



Published in final edited form as:

J Neurol Sci. 2018 March 15; 386: 23–28. doi:10.1016/j.jns.2017.12.032.

Feasibility study of a Targeted Self-Management Intervention for Reducing Stroke Risk Factors in a High-risk Population in Uganda

Mark Kaddumukasa^{1,*}, Jane Nakibuuka¹, Levicatus Mugenyi¹, Olivia Namusoke¹, Bryan Kabaala¹, Carol Blixen², Elly Katabira¹, Anthony Furlan², and Martha Sajatovic³

¹Department of Medicine, School of Medicine, Makerere University College of Health Sciences, P.O. Box 7072, Kampala, Uganda ²Department of Neurology, Case Western Reserve University School of Medicine, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Cleveland, OH 44106, USA ³Departments of Neurology and of Psychiatry, Case Western Reserve University School of Medicine and Neurological and Behavioral Outcomes Center, University Hospitals Cleveland Medical Center, 11100 Euclid Avenue, Cleveland, OH 44106, USA

Abstract

Introduction—Stroke remains a global concern due to increasing lifespan, patterns of industrialization, adoption of harmful western diets, and an increasing prevalence of risk factors such as hypertension, obesity, and diabetes. We investigated an adopted novel self-management intervention, TargetEd mAnAgeMent Intervention (TEAM) to reduce modifiable stroke risk factors in Uganda.

Methods—A six-month, uncontrolled, prospective pilot study to establish feasibility, acceptability and preliminary efficacy of TEAM in Ugandans at high risk for stroke was

*Corresponding author - Mark Kaddumukasa, Department of Medicine, School of Medicine, Makerere University College of Health Sciences, P.O. Box 7072, Kampala, Uganda. Telephone number: +256-414-541188, Fax: +256 414 532204. Doreen Birungi - bdoreen112@gmail.com

Declarations

Ethics approval and consent to participate in this study

Written informed consent was obtained from the next of kin /legal representatives for all study participants. Ethical approval for the study was obtained from Makerere University College of Health Sciences' School of Medicine review board and ethics committee Ref number 2015-073, UNCST Ref Number. HS 1858 and University Hospitals Institutional Review Board, UHCMC IRB number: 04-15-18.

Consent for publication

"Not applicable"

Availability of data and material

All data generated or analyzed during this study are included in this published article

Competing Interests

The authors declare that they have no competing interests.

Authors' Contribution

All authors critically read through the manuscript and revised the manuscript for important intellectual content. All authors discussed the results and commented on the manuscript. All authors read and approved the final manuscript.

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conducted. The primary outcome was change in systolic BP from baseline to 24-week follow-up. Secondary outcomes included change in diastolic BP, serum cholesterol, high and low density lipoprotein (HDL, LDL) and triglycerides.

Results—Mean (SD) baseline systolic BP was 162.9 (\pm 25.6) mmHg while mean (SD) baseline diastolic BP was 99.1 (\pm 13.8) mmHg. There was a significant reduction in mean baseline blood pressure of 163/98.8mmHg to blood pressure of 147.8/88.0 mmHg at 24 weeks, $p=0.023$. There were also significant reductions in the serum total cholesterol levels at 24 weeks with $p=0.001$.

Conclusion—Targeted training in self-management (TEAM) adapted to the Ugandan setting is feasible, highly acceptable to participants and appears to be associated with reduced blood pressure, improved lipid profiles and improved glucose control in diabetics.

Keywords

stroke; blood pressure; risk factors; prevention

1.0 Introduction

Stroke is a neurological condition with a rapidly increasing burden in many low- and middle income countries (LMIC) and is associated with high fatality rates, high morbidity, years of suffering and disability for stroke survivors and families, as well as escalating costs (1-3). Worldwide in 2005, there were an estimated 16 million new strokes and 62 million stroke survivors (4, 5), with future rates expected to increase. While stroke is a growing concern globally, Africa is particularly hard-hit by stroke burden due to rapid growth in population size, expanding lifespan, patterns of industrialization, adoption of harmful western diets, and increasing prevalence of risk factors such as hypertension, obesity, and diabetes (6, 7). Approximately 8% of all first-ever strokes worldwide are in Africa (5, 8).

Importantly, recent work on stroke in Africa (9) projects a further increase of 10.8% incident of stroke cases and an increase of 9.6% in stroke survivors. Risk factors for stroke which were once rare in traditional African societies are unfortunately becoming a major public health problem (10). Western cultural adaptations such as sedentary lifestyle, use of tobacco and alcohol and high fat and cholesterol diet all elevate cumulative stroke risk (1). Increasing population age and urban migration are also associated with increased rates of stroke risk factors such as obesity and diabetes. In some Sub-Saharan African (SSA) countries such as Ghana, South Africa and Cameroon, stroke risk factors have reached epidemic proportions (11-13). In Uganda, the prevalence of hypertension in urban areas is 28.9%, and 25.8% in rural areas while it was 19.5% within the same study area (14, 15). Growing rates of hypertension, diabetes and other factors such as social stressors, coping styles, unemployment and health access issues may be further contributing to the stroke burden in Africa.

For individuals at risk for stroke (including those who have already survived a stroke), major areas of care include; (1) managing stroke risk factors/comorbid illness and treating medical complications, (2) training to enhance independence, (3) supporting psychosocial coping and adaptation, (4) promoting community reintegration, and (5) enhancing quality of life

(16). The American Heart Association (AHA) Guidelines (17) prioritize management of specific modifiable risk factors known to be disproportionately common in blacks, such as hypertension, diabetes, hyperlipidemia, smoking, alcohol use, obesity, and inactivity. Patient engagement with behavioral recommendations such as diet, exercise, and smoking cessation can be difficult (18). However, this can be addressed through self management training. Self-management is a care approach that enables individuals to solve problems as they arise, practice new health behaviors, and gain emotional stability (19). Although a number of reports support self-management training for stroke survivors, (20, 21) there is limited data specific to SSA. Peer support may be a relatively low cost and yet effective way to engage minority or high-risk populations.(22, 23) This 6-month prospective study evaluated effects of a culturally adapted behavioral TargetEd MAnageMent Intervention (TEAM), in 16 individuals at high risk for stroke. We hypothesized that the TEAM intervention would lead to stroke risk-factor reduction and improved health behaviors to minimize stroke risk.

2.0 Materials and Methods

2.1 Study population

The study population included 16 high stroke risk participants recruited from a sub-sample of 440 community participants enrolled in a larger cross-sectional survey of stroke knowledge and attitudes in greater Kampala, Uganda (15). The participants were invited to include a care partner, with whom they felt comfortable with, to attend the intervention sessions. Four peer dyads, who included two peer educators and their two care partners, were recruited and trained to deliver the TEAM intervention with the study nurses. The intervention development process has been described elsewhere (manuscript under review). The TEAM intervention was assessed for feasibility, acceptability, and fidelity, as well as preliminary efficacy for effects on biomarkers including blood pressure (BP), serum glycosylated hemoglobin (HbA1c), and lipid levels, as well as standardized assessment of health behaviors.

We recruited 8 individuals at risk for stroke and 8 individuals who had experienced stroke based on the following inclusion criteria; aged 18 or older, having at least two stroke risk factors (one risk factor must be BP >140/90mmHg) (24), or having had a stroke within the past 5 years, cognitively intact, and able to provide informed consent to study participation. Individuals with known sickle-cell disease were excluded. The study was approved by the local institutional review board (IRB).

2.2 Intervention

Similar to a previous self-management intervention model developed by these investigators, (25-27) TEAM is informed by principles of social cognitive theory. (28, 29) The TEAM approach uses peer dyads (patients who had a stroke or transient ischemic attack and their care partners) to provide support and model behaviors intended to reduce future stroke risk. Consistent with the focus on personal and social roles, the term “care partner” was used rather than “caregiver,” as is frequently seen in the stroke literature. Key components known to be critical for successful post-stroke care among stroke survivors including contents focused on patient and care partner needs, practice in problem-solving, and attention to

emotional and role management were utilized. The TargetEd MAnageMent (TEAM) intervention used in this study consisted of:

1. A 60-minute initial 1:1 session, in which the nurse educator and one of the peer dyad pairs met with the TEAM participant and his/her care partner, and included introductions, orientation, and logistic planning.
2. Six 60-minute group sessions with the 16 high-risk participants and 16 care partners were held approximately weekly after the initial session. These were divided into two groups of 16 per session (8 participants accompanied by his or her care partner). Group sessions were co-led by the nurse educator and a peer dyad, using a detailed curriculum with semiformal scripting.
3. Three brief (approximately 10-20 minutes) monthly telephone sessions were held between the nurse educator and the study participants over the next 3 months. These calls reinforced content from the group sessions, served as a behavioral model, provided social support, and facilitated linkage with other care providers. All TEAM participants continued in treatment with their regular medical care providers. Beyond follow-up research assessments at the same time points as TEAM, there was no interaction between the participants and the research team (see supplementary material in appendix).

2.3 Outcome Measures

The first objective was to establish feasibility of conducting TEAM in this Ugandan setting, including the ability to hire and train peer and nurse educators, enroll participants, and to develop a practical and culturally appropriate curriculum. The second objective was establishing the acceptability of TEAM to participants by assessing program attendance rates, drop outs, and any adverse effects. The third objective was to determine the preliminary efficacy of TEAM based on change in biomarkers and behavioral outcomes from baseline to 24-week follow-up. The primary outcome was change in systolic BP from baseline to 24-week follow-up. Secondary outcomes included change in diastolic BP, serum cholesterol, high and low density lipoprotein (HDL, LDL) and triglycerides. We also evaluated glycosylated hemoglobin (HbA1c) from baseline to 24 week follow up with a focus on individuals with known diabetes. Although the study followed participants for a relatively brief time and we did not expect to see substantial weight change overall, we evaluated body mass index (BMI) to see if there were weight loss trends. A BMI of 25 to 29.9 is referred as “pre-obesity,” a BMI of 30 to 34.9 is class I obesity, 34.9 to 39.9 is class II obesity, and a BMI of 40 or greater is class III obesity (30).

Behavioral outcomes included the Alcohol Use Disorders Identification Test (AUDIT) (31), use of tobacco as measured by the Global Adult Tobacco Survey (GATS) questionnaire(32), and Global Physical Activity Questionnaire (GPAQ) (33).

2.4 Feasibility and fidelity

Attendance for each TEAM session was recorded following Fraser et al, (34). Fidelity was assessed at each session by noninterventionist study staff both quantitatively (e.g., yes/no assessment of complying with appropriate duration and content covered) and qualitatively

(e.g., participant and interventionist interaction). Non-interventionist study staff assessed each TEAM group with each fidelity dimension being rated on a 1 to 10 scale.

2.5 Data Analysis

Descriptive analysis assessed the changes in primary and secondary outcomes. The American Heart Association thresholds (systolic BP 140 mm Hg and/or diastolic BP 90 mm Hg) were used to categorize hypertension at baseline and at follow-up (17). Both 12-week (end of the “intensive” group-format session) and 24-week outcomes (end of telephone follow-up sessions) were of interest in the context of future intervention refinement.

Group comparisons of systolic and diastolic BP measurements, HbA1c, serum cholesterol, low-density lipoprotein (LDL), and high-density lipoprotein (HDL) levels were conducted via analysis of variance ANOVA to compare 3 means, paired T-test to compare two means, Wilcoxon signed rank test to compare two medians, chi-square for trend test used to compare three proportions, and McNemar test to compare two proportions for baseline, 12 weeks and 24 weeks. In order to adjust for potential confounders for change in systolic BP (primary outcome), a score for the difference in systolic BP at week 24 and the baseline was obtained. This score was then regressed with time (coded 0 for baseline and 1 for week 24) variable and the baseline characteristics. The analysis was done both for all enrolled patients (N=16) and among the 13 patients with elevated baseline systolic BP (>140).

3.0 Results

3.1 Feasibility and Attendance

Study enrollment (N=16) was completed over 6 months. TEAM session attendance was robust with only 2 out of 16 participants missing attending any TEAM session at any point. There was minimal attrition in research procedures, with 87.5% retention overall (two participants missed attending the 24-week study assessments due conflicting responsibilities). There were no reported adverse events associated with the study.

3.2 Baseline sample description

As noted in Table 1, the mean age (SD) was 51.7 (± 17.3) years, range of 24 – 80 years, 69% (11/16) female. The mean (SD) baseline systolic BP was 162.9 (± 25.6) mmHg while the mean (SD) baseline diastolic BP was 99.1 (± 13.8) mmHg. All the study subjects were HIV negative at baseline. The mean BMI (SD) was 28.7 (7.2) kg/m². Five study participants had pre-obesity with mean (SD) BMI of 26.6 (0.96) kg/m², two were obesity class I with mean BMI (SD) of 32.9 (0.77), one obesity class II with BMI of 35.2 and two had obesity class III with mean BMI (SD) of 41.5 (1.41) kg/m². Half of study participants (N= 8) had a history of stroke in the previous five years. Among all the study participants, 81% (13/16) had blood pressures more than 140/90mmHg.

With respect to medication treatments at baseline, nearly all (15/16, 94%) were on antihypertensive medications, 50% (8/16) of participants were on captopril and 59% (9/16) on nifedipine. The frequency of use of other antihypertensive drugs among the study participants was bendroflumethiazide, amlodipine and telmisartan at 18.8%, 18.8% and

6.3% respectively. Only one participant (6.3%) was not prescribed anti-hypertensive medications at enrollment. Among those with a previous stroke, only 12.5% (2/16) were receiving aspirin prophylaxis at enrollment. Only one participant was on oral contraceptives at study enrollment. Thirty-eight percent (6/16) of participants were known diabetics at baseline. Among the diabetic participants, 67% (4/6) were taking oral hypoglycemic agents while 33% (2/6), were on insulin. All diabetic participants (6/6) had elevated levels HbA1c >7% at baseline with a mean (SD) percentage of 10.7 (1.7).

With respect to health behaviors, using the GPAQ, 44% (7/16) of participants reported doing work that involved vigorous-intensity activity for at least 10 minutes continuously. Fifty – six percent (9/16) reported no vigorous intensity activity. About 63% (10/16) reported work that involved moderate activity. On the GATS, nearly all (94%, 15/16) reported no current tobacco use. Nearly, 69% (11/16) reported that no one smoked indoors in places where they work. AUDIT scores found only one participant was using alcohol.

3.3 Longitudinal Changes

Table 2 present clinical measurements at the baseline, 12, and 24 weeks. The mean systolic BP (\pm SD) and mean diastolic BP (SD) at 24 weeks for all study subjects was 149.7 ± 22.1 mmHg and 88.6 ± 11.7 mmHg respectively. There were significant reductions in our primary outcome measure, systolic BP, from baseline to week 24 with $p=0.021$. Figure 1 illustrates changes in both systolic and diastolic BP graphically. There were statistically significant reductions in our secondary outcomes of diastolic BP, serum total cholesterol, HDL and triglycerides at 24 weeks, although as noted in Table 2, HDL and LDL changes were not clinically significant and changes in proportion of individuals who had values above optimal target was on only significant for serum total cholesterol. There were no differences between baseline and week 12 ($P=0.062$) or week 12 and 24 ($P>0.999$). Overall, among all the diabetic study participants, the mean HbA1c (SD) significantly reduced by week 24 from 10.7 (1.7) % to 5.8 (2.9) %; $p=0.031$. There was only a trend for reduction in mean BMI from baseline with $P=0.074$, (95% CI: 0.14 – 2.63).

The model coefficients showing the average reduction/difference in systolic BP together with P-values are given in Table 3. The results in Table 3 show that systolic BP at week 24 compared to baseline was significantly lowered by 16.79 mm/Hg ($P=0.036$) and by 20.75 mm/Hg ($P=0.025$) considering all patients and those with elevated systolic BP, respectively. None of the baseline factors confounded change in systolic BP in each case. There were no significant differences in the GPAQ, AUDIT, or GATS from baseline to 24 weeks among the study participants.

4.0 Discussion

Stroke is a major problem within SSA with increased risk among individuals with poorly controlled BP and other factors increasingly common in the population such as elevated cholesterol. An adapted behavioral TEAM approach in this pilot/development study has shown the potential for engaging these high-risk individuals and reducing key stroke risk factors. This 6-month prospective pilot established the feasibility of TEAM in our setting

with high participant acceptability and preliminary efficacy of the intervention based upon key stroke-risk outcomes.

Despite the small sample size, there were still significant improvements in multiple biomarkers indicative of stroke risk. Our primary outcome of mean systolic BP was significantly reduced from 162.9 to 149.7 mmHg at 24 weeks. While 6-month follow blood pressures were still above ideal targets, studies have shown that for every reduction of 10 mmHg systolic or 5 mmHg diastolic, there was a 22% reduction in coronary heart disease events and a 41% reduction in stroke (35, 36). Our study design does not permit extrapolation regarding whether blood pressure declines noted in our pilot work continue beyond the 6-months of the study.

Earlier work by Kronish and colleagues, demonstrated positive effects of peer-led stroke risk reduction interventions on BP, but no change in lipids (37). In the present study, there was a clinically and statistically significant reduction in the total cholesterol by week 24, while change in lipids was not clinically significant. It is possible that observed lack of change with TEAM on lipids, with the exception of total cholesterol, may be due to the fact that dietary changes (inclusion of vegetables and high fiber diets) suggested by the intervention were beyond the financial means of some of the study participants. A recent qualitative study by these authors found that financial issues were a major barrier to stroke prevention and recovery in Kampala, Uganda (38). It also must be noted that in contrast to clinical practice norms in higher resource countries, the majority individuals with elevated serum lipids in this study were not receiving lipid lowering drugs during the study period.

There were improvements in the HbA1c from baseline and all diabetic patients were able to reduce glycemic targets to acceptable levels. The TEAM intervention addresses issues related to healthy diet, physical activity and emphasizing monitoring of both BP and blood sugar. It is possible that this multi-faceted approach could have helped reduce multiple stroke risk factors concurrently. Whereas some individuals personally had significant reductions in their BMI, overall the group did not have significant reductions in the BMI at week 24. Perhaps a more specific focus on weight loss in individuals who were overweight might have yielded more change in this domain. Alternatively, it is possible that significant weight loss may require more than 6 months to occur.

Exercise and physical activity have a well-established evidence base for their benefits in reducing cardiovascular risk factors. Observational studies have found an inverse association between physical activity and stroke risk (39, 40). Although TEAM participants found exercise and activity to be helpful, we were not able to demonstrate change in activity levels. Perhaps, a stronger focus on exercise would be necessary to change this aspect of health behavior. Alternatively, about half of the study participants were already involved in physical activities ranging from moderate to vigorous intensity and there could have been limited potential for increase in activity. Because base rates of tobacco and alcohol use were already extremely low, we similarly found little change in these behaviors at study endpoint.

This study had a number of limitations including small sample size, non-controlled design, and the fact that research staff were not blind to intervention assignment. Participants with

stroke were those with milder deficit who could participate in group programs, this it is not clear that individuals with history of more severe stroke would equally benefit. However, study strengths including a sample that is highly generalizable to urban/suburban Uganda, the 6-month follow-up and standardized research assessments of factors that are highly relevant to future stroke risk make our findings clinically relevant. The practical, written curriculum that can be delivered by credible stakeholders (people at risk for stroke and nurses) optimizes potential for broad scale-up.

5.0 Conclusions

Our study demonstrates that self-management is feasible, culturally acceptable in Uganda and has clinically meaningful reduction in BP and other key stroke risk factors over 6 months follow up. Further studies are needed to evaluate the efficacy of this intervention among a high risk population for stroke before it can be widely implemented in sub-Saharan Africa.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

Acknowledgments

We also thank our study subjects for participating in this study.

Funding

The study was supported by a grant from the National Institutes Health (R21NS094022-01) to Drs. Martha Sajatovic and Elly Katabira. The funders had no role in the study design, collection, analysis, and interpretation of data and in writing the manuscript.

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Highlights

- We investigated an adopted novel self-management intervention, TargetEd mAnageMent Intervention (TEAM) to reduce modifiable stroke risk factors in Uganda.
- Significant reduction in mean baseline blood pressure of 163/98.8mmHg to blood pressure of 147.8/88.0 mmHg at 24 weeks were observed.
- Significant reductions in the serum total cholesterol levels at 24 weeks were noted.

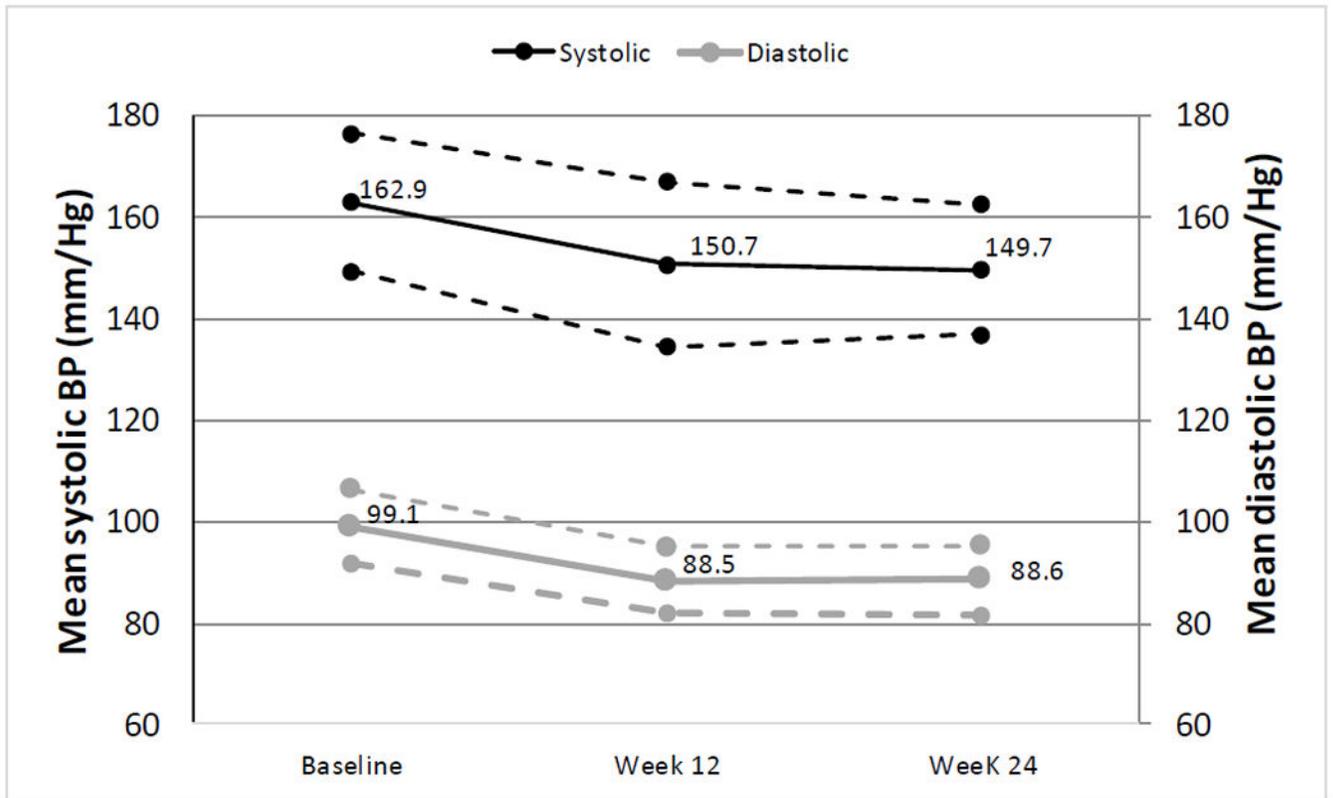


Figure 1.
Change patterns in systolic and diastolic blood pressure from base line to 12 and 24 weeks with 95% confidence intervals as dotted lines

Table 1

Baseline characteristics of TEAM study participants

Variable (N=16)	Summary statistics
Female gender, n (%)	11 (68.8)
Age (years)‡, mean (±SD)	51.7 (17.3), range 24-80 years
Age categories, n (%)	
< 30 years	2 (12.5)
31 – 40 years	4 (25.0)
41 – 50 years	1 (6.3)
51 – 60 years	3 (18.8)
61+ years	6 (37.5)
HIV result: Negative, n(%)	16 (100)
Hypertensive at baseline based on AHA* criteria	
Normal <120/<80mmHg	0 (0.0)
Prehypertension, 120 -139/80-89mmHg	1 (6.3)
Hypertensive stage 1, 140 -159/90-99mmHg	11 (68.8)
Hypertension stage 2 > 160/>100	4 (25.0)
BMI (kg/m ²), mean (±SD)	28.7 (7.2)
Desirable BMI, n = 7	21.5 ±1.7
Pre-obesity Obesity class I, n = 5	26.6 ± 0.9
Obesity class II, n = 2	32.9 ± 0.8
Obesity class III, n = 2	41.5 ±1.4
Individuals with known diabetes n (%)	6 (38%)
HbA1c in known diabetics, mean (SD)	10.7 (1.7)

AHA= American Heart Association

Change in biomarkers among Ugandans with high stroke risk who participated in the TEAM intervention.

Table 2

Variable	Entire sample			Individuals with elevated baseline systolic BP(>140)			P	
	Baseline (N=16)	Week 12 (N= 16)	Week 24 (N=14)	P*	Baseline (N=13)	Week 12 (N=13)		Week 24 (N=12)
Mean (SD)								
Primary Outcome								
Systolic BP (mm/Hg)	162.9 (25.6)	150.7 (30.4)	149.7 (22.1)	0.031	170.4 (22.1)	154.6 (32.5)	152.0 (23.2)	0.021
Secondary Outcomes								
Diastolic BP (mm/Hg)	99.1 (13.8)	88.5 (12.3)	88.6 (11.7)	0.041	101.2 (14.6)	91.2 (11.7)	88.3 (12.1)	0.036
HDL (mg/dL)	49.0 (7.4)	NA	41.3 (3.5)	0.002	48.3 (7.8)	NA	41.3 (3.5)	0.003
LDL (mg/dL)	112.1 (16.0)	NA	122.8 (8.2)	0.128	110.1 (14.0)	NA	124.5 (7.6)	0.012
Triglycerides (mg/dL)	188.8 (75.6)	NA	134.6 (35.0)	0.023	195.9 (78.7)	NA	138.7 (35.5)	0.029
Total cholesterol (mg/dL)	165.0 (66.5)	NA	92.6 (43.1)	<0.001	154.2 (69.1)	NA	88.9 (45.2)	0.001
Additional clinically relevant evaluations								
High total cholesterol (n, %) 200 mg/dL	8 (50.0)	NA	1 (7.1)	0.016	6 (46.2)	NA	1 (8.3)	0.063
High HDL: (n, %) 60 mg/dL	0 (0.0)	NA	0 (0.0)	>0.999	0 (0.0)	NA	0 (0.0)	>0.999
High LDL: (n, %) 130 mg/dL	2 (12.5)	NA	2 (14.3)	>0.999	1 (7.7)	NA	2 (16.7)	>0.999
High triglycerides: (n, %) 110 mg/dL	14 (87.5)	NA	11 (78.6)	0.564	12 (92.3)	NA	10 (83.3)	>0.999
HbA1c (%) in diabetics (N=6)	10.7 (1.7)	NA	5.8 (2.9)	0.032	NA	NA	NA	NA
BMI kg/m2 mean (N=14)	28.7 (7.2)		27.6 (5.7)	0.074	NA	NA	NA	NA

Note: Because of cell counts less than 5, the exact McNemar test was used to compare proportions.

* Statistic is change from baseline to 24 weeks

NA – Not applicable, HDL = serum high density lipoprotein, LDL = serum high density lipoprotein

Table 3

Regression analysis for change in systolic BP

Variable	Entire sample		Individuals with elevated baseline systolic BP (>140)	
	Coefficient (SE)	P	Coefficient (SE)	P
Time (week 24 vs baseline)	-16.79 (7.64)	0.036	-20.75 (8.65)	0.025
Age in years [†]	0.11 (0.25)	0.648	0.54 (0.35)	0.133
Gender (female vs male)	-11.15 (8.49)	0.200	-14.10 (9.93)	0.169
Diabetes (yes vs no)	9.79 (10.14)	0.343	13.11 (10.98)	0.245
BMI (kg/m ²) [†]	-0.77 (0.65)	0.246	-0.75 (0.76)	0.331
Obesity: ≥30 kg/m ²	-11.06 (9.70)	0.265	-10.64 (11.55)	0.368
Overweight: ≥25 kg/m ²	-11.22 (10.00)	0.273	-14.63 (12.24)	0.247
Baseline drugs used:				
Captopril (yes vs no)	10.68 (9.10)	0.251	13.83 (10.37)	0.195
Nifedipine (yes vs no)	11.19 (8.75)	0.211	15.56 (9.53)	0.116
Other drugs ^φ (yes vs no)	10.22 (9.56)	0.294	11.86 (12.95)	0.369

^φ other drugs including bendrofluthiazide, amlodipine, telmisartan, aspirin and oral contraceptives

[†] Coefficient interpretation is done per unit increase in the continuous variable