Reducing the incidence of CVD through dietary intervention is a major focus of health organizations worldwide. For primary prevention of CVD, lifestyle modification including dietary changes should be the foundation and initial intervention for person at risk for cardiovascular diseases CVD than that due to drug treatment of blood cholesterol or hypertension. Cereals & grains are the primary source of calorie for most of the populations in India. Increasing consumption of whole grains has the potential to decrease CHD risk in millions of people. An understanding of which grains can most beneficially affect specific risk factors and thereby reduce CHD events can help health professionals make better public health nutrition recommendations. With few exceptions, published clinical data demonstrate that the consumption of barley products with the heart healthy diet in replacement of rice and wheat can be an effective dietary approach for lowering total and LDL cholesterol. To confirm the efficacy of barley on major risk factors such as blood Pressure, fasting blood lipid profile and body composition this study was designed with the four objectives:

1. To assess the baseline characteristics and disease profile of the study subjects.
2. To assess the differential pattern of dietary intake at baseline and throughout the intervention.
3. To assess the lifestyle & behavioral determinants at baseline and during the trial.
4. To determine the effect of intervention on blood pressure, body composition, blood lipid profile and glucose metabolism as well as on the features of metabolic syndrome.

The study design was Randomized Controlled Parallel Group trial conducted at the OPD of Cardiology at Sir Sundar Lal Hospital Banaras Hindu University Varanasi. Two seventy eight patients of Metabolic Syndrome were recruited among those 205 patients were successfully completed the study. However, there were no significant differences in socio-economic characteristics of participants in intervention and control group who completed the study and dropouts.

Summary of the Findings

6.1 Baseline Characteristics and Disease profile of the Study Subjects

6.1.1 Socio-demographic Characteristics of the Respondents at Baseline

- Majority 57.1% of the respondents were male (59.6% in intervention and 54.5% in control) and 42.9% were female (40.4% in intervention and 45.5% in control).

- Nearly one third 33.7% of the respondents (34.0% in intervention group and 33.7% in Control group) were between the age range of 41-50 years followed by 31.2% (30.1% in Intervention and 32.7% in Control) in the age range of 51-60 years. The mean ages of the respondents were 49.4 ±9.2 years and 52.4±9.6 years in intervention and control group respectively.
Majority 94.6% of the respondents was Hindus with the distribution of (94.2% in intervention & 95% in control) only 5.4% were Muslim. There was no significant difference of religion between intervention and control group (p=0.520).

With regard to caste category, in the intervention group higher proportions of respondents were belonged to general category (45.2%) followed by 44.2% from OBC and 10.6% were from SC/ST category. Although there were no significant differences between the two groups on the basis of their religion and caste.

More than half (57.1%) of the respondents in both the groups were belonged to rural area followed by 27.3% were from urban areas and remaining 15.6% were from slum areas. However the residence wise distribution also showed insignificant (p=0.33).

More than one-third (35.6%) of the respondents in both intervention and control group were educated up to graduation level or above and 36.1% (38.5% in intervention and 33.7% in Control group) of the respondents were educated up to Secondary & higher secondary level.

With regard to the occupational status of the participant, nearly one third 34.1% respondents were housewives (34.6% in intervention group and 33.7% in Control group) followed by 30.7% (28.8% in intervention group and 32.7% in Control group) were doing either govt. or private job.
Summary

- Overall 58.5% (61.5% in intervention group and 55.4% in Control group) respondents were belonged to nuclear family structure; followed by 41.5% were living in a joint family (38.5% in intervention group and 44.6% in Control group).

- As per the socio-economic status of the respondents more than one fourth 27.3% respondents (29.8% in intervention group and 24.8% in Control group) belonged to upper middle class followed by 22.0% were from lower middle class (17.3% in intervention group and 26.7% in Control group).

- The above findings confirm that both the intervention and control group were well matched as per the socio-demographic characteristics at baseline. None of the demographic variables were found to be significant between the two groups. (p>0.05) thus both the groups were found to be comparable.

6.1.2 Present History of Diseases, Treatment Profile and Family History of Diseases.

- Regarding the prevalence of all five components of metabolic syndrome at baseline, highest proportion of respondents were hypertensive which was 82.7% in the intervention group and 81.2% in the control group followed by hypertriglyceridemia which was 78.8% and 79.2% in intervention and control group respectively. Overall 78% respondents were taking medicines at baseline and majority of them were on antihypertensive medications.

- Nearly half 46.3% of the participants reported negative family history of hypertension in their first degree relatives (50% in intervention & 42.6% in
control. And negative family history of diabetes was reported by majority 66.8% (69.2 % in intervention & 64.3% in control) of the respondents. Very few only 12.2% respondents were reported to have positive history of heart disease although insignificant differences was observed between the two groups regarding the family history of diseases.

6.2 Lifestyle (behavioral) Determinants at Baseline and During the Trial.

6.2.1 Physical Activity Pattern of the Respondents.

- Majority of the respondents were reported to lead sedentary or lightly active life style although very small proportion about one third were engaged in moderate or strenuous activities. The proportion of respondents with sedentary lifestyle in the intervention and control group was 36.5% and 35.6% respectively followed by 35.6% were lightly active in the intervention group and 31.7% were in the control group.

- Findings revealed that in the intervention group only 24.1% were engaged in any type of physical activity at baseline that was shifted to 34.6 % at the end (12-week). Similarly in the control group this proportion was increased from 22.7% to 30.6 % at the end. However the within group changes was not reached to significant level in any of the group similarly between group differences was also significant at baseline (p=0.48) and at the end (p=0.32).

- Regarding the type, frequency and timing of the physical activity data showed that both the groups were followed the similar pattern throughout that trial.
6.2.2 Addiction Status of the Respondents at Baseline and During the Trial

- Out of 205, 37.1% of the respondents (39.4% in intervention and 34.7% in control) were never addicted to any harmful substances in their life while half (50.0%) of the respondents (50.0% in intervention and 50.5% in control) were currently taking some type of harmful substances.

- At baseline 71% respondents in the intervention and 66.3% in the control group reported that either they were never smoked or left in the past while 11.5% in the intervention and 11.9% in the control group were smoking ≥6 times in a week.

- Regarding the tobacco intake, At baseline 77.9% in the intervention and 68.3% in the control group reported either they were never consumed or left in the past however this proportion was increased to 86.5% and 81.1% in the intervention and control group respectively.

- Nearly one fourth of the respondents were stated that they were consuming alcohol. Among them 10.6% were occasional user in the intervention group and 12.9% in the control group. Most of the respondent who were taking alcohol 4-5 times in a week they were shifted to either occasional or formal users.

- There were no significant differences between the intervention and control group at baseline and during the trial except tobacco intake.
6.3 The differential Patterns of food & Nutrient Intake at Baseline and Throughout the Intervention

- In the intervention group, all the respondents consuming the recommended portions of barley with the controlled diet. The reported daily intakes of barley in the intervention group were averaged 121±20.1 gm/day and zero in the control group.

- The average increase in soluble fiber through addition of barley (β-glucan) as compared to baseline intake was 3.19 g/d during the trial and it was shown to increase significantly from the control group. (p<0.001)

6.3.1 General Dietary Habits and Practices of the Respondents at Baseline

- The findings showed that majority of them 61.9% were non-vegetarian. The proportion of non-vegetarians was little higher among the intervention group 65.3% as compared to 58.4% in the control group, although the differences was not statistically significant (p=0.31).

- More than half 56.1% (52.9% in intervention and 59.4% in control group) indicated having meal 2 times on a daily basis followed by 39% having their meals three times in a day. However the proportion of 3 meals in a day was about 10% higher in the intervention group but this difference was not close to the significance level (p=0.42).

- Majority 69.2% in the intervention group and 61.4% in the control group having the fixed timing for their meal however about one fourth 26% reported irregular meal timing in both the groups.
More than half 56.5% respondents in both the groups reported to use mustard oil for cooking foods followed by 19% were using soybean oils and 13.1% using safola oils.

6.3.2 Nutrient Intake of the Respondents at Baseline and Throughout the Trial

As expected and according to the protocol, macronutrient intake did not change throughout the trial. For almost all dietary variables, there were no significant time-by-group interactions; nutrient intake in the intervention group was not significantly different from those in the control group.

Both the groups decreased energy intake over the 3-month of study period but there was no significant effect of time were observed. Similarly for the protein intake, it was slightly decreased at 4-week in the intervention group but again it was increased at 8 and 12-week.

Carbohydrate intake was decreased over the time but it was greater in the control group compared to intervention group (time effect=0.03). Similarly, the percentage of energy provided by carbohydrates was reduced in the control group whereas it was increased in the intervention group but both the groups were not differing significantly.

Saturated fat and percentage of energy provided by saturated fat decreased over time (p<0.001), whereas energy provided by polyunsaturated (PUFA) and monounsaturated (MUFA) fat was increased. At the end of trial intake of monounsaturated fat and percentage of energy provided by MUFA was greater
in the control group in contrast it was greater in the intervention group at baseline.

- In fact, the nutrient and dietary fiber intakes did not markedly differ between the two groups at baseline whereas significant differences was found between the two groups at 4, 8 and 12 weeks of intervention. It was mainly due to the intervention strategy that barley was included in the intervention group after randomization which contains high amount of dietary soluble fiber (β-glucan).

- Both the groups significantly increased the intake of total dietary fiber during the intervention and significant main effect of time (p=0.005) and group (p=0.03) was observed. Total dietary fiber and soluble fiber intake was significantly higher in the intervention group as compared to control group.

- Regarding the micronutrient intake of the respondent at baseline, it was found that no significant difference for any micronutrient at baseline except the zinc intake. Zinc intake was comparatively higher in intervention group (4.54±1.4) compared to control group (4.13 ± 1.1) (p=0.02).

- Mean changes over time were not significant for any variables except sodium (decreased over time p=0.002) and phosphorous (increased over time p=0.007) intake. Sodium consumption by both the groups was constantly reduced in both the groups.

- It is evident from the observation, total caloric intakes and the proportions of carbohydrate, protein, and fat consumed by the intervention and control group was similar throughout the trial. Changes over time were not significantly
different for any of the variables between two groups except dietary fiber intake.

6.3.3 Food intake & Consumption Frequency of the Respondents

- According to the protocol the only difference between the two groups was the addition of barley food in the intervention group. None of the respondents were consuming barley before the study has been started in any group. During the three month of intervention all (100%) respondents in the intervention group started to consume barley on a daily basis.

- About three fourth of respondents 72.1% in intervention and 74.3% in control group were reported eating rice on a daily basis (≥6 times/week) but after the intervention daily eaters were reduced to 42.3% in the intervention group and 48.5% in the control group.

- As for as green vegetables, about half 50% in the intervention and 55.4% in the control group were having green vegetables in their daily diet before the counseling but this proportion was shifted to 76% and 63.4% in the intervention and control group respectively. Similarly more than one third (36.5%) in the intervention were having 4-5 times/week which was comparatively higher than the control group (29.7%). But after the intervention most of them shifted to ≥6 times/week.

- Fruit are not consumed as a regular part of the meal by majority of the people in this region diet as they were consumed seldom or never by 44.2% and 46.5% in the intervention and control group respectively. However this
proportion was reduced to 15.4% and 11.9% after the counseling. Although majority of the respondents were started to have fruits after the intervention and the proportions was significantly differed before and after the intervention in both the groups (p<0.001).

- Respondents were also asked about the consumption frequency of non-vegetarian foods as they were reported that 14.4% and 12.8% from the intervention and control group were taking flesh foods or eggs 4-5 times in a week while about a quarter of respondents 25% from the intervention and 23.7% from the control group were consuming ≤3 times in a week.

- Similarly for the deep fried foods, ten percent of the participants from the intervention group and 18.8% from the control group ate deep fried foods daily followed by 18.3% and 14.9% from the intervention and control group were consuming 4-5 times/week and ≤ 3 times /week were reported by 61.5% and 54.5% of the respondents.

- At the initial visit, Out of total only about one third respondents were stated that they were seldom/ rarely consuming sweat dishes while more than one third respondents were having 4-6 times in a week. But after the counseling none of the respondents were in the category of 4-5 times or ≥6 times/week and rarely user were increased from 38.5% to 89.4% in the intervention group and from 27.7% to 87.1% in the control group.
6.4 Effect of intervention on blood pressure, body composition, blood lipid profile and glucose metabolism as well as on the features of metabolic syndrome.

6.4.1 Effect of Intervention on Anthropometry and Body Composition

- Repeated measures of ANOVA revealed that both the groups has significantly lost their weight over time and the effect of time was significant ($P<0.001$); however, there was a strong time by group interaction ($P=0.003$), such that intervention group lost more weight in comparison to control group throughout the trial.

- Mean body weight decreased by (-2.71) kg in the intervention group, significantly more than the (-1.22 kg) in the control group. The corresponding reductions in BMI were (-1.04) and (-0.48) kg/m$^2$ in the intervention and control group respectively. The between-group differences for body weight and body mass index were -2.13 kg (95% CI, −1.2 to −2.9, $P<0.001$) and -2.11 kg/m$^2$ (95% CI, −1.2 to −2.9, $P<0.001$). Mean reductions in waist circumference and waist/hip ratio were also significantly greater in the intervention group, compared with the control group.

- During the intervention, there was a trend toward reduced body fat and visceral fat % in both the intervention and control group and it significantly affected by the length of time ($p<0.001$). Whereas significant time by group interaction was observed for body fat % ($p<0.001$) & visceral fat % ($p=0.007$).
Within group test indicated the mean changes in body fat and visceral fat % decrease significantly at 12 weak by (-2.36 and -1.57) in the intervention group whereas it was (-0.85 and-0.62) in the control group correspondingly. Total body fat reduced by (-7.2%) in the intervention group compared to (-2.55%) in the control group similarly for the visceral fat mean % reductions was (-11.5%) and (-3.49%) in the intervention and control group.

6.4.2: Effect of Intervention on Systolic and Diastolic Blood Pressure.

Both Systolic and diastolic blood pressure was significantly affected by the length of the time (p<0.001). At 12-weak, the mean change in systolic and diastolic blood pressure were (-9.74,) mmhg and (-1.95) mmhg in the intervention group as compared to (-5.00) mmhg and (-1.51) mmhg in the control group. Compared with the control group, intervention group resulted a higher mean change in systolic and diastolic blood pressure with a difference of -4.7 mmhg (95% CI, -0.1 to -9.2, p=0.04) and -0.43 mmhg (95% CI, -0.9 to -1.8, p=0.54) respectively.

6.4.3: Effect of intervention on Fating lipid profile and Fasting Blood Sugar.

Within-group comparisons revealed that 12 weeks of intervention with barley significantly decreased the fasting plasma total cholesterol concentration from their baseline values by a mean change of (-26.9) mg/dl in the intervention group and (-10.7) mg/dl in the control group. Regarding the mean % change between baseline to 12- weak, it was reduced by (-10.7%) and (-4.4 %) in the intervention and control group correspondingly. However, the differences in
change between the groups for mean change was -16.0 (95% CI, -6.2 to-25.9) and -6.28 (95% CI, -1.4 to-11.1) for mean % change.

- Triglyceride concentration followed the same significant pattern of reduction as that of total cholesterol. Respondents in the intervention group significantly reduces fasting blood triglycerides from their baseline values with an average change of -29.2 mg/dl after 3 months which was about just two times higher than -15.0 mg/dl in the control group. Although significant difference was found in the mean changes between the two groups from baseline to 12 weak with the average difference of -14.1 mg/dl (95% CI, -4.2 to -24.1, p=0.005).

- In the same way as for the total cholesterol and triglycerides concentrations, low density lipoprotein cholesterol significantly decreased after three month in both the groups. (P<0.001) The mean changes in intervention group were -14.1 mg/dl and -6.31 mg/dl in the control group with a difference in change between group was -7.84 mg/dl ((95% CI, −1.2 to −14.3, p=0.01).

- No significant differences were detected from baseline to week 12 within either the intervention (p=0.57) or the control group (p=.93) for high density lipoprotein cholesterol. In the intervention group minor increase was observed after the 12 weak that was 0.70 mg/dl whereas in the control group it was negligible in the control group that was 0.07 mg/dl. As like as 5.67 % increase was observed in the intervention group compared to 3.96 % in the control group.
After the three month of dietary treatment, intervention group significantly declined the plasma concentration of very low density lipoprotein by a mean change of -8.18 mg/dl and -3.72 mg/dl in the control group which was insignificant from the baseline. Moreover when we analyze to know the mean % change in the intervention and control group it was reduced -6.5% and -0.63% respectively. Furthermore between-group differences was also proved significant with a differences in mean change was -4.46 mg/dl (95% CI, −1.0 to −7.9).

Within group test reveals that fasting blood sugar significantly declined after the three month in both the groups. (p<0.001) Although the between group difference was proved insignificant with a diff. in mean change of -3.95 mg/dl (95% CI, -0.5 to -3.7, p=0.15) even at the completion of intervention in 12 weak with barley indicated that recommended dose of barley was unable to detect a statistically significant differences as compared to step I diet.

Mean plasma concentrations of total cholesterol, triglycerides, LDL cholesterol, and HDL cholesterol were similar in each of the two groups before starting the intervention with barley. Significant difference between the groups for all of the plasma lipids indicated that the subjects improved their lipid profiles during the course of the study, with significant decreases in total cholesterol, LDL cholesterol, and triglycerides at 3 months and slight but insignificant increases in HDL cholesterol at 3 months.
6.4.4: Effect of Intervention on Prevalence of Components of Metabolic Syndrome.

- Regarding the prevalence of all five components of metabolic syndrome, findings showed that after the three month of active dietary intervention, the prevalence of hypertriglyceridemia and hyperglycemia were significantly decreased in both the groups, however prevalence of hypertension was significantly decreased in the intervention group. At the end of the present study, 45.1 % of the respondents receiving the barley diet and 30.6 % of those receiving the control diet no longer fulfilled the diagnostic criteria of the metabolic syndrome.

- Highest proportional reduction was observed for Hypertriglyceridemia which was -27% in intervention group and -12 % in the control group followed by hyperglycemia which was declined by -26% and -19% in intervention and control group after the 12 week. Proportion of hypertension was reduced by -10% in the intervention group on the other hand it was slightly increased in the control group. Although between group test proved significant differences at 12 weak between the groups for all the components and except central obesity and low HDL cholesterol.

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