

## Original Research Article

# Assessment of effectiveness of an interventional package on treatment adherence of hypertensive patients: a randomized control trial

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### ABSTRACT

**Background:** Hypertension is the most common non-communicable diseases. Strict adherence to prescribed antihypertensive treatments is the key to blood pressure control. The present study was conducted with the objective to develop, implement and assess an interventional package on treatment adherence for hypertensive patients.

**Methods:** A clustered randomized control trial of 3 months conducted in two community sites of Chandigarh. The two sites were first randomized by lottery method as experimental and control sites. Total of 250 subjects (n=125 on each sites) were selected by a systematic random sampling technique (every fourth) from the sampling frame. Diagnosed hypertensive patients taking treatment were included in the study and females with pregnancy induced hypertension were excluded. Participants were interviewed as per Interview schedule. Data was collected from July to November 2018. Interventional package was in the form of booklet and flash card, delivered as one to one teachings. Total of 5 face to face follow ups were done to the experimental group. Control group received routine care. Final evaluation was done at 3rd month in both the groups to assess the effectiveness of an interventional package on treatment adherence. Data analysis and interpretation was done by using chi square, paired t test, unpaired t- test, Mc Nemar test were applied to determine the level of significance at  $p < 0.05$ .

**Results:** The proportion of subjects who were adhered to the treatment has increased from 16% to 68% in the experimental group at third month of follow up. The mean change in systolic blood pressure and diastolic blood pressure were  $26.29 \pm 12.81$  mmHg and  $7.74 \pm 8.95$  mmHg respectively in the experimental group as compared to the control group ( $p < 0.05$ ).

**Conclusions:** The interventional package on treatment adherence among hypertensive patients was effective in improving the treatment adherence.

**Keywords:** Treatment adherence, Hypertension, Cluster randomised control trial, Interventional package

### INTRODUCTION

Hypertension is a silent killer disease. It is one of the major causes that is contributing to the increased in the morbidity and mortality of noncommunicable disease. Globally 9.4 million people die every year due to hypertension.<sup>1</sup> World Health Organization estimates prevalence of hypertension in India is 24%.<sup>2</sup> High blood pressure is the leading risk factor for DALY (disability

adjusted life year) for both sexes. A national representative study of 1.3 million 2018 India showed that hypertension is also evident in the younger age group (18-35 years respectively).<sup>3</sup> The Indian council of medical research (ICMR) has reported that 16% of ischaemic heart disease, 21% of peripheral vascular disease, 24% of acute myocardial infarctions and 29% of strokes are attributed to hypertension.<sup>4</sup> World health statistics 2018 identified four major factors which

contribute to increase blood pressure which includes consumption of unhealthy diet, inadequate physical activity, use of tobacco and tobacco related products and alcohol abuse.<sup>1</sup> Adherence is the key to therapeutic success, it is one of the main crucial health concerns of the public. Hypertension goes largely unrecognized in the community unless its complication supervenes. Non-adherence has been showed to reduce the effect of the treatment, which leads to uncontrolled blood pressure and further attributed to major risk for stroke, heart failure, renal impairment, retinal haemorrhage and visual impairment.<sup>9</sup>

Developments in antihypertensive therapies have been associated with marked reduction in morbidity and mortality from hypertension. These include regular medications, physical activity, following a healthy eating plan such as the dietary approaches to stop hypertension (DASH) diet, and reducing dietary sodium intake. However, despite the existence of effective therapies and the development of evidence-based guidelines there are still significant practice variations and gaps between the prescribed regimens and the adherence to it.<sup>10</sup> Hence, based on literature review and personal experience researcher felt that although there are guidelines for treatment adherence, there is non-availability of comprehensive interventional package. Thus, need was felt to develop and implement a package to improve treatment adherence among hypertensive patients. Hence, the present study aims to evaluate the effectiveness of an “interventional package on treatment adherence” of hypertensive patients.

## METHODS

A clustered randomized control trial was conducted in two communities of Chandigarh, the two areas were first randomized by lottery method as experimental and control sites. The subjects in experiment (n=125) and control (n=125) sites were selected by a systematic random sampling technique (every fourth ) from the sampling frame. Diagnosed hypertensive patients taking treatment were included in the study and females with pregnancy induced hypertension were excluded. Baseline assessment was done on both the experimental and control group. Informed written consent were obtained from the participants. Participants were interviewed as per socio demographic profile. Medication adherence was assessed using Hillbone high blood pressure compliance scale and pillcount. International physical activity questionnaire (IPAQ) (long form) was also used to assess physical activity and interview schedule on dietary habits was developed and validated by experts. Data was collected from July to November 2018. As per the eighth joint national commission (JNC8) blood pressure was measured before and after intervention and during each follow ups.

The interventional package was in the form of booklet and flash card, delivered as one to one teaching to the

participants. The participants were first taught about hypertension, risk factors, sign and symptoms, management, adherence, importance of adherence and different ways to improve adherence. They were motivated to keep reminders for their medications, in the form of a pillbox, alarms, and to keep medication in a constant place. The participants were motivated for brisk walking for 30-60 minutes, three to four days a week. They were counselled to choose foods low in salt content, like fresh fruits and vegetables, avoid foods high in salt content, like pickles, to minimize the salt used in cooking, and refrain from adding extra salt during consumption. Total of 5 face to face follow ups were done. Initially the follow ups were frequent with a gap of 3 days interval which gradually increases by 2 weeks followed by 4 weeks, then 7 weeks and lastly 11 weeks from the first follow up in the experimental group. During each follow up the participants were motivated, counselling to adhere to their prescribed treatment; queries were also answered during follow up. Pill count was also assessed by asking the patients to recall of the number of medication taken in the past 14 days. Control group received routine care. Final evaluation was done at third month in both the groups to assess the effectiveness of an interventional package on treatment adherence. After the post assessment the package was also given to the control group. Data analysis and interpretation was done by using chi square, paired t test, unpaired t- test, Mc Nemar test were applied to determine the level of significance at  $p < 0.05$ .

## RESULTS

A total of 250 hypertensive participants gave consent and were interviewed for the study. Nearly one third of the subjects (36.8%) in experimental and control group (32%) were between the age group of 51-60 years, with the mean age of  $58.05 \pm 10.60$ . as shown in (Table 1). Nearly three fourth of the subjects in both the groups were males. One third (38.4%) of the subjects in the experimental group and (25.6%) in the control group were educated up to high school. Among the participants in experimental (41.6%) and (44%) in control group belonged to lower middle socioeconomic status as per BG Prasad scale 2018.

The participants consuming alcohol were about 7.2% in the experimental and 8% of subjects in control group, where as 4% of the subjects in experimental group and 8.8% in the control group uses tobacco. The clinical characteristics of study patients are shown in (Table 1). Groups were well matched without significant differences in prescribed medications, age when hypertension started and comorbidities, (40%) in the experimental and (26.4%) in the control group had hypertension between 6-10 years. The occurrence of comorbidity were similar in both the groups with more than one third of the participants have diabetes mellitus along with hypertension.

**Table 1: Clinical profile of the patient in experimental group and control group (n=250).**

Variables (n=125)	Experimental group N (%)	Control group N (%)	$\chi^2$ (df), P value
<b>Duration of hypertension (years)</b>			
<1	10 (8.0)	16 (12.8)	19.22# (5) 0.002
2-5	30 (24.0)	55 (44)	
6-10	50 (40.0)	33 (26.4)	
11-20	23 (18.4)	18 (14.4)	
21-30	7 (5.6)	3 (2.4)	
>31	5 (4.0)	--	
<b>Name of the medications</b>			
Beta blocker	31 (24.80)	19 (15.2)	5.11# (4) 0.30
Ace inhibitor	2 (1.60)	4 (3.2)	
Calcium channel blocker	39 (31.2)	36 (28.8)	
Diuretics	01 (0.80)	1 (0.80)	
Angiotensin receptor blocker	52 (41.6)	65 (52)	
<b>Age when hypertension started (years)</b>			
30-35	11 (8.8)	9 (7.2)	9.71 (8) 0.20
35-40	14 (11.2)	12 (9.60)	
40-45	19 (15.2)	8 (6.4)	
45-50	15 (12.0)	22 (17.6)	
50-55	20 (16.0)	15 (12)	
55-60	15 (12.0)	21 (16.8)	
60-65	13 (10.4)	13 (10.4)	
65-70	11 (8.8)	12 (9.6)	
70-75	7 (5.6)	13 (10.4)	
<b>Names of comorbidities</b>			
Diabetes mellitus	48 (38.4)	56 (44.8)	5.64# (4) 0.32
Renal disease	6 (4.8)	7 (5.6)	
Coronary artery disease	10 (8.0)	1 (0.8)	
Congestive cardiac failure	-	7 (5.6)	
Hyper and hypothyroidism	6 (4.8)	1 (0.8)	

Duration of disease (hypertension), control group:  $6.60 \pm 2.57$  (8 months-30 years), experimental group:  $7.22 \pm 6.02$  (9 months-30 years), age when disease (hypertension) started in the patient: control group:  $51.92 \pm 13.94$  (31-78 years), experimental group:  $54.26 \pm 12.31$  (30-80 years) #Yate's corrected chi square.

The participants in the experimental group exhibit a significantly decreases in their systolic blood pressure and diastolic blood pressure, with the mean change  $26.29 \pm 12.81$  mmHg and  $7.74 \pm 8.95$  mmHg respectively in the experimental group as compared to the control group ( $p < 0.05$ ). However, these changes could also be affected by a number of factors such as age, diet, exercises, prescribed medications.

The adherence to dietary habits was assed as shown in (Table 3) where the proportion of consumption of fruits, vegetables was found to be significant at both baseline and end line in both the groups ( $p < 0.05$ ). Whereas, in regards to the consumption of salt, the proportion of participants consuming salt between 5.1-7 g in a day have significantly increased from 18% to 52% respectively in the experimental group as compared to the control group. The number of participants reporting treatment adherence in the experimental and control group is depicted in table

4. At post intervention the item "how often do you eat fast food" have higher portion of respondents who answered none of the time, 1.6% of the participants in the experimental group as compared to 19.2% in the control group. The item "how often do you miss taking HBP pills when careless" also have higher portion of respondents who answered none of the time with 78% of the participants in the experimental group as compared to the control group 56%. The score of adherence shows that the proportion of participants who were perfectly adhered to treatment (as per Hillbone scale) have significantly increased from 16% to more than half (68.8%) in the experimental group as compared to the control group 19.2% to 23.2% ( $p < 0.05$ ) and the pillcount from 19.2% to 45.6% after intervention in the experimental group as compared to the control group 20% to 22% (Table 5). Physical activity has proven to bring about a control in the blood pressure with more than half of the participants (52.8%). In the experimental group have low physical activities and have shown to improve with only 27% have low physical activity after intervention.

**Table 2: Comparison of systolic and diastolic blood pressure of hypertensive patients of control and experimental group at baseline and endline (n=125).**

Parameters (n=125)	Experimental group	Control group	Unpaired t- test
<b>Baseline (mmHg)</b>	154.55±23.44	128.26±10.63	Mean change-26.29±12.81
<b>Systolic blood pressure (mmHg)</b>	110-181	112-160	t value 3.28 p=0.01
<b>Endline</b>	128.77±15.22	129.71±11.40	Mean change-1.45±3.82
<b>Systolic blood pressure (mmHg)</b>	100-160	113-160	t value 2.89 p=0.36
<b>Paired t-test</b>	Mean difference-25.78±8.22 t value 5.26 p=0.01	Mean difference -0.94±0.77 t value 0.90 p=0.35	
<b>Baseline (mmHg)</b>	85.63±19.76	77.85±10.81	Mean change-7.74 t value 2.15
<b>Diastolic blood pressure (mmHg)</b>	70-120	60-110	p=0.03
<b>Endline (mmHg)</b>	75.11±10.33	69.97±13.94	Mean change-5.14 t value 5.68
<b>Diastolic blood pressure (mmHg)</b>	50-100	50-100	p<0.01
<b>Paired t-test</b>	Mean difference 10.52±9.43 t value 3.38 p=0.002	Mean difference 7.88±3.13 t value 9.32 p<0.01	

**Table 3: Comparison of dietary behaviour of hypertensive patients of experimental and control group at baseline and endline (n=125).**

Dietary behaviour	Experimental group		McNemar	Control group		McNemar
	N (%)			N (%)		
	Baseline	Endline		Baseline	Endline	
<b>Number of times fruit's taken prior to the week</b>						
1-2	14 (11.2)	13 (10.4)	<0.01	20 (16.0)	22 (17.6)	<0.01
3-4	109 (87.2)	104 (83.2)		101(80.8)	74 (59.2)	
4-5	2 (1.6)	8 (6.4)		4 (3.2)	29 (23.2)	
<b>Number of times/week vegetables consumed prior to the week</b>						
1-2	17 (13.6)	2 (1.6)	0.002	3 (2.4)	6 (4.80)	0.07
3-5	23 (18.4)	5 (4.0)		12 (9.6)	2 (1.60)	
4-5	29 (23.2)	34 (27.2)		36 (28.8)	19 (15.2)	
>5	66 (52.8)	84 (67.2)		74 (59.2)	98 (78.4)	
<b>Amount of oil consumed in a month (ml)</b>						
120-150	9 (7.2)	1 (0.8)	<0.01	20 (16)	1 (0.8)	<0.06
150-300	21 (16.8)	34 (27.2)		12 (9.6)	39 (31.2)	
300-500	43 (34.4)	75 (60.0)		44 (35.2)	55 (44)	
>500	52 (41.6)	15 (12.0)		49 (39.2)	30 (24)	
<b>Number of times cooked oil is reused</b>						
1	41 (32.8)	53 (41.6)	<0.01	42 (33.6)	43 (34.4)	0.1
2	26 (20.8)	19 (15.2)		29 (23.2)	30 (24.0)	
3	26 (20.8)	7 (5.6)		34 (27.2)	13 (10.4)	
>4	32 (25.6)	2 (1.6)		20 (16)	-	
Never	-	45 (36)		-	39 (31.2)	

Continued.

Dietary behaviour	Experimental group N (%)		McNemar	Control group N (%)		McNemar
	Baseline	Endline		Baseline	Endline	
<b>Number of times processed food is consumed in a month</b>						
Never	16 (12.8)	-	<0.01	12 (9.6)	5 (4.0)	<0.01
Always	48 (38.4)	13 (10.4)		23 (18.4)	11 (8.8)	
Often	39 (31.2)	16 (12.8)		32 (25.6)	32 (25.6)	
Sometimes	22 (17.6)	96 (76.8)		58 (46.4)	77 (61.6)	
<b>Number of times nuts (almonds, walnut) is consumed in a week</b>						
Never	8 (6.4)	15 (12.0)	0.06	41 (32.8)	38 (30.4)	0.002
1	76 (60.8)	47 (37.6)		76 (60.8)	44 (35.2)	
2	32 (25.6)	51 (40.8)		8 (6.4)	40 (32)	
3	8 (6.4)	10 (8.0)		-	3 (2.4)	
4-5	1 (0.8)	2 (1.6)		-	-	
<b>Amount of salt consumption in a day (grams)</b>						
3-5	27 (21.6)	33 (26.4)	<0.01	28(22.4)	60(48.0)	0.008
5.1-7	23 (18.4)	65 (52)		26 (20.8)	48 (38.4)	
7.1-9	21 (16.8)	14 (11.2)		18 (14.4)	11 (8.8)	
>9	54 (43.2)	13 (10.4)		53 (42.4)	6 (4.8)	

**Table 4: Comparison of treatment adherence (as per Hillbone HBP compliance and WHO scale) among hypertensive patients of control and experimental group at baseline and endline (n=250).**

Dietary behaviour	Experimental group N (%)		McNemar	Control group N (%)		McNemar
	Baseline	Endline		Baseline	Endline	
<b>Adherence as per Hillbone scale</b>						
Perfect Adherence =14	20 (16)	86 (68.8)	0.009	24 (19.2)	29 (23.20)	0.1
Imperfect adherence >14-56	105 (84)	39 (31.2)		101 (80.8)	96 (76.8)	
<b>Adherence as per WHO scale</b>						
Adherence >80%	24 (19.2)	57 (45.6)	<0.01	28 (22.4)	25 (20)	0.07
Non adherence <80%	101 (80.8)	68 (54.4)		97 (76.6)	100 (80)	

**Table 5: Comparison of physical activities of hypertensive patients of experimental and control group at baseline and endline (n=250).**

Dietary behaviour	Experimental group N (%)		McNemar	Control group N (%)		McNemar
	Baseline	Endline		Baseline	Endline	
<b>Low (&lt;600METS)</b>	66 (52.8)	27 (21.6)	<0.01	68 (54.4)	38 (30.4)	0.04
<b>Moderate (600-1500 METS)</b>	44 (35.2)	88 (70.4)		47 (37.6)	72 (57.6)	
<b>High (&gt;1500-3000METS)</b>	15 (12.0)	10 (8)		10 (8.0)	15 (12.0)	

**DISCUSSION**

The present study assesses the effectiveness of interventional package on treatment adherence among patients with hypertension in experimental and control group. The patients enrolled in our study are diagnosed hypertensive patients receiving treatments. We have

observed that the “interventional package on treatment adherence” have greatly improved the adherence in the experimental group as compared to the control group. In addition we observed that continuous follow up and reminders also aids in improving adherence. Many studies have reported that there are plenty of interventions that have proven to be successful in improving the adherence to treatment among hypertensive patients

which include educational intervention, behavioural intervention, self- management intervention, counselling, packaging and reminders are some of the interventions. In general, a recommendation for the management of hypertension includes both pharmacological and non-pharmacological interventions. Frequent reinforcement, family support, follow ups greatly help in adherence to these hypertensive treatments and thereby bringing about a control in the bloodpressure and prevent further complications.<sup>12-15</sup>

A major finding in our study is a 3 months intervention which includes educational, counselling, reminders and of with 5 follow ups, have proven to increase the treatment adherence (as per Hill-bone scale) from 16.6% of the participants at pre intervention, to 68% after intervention as compared to the control group. In contrast to the study by Sadulla et al the adherence was 16.2%, probably because there were no follow ups in their study as compared to the present study. However, in a study conducted by Tjønnna et al have 4 follow ups in the study in the form of face to face follow up which is in consensus with the present study with 5 follow ups which have proven to improve the adherence.<sup>16</sup>

Treatment adherence brings about a control in the blood pressure and is also one of crucial step to prevent from further complications. In the present study showed that the mean systolic blood pressure and diastolic blood pressure significantly decreases with the mean change  $26.29 \pm 12.81$  mmHg and  $7.74 \pm 8.95$  mmHg respectively in the experimental group as compared to the control group.

A reduction in the dietary salt intake as one of the measure to tackle hypertension has been tried in various studies. The RCT conducted by Saptharishi et al showed mean change in the blood pressure 2.6/3.7 mmHg reduction.<sup>15</sup> Whereas, the present study has shown a reduction of 25.78/10.52 mmHg in the experimental group. The dietary approach to stop hypertension (DASH) diet recommends that the normal consumption of salt should be in the range of 5-7gm per day.<sup>19</sup> In the present study the proportion of consumption of salt between the range of 5-7 g per days has improved from 18.4% to 52% of the participants in the experimental group as compared to the control group.

Physical activity have proven to improve the blood pressure. Anand through his meta-analysis showed that moderately intense exercise, for example, 30 to 45 minutes of brisk walking, four to five days a week, reduces blood pressure. In concordance, Schwarz et al and Hagberg et al showed similar results, concurring with the results of the present study where, the participants were advised to walk briskly 30-60 minutes for about three to four times a week, they were also motivated to take a walk for groceries rather than taking a vehicle.<sup>5-8</sup>

## CONCLUSION

The study concluded that the “interventional package to improve treatment adherence” among hypertensive patients was effective in improving the treatment adherence and a control in the blood pressure. The study results imply that the package can be used by community health nurses and other health professionals for improving the treatment adherence of hypertensive patients. And it can also be replicated in different settings with larger sample and longer duration to support the findings.

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