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Original Research Article

Effectiveness of mHealth in improving medication adherence among hypertensive patients on follow-up in a tertiary hospital in central Kenya: a randomized controlled trial

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ABSTRACT

Background: Non-adherence to medication is documented in the literature as a major barrier to blood pressure control among patients on treatment for hypertension. This study sought to evaluate the potential effectiveness of a mHealth intervention in supporting medication adherence among hypertensive patients on follow up.
Methods: We undertook a single blind parallel randomized controlled trial among hypertensive patients undergoing follow up care in Nyeri County Referral Hospital between January and December, 2020. The trial comprised of two arms, with a total of 120 patients randomized on a 1:1 ratio. Patients in the experimental group were put on an educational health intervention comprising of mobile phone delivered SMS messages and interactive voice calls. Patients in the control group were continued on the usual care offered in the hospital's medical outpatient clinic. The primary endpoint was medication adherence. Data was analyzed through the intention to treat approach at 5% significance level.
Results: A total of 112 participants (93.3%) were retained in the study at the end of follow up. The proportion of patients who were adherent to their prescribed medications was higher by 38.3% among participants in the experimental arm compared to those in the control group ($p<0.001$). The odds of being adherent to medications was 6.1 times higher for patients who had received the study's intervention compared to those in the control group (95% CI 2.6, 14.3).
Conclusions: The mHealth intervention applied in this study was effective in improving medication adherence among patients on treatment for hypertension.

Keywords: Medication, Adherence, Hypertension, Blood pressure control, mHealth, Intervention

INTRODUCTION

Globally, hypertension is ranked as the leading risk factor for cardiovascular disease and all-cause mortality.[1,2] As of 2019, a total 1.22 billion people aged 30-79 years were estimated to be living with hypertension worldwide, with a large majority of them (82%) being residents of low and middle income countries.[3] In Kenya, existing data indicates that hypertension is a significant public health concern; a nationwide survey conducted in 2015 reported that 28.6% of persons aged 18-69 years were living with hypertension in the country.[4]

Among people with hypertension worldwide, it is estimated that only 23% and 18% of women and men, respectively, have their blood pressure within the recommended levels.[3] In Kenya, existing national population based data indicates that only 12.5% of people with hypertension have their blood pressure controlled.[4] Uncontrolled hypertensions is associated with several

adverse health outcomes, including cardiovascular disease, stroke, chronic kidney disease and dementia.[4-6]

Among several factors that may contribute to poor blood pressure control, non-adherence to prescribed medications has been singled out as the most important barrier to achieving optimal blood pressure control.[5,6] Adherence is defined as the extent to which patients take medications as instructed by their health care providers.[7] Globally, non-adherence to antihypertensive medication is a common problem, with available estimates indicating that 52-74% of people living with hypertension do not adhere to their medications.[8] Though there is no national study that has examined the level of antihypertensive medication adherence in Kenya, the few available studies indicate that between 43% and 85.4% of hypertensive patients in the country are non-adherent to their prescribed medications.[9-12] This situation therefore brings to fore the need for research to identify effective interventions to support long-term medication adherence among hypertensive patients on treatment.

In Kenya, mobile phone ownership currently stands at over 80%, and this development has facilitated the launching of several mobile based service delivery innovations in different sectors of the country's economy.[13] In 2011, the Kenyan Ministry of Health launched a national policy on e-health, with five strategic focus areas, namely: telemedicine, mHealth (delivery of health care through a mobile phone device), health information systems, health information for citizens and e-learning for health care providers.[14] Since then, several mHealth interventions have been successfully tried in improving treatment outcomes for various infectious diseases such as malaria, tuberculosis and HIV and AIDS.[15]

The interventions conducted in these studies have shown that use of SMS messages and phone calls on patients undergoing follow-up significantly contributes to improved medication adherence and retention in care. However, to date, the effectiveness of mHealth based interventions in addressing chronic non-communicable diseases such as hypertension has been not evaluated in the Country. This study therefore sought to investigate the potential effectiveness of applying an educational mobile phone based intervention comprising of SMS text messages and interactive voice calls, in improving medication adherence among hypertensive patients on follow up in a regional referral hospital in central Kenya.

METHODS

Study design and setting

We conducted a parallel single blind randomized controlled trial among hypertensive patients on follow up in Nyeri County Referral Hospital, between January and December, 2020. Nyeri County is one of the 47 counties in Kenya, located in the central region of the Country. The trial's primary aim was to evaluate the hypothesis that sending weekly health educational SMS text messages and making monthly phone calls (mHealth) to hypertensive patients on follow-up would result to an improvement in adherence to their prescribed medications. The trial comprised of two arms: the experimental group receiving the mHealth intervention in addition to the usual care offered in the hospital's medical outpatient clinics, and the control group being continued on usual care only.

Study population and eligibility criteria

Eligible participants were known hypertensive patients who were currently on treatment, and those who were non-adherent to their prescribed medications. At the entry level, patients visiting the medical outpatient clinic underwent an interview using a validated medication adherence questionnaire (MAQ) to identify those who were non-adherent to their medications.[16] MAQ comprises of four "yes/no" questions that assess a patient's experience with their prescribed medications as follows: do you at times forget to take your medicines for hypertension?, are there times when you feel there is no need of taking your medicines for hypertension?, when you feel better, do you sometimes stop taking your medicines for hypertension?, and sometimes if you feel worse when you take your medicines for hypertension, do you stop taking them? According to the operationalization guidelines of the tool, answering "yes" to any of the questions is indicative of sub-optimal adherence to prescribed medications. Hence, all patients who answered "yes" to any of the four questions were identified as non-adherent, and therefore considered eligible for inclusion in the trial.

At enrollment, patients were also asked whether they were in possession of a personal mobile phone, and if so, whether they regularly use SMS messages for communication. Since this study was primarily aimed at evaluating the effectiveness of an intervention delivered through a mobile phone, only patients who reported to own a personal mobile phone, and also being familiar with use of SMS messages were considered eligible to participate in the trial. Newly diagnosed hypertensive patients and those with comorbidities were excluded from participation. Newly diagnosed hypertensive patients were deemed inappropriate for inclusion given that the study was focused on patients who had been taking their prescribed medicines previously.

Sample size determination

Estimation of the minimum number of study participants required to test the trial's hypothesis was based on a 90% statistical power to detect a 34.8% difference in the proportions of patients who were adherent to their medications between the experimental arm and the control group; this effect size was based on a previous study that had applied a similar intervention to hypertensive patients.[17] The computation was done at 5% significance level, and with an adjustment of 40% attrition rate. The calculation was implemented with the open-epi software,

yielding a total of 100 patients.[18] This sample size was further increased by 20% to 120, in order to optimize the statistical power to test the trial's hypothesis. The sample size was apportioned to the two arms of the trial on a 1:1 ratio, that is, 60 per group.

Sampling and randomization

All hypertensive patients who met the eligibility criteria were serially enrolled and randomized into either of the two arms of the trial until the sample size was achieved. The assignment to the study groups was done through the blocked randomization method with a block size of 6; this block size was chosen based on the fact that it is a multiple of the number of treatment groups included in this study. Methodological guidelines for randomization indicate that researchers can choose any block size, provided that it is a multiple of the number of groups included in the trial.[19,20]

An open access randomization software (Random Allocation Software) was used to generate a random allocation sequence for a set of 120 serialized numbers to either of the two groups at 1:1 ratio.[21] All eligible participants were serially enumerated into a list, with each study subject being assigned into either of the two groups according to the corresponding allocation in the pre-generated random sequence. The procedures involved in enrollment and randomization are diagrammatically presented in Figure 1.

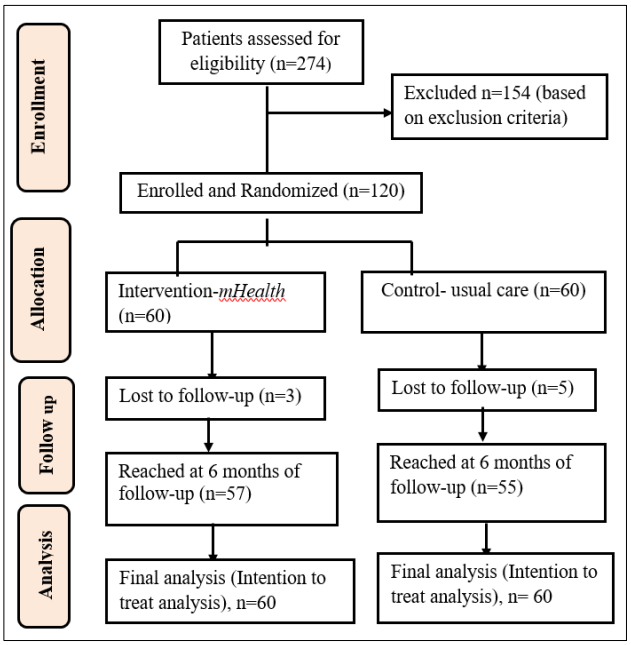

Figure 1: Study flow chart.

Intervention and follow-up

The intervention undertaken in this trial comprised of mobile phone delivered SMS messages and voice calls aimed at educating patients about the basics of hypertension and the need for persistence with medication intake. The content of the messages and voice calls covered information on the asymptomatic nature of hypertension, long term complications of uncontrolled blood pressure and the lifelong nature of hypertension treatment. The messages were tailored to address common hypertension related misconceptions identified from pre-existing studies.[22-24] The content of the messages was also informed by the knowledge gaps established through a baseline survey undertaken before initiation of the trial.

The SMS messages were delivered to the study participants assigned to the experimental arm via a commercially subscribed automated bulk messaging system, bulksms.[25] The hypertension related health information package to be delivered was split into six messages, and uploaded into the bulksms system. The phone numbers of patients in the experimental arm were also uploaded to the messaging system and scheduled to be receiving one message weekly for the ensuing six weeks following enrollment into the study. The messaging system had an inbuilt alert system to show whether the messages were delivered and subsequently received by the intended recipients. Monthly phone calls were also made to the patients in the intervention arm to further educate them about hypertension and the need for persistence to their prescribed medications. The calls were made over a period of 6 months by a trained nurse, with the aid of a written information package to ensure uniformity in communication of the intended health messages. Patients in the control arm continued with the regular care offered in the medical outpatient clinic, and did not have any messages sent to them or receive phone calls during follow-up.

At the end of follow-up, all patients in both arms of the trial were contacted during their next scheduled clinic appointments to ascertain their retention in the trial, and also to have their outcome measures taken. In case a patient did not show up, he/she was contacted via phone to get information on the reason for non-attendance.

Blinding

The randomization and statistical procedures undertaken in this trial were conducted by an independent statistician who was not privy to the study's hypothesis. Masking was also achieved at the level of outcome measurement, where all the research staff involved in data collection were kept unaware of the assignment status of the study participants throughout the data collection process; this measure was applied to minimize information bias. Blinding at the level of participants was not possible since the intervention undertaken in this study was interactive.

Outcome variables and measurements

The primary outcome variable for this study was medication adherence, which was assessed using the proportion of days covered method (PDC).[26] PDC is a pharmacy based measure of adherence that is calculated as

a proportion of days a patient was dispensed with medication over a specified time interval [26]. The measure can be adopted as a continuous variable or operationalized into a binary outcome variable. In this study, PDC was measured over a 6-month interval and dichotomized into two outcomes based on a threshold of 80% that has been adopted in previous studies; those with a PDC <80% were considered non-adherent, while those with PDC ≥80% were classified as adherent.[26] In the hospital where this trial was undertaken, there was an active universal health coverage (UHC) programme where all patients seeking health care services were treated and given their prescribed medications at no cost.

In the hospital's medical outpatient clinics, patients with chronic illnesses such as hypertension were given rolling prescriptions to be obtaining and refilling their medicines every thirty days within the time interval before their next clinic revisit. The hospital also runs an electronic medical records system which captures patient care data, including clinical information and medication prescription and dispensing data. Hence, it was possible to compute PDC from the existing pharmacy dispensing data, both at baseline and at the end of 6 months of follow-up. Data on the number of days' patients were dispensed with antihypertensive medications was abstracted from the electronic medical records system. The baseline PDC was calculated as the proportion of days each patient was covered with medication in the preceding three months before the trial. The primary end point was the proportion of days each patient was covered with medication over the ensuing six months' period of follow up.

The secondary outcome variables were blood pressure control and knowledge about hypertension, with both of these being measured at baseline and at the end of the six months' duration of follow up. Data on blood pressure was obtained from the patients' medical records, and operationally defined as a binary outcome based on the existing Kenyan Ministry of Health guidelines; a blood pressure reading <140/90 mmHg was categorized as controlled while that above 140/90 mmHg was classified as uncontrolled.

Knowledge about hypertension was assessed using a set of four questions which were designed based on a review of previous studies that have identified several commonly misunderstood aspects of hypertension.[22,23] The questions included: do you know the blood pressure reading that indicates good control of hypertension? (if yes, specify); do you know of any health problems that can arise from having high blood pressure? (if yes, specify); can someone be having high blood pressure without experiencing any symptoms? and for how long are you going to be taking your medicines for hypertension? Each correct response per question was assigned 1 point, with a maximum total score of 4; these scores were further converted to percentages, and a cut off of 70% was used to categorize a patient as either having good knowledge (≥70%) or having poor knowledge (<70%). This cut off was adopted from a previous study that had assessed hypertension knowledge among patients with hypertension.[27]

Data analysis

Descriptive statistics, including proportions for categorical variables were applied to summarize data on baseline characteristics and outcome variables. A comparison between the characteristics of study participants in the two study groups was also done through cross tabulation. In line with guidelines given in the Consolidated Standards of Reporting Trials (CONSORT) 2010 statement, no significance testing was applied in comparing baseline characteristics and outcome measurements between the two trial arms.[28] The dependent variables were dichotomized into binary outcomes, and measured as proportions. The proportions of patients who experienced the targeted outcomes (medication adherence, improvement in hypertension knowledge and blood pressure control) at the end of the follow up in both arms of the trial were compared using the chi square test at 5% significance level.

The effect of the trial's intervention on the specified endpoints was estimated by performing logistic regression to compute the odds ratios of a patient experiencing the outcomes if he/she received the intervention.

The statistical procedures undertaken in this trial adopted the intention to treat approach, where the measured outcomes were analyzed as per the original group assignment status for each participant.[29] Missing data for patients who were lost to follow up was addressed using the worst case scenario approach.[30] In this method, the five patients lost to follow up in the control group were assigned good outcomes (being adherent, having controlled blood pressure and having good hypertension knowledge). The converse was applied to the three patients lost to follow up in the experimental arm.

Ethical considerations

The protocol for this trial was ethically reviewed and cleared by Kenyatta University Research Ethics Committee [KU/ERC/APPROVAL/VOL.1 (267)]. The trial was also registered by Kenya National Commission for Science, Technology and Innovation (NACOSTI/P/19/16566/29967).

An approval to conduct the trial in Nyeri County Referral Hospital was sought from Nyeri County Department of Health, and the Management Board of the Hospital. Before enrollment into the trial, all study participants were taken through the entire details of the study, and invited to sign an informed consent if voluntarily willing to participate. Privacy and confidentiality of patient information was ensured by avoiding undue exposure of medical records, and use of unique identifiers when abstracting required information from the electronic medical records system.

RESULTS

Description of study sample characteristics

Overall, the study sample largely comprised of the female gender and older people, although the distribution of these and other socio-demographic characteristics was similar between the comparison groups. The study groups were also similar by baseline clinical and behavioral characteristics such as the number of medications prescribed to a patient, knowledge about hypertension and blood pressure control status. A comparison of the baseline characteristics of the study participants in both arms of the trial is given in Table 1.

Outcome data

At the end of the six months of follow-up, a total of 112 (93.3% of the sample size) study participants were retained in the study, with eight of them being lost to follow up. The outcome measurements for participants in both arms of the trial are presented in the sections below. The missing data for the eight participants who were lost to follow up was imputed using the worst case scenario approach described earlier in the methods section.

Effect of mHealth on medication adherence

Table 2 shows the change in medication adherence six 6 months after implementation of the mHealth intervention. At baseline, participants in both arms of the trial had comparable levels of medication adherence based on the PDC measure: 10% and 11.7% for the experimental and control arms respectively. At the end of 6 months of follow up, the proportion of hypertensive patients who were adherent to their medications was 38.3% higher in the experimental group compared to that of the control group, an indication that the study's intervention had a positive impact on medication adherence ($p<0.001$); (Figure 2). The odds of being adherent to antihypertensive medication was 6.1 times higher for those who had been put on the mobile phone based intervention compared to those who were in the control group (95% CI 2.6, 14.3).

Effect of mHealth on hypertension related knowledge

Figure 2 shows the level of hypertension related knowledge among the study participants both at baseline and at the end of follow up. At baseline, participants in both groups of the trial had comparable levels of hypertension related knowledge; 21.7% and 18.3% among participants in the experimental and the control arms respectively. The intervention led to a statistically significant improvement in hypertension related knowledge among patients in the experimental group over the 6 months of follow up.

At the end of follow up, the proportion of study participants with good knowledge about hypertension was higher by 41.7% among participants in the intervention arm compared to those in the control group ($p<0.001$). The odds of possessing good knowledge about hypertension were 6.4 times higher for those who had received the study's intervention compared to those in the control arm (95% CI 2.8, 14.6).

Table 1: Comparison of baseline characteristics.

Characteristic	Frequency (%) (n=60)	
	Control group	Intervention group
Socio-demographic characteristics		
Gender		
Male	12 (20)	11 (18.3)
Female	48 (80)	49 (81.7)
Total	60 (100)	60 (100)
Age (years)		
30-44	3 (5)	2 (3.3)
45-59	21 (35)	17 (28.3)
≥60	36 (60)	41 (68.3)
Total	60 (100)	60 (100)
Education		
Primary level	33 (55)	37 (61.7)
Secondary level	23 (38.3)	21 (35)
College/university level	4 (6.7)	2 (3.3)
Total	60 (100)	60 (100)
Employment		
Formally employed	7 (11.7)	8 (13.3)
Unemployed	14 (23.3)	17 (28.3)
Self employed	39 (65)	35 (58.3)
Total	60 (100)	60 (100)
Marital status		
Never married	5 (8.3)	6 (10)
Married	44 (73.3)	45 (75)
Divorced/separated	3 (5)	5 (8.3)
Widowed	8 (13.3)	4 (6.7)
Total	60 (100)	60 (100)
Religion		
Christian	56 (93.3)	58 (96.7)
Muslim	4 (6.7)	2 (3.3)
Total	60 (100)	60 (100)
Clinical characteristics		
Number of medicines prescribed		
One	22 (36.7)	20 (33.3)
Two or more	38 (63.3)	40 (66.7)
Total	60 (100)	60 (100)
Daily dosing frequency		
Once	43 (71.7)	45 (75)
Twice or more	17 (28.3)	15 (25)
Total	60 (100)	60 (100)
Blood pressure control		
Controlled	10 (16.7)	8 (13.3)
Uncontrolled	50 (83.3)	52 (86.7)
Total	60 (100)	60 (100)

Table 2: Medication adherence at baseline, and at the end of 6 months of follow up.

Dependent Variable	Time of measurement	Outcomes	Control group (n=60) (%)	Intervention group (n=60) (%)	Test statistic	P value
Medication adherence	At baseline	Adherent	7 (11.7)	6 (10)		
		Non-adherent	53 (88.3)	54 (90)		
	At 6 months	Adherent	10 (16.7)	33 (55)	Chi square X^2 =19.2 df=1	<0.001*
		Non-adherent	50 (83.3)	27 (45)		

*Significant at 5% significance level.

Table 3: Blood pressure control at baseline and at the end of 6 months of follow up.

Dependent variable	Time of measurement	Outcomes	Control group (n=60) (%)	Intervention group (n=60) (%)	Test statistic	P value
Blood pressure control	At baseline	BP controlled	10 (16.7)	8 (13.3)		
		BP not controlled	50 (83.3)	52 (86.7)		
	At 6 months	BP controlled	12 (20)	32 (53.3)	Chi square X^2 =14.4 df=1	<0.001*
		BP not controlled	48 (80)	28 (46.7)		

*Significant at 5% significance level.

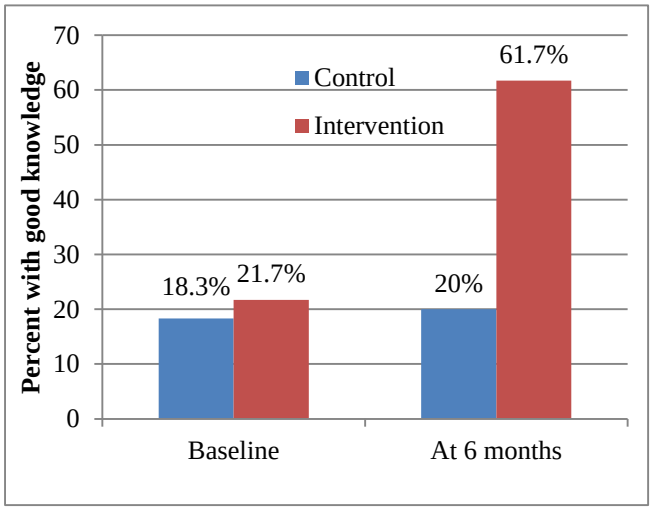

Figure 2: Level of hypertension related knowledge at baseline and after 6 months.

Effect of mHealth on blood pressure control

At the end of follow up, the proportion of patients who had achieved the targeted level of blood pressure control (BP<140/90 mmHg) was higher by 33.3% in the intervention group compared to the control group (Table 3). The odds of having achieved the clinically desired level of blood pressure were 4.6 times higher for participants in the experimental arm compared to those in the control group (95% CI 2.0, 10.3).

DISCUSSION

The primary objective of this study was to assess whether a mobile phone based intervention comprising of educational SMS text messages and interactive voice calls (mHealth) would lead to an improvement in medication adherence among patients on treatment for hypertension in central Kenya. We found that the mHealth intervention led to a statistically significant improvement in medication adherence over 6-months duration of follow up. Patients who received the intervention were 6.1 times more likely to be adherent to their medications compared to those continued on usual care. This finding adds to the growing body of evidence linking mHealth interventions to improved health care outcomes among patients with cardiovascular conditions.[31]

A previous systematic review covering 21 studies found that mHealth interventions were effective in supporting medication adherence.[32] However, a notable observation in this review was that none of the studies covered was from a low and middle income country; and therefore our findings make an important contribution in showing that mHealth interventions may be valuable in supporting medication adherence among patients on treatment for hypertension in a developing country.

The high magnitude of effect noted in our study may be attributed to two features that characterized our intervention. First, the intervention was a combination of SMS messages and interactive voice calls to educate patients about hypertension, and the need for adhering to their medications. It has been shown in previous studies that interventions that are multifactorial and interactive in nature are more likely to produce significant effects on adherence compared to those that apply a single aspect of mHealth, for example, SMS messages only.[32]

A mHealth based trial conducted in 2016 in South Africa, involving randomization of study participants to either of several single interventions (informational SMS messages only, interactive text messaging only and usual care) detected modest changes in medication adherence.[33]

Secondly, the hypertension educational messages covered in our mHealth intervention were tailored to address specific knowledge gaps identified from a baseline knowledge assessment survey that was undertaken before enrollment of study participants. Some of the key areas covered in the health messaging content were the asymptomatic and chronic nature of hypertension; the usefulness and safety of antihypertensive medications in controlling blood pressure and the health complications associated with uncontrolled blood pressure. Emerging evidence indicates that tailored mHealth educational interventions have a higher potential for producing positive health behavior changes, including adherence to medications and blood pressure self-management.[34,35]

The mHealth intervention undertaken in this trial also resulted to an improvement in hypertension knowledge, and this finding can be viewed as the mediating effect for the observed outcome of the intervention on medication adherence. Improved health literacy has been shown in health related theoretical frameworks and past studies as an important influencing factor for uptake of healthy behaviors.[36,37]

The intervention also contributed to improved blood pressure control among patients in the experimental arm. Medication intake is a key component in hypertension care, and therefore the observed effect on blood pressure control may be linked to the intervention's positive influence on antihypertensive medication adherence.[6]

Limitations

Some limitations need to be taken into account when interpreting the findings from our study. First, this study was done on patients undergoing follow up care in a single selected hospital, and therefore the findings may lack generalizability to other patient populations.

Secondly, the intervention and follow up was done over a period of six months, and although this duration has been widely adopted in previous adherence studies, it may be uncertain whether the effects noted here may be sustainable over a longer time span. Further studies with participants drawn from more diverse settings, and with a longer duration of follow up are therefore warranted in future.

CONCLUSION

Use of a mobile phone based intervention comprising of educational SMS messages and interactive voice calls can be considered as an effective measure to support medication adherence among patients on treatment for hypertension in a developing country such as Kenya. Improvement in medication adherence would subsequently contribute to attainment of the desired level of blood pressure control, and ultimately reduce the overall risk of cardiovascular disease among patients on treatment for hypertension.

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