Original Article

Effectiveness of Smartphone Application "Gororokapp" for Type 2 Diabetes Patients' Self-Management in Rwanda: A Randomized Controlled Trial

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Abstract

Background
Type 2 diabetes has become a public health concern, representing more than 90% of all types of diabetes and affecting 536.6 million people worldwide in 2021. It is a disabling condition and is considered a major risk factor for developing chronic complication such as cardiovascular diseases if not well controlled. Studies have shown that individuals with diabetes can make a positive impact on the outcomes of their disease by participating to their healthcare. Contextualized innovative and effective applications are needed to facilitate individuals with diabetes to participate to their care.

Aim
To assess the effectiveness of Smartphone Application "GororokApp" in monitoring of glucose control among type 2 diabetes individuals.

Materials & Methods
A Randomized Controlled Trial (RCT) was used to assess the effectiveness of smartphone application (GororokApp) in monitoring of glucose control for self-management by the patients with type 2 diabetes in Rwanda. Participants in intervention group used the GororokApp and recorded their blood glucose measurements and received health care advice remotely while the control group continued routine care. The participants were followed up over a period of 12 weeks. The primary outcomes were glycated haemoglobin, and daily blood glucose measurements.

Results

After 12 weeks of follow up, the intervention and control, groups demonstrated difference of changes in glycated haemoglobin; whereby in the intervention group the glycated haemoglobin reduced from 8.45 ± 2.93 to 6.89 ± 1.86 ($p \le 0.001$), whereas in the control group the glycated haemoglobin increased from 7.12 ± 2.52 to 8.14 ± 2.17 ($p \le 0.001$).

Conclusion

The smartphone application "GororokApp" is effective in self-monitoring and management of the daily blood glucose levels in intervention group to achieve treatment targets of blood glucose and glycated haemoglobin among individuals with type 2 diabetes.

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Introduction

Type 2 diabetes is one of the major public health concerns affecting people of all ages globally.[1] Type 2 diabetes caused approximately five million deaths in 2017. [1]The International Diabetes Federation (IDF) estimated that 536.6 million people were living with diabetes in 2021. Diabetes is one of the common chronic diseases causing life-threatening complications and reducing life expectancy.[2] The prevalence of diabetes in high-income countries is estimated at 11.1% as compared to 5.5 % in low-income countries. The rising prevalence of type 2 diabetes can be attributed to genetic predisposition, aging, rapid increase in urbanization, and some modifiable risk factors such as smoking, excessive alcohol consumption, physical inactivity, and obesity among others. The evidence supports that self-management significantly contributes to the care of people with Type 2 diabetes.[3,4]

Diabetes management requires long-term self-care by patients, which can be demanding because most patients lack the necessary knowledge, tools, and support. However, research showed that patients rarely self-monitored their glucose levels, had low frequency/duration of physical activity, moderately adhered to recommended dietary and medication behaviour.[5,6]

However, technological interventions such as Continuous Glucose Monitoring (CGM) sensor technology,[5] and Kir'App;[7] have been reported to have a positive impact on diabetes outcomes including improvements in haemoglobin HbA1c levels, diabetes self-management behaviours, and diabetes self-efficacy. Good glycaemic control is an effective way to prevent diabetes complications. Some studies conducted in Rwanda demonstrated that self-management practices are not well integrated into type 2 diabetes patients' care.[8,9] This imposes a heavy reliance on medication to control the disease, yet it is very costly and can lead to further complications related to the lack of control over the disease.

Some observational studies conducted in the Rwandan population explored self-care knowledge and practices in diabetics among adults and reported that 63.7% of the participants were not aware of the importance of pre-exercise snacks/meals, and 70% among them before exercising were not taking a snack/meal. [6] In addition, it was reported that type 2 diabetes patients experience poor health status, lack of motivation, and awareness of the importance of physical activities in the management of type 2 diabetes.[10] However, other studies have demonstrated that self-management of type 2 diabetes using mobile health applications helped in blood glucose self-monitoring, exercises, and diet adherence.[11,12]

A previous randomized control trial among Rwandan diabetic patients assessed the effects of a lifestyle education program on glycemic control among patients with diabetes.[13]The trial demonstrated that lifestyle change education including physical activity, and diabetic care resulted in the reduction of HbA1c levels after 12 months of follow-up in the intervention group.[13,14]

Technological interventions have positive impacts on diabetes outcomes including improvements in haemoglobin HbA1c levels, and diabetes self-management behaviours. [8,9,11,15,16] The use of technology is believed to support an overwhelmed healthcare system with poor accessibility to diabetes-specialized care, and a small number of healthcare providers compared to a large population needed to serve. Therefore, we developed mhealth user friendly tool (GororokApp) for type 2 diabetes patients self monitoring, very specifically taking account into the Rwandan context. The App was customised to the local context specifically for Rwandans considering available and affordable local foods; and meal plans were prepared accordingly. Exercise prescription embedded in the application and its content; were translated into Kinyarwanda, a language that is understood and spoken by the study participants.

This study assessed the effectiveness of a smartphone application (GororokApp) in the self-monitoring of patients with type 2 diabetes in Rwanda. This paper focuses on glycated haemoglobin HbA1C and blood glucose changes as the main outcomes.

Materials and methods

Study Population
The study included participants with type 2 diabetes who attended two referral hospitals; Rwanda Military Hospital and University Teaching Hospital of Kigali, and one private clinic, the Rwanda Diabetes Association Clinic. Recruited participants for the study included those who were diagnosed with type 2 diabetes for at least 1 year, aged 18 years and above,

on regular oral antidiabetic medications, having a smartphone, intact balance, and optimal walking capabilities; and having the minimum literacy level. The study initially obtained 139 participants who were screened for eligibility. The 39 participants who were on insulin therapy, being pregnant, and having diabetic complications were excluded. The remaining 100 participants were randomly allocated into two groups, Intervention Group (IG) (n=50) and Control Group (CG) (n=50) using computer-generated random assignment; whereby the Random Allocation Software-RAS (for the Windows operating system), as a random number generator, was used. The researchers created a sequence of unique random numbers between 0 and 1. All random numbers were equal to the total number of 100 participants. Random numbers were assigned to participants and each participant had a unique random number from the generated list and it was done by a remote and independent IT facility.

Study Protocol
A Randomised controlled trial study was conducted whereby 100 participants using a smartphone application for daily glucose monitoring and remote diabetes care were recruited and followed over a period of 12 weeks. Eleven (11) participants were lost to follow up, specifically three (3) and eight (8), from the intervention and control, groups respectively. The reason being that they lost their phones.

Randomization and blinding were ensured with assigning of the random numbers to the participants and each participant had a unique random number from the generated list and it was done by a remote and independent IT facility.

Demographic data were recorded and included age, gender, marital status, educational level, years since the diagnosis, frequency of medication intake. Eligibility with physical performance tests were conducted using a standardized Six Minutes' Walk-Test to ensure

the physical performance of the participants and their safety during the study follow up. Laboratory measurements were then taken and included glycated haemoglobin, cholesterol, high and low-density lipids, and triglycerides using SD Biosensor Standard F200 Analyzer.

All participants were given a Codefree glucometer and 100 glucose strips for regular blood glucose measurement daily.
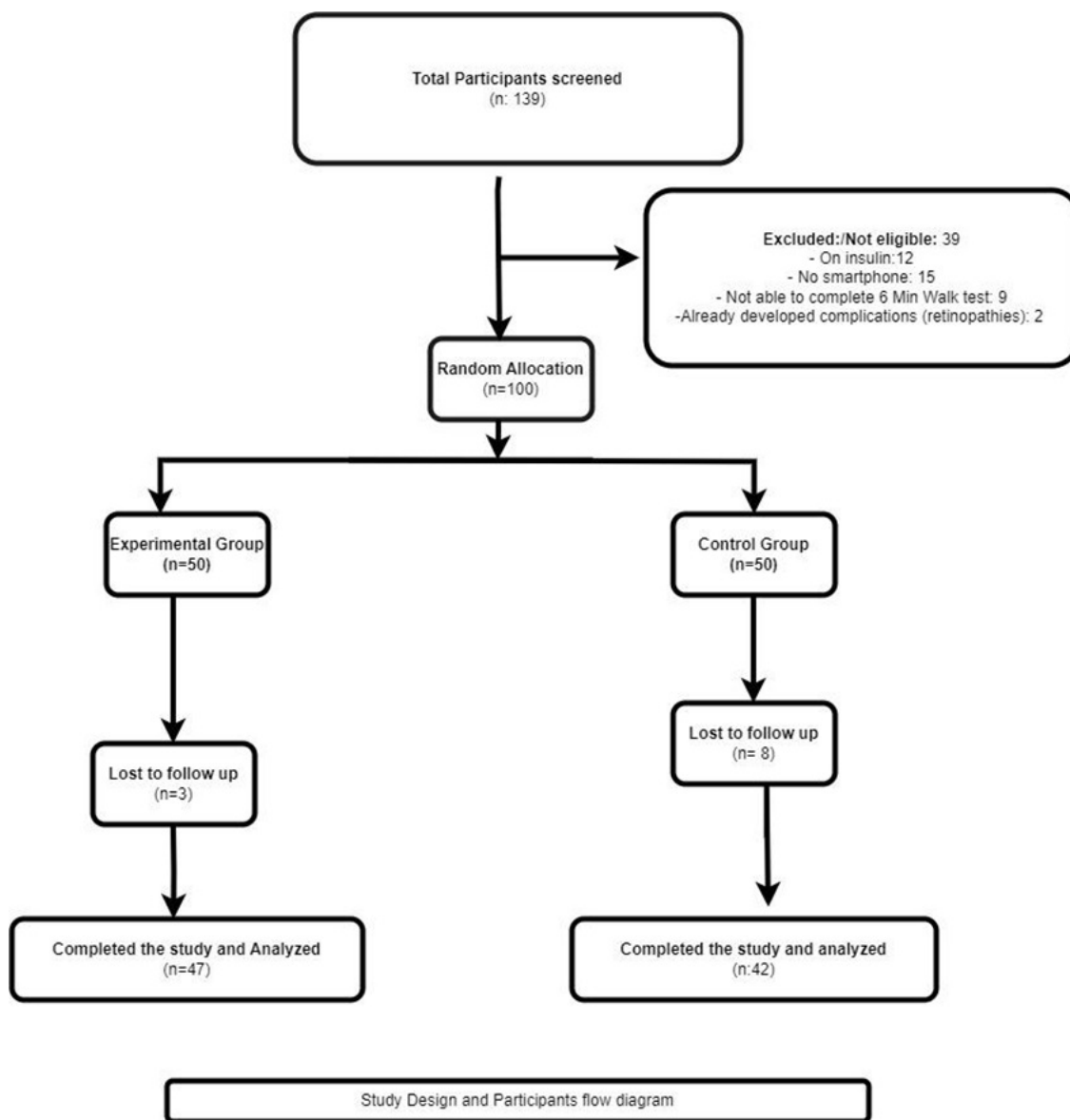
Figure 1. CONSORT Flow Diagram

Study Interventions

Prior to the beginning of the study, the participants received the diet & nutrition, and exercise education session for 15 minutes. The diet plan embedded in the app was the use of the plate model approach. Plate model consists of a visual three parts: half plate vegetables, 1/4 plate staple food (carbohydrate) and 1/4 plate meat (protein). Vegetables low in carbohydrate (amaranth leaves, cabbage etc.) were advised.

If the participant was still feeling hungry after meals, he/she was advised to take additional vegetables only. A commercially available visually sectioned plate was given to intervention group participants. Diet and Meal plans were divided into five categories namely, (1) meal plan for diabetes only, (2) meal plan for diabetes and hypertension, (3) meal plans for diabetes and high cholesterol, (4) meal plans for diabetes and obesity and (5) meal plans for diabetes with being underweight.

All meal plans were uploaded in the app with corresponding nutritional information and recipes. The nutritional education was provided by a dietician and nutritionist. Adapted 80 therapeutic exercises approved by physiotherapy experts in the research team were animated in 3D (three-dimension format) design and were narrated in English and translated in Kinyarwanda. All exercises were embedded in the App. During the follow up intervention group participants were required to daily enter their Blood glucose and blood pressure measurements.

The control group continued receiving the usual routine care. The assessment of the variables was done before and after the study for both intervention and control groups.

Statistical analysis

Collected data were entered, sorted, and cleaned in Microsoft Excel (Windows 10) and then transferred into IBM SPSS Statistics for Windows version 25.0 (IBM Corp, Armonk, NY, USA) for analysis. Mean, percentages were used to report measures of central tendency and frequency distribution. Within group comparison paired t tests were performed to analyse the changes before and after study in both intervention and control, groups. The independent t-test was used for comparison between intervention and control, groups.

Ethical considerations

Ethical clearance was obtained from the University of Rwanda College of Medicine and Health Sciences Institutional Review Board (No. 397/CMHS IRB/2021).

In addition, the study obtained the ethical clearances from Hospitals including Rwanda Military Hospitals, CHUK, and an authorisation from Rwanda Diabetes Association. Written informed consent was obtained from each participant before the start of the trial, the participation was voluntary, and confidentiality of the participants' information was ensured.

Results

The study was conducted over a period of 12 weeks with follow up of patients with type 2 diabetes. The main purpose for this study was to assess the effectiveness of the Smartphone Application "GororokApp" in monitoring the blood glucose and blood pressure, plus medication reminder, physical activity recommendations and appropriate nutrition, as a self – management of the diabetes condition.

Demographic characteristics and status of participants

The study participants' characteristics showed that they were aged 53.61±10.44 years old (Table 1). Their diagnostic history was 5.79 ±5.35 years since the first year of diagnosis with type 2 diabetes. The majority took medications twice per day and the weight category on BMI were generally overweight with a BMI of 27.83 ±3.79 Kg/m2. Their Waist to Hip ratio average was 0.93 ± 0.09.

Table 1. Participants' status and characteristics

A. *Participants' status: Age, Diagnostic History, medication intake frequency, Body Mass Index and Waist to Hip Ratio*

Variable	Statistics (mean ± SD)
Age (years)	53.61 ± 10.44
Type 2 diabetes diagnostic history/Years	5.79 ± 5.35
Med Freq (times)	1.87 ± 0.33
BMI (Kg/cm2)	27.83 ± 3.79
Waist-to-Hip Ratio	0.93 ± 0.09

Table 1. Continued

B. Participants' characteristics: Gender, Education, and Employment

Variable	Statistics (n, %)
Gender	
Male	37(41.57)
Female	52(58.42)
Education level	
Not completed primary	2(2.2)
Primary	23(25.8)
Secondary	42(47.2)
University	22(24.7)
Occupation	
Employed	37(41.57)
Unemployed	20(22.47)
Student	1(1.12)
Retired	10(11.23)
Business	21(23.59)

The distribution of gender, male and female, was 41.17% (37) and 58.43% (52) respectively (Table 1). The majority were educated at a secondary school level representing 47.2% (42). Regarding employment status, self-employed comprised 41.57% (37) and those doing business were 23.59% (21).

Changes in glycated haemoglobin during the study intervention

As shown in Table 2, the intervention group demonstrated a significant change of glycated haemoglobin from 8.45±2.93 to 6.89±1.86 (p-value <0.001), while in the control group the glycated haemoglobin increased from 7.12±2.52 to 8.14±2.17 (p ≤0.001).

Table 2. Glycated haemoglobin changes within groups

Variables	Intervention group			Control group		
	Baseline	12 weeks later	p-value	Baseline	12 weeks later	p-value
HbA1c (%)	8.45±2.93	6.89±1.86	<.001**	7.12±2.52	8.14±2.17	<0.001**
Cholesterol (mg/dl)	146.7±42.21	143.23±31.9	<0.47	159.14±51.18	153.04±36.18	<0.46
HDL (mg/dl)	45.68±11.68	40.55±14.44	<0.06	53.11±15.33	51.09±17.93	<0.4
TG (mg/dl)	149.44±135.37	110.02±56.15	<0.02*	133.4±63.72	129.66±83.72	<0.72
LDL (mg/dl)	74.74±31.75	84.72±29.24	<0.04*	84.5±38.14	91.16±36.92	<0.28
TC/HDL (mg/dl)	3.26±1.09	3.8±1.14	<0.001**	3.12±1.1	3.33±0.85	<0.17

HbA1c, Glycated Haemoglobin; HDL, High-Density Lipids; TG, Triglycerides; LDL, Low-Density Lipids; TC/HDL, Total Cholesterol/ High Density Lipids; *Statistically significant at $p<0.05$; **Statistically significant at $P<0.001$.

Changes in Glycated haemoglobin between groups

The Hb1c in the intervention group varied by 1% as compared to the controls and this change is statistically significant (P≤ 0.001). There was a minor change of less than one percent of total Cholesterol/High-Density Lipids for the experimental group. The High-density lipoproteins increased by 10 in control groups. Surprisingly, the Control group had higher HDL and LDL values than their intervention group counterparts after 3 months.

Table 3. Changes in the Glycated haemoglobin between groups

Variables	Groups	N	Mean (SD)	Mean Difference (95% CI)	t	df	p-value
Hb1c	Intervention	47	6.91(1.86)	-1.23(-2.08 : -0.38)	-2.88	87	≤0.001**
	Control	42	8.14(2.17)				
Cholestérol	Intervention	47	143.23(31.9)	-9.81(-24.15 : 4.53)	-1.35	87	<0.17
	Control	42	153.04(36.18)				
HDL	Intervention	47	40.55(14.44)	-10.54(-17.37 : -3.71)	-3.06	87	<0.001**
	Control	42	51.09(17.93)				
TG	Intervention	47	110.02(56.15)	-19.64(-49.4 : 10.1)	-1.31	87	<0.19
	Control	42	129.66(83.72)				
LDL	Intervention	47	84.72(29.24)	-6.44(-20.61 : 7.72)	-0.9	78	<0.36
	Control	42	91.16(36.92)				
TC/HDL	Intervention	47	3.8(1.14)	0.46(0.03 : 0.89)	2.13	87	<0.03*
	Control	42	3.33(0.85)				

HbA1c, Glycated Haemoglobin; HDL,High-Density Lipids; TG, Triglycerides; LDL, Low-Density Lipids *; TC/HDL, Total Cholesterol/ High Density Lipids; *Statistically significant; ** Statistically very significant at P<0.001.

Blood glucose trend over three months intervention
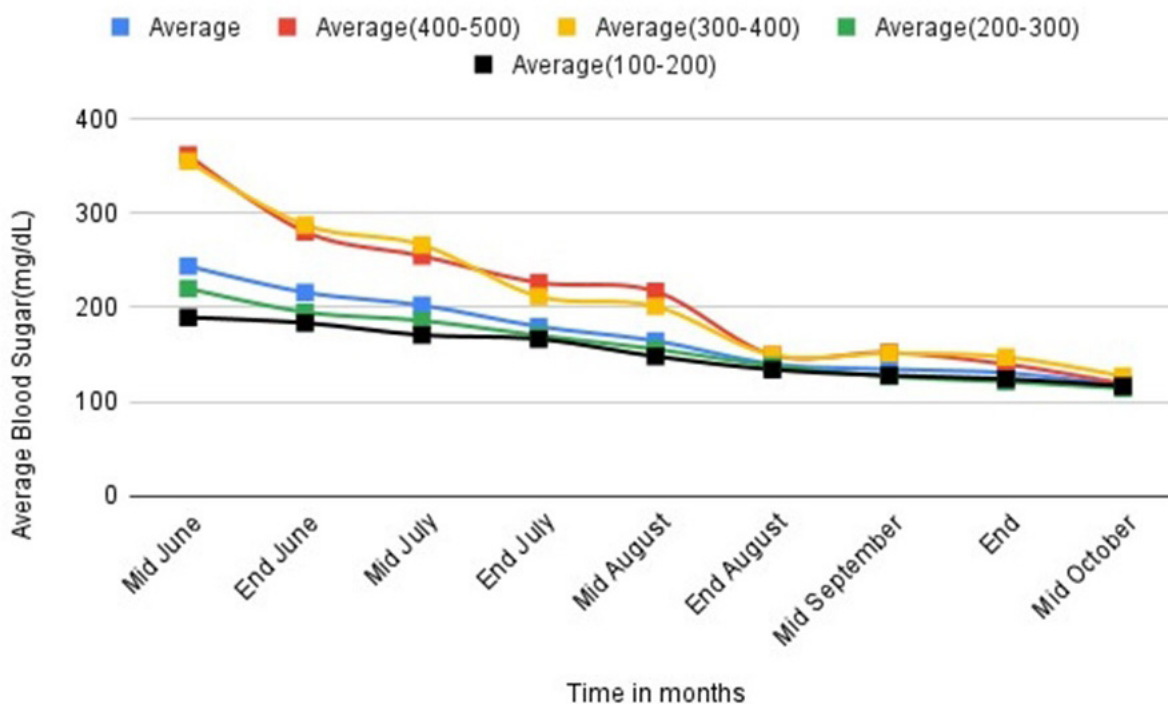
Figure 2. Three months morning blood glucose trends within intervention group

The daily glucose measurements over 3 months, at different times during folow-up, we recorded average daily records twice (bi-montly) each month, from the beginning to the end of the study. The average glycemic measurement shown buy a blue line demonstrates a reduction of blood glucose from 244 ± 90.60 mg/dL to 117.29 ± 28.13 mg/dL.

As shown in Figure 2, participants who were in higher glycemic range 400-500 mg/dL improved their glycemic control and showed a remarkable blood glucose reduction to healthy glycemic range of 100 - 200 mg/dL

Discussion

The randomized controlled trial assessed the effectiveness of smartphone application in the self - management of type 2 of diabetes in Rwandan by improving monitoring and control of blood glucose and other important parameters. The study employed patient self-monitoring of the blood glucose using a smartphone App with features of instant feedback on the recorded measurements. Patients in a control group were followed up over a period of 12 weeks. The trial demonstrated significant changes on HbA1C and daily glucose measurements. The intervention group showed a significant decrease of glycated haemoglobin (8.45%- 6.89%) and this was statistically significant (P-value: 0.001) while the control arm demonstrated an opposite direction (7.12 -8.14%) and this was also significant as well. This study results are similar to those from other studies that assessed the efficacy of the smartphone-based glucose management application using similar methods.[15,17] They have also revelaed that the use of mHealth technology including smartphone application have made improvement in glycated haemoglobin (HbA1C).

The results of this study showed that participants in the intervention group had an overall tendency to reduce their blood glucose levels. Overall, blood glucose level reduced from 244 mg/dl to 117 mg/dl in the intervention group. This can be the effect of patients' engagement in self-monitoring and appropriate response to stabilize the glucose measurements in healthy ranges through health care advice. The application was set to provide constant reminders about the status of patient's measurements. Moreover, participants were able to interact with the health care personnel and get immediate feedback to adjust meal plans and exercises. The evidence supports the importance smartphone- technology in diabetes management. Different studies conducted on the effect of smart phone applications designed to manage diabetes consistently found that those interventions have led to greater glycated haemoglobin reduction and daily glycaemic control.[15,17]

Conclusion and recommendation

The use of this smartphone technology demonstrated positive outcomes in patients self-monitoring of type 2 diabetes. After 12 weeks of intervention, the study showed significant changes in glycated haemoglobin and blood glucose. To our knowledge, the mHealth intervention (GororokApp) in this study is the first of its kind tested for effectiveness for the self-management of the type 2 diabetes developed and contextualised in Rwanda.

The findings from the current study, due to some limitations, should not be generalised, in that it had a small sample size which consisted of only city dwellers.. Therefore, it is important to conduct large-scale studies with large samples of patients with diabetes in Rwanda to validate the results of this study. In addition, researchers recommend the expansion of the GororokApp and upgrade the application to include new features to control more non-communicable diseases.

Authors' contribution

CCN conceived the idea and coordinated all research activities. JG and JN contributed in proposal drafting, data collection, participants follow up and manuscript writing, CB reviewed medical information and intervention guidelines, EB contributed in proposal drafting, data collection, participants follow up and manuscript writing, CM and JDB developed the application and contributed to the analysis. MT contributed to the study protocol development and manuscript writing, RR analysed the data, JR participated in designing research interventions including meal plans and content of the application, MU developed meal plans and proposal writing JCH participated in developing intervention protocols, review of app content and medical advice, LM in the recruitment of study participants,

KJ, and NS contributed to the data collection and participants follow up, CT contributed as a Research Team leader and mentor, contributed in all research activities from proposal to manuscript writing, DKT as principal investigator, he oversees all project and research activities including the paper writing.

Conflict of interest
None

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