Original Article

A Community Trial in Coastal Karnataka using Life Style Modifications to Assess its Impact on Hypertension and Diabetes

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Abstract

Introduction: In the management of hypertension and diabetes mellitus, a systematic response like modifications in lifestyles is needed along with the medication. The study was conducted to determine the impact of comprehensive lifestyle modifications on hypertension and diabetes and to compare it with that of physical activity alone as a health education intervention. **Materials and Method:** A risk factor-based community intervention trial was conducted for one year in 3 villages in coastal Karnataka. The sample of 305 was calculated depending on the expected change in blood pressure and an equal sample size was drawn from each of the villages using a systematic random sampling method. Baseline data on blood pressure level, random blood sugar, and HbA1c levels were recorded. After 1 year of intervention, all the parameters were further recorded along with the adherence to medication for these non-communicable diseases. **Results:** The mean difference between the groups suggested that participants with physical activity intervention reported a statistically significant reduction in systolic blood pressure. In the comprehensive lifestyle modification group, there was a significant reduction in both diastolic blood pressure and glycated hemoglobin levels (21 mmHg and 2.1%; $p < 0.001$). **Conclusion:** The study indicates that in the management of hypertension and diabetes mellitus, the impact of comprehensive lifestyle modifications was more significant compared to physical activity alone.

Keywords: Diabetes mellitus, hemoglobin A1c, hypertension, lifestyle, physical activity

Introduction

According to World Health Organization, non-communicable diseases (NCDs) are one of the 21st century's most significant burdens on global prosperity and productivity, accounting for over 85% of "premature" deaths occurring in low- and middle-income countries. An estimated 1.13 billion people worldwide have hypertension, most (two-thirds) living in low- and middle-income countries.[1] India being the "diabetes capital" of the world has a very high prevalence of metabolic syndrome comprising diabetes, hypertension, hypercholesterolemia, and obesity.[2] In 2019, 9.3% of the global adult population (20–79 years) was estimated to be living with diabetes, and is expected to increase to 10.2% in 2030 and 10.9% in 2045.[3] Diabetes prevalence has been raising more rapidly in low- and middle-income countries than in high-income countries.[4]

An unhealthy lifestyle can contribute to the development of risk factors (NCDs) such as diabetes, hyperlipidemia, cardiovascular diseases (CVDs), and hypertension. About 60% of health-related factors to individual and quality of life are correlated to lifestyle according to World Health Organisation (WHO).[5] An increase in the risk of dying from an NCD increases with the use of tobacco, physical inactivity, the harmful use of alcohol, and unhealthy diets. 1.6 million

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NCD deaths annually can be attributed only to insufficient physical activity. Globally the attributable leading metabolic risk factor for NCD deaths is elevated blood pressure (19%).[1] Understanding the serious impact of modern lifestyle on health is an emerging new concept.

Conventionally our attitude in managing the NCDs (Hypertension and diabetes) had been dedicated to people with established disease through medical care delivery; the strategy has fewer probabilities of benefits in reducing the global impact of NCDs. However clinical trials on several antihypertensive drugs demonstrated only a third of treated hypertensive patients achieve the target values.[6] antidiabetic medication only has shown varying effectiveness ranging from 43%-57% in achieving HbA1c <7%.[7] Decreasing the effect of NCDs requires a more systematic response. Modification or change in lifestyles such as adequate dietary habits and regular practice of physical activities are important components that have been shown to significantly reduce morbidity and mortality rates for most chronic NCDs such as diabetes, hypertension, etc.[8] Whenever appropriate, the more recent guidelines for the management of arterial hypertension recommend establishing lifestyle measures, in all hypertensive patients, including those who require drug treatment.[9]

In the current scenario available literature about the effects of lifestyle modification, in terms of increasing the quantity and quality of physical activity, on overall glycemic control independently or in combination with hypoglycemic drugs are rare. The majority of the studies done in the world support weight reduction and exercise programs along with appropriate drug therapy.[10-12] There is a scarcity of such studies in the Indian population more so specifically in the south region. Therefore, the present study was undertaken to determine the impact of planned intense comprehensive lifestyle modifications like diet, exercise, and tobacco cessation along with regular treatment in patients of hypertension and diabetes with a reduction in blood pressure level and blood sugar control among patients of hypertension and diabetes mellitus respectively. Also, an effort was made to compare the impact of comprehensive lifestyle modifications with that of physical activity alone in reducing blood pressure and sugar level control in patients with hypertension and diabetes. The effect of the intervention on drug adherence was considered as a secondary objective.

Methodology

A community trial was conducted in 3 villages in coastal Karnataka which were situated at an average distance of 12 km from the institution over a period of 2 years from 1st Oct 2018 to 20 Oct 2020. The timeline followed for the study was:

Preparation of modules and questionnaire and validation: 4 months (Oct 2018- Jan 2019)
Training of Health workers for data collection: 1 month (Feb 2019)
Data collection: baseline survey: 1 month (Mar 2019)
Rigorous training of the participants with the modules through trained health workers 2 months (Apr -May 2019)
Followup: 10 months (June 2019 - March 2020)
Endline survey: 1 month (Apr 2020)
Data entry and Analysis: 3 months (May-Jul 2020)
Report writing and Manuscript preparation: 3 months (Aug – 20 October 2020.)

Study population

All patients diagnosed with hypertension and diabetes, at the beginning of the study, were contacted for the study. Those who gave consent and followed the criteria for inclusion and exclusion were enrolled. Inclusion criteria were individuals aged more than 18 years, diagnosed with hypertension and/or diabetics at least 2 years back, on regular treatment, had no drug change in the past 1 year, and random blood sugar (RBS) levels high, and had Hb1Ac more than 7%.[2] In addition to these, the study participants for hypertension were those who were on treatment but with SBP of more than 130 mm Hg or DBP of more than 90 mm Hg. The participants who were both hypertensive as well as diabetic were assessed for control of the disease condition and were included in either of one group. The exclusion criteria were; those with malignant hypertension, secondary hypertension, pregnancy or patients with severe disability, and participants who are confused or comatose and unable to follow instructions.

Sampling procedure

The sample size was calculated assuming the estimated prevalence of 7% [expected change in blood pressure and also the prevalence of diabetes in rural areas (7%) reported from previous studies],[13] absolute precision of 5%, confidence interval of 95% and design effect as 1. The calculated sample size was 99 for one village having a population of about 5000 by means of Open epi software using formula n = [DEFF*Np (1-p)]/[(d2/Z21-α/2*(N-1)+p*(1-p)].

Now as we included 3 villages for study, 100 study subjects each from 2 villages and 105 in the third village were selected by systematic random sampling technique using the family folders maintained in the subcentres. Hence the total sample for the study was 305. These participants had Hypertension or diabetes mellitus or both. It was decided that 30% of participants will be having diabetes as the study is taken up to determine the effect of both hypertension and diabetes.

Study groups

The study samples from each village were randomly assigned to one of two intervention groups and the third as a control group 1 was introduced with a module for physical activity alone (n = 105); group 2 with a comprehensive lifestyle modification module (n = 100); and the third group as control (n = 100).

Data collection

The baseline survey was initiated and data was collected for demographic data, practice of physical exercise, blood pressure measurements, dietary consumption, history of smoking and

alcohol intake, for regularity and dosage using a questionnaire by the participants. Treatment was never deferred during the course of the study without disturbing regular treatment.

At the end of 12 months of the intervention end line survey from the participants for the blood pressure and Random Blood Sugar with the Hb1Ac for all the participants was conducted.

Intervention

The specific module with good evidence for physical activity, and diet modification separately for hypertension and diabetics was prepared in simple format by experts, which had undergone face validation and linguistic validation. The comprehensive lifestyle modification module comprised of dietary changes like intake of salt and sugar, oil consumption, fruit, and vegetable servings, number of meals, modifications in the habits of alcohol intake and smoking in terms of quitting the habit, adoption of regular physical exercises involving the moderate type of activity. The module for physical activity consisted of the nature of work, time duration spent, and number of days in a week spent on performing these activities. The training of health workers on the modules and data collection was carried out.

The modules were introduced through trained health workers to the participants with the involvement of a family members who actually cooks at home for at least the last 2 months. The basic idea behind training of the participant and the family member was to help the person carry out lifestyle modification. Introduction of the module to participants with initial 2 months rigorous training and 10 months follow up was followed.

After intervention, BP was checked every month. The BP was measured by trained medico-social workers using calibrated automatic BP apparatus. Training was given for 5 hours a day for 6 days. The recording of BP was carried out with standardized electronic BP monitoring equipment in a sitting posture following WHO criteria considered for the study. The average of two readings taken in 5 min intervals was taken into account for the final reading.[14] Also, the participant's baseline perception, food habits, physical activity practice, and treatment adherence were recorded.

Tests for RBS and HbA1c were conducted 2 times, at an interval of 6 months: one at the 6th month and the second at the 12th month. One day of training was conducted for these health workers on the use of the glucometer instrument, and the procedures to be followed to obtain consent and blood samples for standardization. Random blood glucose measurements were obtained regardless of the time of the last meal for the convenience of participants using the glucose oxidase method.[2] Measurements were obtained with a finger prick to obtain fresh capillary whole blood under the supervision of trained staff. The procedure was explained and verbal permission was obtained from the respondents before the samples were taken by health workers. The instrument was calibrated to provide plasma equivalent results. Tests for random blood sugar (RBS) levels were carried out 2 times on each participant and those with >200 mg/dl blood sugar levels in any of the 2 readings were tested for Hb1Ac using the immune-turbidimetric method.[2]

To avoid bias the measurements were obtained under the supervision of trained staff and care was taken by training the health workers before initiation of the introduction of modules. The usage of calibrated instruments and standardized techniques to measure the parameters were followed.

At the end of the year there was survey was completed with changes in food habits and physical activity were recorded. The measurements for the blood pressure and Random Blood Sugar with the Hb1Ac for all the participants were recorded [Figure 1].

Statistical analysis

Data were analyzed using IBM SPSS version 19 in terms of frequencies, mean, and standard deviations. Wilcoxon rank test was used before and after statistical analysis Freidman test and Chi-square tests were used between the groups for statistical analysis.

Results

Of the total 305 participants, 211 (70%) were hypertensive and 94 (30%) were diabetic. All 211 hypertensive patients and 91 out of 94 diabetics were included in the study. As the three diabetic patients were shifted to other places there was a loss to follow up. [Figure 1] The mean age of all the study participants was 58.8 ± 11.4 years 112 (36.7%) participants were males and 193 (63.3%) were females. The majority of the hypertensive and diabetic participants belonged to the 41 to 60 years age group, of which the majority were falling in the range of 140-160 mmHg of SBP and 7-9% of HbA1c values. Most of the hypertensive (40.6%) and diabetic patients (22.6%) were females [Tables 1 and 2].

The mean SBP and DBP at baseline in group-1 were reduced by 26.32 mm Hg and 18.4 mm Hg respectively and in group-2 reduced by 10.27 mm Hg and 30.76 mm Hg respectively. The control group did not show any much reduction. This difference between groups was statistically significant focusing to say that DBP reduction was maximum in comprehensive lifestyle modification compared to physical activity alone. The reduction in SBP is high among the physical activity group [Table 3].

The frequency of SBP in lower range (120-140 mmHg) was increased by 76% after intervention as compared to higher ranges (>160 mm Hg) which are reduced by 100% in group-1. This difference was due to a shifting in SBP frequency towards lower ranges from the high range (>160 mm Hg) which was statistically significant. The overall reduction in uncontrolled SBP in group-1 was 32%. Similarly, in group-2, there was an increase in the frequency of SBP in the lower range (120-140 mmHg) by 78% after intervention as compared to higher ranges (>160 mm Hg) which are reduced by 30.6% Overall reduction in uncontrolled SBP in group-2 was 7%. The

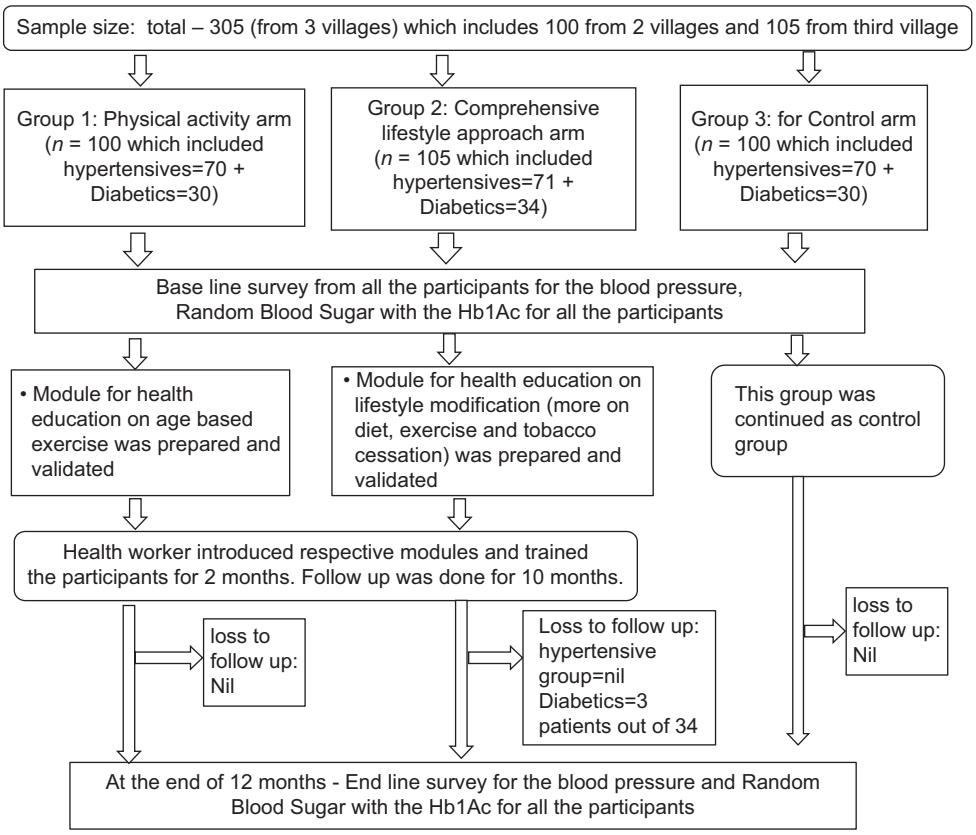

Figure 1: Community trial protocol

Table 1: Age & Gender wise distribution of Hypertensive participants based on Systolic Blood PressureSBP

(mm Hg)	120-140 (%) n=24	140-160 (%) n=115	>160 (%) n=72	Total n=211
Age Group (years)				
Upto 40	2 (13.3)	10 (66.7)	3 (20.0)	15 (100)
41 to 60	13 (11.8)	69 (62.7)	28 (25.5)	110 (100)
61 to 80	9 (10.5)	36 (41.9)	41 (47.7)	86 (100)
Gender				
Female	14 (11.3)	72 (58.1)	38 (30.6)	124 (100)
male	10 (11.5)	43 (49.4)	34 (39.1)	87 (100)

Table 2: Age & Gender wise distribution of diabetic participants based on HbA1c

HbA1c (%)	7-9 (%) n=60	>10 (%) n=34	Total n=94
Age Group (years)			
Upto 40	5 (55.6)	4 (44.4)	9 (100)
41 to 60	30 (60.0)	20 (40.0)	50 (100)
61 to 80	25 (71.4)	10 (28.6)	35 (100)
Gender			
Female	43 (62.3)	26 (37.7)	69 (100)
male	17 (68.0)	8 (32.0)	25 (100)

differences between the two groups and the controlled group are statistically significant [$p < 0.001$] [Table 4].

The frequency of DBP in the range of 91-100 mmHg decreased by 87% but there was a 100% reduction in group >110 mmHg. Overall reduction in uncontrolled DBP was 66% in group-2 which is the highest as compared to group-1 (42%). The group-1 had a reduction in DBP by 100% in the range of 100-110 mm Hg and >110 mm Hg but no difference in numbers with 90-110 mmHg DBP. No reduction in DBP levels was observed in the control group. The differences between the two groups and the controlled group are statistically [$p < 0.001$] [Table 5].

The mean HbA1c reduced by 2.8% from baseline after intervention in group-2 and only 1.84% reductions from baseline in group-1. The group with no intervention showed Hb1Ac increased over a period of time [Table 6]. The frequency of Hb1Ac was found significantly high in the lower range (7-9%) after the intervention compared to the higher range (>10%), in both group-1 and group-2, but the reduction in uncontrolled diabetes is more than 22% in the group with comprehensive lifestyle modification than physical activity alone group-19% with statistically significant ($p < 0.01$) [Table 7].

The frequency of timely intake of drugs after intervention has increased after intervention in both groups but is higher in comprehensive lifestyle modification but not statistically significant. There was not much difference among those who missed drugs occasionally. The regular missing of drugs has drastically reduced [Table 8].

Table 3: The results of lifestyle modification and physical activities on mean blood pressure levels

Hypertensive participants	Baseline SBP Mean (SD)	End line, SBP Mean (SD)	Change from baseline to end line BP,	Baseline DBP Mean (SD)	End line, DBP Mean (SD)	Change from baseline to end line BP,
Group -2 comprehensive lifestyle modification module (n=70)	158.69 (13.51)	148.22 (14.32)	-10.27	91.66 (13.25)	67.01 (17.01)	-30.65
Group -1 physical activity alone (n=71)	157.62 (16.44)	130.97 (29.67)	-26.32	88.84 (11.52)	79.79 (17.32)	-18.94
Control (n=70)	157.17 (16.72)	156.07 (16.7)	-0.9	83.67 (7.89)	82.76 (7.76)	-0.9
p value	0.000*			0.000*		

*Freidman test was used between the groups for statistical analysis

Discussion

The present study reported that most of the participants were in the middle age group (41-60 years) and both hypertension (58.8%) and diabetes (73.4%) were more among females. After intervention with the modules significant improvement in control of SBP, DBP, and HbA1c was noticed in both groups 1 and 2 compared to the control [$p < 0.001$]. It was also noticed that only the mean SBP was significantly improved in group 1 where only the physical activity module was introduced when compared to mean DBP and mean Hb1Ac, which were significantly reduced in group-2, where comprehensive lifestyle modification was introduced [$p < 0.001$].

The frequency change in the ranges of SBP from higher to lower was observed more with physical activity alone modification compared to modifications for the comprehensive lifestyle and even significant change in SBP frequency was noticed in between the groups [$p < 0.001$]. This suggests that for controlling SBP, physical activity is a better option than comprehensive lifestyle modification. The group with comprehensive lifestyle modifications also had a reduction to a lower level but wasn't able to bring in a controlled fashion for SBP. There is a clear message that comprehensive lifestyle modification is good but difficult to achieve, so even if only physical activity is initiated there will be a reduction in blood pressure levels and HbA1c. This proposes that the behavioral change of the participants towards the adoption of lifestyle measures along with their regular medication assist in the good control of hypertension and diabetes mellitus.

The frequency change in DBP from higher to lower range was observed more marked with comprehensive lifestyle modifications compared to physical activity modification alone and even significant change in DBP frequency was noticed between the groups [$p < 0.001$]. Similar reports were given by Yang MH *et al*.,[8] that increased physical activity was associated with successful blood pressure control even Beilin LJ *et al*.,[15] reported in the review that randomized controlled trials of the effects of exercise training showed more consistent fall in blood pressure in those with established hypertension and reductions in SBP was observed around 7 to 11 mm Hg in hypertensives. The improvement in blood pressure levels indicates that systolic blood pressure levels were better controlled by physical activity and diastolic blood pressure and diabetes mellitus were better controlled by a comprehensive lifestyle approach. This further suggests that behavioral changes as interventions should be viable treatment options, at least among those hypertensive individuals who are motivated to make lifestyle changes.[16]

A substantial reduction in the frequency of Hb1Ac was observed in both the groups with intervention but it was more so with comprehensive lifestyle modifications. Also, significant change in the frequency of HbA1c above 10% was observed. Even significant change in Hb1Ac frequency was noticed between the groups [$p < 0.001$] which says this part of a reduction in Hb1Ac clearly needs comprehensive lifestyle modification and only physical activity will not be a good intervention. Yamaoka K *et al*.,[17] revealed the effects of lifestyle modification compared with exercise were not significant in controlling type 2 diabetes. Church TS *et al*.,[18] revealed among patients with type 2 diabetes mellitus, a combination of physical exercises with the control group without exercise improved HbA1c levels. This was not achieved by aerobic or resistance training alone. The systematic review of the 53 studies that evaluated 66 lifestyle intervention programs done by Balk EM *et al*.,[19] reported that compared with usual care, diet, and physical activity promotion programs reduced the burden of type 2 diabetes incidence while improving other cardiometabolic risk factors. Sanghani NB *et al*.,[2] noticed exercise-induced improvements in glycemic control were greater among persons with higher baseline hemoglobin A1c values (>7%).

Golshahi, *et al*.[20] reported that education-based behavioral interventions could modify taking antihypertensive drugs regularly showed significant improvement similar to the present study though it was not a statistically significant difference. Girija Kumari *et al*.[21] reported in their study on the effectiveness of lifestyle modification counseling among diabetics showed significantly lower adherence to regular medication which is contrary to our study but there was a definite improvement noticed after intervention suggesting behavioral interventions like comprehensive lifestyle modifications may improve the drug adherence among both patients with hypertension and diabetes mellitus.

Limitations

Though the present study focused on rural areas, to generalize our findings across all rural communities further research is

Table 4: Change in Frequency of uncontrolled Systolic Blood Pressure before and after intervention

Hypertensive participants	SBP (121-140 mmHg)			SBP (141-160 mmHg)			SBP (≥161 mmHg)			Total		
	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)
Group -2 comprehensive lifestyle modification module (n=70)	5 (7.1)	20 (28.6)	>78%	38 (54.3)	40 (57.1)	>6%	27 (38.6)	7 (10)	<30.6%	70	67	<7%
Group -1 physical activity alone (n=71)	10 (14.1)	38 (53.5)	>76%	37 (52.1)	22 (31.0)	<42%	24 (33.8)	0 (0)	<100%	71	60	<32%
Control (n=70)	9 (12.9)	10 (14.3)	>5%	40 (57.1)	39 (55.7)	<2%	21 (30)	21 (32.9)	>6.9%	70	70	0%
p value		0.0001*			0.0001*			0.0001*				

*Chi square calculated for difference between groups seen, df-2

In group 1 & 2 after intervention due to the reduction of SBP levels to lower ranges difference in numbers (frequencies) before and after groups varies and in some subjects SBP noticed was even below 120 mm of Hg

Table 5: Change in frequency of uncontrolled Diastolic Blood Pressure before and after intervention

Hypertensive participants	DBP (81-90 mmHg)			DBP (91-100 mmHg)			DBP (101 mmHg & above)			Total		
	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)
Group -2 comprehensive lifestyle modification module (n=60)	24 (34.3)	9 (12.9)	<62%	26 (37.1)	5 (7.1)	<87%	10 (14.3)	0 (0)	<100%	60 (60%)	14 (14%)	66%
Group -1 physical activity alone (n=58)	34 (47.9)	34 (47.9)	0%	13 (18.3)	0 (0)	<100%	11 (15.5)	0 (0)	<100%	56 (56%)	34 (34%)	42%
Control (n=47)	40 (57.1)	39 (55.1)	<3.9%	7 (10)	7 (10)	0%	0 (0)	0 (0)	0%	47 (47%)	45 (45%)	4%
p value		0.0001*			0.0001*			0.0001*				

*Chi square calculated for difference between groups seen, df-2

Some of the total participant from all the groups had only >120 mmhg but had DBP <80.

In group 1 & 2 after intervention due to the reduction of DBP levels to lower ranges difference in numbers (frequencies) before and after groups varies and in some subjects DBP noticed was even below 80 mm of Hg

Table 6: The results of lifestyle modification and physical activities on mean HbA1c

Diabetic participants	BaselineHbA1c Mean (SD)	End line, HbA1c Mean (SD)	Change from baseline to end line HbA1c
Group -2 comprehensive lifestyle modification module (n=30)	10.32 (1.65)	8.22 (1.83)	-2.10
Group -1 physical activity alone (n=31)#	9.11 (1.82)	7.97 (3.59)	-1.86
Control (n=30)	8.42 (1.58)	9.02 (1.62)	1.4
p value	0.04*		

#3 patients of 34 diabetes patients did loss to follow up for HbA1c

*Freidman test was used between the groups for statistical analysis

Table 7: Change in Frequency of uncontrolled diabetics before and after intervention

Diabetic participants	Hb1Ac (7-9%)			Hb1Ac (10% and above)		
	Baseline, n (%)	End line, n (%)	Change from baseline to end line, (%)	Baseline, n (%)	End line, n (%)	Change from baseline to end line (%)
Group -2 comprehensive lifestyle modification module (n=30)	11 (36.7)	16 (53.3)	>34%	19 (63.3)	7 (23.3)	<65%
Group -1 physical activity alone (n=31)#	17 (54.9)	15 (50)	<8%	14 (51.6)	9 (40.9)	<25%
Control (n=30)	24 (81)	23 (79.6)	<2%	6 (19)	7 (21.2)	>2%
p value		0.0001*			0.0001*	

#3 patients of 34 diabetes patients did loss to follow up for HbA1c

*Chi square calculated for difference between groups seen, df-2

In group 1 & 2 after intervention due to the reduction of HbA1C levels to lower ranges difference in numbers (frequencies) before and after groups varies and in some subjects HbA1C level noticed was even below 7%

Table 8: The adherence to medication and attitude change towards the disease before and after the intervention

Timely drug intake		Yes			Missed occasionally			Missed regularly		
Study participants		Baseline, n (%)	End line, n (%)	p	Baseline, n (%)	End line, n (%)	p	Baseline, n (%)	End line, n (%)	p
Group -2 comprehensive lifestyle modification module	Hypertensive's (n=70)	22 (31.4)	27 (38.6)	0.373	21 (30.0)	23 (32.9)	0.718	27 (38.6)	20 (28.6)	0.211
	Diabetics (n=30)	7 (23.3)	9 (30.0)	0.561	12 (40)	15 (50)	0.435	9 (30)	6 (20)	0.373
Group -1 physical activity alone	Hypertensive's (n=71)	18 (25.3)	24 (33.8)	0.271	27 (38.0)	22 (31.0)	0.378	26 (36.6)	25 (35.2)	0.865
	Diabetics (n=34)	8 (23.5)	11 (32.3)	0.417	20 (58.8)	18 (52.9)	0.624	6 (20)	5 (14.7)	0.741
Control	Hypertensive's (n=70)	15 (21.4)	16 (22.9)	0.841	31 (44.3)	30 (42.9)	0.865	24 (34.3)	26 (37.1)	0.726
	Diabetics (n=30)	8 (26.7)	9 (30)	0.771	15 (50)	13 (43.3)	0.603	7 (23.3)	8 (26.7)	0.764

*Chi square calculated for before and after intervention in each group

required due to heterogeneity observed in the community in a vast country like India. The multiple BP and other measurements made during the study may also have had some intervention effects in all the groups. The other confounders in the study might have been studied and analyzed in the study is one more limitation. Only intervention groups led to a reduction in BP and HbA1C levels may reflect the high level of motivation among study participants compared control group which was maintained by trained personnel. Further research is needed to capture the direct impact of lifestyle changes and adopt such changes in behaviors in rural communities without assistance from trained personnel.

Conclusions

In the present study conducted on uncontrolled patients with hypertension and diabetes mellitus and on medication, the introduction of a comprehensive lifestyle modification module had a more significant impact in achieving better rates of control of blood pressure and diabetes mellitus compared to physical activity alone. These changes are sufficient to reach treatment goals non-pharmacologically in many individuals not only in low ranges of blood pressure but also in high ranges and also improve the medication adherence by bringing up behavioral changes among the patients. The study also puts forth similar models which can be developed for non-communicable disease control programs using local vernacular language and community participation that will reduce the burden on the medical care delivery system and an overall increase in a healthy population. It may also lead to a step forward in public health programs like hypertension and diabetes control and helps in understanding the effect of community approach and participation in reducing the burden.

Ethical approval

Obtained from Institutional Ethical Committee [Name – Institutional ethical committee, Nitte University, Number: INST.EC/EC/093/2017-18, Date of approval: 27/09/2017]

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Data availability

Deidentified end-line data will be made available only for research purposes upon request.

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Conflicts of interest

There are no conflicts of interest.

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