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Pilot Mobile Phone Intervention in Promoting Type 2 Diabetes Management in an Urban Area in Ghana: A Randomized Controlled Trial

Purpose

The purpose of the study was to evaluate the feasibility and effectiveness of a nurse-led mobile phone call intervention on glycemic management and adherence to self-management practices among patients with type 2 diabetes mellitus (T2DM) in Ghana.

Methods

This was a pilot randomized controlled trial to compare diabetes care as usual to a mobile phone call intervention delivered by nurses in addition to care as usual over a 12-week period in a tertiary referral hospital in Ghana. Sixty patients with T2DM were randomized to either the intervention or the control arm. The intervention group received up to 16 mobile phone calls (mean duration = 12 minutes) from a diabetes specialist nurse in addition to their care as usual. The control group received only care as usual. The pri-mary outcome was the change in A1C over the 12-week

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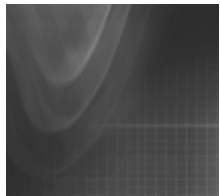
period. The secondary outcomes were changes in self-reported adherence to medication and diabetes self-management measures over the 12-week period.

Results

Mean baseline A1C was comparable between the intervention and control groups (9.54%, SD = 2.00% vs 9.07%, SD = 1.72%, P = .334). After 12 weeks, A1C was significantly lower in the intervention group compared to the control group. The difference in mean A1C in the control group rose by +0.26 ± 1.30% (P = .282; 95% CI, −0.23 to 0.75), whereas that of the intervention group reduced by −1.51 ± 2.67% (P = .004; 95% CI, −2.51 to −0.51). No improvements in self-management were recorded in the control group. In the intervention group, however, the only significant improvement was recorded in the area of foot care practices. Participant recruitment and retention were 100% without any attrition. About 87% (n = 26) of the intervention group completed at least 70% (≥11) of the calls. At the end of the trial, participants who received the intervention rated their satisfaction as 89.3% on average.

Conclusion

A mobile phone follow-up call by nurses emphasizing adherence to self-management practices is feasible and can improve short- to medium-term glycemic management among patients with T2DM.

Introduction

Type 2 diabetes mellitus (T2DM) is a noncommunicable disease that affects a significant proportion of adult Ghanaians.[1] The reported disease prevalence of 3.3% for Ghana by the International Diabetes Federation exceeds any of its neighboring West African countries, including Benin (0.7%), Nigeria (1.8%), and Ivory Coast (2.3%).[2] Additionally, the disease represents a significant cause of mortality in Ghana, with over 11 000 annual diabetes-related deaths recorded, representing the sixth most common cause of fatality.[3]

The recommended treatment regimen for T2DM involves the use of hypoglycemic agents on the background of behavioral and self-care management practices including blood glucose monitoring, dietary modification, exercise, weight management, and foot care.[4-6] Diabetes self-management and education in particular has been linked to achieving good glycemic control and prevention of early morbidity and mortality due to a reduction in macrovascular and microvascular complications.[7-9]

Diabetes care in poor and low-middle-income countries (LMIC) is beset with gaps, especially in the area of diabetes self-management and education leading to poor outcomes.[10,11] A recent publication of the seventh wave of the International Diabetes Management Practice Study, a study involving 66 088 patients with T2DM from poor and LMICs spread across several continents, reported a reduction in the proportion of patients who achieved guideline-recommended glycemic targets (A1C ≤7%) from 36% to 30.1%.[12] Similarly, a multicenter study in Ghana aimed at improving access to innovative medications revealed 70% of the participants had A1C >7%.[13] A high patient load, a virtually nonexistent community health involvement for noncommunicable diseases like diabetes, low health literacy rates, and low self-efficacy have been noted as contributing factors to the poor outcome of patients with T2DM in LMICs.[14]

Self-management education with reinforcement has been shown to improve outcomes associated with chronic diseases like T2DM.[15-17] In both the TRIGGER study[18] conducted in Holland and the NICHE study[19] from Bangladesh, mobile-phone-based text messaging was used to deliver diabetes self-management education with mixed results.[18,19] The sophistication, dexterity, and high literacy rates involved in the use of mobile phone messaging can serve as a drawback in its use as medium of information dissemination.

Mobile phone calls delivering the right information and delivered by a qualified health care personel can overcome most of the barriers enumerated for text messaging as well as cost-effectiveness. In a country like Ghana, with a low literacy rate with poor glycemic outcome and anecdotal evidence of poor adherence to diabetes self-management practices, the widespread ownership of mobile phones can be used as a tool to improve diabetes outcomes.[20] This study was designed to test the feasibility and effectiveness of a nurse-led mobile phone call intervention added to care as usual compared to only usual care in patients with T2DM in a tertiary referral center in Ghana. The authors hypothesized that the intervention being added to care as usual can promote glycemic control and self-care adherence better than care as usual alone among patients with T2DM.

Methods

Research Design

This was a parallel-group, 2-arm randomized controlled pilot trial to assess the feasibility and compare the effectiveness of a 12-week nurse-led mobile phone call intervention in addition to care as usual with only care as usual in patients with T2DM. The trial groups were parallel in the sense that members of each cohort received only the allocated treatment without any cross-overs.

Setting

The study was conducted between January 2017 and January 2018 at the Diabetes Centre of Komfo Anokye Teaching Hospital (KATH) in Kumasi, the second largest urban area in Ghana. Kumasi has an estimated T2DM prevalence of 7%,[21] which is higher than the national prevalence of 3.3%. KATH is a university-affiliated teaching hospital and the most advanced health care facility in the city running an outpatient clinic consisting of over 5000 patients, over 90% of whom are diagnosed with T2DM.[22] On average, patients attend the clinic every day of the week except Thursday. The Diabetes Centre is manned by endocrinologists, diabetes specialist doctors and nurses, and dieticians.

Study Sample and Recruitment

Participants were recruited if they met the following inclusion criteria: (1) at least 18 years old; (2) diagnosed with T2DM without any co-morbidities requiring immediate hospitalization; (3) ability to communicate in English or Asante Twi (a popular local language in Ghana); (4) have access to a personal mobile phone and able to answer calls; (5) have an A1C measurement of >7% not more than 3 months before selection; (6) mentally stable, with no vision, verbal, or hearing impairments; (7) oral hypoglycemic drugs without insulin. Participants were excluded if they: (1) had other forms of DM such as type 1 DM or gestational diabetes or (2) had insulin added to their treatment in the course of the study.

For an effect size of 0.8, at a power of 80%, and an alpha level of 5%, 26 subjects in each group were needed to ensure an adequate trial. An assumed 15% attrition and drop-out rate over the study period was added to make a total sample size of 60 participants. The researchers reviewed about 200 patients' records during the recruit-ment phase of the study with the aim of identifying

patients with T2DM with A1C ≥7%. Notably, there was no eligible participant who refused to partake in the study. Sixty participants who met all the inclusion criteria and consented to be part of the study were selected. Thirty participants each were randomized at 1:1 ratio into either the intervention group or the control group after the baseline measurements using computer-generated randomization sequence numbers.[23] The group allocation was carried out and concealed from the outcome assessors and the interventionists by one author who was not involved in the intervention or outcome assessment.

Ethical approval was given by the Committee on Human Research, Publications and Ethics, School of Medical Sciences, Kwame Nkrumah University of Science and Technology (Reference No. CHRPE/AP/004/17) following administrative approval from the Research and Development Unit of KATH. Individual participants confirmed their voluntary participation by providing written informed consent before enrollment into the study. Participants were assured of personal data protection and confidentiality.

Data Collection Procedures

Intervention and Control

The research team organized a 1-day workshop to reinforce diabetes self-management education at the Diabetes Centre for all participants before the start of the intervention. The aim was to refresh their knowledge on the nature and complications of diabetes as well as their self-management skills regarding diet, exercise, foot care, medication taking, blood glucose monitoring, and management of hypoglycemia. All participants were advised to stick to their scheduled clinic appointments at the Diabetes Centre throughout the study period and beyond.

The current standard practice (the usual care) included an outpatient specialist service with patients scheduled every 1 to 6 months, depending on their diabetes control and complications profile. The other services provided included physician and dietician appointments, laboratory investigations, clinical examinations, group education on self-management practices, and medication refills.

In addition to care as usual, each member of the intervention group received a total of 12 weeks of mobile phone follow-up calls by a nurse with a mean duration of 12 minutes each (2 calls per week for the first 4 weeks, followed by a weekly call for the following 8 weeks, totaling 16 calls). The mobile phone calls were delivered

by a diabetes specialist nurse assisted by a registered nurse. The content of the calls was to reinforce guidelines on diabetes self-management according to book titled *Living With Diabetes* developed by Acheampong et al[24] in partnership with the University of Virginia and the Ministry of Health, Ghana. The content of the brochure was carefully developed to conform to international standards but contextualized to meet the needs of the Ghanaian diabetes population. The content of the calls thus included information on diet, exercise, medication taking, self-monitoring of blood glucose, and foot care. Each call was scheduled at the convenience of the participant to last up to 15 minutes. Additionally, individualized self-management goals were evaluated. Each participant in the intervention group was allocated a diary where the interventionists recorded their call date, time, duration, personalized self-management goals, action plans, and self-management challenges.

Feasibility Assessment

The objective of the feasibility assessment was to evaluate study process measures such as participant recruitment, retention, program participation, and satisfaction.[25] The study authors targeted feasibility as achieved when at least 80% of the intervention participants completed at least 60% (≥10 calls) of the nurse phone calls throughout the 12 weeks per their call diary records, as reported in previous studies.[26,27] At the end of the trial, only the intervention participants rated their satisfaction with the intervention they received on a scale of 0 to 10 (where 0 and 10 represent not satisfied and very satisfied, respectively). This scale was a questionnaire item participants responded to after the intervention period, as used in patient satisfaction surveys.[28] The intervention was deemed as satisfactorily accepted if the average rating was at least 70% (7/10).

Outcome Measures

The primary outcome was the change in A1C level at baseline and after 12 weeks in the 2 groups, and the sec-ondary outcomes assessed were the adherence to self-management regimen/adherence, including diet, exercise, medication taking, foot care, and blood glucose monitor-ing. The A1C level of all participants was measured at the study site using A1C test kit.[29] In addition to demographic characteristics (including blood pressure and anthropo-metric measurements), disease characteristics; the level

of adherence regarding diet, exercise, medications, and foot care; and the frequency of blood glucose monitoring were recorded. Blinding of participants was not possible due to the nature of the intervention.

Adherence Measuring Instrument

Based on the content of Acheampong et al,[24] a self-management adherence questionnaire tool was developed to assess patients' adherence in self-care areas such as diet (5 items), exercise (4 items), medication taking (2 items), foot care (3 items), and blood glucose checking (2 items). Each item was scored on a 5-point Likert scale: always = 5, often = 4, sometimes = 3, rarely = 2, and never = 1. The total score for each area was the sum of the scores of all its items expressed out of 100%. Patient scoring between 20% and 50%, 50% and 70%, and 70% and 100% were graded as low adherence, moderate adherence, and high adherence, respectively, for that self-care area. Before the instrument was used in the study setting, its face validity was verified by an endocrinologist, a dietician, and diabetes specialist nurses at the Diabetes Centre. Both primary and secondary outcome measures were assessed at baseline and repeated after the 12 week intervention period.

Statistical Analyses

Categorical variables were displayed using frequencies and percentages. Continuous variables were presented as means and standard deviations. Chi-square test of independence was used to examine the association between any 2 categorical variables. Independent sample *t* tests were used to analyze the changes in A1C and diabetes self-management at baseline between the control and intervention groups. The paired *t* test was used to compare the baseline and the 12-week posttest means of both groups (control and intervention). Statistical significance for all tests was set at the .05 level, and all analysis were 2-tailed. Data were analyzed using the Statistical Package for Social Sciences (SPSS) Version 26 (SPSS Inc, Chicago, IL, USA) software program.

Results

Baseline Characteristics of Participants

Sixty participants, 30 in each study group, started and completed the study (Figure 1). As presented in Table 1, the majority of the study participants were women
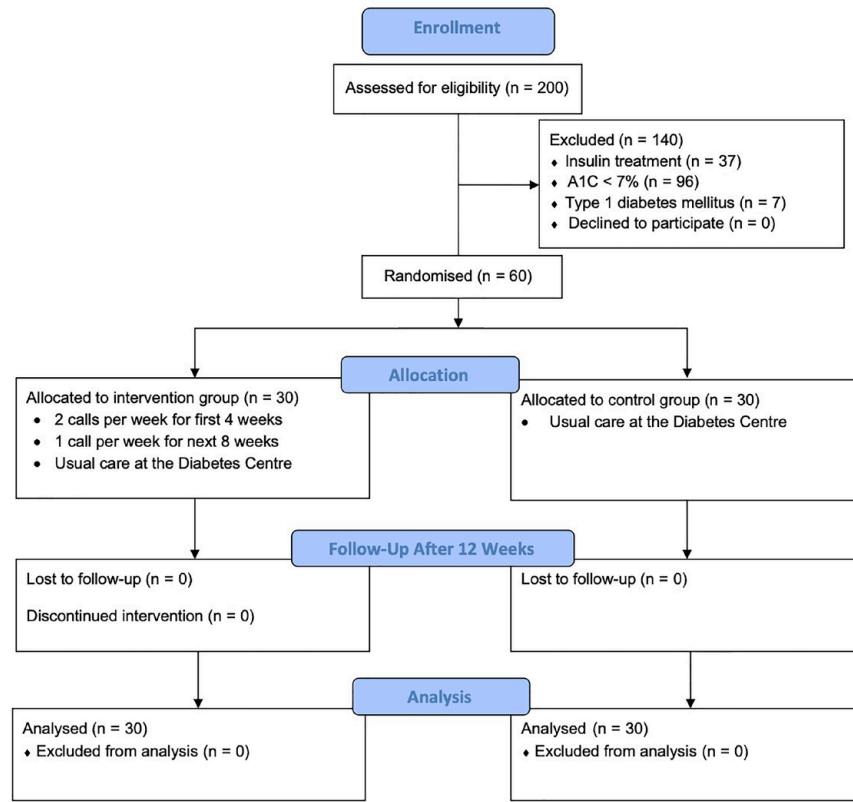
Figure 1. Study flow diagram showing participants recruitment, intervention, analysis numbers.

(n = 47, 78.33%) and had a family history of diabetes mellitus (n = 42, 70%). Both arms of the study were matched in demographic characteristics, mean age, duration of T2DM, baseline A1C, diastolic blood pressure, weight, and body mass index. The mean systolic blood pressure and blood glucose monitoring adherence differed between the groups (see Tables 1 and 2).

Postinterventional Changes in Glycemic Control and Self-Care Adherence

After 12 weeks, A1C was significantly lower in the intervention group compared to the control group. The difference in mean A1C in the control group rose by 0.26% (SD = 1.30%), $P = .282$; 95% CI, −0.23 to +0.75, whereas that of the intervention group reduced by 1.51% (SD = 2.67%), $P = .004$; 95% CI, −2.51 to −0.51. Mean A1C decreased from 9.54 (SD = 2.00) to 8.03 (SD = 2.25), $P = .004$, in the intervention group, whereas it increased in the control group from 9.07 (SD = 1.72) to 9.33 (SD = 1.86), $P = .282$, as presented in Table 2.

The intervention group had slight posttrial improvements in their mean percentage scores for adherence to self-care areas such as diet, exercise, and foot care, whereas that of the control group declined. The intervention group had high diet adherence, 70.00% (SD = 6.28%) to 72.53% (SD = 12.24%), $P = .2$, and foot care adherence, 71.33% (SD = 13.37%) to 78.67% (SD = 15.99%), $P = .056$, compared with the control group, which showed moderate adherence for diet, 66.80% (SD = 9.40%) to 61.73% (SD = 7.62), $P = .003$, and foot care, 67.78% (SD = 12.27%) to 57.77% (SD = 13.37%), $P = .002$. Both study groups had low exercise adherence at baseline, whereas only that of the intervention group improved to moderate; intervention group: 43.83% (SD = 13.37%) to 51.83% (SD = 15.11%), $P = .016$ versus control group: 48.33% (SD = 12.88%) to 44.67% (SD = 11.05%), $P = .154$.

The mean adherence scores for blood glucose monitoring was high for both groups, although they reduced at posttest period compared to baseline; intervention group: 82.00% (SD = 15.40%) to 80.67% (SD = 13.37%),

Table 1

Baseline Characteristics of Study Participants

Variable	Intervention Group	Control Group	*P* Value
Gender of participants, *n* (%)			.347[a]
Male	8 (26.7)	5 (16.7)	
Female	22 (73.3)	25 (83.3)	
Age (y) of participants, mean (SD)	55.07 (10.85)	56.47 (9.83)	.602[b]
Marital status, *n* (%):			.793[a]
Married	17 (56.7)	18 (60.0)	
Unmarried	13 (43.3)	12 (40.0)	
Occupational status, *n* (%)			.136[a]
Employed	25 (83.33)	20 (66.7)	
Unemployed	5 (16.67)	10 (33.3)	
Educational level, *n* (%)			.871[c]
Basic	21 (70.0)	21 (70.0)	
Secondary/tertiary	7 (10.0)	6 (13.3)	
None	2 (6.7)	3 (10.0)	
Monthly income (GHC), *n* (%)			.573[a]
Up to 1000	20 (66.7)	22 (73.3)	
Over 1000	10 (33.3)	8 (26.7)	
Family history of diabetes mellitus, *n* (%)			.260[a]
Yes	23 (76.7)	19 (63.3)	
No	7 (23.3)	11 (36.7)	
Types of oral hypoglycaemic agent, *n* (%)			.398[a]
1	8 (26.7)	11 (36.7)	
2	14 (46.7)	15 (50.0)	
3	8 (26.7)	4 (13.3)	
Diabetes duration (y), mean (SD)	8.83 (6.83)	8.23 (6.28)	.723[b]
A1C (%), mean (SD)	9.54 (2.00)	9.07 (1.72)	.334[b]
Weight (kg), mean (SD)	77.29 (14.55)	71.92 (13.10)	.138[b]
Body mass index (kg/m^2), mean (SD)	29.14 (6.13)	27.61 (4.79)	.286[b]
Systolic blood pressure (mmHg), mean (SD)	134.03 (27.39)	150.93 (24.92)	.015[b]
Dystolic blood pressure (mmHg), mean (SD)	85.23 (17.00)	87.27 (12.90)	.604[b]

[a]Variables analyzed using Pearson χ^2 test.
[b]Variables analyzed using independent sample *t* test.
[c]Analyzed by Fisher's exact test using Monte Carlo's simulation.

P = .687 versus control group: 75.00% (SD = 12.25%) to 74.00% (SD = 13.80%), *P* = .669. Similarly, both groups had moderate medication-taking mean adherence scores that reduced at posttest period compared to baseline measurements; intervention group: 66.33% (SD = 7.18%) to 65.67% (SD = 10.40%), *P* = .774 versus control group:

Table 2

Glycaemic Control and Self-Care Adherence Changes for Both Intervention and Control Groups From Baseline to Postintervention Periods

Variable	Between-Group Differences at Baseline Independent t-Test P Value	Intervention Group Baseline, Mean (SD)	3 mo (Posttest), Mean (SD)	Paired t Test P Value	Control Group Baseline, Mean (SD)	3 mo (Posttest), Mean (SD)	Paired t Test P Value
A1C Level (%)	.334	9.54 (2.00)	8.03 (2.25)	.004	9.07 (1.72)	9.33 (1.86)	.282
Diabetic diet adherence (%)	.127	70.00 (6.28)	72.53 (12.24)	.200	66.80 (9.40)	61.73 (7.62)	.003
Exercise adherence (%)	.190	43.83 (13.37)	51.83 (15.11)	.016	48.33 (12.88)	44.67 (11.05)	.154
Foot care adherence (%)	.294	71.33 (13.69)	78.67 (15.99)	.056	67.78 (12.27)	57.77 (13.37)	.002
Blood glucose monitoring (%)	.056	82.00 (15.40)	80.67 (13.37)	.687	75.00 (12.25)	74.00 (13.80)	.669
Medication adherence (%)	.478	66.33 (7.18)	65. 67 (10.40)	.774	67.67 (7.28)	64.00 (8.14)	.039

67.67% (SD = 7.28%) to 64.00% (SD = 8.14%), P = .039.

Feasibility Assessment

Participant recruitment and retention were 100% without any attrition. None of the eligible participants who were approached refused to join the study. All 60 participants consenting to commence the study completed the study, as shown in the Figure 1 flow diagram. The interventionists attempted all participant calls as scheduled. However, 87% (n = 26) of them were able to complete at least 70% (≥11) of the calls. During posttest measurements, participants who received the intervention rated their satisfaction as 89.3% (8.93/10) on average.

Discussion

The study aimed to assess the feasibility and compare the effectiveness of a nurse-led phone call follow-up intervention in addition to care as usual with care as usual only on the glycemic control and self-care adherence among T2DM patients with suboptimal A1C levels in an urban area in Ghana.

The intervention is feasible in a developing setting such as Ghana with a significant number of T2DM patients with glycemic control and self-management challenges. Possibly due to its novelty, the added clinician support, and

the intervention promises, the study had higher participant recruit-ment, retention, and program participation than similar studies.[26,27] The outcome of the process measures and par-ticipants' satisfaction was beyond authors' expectations and highlights the acceptability and practicality of this pilot study in informing the development of more extensive randomized controlled trials in similar settings.

After the 12-week postintervention period, the intervention group had their mean A1C level improving, whereas that of the control group worsened. Similar trends have been reported in previous studies, systematic reviews, and meta-analyses[26,30,31] where glycemic management improved in patients with T2DM receiving clinician phone call follow-up intervention with care as usual than those receiving only care as usual. Patients with suboptimal glycemic management have a higher risk of developing micro- and macrovascular complications leading to rising diabetes-related morbidities, mortalities, and health care costs.[4,5,32,33] Preventing these complications through the implementation of self-management education and support interventions such as the current pilot is imperative for the resource-limited Ghanaian setting.

The usual care offers self-management education and support for patients but mainly at the clinic site. Practically, patients' self-management and adherence take place in between clinic visits. However, the usual

care lacks continued patient follow-up encounters where individuals are guided by diabetes specialist nurses or clinicians to set and evaluate personalized goals and plan actionable daily self-care activities in between clinic visits, thus reminding and facilitating the translation of self-care knowledge into practical living. Such are the features of the mobile phone intervention and similar interventions,[27] and members who received it had better posttrial diet, exercise, blood glucose monitoring, medication, and foot care adherence than those that did not. This could explain why members of the intervention group had better improvement in their glycemic management. Optimal glycemic management among individuals with T2DM is an ongoing daily process, which is directly reflective of how well the individual is managing himself or herself by adhering to the therapeutic regimen.[5,34]

Proper self-management is a challenge for T2DM patients. A significant number of patients have low adherence to recommended diet, exercise, medication, foot care, and self-monitoring of blood glucose in Ghana[34-36] and other African countries,[37,38] which could lead to frequent hospitalizations. The establishment of additional patient educational support, self-care counseling, and awareness programs tailored to the specific needs of diabetes patients in Ghana have been unequivocally recommended.[34,36,39] The mobile phone follow-up program, which is a novel intervention targeting the promotion of self-management and diabetes care in Ghana, is an example. Diabetes care and education specialists could devote less than 15 minutes of their working hours to reach out to their patients weekly or monthly to assess and support their self-management in between visits. Patients may have the reminder and motivation not to be passive but take charge of their self-care, leading to improvement in their diabetes control. This may increase their workload, but the advantages are far considerable. Engaging patients this way has been reported to promote their participation and sense of ownership of their care, which is essential in chronic disease management.[40-42]

The current pilot has provided some insight on how a mobile phone follow-up program could promote glycemic control and self-management among T2DM patients with suboptimal glycemic control over 12 weeks. However, there are a few limitations to be addressed in follow-on research. The study only included patients with T2DM with raised A1C (>7%) who were on oral hypoglycaemic medications only. Therefore, the findings may not apply to those with other types of diabetes and those on insulin treatment, who are likely to find challenges in management of their disease compared to those on oral mediciations only. Additionally, the study may not have been powered enough to be able to identify other benefits to diabetes self-management practices. Furthermore, the validity of the measuring instrument, although developed with international expertise, is questionable and may have been responsible for the inability of the study to provide a more concrete link between mobile phone call intervention and improvement in diabetes self-management indices. Again, the 12-week follow-up period was deemed not enough to be able to assess other changes, including body composition measurements.

Further studies with the aim of addressing the stated limitations and incorporating other indices, such as lipid profile, are needed to determine the impact of the intervention on lipid profile in patients with T2DM in Ghana. A larger national trial is necessary where the overall cost-effectiveness of this intervention can also be evaluated. Although the interventionists were able to attempt all participant calls as scheduled, the delivery burden on nursing staff was not assessed. It is therefore recommended for future trials to include qualitative evaluation where staff and study participants could be engaged in one-to-one interviews or focused group discussions to explore their perspective of the success, challenges, and mechanism of action of the intervention.

Conclusion

This pilot study demonstrated that nurse-led follow-up mobile phone calls is feasible and have the potential to contribute positively to the provision of nursing and follow-up care for persons with diabetes in Ghana. The intervention has provided the platform for clinicians and patients to be engaged off clinical site to deliberate on issues of self-management at the level of the individual in between outpatient clinic visits.

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