Feasibility Of A Nurse-Led Home-Based follow-Up Hypertensive Care: A Randomized Control Study In A North Central State Of Nigeria

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Abstract

This article reported the development of a nurse-led, home-based follow-up care (HBFC) for hypertensive patients in Ilorin, Nigeria and assessed its feasibility. A Randomized Controlled Trial (RCT) was carried out in a tertiary hospital in Ilorin, Nigeria. For this study, 229 patients were recruited and openly randomized into patients that were followed up at home for 12 months (intervention) and those that were allowed to continue with the usual follow-up care (control) in the hospital using the usual routine hospital visit. The study presented the feasibility assessment of HBFC using three cardinal criteria; evidence of implementation, acceptability and practicability. There were retention rates of 83.9% and 83.3% for the intervention and study groups respectively. While no patients discontinued from among the patients in the intervention group, 13 patients discontinued in the control group. We concluded that it is feasible to conduct a home-based care for hypertension patients in a low resource setting like Nigeria.

Key words: Feasibility, Home-based, Nurse-led, hypertension, Nigeria

Introduction

Hypertension prevalence is on the increase among the Nigeria population and is currently seen as one of the most important chronic diseases in the country.[1-3]The chronic nature of hypertension requires that the patients should be seen on a routine basis by the health workers for medical check-up in what is termed as a "follow-up visits". The goals of the follow-up care are to ensure optimum Blood Pressure (BP) control and prevention of complications from hypertension. Studies in Nigeria have described interrelated challenges to hypertension follow-up care. Currently, the care of hypertensive patients take place almost entirely in health facilities and characterized by the attendant poor access to care.[4-6]

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In addition, studies[7-10] have shown that hypertension is overwhelming the health resources in the Nigerian hospitals by contributing over a fifth of the total hospital utilization. And despite this, almost three-quarters of hypertensive patients are still not on treatment or follow-up in the general Nigerian population even when follow-up treatment was indicated in almost half of them.[11]Due to the challenges to follow-up care in Nigeria, researchers have recommended further studies into health system strengthening, cost reduction strategies and task-shifting strategies on hypertension management in Nigeria.[12-15] Therefore, in order to implement and sustain successful hypertensive control strategies in Nigeria, access to medical care for patients and quality of health care should be ensured and sustained.

Though some studies have explored the effects of community or home-based care on medical outcomes of hypertensive patients,[16-18]only few Randomized Control Trials(RCTs)were cited in the literature.[19-21] The major limitations to most of these studies on home-based care for hypertensive patients were those due to poor study designs, unrealistic intervention, short follow-up period and inappropriate implementation. To bridge this gap and pilot a home based follow-up care study in a low resource country; we designed and implemented an individual open (un-blinded) Randomized Controlled Trial (RCT) in a tertiary hospital located in north-central zone of Nigeria. Therefore, this article reported the development of a home-based follow-up care (HBFC) for hypertensive patients in Ilorin, Nigeria and assessed its' feasibility.

Methods

Study setting: The patients from this study were hypertensive patients recruited from University of Ilorin Teaching Hospital (UITH) located in Ilorin, north-central zone of Nigeria. It has catchment area covering the entire Kwara State and more than five neighboring states. Majority of patients with hypertension are attended to in Medical Outpatients Department (MOPD) and General Outpatients Department (GOPD). On the average, close to 200 hypertensive patients are seen per week in GOPD and MOPD of UITH, Ilorin.

Study design: The research design was an intervention study with an individual open Randomized Controlled

Trial (RCT) which was un-blinded. The study was un-blinded because it is not feasible to blind the home-based care intervention (with an appropriate placebo) without compromising effectiveness of the intervention. The trial was registered with Pan African Clinical Trial Registry (PACTR). Both newly diagnosed and old hypertensive patients of age 40 years and above attending clinic for uncomplicated essential (primary) hypertension were included in this study. Patients who were living outside Ilorin metropolis or who were temporary residents were excluded from the study. Ethical approval was obtained from the Ethical Review Committee (ERC) of University of Ilorin Teaching Hospital.

Sampling process and Sample size determination:

The sample frame was the list of all hypertensive patients attending MOPD and GOPD clinics of UITH, Ilorin, Nigeria using a daily list of patients' attendance with hospital number (obtained from Department of Health Information Management of the hospital). The sampling unit was all eligible hypertensive patients that attended MOPD and GOPD clinics of UITH Ilorin within the month of September 2015 (recruitment period). The sample size was determined using superiority trial formula[22] for individual complete RCT. Therefore a sample size of 140 in each study group was sufficient to detect a clinically important difference of 8.8 point on the SF-36 scale for quality of life between the patients placed on home-based follow-up care and those on usual care, assuming a pooled standard deviation of 12.35, using a tow tailed t-test of the difference between means, a power of 90% and a 95% Confidence Interval (CI).

Baseline screening and Randomization: A total of 406 patients were screened, out of which 299 eligible consented patients were recruited into the study. The research numbers were allocated to eligible and consented patients. An independent Biostatistician in Health Information Unit of the Hospital was responsible for the randomization through allocation sequence and allocation concealment. After eligibility checks and recruitment of patients into the study, a baseline assessment was carried out and the Biostatistician revealed coded assignment for the patient. Code "0" assigned patients to intervention group while code "1" assigned to control (usual) group.
Development, Validation and Process of Home-based Follow-up Care: The guideline was developed using three different but complimentary approaches.[23] The initial module draft was developed using Researchers' personal experience as Doctors in the study setting and consultation with other local experts. This was further complimented by literature search for the best evidence-based practices in hypertension home-based care strategies and; lifestyle modification counseling and health education. The initial approaches led to the development of HBFC activities flowchart, hypertensive home based follow-up care program Algorithm and the HECS. The flowchart was a guide for the nurses on the activities and implementation course for the HBFC while the algorithm depicted the sequence of BP classification and the required action to be taken on individual patients randomized into the intervention group. The Algorithm was guided by the World Health Organization, (WHO) and International Society of Hypertension (ISH) Writing Group guidelines of 2003.[24]The third approach involved the use of qualitative study. This explored challenges and barriers to managing hypertension in a low resource setting like Nigeria and determined the patients' acceptability and preferences for HBFC concept. The thematic analysis of the qualitative studies was used to finalize the delivery methods for the HBFC. The guideline was face-validated with a group of experts for content, appropriateness and relevance to the setting. The Health education and counseling session (HECS) aspect of guideline was adapted from the Australian National Heart Foundation Lifestyle guidelines.[25] All of these activities resulted in the development of the HBFC and guidelines.

The HBFC project staff included four nurses, two Nurse Assistants (NAs) and six Research Assistants (RAs). Cardiologists and Family Physicians from UITH provided supervision to the teams and also ensured ease of referral to the teaching hospital for the patients that required specialty care. The four nurses in this study consisted of two retired nurses and two young nurses of over three years of working experience as clinical nurses. They were recruited based on merit after an initial training exercise. The nurses were allocated into two teams of A and B comprising of two nurses (a retired and a young nurse) and a nurse Assistant per team. Six Research Assistants (RAs) were also recruited as independent Data collectors at baseline and at the end of the study. The nurses and Assistants were trained over a week period on the HBFC project and guidelines. The five cardinal components of HBFC project were;

1. Monthly scheduled Nurse-led home-based visit
2. Medical history and physical examination
3. Home-based Blood Pressure (BP) and Body Mass Index (BMI) monitoring
4. Lifestyle modification and medication Adherence assessment
5. Hypertension Health Education and Counseling Session (HECS) and Adherence Counseling.

Each of the HBFC team was randomly assigned patients to be visited for the 12 month periods. Since there were 149 patients randomized into intervention group, 75 and 74 patients were allocated

randomly to team A and team B respectively (figure 1). The work schedule was from Monday to Friday with an average of 4 to 5 patients visited per day per team. Each patient was visited monthly, meaning there were a total of 12 rounds of follow-up visits. The patients in the control group were allowed to continue with the usual follow-up practice at their respective clinics in UITH, Ilorin. Their treatment was at the discretion of the managing team at UITH. The research protocol required that baseline and end of study assessments were collected from the both the study groups as well.

The teams were made to adhere strictly to the HBFC guidelines and Clinical Report form (CRF). The CRF was used to record monthly data on; clinical history, medical examination, symptoms in the preceding four weeks, clinical measurements (BP, weight and height) and target sets on identified lifestyle modifications. Also included were assessment of patient's adherence to medication, adherence to lifestyle modifications and challenges experienced in the precedingfour weeks of visit. Hypertensive HECS offered to the patients was a detailed (between 25 to 30 minutes) face to face health education and interactive counseling session. The HECS was detailed on importance of lifestyle modification education, dietary advice and adherence to treatment.

Analysis techniques

The feasibility assessment of HBFC was carried out based on the following criteria;[26]

- **Evidence of implementation:** This assessed the development and proof of implementation of HBFC.
- **Acceptability:** The uptake and retention in HBFC intervention by hypertensive patients. This was assessed by collecting data on monthly use and attrition from the intervention group.
- **Practicality**. It explores the extent to which HBFC intervention can be delivered when resources, time, commitment, or some combination thereof are constrained. This was explored using intention to treat analysis and conformed with "once randomized, always analyze" rule of thumb.[27]Analysisincluded all the hypertensive patients by randomized treatment assignment into the study and was regardless of the noncompliance status, deviation from protocol, attrition and any other occurrences after randomization. This is with a view to reflect actual clinical scenario in medical practice.

Results

Socio-demography and Group Equivalence

The age (p=0.471), gender (p=0.759), ethnicity (p=0.126), Literacy (p=0.436) and poverty index

Table 1: Socio-demographic Group Equivalence of the Respondents at Baseline

Socio-demography	Intervention Frequency (n = 149)	(%)	Control Frequency (n=150)	(%)	Test statistics (df)	p-value
Age						
40 - 49	18	(12.1)	16	(10.7)	3.549 (4)[a]	0.471
50 - 59	48	(32.2)	47	(31.3)		
60 - 69	44	(29.5)	58	(38.7)		
70 - 79	29	(19.5)	21	(14.0)		
≥ 80	10	(6.7)	8	(5.3)		
mean± S.D	61.4 ± 11.1		60.9 + 10.6		0.327 (297)[b]	0.744
Gender						
Male	35	(23.5)	33	(22.0)	0,094 (1)[a]	0.759
Female	114	(76.5)	117	(78.0)		
Ethnic group						
Yoruba	144	(96.6)	139	(92.7)	2.335 (1)[a]	0.126
Other Tribes	5	(3.4)	11	(7.8)		
Religion						
Islam	101	(67.8)	96	(64.0)	0.477[a]	0.490
Christianity& other	48	(32.2)	54	(36.0)		
Literacy level						
Not Literate	39	(26.2)	32	(21.4)	3.787[a] (4)	0.436
Primary education	17	(11.4)	11	(7.3)		
Secondary education	24	(16.1)	29	(19.3)		
Higher education	68	(45.6)	75	(50.0)		
Marital Status						
Married	120	(80.5)	109	(72.7)	2.582[a]	0.108
Widowed/Divorced	29	(19.50)	41	(27.3)		
Main Job						
Small Business	85	(57.0)	89	(59.3)	0.761 (4)[a]	0.944
Civil Service	19	(12.8)	17	(11.3)		
Large Business	5	(3.3)	4	(2.7)		
No paid Job	21	(14.1)	18	(12.0)		
Others	19	(12.8)	22	(14.7)		
Poverty index per						
≤ 1 USD	21	(14.1)	108	(8.7)	2.270 (2)[a]	0.321
1 - < 2 USD	29	(19.5)	29	(19.3)		
≥ 2 USD	99	(66.4)	13	(72.0)		

Note: a = χ^2 (Chi-square) test, b = Independent t-test, df = degree of freedom

Table 2: Disease and Drug HistoryGroup Equivalence of Respondents at Baseline

Disease History	Intervention		Control		Test statistics (df)	p-value
	Frequency (n = 149)	(%)	Frequency (n=150)	(%)		
Morbidity duration (years)						
< 1 year	16	(10.7)	17	(11.3)	3.053 (3)[a]	0.384
1 - 5 years	69	(46.3)	59	(39.4)		
6 - 10 years	34	(22.8)	47	(31.3)		
> 10 years	30	(20.2)	27	(18.0)		
Mode of payment						
Out of Pocket	114	(76.5)	110	(73.3)	0.401 (1)[a]	0.526
Other methods	35	(23.5)	40	(26.7)		
Drug Combination						
One	19	(12.8)	14	(9.3)	2.048 (3)[a]	0.563
Two	48	(32.2)	59	(39.3)		
Three	56	(37.6)	53	(35.4)		
>Three	26	(17.4)	24	(16.0)		
Drug Frequency						
Once	119	(79.9)	133	(88.7)	3.731[a]	0.053
Twice & above	30	(20.1)	17	(11.3)		
Drug side effect						
Yes	109	(73.2)	110	(73.3)	0.001 (1)[a]	0.972
No	40	(26.8)	40	(26.7)		

Note: a = χ^2 (Chi-square) test, b = Independent t-test, df = degree of freedom

(p=0.321) of the two study groups were not statistically different thereby ensuring group equivalence (Table 1). Similarly, table 2 shows the group equivalence of disease and drug history among the two study groups. Morbidity duration (p=0.384), drug combination (p=0.563), drug intake frequency (p=0.053) and drug side effect (p=0.972) were not statistically different. The out of pocket expenditure was similar and more than 70% in the 2 study groups (p>0.05).

Implementation of Home Based Follow-up Care

Figure 1, is an adaptation from Consolidated Standard of Reporting Trial[28] (CONSORT) diagram. It shows that a total of 406 patients were screened for eligibility out of which 299 patients were recruited into the study and had baseline assessment. Out of this, 149 hypertensive patients were successfully randomized into intervention group of the study while 150 patients were in the control group of the study. Home based follow-up care intervention was implemented among the randomized hypertensive patients in Ilorin metropolis for 12 months between September 2015 and August 2016. The 149 patients in the intervention group were follow-up monthly for 12 months using a pre-tested and validated home HBFC guideline. The 150 patients in the control group were allowed to continue with the usual hospital care and were left at the discretion of the managing physician at the hospital. The patients in the control group were seen at baseline and at the end of follow-up (12th month) for the purpose of data collection.

The intervention was divided into three sessions of sequential and interrelated activities; Session one consisted of initial screening exercise and involved medical history taking and medical examination. This was contained in daily clinical report form (CRF). Session two involved BP and BMI monitor. The last session is the HECS and consists of two sub-sessions; the lifestyle modification session and the adherence session. The uniqueness of the HBFC guideline was its interactive nature where patients were allowed to talk about the challenges and barriers deterring their compliance with the counseling. Together with the nurses, solutions were proffered to the identified challenges and targets (to be met) were set against the next round of visit. At times the solution included involvement of family or community members. The study successfully implemented a Nurse-led task shifting home-based follow-up care for hypertensive patients over a period of 12 months.

Acceptability: After randomization, only four (4) patients in the intervention group and two (2) patients in control group did not take up allocation into study groups (Figure 1). After 12 months of follow-up, 20 patients and 23 patients were lost to study follow-up in intervention and control groups respectively (Figure 1). This meant retention rates of 83.9% and 83.3% for the intervention and study groups respectively (with combined retention rate of 83.6%). The reasons for attrition in the 2 groups were; mortality (5), travelling (11) and relocation (14). While no patients discontinued from the study in the intervention group, 13 patients discontinued in the control group. Figure 2shows HBFC monthly utilization pattern among hypertensive patients in the intervention group. There was a slight drop from 140 patients that were seen at home by the HBFC teams at the beginning to 129

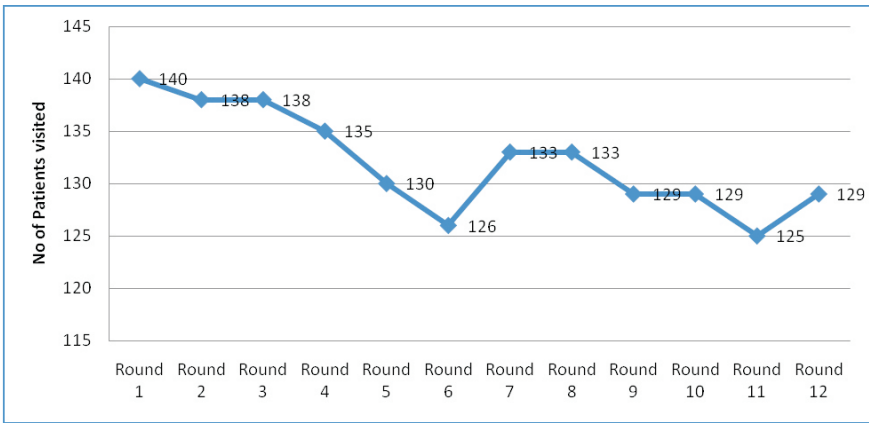

Figure 2: Number of Patients successfully visited at home during the HBFC implementation

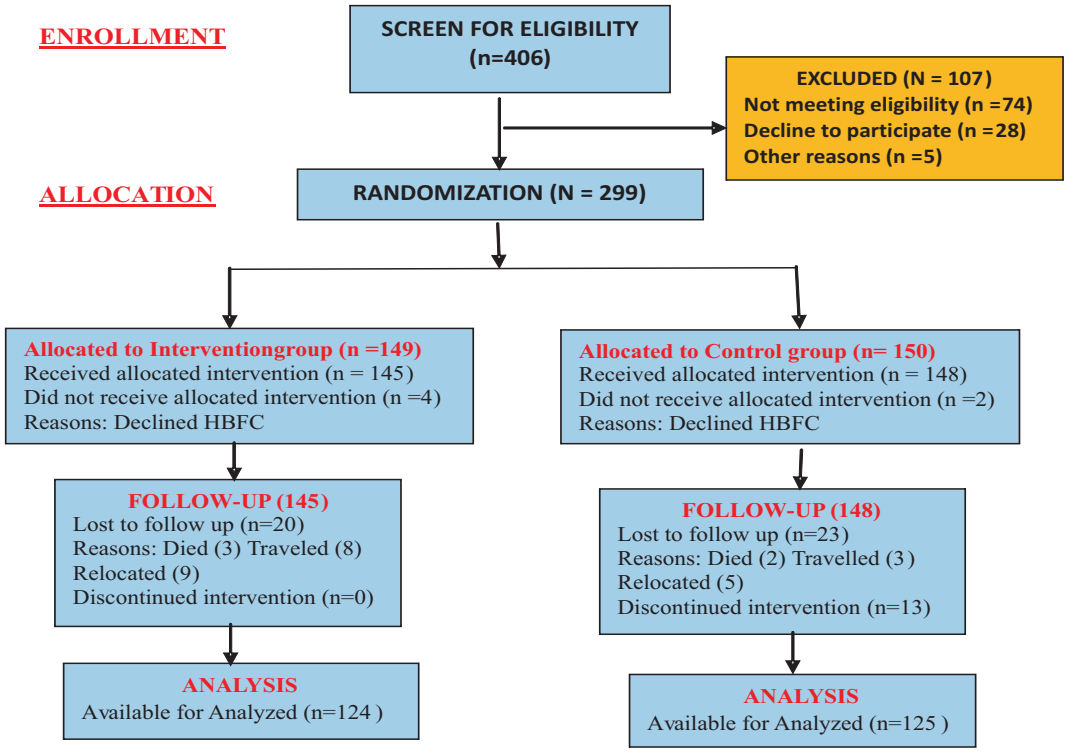

Figure 1: CONSORT Flowchart showing randomization and attrition(adapted from Schulz, Altman, & Moher 2010).

patients seen at the end of study.

Practicality: All the twenty (20) missing data in the HBFC group and 23 missing data in usual care group were included in the final analysis for Intention to Treat (ITT).To ensure ITT analysis, Last Observation Carried Forward (LOCF) method was adopted. This involved that last available measurement of an individual patient prior to the point of discontinuation with the study is retained for the analysis. This ensures practicality of this study and a modest analysis of the effect size.

Discussion

The socio-demographic characteristics and disease history of the intervention (HBFC) group and control (UC) group were comparable and similar at baseline. No statistically significant difference was observed between them. These findings showed the outcome of successful randomization procedures during the recruitment phase. The randomization has effectively reduced the selection bias that could be associated with this research by making the intervention group and the control group looked similar at the baseline.

The HBFC project recruited 299 hypertensive patients from the outpatient clinics of University of Ilorin Teaching Hospital, out of which patients were successfully randomized into intervention and control groups of the study. These patients were successfully followed-up at home over a period of 12 months. The feasibility and effectiveness of task shifting strategies have also been documented by other researchers.[16,29,30] In these studies, several health workers aside Doctors successfully led health teams to achieve community or home-based care for hypertension. The nurses[16,30] and

pharmacists[29] were the commonest task-shifting led health workers documented in the past studies. These studies are similar to this study which showed a successfully implemented nurse-led home based care in Ilorin, Nigeria. This implied that if successfully implemented in low income country like Nigeria, HBFC has the inclination to reduce the clinic follow-up default rate experienced in Nigerian hospital.

One of the major impediments to a prospective study is attrition. And for this study, it was an indirect factor to assess acceptability of our intervention. The combined attrition rate in this study is less than 20%. This is greater than the one recorded by a hospital-based clinical trials on hypertension.[30] The attrition is however lower than other similar RCT studies on hypertension, many of which recorded over 25% attritions.[32-34] According to Dumville et al,[35] researchers have varying opinions about the cut-off point for attrition in randomized controlled trials but the general concession still revolves around validity of greater than 20% attrition rates.[35] It is believed that internal validity may not be assured with a study of over 20% attrition.[35] Therefore, this study was within the acceptable attrition level at which the internal validity of the study is assured.

Reasons for attrition were important factors to feasibility of any prospective study. In this study, majority of the loss to follow-up (attrition) was due to patients that relocated. These were justifiable reasons why participants in any prospective study can be lost. It should also be noted that those patients that travelled were only temporarily away from the study site and they may return later. Mortality and discontinuation by the patients were permanent loss to our study and also represent natural and important course of any health research. Discontinuation from RCT studies is allowed and it is an absolute right of the patients according to the "Autonomy" clause of Helsinki declaration.[36] However, all the patients that discontinued from the study were from the control group which affirmed the probable satisfaction and preference for the intervention which led to the acceptability observed among the intervention group.

This study is a pragmatic RCT study with a superiority trial concept and therefore requires conformity with "once randomized, always analyze" rule of thumb.[27]This is done in order to eradicate noncompliance to intervention protocol and missing outcome measure associated with RCTs studies, intention-to-treat (ITT) analysis was employed for final analysis.[27]This is to ensure modesty in analysis of the superiority trial. It included all the hypertensive patients by randomized treatment assignment into the study and was regardless of the noncompliance status, deviation from protocol, attrition and any other occurrences after randomization. This is with a view to reflect practical clinical scenario and how to address it.

Conclusion

The HBFC intervention was developed and successfully implemented among adult hypertensive patients in Ilorin, Nigeria. The implementation proved that it is feasible to conduct a home-based care for hypertension patients in a low resource setting like Nigeria using nurses as implementer of such strategy. It also proved that it is practicable to carry out a task-shifting strategy with the nurses as team leader under the supervision of doctors to achieve a successful home-based care for hypertensive patients.

Recommendation

It is recommended that the health system, especially the tertiary health services in low income countries should endeavor to adopt the principle of home-based care task shifting strategy using other health professionals like nurses. This has propensity to alleviate the congestions seen at outpatient clinics of hospital in Nigeria.

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