Effects of a school-based intervention to reduce cardiovascular disease risk factors among secondary school students: a cluster randomized controlled trial

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Abstract

Background Globally, cardiovascular disease (CVD) was responsible for 17.5 million deaths, accounting for 46.2% non-communicable disease deaths. In Ghana CVDs has been the leading cause of adult death since 2001. Prevalence of CVD risk factors among adolescents in Ghana has been increasing. Objective of this study was to develop, implement and evaluate the effectiveness of a health education intervention program to reduce CVD risk factors among students. Methods A cluster randomized controlled trial was conducted with a school as cluster over a period of six-months with pre and post intervention evaluations. Participants were public secondary school students (14-19 years) from four schools in Brong Ahafo, Ghana. Students in the intervention group were trained by the researchers whereas those of the control group received no intervention. The intervention included health education and physical activity modules. Follow-up data using same questionnaire were collected within two weeks after the intervention was completed. Intention-to-treat analysis was performed after replacing missing values using multiple imputation method. The generalized linear mixed model (GLMM) was used to assess the effects of the intervention. Results Of the 848 study participants, 836 completed the final assessment at six-month. The GLMM showed the intervention was significant in attaining 0.77($p<0.001$), 0.72($p<0.001$), 0.47($p<0.001$), 0.56($p<0.001$), and 0.39($p=0.045$) higher physical activity, fruits, vegetables, seafood, and water scores respectively for the intervention group over the control group. The intervention was also significant in reducing -0.15($p<0.001$), -0.23($p<0.001$), -0.50($p<0.001$), -0.32($p<0.001$), -0.90($p<0.001$),-0.87($p<0.001$),-0.38($p<0.001$),-0.63($p<0.001$),-1.63($p<0.001$),-0.61($p<0.001$),and -1.53($p=0.005$) carbohydrates, fats and oils, fried eggs, fried chicken, carbonated drinks, sugar, sweet snacks, salted fish, weight, BMI, and diastolic BP. The “odds” of quitting alcohol use in the intervention group was 1.06 times more than in control group. There was no significant effect of the intervention on reducing systolic BP. Conclusions The intervention had positive effect on increasing physical activity, promoting healthy diet, reducing alcohol consumption, weight, BMI, and diastolic BP among students in the intervention arm of the study but had no effect on systolic BP. Findings from this study is recommended to be adopted in the educational curricula in secondary schools.

Keywords: Cardiovascular disease, risk factors, behavioral modification intervention, secondary school students, adolescents

Background

Cardiovascular diseases (CVDs) are the number cause of deaths worldwide (1–3). Globally, an estimated 17.5 million people died in 2012 due to CVDs, which represented 31% of all global deaths (4). The disease affects a third of adult population in the world making it the largest epidemic ever known to mankind (5). In Ghana, CVDs have been the leading causes of all Non-communicable disease (NCD) and institutional deaths in 2008 accounting for 14.5% total deaths (6). According to the Ghana Health Service (7), CVDs are the leading causes of NCD deaths with an estimated 35,000 deaths per year. In a five year review of autopsy cases (19,289) from 2006 to 2010 in one of the teaching hospitals in Ghana found out that more than one-fifth (22.2%) of the deaths were due to CVDs (8). Also CVD rose from the seventh and tenth causes of death in the capital in 1953 and 1966 respectively to the number one cause of death in 1991

and 2001 and has continued as one of the major causes of death since then (9). In 2014, stroke and coronary heart disease (CHD) were ranked as the 2nd and 4th leading causes of death in Ghana accounting for 9.75% and 6.48% of all deaths respectively (10). The WHO (11) has also reported that NCDs accounted for 34% of total deaths and 31% disability adjusted life years in Ghana with CVDs being the leading cause of NCD deaths.

Risk factors of CVDs are of two types which are modifiable and non-modifiable factors. Non-modifiable risk factors include advancing age, male gender, black race–ethnic background, prior stroke/transient ischemic attack or history of coronary heart disease and family history of stroke. On the other hand, modifiable risk factors of CVDs include physical inactivity, unhealthy diet, smoking, alcohol consumption, obesity and hypertension (12). Studies have shown that the risk factors for coronary heart disease and stroke begin in childhood that develops in adulthood (13). This means that risks factors and behavioral lifestyle for CVD should begin at the youthful age. Therefore, prevention of CVDs should be tackled right from an early age. Unfortunately, many people are not aware of CVD and its risk factors (14) and because of this the disease burden keeps on rising. Also, merely educating the general public on CVD and its risk factors seems not to have achieved much. Therefore, adding intervention programmes to education especially for the youth on an ongoing process will equip them in protecting themselves from developing CVD disease in adulthood.

School health interventions programmes have shown consistent improvement on the general health status of students (15,16) and they are ideal places for health programmes (17,18). The WHO (19) estimates that these modifiable risk factors causes 80% of CVDs mainly physical inactivity, unhealthy diet, smoking, alcohol consumption and though CVDs occur in middle and adult ages the risk factors that cause the disease are learned during childhood and carried into adulthood. The aim of this study was to evaluate the effectiveness of a school-based health education intervention programme on CVD risk factors among students in Brong Ahafo Region of Ghana.

Methods

Study design and settings

The study protocol has been reported elsewhere (20). The study was a two arm single blind parallel cluster randomized controlled trial involving four public secondary school students that were recruited into the study from two selected districts in Brong Ahafo region and was guided by the CONSORT statement. There were two schools each in the intervention and control arms of the study. Schools were the unit of randomization, intervention, and analysis. The intervention study was for six months. The study protocol was approved by the Ethics Committees of the University Putra Malaysia and the Kintampo Health Research Centre. This trial was registered with the Pan African Clinical Trial Registry (PACTR201709002540178). Permissions were sought from the Ministry of Education, headmasters, and Chairpersons of Parent Teacher Association of selected schools. Students were exempted from the intervention if they were suffering from serious medical conditions such as heart diseases, asthma, or

respiratory conditions or was advised by a medical professional to restrict physical activities/exercise. Written and signed informed consent were obtained from all participating students and their parents or guardians. Respondents in the intervention arm received a CVD health education intervention, whereas the control group were not exposed to the intervention but went on with their normal school curricula. Students in the control group were wait listed and received the intervention program at the end of the study. Baseline measurements of physical activity, dietary intake, smoking, alcohol consumption, weight, height, diastolic and systolic BP were taken for both the intervention and control groups. A post intervention assessment was then carried out within two weeks (immediately after six months) to evaluate the effectiveness of the intervention.

Sample size

The study would require a >80% power to detect an effect of 0.8 standard deviation at the 5% significance level with 0.8 and 0.9 estimated response and eligibility rates respectively. We also expect a 0.01 yielding a cluster design effect of 1.085. The target sample size for each group was calculated to be 424 students or 848 students in total. To achieve this sample size, students from form one to three were recruited from four schools in two districts.

Selection of schools and Randomization

There were two secondary schools in each of the two districts that were randomly selected for the study and all four secondary schools were enrolled into the study. Randomization technique in the ratio 1:1 for intervention and control groups respectively were carried out. Secondary schools (clusters) were the unit of randomization. Allocation concealment was achieved with sequentially numbered opaque sealed envelopes by an education officer containing treatment allocation cards (intervention and control). The envelopes were then serially numbered from the outside. Schools were randomly assigned to either the intervention or control group of the study on the same day participants were selected for this study. It was however performed after baseline data had been collected.

Sequence Generation and Blinding

A biostatistician who was not involved in the trial generated the allocation sequence. Using a block randomization (1:1 ratio) of two digit blocks A and B (each containing one intervention and one control, to ensure equal distributions in the two groups), two schools each were allocated to intervention and control groups. Health staff who took measurements of students' anthropometry and blood pressure measurements were blinded to participants' groups and were not allowed to take anthropometry and blood pressure measurements at post intervention. Researchers and health gym instructor who facilitated the health education and the physical activity modules could not be blinded as such. Contamination of

the study was minimized since there were intervention and control schools and that schools were far apart each other.

Intervention

The CVD risk factor reduction intervention module was basically divided into two sections. These were the Health Education and Physical Activity Modules. The interactive health education sections, the researchers did education in the schools on CVDs, its risk factors, causes, development and prevention among others in the intervention schools. The intervention schools were visited three times in a week for a period of six months. Each section of the health education lasted for about an hour with a break followed by questions, answers and discussions.

The physical activity module consisted of static hands on exercises delivered by physical education health instructor. The instructor educated students first on the various physical activities and then took them to the school field to undertake the activity. The exercises were structured across the intervention schools. Each physical activity section lasted for about 25-30 minutes. A summary of the intervention is in Table 1.

Table 1 Summary of intervention module

Outcome variables

Primary and secondary outcomes

Primary outcomes in this study was the changes that was expected immediately after the intervention at 6-months after the baseline which were:

1. Physical activity
2. Dietary intake
3. Smoking
4. Alcohol consumption

Secondary outcomes were weight, BMI, diastolic and systolic blood pressures.

Outcome measurements

Assessment of outcomes in both groups, a baseline survey was conducted before the schools were randomly allocated to either intervention or control arms of the study. A follow-up survey was then

conducted within two weeks after the intervention at six months. The survey was self -administered in English by students while weight, height and blood pressure measurements were taken by trained health staff who were not involved in the study. However, health staff who were involved in the baseline survey were not involved in the post assessment survey to avoid measurements bias. Height was measured using SECA Body Meter Model 208 to the nearest 0.1cm. The respondent was asked to stand and look straight, barefooted with heels resting together. Height measurement which appeared in the read-off area was recorded. Weight of student was measured using a digital bathroom scale, TANITA Model HD 309 to the nearest 0.1kg. The student was requested to remove slippers or shoe and anything in the pocket. He/she was then asked to stand upright on the scale and the measurement was taken. Height and weight measurements were used to assess students Body Mass Index (BMI) as a proxy to their nutritional status in terms of underweight, normal, overweight, and obesity. Physical activity was measured using the Physical Activity Questionnaire (PAQ-A) for secondary school students (21). The 7-day recall instrument was administered in a classroom setting to assess general levels of physical activities among students. Each physical activity item was scored on a 5 point scale. The value from 1 to 5 for each of the items used in the physical activity composite score, then the mean of the items which resulted in the final PAQ-A activity summary score. Dietary consumption was assessed using foods that are mostly consumed in Ghana (22,23). Frequency of consumption of foods were scored based on 1 for never dietary consumption, 2 for 2-3 times per week, 3 for 4-5 times per week, 4 for 6 times per week, and 5 for daily intake of a particular food item. Smoking and alcohol questionnaires, Global Youth Tobacco Survey (GYTS) developed by WHO and Centre for Disease Control and Prevention (CDC) (24). It was school-based adolescents' self-administered questionnaire which comprised of a set of core questions that were used to evaluate tobacco and alcohol control and prevention programmes among secondary school students. Students were classified as never, ever, and current smokers and alcohol consumption. Strict confidentiality were ensured among researchers to avoid disclosure of smoking and alcohol statuses to school authorities, teachers, or parents.

Statistical analysis

Data collected were checked, cleaned, and analyzed using IBM Statistical Package for Social Sciences (SPSS) version 22. The data analysis was divided into descriptive and inferential statistics. The level of significance for all the statistical tests was set at 0.05. For mean estimations, 95% confidence intervals (CI) was computed. For descriptive statistics, means and standard deviations (SD) were used as a measure of central and dispersion to summarize continuous variables. Frequencies and percentages were used to summarize categorical variables. Chi-square and independent t-tests were performed to compare baseline characteristics of groups by their socio-demographic factors, family factors, smoking, alcohol and physical activity, BMI, systolic BP, and diastolic BP respectively. At six months, the independent t-tests were performed to determine the between groups differences of total physical activity, dietary intake, weight, BMI, diastolic and systolic BP. Paired sample t-tests were performed to determine the within group differences of the variables. Chi-square and the McNemar tests were performed on smoking and alcohol to determine the between and within groups since the variables were categorical

variables. Intention-to-treat (ITT) analysis was the method that was used to handle missing data in the analysis. Replacement of data was then conducted for each missing variable using the multiple imputation method, following which Generalized Linear Mixed Model (GLMM) analysis was performed to determine the overall effectiveness of the intervention study. The magnitude, also referred to as coefficient of fixed effects were used in the GLMM analysis to determine the overall effectiveness of the intervention study.

Results

The study process in Figure 1 was according to the CONSORT statement. A total of 950 students were assessed from four schools for possible inclusion into the study where 54 did not meet the inclusion criteria and 48 declined to participate. Then the rest (848) were randomly assigned to either the intervention group (two schools) or control group (two schools). At the end of the study at six months five had drop out of the study in the intervention group while the control group was seven. The ITT was utilized to maintain the initial randomization process.

Fig 1 Study Flow Chart Show in Randomization Adapted from CONSORT

Table 2 compares baseline socio-demographic characteristics and CVD risk factors between intervention and control groups. There was no significant difference between the two groups at baseline. The ages of respondents ranged from 14 to 19 years, with mean (SD) age of 16.99 (1.4). Majority of respondents were females (51.5%). Most of the respondents were of Akan ethnicity (53.2%). A total of 20.9% and 23.5% reported of family histories of obesity and hypertension respectively. Mean (SD) physical activity was 2.32 (0.65) in the intervention group and 2.26 (0.60) in the control group. In both groups, mean (SD) consumption of fruits 1.43 (0.48) and fish 1.88 (0.68) were generally low while sugar 2.77 (1.41) and energy drinks 2.04 (1.13) were high. Out of the 40 ever smokers in the intervention group, 34 (85.0%) were current smokers while 26 ever smokers in the control group, 19 (73.1%) were current smokers. In both groups, majority of students tried their first smoke at 14 years (56.1%) with age range 11-17 years. Of the 129 ever consumers of alcohol, 98 (76.0%) were current consumers of alcohol and out of 108 ever consumers of alcohol, 90 (83.3%) were current alcohol consumers in the intervention and control groups respectively. In all, 25.3% tried their first alcohol at age 13 years with age range 10-17 years. The mean (SD) weight was 59.19 (8.49) and 59.59 (7.93) in the intervention and control groups respectively. Mean (SD) BMI in the intervention group was 21.75 (2.85) while the control group was 21.86 (2.47). In both the intervention and control groups, 93 (11.0%) were classified as overweight while 19 (2.2%) were found to be obese. Mean (SD) diastolic BP was 67.66 (7.88) and 68.28 (8.11) and systolic BP was 111.64 (10.14) and 112.30 (9.48) in the intervention and control groups respectively.

Table 2 Baseline comparison between intervention and control groups

Table 3 shows the differences in the outcome variables at six months follow-up between the intervention and control groups. The intervention group had a significantly higher mean difference for physical activity than the control group 0.81 (0.74-0.89). On the other hand, consumption of fruits, vegetables, seafood and water increased significantly while the consumption of carbohydrates, fried eggs, fried chicken, carbonated drinks, sugar, sweet snacks and salted fish decreased significantly in the intervention group compared to the control group. Smoking and alcohol consumption decreased significantly among participants in the intervention than in the control group. Further, there were significant decrease in the intervention arm of the study compared to the control arm for BMI -0.74 (-1.10, -0.37), diastolic -1.78 (-2.86, -0.71) and systolic BP -1.69 (-3.00, -0.37).

Table 3 Changes from baseline to six months and comparison between groups post intervention

Table 4 presents the fixed coefficients of the outcome variable that were studied. The results showed that a student attending the intervention arm of the study is expected to lead to an increase in physical activity by 0.77 times and to decrease weight and BMI by -1.63 and -0.61 respectively as compared to an individual in the control arm of the study. Further, an expected decrease of -1.53 diastolic BP is expected for individuals in the intervention group as compared to individuals in the control arm. However, no significance decrease in systolic BP was expected between the two groups. On dietary habits, a student in the intervention arm is expected to increase consumption of fruits (0.72 times), vegetables (0.47 times), seafood (0.56 times), and water (0.39 times) as compared to an individual in the control group. Furthermore, an intervention student was expected to decrease consumption of other foods such as, carbohydrates (-0.15 times), fats and oils (-0.23 times), fried eggs (-0.50 times), fried chicken (-0.32 times), carbonated drinks (-0.90 times), plain sugar (-0.87 times), sweet snack (-0.38 times) and salted fish (-0.63 times) as compared to an individual student in the control arm. There was no significant differences between the two groups on smoking after the intervention, but the odds of quitting smoking in the intervention group was 6.13 times more than the odds of quitting smoking in the control group ($t=2.251$, $p=0.027$). There was a significant effect between groups ($F(1, 438) = 13.48$, $p<0.001$) on alcohol consumption. The odds of quitting alcohol consumption in the intervention group was 1.06 times more than the odds of quitting alcohol consumption in the control group ($t= -5.176$, $p<0.001$) after the intervention when compared to the baseline. The non-significant effects of smoking and systolic BP could be as a result of the robust nature of the GLMM, though the two variables were significant when analyzed with the t-tests.

Table 4 Magnitude of the Intervention Effect

Discussions

This cluster randomized controlled trial among Ghanaian public secondary school students, the intervention group showed a statistically significant increase in physical activity, fruits, vegetables, seafood, water consumption and reduction in carbohydrates, fats and oils, sweet snacks, carbonated drinks, fried egg, fried chicken, salted fish, alcohol consumption and diastolic BP. There was no significant group difference on smoking but the odds of quitting smoking in the intervention group was higher than in the control group. The intervention was however not effective on systolic BP. This present study is unique in that the intervention was directed at secondary school students to improve healthy lifestyles. This is among a few controlled trials that examined effectiveness of school-based health education intervention for CVD reduction.

Some educational intervention studies among secondary school have shown improvements in reducing CVD risk factors. A randomized controlled trial in Australia (25), showed that an educational intervention program improved physical activity among students in the intervention group when compared to the control group. With regards to dietary intake, some intervention studies have shown higher consumption of healthy foods and reduction of unhealthy food among students in the intervention group (26-28) when compared to the control group. Another school-based intervention study showed significant reduction of weight and BMI among the intervention group while the control group showed significant increase in weight and BMI at the end of the study (29). This is important because weight and BMI reduction reduces the onset of hypertension. The McNemar test indicated significant change of current smokers in the intervention group while the control was not significant. The GLMM showed a non-significance for group effect, while time, group and time interactions were significant. This could probably be as a result of the robustness of the GLMM analysis even though reduction of smoking status were seen in the intervention group. In as much as there was no significant group effect for smoking; group and time interactions were significant. This meant that the odds of quitting smoking in the intervention group was higher than the odds of quitting smoking in the control group. Alcohol consumption among respondents showed similar trends like smoking at six months when chi-square and McNemar tests were performed. There were significant group effects, time, group and time interactions when GLMM test was performed on alcohol consumption which indicated that the odds of quitting alcohol consumption in the intervention group was higher than the odds of quitting alcohol use in the control group. A systematic review and meta-analysis on peer-led interventions to prevent smoking and alcohol use among the youth reported that the odds of smoking and alcohol use were lower in the intervention group as compared to that of the control group at the end of the study (30). Both diastolic and systolic BP showed statistically significant reductions for the intervention when compared to the control group after t-tests analysis was performed. However, the GLMM only showed significant difference between the two groups for diastolic BP but not systolic. Again, this could be due to the robust nature of the GLMM. Some school-based studies have shown significant decreases of both diastolic and systolic BPs (31,32) in the interventions group at the end of the study as compared to this study which findings showed only significant decrease of diastolic BP but not systolic BP.

The present study has several strengths. The cluster randomized study design employed in this study prevented the possibility of cross contamination between the intervention and control groups. The use of standard measurement equipments and single blinding used in this study prevented measurement bias. The developed module is distinct because of the combined expertise from diverse specialties. Attrition was minimal because of the longer hours students spent in school and the different diversity, making it ideal place for health interventions. High response rate in this study at six months helped prevented follow-up bias. The robust nature of the GLMM analysis used in this study allowed for representation of true effect of the intervention. The study also had some limitations; with the questionnaire as a tool of data collection, a lot depended on the truthfulness of respondents. A longer period follow-up may be more suitable in determining the changes that were seen at the end of the study.

Conclusion

A six-months school based CVD risk factor reduction intervention was effective in improving physical activity, alcohol consumption, fruits, vegetables, seafood, plain water, and reduction of carbohydrates, fats and oils, fried eggs, fried chicken, carbonated drinks, sweet snacks, salted fish, weight, BMI, and diastolic BP of secondary school students in Brong Ahafo, Ghana. It is recommended that the CVD intervention program be integrated into the existing curriculum structure of the Ghana Ministry of Education. Implementing the intervention in schools will allow for longer and more consistent impact on the reduction of CVD risk factors among students. It is also recommended that the Ghanaian Ministry of health should incorporate this into their policies and programs at the district, regional and national levels.

List Of Abbreviations

BMI: body mass index BP: blood pressure

CVD: cardiovascular disease GLMM: generalized linear mixed model

IMB: information-motivation-behavioral skills ITT: intention-to-treat analysis

SD: standard deviation

Declarations

Ethics approval and consent to participate

University Putra Malaysia (UPM/TNCPI/RMC/1.4.18.2) and the Kintampo Health Research Centre (KHRCIEC/2017-16) Ethics committees approved the study. Consent were sought from parents/guardians

and students before they could (students) to participate in the study.

Consent for publication

Consent for publication were sought from all students and their parents/guardians.

Availability of data and material

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request.

Competing interest

The authors declare that they have no competing interests.

Funding

No funding was obtained for this study.

Authors' contributions

JA conceived the study, wrote the study protocol, designed the intervention module, managed the field work, data entry, performed the statistical analysis and drafted the manuscript. SMS participated in the study design, helped performed the statistical analysis and helped drafted the manuscript. LR participated in the study design and helped designed the intervention module and the statistical analysis. RAM participated in the study design and helped draft and revised the manuscript. NI helped draft the behavioral modification intervention module and revised the manuscript. SO helped to prepare the field survey and gave critical comments on the manuscript. All authors read and approved the final manuscript.

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Tables

Table 1 Summary of intervention module

MODULE	COMPONENTS	FORM OF DELIVERY	ESTIMATED TIME
Health Education Module	· Module Introduction · CVD Introduction · CVD Risk Factor Introduction · Harmful Effects of Smoking · Quitting Smoking · Barriers to Quitting Smoking · Health Benefits of Quitting/Not Initiating Smoking · Physical Activity Introduction · Simple Physical Activities/Exercises · Fruits and Vegetables Introduction · Fruits And Vegetables Intake/Selection · Introduction To The Types Of Fats · Outcomes of High Fat Intake On Health · Harmful Effects Of Obesity · Harmful Effects Of Excessive Sugar Intake · Promotion Of Frequent Water Intake · Harmful Effects Of Excessive Salt Intake · Harmful Effects of Alcohol · Quitting Alcohol · Barriers to Quitting Alcohol · Health Benefits Of Quitting/Not Initiating Alcohol	· Lectures · Discussions	One hour per session
Physical Activity Module	· Aerobics · Lunge with Twist · Jumping Jacks · Abdominal Crunch · Hamstring Stretch · Wall Sit · Side Arm and Leg Raise · Push Ups · Sit and Reach · Sit Ups · Knee to Chest · Leg Raise · Squat	Hands on (Field exercise)	25-30 minutes per session

Table 2 Baseline comparison between intervention and control groups

	Groups						
Baseline variables	**Intervention**		**Control**		χ^2	*df*	*p-value*
	Frequency (%) (n=424)		**Frequency (%) (n=424)**				
Age (years)					5.958	5	0.310
Mean (SD)	17.05	(1.4)	16.94	(1.4)			
(Range)		(14-19)		(14-19)			
Gender					0.118	1	0.731
Male	208	(49.1)	203	(47.9)			
Female	216	(50.9)	221	(52.1)			
Ethnicity					1.319	4	0.858
Akan	230	(54.2)	221	(52.1)			
Dagarte	83	(19.6)	94	(22.2)			
Konkomba	55	(13.0)	53	(12.5)			
Mo	40	(9.4)	43	(10.1)			
Others	16	(3.8)	13	(3.1)			
Family history of obesity					3.149	1	0.076
Yes	99	(23.3)	78	(18.4)			
No	325	(76.7)	346	(81.6)			
Family history of hypertension					0.164	1	0.685
Yes	102	(24.1)	97	(22.9)			
No	322	(75.9)	327	(77.1)			
Primary outcomes	**Mean (SD)**				***t*-value**	***df***	***p*-value**
Physical activity scores	2.32	(0.65)	2.26	(0.60)	1.34	846	0.180
Diet							
Fruits	1.41	(0.50)	1.44	(0.46)	-1.04	846	0.297
Vegetables	2.27	(0.65)	2.27	(0.66)	-0.06	846	0.949
Protein (seafood)	1.91	(0.64)	1.84	(0.71)	1.40	839.91	0.162
Plain water	3.93	(1.21)	4.01	(1.19)	-1.06	846	0.289
Carbohydrates	1.65	(0.60)	1.70	(0.57)	-1.31	846	0.192
Fats and oils	1.49	(0.48)	1.49	(0.50)	0.14	846	0.888
Fried egg	1.64	(1.00)	1.65	(0.98)	-0.21	846	0.835
Fried chicken	1.90	(1.01)	1.88	(1.02)	0.37	846	0.709
Carbonated drinks	1.90	(1.01)	1.88	(1.02)	0.37	846	0.709
Plain sugar	2.81	(1.40)	2.73	(1.41)	0.90	846	0.367
Sweet snack	1.69	(0.60)	1.63	(0.52)	1.54	828.84	0.123
Salted fish	1.62	(0.98)	1.17	(0.99)	-1.29	846	0.198
	Frequency (%) (n=40)		**Frequency (%) (n=26)**		χ^2	***df***	***p*-value**
Current smoker					1.416	1	0.234
Yes	34	(85.0%)	19	(73.1%)			
No	6	(15.0%)	7	(26.9%)			

Current alcohol intake	**(n=129)**		**(n=108)**		1.944	1	0.163
Yes	98	(76.0%)	90	(83.3%)			
No	31	(24.0%)	18	(16.7%)			
Secondary outcomes	**Mean (SD)**				***t*-value**	***df***	***p*-value**
Weight (Kg)	59.19	(8.49)	59.59	(7.93)	-0.71	846	0.478
BMI scores (Kg/m^2)	21.75	(2.85)	21.86	(2.47)	-0.61	829.48	0.540
Diastolic BP scores (mgHH)	67.66	(7.88)	68.28	(8.11)	-1.14	846	0.256
Systolic BP scores (mgHH)	111.64	(10.14)	112.30	(9.48)	-0.94	846	0.347

Table 3 Changes from baseline to six months and comparison between groups post intervention

	Intervention group			Control group			Between group follow up	
Outcome variables	**n**	**Mean (SD)**	**Mean change from baseline (95%CI)**	**n**	**Mean (SD)**	**Mean change from baseline (95%CI)**	**Mean difference (95CI)**	***p*-value**
Physical activity	419	3.10 (0.52)	0.79 (0.73-0.84)	417	2.29 (0.58)	0.03 (0.02-0.07)	0.81 (0.74-0.89)	<0.001
Diet								
Fruits	419	2.17 (0.49)	0.76 (0.71-0.80)	417	1.48 (0.42)	0.03 (0.01-0.05)	0.69 (0.63-0.75)	0.001
Vegetables	419	2.62 (0.63)	0.36 (0.32-0.39)	417	2.17 (0.59)	-0.10 (-0.13, -0.08)	0.45 (0.37-0.54)	<0.001
Protein (seafood)	419	2.42 (0.86)	0.52 (0.44-0.59)	417	1.82 (0.62)	-0.03 (-0.07, -0.02)	0.60 (0.50-0.70)	<0.001
Plain water	419	4.40 (0.90)	0.48 (0.35-0.60)	417	4.06 (1.24)	0.03 (0.14-0.20)	0.35 (0.19-0.49)	<0.001
Carbohydrates	419	1.58 (0.42)	-0.07 (-0.12, -0.02)	417	1.86 (0.57)	0.16 (0.13-0.19)	-0.28 (-0.35, -0.21)	<0.001
Fats and oils	419	1.26 (0.32)	-0.23 (-0.27, -0.20)	417	1.72 (0.51)	0.24 (-0.21, -0.27)	-0.47 (-0.52, -0.41)	<0.001
Fried egg	419	1.42 (0.80)	-0.22 (-0.29, -0.15)	417	1.95 (1.19)	0.29 (-0.37, 0.21)	-0.53 (-0.67, -0.39)	<0.001
Fried chicken	419	1.49 (0.66)	-0.40 (-0.49, -0.39)	417	1.81 (1.21)	0.06 (-0.06, 0.19)	-0.31 (-0.44, -0.18)	<0.001
Carbonated drinks	419	1.30 (0.55)	-0.59 (-0.69, -0.49)	417	2.18 (1.42)	0.31 (0.15-0.48)	-0.88 (-1.02, -0.73)	<0.001
Plain sugar	419	2.04 (1.18)	-0.77 (-0.91, -0.63)	417	2.83 (1.41)	0.09 (0.02-0.17)	-0.78 (-0.96, -0.61)	<0.001
Sweet snack	419	1.44 (0.38)	-0.25 (-0.28, -0.21)	417	1.76 (0.53)	0.14 (0.11-0.16)	-0.33 (-0.39, -0.26)	<0.001
Salted fish	419	1.27 (0.58)	-0.36 (-0.44, -0.27)	417	1.98 (1.14)	0.09 (0.19-0.34)	-0.71 (-0.83, -0.59)	<0.001
Smoking	40	1 (2.5)	-	26	19 (73.1)	-	-	<0.001
Alcohol	129	5 (3.9)	-	108	87 (80.6)	-	-	<0.001

Weight (Kg)	419	58.47 (8.49)	-0.72 (-0.85, -0.59)	417	60.55 (7.83)	0.92 (0.80-1.04)	-2.08 (-3.19, -0.97)	<0.001
BMI (Kg/m^2)	419	21.47 (2.85)	-0.27 (-0.32, 0.22)	417	22.21 (2.48)	0.34 (0.30-0.39)	-0.74 (-1.10, -0.38)	<0.001
Diastolic BP (mmHg)	419	66.80 (7.67)	-0.84 (-1.10, -0.59)	417	68.59 (8.12)	0.26 (0.18-0.35)	-1.78 (-2.86, -0.71)	0.001
Systolic BP (mmHg)	419	111.13 (9.87)	-0.52 (-0.65, 0.39)	417	112.82 (9.56)	0.34 (0.65-0.56)	-1.69 (-3.00, -0.37)	0.012

Table 4 Magnitude of the Intervention Effect

						95% CI	
Variable	**Coefficient**	**Std Error**	***t*-value**	**Sig.**		**Lower**	**Upper**
Physical activity							
Intervention	0.77	0.130	5.873	<0.001		0.51	0.82
Control	1						
Fruits							
Intervention	0.72	0.092	7.868	<0.001		0.54	0.90
Control	1						
Vegetables							
Intervention	0.47	0.015	31.818	<0.001		0.44	0.49
Control	1						
Seafood							
Intervention	0.56	0.041	13.683	<0.001		0.48	0.64
Control	1						
Water							
Intervention	0.39	0.195	2.01	0.045		0.21	0.78
Control	1						
Carbohydrates							
Intervention	-0.15	0.018	-8.558	<0.001		-0.19	-0.12
Control	1						
Fats and oils							
Intervention	-0.23	0.015	-15.799	<0.001		-0.26	-0.21
Control	1						
Fried eggs							
Intervention	-0.50	0.060	-8.256	<0.001		-0.61	-0.38
Control	1						
Fried chicken							
Intervention	-0.32	0.051	-6.363	<0.001		-0.42	-0.22
Control	1						
Carbonated drinks							
Intervention	-0.90	0.093	-9.723	<0.001		-1.09	-0.72
Control	1						
Plain sugar							
Intervention	-0.87	0.199	-4.381	<0.001		-1.26	-0.48
Control	1						
Sweet snack							
Intervention	-0.38	0.015	-24.54	<0.001		-0.41	-0.35
Control	1						
Salted fish							
Intervention	-0.63	0.048	-13.08	<0.001		-0.73	-0.54
Control	1						
Smoking				**Sig.**	**OR**		
Intervention	1.81	0.805	2.251	0.027	6.13	1.24	10.28
Control	1						
Alcohol							
Intervention	-1.57	0.304	-5.176	<0.001	1.06	0.59	1.92
Control	1						
Weight (Kg)							

Intervention	-1.63	0.376	-4.325	<0.001	-2.36	-0.89
Control	1					
BMI (Kg/m^2)						
Intervention	-0.61	0.145	-4.200	<0.001	-0.90	-0.33
Control	1					
Diastolic BP (mmHg)						
Intervention	-1.53	0.547	-2.787	0.005	-2.60	-0.45
Control	1					
Systolic BP (mmHg)						
Intervention	-0.96	0.075	-12.85	0.880	-1.11	-0.82
Control	1					

Figures

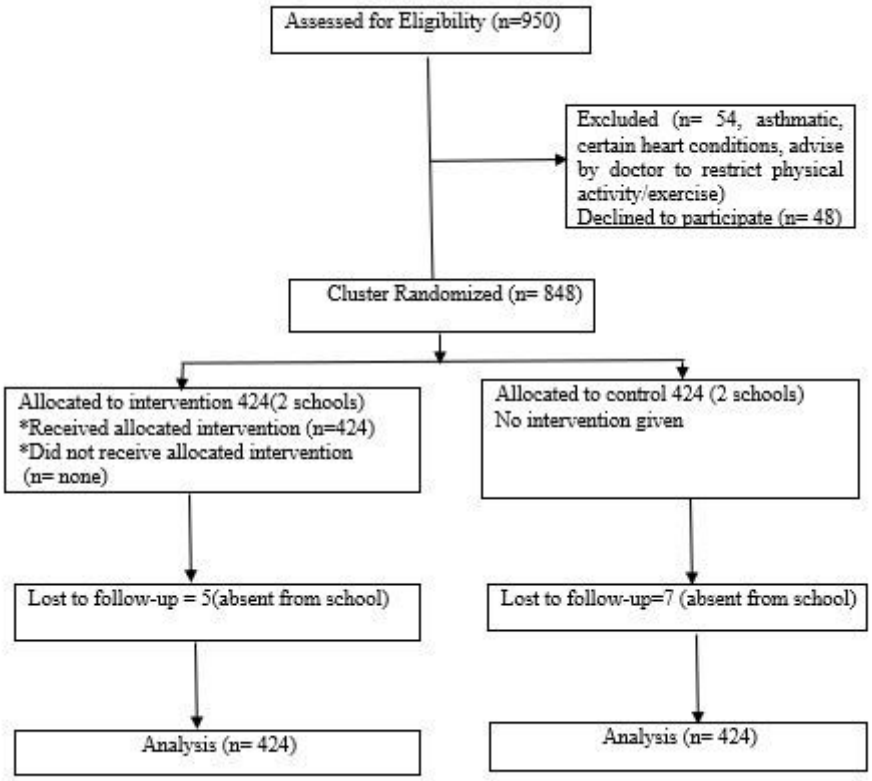

Figure 1

Study Flow Chart Show in Randomization Adapted from CONSORT

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORT2010Checklist.doc