



## Effectiveness of Community-Based Hypertension Intervention Program in a Resource Poor Rural Settings in Tamil Nadu, India

## KEYWORDS

Hypertension control, Life Style Modifications, Blood Pressure, Drugs

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**ABSTRACT** *Background: We conducted a pilot study to determine whether blood pressure control in primary care setting could be improved with the use of community-based volunteers by counselling and monitoring of the hypertensive patients.*

*Methods: We conducted an intervention study with the base-line and followed up blood pressure (BP) measurements among patients with hypertension in two villages of Thiruvallur district, Tamil Nadu. Primary care physician and health workers initiated treatment with either drugs or life style modification (LSM) using WHO protocol for Cardiovascular Disease risk management. Trained community volunteers counselled the patients on LSM and monitored BP monthly. We compared mean systolic Blood Pressure (SBP) and diastolic Blood Pressure (DBP) and proportion with BP control at baseline and follow up. We calculated adjusted Odds Ratios (AOR) and 95% confidence intervals (95%CI) for factors associated with lack of blood pressure control and non compliance to regular drugs.*

*Results: We included 599 patients from Nemam and Gudapakkam villages. Of these, we assessed 571 (95%) at the fourth month post-intervention. Of the 571 patients at the baseline, 163 (29%) were on regular treatment, 73 (13%) were irregular and 52 (9%) had started and stopped drugs. Among 571 patients on LSM, 83% had reduced salt and 61% had reduced oil/fried foods. Most commonly adopted combinations of LSM were reduced salt and oil (60%) and reduced salt and non-vegetarian food (34%). At follow up almost 50% of the patients were on LSM and similar proportion was on LSM and drugs. Difficulty in adhering to LSM changes was experienced by 192 (34%). At follow up, patients on monotherapy were (n=153, 27%), on two drugs (n=107, 19%) and on three drugs (n=11, 2%). Overall proportion with BP control increased from 22% to 49%. Overall mean SBP & DBP decline was 9.4 and 3.9 mmHg respectively. In multivariate analysis, lack of BP control was mainly associated with male sex (2.6; 1.43 - 4.75), difficulty in adhering to LSM (2.1; 1.14-3.88), non-compliance to regular drug intake (4.9; 2.67-8.9).*

*Conclusions: Protocol based approach and use of trained community volunteers to monitor blood pressure and counselling of patients on LSM achieved blood pressure control and increased compliance to drugs due to continuous monitoring and sustained drug supply.*

**Background:**

Cardiovascular disease (CVD) is one of the leading causes of death in India accounting for 29% of the deaths<sup>1</sup>. Hypertension is one of the eight key risk factors identified for cardiovascular disease control<sup>2</sup>. Prevalence of hypertension in India has been reported to range between 20-40% in urban adults and 12-17% among rural adults<sup>3</sup>.

Despite the availability of effective interventions for hypertension, and the widespread dissemination of management guidelines and treatment goals, blood pressure (BP) control rates exceed by 50% only in few countries<sup>4,5,6,7,8,9</sup>.

To achieve hypertension control in resource poor settings, WHO recommends CVD risk management package that has algorithms for non physician health workers and doctors<sup>10, 11</sup>. This package consists of easy to follow protocols for assessing and managing cardiovascular risk and for counselling on diet, physical activity and smoking cessation. At present, in 2008, there is no intervention program for hypertension control at the community level in the public health system in Tamil Nadu, India. There are limited data on hypertension intervention programmes in In-

dia. Therefore, we conducted a pilot study to determine whether blood pressure control in primary care could be improved with the use of community-based trained volunteers for counselling and monitoring. Period of study with first patient in and last patient out was July- Nov 2008, the for first 10 days we recruited all the patients (July1-10) and later all were followed up in 10 days (Nov 10-20).

**Objectives:**

The primary objective of the study was to determine effectiveness of CVD risk management package for hypertension treatment and control with the help of community based trained volunteer in a rural setting in Tamil Nadu in terms of

- i. Proportion of patients under adequate control pre and post intervention
- ii. Mean systolic and diastolic blood pressure pre and post intervention.

The secondary objectives were to determine factors associated with (1) lack of BP control (2) lack of compliance.

**Methods:-****Sample size:**

We required 1300 hypertensives to identify 4% increase in the proportion under adequate hypertension control against a pre-intervention level of 8% (data based on an ongoing cohort study<sup>12</sup>) with the assumptions of an error of 5%, 90% power and 10% loss to follow-up, we assumed effect size to be 4%. However, at the end of the study the actual effect size was 27%, hence, power was beyond the conventional 90%.

**Study setting**

We purposely selected Nemam and Gudapakkam villages of Nemam Health sub center area under Nemam Primary Health Centre (PHC), Thiruvallur district. The purpose was to have a population in rural area for which we knew the hypertensive status of people living there, due to ongoing study as mentioned below.

**Study population**

Reference 12 was conducting a cohort study on CVD risk factors among 25-64 years in the study area. Sampling frame was all hypertension patients identified by the ongoing study and patients above 64 years previously diagnosed with hypertension and taking treatment at Primary Health Centre (PHC).

**Study participants**

We included 599 patients from Nemam and Gudapakkam villages. Of these, we assessed 571(95%) at the fourth month post-intervention. We present results for 571 subjects for whom both baseline and follow-up data are available. (Figure 1)

**Base-line characteristics****Socio-demographic characteristics**

Of the 571, 223 (39%) were males and majority were 35-54 years age group (Table 1). In half of the households the head of the house was engaged in daily wages work (n=289) and 22% were skilled workers. A large proportion [481(84%)] were unable to afford private treatment.

Majority of patients were Daily Wagers and others were skilled workers and small farmers (Table F).

**Study design**

The study design was an intervention for hypertension control with measurement of hypertension and associated factors through cross-sectional survey pre and post intervention.

**Inclusion criteria**

We included patients, (1). 25-64 yrs already diagnosed with hypertension with or without drugs or LSM and pts above 64 years previously diagnosed with hypertension and taking treatment at Primary Health Centre (PHC) (2) willing to participate in the intervention (3) opting to take treatment after counselling and BP monitoring at the community level.

**Prevalence of behavioural risk factors and treatment history at the start of study:**

Prevalence of smoking and regular alcohol among males was little over 30% (Table 1). Adherence to life style modification was present among 273 (48%). One fourth (n=149) of the patients were on hypertensive treatment during the last one month and approximately 20% (n=111) reported that they were complying with the treatment at the time of start of the study. (Table 2).

**Grades of hypertension**

130(22.8%) were under 140/90 mm of Hg at baseline; 272(47.6%) were in Grade 1 (140-159/90-99); 112 were in Grade 2 (19.6%), and 57 in grade 3 (10%) (Table 1).

**Exclusion criteria**

We excluded patients not willing to participate in the programme.

**Operational definitions**

We defined the primary outcome as adequate control of BP (i.e. Systolic BP (SBP) <140 and/or Diastolic BP (DBP) <90 mmHg) in the study population.

We defined secondary outcomes as (1) lack of BP control (SBP >140 and DBP >90 mmHg) (2) non-compliance to intervention included two groups; '**irregular treatment**' defined as those who missed drugs for more than five days in a month and '**started and stopped drugs**' defined as initiated on drugs at baseline and stopped taking drugs at any time prior to the four month follow up.

Grades of hypertension were defined as per WHO criteria<sup>13</sup>.

Grade	Blood pressure (mm Hg)	Systolic	Diastolic
1	Blood pressure (mm Hg)	140-159	90-99
2	Blood pressure (mm Hg)	160-179	100-109
3	Blood pressure (mm Hg)	>180	>110

**Life style modification (LSM):** Adoption of any of the dietary/other behavioral changes including salt reduction, reduction of oil, reduced/quit smoking, reduced/ quit alcohol or started walking for at least a period of three months.

**Regular alcohol intake:** Alcohol consumption at least once a week.

**On treatment:** Taking anti-hypertensive medicines regularly for a period of one month.

**Adopted life style modification:** Adopted any of the life style modification changes.

**Adhered to LSM:** adhered to the LSM changes for a minimum period of three months

**Lost to follow-up:** Available at baseline but were unavailable at four month follow-up after minimum of six home visits, migrated out of study area, out of station or hospitalized.

**Description of Intervention**

Patients were enrolled and initiated either on LSM or combination of drugs and LSM. They were given a patient card that included treatment details. We used WHO CVD risk management protocol for initiating treatment. Protocol included algorithms to determine whether a patient need to be initiated on drugs or LSM, based on blood pressure and other risk factors. It also provided algorithms for increasing dose or adding second drug based on follow up BP readings. The drugs used in the programme were calcium channel blockers (long acting Nifedipine, Amlodipine), beta blocker (Atenolol), and Hydrochlorothiazide. Patients on other drugs were continued as before.

Patients were invited to come for follow up at monthly intervals for BP monitoring, LSM counselling and drugs. In

the interim period, they could visit PHC if required. Patients received drugs every month under the supervision of the study physician.

We identified local volunteers from the study area for LSM counselling and BP monitoring once in a month. We included those living in the same area with minimum school education and willing to participate in the study as volunteers. Volunteers included self-help group leaders, local leaders or those employed in health related jobs. We identified one volunteer for every 40-50 patients and trained them in WHO Protocol including algorithms to follow and taking automatic BP measurements. They were also checked randomly by local doctor for accuracy.

#### Data collection

We used a structured questionnaire and collected data on socio-demographic characteristics, personal and family medical history, treatment and behavioral risk factors, both at pre and post-intervention. In addition, we used a semi structured questionnaire to collect data on various factors associated with lack of control and non-compliance.

We measured weight in the upright position to the nearest 0.1 kg using calibrated scale. We measured height without shoes to the nearest 0.1 cm using calibrated stadiometer. Blood pressure was measured from the right arm after the subject had been sitting for at least five minutes using pre tested and standardised digital automatic blood pressure apparatus (Omron MX3).

#### Quality assurance

The investigators trained the local doctors and health workers for treatment algorithms, and community volunteers for measurement of blood pressure and LSM counselling and assessed their ability to perform by random cross verification.

#### Data analysis

We calculated mean difference for systolic and diastolic BP, and proportions achieving adequate BP control, at pre and post-intervention for the entire study group and by sub-groups. We tested the mean differences in BP by paired 't' test and proportion achieving adequate control by McNemar chi-square test. We used univariate analysis and calculated odds ratio (OR) and 95 Confidence Interval (95% CI). We used multiple logistic regression analysis among patients on drugs, to identify factors independently associated with lack of control and non-compliance to regular drug treatment.

#### Protection of human subjects

The participation in the study was voluntary. Those who were not willing to participate in the study were not denied any of the routine health care services. Written informed consent was obtained from all the participants. Institutional Ethics Committee of National Institute of Epidemiology, (NIE) Chennai approved the protocol.

#### Results:

##### Post-intervention

##### Follow-up status

We lost 28 patients during the follow-up period. Of these, the major reason was non-availability for assessment even after six visits (Figure 1)

##### Treatment status at follow up

At follow up almost 50% of the patients were on LSM and similar proportion was on LSM and drugs. Of the 571 pa-

tients, 163 (29%) were on regular treatment, 73 (13%) were irregular and 52 (9%) had started and stopped drugs (Table 2).

#### Life style modification

Among 571 patients, 83% had reduced salt and 61% had reduced oil/fried foods. Most commonly adopted combinations of LSM were reduced salt and oil (60%) and reduced salt and non-vegetarian food (34%). Difficulty in adhering to LSM changes was experienced by 192 (34%).

#### Drug treatment and side effects

At follow up, (n=153, 27%) patients were on monotherapy, (n=107, 19%) on two drugs, (n=11, 2%) on three drugs. Of the 288 patients put on medications, at baseline, 31% (n=90) reported side effects. Common side effects experienced by the patients were postural hypotension (n=38, 13%), giddiness (n=35, 12%), tiredness (n=22, 8%) and headache (n=19, 7%). Side effects not interfering with daily routine were reported by 63 (22 %).

#### Primary outcome

Primary outcome was measured by comparison of proportion for behavioural risk factors, life style modification and treatment at baseline and follow up and their relation to BP control. There was increase in awareness and adherence in LSM and increase in treatment and compliance rates. (Table 2)

#### Comparison of proportions for blood pressure under control

Overall proportion of subjects with BP under control increased from 22% to 49% at follow up. There was marked increase in proportion under control among females, those taking regular medications and among those who adhered to LSM. (Table 2)

The increase in proportion of patients with BP under control was more among those taking treatment from government services provided through our intervention (9% to 39%).

#### Comparison of SBP and DBP at baseline and follow up

As compared to the base-line level, at the post-intervention, there was a shift to the left of both SBP and DBP distributions (Figure 2 A and B). The mean declines were 9.4 and 3.9 mmHg for SBP and DBP respectively. Mean decline for SBP and DBP was pronounced for higher grades of hypertension at baseline, those regularly taking drugs, and those who adhered to LSM (Table 3). Further, the mean decline was significantly higher for individuals above 65 years, daily wage earners and in those who were aware of the long term complications of hypertension.

**Secondary Objective:** The secondary objectives were to determine factors associated with (1) lack of BP control (2) lack of compliance.

#### 1. Factors associated with lack of control

##### A: Univariate analysis

Among patients on treatment with drugs and LSM (n=288), lack of control was associated with lack of adherence to LSM, regular alcohol consumption, not taken tablets for last one month (non-compliance to regular drug intake), taking only one drug, not reduced salt, not reduced oil, difficulty in adhering to LSM and side effects interfering with daily routine (Table 4).

**B:Multivariate analysis**

In logistic regression analysis, male sex, difficulty in adhering to LSM, non-compliance to regular drug intake were the factors that were significant. Of these risk factors, the strength of association was highest for non-compliance to regular drug intake (Table 4). Based on a qualitative assessment, we identified additional factors such as inadequate dose [98(34%)], lack of motivation for adopting LSM/ taking drugs regularly [90(31%)] and not added second drug [67(23%)].

**2.. Factors associated with non-compliance****A. Univariate analysis**

Among patients on treatment with drugs and LSM (n=288), non-compliance to regular drugs was associated with regular alcohol use, lack of adherence to LSM, not reduced salt, not reduced oil, not reduced non-vegetarian food, taking treatment from the government services other than the study area, not understood the dosage and frequency and side effects interfering with daily routine (Table 5).

**B.Multivariate analysis**

In logistic regression analysis, not understanding the dosage and frequency, side effects interfering with daily routine, taking single drug and taking treatment from the government services other than the study area were associated with non-compliance (Table 5). Those who reported that side-effects due to drugs interfered with their daily routine were eight times likely to be non-compliant as compared to those who did not report such an experience.

**Discussion:**

In the absence of any community-based intervention for improving hypertension control in a rural setting, we used local volunteers to counsel on life-style modification and monitor BP for those with hypertension. We achieved good hypertension control with these interventions especially among those who adhered to LSM or drugs.

The documented success could be due to (1) innovative approach of using community-based volunteers and (2) strict adherence to WHO protocol for hypertension management in resource poor settings.

Our approach was to use volunteers from the local community to achieve good control rates by both monitoring blood pressure every month and by counselling for LSM at the community level itself. Strategy to improve hypertension control through community based BP measurement programs has been shown to be effective in other settings

We adhered to the standard protocol for initiating and scaling up treatment with drugs. This helped us to overcome important barriers for effective blood pressure management due to the inertia/failure to titrate by a treating physician. This was one of the reasons patients taking treatment from our intervention had a significant decline in BP as compared to those taking treatment from private sector where strict protocol approach may not be followed. Secondly, we addressed to the health system factors of cost, availability and distribution of hypertension drugs. We ensured reliable and continuous supply of drugs free of cost at the primary health center through a Government undertaking called Tamil Nadu Medical Services Corporation. Hence, we developed a sustainable and feasible health system model of supply of generic anti-hypertensive drugs for hypertension control.

Further evidence for the success of protocol-based approach is that of effective LSM adoption and adherence in achieving overall hypertension control and in all the sub groups. This could possibly be attributed to the counseling on LSM by local volunteers. In US, hypertension control was 6.2 times greater among patients who reported undertaking LSM. Dietary salt restriction was the commonest LSM adopted in our study consistent with other settings

We observed that difficulty in adherence to LSM and non-compliance to regular drug intake were the important factors associated with lack of BP control. This was very consistent with other studies in different settings. We observed better control among women as they are more likely to adhere to antihypertensive therapy and to achieve better blood pressure control than men, men being more prone to smoking and alcoholism in the study area. More than half of patients started on drugs, adhered to prescribed medications similar to reports in the literature. In our study, not understanding dosage and frequency of medications, side effects and lack of awareness were the key factors for non compliance. Factors mentioned above have been identified as important modifiable factors impacting adherence.

Limitations: Our study had several limitations. Firstly, we used the protocol for hypertension management from the package but health workers from the public health system could play only a limited role in this program because of their pre-existing job responsibilities. However, as a feasibility study, the results are important and could be tested on a wider scale. Secondly, the effectiveness of the approach was based on a very short post-intervention follow-up. It might be too short a time to assess the increase in proportion of patients achieving control. The results from a follow-up of longer period could have been different from what we have observed. Thirdly, the patient response in terms of adoption and adherence to LSM or drugs was based on interview data. We did not quantify individual LSM changes or actual drug consumption by the patients. Further, the choice of study area was based on feasibility for such an intervention. The study population is part of NIE's field practice area hence, one could expect that the compliance and follow-up data given by participants was an over-estimate. However, we observed adherence was directly related to control status and reported side effects directly related to non-compliance. Therefore, we have reason to believe that the role of information bias is limited.

We conclude that the use of community volunteers to monitor blood pressure and counsel on life-style modification for hypertensive patients achieved sizeable increase in blood pressure control and increase in treatment and compliance to drugs. The beneficial effect of LSM and drug compliance in terms of greater control rates and greater BP reduction was seen overall, as well as in various sub groups. Lack of BP control was mainly associated with patient's lack of adherence to LSM and non compliance to drugs. Non-compliance was mainly due to lack of understanding of frequency and dosing and also side effects interfering with daily routine.

Recommendations: Our study points to opportunities to improve the use of primary care services for hypertension control by a unique combination of community and protocol-based approach to hypertension control in resource poor rural settings in India. In order to improve hypertension control we recommend (1) an intervention programme

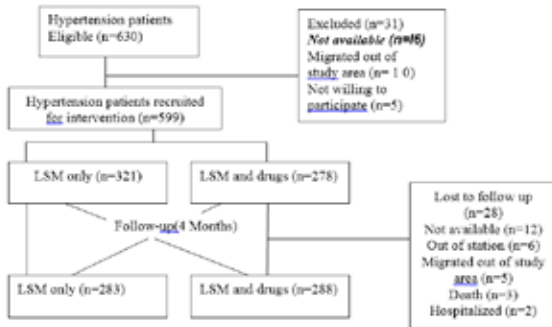
through the existing public health system, with emphasis on volunteer based community involvement, local protocols for hypertension management and ensuring continuous availability of drugs (2) Any hypertension control programme should include counselling for LSM and drug adherence, awareness about the long- term complications of hypertension (3) the need to continue the follow up for extended period for better understanding of determinants for lack of control and non- compliance. **Competing Interest:** None

**Authors Contribution:** The corresponding author did the study and other authors helped him in shaping, writing and monitoring the study project.

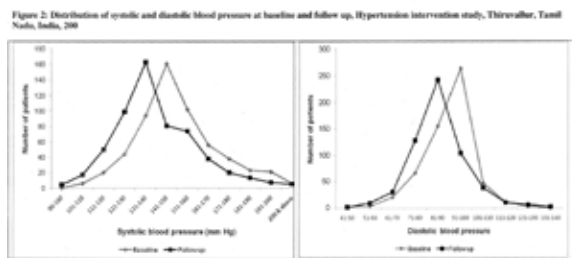
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**Figure 1: Study design and patient flow, Hypertension intervention study, Nemam, Thiruvallur, Tamil Nadu, India, 2008**



**Fig 2: Distribution of systolic and diastolic blood pressure at baseline and follow-up, Hypertension interven-**



**tion study, Thiruvallur, Tamilnadu,India2008FigA&B:**

Table 1: Baseline characteristics of the study population, Hypertension intervention study, Nemam, Thiruvallur, Tamil Nadu, India, 2008

Characteristics	#	Total	(%)
Age group (years)			
25-34	86	571	15.1
35-44	142	571	24.9
45-54	174	571	30.5
55+	169	571	29.6
Gender			
Male	223	571	40.0
Personal medical history			
Diabetes	54	571	9.5
Heart attack	9	571	1.6
Stroke	6	571	1.1
Family history			
Hypertension	97	571	17.0

	Diabetes	73	571	12.8
	Heart attack	25	571	04.4
	Stroke	10	571	01.8
	Kidney disease	8	571	01.4
Behavioural risk factors	Smoking	72	223	32.3
	Smokeless tobacco	56	223	25.1
	Alcohol consumption	121	223	54.3
	Consume alcohol at least once a week	73	223	32.7
	Sedentary lifestyle (sitting >5-hrs /day)	124	571	55.6
	Consume fruits and vegetables at least once a day	164	571	73.5
Prevalence of hypertension by grade	Normal	130	571	22.8
	Grade 1	272	571	47.6
	Grade 2	112	571	19.6
	Grade 3	57	571	10.0

**Table 2: Comparison of proportions for risk factors, LSM, drug treatment at baseline and follow up of the study population, Thiruvallur district, Tamil Nadu, India, 2008**

	Baseline		Follow-up		p value*
	No	%	No	%	
Risk factors					
Smoking (males) (n=223)	72	32.3	63	28.3	0.049
Smokeless tobacco(n=571)	109	19.1	56	9.8	0.000
Alcohol (males)(n=223)	121	54.3	93	41.7	0.000
Regular alcohol(n=223)	73	32.7	74	33.2	1.000
Life style modification					
Aware of LSM	429	75.1	542	94.9	0.000
Adoption of LSM	304	53.2	496	86.9	0.000
Adhering LSM last 3 months	273	47.8	424	74.3	0.000
Drug treatment					
Taking drugs (Antihypertensive) in last one month	149	26.1	238	41.7	0.000
Compliance	111	19.4	164	28.7	0.000

\*McNemar Chi-square

**Table 2 (Cont) : Proportion adequate blood pressure control at baseline and follow up, Hypertension intervention study, Nemam, Thiruvallur, Tamil Nadu, India, 2008**

	Baseline		Follow up		p value*
	No	%	No	%	
Overall (n=571)	130	22.8	282	49.4	0.000
Sex(n=571)					
Male(n=223)	53	23.8	94	42.2	0.000
Female(n=348)	77	22.1	188	54.0	0.000
Drug status on follow up (n=571)					
Regular (n=163)	17	10.4	91	55.8	0.000
Irregular(n=73)	4	5.5	13	17.8	0.049
Started and stopped(n=52)	5	9.6	12	23.1	0.118
LSM (n=571)					
Patients who Adopted and adhered LSM overall(n=424)	90	21.2	224	52.8	0.000
Reduced salt overall(n=471)	100	21.2	248	52.7	0.000

Patients put on LSM only(n=283)	104	36.7	166	58.7	0.000
LSM only: adopted and adhered LSM (n= 198)	72	36.4	125	63.1	0.000
LSM only group: who Reduced salt(n=227)	80	35.2	141	62.1	0.000
Patients put on drugs+ LSM (n=288)	26	9.0	116	40.3	0.000
Drugs+ LSM:adopted and adhered LSM (n=226)	18	8.0	99	43.8	0.000
Drugs+ LSM:reduced salt (n=244)	20	8.2	107	43.9	0.000

\*McNemar Chi-square

**Table 3: Mean systolic blood pressure (SBP) and Mean diastolic blood pressure (DBP) at baseline and follow up, Hypertension intervention study, Nemam, Tiruvallur, Tamil Nadu, India, 2008**

		SBP							DBP					
		N	Baseline		Follow up		Dif-ference	Paired t*	Base-line	Mean	Follow up		Diffe-Rence	Paired t
			Mean	SD	Mean	SD					Mean	SD		
Overall		571	151.6	19.6	141.2	19.9	9.4	10.3	90.4	10.4	86.5	11.9	3.9	7.4
Gender	Male	223	149.2	18.0	143.1	19.8	6.1	4.5	90.7	10.9	88.7	11.8	2.0	2.6
	Female	348	151.4	20.5	140.0	19.9	11.5	9.5	90.1	10.1	85.1	11.7	5.0	7.3
Base line status of hyper tension	Normal	130	128.3	8.4	132.9	17.1	-4.6	-3.0	79.0	7.9	82.9	10.0	-3.9	-4.4
	Grade 1	272	146.9	7.0	139.2	16.9	7.7	6.8	91.7	6.0	86.6	10.9	5.1	6.8
	Grade2	112	165.5	8.3	145.0	19.7	20.5	10.2	95.2	9.2	87.8	12.7	7.4	6.4
Treatment status at follow up for patients on Drugs and LSM	Grade3	57	189.3	13.1	162.1	23.4	27.2	8.5	100.5	12.7	91.4	15.6	9.1	5.2
	Regular	163	157.8	19.8	139.3	16.9	18.5	10.4	92.7	8.7	84.6	9.7	8.1	9.3
	Irregular	73	164.1	19.5	153.9	21.8	10.2	3.7	95.1	11.6	92.7	13.9	2.4	1.4##
Life style modification LSM	Started & stopped	52	163.2	19.7	157.0	24.0	6.2	2.1	92.1	13.0	89.9	15.9	2.2	1.3##
	Adopted & adhered LSM	571	151	19.4	139.3	18.2	11.7	11.6	90.7	9.5	86.0	10.9	4.7	7.8
	Patients put on LSM Only	283	140.6	13.3	136.1	17.1	4.5	3.9	87.5	9.6	85.3	10.9	2.2	2.9
LSM only: Adopted & adhered LSM		198	140.8	13.1	134.3	16.4	6.5	5.1	88.0	8.7	85.3	10.3	2.7	3.1
	Patients on drug +LSM	288	160.4	19.8	146.2	21.1	14.2	10.4	93.2	10.4	87.6	12.6	5.6	7.4
Drug +LSM: Adopted & adhered LSM		226	159.9	19.6	143.6	18.5	16.3	11.0	93.1	9.6	86.6	11.4	6.5	7.7

Overall Gender

Base-line status of hypertension

\*All were statistically significant (p<0.05)

##,### These variables were not statistically significant; Rest of the factors were statistically significant(p>0.05)

**Table 4: Factors associated with lack of control, in patients put on drugs plus LSM, Hypertension intervention study, Nemam, Tiruvallur, Tamil Nadu, India, 2008**

Factors		Proportion with lack of control (%)	Unadjusted Odds		Adjusted Odds ratio		P value
			ratio	Estimate	95 % Confidence interval		
Gender	Female	54	Reference				
	Male	71	2.1		2.6	1.4-4.8	0.00
Difficulty in adhering to life-style modification	No	53	Reference				
	Yes	75	2.7		2.1	1.1-3.9	0.00
Compliance to regular drugs	Yes	45	Reference				
	No	80	4.9		4.9	2.7-8.9	<0.00

Age group (Yrs)	25-34	82	Reference			
	35-44	57	0.29	0.2	0.1-0.7	0.00
	45-54	56	0.28	0.1	0.2-0.1	0.00
	>=55	60	0.34	0.3		0.10
Side effects interfering with daily routine	No	58	Reference			
	Yes	78	2.5	1.3	0.5-3.8	0.10

\* Likelihood ratio 62.663 with 7 df and p value 0.000

**Table 5: Factors associated with lack of compliance to regular drugs in patients put on LSM plus drugs (n=288), Hypertension intervention study, Thiruvallur district, Tamil Nadu, India, 2008**

Factors		Lack of compliance	Unadjusted Odds ratio	Adjusted Odds ratio		
				P value	Estimate	95% CI
Understood dosage and frequency	yes	37.3	Reference			
	No	77.3	5.7	3.4	1.45-8.05	0.005
Side effects interfering with daily routine	No	39.1	Reference			
	Yes	85.2	8.9	8.5	2.61-27.52	0.000
Number of drugs	> 1 drug	26.3	Reference			
	Single drug	55.3	3.4	3.5	1.99-6.18	0.000
Taking private treatment	Yes	25.0	Reference			
	No	47.5	2.7	2.5	1.17-5.29	0.017
Reduced salt	Yes	33.3	Reference			
	No	49.4	3.8	1.7	0.68-4.38	0.249
Reduced oil	Yes	33.9	Reference			
	No	60.8	3.0	1.5	0.74-3.15	0.256
Reduced non-veg food	Yes	33.3	Reference			
	No	49.4	L9	1.3	0.69-2.38	0.417

\* Likelihood ratio 79.259 with 7 df and p value 0.000

**Table A: Treatment status, life style modification, awareness of long term complications at follow up of the study population, Thiruvallur , Tamil Nadu, India, 2008**

Variable		No	%
Treatment status at follow up(n=571)	Regular	163	28.5
	Irregular	73	12.8
	Started and stopped	52	9.1
	LSM only	283	49.6
Life style changes(n=571)	Reduced salt	471	82.5
	Reduced oil/fried foods	349	61.1
	Increased fruit/vegetable intake	33	5.8
	Reduced non-veg food	202	35.4
	Started walking regularly	84	14.7
	Stopped/reduced smoking	11	1.9
Combinations of LSM (n=571)	Stopped/reduced alcohol	12	2.1
	Reduced salt +oil	342	59.9
	Reduced salt +nonveg	193	33.8
	Reduced salt +started walking	76	13.3
	Reduced salt +oil+nonveg	34	6.0
Difficulty in adhering to LSM recommended by doctor(n=571)	Reduced salt +oil+started walking	66	11.6
		192	33.6
Awareness of long term complications of HTN(n=571)	Heart attack	60	10.5
	Stroke	93	16.3
	Others	15	2.6
	Do not know	425	74.4

**Table B: Other medications, side effects, private treatment at follow up of the study population, Thiruvallur district, Tamil Nadu, India, 2008 Side effects**

Frequency of individual side effects in patients put on drugs (n=288)

Variable		Total	No	%
Taking other medications interfering with BP control(n=571)		571	85	14.9
Patient has understood frequency and dosing (n=288)		288	244	84.7
Compliance level among those started on drugs (n=288)	Regular	163	153	93.9
	Irregular	73	63	86.3
	Started and stopped	52	28	53.8
Side effects	side effects in those put on treatment(n=288)	288	90	31.3
	No side effects	288	198	68.8
	Side effects interfering with daily routine	288	27	9.4
	Side effects but not interfering	288	63	21.9
	Side effects in those put on treatment(n=288)	288	90	31.3
	Regular patients(n=163)	163	54	33.1
Frequency of individual side effects in patients put on drugs (n=288)	Irregular patients(n=73)	73	17	23.3
	Started and stopped patients(n=52)	52	19	36.5
	Postural hypotension	288	38	13.2
	Giddiness	288	35	12.2
	Tiredness	288	22	7.6
	Headache	288	19	6.6
	Pedal edema	288	8	2.8
	Taking treatment from private (n=571)	571	63	11.0

**Table C: Comparison of proportions for blood pressure under control at baseline and follow up, of the study population, in those who had adopted LSM, Thiruvallur district, Tamil Nadu, India, 2008**

		Total	Baseline		Follow-up		p value*
			No	%	No	%	
Overall	Overall	571	130	22.8	282	49.4	0.000
Age(Yrs)	25-34	86	22	25.6	38	44.2	0.011
	35-44	142	37	26.1	81	57.0	0.000
	45-54	174	38	21.8	83	47.7	0.000
	55-64	136	31	22.8	64	47.1	0.000
	>65	33	2	6.1	16	48.5	0.000
LSM	Adopted LSM	496	107	21.6	255	51.4	0.000
	Not Adopted LSM	75	23	30.7	27	36.0	0.585
	Adopted and adhered LSM	424	90	21.2	224	52.8	0.000
	Not Adopted and adhered LSM	147	40	27.2	58	39.5	0.030
	Reduced salt	471	100	21.2	248	52.7	0.000
	Not reduced salt	100	30	30	34	0.627	
Difficulty in adhering to LSM recommended by doctor	Yes	192	45	23.4	73	38	0.001
	No	379	85	22.4	209	55	0.000

\*McNemar Chi Square

**Table D: Comparison of proportions for blood pressure under control at baseline and follow up, in those who had adopted LSM, in subgroups of patients, Thiruvallur district, Tamil Nadu, India, 2008**

		Total	Baseline		Follow up		p value*
			No	%	No	%	
LSM only patients(N=283)	Adopted LSM	240	87	36.3	147	61.3	0.000
	Not adopted	43	17	39.5	19	44.2	0.824
	Adopted and adhered	198	72	36.4	125	63.1	0.000
	Not adopted and adhered	85	32	37.6	41	48.2	0.222
	Reduced salt	227	80	35.2	141	62.1	0.000
	Not reduced salt	56	24	42.9	25	44.6	1.000
	Reduced salt and oil	158	55	34.8	101	63.9	0.000
	Reduced salt and started walking	36	12	33.3	23	63.9	0.027
	Not reduced salt and not started walking	52	22	42.3	23	44.2	1.000
Drugs+ LSM patients(N=288)	Adopted LSM	256	20	7.8	108	42.2	0.000
	Not adopted LSM	32	6	18.8	8	25.0	0.754



Adhered LSM	226	18	8.0	99	43.8	0.000
Not adhered to LSM	62	8	12.9	17	27.4	0.64
Reduced salt	244	20	8.2	107	43.9	0.000
Not reduced salt	44	6	13.6	7	15.9	0.549
Reduced salt and reduced oil	184	16	8.7	85	46.2	0.000
Not reduced salt and oil	42	6	14.3	8	19.0	0.754
Redduced salt,reduced oil,and started walking	34	3	8.8	15	44.1	0.002
Not redduced salt,not reduced oil,and not started walking	38	6	36.3	8	61.3	0.754
Reduced salt and started walking	40	4	39.5	18	44.2	0.001
Not reduced salt and not started walking	40	6	36.4	9	63.1	0.549
Difficulty in adhering to LSM =yes	89	8	37.6	22	48.2	0.009
Difficulty in adhering to LSM =no	199	18	35.2	94	62.1	0.000
Started walking	44	4	42.9	18	44.6	0.001
Not started walking	244	22	34.8	98	63.9	0.000

\*McNemar Chi Square

**Table E: Comparison of proportions for blood pressure under control at baseline and follow up, in sub-groups of patients, Thiruvallur district, Tamil Nadu, India, 2008**

	Total	Baseline		Follow-up		%	p value*
		No	%	No	%		
Grades of HTN at baseline: (N=571)							
Normal	130	130	100	86	66.2		
Grade1	272	0		143	52.6		
Grade2	112	0		44	39.3		
grade3	57	0		9	15.8		
Village (N=571)							
Gudapakkam	282	64	22.7	135	47.9	0.000	
Nemam	289	66	22.8	147	50.9	0.000	
Occupation (N=571)							
Daily wages	289	67	23.2	150	51.9	0.000	
Skilled worker	124	29	23.4	56	45.2	0.000	
Small farmer, govt	56	9	16.1	26	46.4	0.000	
Big farmer	19	2		7			
Drivers	62	20	32.3	33	53.2	0.024	
Retired pensioners	7	1		4			
Unemployed/no income	14	2		6			
Taking treatment from private(N=288)							
Yes	52	6	11.5	23	44.2	0.000	
No	236	20	8.5	93	39.4	0.000	
Regularly taking drugs(N=163)							
Not taking pvt. treatment	124	11	8.9	71	57.3	0.000	
Taking pvt. treatment	39	6	15.4	20	51.3	0.001	

\*McNemar Chi Square

**Table E (Contd): Comparison of proportions for blood pressure under control at baseline and follow up, in sub-groups of patients, Thiruvallur district, Tamil Nadu, India, 2008**

	Total	Baseline		Follow-up		p value*
		No	%	No	%	
Awareness of long term complications of HTN						
Not aware of any complications	425	108	25.4	204	48	0.000
Aware of any complications	146	22	15.1	78	53.4	0.000
Taking any other medications interfering with BP control, NS AID s, Steroids, etc						
Yes	86	12	14	35	40.7	0.000
No	485	118	24.3	247	50.9	0.000
Patient has understood frequency and dosing(N=288)						
Yes	244	21	8.6	104	42.6	0.000
No	44	5	11.4	12	27.3	0.092
BMI Asians						
<18.5	52	15	22.8	34	65.4	0.000
18.5-22.99	160	42	26.3	75	46.9	0.000
23.0-27.49	196	56	28.6	96	49	0.000
>27.5	112	14	12.5	54	48.2	0.000

\*McNemar Chi Square

**Table F: Mean systolic blood pressure (SBP) & diastolic blood pressure(DBP) at baseline and follow up India, 2008**

	SBP			DBP			paired t value**	DBP			paired t value*
	Baseline	Follow up	Diff	Baseline	Follow up	Diff					
N	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Mean	SD	Diff
Age Yrs											

25-34	86	144.9	15.70	139.9	16.73	5.02	2.6	92.2	9.95	90.9	12.43	1.34	1.0*
35-44	142	146.6	15.10	135.5	16.78	11.06	6.7	91.8	8.49	87.3	10.32	4.46	4.4
45-54	174	150.2	19.80	142.8	22.35	7.40	4.4	90.2	10.60	87.6	12.34	2.56	2.9
55-64	136	155	22.40	144.6	18.99	10.39	4.9	87.6	11.68	83.0	10.23	4.63	4.1
>65	133	166.1	20.80	146.3	24.44	19.83	5.6	91.8	10.84	79.9	14.02	11.91	4.5
Occupation of respondent (head of household)													
Daily wages	289	151.8	20.79	140.3	20.75	11.48	8.5	89.8	10.58	85.3	11.28	4.54	6.1
Skilled worker	124	149.5	18.92	143.0	17.90	6.56	3.6	91.0	9.73	88.8	12.43	2.27	2.1
Small farmer	56	147.1	14.00	141.1	15.53	6.05	2.6*	90.8	8.97	87.8	10.48	3.02	2.0*
Big farmer	19	157.5	24.00	156.7	27.28	0.79	0.1	89.8	14.06	89.1	13.22	0.74	0.2
Drivers	62	146.0	18.01	136.2	19.65	9.76	3.9	91.2	11.12	87.0	12.72	4.19	2.5
Retired pensioners	7	151.7	13.52	143.4	10.88	8.29*	1.0	87.6	9.41	87.6	4.43	0.00	0.0*
Unemployed/ no income	14	158.2	16.13	143.8	17.68	14.43	2.9	92.4	11.31	79.1	15.54	13.36	2.9
Village													
Gudakkam	282	149.4	18.54	140.3	18.87	9.05	7.4	90.4	9.91	86.1	11.28	4.26	6.2
Nemam	289	151.7	20.48	142.0	20.82	9.68	7.1	90.4	10.92	86.8	12.39	3.54	4.4
Awareness of long term complications of HTN													
Not aware	425	150.3	20.39	141.4	20.55	8.90	8.4	89.8	10.97	86.1	11.60	3.70	6.2
Aware	146	151.2	16.98	140.7	17.84	10.50	6.1	92.0	8.47	87.7	12.55	4.30	4.0
Taking any other medications interfering with BP(NSAIDs, Steroids)													
Yes(n=86)	86	154.6	21.09	144.7	20.91	9.90	3.9	89.8	11.38	86.1	12.27	3.70	2.6
No(n=485)	485	149.8	19.22	140.6	19.65	9.20	9.5	90.5	10.25	86.6	11.78	3.90	6.9

All statistically significant except\*

**Table G: Comparison of SBP and DBP among various sub groups in the study population**

	SBP							DBP						
	N	Mean	SD	Mean	SD	Diff	paired t*	Mean	SD	Mean	SD	Diff	Paired t	
Taking treatment from private(n=288)														
Yes	52	151.1	16.57	142.7	17.34	8.40	3.3	92	8.81	85.4	9.89	6.60	4	
No	236	162.4	19.92	146.9	21.82	15.50	9.9	93.5	10.71	88.1	13.07	5.40	6.4	
Regularly taking drugs (N=163)														
Not taking pvt.tr	124	160.4	19.96	138.8	16.91	21.60	10.4	93.2	8.32	84.7	9.79	8.50	8.8	
Taking pvt.tr	39	149.7	16.86	140.6	16.87	9.10	2.9	91.3	9.80	84.5	9.40	6.80	3.5	
Patient has understood frequency and dosing (n=288)														
Yes	244	160	19.41	144.9	20.81	15.10	10.1	93.3	10.12	87.4	12.58	5.90	7.4	
No	44	162.7	22.07	153.2	21.71	9.50	2.8	92.9	11.94	89.1	12.68	3.80	1.9*	
Regular and understood frequency and dosing	153	157.5	19.33	139.5	17.00	18.00	9.9	92.8	8.84	84.7	9.85	8.10	8.9	
Side effects in patients on drugs (n=288)														
No side effects	198	159.9	18.97	146.5	19.93	13.40	8.6	93.2	10.62	87.8	12.56	5.40	5.8	
Side effects but not interfering with daily routine	63	159.8	20.69	141.1	19.79	18.70	5.9	91.8	9.26	84.7	10.65	7.10	5.2	
Combination(either no side effects or side effects but not interfering with routine)	261	159.9	19.36	145.2	19.99	14.70	10.4	92.9	10.31	87	12.18	5.90	7.5	
Side effects interfering with daily routine	27	165.3	23.69	155.5	28.75	9.80	1.9*	96.5	10.84	93.6	15.00	2.90	1.2	

\* All significant except \*

**Table H: Comparison of Mean SBP and DBP in various sub-groups of the study population**

	SBP						DBP					
	Mean	SD	Mean	SD	Diff	paired t	Mean	SD	Mean	SD	Diff	paired t
LSM (n=571)												
AdoptedLSM (n=496)	150.7	19.01	140.0	18.70	10.70	11.1	90.7	9.66	86.4	11.26	4.30	7.7
Not AdoptedLSM (n=75)	149.9	23.03	149.2	25.09	0.70	0.3*	88.3	14.41	87.2	15.28	1.10	0.7*
Adopted and adhered												
LSM	151	19.42	139.3	18.15	11.70	11.6	90.7	9.54	86.0	10.88	4.70	7.8
NotAdopted and adhered	149.3	20.01	146.7	23.40	2.60	1.4*	89.5	12.63	87.9	14.22	1.60	1.5*
Components of LSM												
Reduced salt	150.9	19.23	139.8	18.84	11.10	11.2	90.8	9.57	86.3	11.26	4.50	7.7

Not reduced salt	148.9	21.08	147.9	23.15	1.00	0.5*	88.4	13.63	87.3	14.36	1.10	0.9*
Patients on LSM only (N=283)												
Adopted (N=240)	140.8	12.89	135.0	16.15	5.80	5.0	87.7	8.81	85.1	10.36	2.60	3.4
Not adopted(N=43 )	139.6	15.24	142.4	20.99	-2.80	-0.8*	86.0	13.39	86.7	13.82	-0.70	-0.3*
Adopted and adhered												
Yes(n= 198)	140.8	13.14	134.3	16.39	6.50	5.1	88.0	8.70	85.3	10.25	2.70	3.1
No(n=85)	140.1	13.59	140.2	18.20	-0.10	-0.1*	86.4	11.51	85.4	12.48	1.00	0.7*
Reduced salt												
Yes(n=227)	140.9	12.92	134.9	16.34	6.00	5	87.9	8.61	85.1	10.27	2.80	3.5
No(n=56)	139.1	14.54	140.9	19.47	-1.80	-0.6*	85.6	12.93	86.1	13.41	-0.50	-0.3*
Reduced salt and oil(n=158)	142.1	12.21	134.6	14.95	7.50	5.5	88.1	8.65	84.9	10.03	3.20	3.2
Reduced salt and started walking												
Yes(n=36)	143.1	10.29	136.0	19.12	7.10	1.9*	89.9	6.80	86.2	13.04	3.70	1.5*
No(n=52 cases)	138.8	14.68	141.2	19.85	-2.40	-0.8*	85.3	13.30	85.9	13.79	-0.60	-0.3*
Difficulty in adhering to LSM recommended by doctor (n=571)												
Yes (n=192)	150	20.30	146.2	21.17	3.80	2.45	90.5	12.01	88	12.81	2.50	2.8
No (n=379)	150.9	19.21	138.7	18.72	12.20	11	90.3	9.53	85.7	11.30	4.60	7

\* All significant except \*

Table I: Comparison of Mean SBP and DBP in various sub-groups of the study population

	SBP							DBP						
	Baseline		Follow up		Diff	paired t	p value	Baseline		Follow up		Diff	paired t	p value
	Mean	SD	Mean	SD				Mean	SD	Mean	SD			
Patients on drug +LSM(n=288)	160.4	19.82	146.2	21.12	14.2	10.4	<0.01	93.2	10.40	87.6	12.59	5.6	7.4	<0.01
adopted LSM(n=256)	159.9	19.17	144.7	19.72	15.2	10.4	<0.01	93.5	9.61	87.6	11.93	5.9	7.5	<0.01
not adopted LSM(n=32)	163.9	24.51	158.4	27.48	5.5	1.6	0.13	91.3	15.37	87.9	17.24	3.4	1.5	0.154
adhered LSM(n=226)	159.9	19.62	143.6	18.54	16.3	11	<0.01	93.1	9.62	86.6	11.40	6.5	7.7	<0.01
not adhered to LSM(n=62)	161.9	20.64	155.6	26.74	6.3	2	0.052	93.8	12.92	91.3	15.78	2.5	1.6	0.123
reduced salt(n=244)	160.2	19.52	144.3	19.89	15.9	10.6	<0.01	93.5	9.66	87.4	12.01	6.1	7.4	<0.01
not reduced salt(n=44)	161.4	21.65	156.6	14.67	4.8	1.6	0.122	91.9	13.84	88.8	15.51	3.1	1.7	0.089
Reduced salt and reduced oil														
Yes(n=184)	159.5	19.54	142.2	18.17	17.3	10.9	<0.01	93.1	9.13	86.9	11.41	6.2	6.9	<0.01
No(n=42)	162.5	21.49	157.8	24.61	4.7	1.5	0.137	92.0	14.16	88.8	15.90	3.2	1.7	0.099
Reduced salt, reduced oil, and started walking														
Yes(n=34)	158.5	18.44	143.1	21.08	15.4	3.9	<0.01	91.7	10.96	86.1	11.24	5.6	2.6	0.02
No(n=38)	163.4	22.22	157.9	25.84	5.5	1.7	0.092	91.8	14.84	88.6	16.66	3.2	1.6	0.128
Reduced salt and started walking														
Yes(n=40)	158.6	19.46	143.8	21.54	14.8	3.5	<0.01	91.7	10.91	86.2	11.55	5.5	2.6	0.01
No(n=40)	162.4	22.41	156.7	25.84	5.7	1.8	0.081	91.7	14.46	88.6	16.20	3.1	1.6	0.116
Difficulty in adhering to LSM														
Yes(89)	161.8	19.87	154.7	23.17	7.1	2.8	<0.01	94.1	12.02	89.4	14.19	4.7	3.5	<0.01
No(199)	159.7	19.82	142.4	18.98	17.3	10.9	<0.01	92.8	9.59	86.8	11.75	6.0	6.7	<0.01
started walking(n=44)	157.9	18.72	144.9	20.91	13.0			91.9	10.48	86.6	11.13	5.3		
not started walking(n=244)	160.8	20.02	146.4	21.19	14.4	9.9	<0.01	93.5	10.38	87.8	12.85	5.7	7	<0.01

Table J: Physician assessment of reasons for lack of BP control and lack of adherence to treatment at follow up of the study population, Thiruvallur district, Tamil Nadu, India, 2008

Physician assessment of reasons for BP not under control (n=289)	No	%
LSM not adopted	200	69.2
Non compliance	103	35.6
Inadequate dose	98	33.9
Lack of motivation for adopting LSM/taking drugs regularly	90	31.1
Not added second/third drug	67	23.2
Physician inertia	32	11.1
Other co-morbidities/disability	32	11.1
Stressful family, personal, work related events	27	9.3
Other drugs interfering with control	21	7.3

	Side effects	9	3.1
	Reduced dosage/frequency on patient's own	7	2.4
	Frequent travel	6	2.1
	Refusal to take drugs	2	0.7
Physician assessment of reasons for irregularity in treatment(n=125)	irregularity in treatment(irregular+ started and stopped)		
	Lack of knowledge about disease complication /need for	93	74.4
	Lack of motivation for adopting LSM/taking drugs regularly	55	44.0
	Absence of symptoms	31	24.8
	Medicine side effects	23	18.4
	Not possible to go to PHC	16	12.8
	Other co-morbidities/disability ability	15	74.4
	Not possible to skip work and lose income	11	44.0

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