IMPACT OF HYPERTENSION HOME-BASED CARE ON HEALTH RELATED QUALITY OF LIFE OF NIGERIAN PATIENTS: RESEARCH CONCEPT, FRAMEWORK AND METHODOLOGY

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ABSTRACT

Background: Public health importance of hypertension have been documented all over the world. In recent years, there has been increase cases of hypertension reported in African countries including Nigeria. The current management strategy of hypertensive cases within hospital setting are characterized by high default rate, non-adherence, poor medical outcomes and poor quality of life. While past studies emphasized use of medical outcomes to assess treatment or intervention outcomes, only scanty studies take into cognizance the quality of life that patients live. Because of the chronicity of hypertension, it is important to begin to assess the Health Related Quality of Life (HRQoL) of patients and begin to use such as an impact assessment of treatment or intervention strategies. This study proposed to develop and implement a home based follow-up care (HBFC) intervention and evaluate the impact of the intervention on the HRQoL of hypertensive patients in Nigeria.

Materials and methods: This study will be a randomized control trial (un-blinded) to be conducted in 3 stages. Stage 1 will develop HBFC program while in stage 2, patients will be recruited, assessed (baseline data), randomized into 2 arms of study and follow-up for 6 months. The third stage will evaluate the impact of the intervention on HRQoL and disseminate the findings. Data will be collected with the use of structured questionnaire which will contain validated tools like SF-36v2 for HRQoL and Morisky scale for medication adherence. Main outcome measurement will be treatment effect using HRQoL while data would be analyzed using SPSS, version 22. Intention to treat (ITT) analysis concept will be employed and main hypothesis will be tested using paired t-test analysis. Level of significance will be set at p-value of < 0.05 and 95% confidence intervals (CI).

Expected outcome: The study will contribute to the existing knowledge on home based care program for hypertensive patients in developing countries where literature is scanty. It will generally give insight into the importance of HRQoL measurement in interventional studies on hypertension and other related chronic diseases in this setting.

Keywords: Hypertension, Health Related Quality of Life, Home-based Care, Research Concept, Framework and Methodology
1.0 INTRODUCTION

Hypertension affects all age groups, gender and race and it was reported in all countries of the World. It is a major cardiovascular disease risk (Lewington et al, 2003) and an uncontrolled hypertension predisposes to various fatal complications like stroke, heart failure and renal diseases (Nelissen et al, 2014; James et al, 2014; Chobanian et al, 2003), making hypertension a disease of high public health burden. Hypertension like any other Non-Communicable Diseases (NCDs) runs chronic course and therefore require life-long medical management (Wagner et al, 2001). This chronicity therefore brings to bear the quality of life the sufferer of hypertension experiences every day of his life. However, quality of life experienced by patients are neither the usual nor the routine assessment of treatment outcomes of patients (Bernochi et al, 2014).

In recent years, increase cases of hypertension has been reported in African countries and this was attributed to the adoption of western lifestyles, epidemiological and demographic transitions (Hendriks et al, 2012; Cappuccio et al, 2004). It is becoming a huge burden to the continent. Similarly, its complications have been reported among African population (Nelissen et al, 2014) and has been shown as the commonest cause of cardiovascular diseases (CVDs) in the continent (Erhun et al, 2005). In Nigeria, hypertension prevalence has been on the increase from 8.8% reported in 1960s (Ogah et al, 2012) to the current prevalence of 46% (Hendriks et al, 2011). There are interrelated factors identified to affect the care of hypertensive patients in Nigeria. Part of which is the care of hypertension that is entirely hospital based, whereby the patient is followed-up in the hospital clinic for the refill of drugs and other medical services on regular basis (van de Vijver, S et al, 2013; Hendriks et al, 2014a; Suleiman et al, 2009). It was also reported that hypertension care within the hospital takes up over one-fifth of total hospital utilization quota (Kolo et al, 2012; Ukoh, 2007; Oguanobi et al, 2013; Onwuchekwa et al, 2010) while at community level, only 25% of those with hypertension are on treatment (Nelissen et al, 2014). Of these small proportion of hypertensives on treatment and among those of them that are 40 years and above, 40% of them will default their clinic follow-up by the third follow-up visit (Ike et al 2003b).

While management of hypertension remains almost entirely hospital based in Nigeria like other African countries, the medical outcomes and their quality of life remain poor. This poor clinical outcomes have been linked to long waiting hours at the clinics, transportation costs and high cost of drugs (Hendriks et al, 2014b; Ilesanmi et al, 2012). These consequently resulted in high hospital follow-up default and poor medication adherence (Kabir et al, 2004). Studies (Adeyemo et al, 2013; Hendriks et al, 2014b; Ilesanmi et al, 2012 and Odu sola et al, 2014) have recommended further research into health system strengthening, cost reduction strategies and task shifting strategies on management of hypertension in Nigeria.

Proposing a home based follow-up care for NCDs like hypertension in Nigeria will be a new and uncommon strategy to this setting. Home or community based care have been used routinely and exclusively for the control of communicable diseases in this setting. Worldwide, this have proven to be an effective strategy to reduce accessibility and affordability to quality health care most especially in the control of communicable diseases like, HIV infection Tuberculosis, Diarrhea diseases and Malaria (Brust et al, 2012; Shah et al, 2012; Thiam et al, 2012). This type of care have the potential of reducing cost of care for the patients, increase adherence to medication, eliminate default in follow-up, and improve lifestyle modification.
These will invariably lead to better medical outcome for the patients and therefore could have positive influence on quality of life of patients.

Health related quality of life (HRQoL), which is becoming an important outcome assessment of chronic diseases like hypertension (Poljičanin et al, 2010) was adjudged to be poor among hypertensive patients in Nigeria (Ogunlana et al, 2009). The concept of HRQoL employs the subjective but effective way of assessing the ultimate goal of treating patients with chronic diseases. Which is to improve the physical and mental wellbeing of the individual patients (Rubin et al, 1999). The direct resultant consequences of the inadequate management and poor clinical outcome of hypertension will be a reduced quality of life (Cleary, 2004; Ferrans et al, 2005). On the contrary however, many intervention studies on hypertension focused more on medical outcome measurements only without looking at the perceived physical and mental wellbeing of the individual patients (Staessen et al, 2004; Magid et al, 2009; Bosworth et al, 2011; Bernochi et al, 2014). Whereas exploring HRQoL of life of patients will give more insight into other predictors of the clinical outcome beyond medical factors. It will also indicate specific domain of quality of life spectrum that the patient is having challenges with. In this article, we presented a protocol on home based follow-up care (HBFC) intervention for hypertensive patients attending a tertiary hospital in Nigeria and the impact of this intervention on the patients’ HRQoL.

2.0 STUDY HYPOTESIS AND OBJECTIVES

The study main research question was; “what are the observed differences in HRQoL outcomes of hypertensive patients followed up at home and those on usual hospital based follow-up care?” This study hypothesized that “hypertensive patients follow up at home have significantly improved health related quality of life outcomes than those follow up at hospital” The specific aims of this study are;

1. To explore (using qualitative methods) factors suitable and appropriate for the development and implementation of home based follow-up care framework among hypertensive patients in Nigeria.

2. To develop and implement a home based follow-up care program for hypertensive patients in Nigeria.

3. To compare the HRQoL of hypertensive patients on home based follow-up intervention as against those on usual hospital based follow-up after 6 months of home based follow-up care program implementation.
3.0 WILSON AND CLEARY MODEL OF HEALTH RELATED QUALITY OF LIFE.

This study will be guided by the revised version of Wilson and Cleary (1995) model of health-related quality of life (HRQoL) (Ferrans et al, 2005). Wilson and Cleary model of 1995 pioneered the causal relationships of HRQoL as a major improvement over other HRQoL models that only characterised different domains of quality of life. This was prompted by the need for a model that could be used in planning health care interventions to improve patients’ HRQoL. The revised version became justifiable because of the increase in rigor and sophistication of quality of life research in the last 30 years (Ferrans et al, 2005). According to Ferrans et al, progress in quality of life researches has been hindered by the fact that term “quality of life” (QOL) has been used to mean a variety of different things, such as health status, physical functioning, symptoms, psychosocial adjustment, well-being, life satisfaction, and happiness (Ferrans et al, 2005). Consequently, many school of thought on QOL observed that comparing findings across studies to draw conclusions or make application in practice was difficult (Wilson I. 2004; Ferrans et al. 2005; Asing-Giwa 2005; Anderson et al. 1999). Therefore the revised version of Wilson and Cleary model addressed these major challenges in QOL researches.

**Figure 1:** Causal model of HRQoL, as revised by Ferrans et al (2005) from the original model by Wilson & Cleary (1995)

The characteristics of individual and environment included in revised version was conceived from McLeroy et al (1988) ecological model as modified by Eyler et al (2002). This model postulated 5 levels of health influence by ecological factors namely (Ferrans et al 2005); (i) intrapersonal factors (characteristics of individual), (ii) interpersonal factors (formal and informal social support systems), (iii) institutional factors (organizations such as schools and healthcare facilities), (iv) community factors (relationships among institutions and informal social networks in a defined area), and (v) public policy (local, state, and national laws and
policies). These level were however re-classified by ferrans et al (2005) revised model into 2 levels namely; individual characteristics (intrapersonal) and environmental characteristics (remaining 4 levels).

These 2 levels were shown to have interrelated effects (Fig 1) on different processes and status that will ultimately determine the Overall quality of life that individual people and patient will live (Ferrans et al 2005). These processes that lead to overall quality of life are discussed as follows;

Biological function is a hidden processes that are ongoing at cellular, molecular and organ levels in the body (Ferrans et al). It is a continuum of ideal function at one end of the spectrum and a severe life-threatening pathological function at the other end (Ferrans et al 2005). According to the revised model (Ferrans et al 2005), Wilson and Cleary (1995) defined symptom as “a patient’s perception of an abnormal physical, emotional, or cognitive state,” which can be categorized as physical, psychological, or psychophysical. However, this important condition are usually neglected and trivialized in clinical practise (Kring DL. 2008). Functional status can be viewed from various perspectives. Similarly and more concisely Stineman et al., (2005) viewed functional status from the perspective of disability or disablement, focused on the loss of function and its effects on everyday life. This domain usually reveals the complications and consequences of disease course. According to Wilson and Cleary, general health perception is an aggregate of all the other 3 attributes preceding this domain and that it is a subjective measurement of patient’s feelings and perceptions (Ferrans et al 2005; Kring DL. 2008). Overall quality of life is a subjective self-evaluation of an individual satisfaction or dissatisfaction with life as a whole (Wilson and Cleary 1995). This subjective well-being assessment does not represent a single construct (Ferrans et al, 2005). Usually it includes pleasant and unpleasant affect, global judgments of life satisfaction, and satisfaction with individual domains of life (Ferrans et al, 2005).

4.0 CONCEPTUAL FRAMEWORK FOR THE STUDY

The home based care model for hypertension will be a major intervention administered by this research. The model will include;

1. Task shifting (multidisciplinary) approach using trained nurses who will follow up uncomplicated hypertensive patients at home using an algorithm and under the supervision and guidance of physicians.

2. Structured home based medical follow-up for hypertensive patients

3. Hypertension health education / promotion module; Lifestyle modification, dietary advice and adherence to treatment counselling.

4. Clinical monitoring of Blood pressure and Body mass Index
According to the Figure 2 shown below the home based care model will influence the health of the hypertensive patients from individual and environmental levels. The individual characteristics will be influenced through hypertension education and counselling session (HECS) which will offered counselling and health education to hypertensive patients on lifestyle modification like cessation of smoking and alcohol, structured and measured exercise and dietary advice (reduce salt intake and high caloric and cholesterol containing diets) (Aghajani et al, 2013; Ebid et al, 2014; Kabir et al., 2004; Wal et al, 2013). Also, the individual characteristics will be influenced by assessing adherence level of the patients and offer adherence counselling (Adeyemo et al, 2013; Odusola et al, 2014; Cote et al, 2005).

At the environmental level, home based care follow-up intervention will increase hypertensive patients’ access to health care and reduce time wasting and beaurecratic bottlenecks usually experience at the health facility. In addition, this intervention will be administered by highly trained and professionally competent cardiovascular nurse as a task shifting strategy (Ogedegbe et al, 2014; Adeyemo et al, 2013). The cultural environment will also be influence by involving the relatives and caregivers of the patients in the HBFC program. The intervention will also monitor blood pressure and body mass index (BMI) at home by the nurses with a view to give set achievable target with the patients before next visit (Magid et al, 2013). This will measure the biological function with the aim of monitoring and improving its performance.

The influences of the home based intervention on individual and environment characteristics will in turn affect the biological function through blood pressure control, lipid profile and blood sugar improvement (Magid et al, 2013). The resultant effect of these on symptoms will be to reduce symptoms of hypertension, cardiovascular disease and other target organs damage (assessed using symptom count). The functional status which is handicapping consequences of organ damage will be improved or be halted and this will ultimately lead to a better general health perception of the patients. The aggregate effect of all of these on the patient will be an overall satisfaction with life. All the characteristics in the inner circle (Figure 2) will be assessed in this study. Blood pressure monitoring will assessed the biological process while symptoms count will assess the symptoms. The functional status, general health perception and overall quality of life will be measured using the SF-36v2® Health survey tool by Quality Metric Incorporated (Maruish [Ed] 2011).
5.0 MATERIALS AND METHODS

5.1 Study setting

This study will be conducted in Ilorin metropolis, Nigeria while patients will be recruited from University of Ilorin Teaching Hospital (UITH), Ilorin. It is one of the federal public teaching hospitals in Nigeria. It takes referral from public and private primary and secondary health care facilities. It also get referral from some of the state specialist hospitals. It has catchment area covering the entire kwara state and 5 neighboring states. It has many clinics that render hypertension care to patients namely; General Outpatients Department (GOPD), Medical Outpatients Department (MOPD), and National Health Insurance Scheme (NHIS) clinic. In these clinics, the patients are attended to by the specialist internists, family physicians, public health physicians, resident doctors, and medical officers.
5.2 Study design

The research design is an intervention study with an individual open randomized controlled trial (un-blinded). The research approach will be in 3 steps as summarized in figure 3. The step one will be a qualitative study, literature search and expert opinion to explore the preferences, perception and experiences of patients, health workers and policies on hypertension follow-up and its managements in the study location. The second and third steps are studies at pre-intervention and post-intervention stages respectively as shown below;

**Figure 3:** Research approach flowchart showing 3 phases of the research

In Step two, a baseline data will be collected after informed consent have been obtained from the recruited eligible patients. Randomization into 2 arms of study will be carried out namely; intervention and control groups. Subsequently, the developed home based follow-up care framework and module will be administered to randomised intervention group. This will be done over a period of 6 months. The post intervention study will form step 3. This will be carried out after 6 months of home based follow-up care. It will evaluate the impact of home based follow-up care on health related quality of life and allows for comparison between baseline and post intervention data.

5.3 Study population

The study population will be all hypertensive patients attending teaching hospital in Ilorin, Nigeria. Sampling population will be hypertensive patients attending General and Medical outpatient clinics of University of Ilorin Teaching Hospital (UITH), Ilorin. Nigeria

5.4 Inclusion criteria

1. All patients with essential (primary) hypertension attending medical outpatients clinic of UITH, Ilorin, Nigeria
2. Hypertensive patient of 40 years of age and above
3. Both newly diagnosed and old patients with not more than a year on treatment
5.5 Exclusion criteria

1. Patients that are on hospital admission as at the time of recruitment
2. Patients with special management requirements like diabetics that are on insulin therapy, chronic renal disease on dialysis and stroke patients on routine physiotherapy.
3. Patient living outside the 3 local government areas of Ilorin metropolis.
4. Patients with target organ damage or established cardiovascular disease.
5. Those hypertensive patients that are temporary residents in Ilorin and are more likely to leave within a period of 6 months after recruitment.
6. Hypertensive patients who has had a household member already selected into study.

5.6 Sample size determination

The sample frame will be all hypertensive patients attending outpatient clinics of UITH, Ilorin, Nigeria using outpatient clinic record (to be obtained from Department of Health Information Management of UITH, Ilorin). The sample size will be determined using superiority trial formula (Zhong, 2009) for individual complete RCT as follows;

\[ N = \frac{2 \left( \frac{Z_{\alpha/2}}{2} + Z_{\beta} \right)^2 \times s^2}{(\mu_2 - \mu_1)^2} \]

Where;
N = Total sample size in each group

\( Z_{\alpha/2} \) = Standard normal deviate corresponding to the confidence level of 95% =1.96 (Noordzij et al., 2010)

\( Z_{\beta} \) = Standard normal deviate corresponding to the power of 90% =1.28 (Noordzij et al., 2010)

\( \mu_1 \) = Observed mean total score of HRQoL using SF-36 scale among the intervention group = 66.80 (Wal et al, 2013).

\( \mu_2 \) = Observed mean total score of HRQoL using SF-36 scale among the control group = 58.02 (Wal et al, 2013).

\( S^2 \) = Pooled standard deviation. This is calculated according to IUPAC (IUPAC, 2006) criteria given the equation
Where; 

\( S_p \) is the Pooled Standard deviation

- \( n_1 = \) Number of cases in intervention group 1 (control) = 48 according to past study on RCT on multidisciplinary intervention on hypertensive patients using Sf-36 scale of measurement for HRQoL (Wal et al, 2013).

- \( n_2 = \) Number of cases in intervention group 2 (Treatment) = 54 according to past study on RCT on multidisciplinary intervention on hypertensive patients using Sf-36 scale of measurement for HRQoL (Wal et al, 2013).

- \( S_1 = \) Standard deviation of HRQoL in intervention group 1 (Control) = 11.89 according to past study on RCT on multidisciplinary intervention on hypertensive patients using Sf-36 scale of measurement for HRQoL (Wal et al, 2013).

- \( S_2 = \) Standard deviation of HRQoL in intervention group 2 (treatment) = 12.73 according to past study on RCT on multidisciplinary intervention on hypertensive patients using Sf-36 scale of measurement for HRQoL (Wal P., et al 2013).

\( n_k \) and \( S_k = \) are the number of cases and standard deviation of nth at value of k

\[ k = \text{the total number of groups} = 2 \text{ in this study} \]

Therefore substituting these values gives;

\[
S_p = \sqrt{\frac{(n_1 - 1)s_1^2 + (n_2 - 1)s_2^2 + \ldots + (n_k - 1)s_k^2}{n_1 + n_2 + \ldots + n_k - k}}
\]

\[
S_p = \sqrt{\frac{(48 - 1)(11.89)^2 + (54 - 1)(12.73)^2}{(48 + 54) - 2}} = 12.3
\]

Substituting \( S_p \) in the original formula (Zhong, 2009) gives;

\[
2 \times \frac{(1.96 + 1.28)^2}{(66.8 - 58.02)^2} \times 152.3 = 42.
\]

Adjusting this for a 30% attrition (drop out of respondents) that is envisaged will give 60 respondents in each group (42/0.7). Further adjustment for 20% (60/0.8) non-response gives 75.

Therefore a sample size of 75 in each study group will be sufficient to detect a clinically important difference of 8.8 point on the SF-36v2 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 two-tailed t-test of the difference between means, a power of 90% and a 95% Confidence Interval (CI). The calculation will be based on an assumption that the SF-36v2 measurements are normally distributed. The sample size will be rounded up to 100 in each group (a total of 200) to allow for increased power for this study. The criterion for significance (alpha) has been set at 0.05 with a 2-tailed analysis design.

5.7 Randomization and patient recruitment

The study will be simple individual randomization, involving hypertensive patients attending outpatient clinics in UITH, Ilorin, Nigeria (figure 4). The sampled population of eligible patients will be pooled over a month period. The researchers and the managing physicians will screen for eligibility, administer study information and obtain informed consent from the patients. The bio-data of eligible patients will be sent to independent Biostatistician in Health Information Unit of the Hospital who will be responsible for the allocation sequence and allocation concealment. Allocation sequence will be carried out to ensure that the allocation to intervention or control arm is purely by chance. This will be carried out by the independent biostatistician using computer-generated random allocation numbers for every of the 200 sampled eligible patients. At the randomization stage, there will be allocation concealment. The allocation concealment in this study is with the aim of reducing selection bias and ensure that the researcher, clinician and the patients are kept unaware of upcoming assignment. This will also be carried out by the biostatistician with the use of number code sequence in a sealed envelope. To reduce attrition and drop-out from this study, only permanent residents of Ilorin metropolis will be included in the study. Those who relocate within the metropolis will be tracked and follow up using information from contact form. The recruitment of the patients will be carried out in the clinic premises where study information sheet will be used to explain to the patients in the language they understand. Patients will be assigned with research number and their research file will be tagged with this number. Full residential address of the respondents will be documented and in addition personal mobile phone number and or family members’ phone will be obtained for tracking purposes.
5.8 Development of guidelines, SOP and training of research team

Development of guidelines and standard operating procedure (SOP) is cardinal to this study. Therefore, HBFC module guideline and SOPs for Blood pressure, height, weight and Body Mass Index (BMI) measurements at home will be developed and validated. Likewise training manuals for the nurses, supervisors and research assistants will also be developed and validated. There will be general training for all the research members at the commencement of the study. This will aim at giving the general objectives of the research, the home based care model concept, the time line, organogram and conduct during the research activities. There will also be lectures on research ethics, overlapping functions and activities and formal line of
communication. During this period, the supervisors who are Doctors will also be trained on their monitoring role and how to carry out effective supportive supervision. Subsequent training will be specific to task of research team cadres. The nurses will be trained on home based care guidelines, Follow-up treatment algorithm for hypertension, guidelines and SOP of BP measurement and anthropometric measurements. They will also be trained on CVD counseling and use of self-applied checklists. During the training, practical scenarios will be simulated and role play will be carried out. There will be a day pilot of the model and tools on field after which adjustment will be made to both the model and the nurses’ skills. The research assistants will be trained on the questionnaire administration, community entry and ethics of data collection (visual and auditory privacy). Their training process will include didactic teaching, role play, practical session and field session. They will also pretest the questionnaire for validation

5.9 Home based follow-up care intervention

The major human resource drivers for this study are nurses using task-shifting strategy. Two nurses with over 10 years working experience as clinical nurses will be recruited for this study. They will be supported by an assistant each. They will be recruited based on merit. The Nurses will be grouped into 2 teams consisting of a senior nurse, and a nurse assistant in each group. Each of the team will be randomly assigned patients to visit per week. The assistants will be graduates of health related courses. They will help with logistics and anthropometry measurements. The work schedule will be from Monday to Friday with an average of 5 patients visited per day per team. Each patients will be visited on a monthly basis, meaning that there will be a total of 6 rounds of follow-up.

After patients are randomized into the 2 arms of study and baseline assessment is done, the intervention group will be followed up at home every month for a period of 6 months (figure 5). The intervention group will be given advised to go for hospital follow-up every third month but with some discretions allowed according to managing physician assessment. The 5 cardinal components of home based follow-up care to be administered during follow-up are (figure 5);

1. Medical history and Physical examination
2. Home based Blood pressure monitoring
3. Home based Body Mass Index monitoring
4. Adherence assessment and monitoring
5. Hypertension education and counselling session (HECS)

These assessment will be rounded up by setting achievable targets with the patients from the observed medical problems and challenges. The control group will not be offered home based follow-up care (figure 5), instead they will be allowed to continue with the usual standard care at the hospital. The clinic appointment schedule and whether to offer non-medication therapy or not is at the absolute discretion of the managing physician. They will also have their baseline assessment like the intervention group. However they will be visited at home after 6 months to have the post intervention assessment administered. Daily report of activity by nurses will be submitted to the supervisor who will also be required to visit the CVD nurses on the field twice a week.
5.10 Data collection

The qualitative data for the development of the home based care intervention will consist of, Focus Group Discussion (FGD) guide to be administered on patients and In-depth Interview (IDI) guide for the health workers. These guides will give insight on hypertensive care preferences together with experiences, challenges and demand pattern by the patients and the health workers. The data collection tools especially questionnaire (quantitative study) will contain SF-36v2 psychometric tool for health related quality of life assessment (Maruish [Ed] 2011) while Morisky scale for patient adherent test (Morisky et al, 2008) will be used to assess adherence. The 2 tools are copyrighted and therefore licence will be obtained from

Figure 5: Home base follow-up care flowchart
Quality Metric Incorporated through Optum insight Life Sciences Inc. and Prof. Donald Morisky respectively. The symptoms assessment will be limited to symptom counts and prevalence. For this study, Symptom counts will be measured as number of symptoms reported by the patients during interview, out of the checklist of common symptoms observed in hypertension (Ogunlana et al, 2009). Baseline data will be collected after recruitment but before randomization while post intervention data will be collected after 6 months of home based care. Data for this study will be collected by trained research assistants who will be independent of the home based care nurses. Interviewer will administered the questionnaire and they will also take required measurements.

Questionnaire would be structured into six sections namely; Socio-demography, Medical history, symptoms count, Adherence pattern, Health related quality of life and Measurements. This will be translated and back translated to Yoruba, language. The language experts from University of Ilorin, Nigeria will be responsible for the translation and back translation of the questionnaire to local languages. The Morisky tool already have a validated Yoruba version which is copyrighted. Required fees will be paid to obtain this tool and its license. Pilot study will be carried out to validate the questionnaire. The questionnaire will also be pretested during training in another hospital. Findings from the pretesting will be used to make amendments to the final questionnaire. The SF-36v2 and Morisky scale will be adapted to local setting after carrying out face and contents validity. Internal consistency reliability using coefficient alpha index (Cronbach, alpha) will be assessed and Nunnally and Bernstein (1994) proposed reliability values of 0.70 or higher will be used as standard for reliability.

5.11 Main outcome measurements

1. Treatment effects using the HRQoL

2. Treatment effects on other intermediary outcome; Blood pressure, grade of hypertension, adherence pattern and symptoms counts

5.12 Data Analysis

Data would be analyzed using SPSS, version 22. Intention to treat (ITT) analysis concept will be employed for final analysis. By this concept, all patients in intervention are analyzed by randomized treatment assignment. This will be regardless of the noncompliance status, deviation from protocol, attrition and or any other occurrences after randomization. Descriptive analysis including calculations of means, 95% confidence intervals (CI) of means and frequencies of categorical variables will be presented. Distributions of categorical socio-demographic predictors would be compared using chi-square tests, with a downward adjustment of statistical significance for multiple comparisons. Pearson correlation coefficient between HRQoL and independent variables would be analyzed to check for the linear relationships and assumptions for further analysis. Both independent student t-test and paired t-test analysis would be used for the bivariate comparative analysis of the HRQoL mean scores of the 2 groups of patients and within each group at baseline and 6 months. Analysis of variance (ANOVA or F-test) will be used to compare means of quality of life outcomes of the independent variables with more than 2 levels like grades of hypertension, symptom counts and adherence pattern.
Hypothesis testing will be explored basically with repeated measures (paired) t-test at baseline and 6 months. The main dependent variable (continuous) will be HRQoL while the main independent variable (IV) will be intervention allocation with 2 arms/levels (HBFC vs usual). Importantly, Analysis of Covariance (ANCOVA) would be carried out when baseline HRQoL is used as a covariate. This will be a major outcome measurement for this research because the ANCOVA will interpret the effect of intervention on quality of life of patients while controlling for the baseline quality of life. To analyze for the different domain of the SF-36v2 scale, multivariate analysis model using MANOVA and MANCOVA will be explored to show strong predictors of different domains of HRQoL. Since the SF-36v2 can be converted to a categorical table of dummy table, logistic regression model will also be explore to show the predictors of HRQoL. Other variables like grade of hypertension blood pressure, comorbidity, complications, gender, socioeconomic status and age will be explored as, independent variables, possible predictors, and or covariates. The level of significant will be set at p-value of less than 0.05.

6.0 EXPECTED BENEFITS OF THE STUDY

This study will contribute to the existing knowledge on home based care program for hypertensive. It will generally give insight into the importance of HRQoL measurement in interventional studies on hypertension and other related chronic diseases. Because health workers in developing countries rely majorly on managing chronic diseases at the hospital, this study will provide a new orientation to the standard management strategy. The findings from the study will advise health managers on importance and prospects of home based care for chronic diseases in low income countries and also provide policy makers and Government with comparative evidence between home based management of hypertension and similar non-communicable diseases. Finally, the study will also be an important pilot research (intervention) upon which other home based care concepts can be built upon in developing countries.

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