The Effect of Auriculotherapy on Pulmonary Findings and Sleep Quality in Patients with Covid 19

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Abstract

Background: Auriculotherapy is a sub-branch of acupuncture and is an effective method in acute and chronic diseases.

Aim: The aim of this study was to evaluate the effect of Auriculotherapy on pulmonary findings and sleep quality in patients with Covid 19.

Methods: The present study is a clinical trial study in which 70 hospitalized patients with Covid 19 with pulmonary findings and low sleep quality were randomly divided into intervention and control groups. Auriculotherapy was performed with electrical stimulation in one session and then Vakaria seed was placed in acupressure points and stimulated for one week (8 times a day for one minute each time). Data collection tools were checklist of pulmonary findings, Pittsburgh questionnaires and demographic characteristics.

Results: The results showed that there was no significant difference between the mean SPO2 score in the two groups before and after the intervention (P = 0.09). There was a statistically significant difference between the mean score of dyspnea (P = 0.003), cough (P <0.008) and overall score of sleep quality in the two groups before and after the intervention (P <0.001).

Conclusion: The results of this study showed that Auriculotherapy is effective on pulmonary improvements and sleep quality in patients with Covid 19.

Trial registration: IRCT, IRCT20180608040007N2. Registered 13 June 2020, https://en.irct.ir/trial/48218.

Introduction:

With the outbreak of Covid 19 in Wuhan, China in December 2019, many efforts have been made around the world to control the epidemic, treat infected patients or reduce their symptoms (1). However, the incidence and mortality rate in the world is still high (2). Various treatment programs have been recommended in this regard, which are: 1- Rest and monitoring, fluid intake and water and electrolyte balance 2- Check blood tests 3- Oxygen therapy based on patient needs 4- Intubation if necessary (3), as well as the initiation of immediate medical treatment required (4). Despite numerous studies on how to treat Covid-19, there is still no accepted treatment protocol for the disease. One of the methods used according to the guidelines recommended in China is the use of traditional Chinese medicine (TCM). In traditional Chinese medicine, herbal medicine, moxa therapy, acupuncture and auriculotherapy are performed based on the symptoms of the disease (3). Auriculotherapy is an effective method with the least side effects in the treatment of acute and chronic diseases that is used in disorders of the locomotors system - nervous - psychological - cardiovascular - urology and gastrointestinal tract (5–8). A study conducted in 2019 in Brazil showed that auriculotherapy is a fast, easy, safe and effective way to treat various health problems and is acceptable to patients (9). In 1990, the World Health Organization introduced acupuncture in the ear as the most advanced and with the best scientific and practical

documentation of all sub-branches of acupuncture (10). The difference between auriculotherapy and acupuncture is the use of a slight current of electricity and the seeds of the vaccaria plant in auriculotherapy instead of needles, which is a relatively invasive procedure. Vaccaria plant seeds, like needles, stimulate the target areas without harming the patient. Stimulation of the points releases neurotransmitters such as endorphins, thereby reducing anxiety and stress in patients and helping to improve patients (11, 12). The World Federation of Acupuncture Associations recommends acupuncture treatment in Covid 19 to stimulate vital energy in the lungs and spleen which maintains visceral function, reduces damage, eliminates pathogens, improves mood, increases self-confidence and thus defeats the disease (13). Another major problem in patients with Covid-19 is poor sleep quality, which leads to worsening of the patient's condition and impaired immune system and changes in the physiological state of the body (14). Therefore, the present study was designed and conducted to evaluate the effect of auriculotherapy on pulmonary findings and sleep quality in patients with Covid 19 as an adjunctive therapy in these patients.

Method:

This clinical trial was performed in Shahid Sadoughi Hospital in Yazd, Iran as a referral center for admission and hospitalization of patients with Covid 19 from 14/6/2020 to 20/8/2020. After reviewing and approving the research proposal in the ethics committee of Shahid Sadoughi University of Medical Sciences of Yazd (Code: IR.SSU.REC.1399.030), it was registered in the Iranian Clinical Trials Register System (IRCT))https://en.irct.ir/trial/48218). Sampling was done by census method from 7 active wards of the hospital in the field of Covid-19 based on inclusion and exclusion criteria.

Inclusion criteria were: positive Covid-19 PCR test, age 10 to 70 years, having a healthy outer ear (no abnormalities or evidence of infection), sleep quality score above 5.

Exclusion criteria were: history of anxiety or depression, use of psychiatric drugs, having a pacemaker-platinum or any metal object in the body based on the participants' self-declaration. Sleep quality was assessed and determined based on the Pittsburgh questionnaire. Participants in the study included 70 patients with a definitive diagnosis of Covid-19 out of 115 patients admitted at the time of the study who met the inclusion criteria. All participants in the study or their guardians received informed written consent after giving full explanations about the type and manner of the study and the benefits and complications of the method used and assurance about the confidentiality of their information. Then, according to the table of random numbers, the participants were divided into two groups of intervention and control (n = 35 / each). For all participants, before the intervention, the number of coughs and the number of days of shortness of breath per day and the amount of SPO2 were recorded by the researcher. The instrument used to measure sleep quality was the Pittsburgh Sleep Questionnaire (PSQI). This questionnaire basically has 9 items, but because question 5 contains 10 sub-items, so the whole questionnaire has 19 items. Scoring is scored on a 4-point Likert scale from 0 to 3. This questionnaire has 7 subscales which are: subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, use of sleeping medication, daytime dysfunction.

A score higher than or equal to 5 indicates poor sleep quality. This questionnaire has high validity and 87% reliability (14, 15). The above information was collected from each participant in a quiet and private environment (with the coordination of the head of the department) for a period of 15 to 20 minutes according to the general condition of the participants.

In the next step, in the case group, after disinfecting the ear with 70% alcohol and drying the desired points(Thymus gland, Adrenal, lung 1&2, Throat, internal nose, larynx, Trachea, (left) and Shenmen, zero point, thalamus point, Anxiety point, sensorial, vital signs, insomnia (right))Fig. 1)), each point was electrically stimulated for 15 seconds by the II POINTER EXCEL device(Serial number 9292124 Scotland, HZ16, IND.COTENS PLUS China).

After auriculotherapy, vaccaria seeds were placed on the desired points. The seeds were on the ear for seven days and patients were instructed to press the seeds 8 times a day for one minute each time for 7 days (16, 17). No special intervention was performed in the control group. It is noteworthy that the routine treatments of Covid-19 in both groups were continued according to the treatment of the infectious disease specialist of the hospital (including tablets: Kaletra, hydrochloroquine, acetaminophen and serum therapy). If patients were discharged during treatment, follow-up would be by telephone. The studied variables (number of cough, frequency of shortness of breath per day, SPO2, sleep quality) in both groups were measured and re-measured by the researcher four weeks after the intervention. The intervention was performed by a skilled researcher using auriculotherapy method and under the supervision of a clinical therapist with experience in the field of neuroscience (auriculotherapist) and with the coordination of the infectious disease specialist.

Statistic Analysis:

Spss software version 25 was used for data analysis. The mean of quantitative variables was compared before the intervention with independent t test and after the intervention with Multivariate analysis of covariance. The comparison of before and after means in each group was performed by paired t test. A significance level of 5% was considered. Variables that were significantly different between the two groups at the beginning of the study and before the intervention (SPO2, cough, ...) were considered as confounding variables and therefore we used MANCOVA analysis method for data analysis.

Findings:

Out of 115 patients admitted at the time of the study, 70 patients with a definitive diagnosis of Covid-19 who met the inclusion criteria were included in the study. One person in the control group due to death and 3 people in the case group (one person due to death and 2 people due to loss up follow up) were excluded from the study. Finally, the data of 32 people in the case group and 34 people in the control group were analyzed and statistically analyzed (Fig. 2). The two groups were matched in terms of occupation, smoking, family history and drug use, but were significantly different in terms of age, sex and education (Table 1).

In both groups, the mean SPO2 score showed a significant increase compared to before the intervention ($P < 0.001$) while there was no significant difference between these scores before the intervention between the two groups ($P = 0.66$). Also, after the intervention, no significant difference was seen between the two groups ($P = 0.09$) (Table 2).

In both groups, the mean score of the number of coughs showed a significant decrease compared to before the intervention ($P < 0.001$). These scores were significantly different between the two groups before the intervention ($P = 0.004$) but no significant difference was seen between the two groups after the intervention ($P < 0.008$) (Table 2).

The mean score of the number of cases of shortness of breath in the intervention group showed a significant decrease compared to before auriculotherapy ($P < 0.001$) but in the control group there was no significant decrease ($P = 0.07$). Also, there was no statistically significant difference between the mean scores of the number of cases of shortness of breath in the two groups before the intervention ($P = 0.21$). But there was a significant difference between the two groups after the intervention (P- = 0.03) (Table 2).

The mean total score of sleep quality in the intervention ($P < 0.001$) and control ($P = 0.018$) groups showed a significant decrease compared to before the intervention. There was a statistically significant difference between the two groups before the intervention ($P < 0.001$) but there was no significant difference between the two groups after the intervention ($P < 0.001$) (Table 3).

Table 1
Demographic characteristics of the participants

Variables		Intervention groups n (%)	Control groups n (%)	P-value
age*		42.71 ± 13.17	48.18 ± 11.49	P = 0.01
sex**	Female	14(43.3)	23(67.6)	P = 0.04
	Male	18(56.3)	11(32.4)	
occupation **	Employee	13 (40.6)	7 (21.2)	P = 0.14
	Free	8(25)	6(18.2)	
	Housewife	10(31.3)	19(57.6)	
	Unemployed	1(3.1)	2(3)	
education **	High school	6(18.8)	18(56.3)	
	Diploma	12(37.5)	4(12.5)	
	Associate Degree	4(12.5)	3(9.4)	
	Bachelor	5(15.6)	3(9.4)	
	MA	2(6.2)	1(3)	
	P.H.D	3(9.4)	3(9.4)	
smoking**		3(9.4)	1(3)	P = 0.28
family history **		14(43.8)	10(30.3)	P = 0.19
Drug history**		9(28.1)	13(39.4)	P = 0.24

*Data presented as Mean ± S.D.; Student's *t* test

** Data presented as n(%);**Chi-Square** test

Table 2
Comparison of mean arterial oxygen levels, number of coughs and shortness of breath per day

variable	Group	Before	After	P_value□□□
SPO2(unit)	Auriculotherapy	93.10 ± 2.45	96.23 ± 1.22	< 0.001
	Control	93.40 ± 2.54	95.70 ± 1.08	< 0.001
	P	0.66□	0.09□□	
Cough(unit)	auriculotherapy	26.61 ± 21.62	0.78 ± 2.57	< 0.001
	Control	12.51 ± 15.29	4.63 ± 11.65	< 0.001
	P	0.004□	0.008□□	
Dyspnea(unit)	auriculotherapy	23.12 ± 22.68	0.40 ± 1.38	< 0.001
	Control	7.48 ± 10.21	5.65 ± 9.97	0.007
	P	< 0.001□	0.003□□	

□ Independent T Test

□□ Mancova

□□□Paired T Test

Table 3
Comparison of average sleep quality scores of the studied groups based on the Pittsburgh Sleep Questionnaire (PSQI)

Variable	group	Before	After	P_value
sleep duration	auriculotherapy	2.40 ± 1.07	0.750 ± .879	< 0.001
	control	1.64 ± 1.25	1.64 ± 1.15	0.10
	P_value	0.011	< 0.001*	
sleep latency	auriculotherapy	2.78 ± 0.60	1.18 ± .73	< 0.001
	control	2.08 ± 1.08	1.82 ± 1.14	0.027
	P_value	0.002	< 0.001	
sleep disturbances	auriculotherapy	2.28 ± 0.63	2.50 ± 4.57	0.783
	Control	1.47 ± 0.56	6.97 ± 4.93	< 0.001
	P_value	0.001	< 0.001	
habitual sleep efficiency	auriculotherapy	1.750 ± 1.21	0.34 ± .90	< 0.001
	Control	1.00 ± 1.20	1.17 ± 1.31	0.160
	P_value	0.015	< 0.001	
daytime dysfunction	auriculotherapy	3.65 ± 1.97	1.90 ± 0.96	< 0.001
	Control	2.41 ± 2.43	1.23 ± 1.23	< 0.008
	P_value	0.026	< 0.001	
use of sleeping medication	auriculotherapy	1.187 ± 1.40	0.281 ± .81	< 0.001
	Control	0.79 ± 1.12	0.73 ± 1.18	0.67
	P_value	0.21	0.001	
subjective sleep quality	auriculotherapy	2.53 ± .56	0.71 ± .81	< 0.001
	Control	2.14 ± .70	1.64 ± .81	< 0.001
	P_value	0.018*	< 0.001	
total	auriculotherapy	14.84 ± 3.48	4.12 ± 3.57	< 0.001
	Control	10.38 ± 5.20	9.11 ± 5.44	0.018
	P_value	< 0.001*		

*Independent T Test

Mancova

Paired T Test

Discussion:

The present study investigated the effect of adjuvant auriculotherapy treatment on pulmonary findings and sleep quality in patients with Covid 19. Our findings showed that the mean SPO2 score in both auriculotherapy and control groups increased significantly after the intervention. Although there was a slight increase in the mean score of arterial oxygen in the auriculotherapy group compared to the control group, but this difference between the two groups was not significant after the intervention. In other words, adjuvant therapy with auriculotherapy did not help to improve SPO2 in patients. Zhang et al. (2019) also reported that after electrical stimulation of acupuncture points through the skin, there was no significant difference between the intervention and control groups in terms of SPO2 levels after the intervention (17).

A study by Lee et al., Which was conducted to evaluate the effect of acupuncture on the treatment of physiological respiratory parameters in patients with amyotrophic lateral sclerosis, showed that acupuncture leads to an increase in SPO2 (18). We also achieved this result by comparing before and after patients in the intervention group. However, Dellovo (2019) et al. Concluded in their study that auriculotherapy had a significant effect on increasing the SPO2 of patients undergoing third molar extraction (16), which was not in line with our study. This may be due to the fact that in our study the patients' anxiety was higher than their study, and also the cough and shortness of breath that existed in the patients in our study. In the present study, the number of cases of shortness of breath in the auriculotherapy group showed a significant decrease compared to before the intervention, and the difference between the two groups was also significant after the intervention. This result could indicate the effect of auriculotherapy on improving the shortness of breath in patients with Covid-19. Von Trott et al. (2020) in a meta-analysis study showed that acupuncture is effective in reducing shortness of breath in patients with chronic obstructive pulmonary disease (19). Another meta-analysis and systematic review conducted by Zhang et al. In 2020 showed that acupuncture may be effective in improving shortness of breath in patients with coronary heart disease (20). Also in the study of Bauml et al. (2015), acupuncture was effective on the rate of shortness of breath in patients with lung cancer (21). But other studies, such as those of Vickers et al. (2005), showed that acupressure was not effective in improving shortness of breath in patients with advanced lung and breast cancer who had severe shortness of breath (22). This difference in results may be due to sample size, type of disease, and study participants. In the present study, in both groups, the mean score of the number of coughs per day showed a significant decrease compared to before the intervention. There was also a significant difference between the two groups after the intervention. This indicates the effect of auriculotherapy on reducing the number of coughs in patients with coronary heart disease. Previous studies have shown the effect of acupuncture on cough after infection, especially colds (23, 24), which according to the similarities between the two methods can be said that our results also confirm the results of those studies.

Further reduction of sleep quality score in the auriculotherapy group in the present study indicates a better improvement in sleep quality with this adjuvant treatment method. Also, in comparing the two groups after the intervention, a significant difference was observed in improving the quality of sleep in the auriculotherapy group compared to the control group. Regarding the components of sleep quality, in all cases (Including sleep duration, sleep delay, sleep efficiency, daily dysfunction, use of sleeping pills, and mental quality of sleep) except sleep disorders, the method of auricular therapy was effective and there was a significant difference between the intervention group and the control group. In their study (2020), Khaledi et al. Achieved similar results regarding the effect of acupuncture on sleep quality in chronic insomnia, which was measured by kinematics test (25). In 2019, Ren also considered the effect of auricle therapy on primary sleep disorder to be effective (26). Also, Valiani et al. (2018) by examining the effect of auriculotherapy on sleep quality in patients with MS, declared this method effective in improving sleep quality in these patients (27). Studies confirm the effect of acupuncture on the secretion of melatonin (one of the important hormones in improving sleep quality) that can explain the physiological effects of acupuncture on the central nervous system in the process of improving sleep quality (26, 28). However, Fagner (2017) and Chung (2016) did not consider auriculotherapy to be effective in improving sleep quality (29, 30), which may be due to the small sample size mentioned in the studies. Limitations of the study: Fear and anxiety about the disease, unknown disease, lack of standard treatment and mortality due to the disease were the limitations of the present study. Therefore, it is suggested that further studies be performed on the effect of auriculotherapy on pulmonary findings and other problems associated with Covid 19.

Conclusion:

The results of the present study showed the effectiveness of auricular therapy in improving respiratory symptoms including shortness of breath and cough in patients with Covid 19. It also had a positive effect on improving the sleep quality of these patients. Therefore, the use of auriculotherapy as a low-cost, easy and without side effects in patients with Covid 19 is recommended along with modern medicine.

Abbreviations

COVID-19
Coronavirus
TCM
Traditional Chinese medicine
W.H.O
World Health Organization
IRCT
Iranian Clinical Trials Register System
PSQI
Pittsburgh Sleep Questionnaire.

Declarations

Acknowledgment:

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Authors' contributions:

Study concept and design: M.M., V.M., and AM.Z. analysis and interpretation of data: T.MJ., Kh.MB and Kh.AR. drafting of the manuscript: M.M. and Kh.MB critical revision of the manuscript for important intellectual content: M.M., AM.Z., V.M., ShY.M., A.L., and ZM.H. statistical analysis: T.MJ., M.M.

Availability of data and material:

Data is available and will be provided upon request.

Ethics approval and consent to participate:

The study protocol was approved in the ethics committee of Shahid Sadoughi University of Medical Sciences of Yazd (Code: IR.SSU.REC.1399.030). Patients were informed about the purpose and methods of the study before requesting consent to participate. Patients who agreed to participate signed a written consent before participating in the study.

Consent for publication:

Not applicable.

Declaration of conflicting interests:

There are no conflicts of interest.

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Patient consent:

Obtained.

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Figures

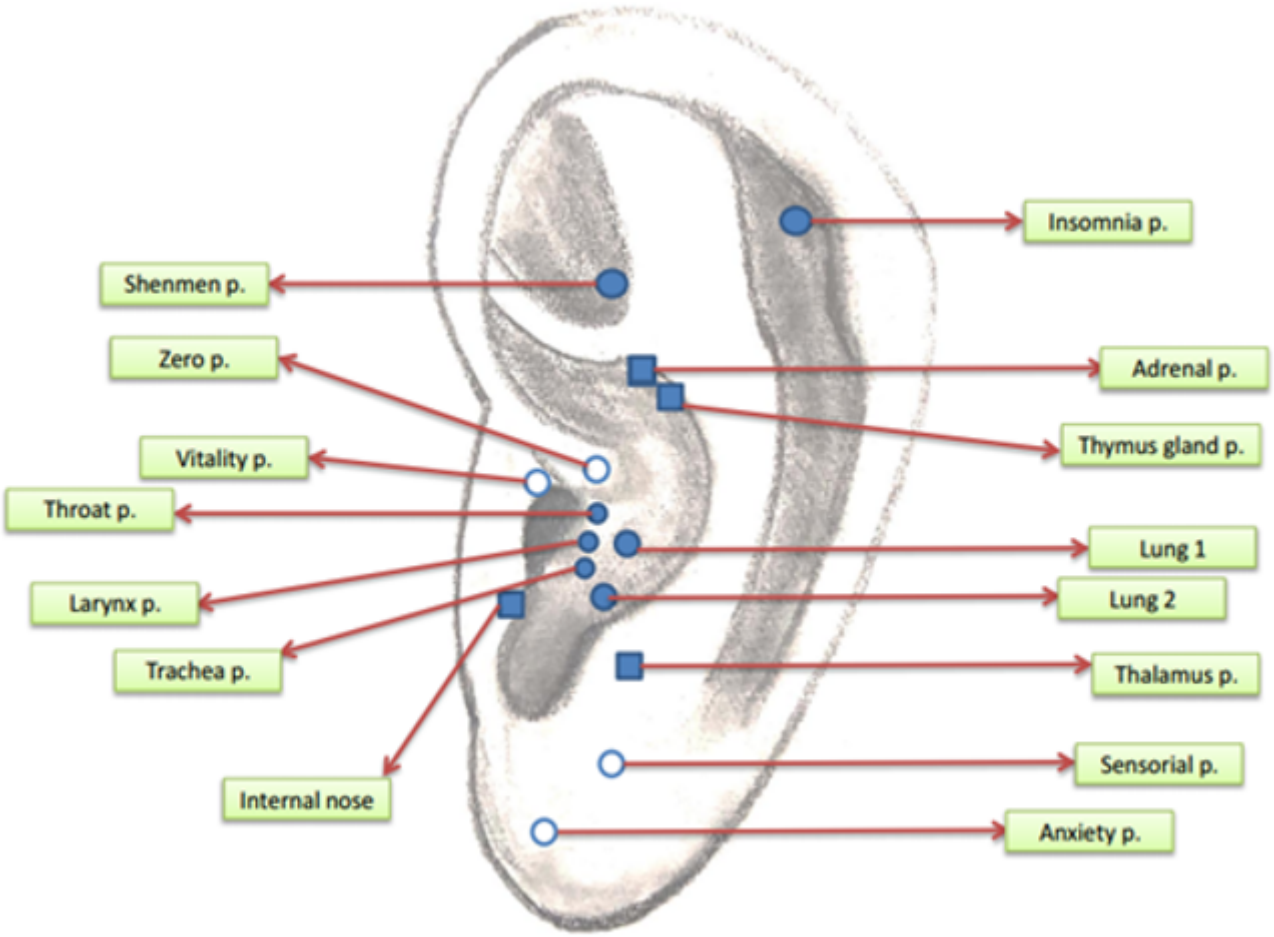

Figure 1

Location of the ear pressure points used in the study.

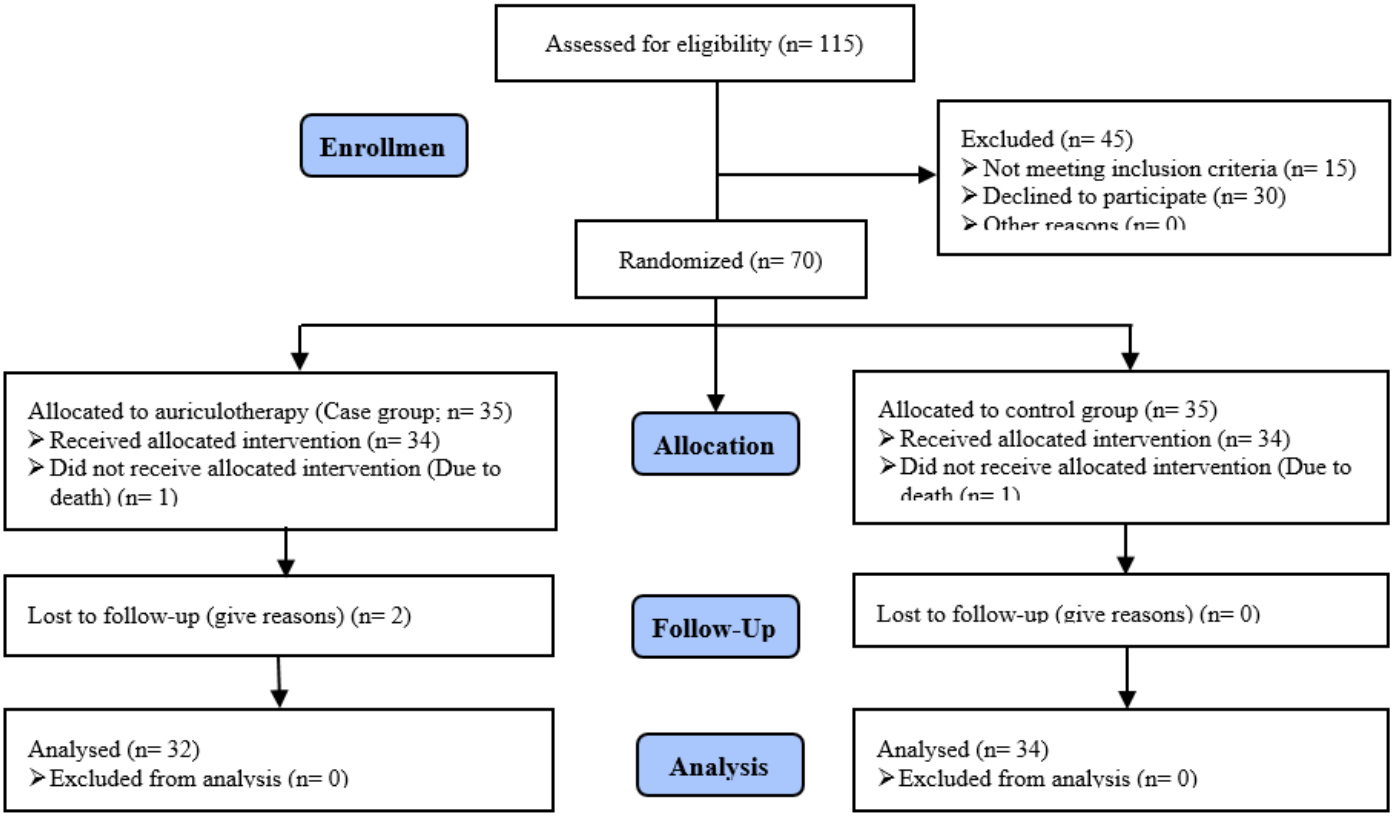

Figure 2

The study consort flowchart