

A Randomized Controlled Trial to Assess the Effectiveness of Warm Foot Soak Therapy on Reduction of Blood Pressure Among Hypertensive Patients

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Abstract

Introduction: Hypertension is known as the “silent killer” because of its uncertain symptom. Therefore, early detection efforts are needed such as regular blood pressure check and effective management. Both Pharmacological and Non-pharmacological management strategies for hypertension. This study aimed to determine the effectiveness of one of the non-pharmacological management :“warm water foot soak therapy” in reduction of blood pressure among hypertensive patients.

Method: Experimental study design - Randomized Controlled Trial was conducted among 60 hypertensive patients using convenient sampling technique. Participants were randomly and equally allocated into Experimental and Control group with the help of computer generated randomization list. Sequentially Numbered Opaque Sealed Envelope (SNOSE) were used for allocation concealment. Experimental group received “Warm foot soak therapy” of both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 consecutive days. Before and after intervention blood pressure assessment were taken in both groups. Data were analyzed using SPSS ver. 27

Result: Homogeneity of socio-demographic, clinical and pre-intervention blood pressure among both groups were statistically established using chi-square test ($p > 0.05$). Paired t test concluded that, warm foot soak therapy were having statistically significant effect on blood pressure ($p < 0.05$) and there was a significant reduction in blood pressure among hypertensive patients ($p=0.01$). The study also discovered that there is no significant association between selected sociodemographic & clinical variables with pre-interventional change in blood pressure except for the dietary pattern (Veg) in both groups & presence of comorbidity (DM) in experimental group among hypertensive patients at level of significance 0.05.

Conclusion: The study demonstrated that warm foot soak therapy have an effect on reduction of blood pressure among hypertensive patients.

Keyword: Hypertension, Warm foot soak therapy, Reduction of blood pressure, hypertensive patients, non- pharmacological management.

Introduction

“ The silent killer ” refers to hypertension, an asymptomatic condition marked by increased systolic and diastolic blood pressure (Potter & Perry, 2005).⁽¹⁾ It is the biggest single cause of an increase in mortality and worldwide disease burden. (2015) Poulter, Prabhakaran, and Caulfield.⁽²⁾ According to the global burden of hypertension, 1.56 billion persons were predicted to have high blood pressure by 2025, up from the expected one billion in 2017. Now One of the most common chronic diseases in India is hypertension. Age, gender, marital status, employment, alcohol consumption, excessive salt intake, and smoking history are just a few of the risk factors that have been connected to hypertension.⁽³⁾ Hypertension can be managed and controlled with the appropriate care, despite the fact that there is no ideal medication for it. The mortality and morbidity linked to hypertension can be decreased by effective treatment adherence combined with blood pressure-influencing factors. Generally speaking, managing hypertension can be done with or without the use of pharmaceuticals. Although taking drugs can provide temporary alleviation from problems, pharmacological therapy makes use of a variety of drug classes. Non-pharmacological management techniques include herbal therapy, nutritional therapy, progressive relaxation, breathing exercises, music therapy, acupuncture, reflexology, aromatherapy, and hydrotherapy which is spreading quickly both among rural and urban populations.⁽⁴⁾

Although a multitude of medications and treatment methods exist for hypertension, none ensure complete recovery. The two main goals of hypertension therapy are to maintain blood pressure (BP) within the normal range and to enhance the health and quality of life of older adults.⁽⁵⁾

In general, there are two approaches to managing hypertension: pharmacological and non-pharmacological. According to the 2017 AHA/ACC recommendation, patients with stage 1 hypertension who do not have these symptoms should have their 10-year risk of cardiovascular disease calculated. It makes sense to conduct lifestyle modification alone for three to six months if the risk is less than 10%. It is advised to change one's lifestyle and take medicine for stage 2 hypertension in patients with pre-existing conditions such as diabetes mellitus, chronic kidney disease, and a 10-year risk of cardiovascular events of 10% or higher. Pharmacological management makes use of medications such as beta blockers, calcium channel blockers, vasodilators, and diuretics in relation to the degree of adherence and mechanism of action of the medicine. The side effects of this pharmaceutical treatment differ according on how long and how intense it is. Drug administration-related adverse effects, geriatric disobedience in taking antihypertensive medications, and dependency effects are just a few of the issues with pharmacological therapy for the aged (Aronow & Banach, 2012).⁽⁶⁾ In order to support pharmacological treatment, nonpharmacological management might be used (Muttaqin, 2009).⁽⁷⁾

Lifestyle changes such as giving up smoking, cutting back on excessive alcohol intake consuming less salt and fat, eating more fruits and vegetables, losing weight, exercising, and receiving complementary therapy are examples of non-pharmacological management.⁽⁸⁾ Individual lifestyle factors each have a partially additive influence on blood pressure reduction, which increases the effectiveness of pharmaceutical treatment. There are various forms of hydrotherapy, including sitz baths, water massages, compressing, wrapping with a damp towel, and soaking feet. Warm water is used in non-pharmacological techniques like foot soak therapy to relax blood vessels, muscles and improve blood flow.⁽⁹⁾

Heat is known to cause the body to expand blood vessels, lower blood viscosity, relieve tense muscles, speed up tissue metabolism, and widen capillaries. The body needs heat therapy for these reasons.

It is known that stimulating the pituitary gland causes endorphin chemicals to be released, which activate the parasympathetic nervous system and decrease activity instead of the sympathetic nerves. This causes

a generalized vasodilation, which lowers blood pressure and decreases peripheral resistance.⁽¹⁰⁾ There are nerve sites on the human foot soles that correspond to different body organs. Warm water between 31 and 37 °C produces vasodilation, which can open blood flow, so there may be a drop in blood pressure following the warm water foot bath.

One of the most prevalent diseases impacting people on a global scale is hypertension. In order to reduce the prevalence of hypertension in the general population, health care practitioners must not only diagnose and treat individuals with hypertension but also encourage a healthy lifestyle and preventive measures.⁽¹¹⁾ Non-pharmacological management should begin in the early stages of the illness and should be continued with hypertension medication strategies. Warm water is used in techniques like warm foot soak therapy to relax blood vessels, muscles, and tissue and enhance blood flow. The need of this study is to assess the effectiveness of warm foot soak therapy on the reduction of blood pressure among hypertensive patients and to associate the pre-interventional change in blood pressure among hypertensive patients with selected demographic and clinical variables.

Material And Methods

Design & Setting

Using experimental randomized controlled trial data were collected from Non-Communicable Disease(NCD) clinics of Urban Primary Health Center(UPHC) in Central India for a duration of one month.

Sample Size and Sampling

Participants were selected using a convenience sampling technique. The sample size was estimated using OpenEpi Software(9) based the comparison of two independent means. By considering the minimum expected mean (SD) difference between control and intervention groups, the sample size was estimated to be 30 in each group at a 5% level of significance and 80% power. The inclusion criteria consist patients who are giving consent for study participation, Adult patient diagnosed with stage 1 & stage 2 hypertension according to the AHA guideline, Patient who can assume sitting position for a period of 30 minutes atleast. Whereas, patients diagnosed with stage 3/ hypertensive crisis according to AHA guidelines, Having other lower limb complications like ulcer, lesions ,allergy , trauma ,acute inflammation and heat intolerance were excluded from the study.

Randomization

Allocation Concealment Mechanism

The allocation sequence was computer generated number and it was placed in sequentially numbered opaque sealed envelopes (SNOSE) .

Randomization Implementation

Allocation concealment was done by a student who is not involved in the recruitment of patients. Those envelopes were used by the researcher in enrolling the participants and assigning them into control and intervention groups. (Figure No. 1)

Data Collection Instruments

Tool of the study consist of three parts : Socio demographic variables (8 items), Clinical variables (3 items) and Table to record Pre and post interventional blood pressure assessment of both groups. Content validity of the tool was obtained from 10 experts in the field of nursing. All items in sociodemographic

sheet having I-CVI greater than 0.78 and S-CVI 0.92. All items in clinical profile sheet having I-CVI greater than 0.78 and S-CVI 0.98. Reliability of the tool was assessed during pilot study by collecting data from 10 study participants. In this study it is checked by Cronbach’s alpha, a way of assessing reliability by comparing the amount of shared variance/ covariance¹⁶. Cronbach's Alpha of 0.868, hence it is statistically significant and thus tool found to be reliable. Calibration of research instrument : Digital Sphygmomanometer was done.

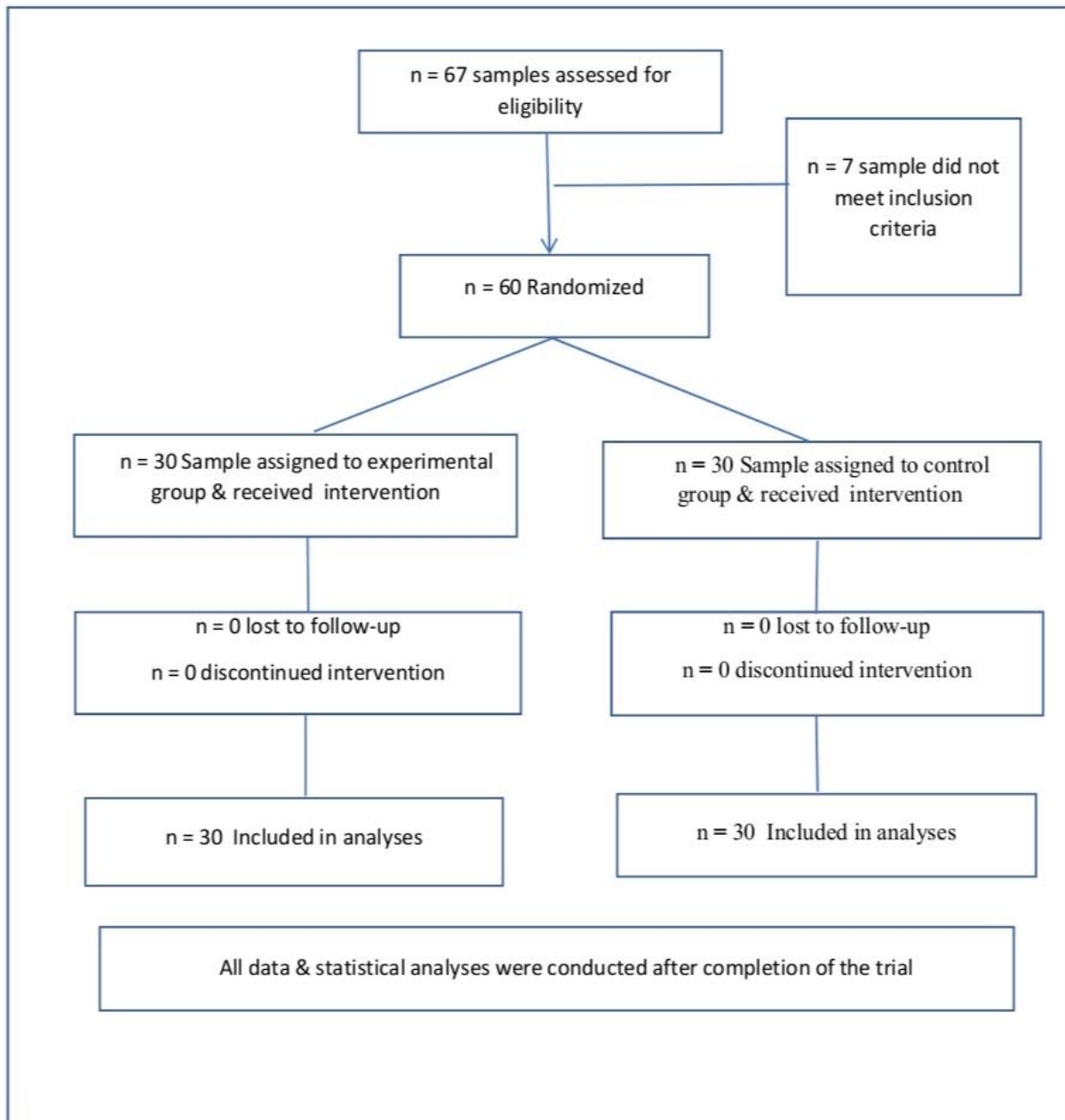


Figure No. 1 : Consort Diagram of study

Intervention & Data Collection

Warm foot soak therapy is the dipping and soaking both feet for 10-15 cm above ankle in warm water of temperature 37-40 degree Celsius for 15 minutes, once a day for 3 days. Informed consent was obtained after full disclosure of study to the participants. Administered self structured questionnaire for pre-

intervention data collection including sociodemographic data and clinical sheet. Pre- interventional blood pressure assessment of both control and experimental group using digital sphygmomanometer and recorded in observation sheet. Intervention : warm foot soak therapy were given only for experimental group. After the intervention, post- interventional blood pressure assessment of both control and experimental group using digital sphygmomanometer and recorded in observation sheet. Compared the mean blood pressure before and after intervention in both control and experimental group to find out efficacy of intervention. Pilot study was conducted in UPHC for a week from 14/09/2023 to 20/09/2023. During pilot study, practicability of the tool, feasibility of study and intervention efficacy was assessed. The main data collection was from 21/09/2023 to 30/10/2023.

Data Analysis

All the statistical analyses were done using IBM SPSS 27. The distribution of sociodemographic and clinical variables were expressed as frequency and percentages. Kolmogorov-Smirnov (KS) test were used to find the data are taken from normal distributed population. Comparison of baseline characteristics between the groups was done using the Chi-square test. Independent Student t-test and paired t-test were used to find the effectiveness of intervention of both groups. Association of pre-interventional change in blood pressure among hypertensive patients with selected demographic and clinical variables were done using the Chi-square test.

Results

The data was normally distributed and the groups were homogeneous and in terms of both sociodemographic and clinical variables ($P > 0.005$). (Table No. 1 & 2). By comparing mean blood pressure and standard deviation before and after intervention among both groups it is evident that the intervention : warm foot soak therapy was effective among hypertensive patients & had a significant change in blood pressure (SBP : 3.55 ± 0.07) (DBP : 3.11 ± 0.054) (Table No. 3). To assess the effectiveness of warm foot soak therapy Independent t test statistics (among participants) (Table No. 4) and Paired t test statistics (within the groups) (Table No. 5) of Experimental and Control and paired t-test had significant difference were found in pre interventional and post interventional SBP & DBP among experimental and control group ($p < 0.05$). There were no any significant association noted between sociodemographic and clinical variables with pre-interventional blood pressure except for the dietary pattern : vegetarian diet in both control and experimental group and presence of comorbidity : Diabetes Mellitus (DM) in experimental group among hypertensive patients ($P < 0.05$) (Table No. 6).

Table No. 1: Frequency and percentage distribution and homogeneity testing of Sociodemographic variables in Experimental and Control group

(N= 60)

VARIABLE	OPTIONS	EXPERIMENTAL GROUP		CONTROL GROUP		CHISQUARE VALUE	P VALUE
		FREQUENCY	PERCENTAGE	FREQUENCY	PERCENTAGE		
AGE	a) <30 years	0	0%	0	0%	4.451	0.439 (NS)
	b) 30-60 years	18	60%	29	97%		

	c) > 60 years	12	40%	1	3%		
GENDER	a) Male	16	53%	14	47%	0.201	0.654 (NS)
	b) Female	14	47%	16	53%		
OCCUPATION	a) Govt employee	0	0%	0	0%	4.066	0.397 (NS)
	b) Private employee	3	10%	6	20%		
	c) Home maker	17	57%	16	54%		
	d) others	10	33%	8	26%		
DIETARY PATTERN	a) Veg	24	80%	15	50%	0.403	0.526 (NS)
	b) Non veg	6	20%	15	50%		
SMOKING	a) Smoker	3	10%	1	3%	0.328	0.439 (NS)
	b) Non-smoker	27	90%	29	97%		
H/o ALCOHOLISM	a) Yes	2	7%	2	7%	0.115	0.735 (NS)
	b) No	28	93%	28	93%		
BMI	a) <18.5	1	3%	0	0%	3.492	0.174 (NS)
	b) 18.6-24.9	9	30%	17	57%		
	c) >25	20	67%	13	43%		

Chi square and p value ($p > 0.05$) in Table No. 1 suggests that there is no significant difference in Experimental and Control group regarding distribution of sociodemographic variables.

Table No. 2 : Frequency and percentage distribution and homogeneity testing of Clinical variables in Experimental and Control group (N = 60)

VARIABLES	OPTIONS	EXPERIMENTAL GROUP		CONTROL GROUP		CHI SQUARE VALUE	P VALUE
		FREQUENCY	PERCENTAGE	FREQUENCY	PERCENTAGE		
Duration of HTN	a) < 1 year	2	8%	10	33%	11.198	0.243 (NS)
	b) 2-4 years	14	46%	11	36%		
	c) > 4 years	14	46%	9	31%		
Use of Anti-HTN drug	a) Yes	30	100%	29	97%	14.483	0.41 (NS)
	b) No	0	0%	1	3%		

No. of Anti-HTN drugs	a) 1	27	90%	29	97%	0.115	0.735 (NS)
	b) 2	3	10%	0	0%		
	c) >2	0	0%	0	0%		
	d) no medicine	0	0%	1	3%		
Co-morbidities present	a) Yes	26	87%	19	63%	0.017	0.896 (NS)
	b) No	4	13%	11	37%		
Co-morbidities	a) DM	25	83%	18	60%	10.26	0.376 (NS)
	b) No	4	13%	9	30%		
	c) Others	1	3.30%	3	10%		

Chi square and p value ($p > 0.05$) in Table No. 2 suggests that there is no significant difference in Experimental and Control group regarding distribution of clinical variables.

Table No. 3 : Mean and Standard Deviation of Blood pressure among Both Experimental and control Groups Before & After Intervention (N=60)

GROUP	PARAMETER	PREINTERVENTIONAL (Mean & SD)	POSTINTERVENTIONAL (Mean & SD)
Experimental	SBP	136.27 ± 8.66	132.72 ± 8.59
	DBP	82.18 ± 5.95	79.07 ± 6.004
Control	SBP	135.44 ± 11.88	135.53 ± 12.01
	DBP	81.27 ± 7.01	81.57 ± 7.04

(SD : Standard Deviation, SBP : Systolic Blood Pressure, DBP : Diastolic Blood Pressure)

By comparing mean blood pressure before and after intervention among both groups it is evident that the intervention : warm foot soak therapy was effective among hypertensive patients & had a significant change in blood pressure (SBP : 3.55 ± 0.07) (DBP : 3.11 ± 0.054)

Table 4 : Independent t test statistics within participants in Experimental group and Control group on Effectiveness of warm foot soak therapy

Pair	t Value	df	p Value
Pre Interventional SBP OF E&C	0.31	58	0.758 (NS)

Pre Interventional DBP OF E&C	0.532	58	0.597 (NS)
Post Interventional SBP OF E&C	-1.044	58	0.301 (NS)
Post Interventional DBP OF E&C	-1.497	58	0.144 (NS)

(SBP : Systolic Blood Pressure , DBP : Diastolic Blood Pressure, E : Experimental, C : Control, t value : Independent t test value, df : Degree of freedom, NS : Not Significant)

There is no significant difference were found in pre interventional and post interventional SBP & DBP among experimental and control group at level of significance 0.05.

Table 5 :Paired t test statistics among participants in Experimental group and Control group on Effectiveness of warm foot soak therapy (N=60)

Pair	Mean Difference	Standard Deviation	t Value	P Value
Pre SBPE-Post SBPE	3.5546	1.17	16.629	0.01 (S)
Pre DBPE-Post DBPE	3.118	1.6	10.673	0.01 (S)
Pre SBPC-Post SBPC	-0.916	1.475	-0.34	0.736 (NS)
Pre DBPC-Post DBPC	-0.2793	0.548	-2.75	0.173 (NS)

(Pre SBPE : Pre interventional Systolic Blood Pressure of Experimental group, Post SBPE : Post interventional Systolic Blood Pressure of Experimental group, Pre DBPE : Pre interventional Diastolic Blood Pressure of Experimental group, Post DBPE : Post interventional Diastolic Blood Pressure of Experimental group, Pre SBPC : Pre interventional Systolic Blood Pressure of control group, Post SBPC : Post interventional Systolic Blood Pressure of Control group, Pre DBPC :Pre interventional Diastolic Blood Pressure of control group, Post DBPC : Post interventional Diastolic Blood Pressure of Control group, t value : paired t test value, S : significant, NS : Not Significant, df : degree of freedom)

From the table its clear that calculated t value is more than tabulated t value for pair 1 & 2(16.629& 10.673) that is for experimental group and calculated t value is less than tabulated t value for pair 3 & 4 (-0.34 & -2.75) that is for control grp. There will be significant change in blood pressure among hypertensive patients who are receiving warm foot soak therapy at 0.05 level of significance.

Table 6 : Association of pre-interventional change in blood pressure among hypertensive patients with selected demographic and clinical variables

SOCIODEMOGRAPHIC & CLINICAL VARIABLES	EXPERIMENTALGROUP			CONTROLGROUP		
	Chi square Value	df	P value	Chi square value	df	P value
AGE	3.025	2	0.22 (NS)	4.334	3	0.227 (NS)

GENDER	0.81	2	0.66 (NS)	4.817	3	0.816(NS)
OCCUPATION	1.509	4	0.845(NS)	6.688	6	0.351 (NS)
DIET	6.090	2	0.032 (S)	8.221	3	0.042 (S)
SMOKING	SMOKING IS A CONSTANT			1.099	3	0.77 (NS)
ALCOHOLISM	2.069	2	0.355 (NS)	0.33	3	0.96 (NS)
BMI	2.54	2	0.281 (NS)	4.058	6	0.669(NS)
DURATION OF HTN	3.156	4	0.475 (NS)	1.772	6	0.939(NS)
USE OF Anti-HTN DRUG	1.353	2	0.508 (NS)	3.7	3	0.296 (NS)
NO. OF Anti-HTN DRUGS	2.069	2	0.355 (NS)	0.3	3	0.96 (NS)
PRESNCE OF COMORBIDITIES	7.515	2	0.023 (S)	3.625	3	0.305 (NS)
TYPE OF COMORBIDITY	8.957	4	0.062 (NS)	7.755	6	0.257 (NS)

(N=60)

(df : Degree of Freedom, NS : Not Significant, S : Significant, BMI : Body Mass Index)

Data of chi square value showing no significant association between selected sociodemographic & clinical variables except for the dietary pattern: vegetarian diet in both control and experimental group and presence of comorbidity : Diabetes Mellitus (DM) in experimental group with pre-interventional blood pressure among hypertensive patients at level of significance 0.05.

Discussion

In order to reduce the prevalence of hypertension in the general population, health care practitioners must not only diagnose and treat individuals with hypertension but also encourage a healthy lifestyle and preventive measures. Warm foot soak therapy is considered effective, particularly for the elderly, because it can be used in a more straightforward and affordable way, which enhances its therapeutic effects. Additionally, since water is a readily available source of life, hydrotherapy has the potential to become a mainstay treatment, particularly for lowering blood pressure in the elderly. ⁽¹²⁾

A cross-sectional study was conducted to evaluate the prevalence of Hypertension and its related factors and to estimate the awareness, treatment and adequacy of Hypertension control among 640 participants aged 25-64 years among urban populations in Varanasi. The result showed that Hypertension prevalence was 32.9 percent (males: 40.9 percent, females: 26.0 percent).⁽¹³⁾ Tobacco and alcohol use, overweight, obesity and abdominal obesity were associated with Hypertension. The study concluded that about a third of the participants were hypertensive and about half of the participants were pre- hypertensive in this region. The level of awareness, treatment and control of Hypertension was very low. Survey on Administration of Hypertension With Non-pharmacological Mediations: This article has compiled ponders like efficient surveys, meta-analyses, and randomized controlled trials and looked into the part of

non- pharmacological administration of HTN, counting way of life adjustments like work out, weight misfortune, dietary intercessions like dietary approaches to halt hypertension (Sprint) eat less, moo sodium slim down, constraining liquor utilization, smoking cessation and push administration to assist control blood weight.⁽¹⁴⁾ Be that as it may, non-pharmacological intercessions ought to be started in an early stage, and for proper administration of HTN, we may have to be incorporate both pharmacological and non-pharmacological mediations. Weight misfortune is the foremost advantageous non- pharmacological intervention to oversee HTN, taken after by the DASH slim down, work out, liquor, smoking, and administration of stretch.⁽¹⁵⁾ These ought to be started within the early stage and utilized in conjunction with pharmacological intercession as it were to be profoundly viable. Clinicians play a pivotal part in clarifying the dangers of untreated HTN to patients and emphatically empowering them with respect to long-term adherence to way of life mediations like weight misfortune, work out, bringing down liquor utilization, and smoking cessation. The utilize of portable innovation and individual computerized gadgets can be successful to assist track and keep up sound way of life changes like weight misfortune and work out, particularly when back and responsibility through dynamic intercession are not accessible.⁽¹⁶⁾

An orderly audit on Nurse-led telehealth intercession to discover its adequacy on diminishing hypertension. Hypertension could be a open wellbeing concern for numerous nations thus this precise audit points to synthesize accessible prove on the viability of nursing-led telehealth mediations in decreasing blood weight in hypertensive patients. The World Wellbeing Organization has set up a worldwide objective to decrease the predominance of non- communicable maladies, counting hypertension, which is related with cardiovascular malady. Inaccessible nursing mediations can possibly reduce the burden on the healthcare framework and advance a more beneficial populace.⁽¹⁷⁾

The impact of foot dousing treatment with warm water on blood weight in elderly. Foot drenching treatment was drained 5 days inside 15 minutes for each session. Information were analyzed by utilizing subordinate and autonomous t test with certainty interim of 95% ($\alpha = 0.05$).⁽¹⁸⁾ There was noteworthy contrast of blood weight after treatment (p systolic = 0.001; p diastolic = 0.001). In the mean time, there was no critical contrast of blood weight in control bunch (p systolic = 0.682; p diastolic = 0.185). In both bunches, the blood weight of elderly with hypertension declined but higher within the mediation bunch than within the control bunch.⁽¹⁹⁾ There was a noteworthy contrast of blood weight between two bunches (p sistolik = 0.001 and p diastolic = 0.001). The unwinding impact of foot drenching treatment invigorates the pituitary organ to discharge endorphine hormone, causing systemic vasodilation. Subsequently, foot splashing treatment utilizing warm water influences the blood weight on elderly with hypertension.

Several studies have also reported that warm foot soak therapy is effective in reducing blood pressure. Most of the studies provided warm foot soak therapy for greater than 72 hours and for a duration of 15-20 minutes. The current results is well ongoing with the result of a survey conducted by Kappes et al as the respondents were perceived warm foot soak therapy to have positive effect to reduce blood pressure among hypertensive patients. Judith et al (2022) concluded significant reduction in post-test mean score in experimental group than control group found statistically significant at p value = 0.001.⁽²⁰⁾

Although the interventions in this study had demonstrated significant effects in reducing blood pressure among hypertensive patients , it had some limitations. Firstly, Non-probability sampling technique was used for selecting study participants. Secondly, the duration of of study were not sufficient to generalize the findings. Thirdly, this study consumed long time (45 ,in) to complete intervention .

Research Highlights

- Dissemination of information can be done to update the knowledge regarding cost-effective treatment options.
- Warm foot soak therapy can be incorporated in Non-pharmacological/ complimentary management of hypertension

Recommendation

A further study is recommended to find the long term effect of warm foot soak therapy on reducing blood pressure.

Conclusion

In order to support pharmacological treatment, Warm foot soak therapy can be incorporated in Non-pharmacological/ complimentary management of hypertension. The current study aimed to assess the effectiveness of warm foot soak therapy among hypertensive patients. Warm foot soak therapy found to be effective in reducing the systolic and diastolic blood pressure (p value < 0.05). There were no any significant association noted between sociodemographic and clinical variables with pre-interventional blood pressure except for the dietary pattern : vegetarian diet in both control and experimental group and presence of comorbidity : Diabetes Mellitus (DM) in experimental group among hypertensive patients at level of significance 0.05.

Conflict of Interest

There is no conflict of interest with anybody/any organization.

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