Effect of Covi-soup on Random Blood Sugar and Blood Pressure among Patients with Type II Diabetes and Hypertension in Kenya

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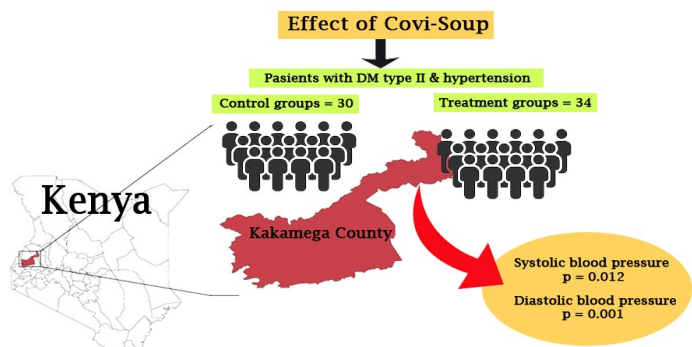
ABSTRACT

Non-communicable diseases (NCDs) are posing a serious global challenge due to the high impact on health and mortality. These diseases are becoming more prevalent in low and middle-income countries. Therefore, this study aimed to test the effect of Covi-soup on random blood sugar (RBS) and blood pressure among patients with type II diabetes mellitus and hypertension. This was a pilot study conducted in Kakamega County, Kenya. Simple systematic sampling was used in identifying respondents and allocating them to the groups. A total of 64 respondents were involved in this study, with 34 and 30 assigned to the treatment and control groups. The treatment group received Covi-soup, containing butternut squash, ginger, garlic, sunflower pepper, chia seeds, and turmeric, while the control consumed a rice soup. There was no significant difference in baseline RBS and systolic pressure levels in the treatment and control with (P =0.909) and (P =0.218), respectively. There was no positive change in RBS, but a positive change was reported in systolic and diastolic blood pressures (P ≤0.187), (P ≤0.012), and (P ≤0.001) after an intervention. Furthermore, there was a significant difference in RBS, systolic blood pressure, and diastolic blood pressure values of the treatment and non-treatment. The consumption of Covi-soup by patients with type II diabetes mellitus and hypertension for 3 months resulted in reduced blood pressure and random blood sugar levels.

ABSTRAK

Penyakit tidak menular (PTM) merupakan tantangan global yang penting karena menyebabkan dampak kesehatan dan kematian. Penyakit ini menjadi lebih umum di negara-negara berpenghasilan rendah dan menengah. Oleh karena itu, penelitian ini bertujuan untuk menguji pengaruh sup Covi terhadap gula darah acak (GDA) dan tekanan darah pada pasien diabetes melitus tipe II dan hipertensi. Studi ini dilakukan di Kakamega County, Kenya, melalui pendekatan sampling sistematis sederhana. Pengambilan sampel sistematis sederhana digunakan untuk mengidentifikasi responden dan mengalokasikannya ke dalam kelompok. Sebanyak 64 responden terlibat dalam penelitian ini, dengan 34 dan 30 ditugaskan ke kelompok perlakuan dan kontrol. Kelompok perlakuan diberi sup Covi yang berisi butternut squash, jahe, bawang putih, lada bunga matahari, biji chia, dan kunyit, sedangkan kelompok kontrol mengonsumsi sup nasi. Tidak ada perbedaan yang signifikan pada GDA awal dan tingkat tekanan sistolik pada perlakuan dan kontrol dengan masing-masing (P = 0.909) dan (P = 0.218). Tidak ada perubahan positif pada RBS, tetapi perubahan positif dilaporkan pada tekanan darah sistolik dan diastolik (P≤0.187), (P≤0.012), dan (P ≤0.001) setelah intervensi. Selain itu, ada perbedaan yang signifikan pada nilai GDA, tekanan darah sistolik, dan tekanan darah diastolik dari perlakuan dan non-perawatan. Konsumsi sup Covi oleh pasien diabetes melitus tipe II dan hipertensi selama 3 bulan mengakibatkan penurunan tekanan darah dan kadar gula darah acak.

GRAPHICAL ABSTRACT



Keyword
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INTRODUCTION

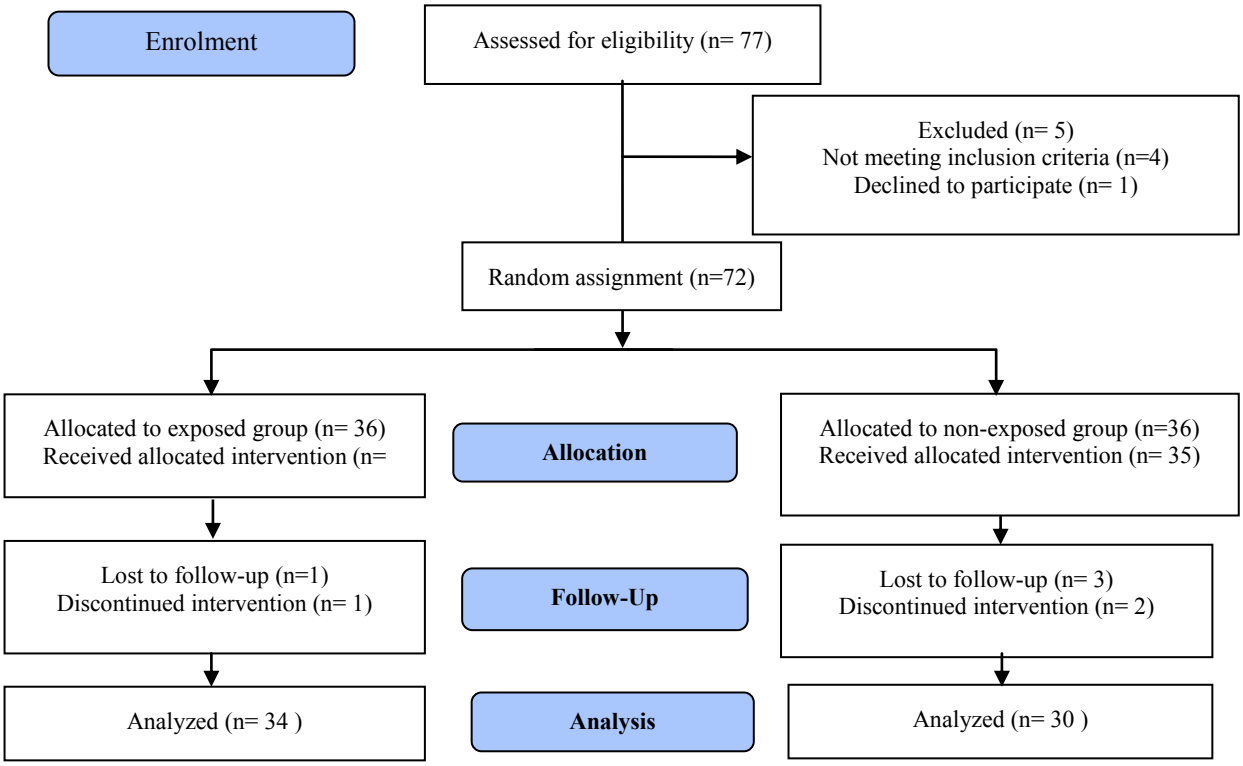
Non-communicable diseases (NCDs) are a leading cause of death worldwide and pose a serious threat to public health. According to WHO report, these diseases kill 41 million people each year which is equivalent to 74% of total deaths globally (World Health Organization, 2018). In 2018, a total of 17,733 Kenyan individuals succumbed to type II diabetes mellitus and its associated complications, while the prevalence of hypertension (HTN) was documented at 24.5% (Mohamed et al., 2018). Alterations in lifestyle and the unsustainability of urbanization have also significantly impacted public health. Therefore, prioritizing health promotion emerges as a crucial element in the management and prevention of diabetes mellitus (Bigna & Noubiap, 2019). Diabetes and hypertension coexist in 60 to 70% of the patients, and share many risk factors, such as obesity, physical inactivity, aging nutrition transitions, socioeconomic changes, and underlying pathophysiological mechanisms (Oktay et al., 2018). This increases the risk of complications and mortality, as well as requires integrated management and care.

Previous studies on diabetes and hypertension primarily focused on dietary modifications and nutrition counselling interventions (Dash et al., 2020; Magkos et al., 2020; Medina-Remón et al., 2018; Rasmussen et al., 2020). However, there has been limited exploration of strategies that utilize food-based interventions to effectively manage these conditions. Butternut squash, ginger, garlic, sunflower seeds, pepper, chia seeds, and turmeric have been employed in the management of hypertension and type II diabetes mellitus. However, there is limited information regarding their appropriate combination for documented benefits. Combining these ingredients can enhance nutritional composition and density, improving disease management. Furthermore, Masinde Muliro University of Science and Technology has developed an innovative product called Covisoup, incorporates butternut squash, ginger, garlic, sunflower seeds, pepper, chia seeds, and turmeric. Each serving of this soup contains 62 kilocalories and the selection of ingredients was based on medicinal and nutritional values, as well as availability in local markets.

By improving insulin sensitivity and associated metabolic disorders, garlic has been demonstrated to control blood glucose levels (Padiya & Banerjee, 2013). In patients with type II diabetes mellitus, curcumin has been shown to ameliorate resistance by increasing the transcription of insulin-responsive genes (Marton et al., 2021). The bioavailability and absorption of medications and nutrients have been proven to be greatly enhanced by piperin. Meanwhile, pepper aids in glycaemic management by inhibiting hepatic glycogenesis (Prasad & Tyagi, 2015). Oral consumption of ginger reduces blood pressure by blocking voltage-dependent calcium channels (Toscano et al., 2014). Transient receptor potential vanillin 1 (TRPV1) channels in the blood vessel lining are also activated by pepper and lower blood pressure. In addition, chia seeds have been shown to decrease blood pressure due to high levels of omega-3 fatty acids acting as blood thinners (Toscano et al., 2014). Garlic and turmeric promote blood pressure regulation by lowering the low-density lipoprotein (Arreola et al., 2015).

Chia seeds have a high fiber and low carbohydrate content. They can lower blood sugar levels and improve insulin sensitivity after consuming 6 grams daily for two weeks (Toscano et al., 2014). Ginger is another food that can reduce blood sugar and cholesterol levels (Hajimoosayi et al., 2020). Studies showed that it can lower blood glucose, cholesterol, and triglycerides, as well as increase good cholesterol levels in diabetic rats (Ali et al., 2008). Furthermore, it can reduce insulin resistance when

Figure 1
Study Profile



taken 2 grams daily for two months (Zhu et al., 2018). Butternut squash contains various types of indigestible fiber and has numerous potassium, which can help regulate blood pressure (Li, 2020). Pepper is an anti-inflammatory agent that can protect the brain from depression and enhance the absorption of nutrients and drugs (Srinivasan, 2014). A study in India found that patients with diabetes mellitus had better blood sugar control after eating 5 grams of sunflower seeds daily (Srinivasan, 2014).

According to Anh et al. (2020), ginger can activate the muscarinic receptors and block the volatile-dependent calcium channels. Chia seeds, which are rich in Omega three fatty acids, may have a beneficial effect on blood pressure (Ullah et al., 2016). Similarly, garlic supplements can lower blood pressure, as a meta-analysis of 12 trials with 553 hypertensive patients found that systolic and diastolic blood pressures were reduced by 8.3 mmHg and 8 mmHg, respectively (Ried et al., 2008; Sethi et al., 2014; Wang et al., 2017).

One of the factors influencing blood pressure is the calcium channels, which can be affected by sunflower seeds. Sunflower also contains magnesium, recognized for its potential in alleviating symptoms associated with hypertension (Nandha et al., 2014). In addition, butternut squash has polyphenols used to regulate blood pressure (Li, 2020; Mahmoodpoor et al., 2018; Sagam et al., 2023). There is limited study on the effects of Covi-soup, which contains both ingredients, on blood pressure and sugar in patients with hypertension and type II diabetes mellitus. This study examines the impact of Covi-soup on random blood sugar (RBS) and pressure levels to provide suggestions for future analysis.

METHODS

This pilot study was conducted at the Kakamega County Teaching and Referral Hospital in Kakamega County, Kenya, between

Table 1
Sociodemographic Characteristics of The Respondents

Sociodemographic characteristics	Treatment group (n=34)		Control group (n=30)		*P-value*
	n	%	n	%	
Age					
30- 50 years	9	26.47	15	50.00	
51-60 years	11	32.35	11	36.67	0.030*
61-80 years	14	41.18	4	13.33	
Education					
No education	4	11.76	4	13.33	
Primary	15	44.12	4	13.33	0.052
Secondary	9	26.49	13	43.33	
Tertiary	6	17.6	9	30.00	
Gender					
Female	25	73.53	10	33.33	0.593
Male	9	26.47	20	66.67	
Duration of illness in years					
3 or less	13	38.24	10	33.33	0.166
>3 - 5	21	61.76	20	66.67	
Occupation of the respondents					
Employed with a salary	8	8.82	5	16.67	
Small scale trading	11	32.35	5	16.67	
Casual labor	14	41.18	15	50.00	
Not employed	6	17.65	5	16.67	0.468
BMI in kg/M^2					
18.5-24.9	7	20.59	4	13.30	
25-29.9	14	41.18	10	33.30	0.535
>30	13	38.24	16	53.30	

Note: *p ≤0.05; n= total respondents; %= percentage

May and August 2021. The respondents were divided into treatment and control groups, which received Covi-soup and rice soup, respectively. In the study period, the two groups received a daily ration of 16.35 grams of one sachet for three months. Furthermore, the primary outcomes of interest were the respondents' blood pressure and RBS levels.

This study involved assessing diabetic patients who visited the Kakamega County Teaching and Referral Hospital's diabetic clinic and enrolling those who met the eligibility criteria and providing consent. In addition, the respondents were randomly selected and assigned to the intervention or control group. This study included patients who were 30-80 years old since this range had the highest prevalence of diabetes and hypertension in previous studies, those with type II diabetes mellitus and hypertension, patients taking metformin for type II diabetes mellitus and first-line antihypertensive drugs, and those ill for less than 5 years. It excluded patients who were critically ill, pregnant, or had other comorbidities besides diabetes and hypertension. The duration of illness was obtained by both patient recall and medical records. Meanwhile, the groups received standard care, and the respondents returned to the facility every 21 days after recruitment to monitor the soup preparation, adverse effects, and contamination. All respondents received a demonstration of how to prepare and administer the soup at baseline. This study lasted for three months, and each respondent consumed one serving of Covi-soup or rice soup daily.

The extent to which patients shared allocated diets with other members was evaluated through interviews conducted during their follow-up visits at the hospital. Meanwhile, clear instructions were provided to bring the empty

Table 2
Baseline Characteristics of Study Respondents

Variables	Control group		Treatment group		*P-value**
	Mean	CI	Mean	CI	
Random blood sugar (mmol/l)	12.5	11.4-13.9	12.5	11.3-13.9	0.599
Systolic blood pressure (mmHg)	150.5	143.6-157.4	156.3	149.8-162.8	0.730
Diastolic blood pressure (mmHg)	107.7	107.0-116.5	100.9	97.3-104.6	0.247

Note: CI= 95% confidence intervals as indicated; *= statistical analysis was performed using the student t-test.

packets as evidence. To promote adherence to the preparation and consumption guidelines, regular phone calls and text messages were employed twice a week. Face-to-face meetings with the doctor and nutritionist were also arranged to reinforce compliance. Additionally, a chart reporting adherence was prominently shown at the clinic to serve as motivation. This approach proved valuable in obtaining reliable and honest feedback and enhancing adherence to the prescribed diets. The respondents were explicitly instructed not to share the rations received. To ensure quality control, information was collected through a 24-hour recall and a 7-day food frequency questionnaire. Furthermore, a comprehensive demonstration on soup preparation and administration was provided during enrollment and facility visits

Glucometer (Accu Check Advantage®, Roche-Basel, Switzerland) was used in taking RBS measurements. A blood sugar test was also performed and the average of three readings was used. Blood pressure was measured using the Omron M6 Compact (HEM-7000-E, Omron Healthcare Corporation, Kyoto, Japan). Before taking a blood pressure reading, respondents followed a standardized procedure. They observed a 30-minute waiting period after eating or consuming caffeine products and ensured an empty bladder, assumed a comfortable seated position, as well as raised their left arm to the level of the heart. Placing the arm on a desk, stillness was maintained for a duration of 3 to 5 minutes. Subsequently, three readings were taken, and the average of these readings was utilized for analysis. The study assistants took anthropometric measurements at the beginning and end of the study. Weight was measured to the nearest 0.01 kilograms on a calibrated bathroom scale and height to the nearest 0.01 centimeters on a calibrated stadiometer. The measurements were taken twice and the average of the two readings was used. In addition, the equipment was calibrated after every 10 respondents. Kolmogorov-Smirnov test was used to check the normality of the data, while SPSS version 20 calculated frequencies, means, percentages, and confidence intervals. The paired t-test was applied to assess the treatment effect on the main variables.

This study followed the ethical principles of the Declaration of Helsinki and obtained approval from the Institutional Ethics Research Committee of Masinde Muliro University of Science and Technology with reference number (MMUST/IERC/026/2021), and the National Commission for Science, Technology, and Innovation (NACOSTI) with reference number (License No: NACOSTI/P/21/14402) to conduct the study. The Ministry of Health Kakamega County and Kakamega County Teaching and Referral Hospital also granted permission. The study respondents provided written consent before taking part in the study.

RESULTS

As depicted in figure 1, the initial pool consisted of 77 respondents who were evaluated for eligibility. Subsequently, they met the

Table 3
Intra-group Comparison of Blood Sugar and Blood Pressure

Variables	Control group					Treatment group				
	Before		After		P-value	Before		After		P-value
	Mean	CI	Mean	CI		Mean	CI	Mean	CI	
Random blood sugar (mmol/l)	12.5	11.4-13.9	12.7	11.3-13.9	0.912	12.5	11.3-13.9	8.9	8.3-9.7	0.187
Systolic blood pressure (mmHg)	150.5	143.6-157.4	152.2	145.7-158.7	0.721	156.3	149.8-162.8	131.1	127.3-134.9	<0.012*
Diastolic blood pressure (mmHg)	107.7	107.0-116.5	100	98.7-104.8	<0.001*	100.9	97.3-104.6	88.8	87.5-91.1	<0.001*

Note: CI= 95% confidence intervals as indicated; *= significant

criteria and were assigned to treatment and control arms, each comprising 36. Within the treatment group, there was 1 case of lost follow-up and 1 respondent who discontinued their participation. In the control group, 3 respondents were lost to follow-up and 2 discontinued their involvement in this study.

According to table 1, the treatment group consisted of more females (73.53%, n=25) than males (26.47%, n=9), while the control had more males (66.67%, n=20) than females (33.33%, n=10). The most common level of education in the treatment group was primary (44.12%, n=15), while in the control group, it was secondary (43.33%, n=13). Most of the respondents were casual laborers, with 41.18% (n=14) and 50% (n=15) in the treatment and control groups, respectively. The BMI distribution of the respondents differed between the groups, with 41.18% (n=14) and 53.3% (n=16) of the treatment and control groups having a BMI of 25-29.9 kg/M^2 and above 30 kg/M^2.

According to table 2, the mean RBS for the treatment and control groups was 12.5 mmol/L at baseline. The control group's mean systolic blood pressure was 150.5 mm/Hg and treatment group's mean was 156.3 mm/Hg. Besides that, the control group's mean diastolic blood pressure was 107.7 mm/Hg and treatment group's mean was 100.9 mm/Hg.

According to table 3, the mean RBS for the treatment and control groups was 12.5 mmol/L at baseline. Meanwhile, the values differed at 8.9 mmol/L and 12.7 mmol/L for treatment and control groups at follow-up. There was no significant change in RBS in the treatment ($p \leq 0.187$) and control groups ($p=0.912$). The treatment group's mean systolic blood pressure was 156.3 mm/Hg and 131.1 mm/Hg at baseline and follow-up. The mean systolic blood pressure in the control group was 150.5 mm/Hg at baseline and 152.2 mm/Hg at follow-up. Systolic blood pressure changed significantly in the treatment group ($p \leq 0.012$), but not in the control ($p = 0.721$). The treatment group at baseline, the mean diastolic pressure was 100.9 mm/Hg and at follow-up, it was 88.8 mm/Hg. Baseline and follow-up diastolic blood pressure measurements in the control group were 107.7 mm/Hg and 100 mm/Hg. The diastolic blood pressure dropped significantly ($p \leq 0.001$) in the treatment and control groups. According to table 4, there was a difference in diastolic blood pressure and RBS level means between groups after the intervention with a p-value of <0.001.

DISCUSSION

RBS is an important indicator of disease prognosis in diabetes patients. The results in the treatment group were significant, hence, Covi- soup did not have a positive change in RBS levels. The findings of a study testing the

Table 4
Inter-group Comparison

Variable	Mean difference	95% Confidence interval		P-value
Blood sugar (mmol/L)	-3.831961	-5.425625	-2.238296	<0.001*
Systolic BP (mmHg)	-21.1451	-28.30478	-13.98542	<0.001*
Diastolic BP (mmHg)	-13.472549	-14.64177	-4.303324	<0.001*

Note: *= significant

effects of sunflower on type 2 diabetic mice's blood glucose and lipid profile found the same results (Nandha et al., 2014, Wang et al., 2017). Ginger has previously been shown to lower glucose levels, increase insulin sensitivity and enhance antioxidant activity. Meanwhile, daily ginger root supplementation significantly lowered blood glucose levels. The plant had an effect in a systematic review and meta-analysis of ten randomized controlled trials on glucose and insulin sensitivity (Wang et al., 2017). The underlying mechanism involved inhibiting glucosidase and –amylase enzymes involved in complex carbohydrate digestion and absorption (Yoshizaki et al., 2009).

The findings were contrary to previous results that turmeric affected glycemic status (Clark et al., 2019). In another study, garlic reduced glucose parameters and improved therapeutic effects in type II diabetes mellitus patients (Padiya & Banerjee, 2013). This was also replicated in a meta-analysis where garlic was shown to improve blood sugar control and also played a positive role in low-density and high-density lipoprotein (Wang et al., 2017). Cholesterol levels also played an extremely important role in blood sugar regulation due to its connection to obesity and overweight. In a study conducted in India, the impact of sunflower seeds on fasting blood glucose levels was investigated among patients diagnosed with type II diabetes mellitus. The findings showed a significant reduction in blood glucose levels as a result of sunflower seed consumption (Nandha et al., 2014). Individual Covi-soup ingredients' effects were studied, and the results were mixed in terms of positive and negative effects. There was limited information on studies carried out on combined ingredients, hence, the results were compared to individual Covi-soup ingredients.

Blood pressure played a significant role in the care of patients with hypertension and diabetes mellitus. Previous studies linked individual ingredients in Covi-soup to blood pressure regulation. The results indicated a significant difference between the diastolic blood pressure values of the control and treatment groups, both at baseline and after the study. Essentially, a significant difference was also observed between the control and treatment groups following the intervention, suggesting that the respondents' blood pressure had changed as a result of consuming Covi-soup. A subset of studies with a mean age of 50 years, an 8-week follow-up period, and ginger doses of 3 g/d showed significant reductions in both systolic and diastolic blood pressure (Ali et al., 2008). A beneficial effect of curcumin administration was also reported on systolic blood pressure (Shango et al., 2021). The findings were congruent with the results of another study, where the DASH diet and increased walking were connected to clinically meaningful reductions in the values obtained from ambulatory blood pressure monitoring (ABPM) in hypertensive patients with type II diabetes mellitus (de Paula et al., 2017). According to a meta-analysis of 12 trials involving 553 hypertensive patients, garlic supplements reduce sys-

tolic and diastolic blood pressure by 8.3 mmHg and 8 mmHg, respectively (Ried et al., 2008). The majority of the studies have been conducted on individual Covi-soup ingredients. Therefore, the results have been compared to individual ingredients because of the limited information on combined ingredients.

CONCLUSIONS

This study indicated that Covi-soup intake for three months lowered both blood pressure and RBS levels. Therefore, Covi-soup may be beneficial for patients suffering from type II diabetes mellitus and hypertension, but more analyses are needed to confirm this result. This study depended on the respondent's memory to record the length of illness and diet history and was vulnerable to recall bias. This was controlled by using the respondents' clinic card, as well as probing to obtain a more representative picture of the respondents' duration of illness and diet history. This study employed simple random sampling, which resulted in an uneven distribution of respondents across the two groups concerning age, sex, occupation, and education status. RBS levels were also utilized as a measure, but it was not deemed reliable for assessing changes in RBS levels over time. Therefore, the results should be interpreted with caution and the strength was that dietary intake information was collected for quality control. Concerning the recommendation, further study should be conducted on other key outcomes such as HbAIC and lipid profile on a larger population to enhance the generalizability of these findings.

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AUTHORS' CONTRIBUTIONS

Caleb K. Sagam wrote the first draft of the manuscript, performed the data analysis, conceived and designed study. Antonette Kivelenge acquired data and conducted the study. Lucy Mutuli oversaw the data collection process. Jane Situma conceived and designed study and with Lucy Mutuli provided supervision and editorial guidance throughout the study. Caleb K. Sagam, Jane Situma, and Antonette Kivelenge developed the Covi-soup as a tool for data collection.

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COMPETING INTERESTS

The authors confirm that all of the text, figures, and tables in the submitted manuscript work are original work created by the authors and that there are no competing professional, financial, or personal interests from other parties.

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