Effect of a nutrition education programme on metabolic risk factor and metabolic syndrome in adults with type 2 diabetes mellitus at a Level 5 Hospital in Kenya: “a randomized controlled trial”

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Abstract

**Background** Type 2 diabetes mellitus; a chronic disorder characterized by poor glycemic control, is a life threatening condition of global public health concern which worsens in the presence of metabolic syndrome (MetS) and associated risks. However, application of lifestyle intervention may reduce this risk. The aim of the current study was to evaluate the effect of nutrition education programme with inclusion of peer to peer support on MetS and Mets risk factors in type 2 diabetes mellitus patient.

**Methods** This was a randomized controlled trial with two intervention groups and one control. The intervention groups included nutrition education peer to peer support group (NEP) (n=51) and nutrition education group (NE) (n=51) which participated in an eight week (2 h per week) group nutrition education sessions and follow-up sessions for six months. The NEP in addition had a peer to peer support component on weekly basis for the eight weeks of training and monthly support for six months. The control group (C) (n 51) received standard care. Outcomes were assessed at 6 months. An intention-to-treat analysis was conducted using analysis of co-variance (ANCOVA).

**Results:** Differences in MetS were -38.1 and -31.7% (P<0.01) at 6 months in the NEP group as per Harmonized and WHO criteria respectively. Significant improvement was seen in number of participant achieving recommended waist circumference; WC (33.9 %) and high density lipoprotein; HDL (35.2%) in the NEP group and blood pressure; BP (reduction by 39.2 and 31.6) as per harmonized and WHO criteria respectively in the NE group. Six month post intervention statistical mean change was also noted six month post intervention in; weight lost (-6.26kg), BMI (-2.37 kg/m²), waist hip ratio; WHR (-0.03), WC (-14.51 cm) and HDL (+0.34mmol/l in the NEP group and diastolic blood pressure; DBP (-5.17 mmhg) in the NE group. Comparison of the NEP and NE with control showed that NEP and NE had better outcome.

**Conclusions:** Nutrition education with inclusion of peer to peer support was of clinical benefit in reducing metabolic outcomes and MetS in Type 2 diabetes mellitus patient. Optimal goal setting and self-effective training could benefit future nutrition education programmes with peer to peer support component for people with Type 2 Diabetes and at risk of Mets.

**Background**
Type 2 Diabetes mellitus is heterogeneous metabolic disorder characterized poor glycemic control [1]. It is a global public health problem and one of the most common life threatening condition globally due to its related complication with more and more people living with condition each year[1–4]. It is a debilitating and costly disease that undermines economic development of a country due to it is associated morbidity and mortality [3,4]. Type 2 Diabetes cost everyone, not just those with diabetes, however, the largest costs are not on expenditure for diabetes care, they are on disability, management of complications and economic stagnation[1].

Type 2 diabetes mellitus is related to Metabolic syndrome (MetS); a cluster of interrelated clinical factors that include insulin resistance, dyslipidemia, excess weight and elevated blood pressure [2]. Presence of MetS in Type 2 diabetes mellitus patient is a very common clinical problem of global public health concern [5–10]. Metabolic syndrome (MetS) is associated with a 5-fold increase in Type 2 diabetes mellitus which worsens in presence of poor glycemic control and a 3-fold increase in cardiovascular diseases [2,5–7,11–13]. Due to increased prevalence of obesity, surplus energy intake and sedentary lifestyle Mets in Type 2 Diabetes mellitus patient is becoming worldwide epidemic [14]. Presence of MetS in Type 2 diabetes mellitus patient leads to an increase in micro vascular and macro vascular complication which worsens in the presence of associated risks factors [5,9,19,10–13,15–18]. A higher prevalence of between 50-80% of MetS in Type 2 Diabetes mellitus patient using different definitions have been reported in different parts of the world [15,20–24]. Similar prevalence have been reported across the globe in the general population[15,25–28]. In Kenya high prevalence’s of MetS and associated metabolic risk factors have been reported on general population [28,29]. However data on existence of MetS in Type 2 Diabetes mellitus population as well as intervention to address MetS in Type 2 diabetes mellitus in in Kenya have not been reported.

Metabolic syndrome (MetS) in Type 2 diabetes mellitus has been associated with several metabolic factors. These include obesity a major determinant of insulin resistance, elevated waist circumference, dyslipidemia and increased blood pressure [2,7–11]. These factors are also significant
to progression of Type 2 Diabetes mellitus as well as related complication. An upward trend in these risk factors has been reported and this pose a greater challenge due to increased health cost, morbidity, and mortality [18,30–33].

Lifestyle and behavioral factors play an significant role in the development of Type 2 Diabetes mellitus as well as MetS in Type 2 diabetes mellitus patients[34–36]. Lifestyle intervention including nutrition education and physical activity has been shown to be effective in improving clinical outcomes in individuals with Type 2 diabetes mellitus as well as improving metabolic outcomes in Type 2 diabetes mellitus patients [34–37]. However, achieving lifestyle modification that include among others; healthy diet and, physical activity is often the most challenging aspect of care to accomplish in patient management. This might be due to poor self-control, lack of information, financial constraints among others. This can be improved through health education and awareness creation on positive lifestyle changes aimed at addressing deleterious effects of an unhealthy diet (high intake of fat, sugar and salt) and physical inactivity on patient condition [36,38]. Inclusion of peer support might aid in management of the condition further.

Peer to peer support in chronic disease management (like Type 2 diabetes mellitus, Mets) have been shown to provide social and emotional support, help people apply disease management or prevention plans in daily life and link individuals with clinical, community, and other resources [39–41]. Additionally studies have shown that effectiveness of diabetes education on lifestyle modification can be enhanced further through inclusion of peer to peer support [40,42–46]. However, despite the established role of lifestyle intervention and peer to peer support in improving Type 2 diabetes mellitus and MetS risk factor control, its contribution to Type 2 diabetes mellitus and MetS management in Africa, including Kenya, is not well established. Therefore the purpose of the present study was to implement a nutrition education (NE) programme with peer to peer support and evaluate its effect on, MetS and MetS risk factors on adults with Type 2 Diabetes
Methodology

Study setting

The study was conducted at Thika Level 5 Hospital (TL5H) in Kiambu County, Kenya at the Diabetes Comprehensive Care Clinic (DCC) which attends to approximately one hundred patients per week and has an average of one thousand patients [47]. The DCC is an out-patient clinic that operates on a daily basis. Diabetic patients, self and non-self-referred from the County and nearby areas attend the clinic on appointment days for routine blood glucose monitoring, medical checkup (blood pressure) and nutrition status checkup (body mass index; BMI), treatment and collection of medication. Newly diagnosed patient with either Type 1 or Type 2 Diabetes mellitus are also referred here from other clinic (either from the hospital or neighbouring healthy facilities) for further management. The clinic serves both male and female with Type 1 diabetes mellitus and Type 2 diabetes mellitus. The patients are mainly from low and middle income social economic background. During the clinic day health talk on general diabetes care management with minimal demonstration is given. However the education given is not exhaustive as only thirty minutes are allocated. The content covered during the health talk has a very small component on nutrition and physical activity component that is given with no demonstration. In addition the patient arrived at different times therefore, not all who benefits from the talk. This call for a detailed programme aimed at enhancing patient nutrition knowledge level using nutrition and exercise management in relation to Diabetes. The current study aimed at studying the effect of nutrition education programme with peer to peer support on MetS indicators and MetS in Type 2 diabetes mellitus patient.

Study design and ethics

This was a randomized controlled trial with two intervention group (nutrition education; NE and Nutrition education and peer to peer support; NEP) and a control group(C). The study was approved by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (Permit No. KNH-ERC/A/232) and the National Commission for Science, Technology and Innovation (NACOSTI) (Permit No. NACOSTI/P/16/83452/10118). Study participants gave a written informed consent.
Study participants

Study participants were men and women aged 20–79 years with Type 2 diabetes mellitus attending the Diabetes Comprehensive Care (DCC) center at TL5H. They were recruited during their daily clinic attendance while waiting to see a health professional. Recruitment was done over a period of 2 months from August 2016 to October 2016. All patients who met the following criteria were selected: patients suffering from Type 2 diabetes mellitus aged between 20-79 years, regular attendance at the DCC; not pregnant; with no complication like renal failure, congestive heart failure, stroke and not planning to move from the study area during the study period. A total sample size of 153 patients was recruited for the study.

Sample size determination

To confer 90% power at 5% level of significance and detect an absolute effect size of 30% improvement on metabolic syndrome (MetS) in Type 2 diabetes mellitus patient (i.e. from 45% to 15% with intervention), we needed to include 46 study participants in each study arm using the formula by Armitage et al., [48] and Lwanga and Lemeshow [49]. The sample size was subjected to a correction factor of 10% to cater for attrition thus each arm had 51 participants making a total sample size of 153 patients.

Randomization

The study consisted of three groups, two intervention groups nutrition education peer to peer support group (NEP) and nutrition education group (NE) that received nutrition education with peer to peer support and nutrition education respectively and control group (C) that received standard care. Participants were randomized to either of the intervention groups or control group with the use of random numbers. To allow equal chances for participants, randomization was stratified on the basis of sex and age. Sealed sequentially numbered opaque envelopes per each stratum (1-3) mixed using the lottery method were used. The participants were requested to pick an envelope each and join
their groups (1-3). A volunteer from each group was then requested to move forward and pick another envelop each containing their treatment allocation (NE, NEP and C). Upon confirmation of the treatment allocation, the participants were allocated to their treatment group by the principal investigator (PI), and the group members recorded. Each group was assigned 51 participants. After randomization baseline data was collected from all the participants.

**Intervention**

Before random assignment to control or intervention groups, all study participants received standard education that covered content on diabetes pathophysiology, risk factors, symptoms, complications, hyperglycemia and hypoglycemia symptom and foot care treatment goals and modalities. This was done by the principal investigator (PI) together with a clinician who runs the clinic (Registered Clinical Officer with a Bachelor of Science degree in Clinical medicine). Pictorial flip charts and additional learning material with diabetes management information adapted from MoPHS diabetes prevention and management guideline [50], NorvoNodisk changing diabetes poster as well as MOH diabetes posters in addition to what the(PI) had prepared after review of different literature were used. Different teaching method that included lecture, discussion demonstration role play and group work were used to deliver the information. After the standard education, one of the intervention group received eight week nutrition education in combination with importance of physical activity (NE group), while the second group received nutrition education, importance of physical activity programme with peer to peer support emphasis (NEP group). The control group received the standard education given to all groups and standard care. The nutrition education included weekly (120 minutes each) nutrition classes conducted over eight weeks by the researcher. The nutrition education curriculum was developed by the PI after review of related literature on nutrition management of diabetes and importance of peer to peer support in management of diabetes. The PI also applied her experience gained in her practice as a nutritionist. The NE curriculum was written in English and supplemented by photos and illustrations to help the patient understanding the content better.
The curriculum focused on nutrition in relation to diabetes, food portion control for weight reduction, use of healthier food choices, an individualized meal planning; glycemic index and glycemic load of different food and their importance in blood glucose control; food pyramid and its use together with food exchange list (Table 1). Patient learnt about the basics food groups, the difference between simple and complex carbohydrates and their relation to glycemic index and glycemic load, fibre content of different cereals and starches, the difference between saturated and unsaturated fats and their relation to diabetes management; sources of protein and the different nutrient content of each; hidden calories contained in beverages; and the micronutrient and fiber values of fruits and vegetables. The nutrition content was presented using lectures, demonstration, discussion, and other participatory method. The nutrition education curriculum was first tested in a subgroup (10% of sample) of patients not involved in the study before the actual implementation.

The physical activity lesson were adapted from the WHO strategy on diet and physical activity and health [51] WHO Global recommendation on physical activity for health [52] and Kenya Diabetes Educator manual [53] which were modified by the researcher with the help of a physiotherapist to suit the study patient. The aim of the physical activity was to ensure that patients accumulate a minimum of 150 min of moderate intensity exercise each week from personal activity at home that includes walking, digging, jogging, cycling, house hold duty, aerobics and sport activities. The participants were encouraged to perform the exercise at least 3 days each week with no more than two consecutive days without exercise. During the intervention the patient were led through the importance of physical activity as well as demonstration on activities they can do at home by an experienced physiotherapist in diabetes management. The participants were encouraged to continue with the exercises at home in addition to normal routine work.

Previous studies have highlighted the importance of peer support in management of chronic conditions[54]. Participants in the NEP group were grouped in small support group (5-10 participants)
depending on the location they came from as well as age cohort during the intervention period and these groups continued during the follow up period. After each education session they were encouraged to set and share with each other weekly goals for specific changes in their eating and physical activity behavior aimed at making healthy food choices, reduction of portion sizes and being active. The patient reported on their progress to the group members at the beginning of the next session. After the eight weeks training sessions the patient were followed and their goal presented to other members in the subgroup on monthly basis for six month. A trained peer educator living with diabetes for 13 years from Kenya Defeat Diabetes Association (KDDA) joined the PI during the monthly meeting and encouraged the patient in the peer support groups by sharing his experience. Together with the PI he also assisted them review their goals during monthly meeting and if there was any adjustment required done. Also group counseling was done on each visit for patient requiring more support. The intervention was done for a period of eight weeks which was adequate for the implementation of the curriculum. The implementation started from last week of 24\textsuperscript{th} October 2016 to 23\textsuperscript{rd} December 2016.

**Follow up**

The intervention run for eight weeks and follow up done monthly. After the end of the eight weeks intervention the patient were requested to be coming to the hospital monthly on selected days for follow up. At the start of the study the patient were given appointment cards developed by the PI indicating the day they are supposed to come for the appointment. The researcher also got phone numbers for the participants which assisted in follow up. A call was given to the participant reminding them on the appointment one week to the appointment day and two days to the appointment day to ensure they avail themselves. Those who did not turn up would be given another day and be reminded again of their appointment. For those who could not make to come after second reminder, they were followed in their home and requested to come for the appointment. This prevented loss to follow up. Patient in the NEP group continued with peer to peer support during the follow up period.
### Table 1: Nutrition education curriculum

| Week Introduction week | Topic | Content and activities | Participants |
|------------------------|-------|------------------------|--------------|
|                        | What is diabetes and how it is managed | Nature of disease (explanation of what happens when one has diabetes, including body’s response to food in diabetic/non-diabetic states, insulin action, causes/risk factors, types) Symptoms and complications medication and their roles in treatment Aim for treatment and targets for good control Causes, symptoms and management of hypoglycemia and hyperglycemia Foot care and eye care. | All participants |
| Week One | Dietary guidelines on healthy eating | Principal of healthy eating: importance of regular and varied meals Guided discussion on improving dietary variety Cereals and starches as well as root and tuber groups and their role in diet Different type of starches and cereals, carbohydrate content and how it affects blood glucose Some healthy ways to include starches in meals Demonstration of portion/serving sizes of different cereals and starches Group work: practices on portioning and serving of starches | Intervention groups |
| | Dietary guidelines continued; Overview of food groups and their role in diabetes management | | |
| Week Two | Dietary guidelines continued; Overview of food groups and their role in diabetes management | Specific guidelines for cereals preparation Legumes group and nut and seed groups and their role in diet Carbohydrate content in | |
| | | | |
Week Three
Dietary guidelines continued; Overview of food groups and their role in diet
Their role in diabetes management
Trimming of fat in meat
Reduction of cream in milk
Different milk product and how to include different serving portion
Importance of minimizing of processed meat in diabetes and chronic disease management

Week Four
Dietary guidelines continued; Overview of food groups and their role in diabetes management
Vegetables and fruits
How to improve vegetables supply at home
Importance of vegetables and fruit in diabetes management
Carbohydrate content in fruits and vegetables and how it affects blood glucose
Demonstration of different vegetables and fruits
Group work: participant in groups to name different fruit and vegetables demonstrated and indicate how they will improve their supplies

Week Five
Dietary guidelines continued; Overview of food groups and their role in diabetes management
Fats and oil and their role in diabetes
Importance of fat and oil
Sources of fat
Type of fats (saturated and unsaturated), Their sources and effect of each in the body.
Some healthy way to include fat and oils in the diet
Group activity: label reading of fat and oil products on display and identification of different content of different component of triglycerides, saturated fat and unsaturated fat levels.

Week Six
Meal planning: portions and meal frequency
Facilitated group review of the effect of different food group on blood glucose
Discussion on importance of food portion control and regular meals
Guidelines for portion sizes
Demonstration: portion sizes (household measures, Zimbabwe hand jive, plate...
Week Seven

**Glycemic index and its importance in diabetes management**

- Group activity: practice portioning various commonly used foods
- Reflection and group discussion about portion sizes and associated issues such as hunger
- Planning meals on a limited budget, emphasis on variety and balance within available resources
- Importance of timing and combining meals
- Role of glycemic index and glycemic load in blood glucose control
- Glycemic index and glycemic load of different foods
- Examples of glycemic index of various foods
- Group activity: classifying food in terms of glycemic index
- Label reading of different foods: reflection on current practices related to dietary guidelines and label reading plus group discussion

Week Eight

**Physical activity**

- Importance of physical activity in blood glucose control
- When to exercise
- Group activity: demonstration of the exercises by group leaders and
- All participant participate in exercise programme

**Post Evaluation, Handouts:** pamphlet and wall poster

**Intervention groups**

**Post evaluation and issue of All handouts, pamphlets and wall posters**

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**Measurements**

Data on weight, height, waist circumference, blood pressure and fasting blood sugars; were obtained at baseline and monthly for a period of six months. Data on glycated hemoglobin and lipid profile (HDL, LDL, total triglycerides and total cholesterol) was collected at baseline and after six months. A physician and clinical officer were also present during the study period to manage any patient requiring medical treatment.

**Anthropometry and clinical data**

Anthropometric measurement that includes weight, height, waist and hip were collected at baseline,
during monthly follow up and post evaluation after six months. Height and weight were measured using standard methods with the participant wearing light clothes and no shoes[55]. The weight was determined to the nearest 0.1kg using a calibrated electronic weigh scale (Seca) and height to the nearest 0.1 cm using a stadiometer attached to the weighing scale. Body mass index (BMI) was then be calculated as weight (kilograms)/height (meters) 2 and classified as per WHO classification [55]. The waist circumference and hip circumference were measured according to standard guideline[56]. Waist circumference was measured mid-way between the lower rib margin and the iliac crest with flexible anthropometric tape the nearest 0.5 cm while hip circumference was measured as the maximal circumference around the buttocks posteriorly and pubic symphysis anteriorly.

**Blood pressure**

Blood pressure of the patient was also taken monthly. It was measured in the supine position using a mercury sphygmomanometer (model: Autortensio® noSPG440) by trained nurses with at least a 10-min rest period before the measurement.

**Laboratory assay**

Blood samples were collected from each participant while in a seated position after fasting for at least 8-12hrs for determination of serum triglycerides (TG), total cholesterol (TC), high density lipoprotein (HDL-c), low-density lipoprotein cholesterol (LDL-c), glycated hymoglobin (HbA1c) at baseline and 6 month post intervention. Fasting blood glucose was determined monthly. Levels of serum TG, total cholesterol (TC), high density lipoprotein (HDL-c), low-density lipoprotein cholesterol (LDL-c), were determined by enzymatic method[57–63]. Glycated Hemoglobin (HbA1c) and blood glucose were determined using high-performance liquid chromatography and glucose oxidase method respectively [64,65].

**Metabolic syndrome definition**
Metabolic syndrome in the study was defined according to the definition of WHO [64] and “Circulation for Harmonizing the Metabolic Syndrome” criteria [2,11]. The later requires the presence of at least three of the following five components: Fasting blood sugar of 100mg/dl or 5.6mmol/l or drug treatment of elevated glucose, central obesity for Africans (waist circumference ≥94 cm in males and ≥80 cm in females), elevated triglycerides (≥1.7 mmol/l or 150mg/dl and/or the use of triglyceride-lowering drugs), reduced HDL cholesterol (<1.0 mmo/l or <40mg/dl in males and <1.3 mmol/l or 50mg/dl in females) and elevated blood pressure (systolic blood pressure ≥130 mmHg and/or diastolic blood pressure ≥85 mmHg and/or the use of antihypertensive drugs).

World Health Organization criteria also requires the presence of Type 2 diabetes mellitus, impaired glucose tolerance or insulin resistance, and any two of the following:(1) body mass index (BMI) ≥ 30 kg/m2 and/or waist-to-hip ratio >0.90 (male), >0.85 (female); (2) blood pressure ≥140/≥90mmHg or on hypertension medication; and (3) triglyceride ≥ 1.7mmol/Land/or HDL-C < 0.91mmol/L (male), <1.01mmol/L (female).

**Data analysis**

The data was analyzed using statistical package for social science (SPSS version 20). Data are present as means ± SD or SE for continuous variables and percentages for categorical variables. Chi square test was used to compare groups for categorical variables and Analysis of Co-variance (ANCOVA) was used to compare means difference between groups. Statistical significance was considered for p value <0.05.

**Results**

**Participants**

One hundred and fifty three participants (153; 40.5% male and 59.5% female) were included in the study. As shown in Table 2 there was no significant difference in the baseline characteristic of the study participant. Additionally out of one hundred and fifty three (153) participants who were
randomized, one hundred and forty three (143; 93.5%) completed the study. The mean age of the participant was 56.07 years; with 46.4% of the participant having a family history of diabetes; 77.8% having poor glycemic control (HbA1c>7%) and 58.2% had lived with diabetes for 1-5 years prior the study. Moreover the prevalence of MetS was 86.3% and 88.2% as per WHO and Harmonized criteria respectively at baseline.

Table 2: Baseline characteristics of the study participants

| Parameter                        | NEP Mean±SD or n (%) | NE Mean±SD or n (%) | C Mean±SD or n (%) |
|----------------------------------|----------------------|---------------------|-------------------|
| **Age in years**                 |                      | 57.08 ± 10.88       | 55.32 ± 12.34     | 55.80 ± 11.97    |
| YLWD*                            | Male                 | 5.90 ± 7.10         | 7.02 ± 6.93       | 7.04 ± 6.63      |
| Gender†                          | Female               | 34 (61.7)           | 27 (52.9)         | 30 (55.8)        |
|                                 | Married              | 45 (88.2)           | 43 (84.3)         | 41 (80.4)        |
| Marital status†                  | Divorced/separated/ | 6 (11.8)            | 8 (15.7)          | 10 (19.6)        |
|                                 | windowed             |                     |                   |                   |
| Income†                          | <1000                | 26 (51.0)           | 21 (41.2)         | 25 (49.0)        |
|                                 | 1001-5000            | 13 (25.5)           | 7 (13.7)          | 12 (23.5)        |
|                                 | 5001-10000           | 5 (9.8)             | 9 (17.6)          | 9 (17.6)         |
|                                 | >10000               | 7 (13.7)            | 14 (27.5)         | 5 (9.8)          |
| Occupation†                      | Formal employment    | 2 (3.9)             | 1 (2.0)           | 3 (5.9)          |
|                                 | Casual employment    | 1 (2.0)             | 4 (7.8)           | 5 (9.8)          |
|                                 | Farming              | 22 (43.1)           | 21 (41.2)         | 20 (39.2)        |
|                                 | Business             | 15 (29.4)           | 18 (35.3)         | 15 (29.4)        |
|                                 | Unemployed           | 11 (21.6)           | 7 (13.7)          | 8 (15.7)         |
| Complication†                    | Foot disease         | 5 (9.8)             | 7 (13.7)          | 5 (9.8)          |
|                                 | Eye problem          | 13 (25.5)           | 12 (23.5)         | 11 (21.6)        |
|                                 | Kidney problem       | 0 (0)               | 2 (3.9)           | 0 (3.9)          |
|                                 | Neuropathy           | 1 (2.0)             | 0 (0)             | 3 (5.9)          |
|                                 | Arthritis            | 6 (11.8)            | 7 (13.7)          | 5 (9.8)          |
| FHD†                             | Yes                  | 28 (54.9)           | 22 (43.1)         | 21 (41.7)        |
|                                 | No                   | 23 (45.1)           | 29 (56.9)         | 30 (58.8)        |
|                                 | Oral                 | 45 (92.4)           | 37 (73.5)         | 44 (82.8)        |
| Medication†                      | Insulin              | 9 (5.9)             | 6 (3.9)           | 4 (2.6)          |
|                                 | Oral plus insulin    | 2 (1.3)             | 3 (2.0)           | 3 (2.0)          |

* data presented as mean±SD
†Data presented as proportion (n) and percentages%

Statically significance at p<0.05; chi ($\chi^2$) square test.

As shown in Table 3 there was no significant difference between the groups in the anthropometric (weight, BMI, WC, HC, WHR), clinical (SBP, DBP) and biochemical variables (HbA1c, TC, TG, HDL, LDL and FBS) at baseline. There was significant difference in mean weight lost \[f(2,124)=15.579, p<0.01\] as well as mean BMI reduction \[f(2,124)=15.403, p<0.01\], WC reduction \[f(2,124)=13.371, p<0.01\], HC reduction \[F(2,124)=18.36(p<0.01)\] and WHR reduction \[f(2,124), p=0.005\] between the groups.
post intervention. Nutrition education peer to peer support group (NEP) showed the greatest weight loss (-6.26 kg) as well as greatest reduction in BMI (-2.37kg/m$^2$), WC (-14.51cm), HC (-6.16cm) and WHR (-0.03) respectively (Table 3). Moreover there was significant difference in mean DBP [f (2,124), p=0.03] between groups with NE group presenting the greatest reduction in DBP (-5.17mmhg). Additionally a significant mean increase in HDL [f (2,124), p=0.01]) was also seen between groups with NEP group exhibiting the greatest increase in HDL (+0.34mmol/l) (Table 3). There was an increase in LDL levels [f (2, 124) p=0.04] in the entire group that was significant with C group having the greatest increase (1.23mmol/l).

Furthermore post intervention significant mean difference (p<0.05) between the NEP and NE as well as NEP and control (C) was seen in weight lost (4.99 kg and 6.89kg respectively); BMI reduction (1.89 kg/m$^2$ and 2.67 kg/m$^2$) respectively; WC reduction (9.73cm and 16.46cm respectively) and WHR reduction (0.03 and 0.04 respectively) respectively (Table 3). Post intervention significant mean difference between NEP and NE was seen TG (0.52mmol/l) and HDL (0.28mmol/l) (Table 3). Moreover post intervention significant mean difference between NEP and C was also seen in HC (10.20cm), HbA1c (1.30%), TC (0.69mmol/l) and LDL (0.86mmol/l) with a difference of 4.99kg and 7.06cm respectively (Table 3). There was no significant mean difference for the other metabolic parameters between the intervention groups (NEP and NE) and C group (Table 3).

As shown in Table 4 there was no significant difference in MetS prevalence and metabolic risk factors (increased WC, high WHR, high FBS, elevated BP, elevated TG, reduced HDL, elevated TC, Elevated LDL) as well as in high BMI(>25kg/m$^2$) at baseline. There was a statistical significant reduction in prevalence of patient with increased WC (reduction from 92.2% to 58.3%; p<0.01), and reduced HDL (reduction from 37.3% to 2.1%; p=0.03) respectively in the NEP group 6 month post intervention as compared to the other groups (Table 4). Statistical significant reduction in prevalence of participant with increased BP (reduction by 39.2 and 31.6 as per harmonized and WHO criteria respectively) was
also observed in the NP group compared to the other groups (Table 4). Additionally statistically significant reduction in prevalence of participant with increased TG (reduction by 28.3%) was also observed in the NEP group compared to the other groups. In terms of HbA1c, FBS, and TC slight improvement that was not significant was noted in the entire groups (Table 4). Moreover there was no significant difference in MetS prevalence and number of MetS risk factors among the groups at baseline using the two criteria. After six month post intervention the prevalence of MetS dropped significantly in the NEP (p<0.01) compared to the other groups (drop of 38.1% and 31.7% as per harmonized and WHO criteria) (Table 4). All the participants had Type 2 Diabetes with over half (60.2%) having more than three MetS risk factors at baseline. Statistical significant difference (p<0.01) was seen 6 month post intervention among groups in number of MetS risk factors per participant with NEP groups showing the greatest reduction (34.7 % and 42.3%) of the participant in NEP group shifted from having >3 MetS risk factor to 1 and 2 MetS risk factors 6 month post intervention as per harmonized and WHO criteria) (Table 4).

Table 3. Changes in metabolic outcomes and differences between groups six month post intervention

| Parameter  | Baseline data | Changes in clinical parameters six month post intervention++ |
|------------|--------------|--------------------------------------------------|
|            | NEP (n=51) Mean ± s.d | NE (n=51) Mean ± s.d | C(n=51) Mean ± s.d | P value | NEP (n=48) Mean (SE) | NE(n=49) Mean (SE) |
| Weight     | 72.06±14.42  | 69.61±10.22 | 71.91±12.09 | 0.52 | -6.27(0.87) | -1.27(0.8) |
| BMI(Kg/m²) | 27.64±5.72   | 26.34±4.16  | 27.11±4.04  | 0.38 | -2.37(0.34) | -0.48(0.3) |
| WC(cm)     | 101.92±9.51  | 98.90±9.71  | 101.71±10.20 | 0.23 | -14.51(1.34) | -4.78(1.2) |
| HC(cm)     | 106.16±7.14  | 102.69±11.90 | 101.71±7.74 | 0.09 | -6.16(1.28) | -5.21(1.2) |
| SBP(mmHg)  | 145.33±21.33 | 146.04±19.50 | 139.98±18.66 | 0.25 | -13.39(3.53) | -14.77(3.5) |
| DBP(mmHg)  | 87.88±10.37  | 90.69±8.79  | 88.12±9.15  | 0.26 | -1.58(198) | -5.17(1.9) |
| Hba1C (%)  | 8.81±1.94    | 8.37±1.81   | 8.28±1.81   | 0.31 | -2.04(0.39) | -1.48(0.3) |
| FBG(mmol/l) | 11.12±2.73   | 11.41±4.40  | 10.50±2.77  | 0.38 | -2.59(0.66) | -2.95(0.6) |
| TC(mmol/l) | 5.23±1.43    | 4.77±1.07   | 4.91±1.13   | 0.12 | -0.38(24) | +0.13(0) |
| TG(mmol/l) | 2.32±1.37    | 2.00±0.92   | 2.39±0.89   | 0.16 | -0.67(0.18) | -0.15(0.1) |
| HDL(mmol/l) | 1.30±0.29    | 1.55±0.39   | 1.31±0.31   | 0.07 | +0.34(0.073) | +0.06(0) |
| LDL(mmol/l) | 2.45±1.48    | 2.37±1.21   | 2.05±1.14   | 0.24 | +0.38(0.24) | +0.53(0) |
| WHR        | 0.96±0.07    | 0.98±0.08   | 0.95±0.09   | 0.23 | -0.027(0.008) | +0.002(0) |

Data are presented as mean ± standard deviation or SE of the mean. ANCOVA was used for between-groups comparisons, with a significance level of P* < 0.05 and p**<0.01. BMI: body mass index, WC: waist circumference, HC: hip circumference, WHR: waist-to-hip ratio, SBP: systolic blood pressure, DBP: diastolic blood pressure, FBG: fasting blood glucose, HDL: high density lipoprotein, LDL: low density lipoprotein.
density lipoprotein, TG: triglycerides, TC: total cholesterol and HbA1c – glycated hemoglobin. NEP:
Nutrition education peer to peer support group, NE: Nutrition education intervention group, C: control
group
Kg=kilogram/metre2, Cm=centimeter, mmhg- Millimeters of mercury, mmol/l= milimmole per litre
Adjusted for age, gender, marital status, education level, family history of diabetes, years lived with
diabetes, complications and medication use.

Table 4. Prevalence of MetS risk factors at baseline and six month post intervention

| Parameter              | NEP n (%) | NE n (%) | C n (%) | χ² | p value |
|------------------------|-----------|----------|---------|----|---------|
| High HbA1c             | 43(84.3)  | 38(74.5) | 38(74.5) | 1.89 | 0.39    |
| High FBS               | 51(33.3)  | 51(33.3) | 51(33.3) | 5.64 | 0.06    |
| High WHR               | 45(88.2)  | 48(94.1) | 40(87.8) | 11.101 | 0.09 |
| BMI>18.5-24.9          | 47(92.2)  | 45(88.2) | 47(92.2) | 0.629 | 0.73    |
| >25-29.9               | 37(72.5)  | 45(88.2) | 37(72.5) | 4.84  | 0.089   |
| >30-34.9               | 15(29.4)  | 27(52.7) | 25(49.0) |      |        |
| >35-40                 | 11(21.6)  | 3(5.9)   | 6(11.8)  |      |        |
| Elevated WC            | 57(32.7)  | 40(71.0) | 30(59.0) | 4.388 | 0.11    |
| Elevated BP a          | 34(66.7)  | 38(74.5) | 28(54.9) |      |        |
| Elevated BP b          | 32(62.7)  | 28(54.9) | 39(76.5) | 4.083 | 0.13    |
| Elevated TG            | 19(37.3)  | 11(21.6) | 14(27.5) | 3.126 | 0.21    |
| Reduced HDL-C a        | 26(51.0)  | 16(31.4) | 22(43.1) | 4.083 | 0.13    |
| Dyslipidemia           | 29(59.9)  | 15(29.4) | 24(47.1) | 7.994 | 0.244   |
| Elevated TC            | 46(90.2)  | 44(86.3) | 45(88.2) | 0.378 | 0.828   |
| LDL                    | 46(90.2)  | 45(88.2) | 41(80.2) | 2.318 | 0.31    |
| MetS a                 | 3(5.9)    | 9(17.6)  | 19(37.3) | 13.323 | 0.101   |
| MetS a                 | 1(2.0)    | 0(0.0)   | 19(37.3) | 2.492 | 0.65    |

Data are presented as proportion; n (percentages; %) chi-square (χ2) test; *statistical significance at
p value<0.05
BMI obese >30 kg/m2, Elevated Waist hip ratio (WHR)>0.9 for men and >1.0 for women, Elevated
blood pressure \(^a\) >140/90mmHg or treatment of previously diagnosed hypertension (WHO criteria);
Elevated blood pressure \(^b\) >130/85mmHg or treatment of previously diagnosed hypertension (harmonized criteria). Reduced serum HDL cholesterol (a) <0.9 mmol/L for men or <1.0 mmol/L for women or specific treatment for this abnormality (WHO criteria); Reduced serum HDL cholesterol \(^b\) <1.0 mmol/L for men or <1.3 mmol/L for women or specific treatment for this abnormality (harmonized criteria), Elevated triglycerides (TAG) >1.7 mmol/L or specific treatment for this abnormality (both criteria), Waist circumference (WC) ≥94 cm for men or ≥80 cm for women, Elevated TC>5.2mmol/l, Elevated LDL-cholesterol>2.6mmol/l.; MetS\(^a\):Harmonized criteria; MetS\(^b\):WHO criteria.

Discussion

The current study determined the effect of nutrition education programme (nutrition education with emphasis on peer to peer support) on metabolic risk factors and MetS in patient with Type 2 diabetes mellitus. The study reported a significant reduction in MetS prevalence and number of MetS risk using the WHO and harmonized criteria in the NEP group in comparison with the other groups Metabolic syndrome(Mets) a risk factor for Type 2 Diabetes and cardiovascular disorder, has been associated with lifestyle and behavior risk factors such as unhealthy diet, physical inactivity as well as obesity [2,11,15,66–69]. Presence of MetS as well as its associated risk in Type 2 diabetes mellitus patient have been linked with increased macro vascular complication in addition to cardiovascular complication [16,70,71]. However application of lifestyle changes has been shown to improve metabolic outcome as well as reducing MetS prevalence in Type 2 Diabetes mellitus patient and general population. Several lifestyle intervention studies carried on Type 2 Diabetes mellitus have shown positive outcome in metabolic parameters as well as MetS prevalence and are in support of the current study[21–28]. Inclusion of peer support improved the outcomes further[39].

The current study demonstrated that nutrition education had a beneficial effect on metabolic parameters with inclusion of peer to peer support significantly improving the benefit further.

Improvement in mean change of metabolic parameter [BMI, WC, WHR, BP, HbA1c, lipid profile (TC,
HDL & TG)); as well as prevalence of participant who achieved recommended metabolic outcome levels in BMI, WC, BP, TG, HDL as well as MetS prevalence was seen in both NE and NEP groups. However significant improvement was seen in the NEP group six month post intervention in BMI, WC, HC and WHR respectively as well as weight lost. Additionally significant statistical change in proportion of individual who achieved recommended WC in the NEP was seen six month post intervention. Moreover the current study also reported a significant statistical change in proportion of patient who achieved recommended levels of HDL as well as increased mean change in HDL in NEP group compared to other groups six month post intervention. Nutrition education is a main component in diabetes education and has been shown to improve dietary behavior and clinical outcomes in persons with diabetes and the current study support this[38,42,79]. Previous study have demonstrated nutrition education or, lifestyle intervention, aimed at correcting dietary behavior and enhancing physical activity in management of Type 2 diabetes mellitus as well as MetS in type 2 diabetes mellitus patient have shown a positive outcome in metabolic parameters[36,38]. Inclusion of peer to peer support in the lifestyle intervention have been shown to have a better clinical outcome[43,80,80,81].

Decrease in BMI, WC and WHR as well as elevated HDL key metabolic risk factors in Type 2 diabetes mellitus patient as well as Type 2 diabetes mellitus patient with MetS have been shown to be beneficial in reducing associated micro and macro vascular as well as cardiovascular complication. Additionally a study by Saboya et al [77], Blackford et al [75] and Gerstel et al[78] showed significant reduction in either metabolic parameters like BMI, WC, SBP after application of lifestyle programme done through nutrition education administered orally or through printed material or online interaction and are in support of the current study. Increased HDL-C level play an important role in Type 2 Diabetes patient as well as MetS as it has been associated with reduced incidence of obesity and high blood pressure major risk factors to type 2 diabetes complication as well as cardiovascular risk factors. The reduced prevalence of participant with elevated HDL in the current study in the NEP as well as reduced mean HDL-c might have some clinical benefit.
Nutrition education is fundamental in management of Type 2 diabetes mellitus and MetS. Studies have reported improved outcome in blood pressure of patient with Type 2 diabetes mellitus who have been involved in a nutrition education programme. The current study support this as it reported statistical significant mean change DBP in the NE group six month post intervention and significant improvement in proportion of participant achieving recommended blood pressure level (39.2% and 31.6 % as per WHO and Harmonized criteria definition) in the NE group six month in comparison with the other. Improvement in proportion of patient achieving recommended BP was also seen in the NEP group but was not significant. This might indicate that nutrition education had a role to play in management of Type 2 diabetes mellitus leading to good metabolic outcomes. The current study showed no significant effect on mean change in TG, TC, HbA1c and FBS in the intervention groups as compared to control, but some improvement was seen mean HbA1c, TC and TG in the NEP group compared to NE and control. Lifestyle change adopted after the education might have contributed to the significant reduction in the metabolic risk (BMI, WC, SBP, and DBP &HDL) factors. Inclusion of the peer to peer support might have contributed further to the significant difference in some metabolic risk factor between NEP and control as compared to NE and control.

Peer to peer support supporting chronic disease management like diabetes have been associated with reduced burden of the disease, weight loss, improved glycemic which may be due to behavior change and enhanced self-management[82–86]. The current study is comparable to previous study that reported an improvement of either HbA1c, BP and lipid profile after inclusion lifestyle management and/or peer to peer support in management of Type 2 diabetes[41,81,87,88]. The decrease in WC, WHR,BMI and HDL in the NEP group was in agreement with the results from lifestyle study employing nutrition education and peer to peer support [40].Decrease in the WC, WHR, and BMI indicate reduced risk in cardio-metabolic risk[89–91]. Study have also shown strong correlation between BMI and WC with glycaemia, triglyceride, HDL and blood pressure[92]with reduced level of BMI and WC being associated with low MetS prevalence which is in concordance with our study.
In interpreting the result of this study some limitation need to be considered. The study period was limited to six month and this allowed assessment of short-term effect of the intervention. Longer period of follow-up have been recommended in order to understand more of the sustainability of a peer-led intervention program and also in order to ensure long-term reduction of metabolic risk in type 2 diabetes mellitus Additionally the study was carried out in a public hospital setup where patient population is of middle and low income that refer them freely for care hence the results can only be compared to a similar population. The current study reported significant improvement of metabolic parameters and MetS prevalence on application of lifestyle intervention and might be a useful base for community based study targeting Type 2 Diabetes population. The current study was also unique as it incorporated peer to peer support in management of Type 2 Diabetes hence contributing to its strength. The study also had a high retention rate (93.7%) and received positive feedback from patient on their monthly visits that were encouraging.

Conclusion
In conclusion nutrition education programme with inclusion of peer support in for individuals with Type 2 Diabetes mellitus and at a risk of MetS resulted in positive clinical results. The research results showed a significantly improved reduction in major metabolic outcome that were achieved in the NEP group an indication peer support had a clinical benefit. The findings from the study demonstrate that an NEP programme tailored to the participants’ needs improved clinical outcomes (BMI, WHR, HDL, TG and BP). Additionally, in order to maximize the benefits from NEP interventions for people with Type 2 diabetes and at risk of MetS future studies should optimally apply individualized goal setting in addition to group session, self-efficacy skilled training as well as encouraging individual self-assessment and management.

Abbreviations
MetS-metabolic syndrome; HbA1c: glycated hymoglobin; WHO: World Health Organization; WC: waist circumference; HDL-c: High Density Lipoprotein cholesterol; TG: Triglyceride; Total Cholesterol; LDL-C: Low Density Lipoprotein; BMI: Body Mass Index; WHR: Waist Hip Ratio; CVD: Cardiovascular Disease;
Declarations

**Ethical approval and consent to participate**

Ethical approval was obtained from Kenyatta National Hospital and University of Nairobi Ethical Committee (Permit No. KNH-ERC/A/232). Administrative approval for the study was obtained from the National Commission for Science, Technology and Innovation (NACOSTI) Permit No. NACOSTI/P/16/83452/10118, the Ministry of Interior and Co-ordination of National Government, County Commissioner Kiambu Permit No. ED.12/1/VOL.IV/92, Ministry of Education Kiambu Permit No. KBU/CDE/HR/4/VOL.II (138) county health officials and health facility administrators. Study participants gave a written informed consent before commencement of data collection.

**Trial registration**

The study have been registered by Pan African Clinica Trial Registry; Registration No. PACTR201910518676391

**Consent to publish** Not applicable

**Availability of data and materials**

All the data set used and/or analyzed during the current study are in custody of Thuita Ann and are available on request.

**Competing interests**
The authors declare that they have no competing interests.

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**Authors’ contributions**

All the authors’ contributed to the conception and design of the study. B.K, O.A and M.A supervised the study T.A collected and analyzed the Data as well as Draft of the Manuscript. All the authors contributed to the interpretation of the results and revision and approval of the manuscript.

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