Effectiveness of community-based hypertension intervention program in a rural setting in Tamil Nadu, India, 2008

By

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Certification

This is to certify that this dissertation, "Effectiveness of community based hypertension intervention programme in a rural setting in Tamil Nadu, India, 2008",submitted by Dr. J.Stanley Michael, in partial fulfillment of the requirements for the degree of Master of Applied Epidemiology, is the original work done by him and has not been submitted earlier, in part or whole, for any other (Publication or degree) purpose.

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Director

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"Gratidude is the memory of the heart"

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(J. Stanley Michael)

Table of contents

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Abstract

Background:

We conducted a pilot study to determine whether blood pressure control in primary care could be improved with the use of community-based volunteers for counseling and monitoring.

Methods:

We conducted an intervention study with the base-line and follow 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 protocol. Community volunteers counseled on LSM and monitored BP monthly. We compared mean systolic (SBP) and diastolic (DBP) BP 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:

Of the 599 patients recruited, 571 patients were available for follow-up. At the base-line, the 571 were on LSM only (50%) or regular drugs (29%) or irregular drugs (13%) and started & stopped drugs (9%). 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). Non-compliance to regular drugs was associated with lack of understanding frequency and dosing (3.4; 1.45-8.05) and side effects interfering with daily routine (8.5; 2.61-27.52).

Conclusions:

Protocol based approach and use of community volunteers to monitor blood pressure and counsel on life-style modification achieved blood pressure control and increase in treatment and compliance to drugs

1. Introduction

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

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

To achieve hypertension control in resource poor settings, WHO recommends CVD risk management package that has algorithms for non physician health workers and doctors.[10,11] This package consists of easy to follow protocols for assessing and managing cardiovascular risk and for counseling on diet, physical activity and smoking cessation.

At present there is no intervention program for hypertension control at the community level in the public health system in Tamil Nadu. There are limited data on hypertension intervention programmes in India. Therefore, we conducted a pilot study to determine whether blood pressure control in primary care could be improved with the use of community-based volunteers for counseling and monitoring.

2. Methods

2.1 Objectives:

The primary objective was to determine effectiveness of CVD risk management package for hypertension treatment and control 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.

2.2 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[12]) with the assumptions of an α error of 5%, 90% power and 10 % loss to follow-up of 10%. We assumed effect size was 4%, however, at the end of the study the actual effect size was 27%, hence, power was beyond the conventional 90%. (Annexure I)

2.3 Study setting

We purposively selected Nemam and Gudapakkam villages of Nemam Health sub center area under Nemam Primary Health Centre (PHC), Thiruvallur district.

2.4 Study population

NIE is conducting a cohort study on CVD risk factors among 25-64 years in the study area[12] . Sampling frame was all hypertension patients identified by the ongoing study

and patients above 64 years previously diagnosed with hypertension and taking treatment at PHC.

2.5 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.

2.6 Inclusion criteria

We included patients (1) already diagnosed with hypertension (2) willing to participate in the intervention (3) opting to take treatment outside after counseling and BP monitoring at the community level.

2.7 Exclusion criteria

We excluded patients not willing to participate in the programme.

2.8 Operational definitions

We defined the primary outcome as adequate control of BP (i.e., Systolic BP (SBP) <140 and 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. [13]

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

Loss 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.

2.9 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 CVD risk management protocol for initiating treatment. Protocol included algorithms[11] (Annexure II) to determine whether a patient need to be initiated on drugs or LSM

based on blood pressure and other risk factors. It also provided algorithm 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 counseling 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. Volunteers included self-help group leaders, local leaders or employed in health related jobs. We identified one volunteer for every 40-50 patients.

2.10 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. (Annexure III)

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 digital automatic blood pressure apparatus (Omron MX3).

2.11 Quality assurance

The investigators trained the doctors and health workers for treatment algorithms, and community volunteers for measurement of blood pressure and LSM counselling.

2.12 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.

2.13 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 (Annexure IV). Institutional Ethics Committee of NIE approved the protocol.

3. Results

3.1 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. (Annexure V : Figure 1)

3.2 Base-line characteristics

3.2.1 Socio-demographic characteristics

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

3.2.2 Prevalence of behavioral risk factors and treatment history

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. (Table 2)

3.2.3 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).

3.3 Post-intervention

3.3.1 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 (Annexure V: Figure 1)

3.3.2 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 patients, 163 (29%) were on regular treatment, 73 (13%) were irregular and 52 (9%) had started and stopped drug (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, patients were on monotherapy (n=153, 27%) or on two drugs (n=107, 19%) or on three drugs (n=11, 2%)

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 %).

3.3.3 Primary outcome

Comparison of proportion for behavioral risk factors, life style modification and treatment at baseline and follow up

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 (Annexure V: 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 aware of the long term complications of hypertension.

3.3.4 Secondary outcomes

3.3.4.1 Factors associated with lack of control

3.3.4.2 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).

3.3.4.3 Multivariate analysis

In logistic regression analysis, male sex, difficulty in adhering to LSM, non-compliance to regular drug intake factors remained 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%)].

3.3.4.4 Factors associated with non-compliance

3.3.4.5 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, not understood the dosage and frequency and side effects interfering with daily routine (Table 5).

3.3.4.6 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 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.

4. 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 counseling 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. [14,15]

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. Firstly the inertia/failure to titrate by a treating physician.[16,17] 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 the health system factors of cost, availability and distribution of hypertension drugs[18]. 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[19]. 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. [20] Dietary salt restriction was the commonest LSM adopted in our study consistent with other settings.[21]

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.[22] 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.[23]

More than half of patients started on drugs, adhered to prescribed medications similar to reports in the literature.[24] 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.[19]

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. Thirdly, 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 compliance to drugs. Non-compliance was mainly due to lack of understanding frequency and dosing and side effects interfering with daily routine.

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 order to improve hypertension control we recommend (1) an intervention programme through the existing public health system, with emphasis on community involvement, protocols for hypertension management and ensuring 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.

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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
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
	Diabetes	73	571	12.8
	Heart attack	25	571	4.4
	Stroke	10	571	1.8
	Kidney disease	8	571	1.4
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 >5-6hrs /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 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 adheredLSM (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					
			Baseline		Follow up		Difference	Paired t *	Baseline		Follow up		Difference	Paired t
		N	Mean	SD	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 hypertension	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
	Grade1	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
	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
Treatment status at follow up for patients on Drugs and LSM	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†
	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‡
Life style modification	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

* All were statistically significant

† § These variables were not statistically significant; Rest of the factors were statistically significant

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 ratio	Adjusted Odds ratio		P value
				Estimate	95% Confidence interval	
Gender	Female	54	Reference			
	Male	71	2.1	2.6	1.4-4.8	0.0
Difficulty in adhering to life-style modification	No	53	Reference			
	Yes	75	2.7	2.1	1.1-3.9	0.
Compliance to regular drugs	Yes	45	Reference			
	No	80	4.9	4.9	2.7-8.9	<0.0
Age group (Yrs)	25-34	82	Reference			
	35-44	57	0.29	0.2	0.1-0.7	0.
	45-54	56	0.28	0.1	0.2-0.1	0.
	>=55	60	0.34	0.3	0.1-1.1	0.
Side effects interfering with daily routine	No	58	Reference			
	Yes	78	2.5	1.3	0.5-3.8	0.

* 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	>1drug	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	1.9	1.3	0.69-2.38	0.417

* Likelihood ratio 79.259 with 7 df and p value 0.000

Annexure I: Sample size formula

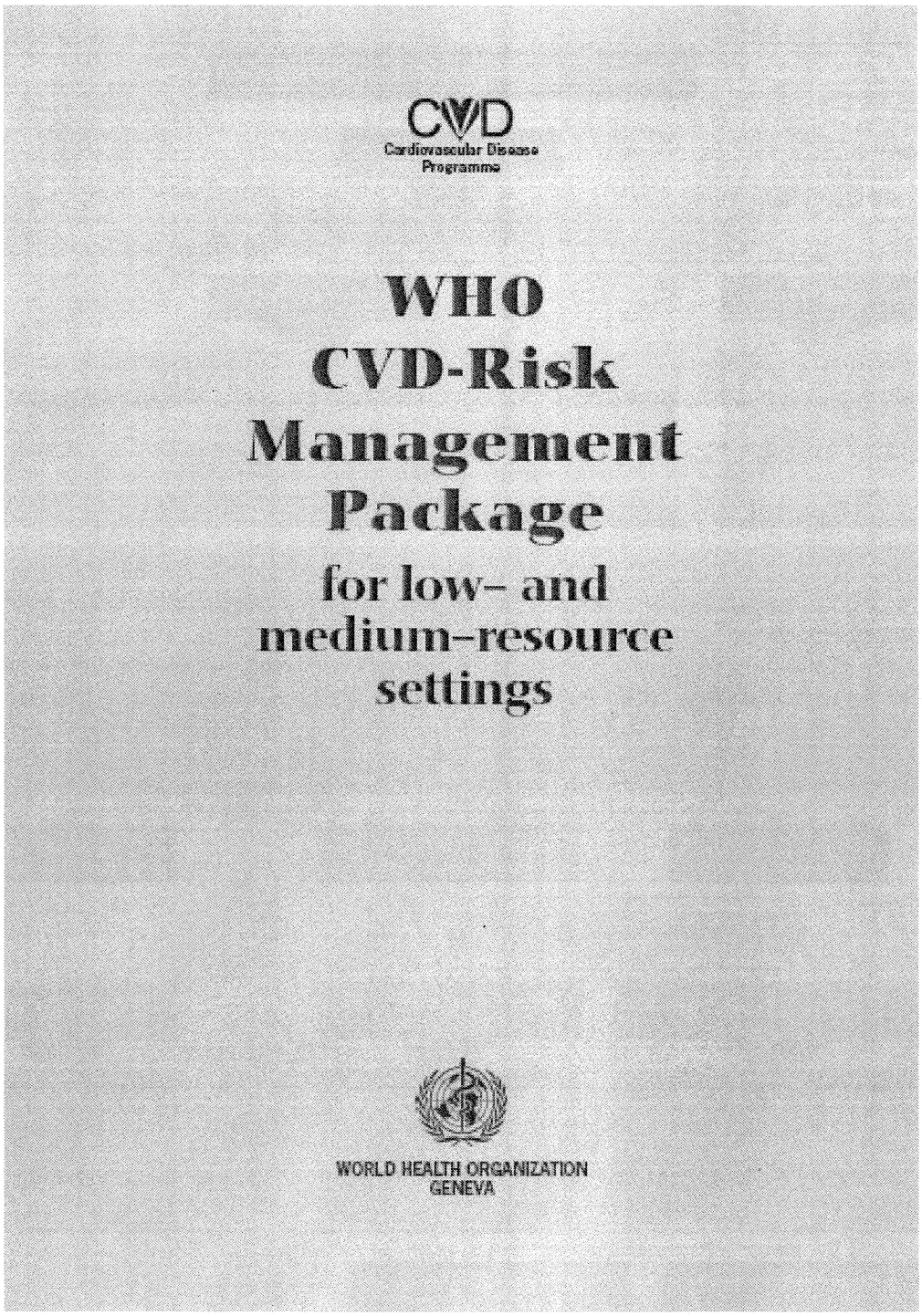
The outcome measure is dichotomous (e.g. under adequate control/not under adequate control), the difference between the two will be tested by a **paired chi-square test (McNemar's test).**

the number of patients (N) required is given by the formula

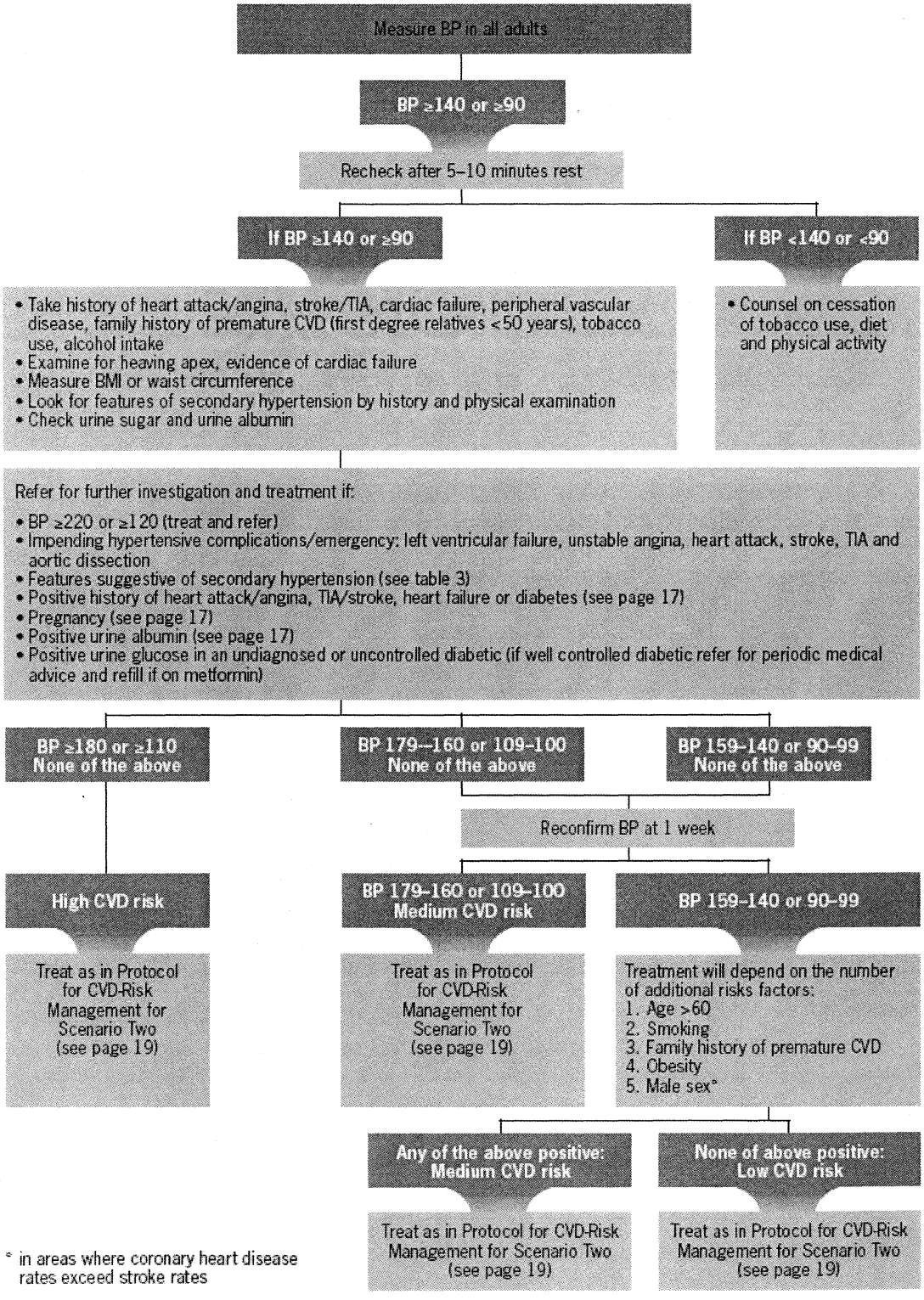
$$N = \frac{[Z_\alpha \sqrt{f} + Z_\beta \sqrt{f - d^2}]^2}{d^2}$$

Where $f = [(P_1 + P_2 - 2 P_1 \times P_2) - d^2]$; P_1 = baseline proportion, P_2 = post-intervention proportion ,of patients under adequate control; d = difference in the two proportions.

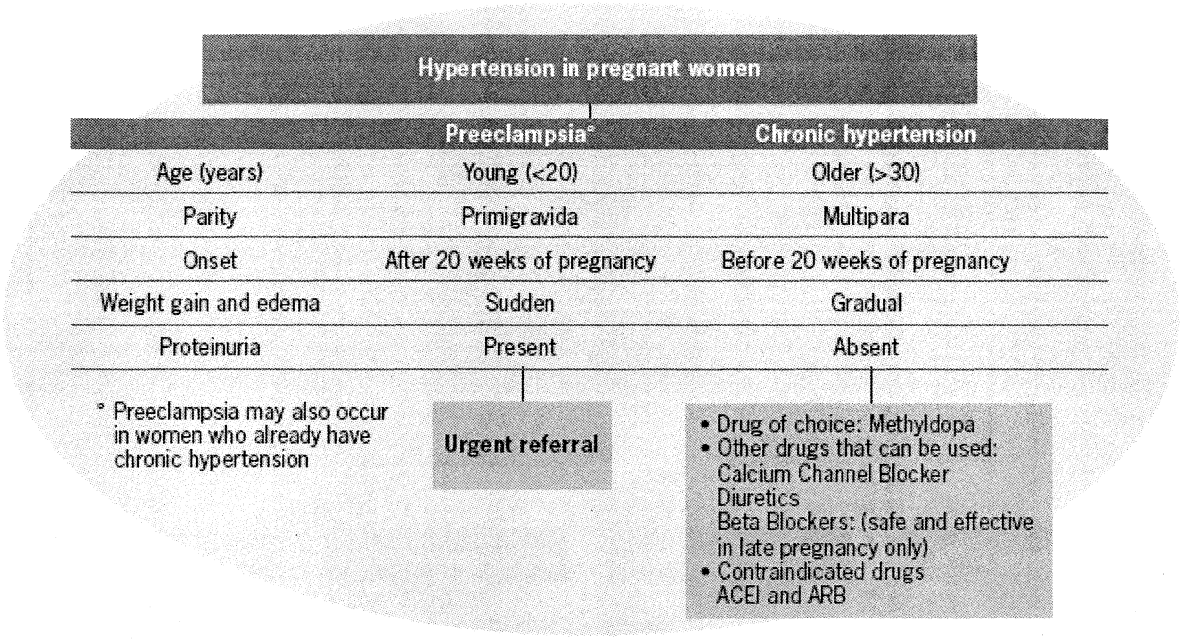
Annexure II

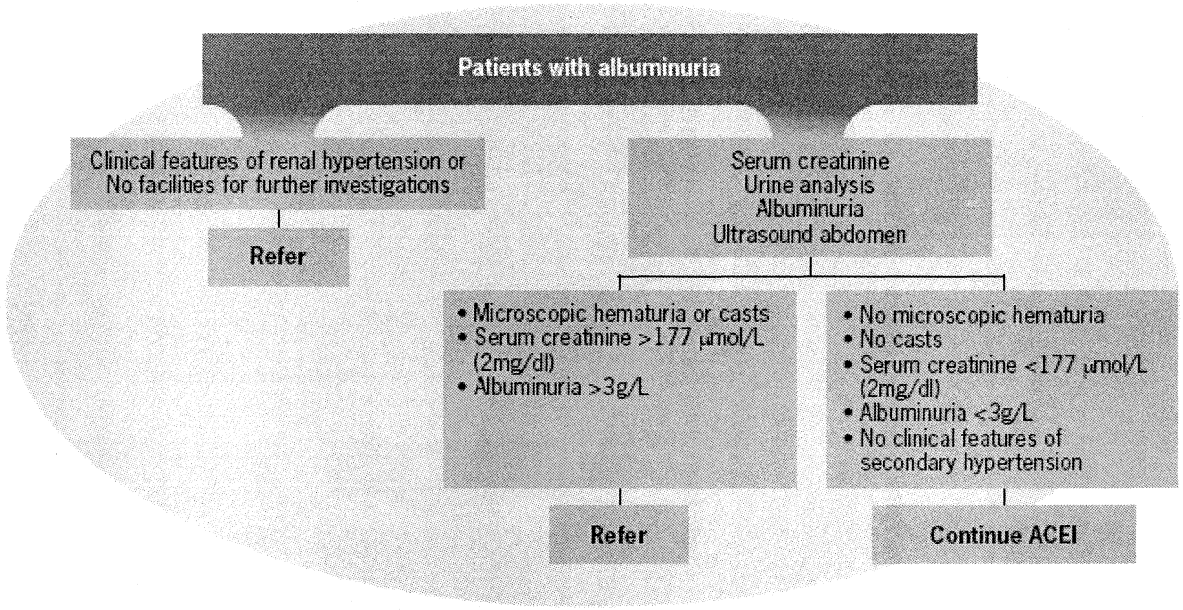

CVD
Cardiovascular Disease Programme
WHO CVD-Risk Management Package
for low- and medium-resource settings
WORLD HEALTH ORGANIZATION
GENEVA

Scenario Two: Protocol for CVD–Risk Assessment (Medical doctor or specially trained nurse)



° in areas where coronary heart disease rates exceed stroke rates





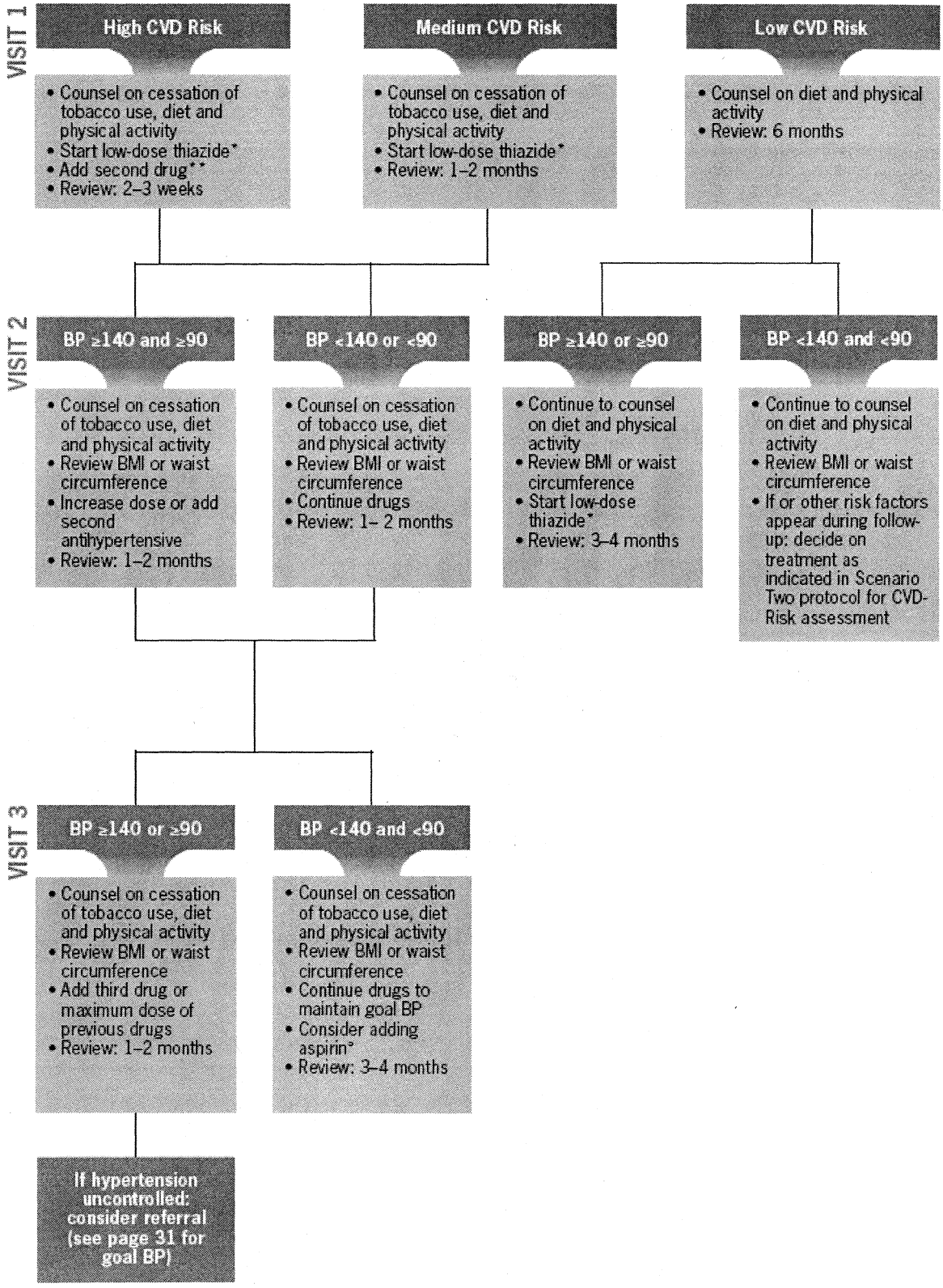
* Thiazide diuretic: Hydrochlorothiazide starting dose 12.5 mg (low-dose) to be increased up to 25 mg (maximum dose)

** Second drug option: if no compelling indication, use the cheapest out of beta-blockers or calcium-channel blockers or ACE-Inhibitors

If drugs given above are not available: use methyldopa or reserpine or fixed dose combination

° In areas where coronary artery diseases rates exceed stroke rates

Scenario Two: Protocol for CVD–Risk Management (Medical doctor or specially trained nurse)



Counsel your patient to

Eat a "heart healthy" diet

Stop tobacco use (see protocol page 21)

Take regular physical activity

- **SALT (sodium chloride)**
  Restrict to less than 5 grams (1 teaspoon) per day

  Reduce salt when cooking, limit processed and fast foods
- **FRUITS AND VEGETABLES**
  5 servings (400–500 grams) of fruits and vegetable per day

  1 serving is equivalent to 1 orange or apple or mango or banana or 3 tablespoons of cooked vegetables.
- **FATTY FOOD**
  Limit fatty meat, dairy fat and cooking oil (less than two tablespoons per day)

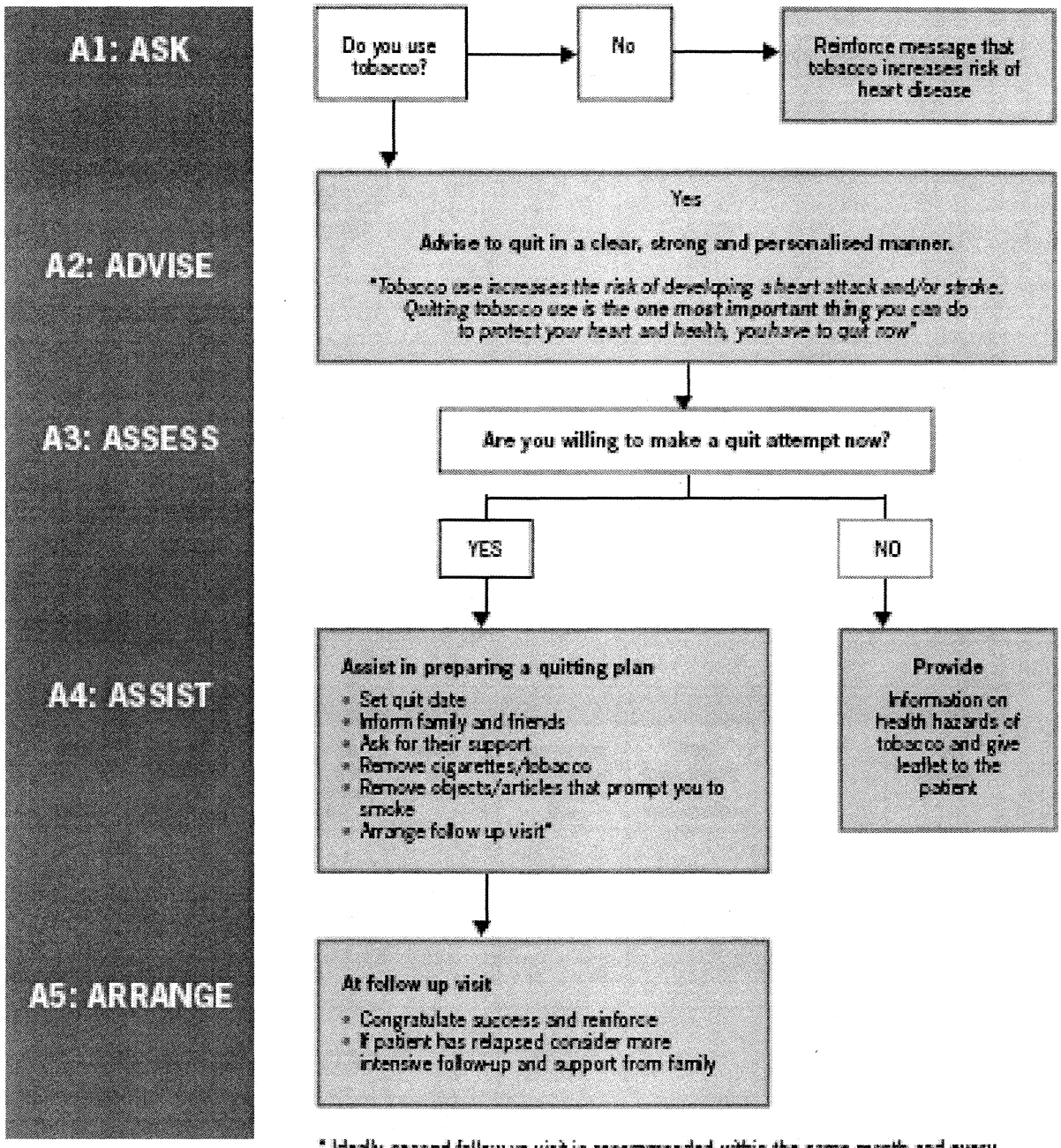
  Replace palm or coconut oil with olive/soya/corn/ rapeseed/safflower oil.

  Replace other meat with chicken (without skin)
- **FISH**
  Eat fish at least three times per week, preferably oily fish such as tuna, mackerel, salmon
- **ALCOHOL**
  Avoid heavy alcohol intake.
  Men: no more than 2 drinks per day
  Women: No more than 1 drink per day

- **PHYSICAL ACTIVITY**
  Progressively increase moderate physical activity such as brisk walking, cycling to at least 30 minutes per day

PLEASE REFER TO THE TRAINING MANUAL FOR FURTHER INSTRUCTIONS

Scenario Two: Protocol for counselling on cessation of tobacco use The 5 steps – 5 As (Medical doctor or specially trained nurse)



* Ideally second follow-up visit is recommended within the same month and every month thereafter for 4 months and evaluation after 1 year. If not feasible, reinforce counselling whenever the patient is seen for blood pressure monitoring.

PLEASE REFER TO THE TRAINING MANUAL FOR FURTHER INSTRUCTIONS

Scenario Two: Patient Record Card

Mr Mrs Miss ..... Age ..... Clinic No ....

❑ Essential hypertension ❑ Secondary hypertension

ASSOCIATED CLINICAL CONDITION	TARGET ORGAN DAMAGE
❑ Coronary heart diseases	❑ Left ventricular hypertrophy
❑ Congestive heart failure	❑ Microalbuminuria (0.2–3g/L)
❑ Cerebrovascular disease	❑ Hypertensive retinopathy
❑ Renal disease (albuminuria >3g/L, creatinine >177µmol/L – [2mg/dl])	
❑ Peripheral vascular disease	
❑ Diabetes	

Any other significant diagnosis

INVESTIGATIONS

	Date	Date	Date
Fasting blood glucose			
Creatinine			
Electrolytes			
Lipids			
Urine albumin			

ECG

Date	Blood pressure (mmHg)	Counselling on diet and physical activity (Yes/No)	Tobacco use (Yes/No)	Counselling on cessation of tobacco use	*BMI/ body weight waist circumference	Type of drug	Drug dosage

* Indicate kg/pounds and cm/inches

Please complete this part only if patient needs referral

Date .....

Reason for referral .....

.....

Current medications .....

Annexure III
National institute of Epidemiology
Patient (pre and post intervention) information sheet

1. Patient name: **2. Age:** **3. Sex:**

4. Address

5. NIE-ID no. **6. PHC ID no.**

7. History (Encircle appropriate response)		
a.	Do you currently **smoke**?	1-Yes 2- No
b.	Do you currently use **smokeless tobacco** in any of the smokeless forms?	1-Yes 2- No
c.	Do you **currently** consume **alcohol**?	1-Yes 2- No
d.	If Yes, Do you consume **alcohol** at least once a week?	1-Yes, 2- No, 9- Not applicable
e.	Does your work involve **sitting** more than 5-6 hours in a day?	1-Yes 2- No
f.	Do you consume **fruit and/or vegetables** at least once in a day?	1-Yes 2- No
g.	Did any of your **family members** (brother, sister, mother, father) suffer from any of the following **diseases**?	1- Hypertension 2- Diabetes 3- Heart attack 4- Stroke 5- Kidney disease
h.	Have you ever been told by doctor/nurse/health worker that you suffer from any of the following **diseases**?	1- Hypertension 2- Diabetes 3- Heart attack 4- Stroke 5- Kidney disease
8. Life style modification		
a.	Are you **aware** that you need to make some changes in your **daily routines** such as dietary changes, stopping smoking, alcohol or increasing physical activity?	***1–Yes, 2–No, 3-Not sure***
b.	***Have you made*** *some changes* ***in your*** *daily routines* ***such as dietary changes, stopping smoking, alcohol or increasing physical activity?***	1–Yes, 2–No, 3-Not sure
If yes, go to next question, If no go to **treatment history**		
c.	***Have you been*** *adhering* ***to changes in the daily routines for*** *at least three months?*	1–Yes, 2–No, 3-Not sure
9. Treatment history		
a.	***Have you taken*** *tablets* ***for blood pressure for*** *last one month?*	1–Yes, 2–No
b.	***If yes, did you*** *miss* ***tablets for*** *more than five days* ***in last one month?***	1- Yes, 2- No

8. Examination

a. Weight (kg)..... | | | | | | |

b. Height (cm)..... | | | | |

c. Blood pressure (mm/Hg)..... | | | | |

d. Pulse rate (per/min)..... | | | |

e. Other examination findings:

Details of treatment initiated/ modified at PHC/HSC(To be filled by doctor)

Whether referral is required: Yes No

Drugs newly started with dose

Drugs modified

Drugs continued as before

Additional data collected post intervention

15. If patient has adopted life style changes, ask this question, otherwise go to next question,

What life style changes have you done in the past three months?

a. Reduced salt/salt containing foods
b. Reduced oil/fried foods
c. Increased fruit/vegetable intake
d. Reduced non-veg food
e. Started walking regularly at least 3-4 times a week
f. Stopped/reduced smoking
g. Stopped/reduced alcohol

16. Did you have any difficulty in adhering to life style changes recommended by doctor?
Yes-1, No-2

17. Are you taking treatment from private doctor/hospital for hypertension / diabetes / heart disease?
Yes-1, No-2

18. Are you aware of the long term complications that may arise due to hypertension?
Heart Attack-1, Stroke-2, Others-3, Do not know-4

19. Are you taking any other medications for other problems? List the medications.

20. If patient is on medications, ask them frequency and dosing. Assess whether patient has understood dosing and frequency.
Yes-1, No-2

21. What is your occupation? If housewife, ask husband / son / head of the household occupation?

TO BE FILLED BY DOCTOR

22. Are you able to afford BP drugs on regular basis from private?
Yes-1, No-2
23. Did you experience any side effects after starting tablets for blood pressure?
Yes-1, No-2, Not applicable-9

a. Postural hypotension (Giddiness on waking up)
b. Tiredness

c. **Calcium channel blockers:** Pedal edema, Headache, Giddiness, Noctural diuresis, Gingival hyperplasia
d. **Beta blockers:** Depression, Insomnia, Peripheral vascular disease, Erectile dysfunction
e. **Thiazide:** Tiredness, gout, nocturia, polyuria, erectile dysfunction
f. **ACEI:** Cough

24. Did the side effects interfere in your day to day routine?
Yes-1, No-2, Not applicable-9

25. Why did you not adhere to tablets?
Adherence-1, Non adherence-2, Not applicable-9
List the reasons

26. If BP is not under control, identify the reason for lack of control.
a. LSM not adopted: (mention what is not adopted)
b. Compliance
c. Inadequate dose
d. Not added second drug
e. Other drugs interfering with control
f. Stressful family/ personal/ work related events
g. Recent illness
h. Other causes
i. Lack of motivation for adopting LSM/taking drugs regularly
j. Other co-morbidities/disability _____

27. Have you been taking treatment regularly since card was issued? If not, what are the reasons for not taking treatment?
Yes-1, No-2
a. Lack of knowledge about disease complication/need for treatment
b. Absence of symptoms
c. Not possible to skip work and lose income
d. Medicine side effects
e. Not possible to go to PHC
f. Others
g. Lack of motivation for adopting LSM/taking drugs regularly
h. Other co-morbidities/Disability_____

28. We had issued card for you for hypertension and suggested you regular treatment and follow up. Is this program acceptable to you?

Patient Monitoring Sheet

Patient name:
Age:
Sex:
NIE-ID no.
PHC ID no.

Date	SBP	DBP	Counseling on diet/physical activity/ tobacco cessation	Weight	Drug with dose

Annexure IV

Effectiveness of community-based hypertension intervention program in a rural setting in Tamil Nadu, India, 2008

Department of Public Health, Tamil Nadu
National Institute of Epidemiology, Chennai

Consent form

We are from Department of Public health, Tamil Nadu. Staff from National Institute of Epidemiology an organization under Govt. of India had earlier screened you for hypertension. As per the blood pressure measurements, you have hypertension. Hypertension ,if left untreated can cause heart disease,kidney disease,stroke and other complications. Therefore it is advisable that you regularly check your blood pressure and take medications if necessary. Around 1400 hypertensives have been identified in Nemam and Kuthambakkam health sub-centre areas. We are now conducting a feasibility study to determine the effectiveness of a village health nurse based hypertension control programme to make treatment available at your village level.Your village health nurse will measure your B.P. and offer you counseling .Medicines if required will be available at the health sub-centre itself and doctor will also examine you if required.If you agree to initiate or continue treatment from health sub-center , you will be given a patient card. Doctor at PHC or from mobile medical team will initiate you on treatment. You can show your patient card and collect medicines once in 15 days from village health nurse, doctor from mobile medical team or if feasible from Nemam PHC. Village health nurse will record your BP before giving medicines. If BP is very high, she will ask you to see doctor at PHC.

If you agree to participate in the study, our staff member will ask you questions related to risk factors and diseases mentioned above. We may contact you at repeated intervals to inquire regarding above-mentioned diseases and risk factors.

Your participation in the study is voluntary. You may refuse to participate or end your participation at any time or skip any question; you do not wish to answer.Even if you refuse to participate in this study, you will not be denied the routine health care facilities.You can also continue with your treatment at private facilities and avail of the counseling and monitoring facilities.

The information collected will be kept confidential. This information will not be divulged to anyone. A special number will be assigned to each person, which number belongs

to which person will be kept under lock and key.The medicines being used in this study are being routinely used in all government hospitals and they do not have any major side-effects.By participating in this study, you will get the benefit of counseling and medicines at your health sub-centre itself. If you wish to find more about this study, you can ask all the questions you want. For any further information you can contact Dr Stanley Michael,Cell no:94447 06007, National Institute of Epidemiology, # R-127, 3rd Avenue, Ambattur Housing Board, Phase I and II, Chennai – 600 077 Phone no.: 04426357469.

If you agree to participate in this project please sign/put your left thumb impression in the place mentioned.

I have read the above information/the above information has been read to me in my own language. I have had an opportunity to ask questions and the questions that I have asked, have been answered to my satisfaction. I consent voluntarily to participate in this study.

Name of the respondent Signature/thumb impression
(Respondent)

Signature of the interviewer Date:

Annexure V Figures

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

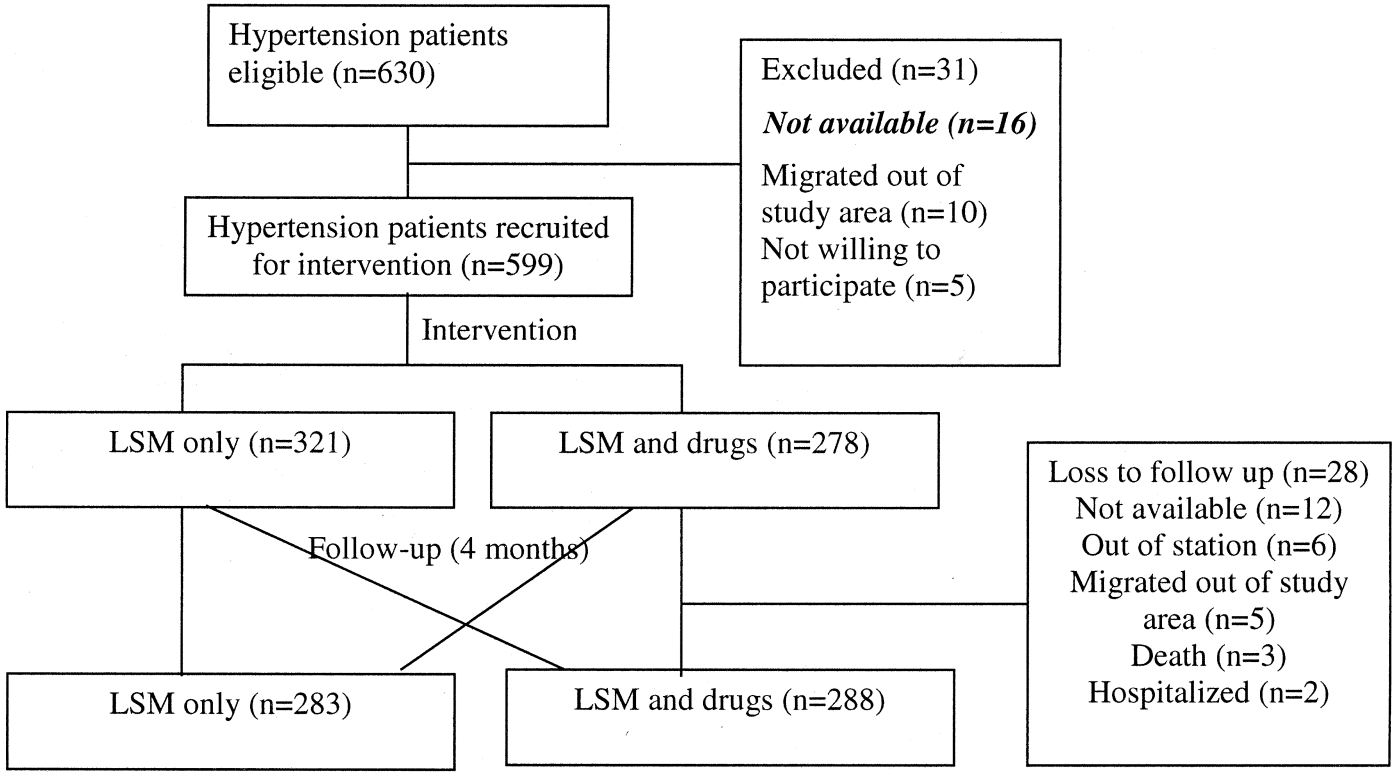
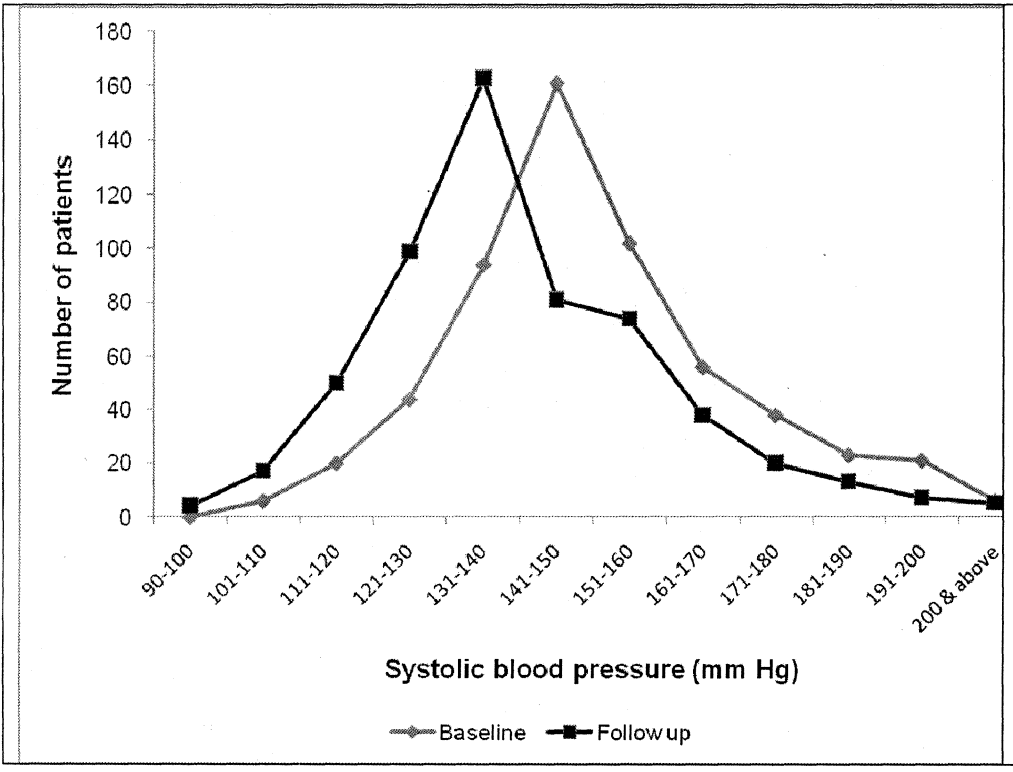


Figure 2: Distribution of systolic and diastolic blood pressure at baseline and follow up, Hypertension intervention study, Thiruvallur, Tamil Nadu, India, 200



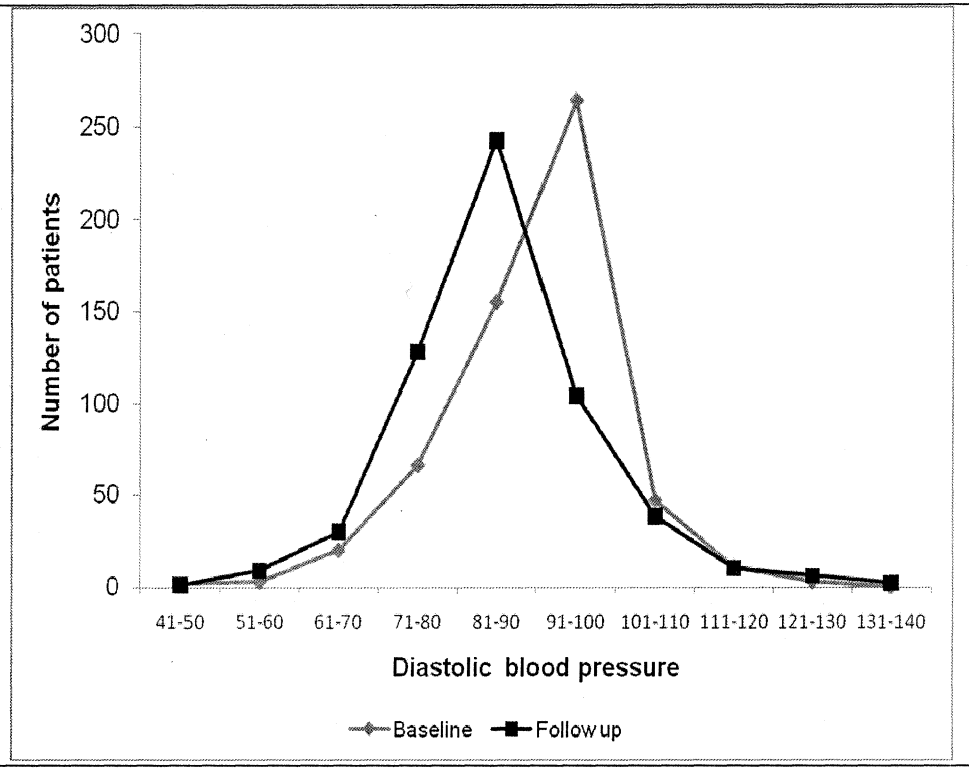


Table A: Treatment status, life style modification, awareness of long term complications at follow up of the study population, Thiruvallur , Tamil Nadu, India, 2008

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
	Stopped/reduced alcohol	12	2.1
Combinations of lsm(n=571)	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
	Reduced salt +oil+started walking	66	11.6
Difficulty in adhering to LSM recommended by doctor(n=571)		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

		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
	Irregular patients(n=73)	73	17	23.3
	Started and stopped patients(n=52)	52	19	36.5
Frequency of individual side effects in patients put on drugs (n=288)	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

		Baseline			Follow-up		
		Total	No	%	No	%	p value*
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	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 sub-groups of patients, Thiruvallur district, Tamil Nadu, India, 2008

			Baseline		Follow up		
		Total	No	%	No	%	p value*
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 adheringto 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

			Baseline		Follow-up		
		Total	No	%	No	%	p value*
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.tr	124	11	8.9	71	57.3	0.000
	Taking pvt.tr	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

			Baseline		Follow-up		
		Total	No	%	No	%	**p value***
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,NSAIDs,Steroids,etc	Yes	86	12	14	35	40.7	0.000
	No	485	118	24.3	247	50.9	0.000
Patient has understood freqency 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					
		Baseline		Follow up				Baseline		Follow up			
	N	Mean	SD	Mean	SD	Diff	paired t value[††]	Mean	SD	Mean	SD	Diff	paired t value*
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, government	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													
Gudapakkam	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					
		Baseline		Follow up				Baseline		Follow up			
	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 freqency 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 sifnificant except *

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

	SBP						DBP					
	Baseline		Follow up				Baseline		Follow up			
	Mean	SD	Mean	SD	Diff	pairedt	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

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

	SBP							DBP						
	Baseline		Follow up			paired	p	Baseline		Follow up			paired	
	Mean	SD	Mean	SD	Diff	t	value	Mean	SD	Mean	SD	Diff	t	p value
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
Redduced 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	i9.46	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

		No	%
Physician assessment of reasons for BP not under control (n=289)	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	15	74.4
	Not possible to skip work and lose income	11	44.0

Review of Literature

1. Burden of cardiovascular diseases

1.1 Global burden

Cardiovascular disease is major cause of mortality and morbidity leading to 30.9% of the deaths worldwide[1].In 1990, developing countries accounted for 68% of the total global deaths due to non communicable diseases and 63% of the global mortality due to cardiovascular diseases. In addition CVD deaths in developing countries occur in younger individuals in higher proportion. In 1990, proportion of CVD deaths occurring below the age of 70years was 26.5% in the developed countries compared with 46.7% in developing countries[2].

1.2 Burden in India:

India contributes 17% to the global mortality due to CVD.[2] Based on projected demographic trend, cardiovascular disease would emerge as the single largest contributor to mortality by 2015 in India[3]. CVD mortality is expected to rise 103% in men and 95% in women between 1985 and 2015 and account for 34% of mortality in men and 31% in women.[3] Prevalence of coronary heart disease is estimated to be 10% in urban India based on several surveys.[4]

1.3 Reasons for high CVD burden in India:

The factors contributing to the rising prevalence are urbanization, high risk factor levels, the relatively early age at which they manifest, the large sizes of the population and the high proportion of individuals who are young adults or middle aged in developed countries[5].

WHO identified eight key risk factors for cardiovascular disease control. These risk factors are (1) smoking (2)alcohol (3) low fruit and vegetable intake (4) physical

inactivity, (5) obesity, (6)hypertension, (7) diabetes and (8) hypercholesterolaemia.[6] Among them hypertension is one of the important risk factors for which there is evidence regarding effectiveness of life style modification and drug therapy.

2. Burden of Hypertension

Global burden

Hypertension affects approximately 1 billion individuals worldwide.[7,8]Globally, the reported prevalence of hypertension in the adult population varies widely,[8,9,10] but the overall number of adults with hypertension worldwide was recently predicted to exceed 1.5 billion by 2025.[7]This global pandemic is of great public health concern because hypertension is the single most important cause of attributable mortality.[11] Approximately two-thirds of all strokes and one half of all ischaemic heart disease are directly attributable to hypertension.[12]

2.1.1. Prevalence of High Blood Pressure in Higher- and Lower-Income Regions

There are important regional variations in blood pressure distributions, even taking into account potential differences in the technique of blood pressure measurement. For example, in both sexes, for all ages above 45 years, average blood pressure levels are highest in populations from Eastern Europe and Russia. Average levels are also particularly high in the Middle East, North Africa, and parts of sub-Sahara Africa.[11] Classifications of hypertension vary, but on the basis of a single blood pressure measurement >=140 mm Hg systolic or >=90 mm Hg diastolic, approximately 1 in 4 adults, worldwide, had hypertension.[13] Currently, this equates to 1 billion individuals, and this number is expected to grow to 1.5 billion (30% of the global population) by 2025, solely as a consequence of increases in both total population size and the proportions within populations reaching older ages. In higher income regions, the number of hypertensive individuals is predicted to grow by 70

million people from 2000 to 2025, whereas in lower-income regions, the number is predicted to grow by 500 million over the same period. In China and India alone, the total number with hypertension is expected to increase to 500 million by 2025.[13]

Although demographic changes in populations will have the greatest short-term consequences for changes in population blood pressure distributions and hypertension prevalence, other factors are likely to augment these changes. In particular, progress in economic development, with consequent increases in obesity because of greater food availability and choice, and a reduction in physical activity can be expected to further increase mean blood pressure levels and the proportion with high blood pressure in lower income regions such as China and India.[14,15,16]

2.1.2. Effects of Blood Pressure on Disease Burden in Higher- and Lower-Income Regions

Large-scale epidemiological studies have clearly demonstrated the enormous impact of non optimal blood pressure levels on the risks of major cardiovascular events in both higher- and lower-income regions. [17,18,19] The Asia Pacific Cohort Studies Collaboration, which involved 500 000 individuals followed for several years on average, has demonstrated direct continuous associations of usual levels of systolic and diastolic blood pressure with the risks of coronary heart disease and stroke in both white and Asian populations.[18,20] Evidence shows approximately two thirds of all stroke and half of all coronary disease can be attributed to non optimal blood pressure. [12,21] This represents 7million deaths and 64 million disability-adjusted life years each year. Lower-income countries suffered approximately two thirds of the total burden of blood pressure–related disease. The two countries experiencing the greatest burden of blood pressure–related diseases were India and China. However, whereas stroke was the most common type of blood pressure–related disease in China, coronary disease

was more common in India. Compared with higher-income regions, these and other lower-income regions had a greater proportion of blood pressure–related disease occuring among people of middle age. [21] The relationship between blood pressure levels and non cardiovascular diseases risk has been less well defined, although similar relationships between blood pressure levels and the risk of end-stage kidney disease have been described in large studies of white[22] and Asian populations.[23]

2.2. Burden in India

2.2.1 Prevalence of hypertension in rural areas

2.2.1 Cross-sectional surveys in 90s

In a community survey done in rural Rajasthan among individuals over 20 years, prevalence of Hypertension was found to be 21%.[24] In a study done in rural south Indian community in subjects aged over 20 years, the prevalence of hypertension was 12.5%. The prevalence of hypertension in the highest socioeconomic group (22.5%) was more than twice that in the lowest socioeconomic group (8.8%).[25]

A study from central India revealed a prevalence of hypertension of 4% rising to 19% in more than 60 years age group.[26] In a study done in Punjab risk factors, in individuals > 30 yrs living in 3 villages, the prevalence of hypertension, was found to be 14.5%.[27] A study was done in seven rural and nonindustrialised villages around Raipur Rani block in the state of Haryana, India, to determine the prevalence of hypertension and its associated risk factors in individuals 16 to 70-year age group. 4.5% were found to be hypertensive according to JNC V criteria (BP of > or = 140/90 mm Hg). Mean systolic and diastolic blood pressures were 116.9 and 71.7 mmHg in males and 119.1 and 72.7 mm Hg in female subjects respectively ($P < 0.001$).[28]

2.2.2 Cross-sectional surveys between 2001-2007

A study on prevalence of hypertension was carried out in rural Assam where three thousand one hundred and eighty individuals (1441 men and 1739 women), > or =30 years of age were surveyed. The overall prevalence of hypertension using JNC VI was 33.3%. Among the patients with hypertension, 21.6% were aware of their illness.[29]

In rural areas surrounding Pune, a cross-sectional survey was carried out among a random sample of 406 people of 30 years and the prevalence of systolic hypertension was 18.5 % and diastolic hypertension was 15 %.[30]

A cross-sectional survey was done in a rural population in Andhra Pradesh. Data was collected from 345 adults aged 20 to 90. The mean systolic blood pressure was 116 (114-117) mm Hg, diastolic blood pressure 73 (114-120) mm Hg and prevalence of hypertension was 20.3% (16.2-24.4%).[31]

2.2.2 Prevalence of hypertension in urban areas

Prevalence of hypertension in multicentric study carried out in ten centers around India was 27.7%.[32] In a study done in Chennai, Pre-hypertension and Hypertension were prevalent in 901(39.8%) and 615(27.2%) subjects respectively.[33]

2.2.3. Effects of Blood Pressure on Disease Burden in India

Hypertension is one of the leading and treatable causes of cardiovascular deaths. Hypertension is responsible for 16% of ischaemic heart disease, 24% of myocardial infarction and 29% of stroke.[34]

3. Awareness and control of hypertension

3.1. Hypertension Control

3.1.1. Global

The prevalence of hypertension is around 25-30% of adult population (20-60 years age) in both developed and developing countries, rising to about 60-70% in the seventh decade. Even in developed countries like USA, Canada and Japan, only 60-70% of the hypertensives are aware of their problem(Detection rate). Among the detected hypertensives in USA only around 60-70% of them are on anti-hypertensive treatment; and only 30% of the hypertensives are under adequate control.

3.1.2 Asia

In Taiwan - among the hypertensives, only 20% are aware of their problem and only 2 % of the hypertensives are under adequate control. In Asian countries the proportion of hypertensives under adequate control ranges from around 1% in Korea to around 8% in China.

3.1.3 India

Studies done in urban high resources settings like large industries show the awareness levels are only around 28-37% and the percentage of hypertensives under adequate control is only under 18%.[35]

3.1.4 Tamil Nadu

In rural Tamil Nadu, 25% of all deaths are due to cardiovascular diseases.[36] A cross-sectional survey carried out by NIE in rural population showed prevalence of hypertension was 20%. Among them 80% were newly detected. Among those who were previously diagnosed, less than half were on treatment. In a follow up study of already identified hypertensives and a cultural epidemiology study of a subgroup of them, the factors for noncompliance of treatment were identified at two levels-

individual level and health system based. Lack of awareness about risks and potential benefits of control, inability to change certain behaviors like a high carbohydrate diet, physical inactivity etc were the individual level factors identified. The health system based factors for noncompliance were issues of accessibility, availability and afford ability. Most of the patients reported that there was no motivation to seek treatment, as most of the hypertensives were asymptomatic. (unpublished data)

4. Strategies for improving Hypertension Management and control

A Working Group including representatives of nine international health-care organizations was convened to review the barriers to more effective blood pressure control and propose actions to address them. The Working Group identified five core actions, which should be rigorously implemented by practitioners and targeted by health systems throughout the world: (1) detect and prevent high blood pressure; (2) assess total cardiovascular risk; (3) form an active partnership with the patient; (4) treat hypertension to goal and (5) create a supportive environment. These actions should be pursued with vigour in accordance with current clinical guidelines, with the details of implementation adapted to the economic and cultural setting[37].

5. Barriers to the prevention of Blood pressure related diseases in lower income regions

5.1 Drug Costs

There are many barriers to the provision of appropriate blood pressure–lowering therapy in resource-poor settings, but drug costs should not be one of them. For example, the diuretic hydrochlorothiazide can be purchased internationally for 0.3 cents per 25-mg tablet, the beta-blocker atenolol for 1 cent per 100-mg tablet, and the angiotensin-converting enzyme inhibitor enalapril for 2 to 3 cents per 20-mg tablet. On this basis, 1 year's supply of hydrochlorothiazide should cost approximately $1

per person, and the total annual cost of purchasing drug for all of those with a 25% 10-year risk of a major cardiovascular event would be approximately $50 million in each of China and India. Assuming that such treatment reduced the 10-year risk of a major cardiovascular event from 25% to 20%, the drug costs for the prevention of each fatal or serious event would be approximately $200. Such costs are within the financial capacity of all but the very poorest countries. In addition, whereas the cost of some generic drugs from wholesalers may be low, the price at which the same drug is provided to a patient is often grossly inflated. Moreover, there are often financial incentives for healthcare providers to selectively prescribe more expensive drugs despite there being no clear advantage over cheaper drugs, such as diuretics.[32,38]

5.2.Structural Barriers

The prevention of blood pressure–related diseases requires a primary health care system that can identify those at high risk, ensure regular monitoring of their health status, and provide an uninterrupted appropriate and affordable treatment supply. Each of these poses its own unique challenges in many lower-income regions. With respect to identifying those at high risk, algorithms developed for Western populations typically require laboratory blood tests for total, low-density lipoprotein, and high-density lipoprotein cholesterol and fasting blood glucose.[39,37] In many resource-poor settings, laboratory access can be difficult and expensive. For example, in lower-income regions such as India, only a minority of all those with high blood pressure are aware of their condition. [40,41,42,43,44] Improving the identification of individuals at high risk of blood pressure–related diseases will require educational programs aimed at both healthcare providers and consumers. The capacity to provide long-term monitoring of those at high risk is an essential criterion for the effective prevention of blood pressure–related diseases. In many situations, primary healthcare

services have provided only episodic care with little record kept of previous visits.[45] Continuity of care also requires access to an uninterrupted and affordable drug supply. Guidelines for lower-income regions should be developed with due regard to the important role played by nonphysician health workers, who provide a large proportion of primary healthcare services.[32]

5.3. Policy Barriers

In many countries there are policy barriers to the implementation of blood pressure–lowering treatment programs. Most common is the restrictive focus of prevention programs on infectious disease and sometimes on HIV/AIDS alone.

Many lower-income countries face a double burden of communicable and noncommunicable disease, yet few allocate resources to demands on the basis of cost-effectiveness or even disease burden. Multilateral organizations, such as the World Health Organization and the World Bank, have been partly responsible for this unbalanced approach through the setting of Millennium Development Goals[46] that excluded any mention of chronic disease prevention. Fortunately, in recent years both World Health Organization[47] and the World Bank[48] have recognized the importance of chronic diseases, including blood pressure–related diseases, as a cause not only of premature death and disability but also as a threat to social and economic development. This may herald the beginning of a rebalancing of investment priorities for health care in at least some lower-income countries. However, the prioritization of blood pressure control as a strategy to improve health status will require evidence that worthwhile benefits can be achieved at a price that is affordable. This requires a markedly different approach to that adopted in higher-income countries in which treatment programs are primarily physician centered and often use expensive diagnostic procedures (eg, 24-hour blood pressure measurement or echocardiography)

and on-patent drugs. As indicated above, lower-income regions require approaches that can be implemented by nonphysician healthcare workers using simple assessment tools and low-cost drugs. Different strategies are probably required in urban and rural areas, but both require outreach programs to access disadvantaged population subgroups.[32]

5.4.The health-care provider and patient perspectives

Hypertension prevention, requires fundamental shifts in awareness and understanding leading to diet and lifestyle changes. The problem of inadequate detection and treatment must be addressed, to ensure that individuals with hypertension are successfully maintained at or below target blood pressure goals. A strategic shift is required at multiple levels within health-care systems from the current emphasis on acute disease towards more effective management of chronic illness. [49,50]

Effective management of hypertension requires vigorous and sustained intervention, involving regular consultations, a willingness to titrate therapy until goals are reached, and the follow-up of patients into the long term. One important barrier to sustained and effective blood pressure management is clinician inertia, whereby physicians treating hypertension are unwilling to increase the intensity of drug treatment even though they see patients regularly and are aware that blood pressure goals have not been achieved.[51,52,53,54,55] The causes of the problem are varied, and include a lack of knowledge about the relative risks and benefits of rigorous blood pressure management and resistance to implement guidelines.[46,56] Health-care professionals should therefore be urged to keep in mind that it is not sufficient merely to bring patients close to goal. Rather, they need to treat hypertension to or below goal. The intensity of treatment should be increased with

respect to dose and/or selection of medication until this objective is achieved, with the requirement that treatment should also remain well tolerated.[32] One of the most central challenges for health-care professionals in improving blood pressure goal rates concerns their relationship with the patient, and the means by which patient-related causes of poor blood pressure control are addressed.[32]

6. Interventions for Hypertension

International experts recommend life style modifications and non-drug therapies in the prevention and management of hypertension. The first step in the management of patients of any age who have hypertension should be a reduction in salt intake (from 9 to 6 gr/day), either alone or in combination with drug therapy to which is often additive. A high potassium diet achieved with an increase in the consumption of fruit, vegetables and pulses, weight reduction, regular dynamic exercise, smoking cessation, and reduction of alcohol are also recommended. Although lifestyle measures are remarkably useful because of their low cost, their effectiveness is related to the patient's ability and motivation to change and to maintain this change.[57]

6.1. Life Style Modification

Meta-analysis of 25 randomised controlled trials showed a blood pressure reduction of 4.4/3.6 mm Hg for a 5 kg weight loss. A dose response was observed, that is, the greater the weight loss, the greater the blood pressure reduction.[58] An average reduction in urinary sodium excretion of 77mmol/24 hours is associated with a reduction in blood pressure of 2.54/1.96 mm Hg.[59]In the Dietary Approach to Stop Hypertension (DASH) diet trial, the difference of systolic blood pressure between the DASH-low sodium group and the control high sodium group was an impressive reduction of 7.1 mm Hg in participants without hypertension and 11.5 mm Hg in participants with hypertension.[60]

The Trial of Non pharmacological Interventions in Elderly(TONE) showed that a combined intervention reducing average body weight by 3.5 kg and sodium intake by 40mmol/day in elderly patients(60 to 80years) was associated with a 30% reduction in blood pressure.[61]

A meta analysis by Xin et al estimated a reduction in systolic and diastolic blood pressure of 3.31/2.04 mm Hg, respectively, for an average 76% reduction in alcohol consumption from a baseline of three to six drinks per day.[62]

In a meta analysis of 54 randomised controlled trials including 2419 participants, aerobic exercise was associated with a reduction in blood pressure of 3.84/2.58 mm Hg (114),which was independent from weight change.[63]

The risk of coronary heart disease in hypertensives was increased two to three- fold by smoking, even though coronary heart disease is already the commonest cause of death in hypertensives.[64] Smokers tend to be undertreated and they have a higher daytime blood pressure than nonsmokers do.[65] Additionally, when treated, smokers do not receive full protection from the antihypertensive treatment compared with nonsmokers. [66, 67, 68]

6.2. Drugs, Classes of drugs

Five major classes of antihypertensive agents – thiazide diuretics, calcium antagonists, ACE inhibitors, angiotensin receptor antagonists and b-blockers – are suitable for the initiation and maintenance of antihypertensive treatment, alone or in combination. b-blockers, especially in combination with a thiazide diuretic, should not be used in patients with the metabolic syndrome or at high risk of incident diabetes. The main benefits of antihypertensive treatment are due to lowering of blood pressure per se, and are largely independent of the drugs employed, and all can adequately lower blood pressure and significantly and importantly reduce cardiovascular outcomes. Therefore all these drugs are suitable for the initiation and maintenance of antihypertensive treatment either as monotherapy or in some combinations with each other. Each of the recommended classes may have specific properties, advantages and limitations.

Because in many patients more than one drug is needed, emphasis on identification of the first class of drugs to be used is often futile. Nevertheless, there are many conditions for which there is evidence in favour of some drugs versus others either as initial treatment or as part of a combination.[69]

7. Interventions programs for hypertension in low resource settings

7.1. Strategy and examples of intervention programs in low resource settings

The effective interventions for hypertension control are two pronged; population based and targeted interventions for high risk groups. Health education (life style modification, reducing obesity, salt restriction, physical activity) and policy changes(banning tobacco, mandatory labeling of salty foods) are the population based interventions. The high risk group targeted interventions include screening, early treatment, ensuring compliance and adequate control. Life style modification

decreases BP,enhances anti-hypertensive drug efficacy and decreases cardiovascular risk.[70]

An aboriginal chronic disease outreach program carried out in a remote, low resource community in Australia showed that involving local health workers for hypertension screening and management was effective in reducing mortality and morbidity due to hypertension related diseases. The study showed that among people who were initiated on treatment,45% had drop in systolic BP more than or equal to 5mm of Hg and 37% had a drop of more than or equal to 10mm of Hg. Mean systolic BP fell by 14mm Hg and mean diastolic BP fell by 12mm of Hg.[71]

In India, there is only one community based study that showed effectiveness of domiciliary screening and treatment and control of hypertension in rural Tamilnadu using health workers. In a population of 20000, using community based volunteers and low cost locally available generic antihypertensive and oral antihyperglycemic drugs; diabetes, and hypertension were well controlled in majority of subjects. [72,73] The prevalence of kidney disease (defined as GFR less than 80 ml/mi by MDRD formula) was 8.5/1000 in the screened and treated population 8 years after the program started as against a prevalence of 22.5/1000 in a neighboring unscreened population.[72] The cost per person of the program was well within the per capita health expenditure of the country.[73]

7.2. WHO CVD risk management package for low & medium resource settings

The WHO developed a non physician health worker based CVD risk management package for low and medium resource settings.[74] It consists of easy to follow protocols for assessing and managing cardiovascular risk and for counseling on diet, physical activity and smoking cessation. It also has a training manual for training health care providers. The reliability study carried out by WHO for this

protocol showed health workers can be retrained to reliably and effectively assess and manage CVD risks in primary health care settings and the WHO package could be a useful tool for scaling up the management of CV disease in Primary Health Care. Health workers can be retrained to reliably and effectively assess and manage cardiovascular risks in primary health care settings. The WHO CVD risk management package for low & medium resource settings could be a useful tool for scaling up the management of cardiovascular diseases in Primary Health care.[75]

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