Original Article

Effectiveness of Lifestyle Counselling in Management of Hypertension and Diabetes in an Urban community of Manipur: A Quasi-Experimental Study

Jalina Laishram[1], Pooja Akoijam[2], Soubam Christina[3], Thoudam Reena Devi[4], Avantika Gupta[5], Brogen Singh Akoijam[6]

[1]Assistant Professor, [2,3,4,5]Senior Resident, [6]Professor and Head, Community Medicine, RIMS, Imphal, Manipur

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Abstract

Background: Lifestyle counselling is an effective, non- invasive way to manage weight, glycemic control, blood pressure and to reduce the risk of fatal complications in hypertensives and diabetics.

Objective: To assess the effectiveness of lifestyle counselling in management of hypertension and diabetes in an urban community of Manipur, India.

Methods: A quasi-experimental study was conducted among 51 cases each in intervention and control groups. Study population was known cases of hypertension and/or diabetes. One-on-one lifestyle counselling was done on the four risk behaviors (unhealthy diet, insufficient physical activity, tobacco and alcohol use). Effectiveness was assessed by a modified version of WHO STEPS questionnaire and physical and biochemical measurements collected at baseline and 6 months post-intervention. Chi-square test, independent t-test and paired t-test were used.

Results: There was no significant difference at baseline and post-intervention blood pressure, BMI and waist-hip ratio and random blood sugar between intervention and control group.

Within group comparison showed a significant decrease in random blood sugar in

the control group (p=0.044).

Conclusion: Our results found no effect of the intervention among people with hypertension and diabetes. More intensive intervention sessions might be required to see a significant change in the control of hypertension and diabetes.

Key-words: Lifestyle counselling, quasi-experimental study, WHO STEPS, NCDs

Corresponding Author: Jalina Laishram, Assistant Professor, Community Medicine, RIMS, Imphal, Manipur.

E-mail: jalinalaishram@yahoo.in

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Introduction

Non Communicable diseases (NCDs) are one of the major challenges for public health in the 21st century. The major NCDs are cardiovascular diseases, cancers, chronic respiratory diseases and diabetes. Physical inactivity, unhealthy diets (diets low in fruit, vegetables, and whole grains, but high in salt and fat), tobacco use (smoking, second hand smoke, and smokeless tobacco), and the harmful use of alcohol are the main behavioural risk factors for NCDs. These factors are modifiable and aid in prevention of the diseases.[1]

In 2008, NCDs accounted for 5.2 million deaths in India. In a report "India: Health of the Nation's States" by Ministry of Health and Family Welfare (MOHFW), Government of India (GOI), it is found that there is increase in the contribution of NCDs from 30% of the total disease burden- 'disability-adjusted life years' (DALYs) in 1990 to 55% in 2016 and also an increase in proportion of deaths due to NCDs (among all deaths) from 37% in 1990 to 61% in 2016. This shows a rapid epidemiological transition with a shift in disease burden to NCDs.[2]

It is important to also focus on those diagnosed to be aware and modify any risk behaviour to control their disease apart from already being under treatment. Management of NCDs requires empowered patients in addition to health services tailored to the social and life characteristics of individuals. Lifestyle counselling is an effective, non- invasive way to empower patients to manage weight, glycemic control, blood pressure and to reduce the risk of fatal complications in hypertensive or T2DM patients.[3-7] Studies done in other parts of the world have seen improvements in knowledge, attitude, and practice in managing hypertensive and type 2 diabetes mellitus (T2DM) patients, treatment outcomes and quality of life.[7]

There is a dearth of studies on this topic in the north-eastern region of India. Hence, this study was conducted to assess the effectiveness of lifestyle counselling in management of hypertension and diabetes in an urban community of Manipur, India.

Materials and Methods

This quasi-experimental study was conducted in the urban field practice area of a tertiary care teaching institute in Imphal, Manipur. Study area has 6 clusters with an approximate population of 5000. Data collection period was from September 2022 to April 2023.

Study population was people with diagnosed hypertension and/or diabetes mellitus living in the study area. Inclusion criteria were those aged 30 years and above, living in the area of study for one year or more, conscious and capable of effective oral communication without help and available to participate in assigned counselling and health-related activities.

Pregnant women, those with severe illness or diseases that need special care like malignancy, heart failure, kidney disease, etc., those who were bedridden and psychiatric illness were excluded from the study.

Sample size: Taking power 80%, 5% error and $mean_1$ as 125.5± 9.7 (mean systolic BP in intervention group at 6 months) and $mean_2$ as 130.9±11.3 (mean systolic BP in control group at 6 months) from a study conducted by Kumari G[3], the calculated sample size was 51 in each group using the formula, $N= (\sigma_1^2+\sigma_2^2/K) (z_{1-\alpha/2}+z_{1-\beta})^2 / (m_1-m_2)^2$

Sampling: Cluster sampling was done. Out of the 6 clusters 4 were selected by lottery method. Two clusters each were allocated into intervention and control group by lottery. A list of all eligible persons was made for the selected four clusters using the family folders maintained by the Department of Community Medicine of the institute and they were approached for recruitment as study participants. If there were two or more eligible persons in one household only one was selected by lottery. Recruitment continued until a sample size of 51 each was achieved in intervention and control groups.

Intervention:

In this study, lifestyle counselling was the intervention. The H of the HEARTS package was used.[8] The topics focussed on 4 modifiable risk factors i.e., unhealthy diet, insufficient physical activity, tobacco use and harmful use of alcohol.

The intervention group had one-on-one counselling sessions on each of the modifiable risk factors using pamphlets, charts, pictures. The counselling sessions were given by trained investigators. Each session lasted about 30 minutes on an average. The session started immediately after the baseline demographic, risk behaviour and biomedical measurements. After this one-on-one counselling, related infographics and messages were sent using WhatsApp once every 2 weeks to the participants in the intervention group for the next 5 months before the follow-up measurements were taken.

The control group did not receive any intervention and there were asked to follow the usual care of management as done before.

Data Collection:

Data were collected using an interview method at the participant's residence maintaining privacy and following all COVID appropriate behaviors. A structured questionnaire modified from the WHO STEPPS questionnaire[9] was used. It consisted of 4 parts: socio-demographic details and details on behavior of modifiable risk factors (unhealthy diet, insufficient physical activity, tobacco use and harmful use of alcohol), history of hypertension/diabetes and, physical and biochemical measurements. Baseline measurements of height, weight, random sugar level, blood pressure were taken by the investigators using study tools which were calibrated on each day of taking measurements. This was followed by lifestyle counselling sessions. The same questionnaire and measurements were taken after the intervention using the same methods. The measurements were repeated at 6 months post-intervention.

Mean change in blood pressure and mean change in random blood sugar measurements were primary outcome variables. Change in anthropometric measurements were secondary outcome variables.

Procedure of measurements:

Blood pressure was measured using digital BP instrument (OMRON HEM-7120). Participant was seated and rested for 15 minutes before taking the BP measurement. The average of the three readings was taken. The participant was allowed to rest for 3 minutes between each of the readings. Random blood sugar was measured using glucometer (One touch select plus with strips & lancets). Weight was measured in kilogram to the nearest 0.1kg using digital weighing machine (Omron HN 286). Before taking height measurement, the subject was instructed to remove any footwear and head gear. The height measurement was recorded to the nearest 0.1 cm using a portable stadiometer. Waist circumference was measured without clothing directly over the skin and hip circumference was measured over light clothing using a non-stretchable measuring tape.

Statistical Analysis:

Data collected were checked for completeness and consistency. Data were entered into IBM SPSS 26 for Windows (IBM Corp. 1995, 2012). It was summarized using descriptive statistics like mean, percentage and standard deviation. Chi-square test was done to check for association between categorical variables. Independent t-test and paired t-test was used to compare the continuous variables within the group and between the two groups.

Ethical Issues:

Ethical approval was obtained from the Research Ethics Board, RIMS, Imphal. Informed verbal consent was obtained from the participating individuals. No names were taken to maintain confidentiality, instead a unique code number was used for each participant. Data collected were kept secured and were accessed only by researchers. The control group received the sessions after the 6-month follow up was done. This study was registered in Clinical Trial Registry of India (CTRI/2022/05/042459).

Results

A total of 102 hypertensives and diabetics participated in the study, 51 each in intervention and control group. In Intervention group 36 had hypertension, 6 had diabetes mellitus and 9 had both hypertension and diabetes. In Control group 26 had hypertension, 14 had diabetes mellitus and 11 had both hypertension and diabetes.

Table 1 shows the background characteristics of the study participants. Intervention group had a significantly higher mean age (65±12 yrs vs 60±9.80 yrs) and higher education compared to the control group. The study findings are shown in the following tables.

Table 1. Comparison of background characteristics between intervention and control group (N=102)

Background Characteristics	Intervention Group (N=51)	Control Group (N=51)	p-value
	n(%)	n(%)	
Age (years) (Mean ± SD)	65±12.12	60±9.80	0.018
Gender			
Male	27(52.9)	21(41.2)	0.234
Female	24(47.1)	30(58.8)	
Marital status			
Married	44(86.3)	46(90.2)	0.539
Widow(er)	7(13.7)	5(9.8)	
Highest educational qualification			
Illiterate	10(19.6)	19(37.3)	0.001
Up to Class 12	18(35.3)	26(51.0)	
≥ Graduate	23(45.1)	6(11.8)	
Currently working			
Yes	15(29.4)	20(39.2)	0.297
No	36(70.6)	31(60.8)	
No. of adults in household (Mean ± SD)	4.53±1.51	4.31±1.94	0.533
Monthly household income (Rs) Median (IQR)	39,000 (20,000-60,000)	30,000 (20,000-50,000)	0.148*
No. of family members (Mean ± SD)	5.73±2.04	5.45±2.44	0.539

*Mann Whitney U test

Table 2. Comparison of tobacco use, alcohol consumption, diet between intervention and control group at baseline and follow-up (N=102)

Characteristics	Baseline		p-value	Follow-up		p-value
	Intervention n(%) /(Mean±SD)	Control n (%) /(Mean±SD)		Intervention n (%) /(Mean±SD)	Control n (%) /(Mean±SD)	
Current history of smoking	(N=51)	(N=51)		(N=51)	(N=51)	
Yes	25(49.0)	23(45.1)	0.692	3(5.9)	4(7.8)	
No	26(51.0)	28(54.9)		48(94.1)	47(92.2)	1.00*
Past history of smoking						
Yes	2(7.7)	5(17.9)	0.423*	-	-	-
No	24(92.3)	23(82.1)		-	-	
Ever consumption of alcohol						
Yes	22(43.1)	26(51.0)	0.427	-	-	-
No	29(56.9)	25(49.0)		-	-	
Alcohol consumption within the past 12 months						
Yes	15(68.2)	19(73.1)	0.710	-	-	-
No	7(31.8)	7(26.9)		-	-	

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Alcohol consumption in the past 30 days						
	N=15	N=19		N=5	N=5	
Yes	4(57.1)	1(33.3)	1.00*	4(80.0)	2(40.0)	0.524*
No	11(42.9)	18(66.7)		1(20.0)	3(60.0)	
Frequency of fruits intake						
	(N=51)	(N=51)		(N=51)	(N=51)	
Days /week	3.63±1.51	3.67±2.36	0.920	4.39±2.7	2.37±1.75	0.000
Servings/day	1.35±0.52	1.41±0.76	0.647	1.27±0.86	1.28±0.78	0.952
Servings/day/week	0.70±0.40	0.79±0.69	0.458	0.89±0.81	0.49±0.48	0.033
Frequency vegetable intake						
Days/week	6.65±0.89	6.29±1.15	0.087	6.25±1.4	7.45±10.07	0.406
Servings/day	2.16±0.62	1.98±0.54	0.122	3.68±10.5	7.8±20.3	0.194
Servings/day/week	2.06±0.65	1.79±0.58	0.033	2.01±0.97	1.88±0.70	0.423
Frequency of salt intake						
Adding salt or a salty sauce right before or during eating						
Often/Sometimes	11(21.6)	11(21.6)	1.000	12(23.5)	10(19.6)	0.630
Rarely/Never	40(78.4)	40(78.4)		39(76.5)	41(80.4)	
Adding salty seasoning or a salty sauce in cooking or preparing foods in household						
Always/Often /Sometimes	18(35.3)	26(51.0)	0.110	29(56.9)	23(45.1)	0.235
Rarely/Never	33(64.7)	25(49.0)		22(43.1)	28(54.9)	
Eating processed food high in salt						
Often/Sometimes	13(25.5)	19(37.3)	0.200	11(21.6)	13(25.5)	0.641
Rarely/Never	38(74.5)	32(62.7)		40(78.4)	38(74.5)	
Perception regarding amount of salt or salty sauce consumed						
Too much	2(3.9)	6(11.8)	0.269*	3(5.9)	4(7.8)	1.00*
Just the right amount/Too little	49(96.1)	45(88.2)		48(94.1)	47(92.2)	

*Fisher's Exact test

Table 3. Comparison of physical activity between intervention and control group at baseline and follow-up (N=102)

Physical activity	**Baseline**		**p-value**	**Follow-up**		**p-value**
	Intervention n(%)/ (Mean±SD)	**Control n(%)/ (Mean±SD)**		**Intervention n(%)/ (Mean±SD)**	**Control n(%)/ (Mean±SD)**	
Vigorous-intensity activity at work for least 10 minutes continuously						
Involvement	(N = 51)	(N = 51)		(N = 51)	(N =51)	
Yes	4(7.8)	8(15.7)	0.357*	5(9.8)	8(15.7)	0.373
No	47(92.2)	43(84.3)		46(90.2)	43(84.3)	
No. of days / week	(N = 4)	(N = 8)	0.032	(N = 2)	(N = 8)	0.453
	3.50±2.51	6.25±1.38		7.00±.00	6.25±2.121	
Duration/day (minutes)	(N = 4)	(N = 8)	0.452	(N = 2)	(N = 8)	0.630
	172.50 ±208.02	262.50 ±178.38		276.00 ±116.9	230.6 ±181.23	

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Moderate-intensity activity at work for least 10 minutes continuously						
Involvement	(N=51)	(N=51)	0.015*	(N=51)	(N=51)	0.181*
Yes	14(27.5)	26(51.0)		17(34.0)	24(47.1)	
No	37(72.5)	25(49.0)		33(66.0)	27(52.9)	
No. of days/ week	(N=14)	(N=26)	0.214	(N=17)	(N=24)	0.122
	4.86±2.38	5.74±1.83		6.0±1.5	5.04±2.15	
Duration/day (minutes)	(N=14)	(N=26)	0.638	(N=17)	(N=24)	0.037
	37.50±27.50	41.96±27.82		147.05±148.155	67.08±88.10	
Walking/cycling (pedal cycle) for at least 10 minutes continuously to get to and from places						
Response	(N=51)	(N=51)	0.101*	(N=50)	(N=51)	0.129*
Yes	20(39.2)	30(58.8)		18(36.0)	26(51.0)	
No	31(60.8)	21(41.2)		32(64.0)	25(49.0)	
No. of days/ week	(N=20)	(N=30)	0.021	(N=17)	(N=25)	0.837
	5.74±1.910	4.31±2.08		5.5±1.73	5.4±2.1	
Duration/day (minutes)	(N=20)	(N=30)	0.810	(N=17)	(N=25)	0.960
	33.61±33.64	35.86±35.05		35.29±13.74	34.800±38.68	
Vigorous-intensity sports, fitness or recreational activities [running or football] at least 10 minutes continuously						
Response	(N=51)	(N=51)	1.000*	(N=51)	(N=51)	1.000*
Yes	2(3.9)	1(2.0)		2(4.0)	2(3.9)	
No	49(96.1)	50(98.0)		48(96.0)	49(96.1)	
No. of days / week	(N=2)	(N=1)	0.232	(N=2)	(N=2)	0.095
	6.50±0.707	5.00±0.00		7.0±.00	5.5±.707	
Duration/day (minutes)	(N=2)	(N=1)	-	(N=2)	(N=2)	0.533
	60.00±0.60	90.00±0.00		90.00±42.42	60.00±42.42	
Moderate -intensity sports, fitness or recreational activities [brisk walking, cycling, swimming, volleyball] at least 10 minutes continuously						
Response	(N=51)	(N=51)	0.138	(N = 46)	(N = 49)	0.328
Yes	18(35.3)	10(19.6)		9(19.6)	6(12.2)	
No	33(64.7)	41(80.4)		37(80.4)	43(87.8)	
No. of days/ week	(N=18)	(N=10)	0.157	(N=9)	(N=6)	0.963
	6.28±1.67	5.20±2.2		4.8±2.31	4.83±2.13	
Duration/day (minutes)	(N=18)	(N=10)	0.78	(N=9)	(N=6)	1.00
	42.50±16.11	31.50±13.34		33.33±17.5	33.33±16.3	

*Fisher's Exact test

Table 4. Comparison of Blood pressure, BMI and Waist-hip ratio between intervention and control group at baseline and post-intervention follow-up

	Baseline			Follow-up		
Measurements	**Intervention, N=51 (Mean±SD)**	**Control, N=51 (Mean±SD)**	**p-value***	**Intervention, N=51 (Mean±SD)**	**Control, N=51 (Mean±SD)**	**p-value***
Systolic blood pressure (mmHg)	141.91±17.09	137.02±14.01	0.117	140.73±17.48	139.94±22.3	0.842
Diastolic blood pressure (mmHg)	84.76±12.01	88.60±11.51	0.102	85.16±10.37	92.15±42.02	.252
BMI (kg/m^2)	26.40±4.49	26.11±3.82	0.726	26.98±4.69	25.86±3.90	0.193
Waist-hip ratio	0.95±0.06	0.96±0.08	0.325	0.94±0.069	0.93±0.06	0.576
Random Blood Sugar (mg/dl)	193.90±96.26	207.31±108.65	0.535	176.25±79.89	174.53±76.53	0.722

*Independent sample t-test

Table 5. Within group comparison of mean change in the blood pressure and blood sugar from baseline to post-intervention follow up (N=102)

Group	**Parameters**	**Mean±SD**	**p-value***
Intervention	Systolic Blood Pressure (mmHg)	⁻1.17657±13.88	0.548
	Diastolic Blood Pressure (mmHg)	0.4052±11.00	0.794
	Random Blood Sugar (mg/dl)	⁻17.6471±103.56	0.229
Control	Systolic Blood Pressure (mmHg)	⁻3.8562±23.21	0.241
	Diastolic Blood Pressure (mmHg)	3.5425±41.12	0.541
	Random Blood Sugar (mg/dl)	⁻32.7843±113.203	0.044

*Paired t-test

Table 6. Between group comparison of mean change in the blood pressure and blood sugar from baseline to post-intervention follow up (N-102)

Parameters	**Mean change**		**P-value***
	Intervention group (N=51) Mean ± SD	**Control group (N=51) Mean ± SD**	
Systolic Blood Pressure (mmHg)	⁻1.17657±13.88	⁻3.8562±23.21	0.481
Diastolic Blood Pressure (mm/Hg)	0.4052±11.00	3.5425±41.12	0.600
Random Blood Sugar (mg/dl)	⁻17.6471±103.56	⁻32.7843±113.203	0.483

*Independent t-test

Discussion

Smoking rate was higher as in this study compared to other studies.[3,6,10,11] At 6 months follow-up, the number of current smokers in our study reduced in both the groups. Other studies[3,4] also reported a reduction in smoking post intervention.

Both groups were found to be obese. Between group difference in pre-test and post-test in BMI was not significant in our study and similar finding was also reported by Kumari et al.[3] Al-Sinani et al[6] noted

no change in BMI in men at follow-up but women showed improvement.

In post-intervention follow-up both groups showed a reduction in mean systolic blood pressure but this was not significant. Similar finding was reported in other studies.[10,12] Kumari et al[3] reported a significant reduction both in systolic and diastolic blood pressure at 6 month and 12 month follow-up. This difference could be due to the different methods and duration of intervention employed in our respective studies.

In our study, there was a significant reduction in random blood sugar level in the control group from baseline to follow-up. When we compared the mean change in blood sugar between the intervention and control, there was reduction in both the groups and the reduction was more in the control group but not statistically significant. Other studies[3,6] showed a significant reduction in fasting and post prandial blood glucose.

Main study limitation was that participants could not be blinded due to the nature of the intervention. There might be a chance of contamination but that would have been minimal as the intervention and control communities were located far apart in distance. Practice questions were self-reported and there was a possibility of response bias or social desirability bias which can lead to under reporting of undesirable behavior.

The follow-up period of 6 months might not be enough for lifestyle changes and modifications which might require multiple sessions to reinforce the participants.

Conclusion

Our results found no effect of the intervention among people with hypertension and diabetes. Had we performed intensive intervention with several sessions, the results might have been more favorable than what we have found.

We recommend multiple counselling sessions with frequent household visits by trained health personnel. This might help in lifestyle modifications to see better outcomes in control of hypertension and diabetes. Further research with larger sample size and longer follow-up might be needed to assess the effect of lifestyle counselling.

Ethical Clearance: This study was approved by Research Ethics Board RIMS bearing reference no. A/206/REB/Prop(FP) 170/98/10/2022 dated 22/02/2022.

Conflicts of interest: Nil

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