

Effect of non-pharmacological interventions on adults with cardiovascular risk in a rural community

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ABSTRACT

Background: Non-communicable diseases (NCDs) are the leading cause of morbidity and mortality worldwide, with three-fourth of deaths occurring in low- and middle-income countries (LMICs) like India. Currently, three out of the top five causes of morbidity and mortality in the country are NCDs. **Objective:** This study evaluated the impact of non-pharmacological interventions as a comprehensive approach toward adults with cardiovascular risk in Indian rural communities. **Material and Methods:** It was a quasi-experimental study conducted in Rishikesh, a holy city of Uttarakhand known as the world's yoga capital at the foothills of Himalaya. Out of 87 villages, four villages were randomly selected. Eighty-eight participants were enrolled (22 from each village and household). It was a multi-stage random sampling. All the participants with cardiovascular risk and age >30 years were recruited. Pregnant, severely ill, and unwilling to consent were excluded. Non-pharmacological intervention as a comprehensive approach, including yoga, meditation, mental health counseling, dietary counseling, tobacco, and alcohol cessation counseling has been provided to cardiovascular risk participants. **Results:** Data of 76 participants were analyzed as the per-protocol analysis method. The drop-out rate was 13.63%. Male and female participants were 52 (68.4%) and 24 (31.6%) in number. Mean age of the participants was 55.28 ± 13.64 years. Diastolic blood pressure or DBP ($P = 0.017^*$), systolic blood pressure or SBP ($P = 0.008^{**}$), waist circumference (WC) ($P = 0.000^{**}$), waist-to-hip ratio ($P = 0.000^{**}$) and waist-to-height ratio ($P = 0.000^{**}$) significantly improved in the post intervention group. **Conclusion:** Non-pharmacological interventions as a comprehensive approach can significantly reduce modifiable risk factors for cardio-metabolic disease.

Keywords: Alcohol abuse, dietary counseling, mental health counseling, tobacco cessation, yoga

Introduction

Globally, cardiovascular diseases (CVDs) contributed to 31% of all deaths, including 85% of deaths due to non-communicable diseases (NCDs). In 2015, CVDs caused 37% of deaths in people with less than 70 years in low- and middle-income countries (LMICs).^[1] NCDs are the leading cause for morbidity and mortality worldwide, with three-fourth of deaths occurring

in LMICs like India. In 1990 and 2016, disease burden increased from 48% to 75% in India due to NCDs only.^[2] It was also observed that hypertension and diabetes are highly prevalent among the Indian population, representing a high stroke and heart attack rate.^[3] From 1990 to 2016, in a detailed analysis of cardiovascular risk factors in India, systolic blood pressure (SBP) and dietary pattern were found to be equal contributors to CVDs (56.4%). Next to them, raised total cholesterol (29.4%), tobacco use (18.9%), raised fasting plasma glucose (16.7%), and raised body mass index (BMI) (14.7%) were reported as the most prevalent risk factors for CVDs in Indian population.^[4] Age and gender are non-modifiable risk factors but the addiction of tobacco, smoke, alcohol, unhealthy diet, physical inactivity, and overeating are the

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influential modifiable risk factors for heart diseases and stroke. These risk factors may affect blood pressure (BP), blood glucose, blood lipids, and weight as well. However, these factors can be minimized with behavioral modification.^[1,5] Timely identification and management are required to delay the progression of future complications. Yoga can control physiological variables such as BP, respiration rate, heart rate, and metabolic rate to improve overall exercise capacity. Yoga reduces stress-mediated inflammation and metabolic dysfunction, modulates cardiovascular reactivity to stress, and modulates health behaviors that pose a CVD risk.^[6] Yoga improved self-rated health quality after an acute myocardial infarction as cardiac rehabilitation in Indian participants but the researcher stated a lack of statistical power.^[7,8] Along with the evidence of poor adherence to yoga interventions,^[9] we also planned to incorporate all of these facts and evaluate the comprehensive approach, including yoga, meditation, mental health counseling, dietary counseling, tobacco, and alcohol cessation counseling, with a longer duration on adults with metabolic risk in Indian rural communities.

Material and Methods

Study design, sampling technique and setting - A quasi-experimental study was performed in Rishikesh, a holy city of Uttarakhand known as the world's yoga capital at the foothills of the Himalayas. Out of 87 villages, four villages were selected randomly. Twenty-one participants were selected from each village and household. All the participants aged >30 years were recruited in the study as per NCD control's national guidelines [Figure 1].

Sample size

Based on a previous study, the mean fall in BP after exercise was documented to fall from 132.3 ± 11.3 to 126.9 ± 10.3 .^[10] With a confidence interval of 95% and power of 90%, the total sample size came out to be 88, considering a 20% dropout rate.

Inclusion and exclusion criteria

- All participants who had metabolic syndrome (hyperglycemia with fasting blood sugar (FBS) ≥ 100 mg/dL or HbA1c $\geq 5.6\%$; hypertension with SBP ≥ 130 mmHg or DBP ≥ 85 mmHg; smoking; BMI $>25\%$ with WC for men >90 cm, WC for women >80 cm; 3/5 risk assessment) were included for intervention.
- Pregnant and severely ill participants, and those unwilling to consent were not included.

Ethical consideration

Ethical approval (AIIMS/IEC/19/579) was taken from Institutional ethical committee.

Non-pharmacological interventions

Non-pharmacological interventions as a comprehensive approach, including yoga, meditation, mental health counseling,

group counseling sessions (dietary), tobacco and alcohol cessation counseling were provided to individuals with cardiovascular risk factors, in the following manner.

Yoga therapy for six months: It consisted of weekly yoga sessions for one hour in a common place followed by doorstep encouragement to follow the asana and pranayama at home under the supervision of yoga teacher. A total of 26 sessions were conducted.

Yoga practices

Cleansing practices: Kapalbhathi, agnisar kriya, surya namaskar

Asanas: Trikonasan, tadasan, yoga mudra, tiryak tadasan, veerasan, vakrasan, ardhmatsyendrasan, ushtrasan, bhujangasan, sarvangasan, dhanurasan, naukasan, pavanmuktasan, setubandhasan, matsyasan, shavasana.

Regulated breathing practices: Pranayama, chandra bhedan, bhastrika, anulom vilom, bhramari, sitkari

Hand gestures: Linga mudra, surya mudra, prana mudra, apan mudra, gyan mudra, meditation

Yogic relaxation: Yoga nidra^[11,12]

Group counseling sessions (dietary): This consisted of a client attending a total of three sessions with a counselor, with intensive door-to-door follow-up by a medical social worker (MSW).

Tobacco and alcohol cessation clinics were started once a week for a habitual smoker.

Participants were motivated for early morning exercise for at least for 30 minutes in a day and were asked to participate in yoga sessions as well. Risk factors for CVDs have been illustrated with pictorial and audio-visual aid.

A total of three counselling sessions for each participant in a group of 22, such as behavioral therapy, stress management, coping strategies and resilience for family and domestic hassles, relaxation exercises and meditation were conducted among participants.

Group counselling for nutrition including Dietary Approach to Stop Hypertension (DASH) diet, cultural and local dietary habits and its effects on cardiovascular health were also emphasized.

Counseling for high glycemic index and saturated food and its effect on cardiovascular health were also demonstrated with the help of pictorial information.

Smoking cessation session was started under this project which was based on weekly consultation on every Sunday. Behavioral and preventive therapy was used only. The time for each session was 30 to 45 minutes for each group.

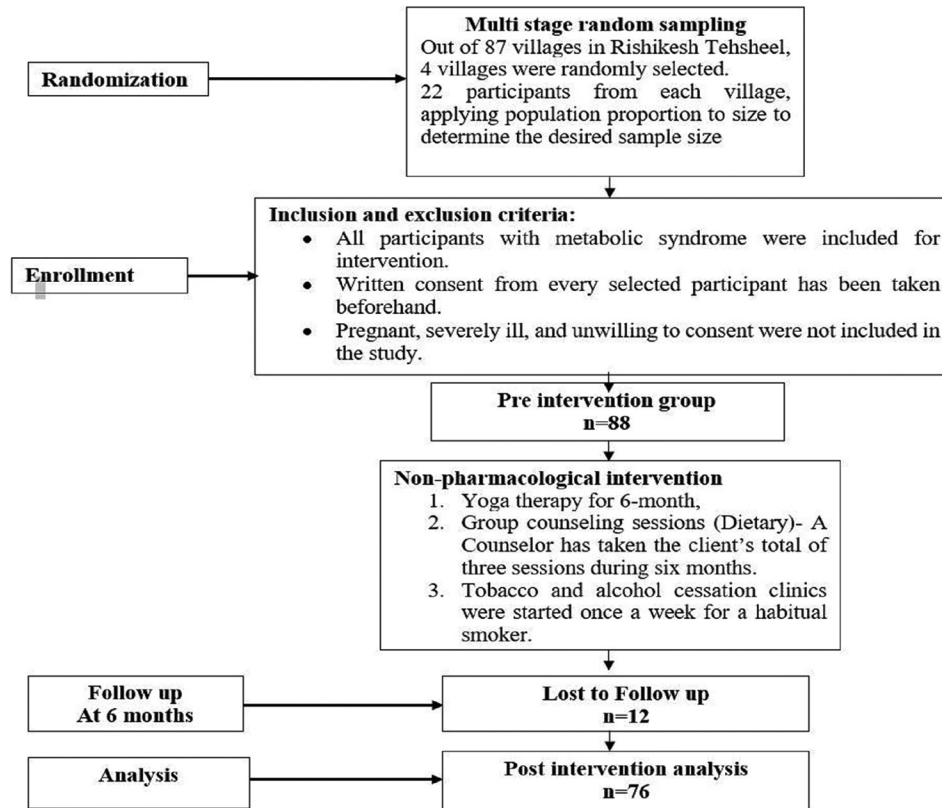


Figure 1: Flowchart of the study

Metabolic syndrome

Hyperglycemia is considered as (FBS ≥ 100 mg/dL or HbA1c $\geq 5.6\%$); hypertension (SBP ≥ 130 mmHg or DBP ≥ 85 mmHg); smoking; BMI $> 25\%$, WC for men > 90 cm, women > 80 cm; 3/5 risk assessment.^[13]

Cardiovascular diseases

It includes coronary artery diseases (angina and myocardial infarction).^[14] Other CVDs are stroke, hypertensive heart disease, heart failure, rheumatic heart disease, arrhythmia, congenital heart disease, cardiomyopathy, valvular heart disease, carditis, peripheral artery disease, thromboembolic disease, aortic aneurysms, and venous thrombosis.^[15]

Cardiovascular risk factors

Non-modifiable factors include age, gender, and family history. However, modifiable factors include high BP, high sugar, obesity, physical inactivity, unhealthy diet, stress/depression, alcohol and tobacco, and poor health-seeking behaviors.^[16]

Data collection and Data analysis

After six months, baseline parameters were re-measured to assess the impact of non-pharmacological intervention. Data was compiled in a Microsoft Excel sheet and analyzed in Statistical Package for the Social Sciences (SPSS) software version 23. Results of the study were tabulated in the form of frequency and

percentage. Paired *t* test was applied to assess the differences in pre- and post-intervention groups. A *P* value less than 0.05 with 95% confidence interval was considered significant.

Results

Table 1

A total of 76 participants were analyzed for an outcome as per the protocol analysis method. The dropout rate was 13.63%. A majority (68.4%) of the participants were male. Mean age of participants was 55.28 ± 13.64 [Table 1].

We noted a small but significant mean reduction in the post-intervention group such as SBP, waist-to-hip ratio, DBP, WC, and waist-to-height ratio [Table 2].

DBP ($P = 0.017^*$), SBP ($P = 0.008^{**}$), WC ($P = 0.000^{**}$), waist-to-hip ratio ($P = 0.000^{**}$) and waist-to-height ratio ($P = 0.000^{**}$) showed significant difference between the pre- and post-intervention groups. We did not observed any significant mean difference in the BMI ($P = 0.768$) of both groups [Table 3].

Discussion

Yoga as a combination of physical, mental and spiritual disciplines keeps our body healthy, our mind calm, and balances

our nervous system.^[17] It stimulates the vagus nerve, enhances parasympathetic activity, and leads to positive cardiovascular function changes.^[17] Evidence suggest that all interventions such as yoga, dietary intervention, and behavioral counseling individually affect anthropometric parameters such as body weight, BMI, fat-free mass, fat mass, WC, and metabolic parameters (SBP and DBP) in overweight people.^[18,19] In resource-limited countries, BMI, duration of diabetes, DBP, body-fat percentage, SBP, and

cholesterol had significant association with insulin resistance in type 2 diabetes mellitus (T2DM) patients, which affect the quality of life of both genders in a nearly similar pattern.^[20,21]

Yoga therapy and dietary counseling

The present study's results were supported by a study in which routine yoga practice had association with weight loss in overweight individuals.^[22] Yazdanparast F *et al.*^[23] found that yoga practice with a less restricted diet is more effective in losing weight than a typical energy restriction diet. In the present study, we also noted a significant decline in WC, waist-to-hip ratio, and waist-to-height ratio in the post-intervention group. However, researchers found that intensive lifestyle changes may lead to a reversal of coronary atherosclerosis after five years.^[24] In a community trial, yoga therapy was effective in reducing DBP.^[25] In contrast, a trial reported a significant reduction in BP in both groups.^[26]

Education and counseling

A study reported on the significant impact of education and counseling on the health promotion model in promoting healthy behaviors among obese women. A researcher reported 24% more reduction in BMI in the post-intervention group.^[27] In a systematic review of hospital-based studies, behavioral modification and counseling significantly affected physical activity and reduced the BMI, and WC of patients.^[19] In our study, we found a significant reduction in the waist-to-hip ratio in the post-test but not with BMI. Murtagh EM *et al.*^[28] had not observed any difference in reducing sedentary behavior. Consistent with the present study, a researcher reported that e-counseling at 12-month endpoints reduced the DBP, non-high-density lipoprotein, total lipoprotein cholesterol, and cholesterol, total lipoprotein cholesterol/high-density lipoprotein cholesterol ratio in a multicenter trial.^[29] A study evaluated the effectiveness of diabetes education and self-management and showed a significant weight reduction of 2.98 kg in the intervention group; it also affects the smoking, behavior, and understanding toward disease and their belief positively at 12 months endpoint.^[30] Although these studies' findings were consistent with our study, we have not noted a reduction in these patients' BMI. These variations may be explained by 43.4% of participants with T2DM and 47.4% of participants with hypertension.

After reviewing the literature, we noticed that researchers had observed the outcomes with single intervention. Few researchers had observed the outcomes with a combination of yoga therapy and dietary therapy. However, our study contributes to the present state of knowledge that a comprehensive approach including yoga therapy with meditation, mental health counseling, dietary counseling, tobacco, and alcohol cessation counseling for the long term, may provide better outcomes regarding anthropometric and metabolic parameters in the rural community.

This study adds to the knowledge of the primary care physician as it is a community trial of non-pharmacological intervention

Table 1: Characteristics of participants n=76

Variables	Categories	F (%)	
Age (years)	Mean±SD	55.28±13.64	
	<35		4 (5.3)
	36-50		24 (31.6)
	51-65		30 (29.5)
	>65		18 (23.7)
Gender	Male		52 (68.4)
	Female		24 (31.6)
Qualification	Uneducated		6 (7.9)
	Primary school		6 (7.9)
	Matriculation		28 (36.8)
	Higher secondary education		8 (10.5)
	Graduation		28 (36.8)
Occupation	Housewife		40 (52.6)
	Own business		5 (6.6)
	Private job		19 (25)
	Retired		12 (15.8)
Socioeconomic status	Lower		33 (43.4)
	Middle		23 (29.8)
	Lower middle class		20 (26.3)
Addiction	No		34 (44.7)
	Smoke		4 (5.3)
	Tobacco		29 (38.2)
	Alcohol		9 (11.8)
Total members in the family (mean±SD)	12±2.03		
	<5		48 (63.2)
	6-10		23 (30.3)
	>10		5 (6.6)
Diabetes	No		43 (56.6)
	Yes		33 (43.4)
Hypertension	No		40 (52.6)
	Yes		36 (47.4)

Table 2: Summary of continuous variables n=76

Variables	Pre-intervention		Post-intervention	
	Mean	Std. Deviation	Mean	Std. Deviation
Age (years)		55.2895±13.64191		
BMI (kg/m ²)	24.5461	4.85503	24.4613	3.74452
Weight (kg)	62.1289	11.49427	60.8382	8.59584
Waist circumference (cm)	36.1579	6.50549	35.4342	6.39653
Hip circumference (cm)	98.0574	18.37284	98.0574	18.37284
Waist-to-hip ratio	0.9373	0.02931	0.9194	0.04345
Waist-to-height ratio	1.7722	0.23275	1.6065	0.22581
DBP (mmHg)	83.1053	9.64791	81.1974	7.11434
SBP (mmHg)	141.832	17.21967	137.582	7.68768

Note: BMI, Body mass index; WHR, Waist-to-hip ratio; WHtR, Waist-to-height ratio; DBP, Diastolic blood pressure; SBP, Systolic blood pressure

Table 3: Differences between pre-intervention and post-intervention groups

Variables	Paired Differences					t	df	Sig. (2-tailed)
	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference				
				Lower	Upper			
DBP (mmHg)	1.90789	6.78857	0.77870	0.35664	3.45915	2.450	75	0.017*
SBP (mmHg)	4.25000	13.65882	1.56677	1.12883	7.37117	2.713	75	0.008**
Weight (kg)	1.29079	10.24630	1.17533	1.05059	3.63217	1.098	75	0.276
Waist circumference (cm)	0.72368	1.63787	0.18788	0.34941	1.09795	3.852	75	0.000**
BMI (kg/m ²)	0.08478	2.49151	0.28580	0.48456	0.65411	0.297	75	0.768
WHR	0.01784	0.03974	0.00456	0.00875	0.02692	3.912	75	0.000**
WHtR	0.03425	0.07616	0.00874	0.05165	0.01685	3.921	75	0.000**

Paired t test applied, P value significant as <0.05*, <0.01**. Note: BMI, Body mass index; WHR, Waist-to-hip ratio; WHtR, Waist-to-height ratio; DBP, Diastolic blood pressure, SBP- Systolic blood pressure

affecting the modifiable cardiometabolic risk factors of patients attending primary care health facilities in a rural community.

Conclusion

Non-pharmacological interventions affect the DBP and SBP, WC, waist-to-hip ratio, and the waist-to-height ratio of patients with cardiovascular risk. Results suggested for further clustered, randomized, controlled trial to see the efficacy of comprehensive approach of non-pharmacological interventions on cardiovascular risk factors.

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Declaration of patient consent

The authors certify that they have obtained all appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

Key message

Adding to the knowledge of primary care physicians, non-pharmacological intervention affects the modifiable cardio metabolic risk factors of patients attending primary care health facilities in rural community.

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Conflicts of interest

There are no conflicts of interest.

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