Biomed Res 2017;28:5224-8.

20. Yeh M-L, Chang Y-C, Huang Y-Y, Lee T-Y. A randomized controlled trial of auricular acupressure in heart rate variability and quality of life for hypertension. Complement Ther Med 2015;23:200-9.
21. Ferreira AP, Rocha TC, Neto AFE, da Silva Rodrigues KL, Barretto L, Aleixo PdSR. Acute cardiovascular response to a session of auriculotherapy in normotensive individuals. Rev Bras Cien Med Saúde 2016;4:1-7.
22. Vas J, Aranda-Regules JM, Modesto M, Aguilar I, Barón-Crespo M, Ramos-Monserrat M, *et al*. Auricular acupuncture for primary care treatment of low back pain and posterior pelvic pain in pregnancy: Study protocol for a multicentre randomised placebo-controlled trial. Trials 2014;15:288.
23. Puangsricharern A, Mahasukhon S. Effectiveness of auricular acupressure in the treatment of nausea and vomiting in early pregnancy. J Med Assoc Thai 2008;91:1633-8.
24. Kocher Z, Hobbs V. Integrating acupuncture for preeclampsia with severe features and HELLP syndrome in a high-risk antepartum care setting. Med Acupunct 2019;31:407-15.
25. Kim J-H, Jung HJ, Kim T-H, Lee S, Kim J-E, Kang K-W, *et al*. Auricular acupuncture for prehypertension and stage 1 hypertension: Study protocol for a pilot multicenter randomized controlled trial. Trials 2013;14:2-7.
26. Gao JL, Chen G, He HQ, Liu C, He QY, Li J, *et al*. The effect of auricular therapy on blood pressure: A systematic review and meta-analysis. Eur J Cardiovasc Nurs 2020;19:20-30.
27. Song RG, Li SJ, Liu W. Auricular pressure combined with medicine in the treatment of hypertension. Zhongguo Zhong Yao Za Zhi (in Chinese) 2015;35:95-6.
28. Zhao ZH, Zhou Y, Li WH, Tang ZH, Xia TW, Han-Li. Auricular acupressure in patients with hypertension and insomnia: A systematic review and meta-analysis. Evid Based Complement Alternat Med 2020;2020:7279486.