UNIVERSITI PUTRA MALAYSIA

IMPACT OF HOME-BASED FOLLOW-UP CARE INTERVENTION ON HEALTH-RELATED QUALITY OF LIFE AMONG HYPERTENSIVE PATIENTS AT A TEACHING HOSPITAL IN ILORIN, NIGERIA

BOLARINWA OLADIMEJI AKEEM

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Thesis Submitted to the School of Graduate Studies, Universiti Putra Malaysia, in Fulfillment of the Requirements for the Degree of Doctor of Philosophy

November 2016

DEDICATION

This thesis is dedicated to Almighty Allah, the most beneficent and the most merciful. To *"Idy"* for your prayers, dedication, motivation and unconditional love. Ultimately, for keeping the boys on check whenever 'am away and keeping home and businesses running effectively and excellently in my absence. And to my boys; 'Segun, 'Siji and 'Semi, for not given too much of headaches. Love you guys to the moon!

Abstract of thesis presented to the Senate of Universiti Putra Malaysia in fulfillment of the requirement for the degree of Doctor of Philosophy

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Chairman : Assoc. Prof. Muhamad Hanafiah Bin Juni. MD, MPH, MSc
Faculty : Medicine and Health Sciences

Introduction: The usual care for hypertension within hospital settings in Nigeria is characterized by poor medical outcomes and poor health related quality of life (HRQoL). Of those few studies that have implement home based interventions on hypertension, not many of them used HRQoL as an outcome measure. This study developed, implemented and assessed the impact of home based follow-up care on HRQoL of hypertensive patients attending outpatients' clinics in Ilorin, Nigeria.

Methodology: An individual open (un-blinded) Randomized Controlled Trial (RCT) was conducted among 229 consented hypertensive patients in two outpatients' clinics of University of Ilorin Teaching Hospital, Ilorin, Nigeria using systematic random sampling. A total of 149 and 150 patients were randomly allocated to intervention and control groups respectively. The intervention was a six month task-shifting (Nurse driven) home based follow-up care. The primary outcome measurement was HRQoL. Data was collected with the use of pretested questionnaire that contained validated SF36v2 and MMAS-8 tools for the assessment of HRQoL and medication adherence respectively. Data was analyzed with intention-to-treat principle. The SPSS version 22 software was used for analysis and both descriptive and inferential statistics were presented. Treatment effects were measured with the t-tests, ANCOVA and MANCOVA analysis. Significant levels were set at p-value of <0.05 and 95% Confidence Interval (CI).

Results: A total of 29 and 31 patients dropped out of intervention and control groups respectively, making a combined attrition rate of 20.1% in this study. At baseline only general health (50.44) and vitality (52.68) of the 8 subscales of HRQoL had better score than the reference population average of 50.00 ($\pm$10). Both physical and mental components of the HRQoL were below population average. The between group treatment effect was not statistically significant ($p>0.05$) while within group treatments effects were statistically significant for both intervention and control arms

($p<0.05$). After controlling for age and baseline HRQoL, intervention group had improved physical component of HRQoL than the control group. The intervention group also had statistically significant improvement in blood pressure control, medication adherence and symptom counts ($p<0.05$).

Conclusion: The home based follow-up care intervention by this study was shown to impact positively on physical component of HRQoL after controlling for baseline HRQoL and age of the patients. Symptom count, medication adherence and blood pressure control were positively impacted upon by the home based follow-up intervention.

Keywords: Hypertension, quality of life, randomized control trial, home based care, Ilorin.

Abstrak tesis yang dikemukakan kepada Senat Universiti Putra Malaysia sebagai memenuhi keperluan untuk ijazah Doktor Falsafah

IMPAK INTERVENSI PENJAGAAN RAWATAN SUSULAN DI RUMAH KE ATAS KUALITI HIDUP BERKAITAN KESIHATAN BAGI PESAKIT HIPERTENSI MENGUNJUNGI HOSPITAL PENGAJARAN DI ILORIN, NIGERIA

Oleh

OBOLARINWA OLADIMEJI AKEEM

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Pengerusi : Profesor Madya Muhamad Hanafiah Bin Juni. MD, MPH, MSc
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Pengenalan: Penjagaan biasa bagi hipertensi dalam lingkungan persekitaran hospital di Nigeria dicirikan oleh hasil perubatan yang lemah dan kesihatan tidak baik yang berkaitan dengan kualiti hidup (HRQoL). Beberapa kajian yang cuba untuk mengimplementasikan intervensi berdasarkan rumah, tidak banyak kajian yang menggunakan HRQoL sebagai ukuran hasil. Kajian ini, oleh sebab itu, memperkembangkan, mengimplementasikan, dan menilai impak penjagaan rawatan susulan berdasarkan rumah terhadap HRQoL bagi pesakit hipertensi yang mengunjungi klinik pesakit luar di Ilorin, Nigeria.

Metodologi: Trial Terkawal Terawak (RCT) terbuka individu (un-blinded) telah dijalankan dalam kalangan 229 pesakit hipertensi yang bersetuju di dua buah klinik pesakit luar Universiti Hospital Pengajaran Ilorin, Ilorin, Nigeria menggunakan persampelan rawak sistematik. Sebanyak 149 dan 150 pesakit telah dipilih secara rawak, masing-masing merupakan kumpulan intervensi dan kawalan. Intervensi tersebut merupakan 6 bulan penjagaan rawatan susulan berdasarkan pertukaran tugas (berpacukan jururawat) rumah. Pengukuran hasil utama ialah HRQoL. Data telah dikumpul dengan menggunakan soal selidik praujian yang masing-masing mengandungi SF36v2 yang telah divalidasikan dan alat 8 MMAS bagi penilaian HRQoL dan kepatuhan medikasi . Data telah dianalisis menggunakan prinsip niat untuk merawat. Perisian SPSS versi 22 telah digunakan untuk analisis dan kedua-dua statistik deskriptif dan inferensial telah dkemukakan. Kesan rawatan telah diukur dengan ujian t dan analisis ANKOVA dan MANKOVA. Tahap signifikan telah disetkan pada nilai $p<0.05$ dan 95% Interval Keyakinan (CI).

Dapatan kajian: Keseluruhan 29 dan 31 pesakit, masing-masing berhenti daripada kumpulan intervensi dan kawalan, menjadikan kadar keciciran digabungkan sebanyak 20.1% dalam kajian ini. Pada peringkat dasar, hanya kesihatan umum (50.44) dan vitaliti (52.68) bagi 8 subskala HRQoL mempunyai skor yang lebih baik daripada purata populasi rujukan 50.00 ($\pm$10). Kedua-dua komponen fizikal dan mental HRQoL adalah di bawah purata populasi. Kesan rawatan antara kumpulan didapati tidak signifikan secara statistik ($p>0.05$), manakala kesan rawatan dalam kumpulan adalah signifikan secara statistik bagi kedua-dua intervensi dan pemegang kawalan ($p<0.05$). Selepas kawalan bagi umur dan HRQoL dasar, kumpulan intervensi telah memperbaiki komponen fizikal HRQoL daripada kumpulan kawalan. Kumpulan intervensi juga mempunyai peningkatan yang signifikan secara statistik dari segi kawalan tekanan darah, kepatuhan medikasi dan kiraan simptom ($p<0.05$).

kesimpulan: Intervensi penjagaan rawatan susulan berdasarkan rumah dalam kajian ini telah menunjukkan untuk memberikan impak yang positif terhadap komponen fizikal HRQoL selepas kawalan bagi HRQoL dasar dan umur pesakit. Komponen mental HRQoL didapati tidak memberikan kesan oleh intervensi. Kiraan simptom, kepatuhan medikasi dan kawalan tekanan darah didapati mempunyai impak yang positif melalui intervensi rawatan susulan berdasarkan rumah.

Kata kunci: Hipertensi, kualiti hidup, trial kawalan terawak, penjagaan berdasarkan rumah. Ilorin.

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This is to confirm that:

- the research conducted and the writing of this thesis was under our supervision;
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LIST OF ABBREVIATIONS

ANCOVA	Analysis of Covariance
ANOVA	Analysis of Variance
BMI	Body Mass Index
BP	Bodily Pain
CHF	Congestive Heart Failure
CI	Confidence Interval
CONSORT	Consolidated Standards of Reporting Trials
CRF	Clinical Report Form
CVD	Cardiovascular Disease
GOPD	General Out-patients Department
GEE	Generalized Estimating Equation
GH	General Health
HBFC	Home Based Follow-up Care
HBI	Home Based Intervention
HBP	High Blood Pressure
HECS	Health Education and Counseling Session
HRQoL	Health Related Quality of Life
ITT	Intention-to-treat
JNC	Joint National Committee
LMIC	Low and Middle Income Countries
MANCOVA	Multivariate Analysis of Covariance
MCS	Mental Component Summary
MH	Mental Health
MI	Myocardial Infarction
MLS	Multiple Linear Regression
MMAS-8	Morisky Medication Adherence Scale - 8 item
MOPD	Medical Outpatients Department
NCDs	Non-Communicable Diseases
PCS	Physical Component Summary
PF	Physical Functioning
PP	Per protocol
PRISMA	Preferred Reporting Items for Systematic Reviews and Meta-Analyses

QOL	Quality of Life
RAs	Research Assistants
RCT	Randomized Controlled Trials
RE	Role Emotional
RP	Role Physical
SF	Social Functioning
SF-36v2	Short Form 36-item version 2 for health related quality of life measure
SLR	Simple Linear Regression
SOP	Standard Operation Procedure
SPSS	Statistical Package for Social Sciences
TOD	Target Organ Damage
UITH	University of Ilorin Teaching Hospital
UPM	Universiti Putra Malaysia
US	United State
VT	Vitality
WHO	World Health Organization

CHAPTER 1

INTRODUCTION

1.1 Background of the Study

Hypertension or high blood pressure (BP) is a chronic condition in which the systemic arterial blood pressure is elevated. The Report of the Panel appointed to the Eighth Joint National Committee (JNC-8) on Guidelines for the Management of Hypertension in adults (James et al. 2014) and the previous Seventh JNC (JNC-7) (Chobanian et al. 2003) defined hypertension as a mean systolic blood pressure (SBP) of 140 mmHg and above occurring concurrently with or as an isolated mean diastolic blood pressure (DBP) of 90 mmHg and above. Someone could also be said to be hypertensive if in addition to earlier stated conditions or as an isolated case, made a self-report of a medical diagnosis of hypertension (or being on current treatment for hypertension with prescription antihypertensive medication) (James et al. 2014; Erhun, Olayiwola, Agbani, & Omotoso, 2005). There is a continuous, consistent, and independent relationship between elevated BP and risk of cardiovascular events (Lewington, Clarke, Qizilbash, Peto, and Collins, 2002). Studies have shown that the higher the BP, the greater is the chance of heart attack, heart failure, stroke, and kidney diseases (James et al. 2014). These are continuous and irreversible damages to the body organs called target organ damage (TOD), making hypertension one of the leading causes of morbidity, mortality and disability (Nelissen et al.2014).

Hypertension affects all age groups and has been reported in all countries of the world, though with varying prevalence. In the past years, it was thought to be rare in rural Africa, but hypertension and its complications, including stroke, heart failure, and renal failure, have been reported amongst African races all over the world (Cappuccio et al. 2004). Particularly, it is on the increase in sub-Saharan Africa and it has been projected to increase tremendously over the next decades with increase in morbidity, mortality and disability (Echouffo-Tcheugui, Kengne, Erqou, & Cooper, 2015; Hendriks et al. 2012). Hypertension is now widely reported in both rural and urban settings of Africa (Hendriks et al. 2011) and is the most common cause of cardiovascular disease on the continent (Erhun et al.2005). However in Nigeria, though the burden of communicable (infectious) diseases remains persistently high, non-communicable diseases like hypertension are likewise on the increase. This trend is assuming both epidemiological and demographic transitions and experts have termed these trends as “double tragedy” situation for the country (van de Vijver et al.2013).

Assessing from the aforementioned reasons, coverage of hypertensive healthcare services have been inadequate in a low resource country like Nigeria. For instance, a study in Nigeria reported that up to three-quarters of hypertensive patients were not on treatment even when treatment was indicated in almost half of them (Nelissen et al. 2014). Additionally, poor medical outcomes have been recorded among the

hypertensive patients in Nigeria by researchers (Nelissen et al. 2014; Ike & Onwubere 2003). Consequently, poor quality of life was shown to be a major impact of these poor medical/clinical outcomes amongst patients with hypertension in Nigeria (Ogunlana, Adedokun, Dairo, & Odunaiya, 2009).

Just like it is important in all forms of chronic illnesses to maintain optimum state of wellbeing, there is need to maintain improved quality of life among hypertensive patients. World Health Organization (WHO), defines quality of life as "individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns" (WHOQOL Group, 1998). One of the most important goals of all health interventions or programme is to improve the quality of life of persons affected by disease. In the domain of physical health and illness, quality of life refers to person's self-evaluation of health or to their perceived functional status and well-being (Wandell, 2005). This simply means the degree to which a person enjoys the important possibilities of his life (Odili, Ugboka, & Oparah, 2010). Other definitions as given by many authors corroborated the above definitions (Issa & Bayewu 2006; Von Steinbuchel, Lishetzke, Gurny. & Eid, 2006; WHOQOL GROUP, 1998). The different definitions of quality of life stem from the multi-disciplinary use of the term.

1.2 Problem Statement

The prevalence of hypertension in Nigeria has increased from an initial prevalence of 8.8% in 1960s to the current prevalence of between 16% and 46% (Akinlua, Meakin, Umar, & Freemantle, 2015; Ogah et al. 2012; Hendriks et al., 2011; Ofuya, 2007; Chobanian et al. 2003). World Health Organization (WHO, 2011) reported an age-standardized prevalence of 49% for the country thereby buttressing the huge burden of hypertension in Nigeria. In addition, Target Organ damage (TOD) due to hypertension is seemingly becoming a huge public health problem in Nigeria (Nelissen et al. 2014; Kolo et al, 2012). High prevalence of TOD of over 30% has been reported among Nigerian population (Nelissen et al, 2014). In this study, an increased odd of developing cardiovascular complication among the hypertensive patients was shown with a direct and linear association with increase in hypertension severity (Nelissen et al, 2014). The implication of the increasing hypertension in Nigerian population is that it is presently overwhelming the health system, reducing the quality of care, increasing the cardiovascular diseases (CVDs) and mortality attributable to both hypertension and CVDs (Kolo et al, 2012; Onwuchekw & Chinenye, 2010; Ukoh, 2007).

Studies in Nigeria have described interrelated challenges to hypertension care. Currently, the care of hypertensive patients takes place almost entirely in health facilities thereby reducing the access to care (van de Vijver et al, 2013; Hendriks et al. 2014a; Suleiman, Sulaiman, & Albarq, 2009). More studies (Oguanobi et al, 2013; Kolo et al, 2012; Onwuchekwa & Chinenye, 2010; Ukoh, 2007) have shown that hypertension consistently contributes over 20% of total hospital utilization quota in Nigeria thereby overwhelming the health facilities, increasing the workload of the

few highly skilled personnel and reducing the overall quality of care. Despite the high quota of healthcare utilization attributable to hypertension, up to three-quarters of hypertensive patients are still not on treatment in the general Nigerian population even when treatment was indicated in almost half of these numbers (Nelissen et al, 2014). Because of the chronic nature of hypertension, patients suffering from it are expected to be seen on a regular basis by the health worker for check-up in what is termed "follow-up visits". Interestingly, while the service coverage for hypertension is observed to be inadequate, studies in Nigeria have shown high default rate among hypertensive patients attending clinics for follow-up visits. Over 40% default rate had been reported among hypertensive patients by their third follow-up visit (Ike, Anisiuba, Onwubere & Ikeh, 2003). This was shown to be high among patients of 40 years and beyond and those on multiple antihypertensive drugs.

In addition, factors responsible for high default rate among hypertensive patients in Nigeria have been identified. Part of which were high costs of antihypertensive drugs (Osibogun & Okwor, 2014; Hendriks et al, 2014b; Ilesanmi, Ige, & Adebiyi, 2012) and inconvenient clinic operating hours coupled with long waiting hours (Odusola et al, 2014). Aside these factors, there are also indirect costs which constitute those expenditures incurred by the patients in terms of loss man hour as a result of hospital visits, transportation cost which may include accompanying relatives and other costs due to bureaucracy within hospital setting (Ilesanmi et al, 2012). These constitute impediments to healthcare, as a result of financial inaccessibility to healthcare. Poor adherence to treatment has also been a major contributory factor to clinical outcome among hypertensive patients in Nigeria. Drug compliant study (Kabir, Iliyasu, Abubakar, & Jibril, 2004) has shown that up to a quarter of non-adherent patients and patients with low monthly income will miss their hospital follow up. Recommendations has been to further research into health system strengthening, cost reduction strategies and task shifting strategies on hypertension management in Nigeria (Odusola et al, 2014; Hendriks et al, 2014b; Adeyemo et al, 2013; Ilesanmi et al, 2012;).

The direct resultant consequences of inadequate management and poor clinical outcome of hypertension will be a reduced quality of life (Cleary, 2004; Ferrans, Zerwic, Wilbur, & Larson, 2005). Lower quality of life has been reported among hypertensive patients with poor clinical variables and outcomes (Ogunlana et al, 2009). Assessment of quality of life of hypertensive patients is not common in the clinical practice and research and this may be responsible for the dearth of HRQoL studies in the Nigeria. Quality of life assessment is becoming important to the clinicians and researchers because it is the perception and feeling of the patient about his illness and other determinants of the course of his illness which may not be appreciated within the purview of medical assessments only.

1.3 Significance of the Study

The current reality is that the management of hypertension remains entirely hospital based while adherence, clinical outcomes and quality of life remain sub-optimal among hypertensive patients (Ogunlana et al, 2009). In addition, social support which has been shown to assist patients with hypertension to have better clinical outcome (Osamor, 2015) will not be achievable with hospital management alone. Therefore 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. Additionally, there is need to re-align and simplify the management strategies of hypertension, reduce the hospital bureaucracy, bring the health care services closer to the patients in the community to garner social support for their treatment and allow task shifting practice (by allowing other health care professionals to participate more in the care of chronic diseases in a multidisciplinary approach). Such approach has been adjudged to be feasible in a home or community settings (Ogedegbe et al, 2014; Brust et al, 2012; Shah et al, 2012; Thiam et al, 2012).

In terms of clinical outcome assessment of patients, home based care management concept (which is adopted for this study) is becoming popular in medical science because of the need to increase access to medical care, reduce the health facilities work load, simplify disease management strategies, reduce the cost of managing diseases and remove other deterrents to treatment adherence (Ogedegbe and Schoenthaler. 2006; Ogedegbe et al, 2014). It has proven to be an effective strategy to reduce accessibility and affordability to quality health care in developing countries 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).

In chronic conditions such as hypertension, HRQoL is an especially important outcome, given their lifelong (chronicity) nature and the need for daily self-management (Poljičanin et al, 2010). Though many studies have implemented intervention studies on hypertension, almost all of them evaluated their studies using medical/clinical outcomes assessment like blood pressure control and TOD (Bernochi et al, 2014; Bosworth et al, 2011; Magid et al, 2009; Staessen et al, 2004; Anderson et al, 2000). Specifically, hypertension interventional studies that adopted HRQoL to assess patient's outcome are very sparse (Aghajani et al, 2013; Saleem et al, 2013; Wal et al, 2013). So far in the literature, no intervention studies on hypertension were sighted in the study area, (Ilorin, Nigeria) that used HRQoL to evaluate study outcome.

1.4 Research Question

1. Is it feasible to carry out home based follow-up care intervention among patients with hypertension in Ilorin, Nigeria
2. What are the observed mean differences in HRQoL outcomes of hypertensive patients followed up at home and those on usual hospital follow-up after 6 months of implementation?

1.5 General Objective

To develop, implement and determine the impact of home based follow-up care intervention on the health related quality of life of hypertensive patients in Ilorin, Nigeria.

Specific Objectives

1. To identify the predictors (obesity, symptoms, stage of hypertension, adherence and medical history) of baseline HRQoL of life of hypertensive patients in Ilorin, Nigeria.
2. To explore (using qualitative methods and literature search) factors suitable and appropriate for the development and successful implementation of home based follow-up care framework among hypertensive patients in Nigeria.
3. To develop and implement a home based follow-up care program for hypertensive patients in Nigeria.
4. To determine the pattern of baseline HRQoL of hypertensive patients in Ilorin, Nigeria.
5. To compare mean HRQoL of hypertensive patients on home based follow-up intervention as against those on usual hospital based follow-up (between and within groups) after 6 months of intervention.
6. To assess the effect of home based care on other intermediate clinical outcomes like BP, symptoms count, BMI and medication adherence.

1.6 Research Null Hypothesis

Ho = There is no significant difference between the HRQoL of patients followed up at home and those followed up at the hospital after 6 months of intervention

Ho = There is no significant difference between the HRQoL of patients followed up at home and those followed up at the hospital after controlling for baseline HRQoL

1.7 Main Outcome Measures

1. Primary outcome measurements. This is mainly health related quality of life (HRQoL) of hypertensive patients. Included scales and component summary scores
2. Intermediate outcome measurements. These are symptoms and clinical outcome measurements that precede and predict HRQoL. These are; blood pressure (BP), body mass index (BMI), medication adherence and symptom counts.
3. Predictors of HRQoL of hypertensive patients; socio-demography, disease history, access to care and clinical profile.
4. Differences in HRQoL of control group at the baseline and post intervention = mean difference in control group (within group effect)
5. Differences in HRQoL between intervention group and usual (control) group at post intervention = treatment effect (between group effect)

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