Effect of Behaviour Change Communication on Metabolic Syndrome and Its Markers among Ethiopian Adults: Randomized Controlled Trial

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Abstract

Background: Metabolic syndrome (MetS) is a global public health problem with dire consequences on health, social and economic development. In Ethiopia although MetS has been increasing since the past few decades, there is no study that evaluated the effect of interventions. This study aimed to assess the effect of nutrition behaviour change communication on MetS and its markers.

Methods: An individually randomized controlled trial was conducted using a parallel design among Ethiopian adults working in Jimma University from of September 1, 2015 to January 15, 2016 for the intervention group. A sample size of 230 was calculated using GPower 3.0 assuming an effect size of 0.4, margin of error of 0.05, power of 81%, with an intervention to control ratio of 1. The eligibility criteria include: not having any physical disability and having baseline data. Study population was randomly selected from eligible population (n=704) and allocated into intervention (n=115) and controls (n=115) groups using simple randomization method. The intervention arm was given behaviour change communication using power point presentation, facilitated group discussion on MetS and effective dietary and life style behaviours every month for three months. An Amharic language brochure was also given after the first training and a text message reminder about key behaviours was sent to each individual every two weeks. Data on background characteristic, anthropometry, and clinical parameters and blood samples were collected by trained data collectors in the Nutrition and Dietetic Laboratory of Jimma University. The laboratory analyses were done in Mettu Karl Hospital for lipid profiles and in JUCAN project laboratory for fasting blood sugar. Primary outcomes of the study were metabolic syndrome and its components. Difference in the differences of metabolic syndrome components between baseline and endline (end of intervention) were compared by the intervention status. Multivariable linear regression models were fitted to isolate independent predictors of difference in differences of metabolic syndrome components. A multivariable logistic regression model was used to identify predictors of MetS at the end line.

Results: Overall, there was a significant difference ($P<0.001$) in the prevalence of MetS between intervention (11.6%) and control groups (37.5%) on the end line survey. On multivariable logistic regression analyses, control groups were 8.5 times more likely to have MetS compared to intervention groups (AOR=8.53, 95%CI: 3.60, 20.21, $P<0.001$). There was a significant mean difference in differences in most components of metabolic syndrome and other lipid profiles except HDL ($P=0.717$) in the intervention group. The mean difference in differences in waist circumference was 6.3 cm ($P<0.001$), while that of systolic blood pressure (BP) and diastolic BP were 6.1 mmHg ($P<0.001$) and 3.6 mmHg ($P=0.001$), respectively. Likewise the difference of differences between intervention and control groups was 30.7 mg/dl ($P<0.001$) for T.Cholesterol, 55.5 mg/dl ($P<0.001$) for triglycerides, 21.9 mg/dl ($P=0.015$) for LDL and 22.2 mg/dl ($P<0.001$) for fasting blood sugar. Further multivariable linear regression analyses showed that after adjusting for many variables, there was a significant difference in difference between intervention groups in the components of MetS. For the intervention group the mean difference in differences was 6.1cm ($\beta=6.1$, $P<0.001$) for waist circumference and 4.2 mm Hg ($\beta=4.2$, $P<0.05$) for diastolic blood pressure and 6.5 mmHg ($\beta=6.5$, $P<0.001$) for systolic blood pressure compared with controls. Similarly, the mean difference in differences was higher in the intervention group by 19.9 mg/dl ($\beta=19.9$, $P<0.05$) for FBS, 57.5 mg/dl for TG ($\beta=57.5$, $P<0.05$), 24.40 mg/dl for LDL ($\beta=24.4$, $P<0.05$) and 30.9mg/dl for T.Cholesterol ($\beta=30.9$, $P<0.001$). This trial is retrospectively registered on Pan African Clinical Trial Registration with unique identification number of PACTR202003465339638.

Conclusion: The study demonstrated that nutrition and life style behaviour change communication has a significant positive effect in reducing metabolic syndrome and its components. Although the study was conducted in an institutional set up, the results imply that enhancing such an intervention have a great potential to curb the emerging burden of chronic non-communicable diseases in Ethiopia. Future research should examine how sustainable such behaviour changes are using a community based study.

Introduction

Since few decades back, the burden of metabolic syndrome and chronic non-communicable diseases is emerging in developing countries at an alarming rate (1-2). Recent evidence shows that consequent to the globalization, change in dietary pattern and decline in physical activity levels, the magnitude of overnutrition is escalating on top of high prevalence of undernutrition leading to a double burden in sub-Saharan Africa (3-4).

The global prevalence of non-communicable diseases (NCDs) is on the rise, with the majority of the increase occurring among populations in developing countries (5). In Sub-Saharan Africa (SSA) where Ethiopia is situated, although infectious diseases still cause the majority of mortality (69% of deaths), chronic non-communicable diseases such as cardiovascular disease, diabetes mellitus (DM), chronic respiratory disease and cancers, contribute nearly a quarter of deaths (6). This picture is changing as SSA is undergoing an epidemiological transition with a rapidly increasing burden of chronic non-communicable diseases and associated mortality. In SSA, NCDs are projected to surpass infectious diseases (which are typically endemic to developing countries) by 2030 (5). As the prevalence of chronic non-communicable diseases is increasing, the interface between NCDs and infectious diseases is becoming clearly apparent implying the need for intervention strategies that can address both problems. For instance, an increasing prevalence of diabetes may hinder efforts for tuberculosis control, increasing the number of susceptible individuals in populations where tuberculosis is endemic, and making successful treatment harder (3-4). On the other hand, the high prevalence of HIV infection in developing countries, especially in sub-Saharan Africa and concomitant anti-retroviral therapy leads to an upsurge of MetS (7-8).

Evidence shows that Ethiopia is having the burden of MetS and mortality from chronic non communicable diseases that are linked to overnutrition and life styles changes. Prevalence of MetS was reported to be 14.0% in men and 24.0% in women using IDF criteria; while individual components are prevalent among an apparently healthy working population in Ethiopia (9-10).

These findings indicate the need for evidence-based health promotion and disease prevention programs. Several studies in different countries demonstrated that varying levels of life style change interventions can reduce/reverse MetS (11-12). Another study showed that delivery of a structured group education programme to individuals with MetS improved management of cardiovascular and diabetes risk factors (11). However, these issues were not documented in Sub-Saharan Africa in general and in Ethiopia in particular. .

Although the magnitude of MetS and chronic non communicable diseases is increasing in Ethiopia, there is no any organized public health intervention to prevent the occurrence of these problems and their risk factors. The health care system has limited itself to treating full-blown cases of MetS and its components. There no intervention that is underway to address this emerging problem. Studies elsewhere, had demonstrated that dietary intervention can prevent MetS (13-14). The effectiveness of interventions on MetS has not been evaluated in Ethiopian set up. The aim of this study was to evaluate the effect of nutrition and life style behaviour change communication (BCC) intervention on MetS and its markers.

Methods And Materials

Study Area and Period

The study participants were recruited from Jimma University, which is a public higher educational institution established in December 1999. Jimma Town is 357 km southwest of Addis Ababa. The university has two institutes and six colleges encompassing a total of 1341 academic and 5444 administrative staffs. Evidences show that components of metabolic syndrome such as diabetes mellitus, hypertension and cardiovascular problems are common in the working population (9-10).

Trial design: An individually randomized controlled trial using a parallel design was employed to determine the effect of nutrition and life style behavior change communication (BCC) on MetS and its components.

Participants: Administrative and academic staffs of Jimma University who were involved in the baseline survey (n=704) for developing anthropometric cut-offs (15) were eligible for enrolment into the study. Those who have physical disability including deformity (Kyphosis, Scoliosis), pregnant women, limb deformity that prevents standing erect were excluded.

Sample size: A sample size of 230 was calculated using Gpower 3.0 software assuming an effect size of 0.4 for the mean difference in differences of fasting blood sugar (the commonest component of MetS), margin of error of 0.05, power of 81%, with an intervention to control ratio of 1 and adding 26 for loss to follow up. FBS was used for sample size calculation as it gave the largest sample to have adequate power.

Randomization: The sample was randomly selected from eligible population and allocated to intervention group (those exposed to nutrition and life style behavior change communication) and the control group (those who did not receive any intervention). A simple randomization was done to allocate participants to the intervention (n=115) and control (n=115) arms using ENA Smart software.

Intervention: Six months after baseline data collection, the behavioural change communication intervention continued for three months starting from second half of September, 2015 and up to December 30, 2015. To avoid information contamination the end line data were collected in the first half of September 2015, from the control group and from December 30 to January 15, 2016 for the intervention group. The intervention group was given a face to face behaviour change communication through different strategies including power point presentation for a group of 20 people and facilitated group discussion using evidence on real examples of cases with metabolic syndrome and effective dietary and life style behaviours. The training was delivered every month for three months in Jimma University by the research team members including senior nutritionist, cardiologist, and senior nurses. Each month, the training was given in morning and afternoon sessions for three days with each session lasting for four hours. Each of the intervention group members was given a two page Amharic language brochure to take home after the first training. The study subjects were also reminded the key mottos of the behaviours emphasized during the training through text messages every two weeks, while the control group received nothing before data collection (Table 1). The key messages included : “ your menu should be colourful, avoid the three whites including: fat, sugar and salt, have a diversified diet, aerobic exercise, drink plenty of water, avoid sources trans fats, avoid smoking, avoid khat chewing, avoid unsafe intake of alcohol (≥ 2 drinks per day), have a quality and adequate sleep and avoid sitting for long time”, After the end line data were collected, similar information was given to the control group.

Compliance: Compliance to the intervention was measured through checking the attendances of the monthly training sessions, the number of reminder text messages sent to each person every two weeks and the number of intervention participants who received the two page brochure summarizing the training. All the training was given according to the protocol except that two participants missed one and two training sessions.

Outcomes: Primary outcomes of the study are metabolic syndrome and its components including: waist circumference, systolic and diastolic blood pressures, fasting blood sugar, triglyceride levels, high density lipoproteins, total cholesterol and low density lipoproteins. Data collectors who did all anthropometric, clinical parameters measurements and laboratory technologists who did the blood sample analyses were blinded.

Measurements

This study was conducted in accordance with WHO's Stepwise (STEPS) approach for non-communicable disease (NCD) surveillance(16), which is characterized by the use of questionnaires to capture data on risk factors (Step 1): simple physical measurements (Step 2): and biochemical measurements (Step 3) .The STEPs questionnaire was supplemented with additional questions to gather context specific data in the study area. The questionnaire was used to collect data regarding the general socio-demographic characteristics of the population including: age, sex, and education level. Questions included in the behavioural risk factors such as tobacco, alcohol, physical inactivity and Khat consumption (a natural stimulant with amphetamine-like effects commonly used for social recreation in Ethiopia) (17). Experienced research nurses were trained for five days on the contents of the questionnaire, ethical issues and on data collection procedure. All blood sample collections, questionnaire based interviews, anthropometric measurements and blood pressure measurements were done in the laboratory of Department of Nutrition and Dietetics of Jimma University.

Body composition: Body fat percent (adiposity) was determined both at baseline and end line using different anthropometric indices: Body Mass index (BMI) and Waist Circumference (WC). Baseline Body fat percent was measured using air displacement plethysmography (ADP) (life Measurements) following standard procedures (15). Weight was measured with a solar powered scale which was accurate to 100 grams (Model 871, Seca, Germany). Height was measured with an adjustable portable stadiometer which was accurate to 0.1 cm. Waist circumference was measured with a fixed tension tape, at the midpoint between the lower costal margin at the mid-clavicular line and anterior-superior iliac crest (18) in a private place with no clothing on the upper part of the body. To ensure the data quality, Calibration and validation of anthropometric equipments and standardization of anthropometric measurers was done and a coefficient of variation of < 3% was taken as acceptable.

Blood pressure, Lipid Profiles and Fasting blood Glucose: Three blood pressure measurements were taken after individuals had rested for 5 minutes for the first measurement and with a difference of five minutes between successive measurements. In accordance with the WHO recommendation the mean systolic and diastolic BP measurements were considered for analyses. A five ml blood samples was collected from each individual in the morning after overnight fasting using proper sanitation and infection prevention techniques. Serum was used for the measurement of triglycerides (TG), total cholesterol (TC), high-density lipoprotein cholesterol (HDL), low-density lipoprotein cholesterol (LDL), glucose concentrations. Details of the methods are published elsewhere (15)

For the end line data, a five ml blood specimen was collected by senior medical laboratory technologist and the serum was separated from the whole blood within 30 minutes and transferred to Nunc tubes and stored in -20 °C refrigerator. After all the specimens were collected, the serum was packed with ice and transported to Mettu Karl Hospital laboratory for determination of lipid profiles using HumaStar 80 (Germany) following standard operating procedures. Fasting blood sugar was determined in Jimma University specialized hospital (JUSH) at JUCAN project laboratory using Humastar within two hours of collection.

Statistical Analyses

Data were doubly entered into Epidata 3.0 and exported to SPSS for windows version 20 (Inc, Chicago, IL, USA) for cleaning and analyses. The data were cleaned for outliers and missing values before analyses. After excluding a total of six participants (3 interventions and 3 controls) due to loss to follow up and incomplete data (Figure 1) a final sample size of 224 participants (intervention=112 and control =112) was analyzed. As there were baseline differences in some variables between intervention and control groups, difference in differences was employed in all analyses for comparison of the intervention and control arms to determine the effectiveness of the intervention on MetS components. The end line measurements were subtracted from baseline measurements for both intervention and control groups and the differences in differences were compared using independent sample t-test and multivariable linear regression model were used for comparing mean difference in differences. Assumptions including normality, linearity and absence of multi-collinearity and homoscedasticity were checked using Q-Q plots and variance inflation factor.

For the differences in proportions between intervention and control groups at end line chi-square test was used. Multivariable logistic regression model was used to isolate independent predictors of metabolic syndrome at the end of the intervention. For the multivariable logistic regression, multicollinearity and model fitness were checked using standard error <2.0 and Hosmer Lemeshaw test ($P>0.05$), respectively. Statistical significance was declared at < 0.05 .

Operational Definition of Terms

Intervention group – Randomly selected adults who were given nutrition and health life style behavior change communication for three months.

Control group – Randomly selected adults who were not given nutrition and health behavior change communication.

Duration of the intervention: The time during which the life style medication behavior changes communication was given to the intervention group (three months starting from the second half of September 2015 to the December 30, 2015).

Components of Metabolic syndrome based on IDF criteria (20) as follows:

- Raised TG level: > 150 mg/dL (1.7 mmol/L), or specific treatment for this lipid abnormality
- Reduced HDL cholesterol: < 40 mg/dL (1.0 mmol/L) in males and < 50 mg/dL (1.3 mmol/L) in females, or specific treatment for this lipid abnormality.
- Raised blood pressure: systolic BP ≥ 130 or diastolic BP ≥ 85 mm Hg, or treatment of previously diagnosed hypertension.
- Raised fasting plasma glucose (FPG) ≥ 100 mg/dL (5.6 mmol/L), or previously diagnosed type 2 diabetes If above 5.6 mmol/L or 100 mg/dL.
- Central obesity was defined as waist circumference ≥ 80 for women and ≥ 94 for men.

Metabolic syndrome (MetS) is defined in accordance with the IDF as presence of abdominal obesity and three or more MetS components described above (19-20).

Results

Baseline background characteristics of the study participants are presented in Table 2 below. The mean ($\pm$ sd) age of the study participants were 36.9($\pm$ 10.0) years for intervention and 37.7($\pm$ 10.0) for control groups. The proportion of males and females was 50.9% and 49.1% for the intervention and 43.8% and 56.3% for control groups. The intervention and control groups were similar in terms of their baseline level of total cholesterol, triglyceride, systolic and diastolic blood pressures, body fat percent and body mass index. However, the intervention group had higher LDL (94.0 $\pm$ 43) mg/dl compared to 84.6 ($\pm$ 77.3) mg/dl for the controls. Likewise, the level of HDL was low in the intervention (58.7 $\pm$ 28.7) mg/dl group compared to the controls (68.3 $\pm$ 63.4) mg/dl. Conversely, fasting blood sugar was slightly lower in the intervention group (97.1 $\pm$ 21.6) mg/dl compared with the control group (102.4 $\pm$ 39.6) mg/dl.

In Table 3, comparison of levels of metabolic syndrome components and lipid profiles at baseline and end line was made and the differences in the differences between the baseline and end line values were compared by the intervention status. The results showed that there was a significant difference in differences in most components of metabolic syndrome and other lipid profiles except HDL ($P=0.717$). The mean difference of differences in waist circumference was 6.3 cm ($P<0.001$), while that of systolic blood pressure (BP) and diastolic BP were 6.0 mm Hg ($P<0.001$) and 3.6 mm Hg ($P=0.001$), respectively. Likewise the difference of differences between intervention and control groups was 30.7($P<0.001$) for T.Cholesterol, 55.5($P<0.001$) for triglycerides, 21.9($P=0.015$) for LDL and 22.2 ($P<0.001$) for fasting blood sugar.

Further multivariable linear regression analyses showed that after adjusting for many variables, there was a significant difference in differences between intervention and control groups in the components of metabolic syndrome that are based on physical measurements. For the intervention group the mean difference in differences was 6.1cm ($\beta=6.1$, $P<0.001$) for waist circumference and 4.2 mm Hg ($\beta=4.2$, $P<0.05$) for diastolic blood pressure and 6.5 mmHg ($\beta=6.5$, $P<0.001$) for systolic blood pressure compared with controls. The other variable significantly associated with diastolic blood pressure was baseline body fat percent of the study participants. For a unit increase in baseline body fat percent, the mean difference in differences of diastolic blood pressure was lower by 2.0($\beta=2.0$, $P<0.05$) mmHg (Table 4).

The results of another multivariable linear regression analyses presented in Table 5 showed that after adjusting background variables, the intervention group had high difference of differences in LDL, Triglycerides, T.Cholesterol and fasting blood sugar (FBS). The mean difference in differences was higher in the intervention group by 19.9 mg/dl ($P<0.05$) for FBS, 57.5 mg/dl for TG($P<0.05$), 24.40 mg/dl for LDL ($P<0.05$) and 30.9mg/dl for T.Cholesterol ($P<0.001$).

Other variables associated with LDL were sex and monthly income. The difference in differences was lower by 30.5 mg/dl ($\beta=30.3$, $P<0.01$) for LDL among males. Conversely, those who had high income and medium income had higher difference in differences for LDL by 45.7 mg/dl ($\beta=45.7$, $P<0.01$) and 37.9 mg/dl ($\beta=37.9$, $P<0.01$), respectively. For T.Cholesterol, those in the high income and medium income category had higher mean difference in differences by 36.2 mg/dl ($\beta=36.2$, $P<0.05$) and 33.1 mg/dl ($\beta=33.1$, $P<0.05$), respectively. Similarly, males have significantly higher difference in differences of TG by 54.9 mg/dl ($\beta=54.9$, $P<0.01$). Likewise, for a unit increase in base line fat mass the difference in differences of TG was higher by 2.12 mg/dl ($\beta=2.12$, $P<0.01$). Difference of the differences in FBS was significantly associated with sex and baseline body fat percent. Being male increased the difference in differences at the end line by 13.28 mg/dl ($\beta=12.38$, $P<0.05$). For a unit increase in baseline body fat percent, the difference in difference of FBS increased by 0.66 mg/dl ($\beta=0.66$, $P<0.001$) (Table 4).

The results showed that in both intervention and control groups, small proportion of the study participants were free of any of the MetS components (13.4% for intervention vs 5.4% for controls). Large proportion of both intervention and control groups have atleast one or two of the metabolic syndrome components. However, there was a significant difference in the proportion of intervention and control groups with three or more metabolic syndrome components(Figure 2).

Overall, there was significant difference ($P<0.001$) in the prevalence of metabolic syndrome between intervention (11.6%) and control groups (37.5%) at the endline, while there is no significant difference in the baseline survey (Figure 3). This difference between intervention and control groups at the endline survey was consistent across the different sexes (Figure 4).

The results of multivariable logistic regression showed that variables including: intervention, sex, age base line body fat percent were independent predictors of MetS. Control groups were 8.5 times more likely to have MetS compared to intervention groups (AOR=8.53, 95%CI: 3.60, 20.21, $P<0.001$). Males were 10.2 times more likely to have MetS as compared to females (AOR=4.71, 95%CI: 2.60, 39.84, $P=0.001$). Similarly for one year increase in age the likelihood of having MetS was higher by 6% (AOR=1.06, 95%CI: 1.01, 1.11, $P=0.029$). Likewise, for a unit increase in baseline body fat percent, the odds of having MetS increased by 11% (AOR=1.11, 95%CI: 1.04, 1.18, $P=0.001$) (Table 6).

Discussion

The study demonstrated a significant positive effect of behaviour change communication implemented for three months on MetS and its components, which is consistent with a 12 week yoga-based lifestyle intervention among Indian adults with metabolic syndrome (21) and a 12 week life style education interventional in Thai adults (22). A systematic review of randomized controlled trials in different population groups also showed positive effect of life style modification interventions starting from 10 weeks duration (23). In this study, the likelihood of having MetS was 8.5 times higher among the control group after adjusting for background variables indicating the significance of lifestyle modification interventions in the prevention of MetS and related non-communicable diseases. This finding is consistent with the report of meta analyses of randomized controlled trials that showed life style modification intervention were effective in resolving MetS and reducing the severity of related abnormalities including fasting blood glucose, waist circumference, systolic blood pressure (SBP) and diastolic blood pressure (DBP), and triglycerides in subjects with MetS (12, 13,24).

The positive results imply the need for adopting lifestyle modification programs in the management of MetS and its components (25-26). It was also reported that modifying diet together with frequent physical exercise can reduce the triglycerides concentration as well as SBD and DBP (24, 27, 28). The need for implementing effective lifestyle modifications to prevent MetS and its health consequences has been indicated (24, 29).

Sex and age were other variables associated with metabolic syndrome. It was observed that males were 4.7 times more likely to have MetS as compared to females, which is consistent with other reports (30). For one year increase in age, the likelihood of MetS was higher by 6%, which is similar to a report from elsewhere (31). The relationship between MetS components with older age and male sex has also been reported (32).

It was also observed that the intervention group has significantly ($P<0.05$) higher difference in differences between baseline and end line surveys for serum levels of FBs, Triglycerides and T.cholesterol and higher levels of HDL compared to the control group. A similar finding was reported by studies from elsewhere (24; 27, 33). Likewise, the intervention group had a significant difference in differences in waist circumference similar to reports of studies elsewhere (34-35).

The results showed that intervention group the mean difference in differences was 4.2 mmHg ($P<0.05$) for diastolic blood pressure and 6.5 mmHg ($P<0.001$) for systolic blood pressure compared with controls. This finding is consistent with another study which showed that the mean diastolic blood pressure (DBP) and triglycerides decreased significantly in the intervention group in both sexes (36). A positive effect of life style modification on blood pressure has also been reported among Korean adults (37, 38).

It has been documented that interventions incorporating dietary, physical activity and other life style changes exerts beneficial effects on the various components of the MetS and improves overall survival (13, 24, 27, 28, 29). However, interventions targeting life style changes have the potential to succeed only if they are executed early to offer strong evidence to substantiating the development of appropriate public policies (14, 23).

Baseline body fat percent of the study participants was significantly associated with diastolic blood pressure such that for one percent increase in baseline body fat percent the mean difference in differences in diastolic blood pressure was lower by 0.2mmHg ($P<0.05$). This could be related the effect of high body fat percent on the cardiovascular system which minimizes the difference in the blood pressure changes. The effect of body fat percent on increasing blood pressure has been documented by other studies (13, 38, 39).

Multivariable linear regression analyses showed that the intervention has high difference of differences in LDL, Triglycerides, T.Cholesterol and fasting blood sugar (FBS). A similar positive effect of life style modification was reported on lipid profiles (40-41) and blood sugar level (42). It was also observed that the difference in differences was lower by 30.5 mg/dl for LDL among males compared to females. This indicates that at the end of the follow up period, the decrease in LDL cholesterol was lower among men. The relationship between gender and lipid profile is age dependent. At younger age men tend to have higher levels of LDL, while this relationship gets reversed during older age especially after menopause where women tend to have higher level of LDL (43) implying the need for careful interpretation of this finding.

Similarly, participants who had high income and medium income had higher difference in differences for LDL and T.Cholesterol compared with those in lower income. Evidence shows that an increase in income without change in educational status was associated with poor lipid profiles (44). However, the positive association of income with differences in differences of LDL and T.Cholesterol could be due to the fact that income is highly associated with educational status in the study population (university staff), which in turn may affect the level of adherence to the behaviour change interventions(45).

The positive findings of the behaviour change communication observed in this study have wider practical implications for Ethiopia where both modifiable and non-modifiable risk factors for chronic non-communicable diseases are increasing from time to time while the commensurate preventive intervention are lagging behind. The non-modifiable risks factors include increased life expectancy to over 64 years (46) and history of high proportion of early life stunting (47-51). Early life stunting could generate a huge potential for emergence of epidemics of chronic non-communicable diseases due to organ stunting. It has been reported that early childhood malnutrition including during the fetal period leads to occurrence of chronic non-communicable diseases later in life (52). The modifiable risk factors include dietary transitions to more processed and low fibre high calorie diet and sedentary and motorized way of life (53-55). The positive effect of the intervention documented in these modifiable risk factors implies the need for enhancing such interventions using different strategies through the involvement of different sectors to curb the upsurge of non-communicable disease and associated consequences in the years to come.

The study employed an individually randomized controlled trial to generate empirical evidence on the effectiveness of intervention approaches, which could potential lead to information contamination. To minimize this, the end line data were collected from the control group earlier than the intervention group, which is not expected to have an effect in their dietary and other behavioural factors as the data from both groups was also collected in the same season. As this study was done among university staff who may be a group of highly motivated participants, the findings may not be generalizable to the community setup. However, the sample involved both academic and administrative staff including gardeners, cleaners, guards who are closer in background characteristics to the community making the concern minimal. This study evaluated an intervention that lasted for three months. If it is integrated to the existing health system the cost incurred for purpose is insignificant. However, our study did not capture serial measurements of MetS and its components to come up with a suggestion on the minimum number of days required for such an intervention to bring about significant change, which is the limitation of this study. However, three months is not also a long time given the chronic nature the metabolic changes. Future research should determine the minimum number of days required to have a significant effect on the outcome variables.

Conclusions

The study demonstrated that nutrition and life style behaviour change communication has a significant positive effect in reducing metabolic syndrome and its components. Although the study was conducted in an institutional set up, the results imply that enhancing such an intervention have a great potential to curb the emerging burden of chronic non-communicable diseases in Ethiopia. Future research should examine how sustainable such behaviour changes are using a community based study.

Abbreviations

ADP: Air Displacement Plethysmography; BMI: Body Mass Index; ROC: Receiver Operating Characteristics Curve; WC: Waist Circumference; WHR: Waist to Hip Ratio; WHtR: Waist to Height Ratio

Declarations

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Availability of data and materials

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

Authors' contributions

MS and TB conceived and planned the study. MS, DL, MST, TY, TB and ET implemented the study. MS and TB did the analyses. MS drafted the manuscript. DL, MST, TY, TB and ET critically reviewed the manuscript. All authors gave input to the manuscript and read and approved the final version.

Ethics approval and consent to participate

The study protocol was ethically approved by the Ethical review board of Jimma University before the start of the study on February 5, 2015 with a reference number of: RPGC/691/07. Adequate explanation was given to each participant and informed consent was obtained before data collection. To keep anonymity of all data, no personal identifiers were used except unique ID number. So, unlinked anonymous method was used, where the study subjects and their blood samples were matched later during analyses without revealing any personal identifiers. Informed verbal consent was obtained from each study subjects prior to the administration of questionnaire after the purpose of the study was explained to respondents. The study participants were informed that they will have the right to refuse or discontinue participating in the research without any compromise in the service they are getting from the respective facilities. Finally, the study participants were given their laboratory results printed on a slip that has only their unique identifier. This trial is retrospectively registered on Pan African Clinical Trial Registration with unique identification number of PACTR202003465339638.

Consent for publication

This is not applicable as the study does not have individual person's data.

Competing interests

Authors do not have any competing interests.

The authors declare that they have no competing interests.

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Tables

Table 1. Intervention protocol for nutrition and life style behaviour change communication (BCC) among Employees of Jimma University, Ethiopia

Key action(message)	Strategy of intervention	Responsible	Frequency	Compliance Parameter
· Consumption of Diversified Diet (The six food groups)	leaflet with key message (in Amharic)	Research Team members	Once	Number of intervention participants who received the leaflet
· Exercise(Moderate intensity exercise of 30 minutes at least for 3 days a week)				
· Life styles(no smoking, alcohol drinking, no khat chewing, getting adequate sleep of 6-8 hours, not sitting /reclining for long time)	Power point presentation and discussion of evidences on metabolic syndrome and dietary and life style behaviours	Research Team members	Once a month	Frequency & attendance
· Drinking more water	Reminders (key mottoes of the behaviours were sent by text message (Group e-mail as applicable)	Research Team Members	Every Saturday once in 15 days	Frequency
· Metabolic syndrome and its risk factors, consequences				

Table 2. Baseline background characteristics of intervention and control groups, Jimma University, Ethiopia

Variables	n	Intervention (n=112)	Control(n=112)
		Mean(±sd)	Mean(±sd)
Sex: n(%)			
M	106	63.0(50.9)	55.0(43.8)
F	118	49.0(49.1)	57.0(56.3)
Age(Yrs)	224	36.9(9.0)	37.7(10.0)
FBS (mg/dl)	224	97.1(21.6)	102.4(39.6)
HDL (mg/dl)	224	58.7(28.7)	68.3(63.4)
Total Cholesterol(mg/dl)	224	182.3(38.8)	182.6(52.4)
TG (mg/dl)	224	147.8(102.3)	148.5(84.7)
LDL (mg/dl)	224	94.0(43.0)	84.6(77.3)
Systolic Blood Pressure(mm Hg)	224	117.6(11.6)	118.4(13.9)
Diastolic Blood Pressure(mm Hg)	224	77.9(9.4)	77.91(9.1)
Waist Circumference (cm)	224	86.3(12.8)	85.5(12.8)
Body fat percent (%)	224	31.4(11.2)	31.5(10.9)
Body mass index (kg/m ²)	224	25.3(4.9)	25.0(5.2)
Weight(kg)	224	67.9(13.4)	67.0(13.3)

Table 3. Differences in differences between baseline and end line measurements of metabolic syndrome components and lipid profiles and among intervention and control groups, Jimma University, Ethiopia

Metabolic syndrome components and lipid profile	Intervention			Control			Difference in Differences	
	Baseline	End line	Difference (BL - EL)	Baseline	End line	Difference (BL - EL)		
	Mean(±SD)	Mean(±SD)	Mean(±SD)	Mean(±SD)	Mean(±SD)	Mean(±SD)	Mean(±SE)	P
Waist Circumference(cm)	86.3(12.8)	80.8(12.7)	5.6(7.2)	85.5(12.7)	86.2(12.8)	-0.7(5.9)	6.3(1.7)	<0.001
Systolic BP(mmHg)	117.8(11.8)	107.8(15.0)	10.0(12.7)	118.2(13.8)	114.2(16.3)	4.0(11.9)	6.0(1.7)	<0.001
Diastolic BP(mmHg)	77.8(9.4)	70.9(9.4)	6.9(6.2)	77.9(9.1)	74.5(9.8)	3.4(7.7)	3.6(1.1)	0.001
T. Cholesterol(mg/dl)	182.3(38.8)	139.2(35.4)	43.0(35.3)	182.6(52.4)	170.3(50.4)	12.2(70.9)	30.7(7.5)	<0.001
Triglyceride(mg/dl)	147.8(102.3)	98.6(54.7)	49.5(83.1)	148.5(84.7)	154.4(87.7)	-6(10.6.1)	55.5(12.9)	<0.001
HDL(mg/dl)	58.7(28.7)	42.5(11.5)	16.4(29.8)	68.3(63.4)	49.5(17.8)	18.8(64.0)	-2.4(6.7)	0.717
LDL(mg/dl)	94.0(43.0)	76.9(27.9)	16.8(43.2)	84.6(77.3)	89.7(32.4)	-5.1(83.5)	21.9(8.9)	0.015
Fasting Blood Sugar(mg/dl)	97.1(21.4)	78.8(21.9)	18.4(28.8)	102.3(38.9)	106.2(37.1)	-3.9(24.8)	22.2(3.6)	<0.001
Weight(kg)	67.9(13.4)	65.9(12.3)	2.0(4.7)	67.0(13.3)	65.4(13.1)	1.6(4.7)	0.4(0.6)	0.494
BMI	25.3(4.9)	24.5(4.6)	0.7(1.7)	67.0(13.3)	24.3(5.1)	0.6(1.7)	0.1(0.2)	0.565

BL= Baseline. EL= End line, BP= Blood Pressure, SE= Standard error, SD- Standard Deviation.

Table 4. Multivariable linear regression model predicting the mean baseline to end line difference in the differences in the components of metabolic syndrome that dependent on physical measurements of study participants, Jimma university, Ethiopia

Variables	Differences in differences of Waist circumference and Blood pressure between Baseline end line (Baseline – End line)		
	Waist Circumference (cm)	Systolic BP (mmHg)	Diastolic BP (mmHg)
	β (95%CI)	β (95%CI)	β (95%CI)
Sex	2.0 (2.1, 6.1)	1.6(-6.0 , 9.3)	0.8(-4.8, 6.4)
Male			
Female (Ref.)			
Age(Yrs)	0.2(0.0, 0.4)	-0.1(-0.4, 0.3)	0.1(-0.1, 0.4)
Monthly income	-2.0(-7.4, 3.3)	9.2(-0.8, 19.3)	5.4 (-1.9, 12.8)
High income	0.6(-3.4, 4.5)	1.5(-6.0, 8.9)	0.0 (-5.5, 5.5)
Medium income			
Low(Ref.)			
Educational Status	2.4(-1.5, 6.4)	5.1(-2.2, 12.5)	-0.2 (-5.6, 5.2)
High School and below(Ref.)	2.7(-2.1, 7.5)	-4.9(-13.9, 4.2)	-4.1 (-10.8, 2.5)
Diploma			
Degree and above			
Intervention	6.1(4.2, 8.9)***	6.5 (3.1, 9.9)**	4.2 (2.1, 6.4)**
Yes			
Control(Ref.)			
Baseline body fat percent	0.1(-0.1, 0.3)	-0.1(-0.5, 0.2)	-0.2(-0.3, -0.1)*

Parameters adjusted for Number of days of Moderate intensity exercise in a week, Hours of sleep in a day and Takes break after long hours of sitting

Maximum Variance inflation factor in all models = 4.2.

Ref. :reference category.

***P<0.001, *P<0.05.

Table 5. Multivariable linear regression models predicting mean baseline to end line differences of the differences in the components of metabolic syndrome that dependent on Laboratory analyses of blood sample of study participants, Jimma University, Ethiopia

Variables	Baseline end line differences of lipid profiles and Fasting blood sugar(Baseline – End line)				
	FBS	HDL	TG	LDL	CHOL
	β (95%CI)	β (95%CI)	β (95%CI)	β (95%CI)	β (95%CI)
Sex					
Female(Ref.)	13.28(2.6, 24.0)*	11.9(-13.5, 37.3)	54.9(15.8, 94.1)**	-30.46(-57.7, -3.24)**	-20.6(-49.4, 8.1)
Male					
Age(Yrs)	-0.7(-1.5, 0.2)	-0.1(-1.1, 1.0)	-0.2(-3.0, 2.5)	-0.29 (-1.52, 0.94)	-0.1(-1.3, 1.1)
Monthly income	-6.0(-32.4, 20.4)	-7.0(-40.4, 26.5)	-15.4(-103.3, 72.6)	45.69(7.05, 84.32)**	36.19(3.6, 68.8)*
High income	-3.6(-23.2, 16.0)	-9.1(-33.9, 15.7)	40.2(-25.2, 105.5)	37.94(10.38, 65.50)**	33.07(9.8, 56.3)*
Medium income					
Low(Ref.)					
Educational Status	5.4(-14.0, 24.9)	4.94(-0.57, 30.44)	16.6(-47.9, 81.0)	-0.99(-32.77, 32.79)	-16.6(-44.3, 11.2)
Degree and above (Ref.)	14.3(-9.6, 38.2)	10.8(-19.3, 40.9)	23.0(-56.2, 102.2)	28.30(-6.92, 63.51)	-20.0(-54.1, 14.1)
Diploma					
High School and below					
Intervention	19.9(12.39, 27.40)**	-5.57(-19.9, 8.84)	57.53(30.1, 85.0)**	24.40(5.3, 43.47)*	30.87(14.8, 46.9)***
Yes					
Control(Ref.)					
Baseline body fat percent	0.66(0.15, 1.16)*	-0.3(-1.4, 0.9)	2.12(1.28, 4.96)**	0.11(-1.17, 1.40)	-0.7(-2.0, 0.6)

Parameters adjusted for number of days of moderate intensity exercise in a week, hours of sleep in a day and Takes break after long hours of sitting

Maximum Variance inflation factor in all models = 4.2.

TG= Triglyceride, HDL: high density Lipoprotein. LDL: low density lipoprotein, T.Chol: Total Cholesterol, FBS: Fasting blood sugar. **P<0.001,**P<0.01, *P<0.05.

Table 6. Multivariable logistic regression model predicting the likelihood of having metabolic syndrome at the end of the intervention of study participants, Jimma University, Ethiopia

Predictors	β	RR	95% C.I.		P
			Lower	Upper	
Sex					
Male	2.32	10.19	2.60	39.84	0.0010
Female		1.00			
Age (Years)	0.05	1.06	1.00	1.11	0.0400
Intervention					
No	2.00	7.42	3.00	18.38	<0.0001
Yes		1.00			
Monthly income Tertile					
Low		1.00			
Medium	-0.28	0.75	0.16	3.54	0.7190
High	-0.27	0.76	0.22	2.66	0.6710
Educational Status					
Degree and above	-0.07	0.94	0.23	3.79	0.9250
Diploma	0.15	1.16	1.08	1.24	<0.0001
High School or below		1.00			
Baseline fat percent	0.15	1.16	1.08	1.24	<0.0001

Hosmer Lemeshaw ($P=0.068$), Maximum Standard error=0.790
AOR- Adjusted odds ratio, CI= Confidence Interval.

Figures

Figure 1
Trial flow diagram for the effect of behaviour change communication on metabolic syndrome and its markers among workers of Jimma University, Ethiopia

Figure 1

Trial flow diagram for the effect of behaviour change communication on metabolic syndrome and its markers among workers of Jimma University, Ethiopia

Figure 2
Proportion of study participants with different components of metabolic syndrome in the intervention and control groups at the end line, Jimma University, Ethiopia

Figure 2

Figure 3

Baseline and endline differences in the proportion of metabolic syndrome among intervention and control groups, Jimma University, Ethiopia

Figure 3

Baseline and endline differences in the proportion of metabolic syndrome among intervention and control groups, Jimma University, Ethiopia

Figure 4

Prevalence of metabolic syndrome between intervention and control groups at the end line by sex, Jimma University southwest Ethiopia

Figure 4

Prevalence of metabolic syndrome between intervention and control groups at the end line by sex, Jimma University southwest Ethiopia