The effect of a lifestyle modification adherence tool on risk factors in patients with chronic hypertension compared to usual management

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This dissertation is submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in fulfilment of the requirements for the degree of Master of Science in Physiotherapy

Declaration

I, Janine Webber, declare that this dissertation is my own work. It is being submitted for the degree of Masters of Science in Physiotherapy at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at this or any other university.

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<u>Abstract</u>

Background

Poor adherence to lifestyle interventions and medication-taking poses a problem universally. However, there are interventions to help patients adhere to treatment regimens and in turn, lower the risk of cardiovascular disease by decreasing blood pressure. These interventions need to be investigated further. Change in risk factors as a result of a lifestyle modification adherence tool in patients with chronic hypertension is not clear and will be further investigated in this study.

Aim

To determine the effect of a lifestyle modification adherence tool in patients with chronic hypertension and compare this with usual management.

Objectives

- 1. To compare the changes in:
- Blood pressure
- Waist-hip ratio
- Weight and body mass index
- Blood glucose, cholesterol, triglycerides, HDL and LDL levels
- Exercise Capacity

between two experimental and one control group at baseline and after a six month intervention using a lifestyle modification tool

2. To determine the sustainability of the intervention three months after the intervention is concluded.

Design

The study design was a quantitative, longitudinal randomized control trial consisting of two experimental and one control group.

Method

Ninety subjects at the hypertension clinic at Helen Joseph Hospital were sampled consecutively and then randomized using computer generated randomization and concealed allocation.

The study consisted of three groups, two experimental and one control group.

All three groups underwent the usual treatment in the Hypertension Clinic. Experimental group one (EG1) received the Lifestyle Modification Adherence Tool (LMAT) as well as a once-a-month telephone call from the research assistant. Experimental group two (EG2) received only a once-a-month telephone call from the research assistant. The control group (CG) received the standard treatment at the clinic.

The significance of the study was set at p=0.05. A Students t-test (independent) was used to compare variables between groups at baseline. The Pearsons Chi Square test was used to compare and analyze non parametric data at baseline.

Change in blood pressure, waist-hip ratio, weight and body mass index, glucose levels and exercise capacity between control and intervention groups was established using an ANCOVA.

Pairwise t-tests were used to compare p-values between groups one and two; one and three and; two and three.

Results

No reductions in weight and body mass index (BMI) were observed. Significant differences in EG1 for waist/hip ratios were noted compared with the EG2 (p=0.04) and CG (p=0.04) between month 0 and month 6. Blood pressure reductions were greater in EG1 compared with EG2 and the CG at six months but greater drops in blood pressure were noted in EG2 compared with EG1 and the CG between six and nine months. However, these differences were not significant. Significant reductions were observed in blood glucose levels in the EG1 compared with EG2 group between month 6 and month 9 (p=0.05). There were also significant reductions in the EG2 in triglycerides and low density lipoprotein (LDL) between month 0 and month 6 compared with the CG (p=0.04 and p=0.03 consecutively) and significant LDL reductions in both EG1 and EG2 between month 6 and month 9 compared with the CG (p=0.02 for both comparisons). Walking distances improved minimally in both EG1 and EG2 but these changes were not significant.

Conclusion

Although not all results were significant, diary and telephone interventions and telephone only intervention to improve adherence did show a positive trend towards improvements in risk factors of patients with chronic hypertension.

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Abbreviations

WHO	World Health Organisation
CVD	Cardiovascular Disease
GDoH	Gauteng Department of Health
JNC-7	Seventh report of the Joint National Committee
JNHGWG	Joint National Hypertension Guideline Working Group
TOD	Target Organ Damage
BMI	Body Mass Index
DASH	Dietary Approaches to Stop Hypertension
SMS	Short Message Service
SDM	Shared Decision Making
PDA	Personal Digital Assistant
PLC	Patient Learning Centre
LMAT	Lifestyle Modification Adherence Tool
ANCOVA	Analysis of Co-Variance
HDL	High Density Lipoprotein
LDL	Low Density Lipoprotein
EG1	Experimental Group 1
EG2	Experimental Group 2
CG	Control Group
SBP	Systolic Blood Pressure
DBP	Diastolic Blood Pressure

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Chapter 1 – Introduction

The management of hypertension has been widely researched throughout the world, especially in the last decade. Many studies have shown ways to best prevent and reduce the complications of untreated hypertension (JNC-7, 2003, JNHGWG, 2006, Leenen et al, 2010, Appel et al, 2003, Ramsay et al, 1999 and Alhuwalia et al, 1997). According to Miller et al (2002), hypertension, as a risk factor, is commonly associated with cardiovascular disease.

In South Africa, a report by Professor Krisela Steyn (Department of Medicine, University of Cape Town) states that an average of 195 people died due to cardiovascular disease every day between 1997 and 2004, and that this figure is estimated to increase by 41% in 35 – 64 year old people (working age) between 2007 and 2030 (Steyn, 2007). Direct and indirect costs for cardiovascular disease and stroke are eight billion rand per annum (Mbewu, 2007). Professor Mbewu also states that 80% of heart disease and stroke is preventable by adhering to healthy habits such as good diet, exercise and not smoking (www.medical.bizcommunity.com). In many South African hospitals hypertension management guidelines are not adhered to resulting in poor blood pressure control (Stewart et al, 2005, Daniels et al, 2000 and Kalk et al, 2000). In order to see effective changes in the management of patients with hypertension, we must find a way to enhance adherence to well researched regimens.

Despite a large number of studies on patient adherence conducted during the past two and a half decades, the dilemma of adherence to hypertension regimens persists (Jokisalo et al, 2002). Studies show that adherence to lifestyle modifications and medication-taking in patients with chronic hypertension is problematic (Stewart et al, 2005, Gohar et al, 2008). Patient adherence is more than just adherence to medication prescription. It can also include failure to keep appointments, exercise, adherence to recommended dietary or other lifestyle changes or other preventive health practices (Miller et al, 2002).

The norm for adherence rates is about 50% for medications and is much lower for regimens that require lifestyle changes or changes in behaviour (Haynes et al, 2002). This leads to progressive disease and poor prognoses and therefore has implications for quality of life, lifespan and economic inefficiency (Neuhouser et al, 2002).

There are many reasons for non-adherence to preventive and therapeutic lifestyle recommendations among patients at high risk of cardiovascular disease. Patients' main reasons for not adhering to lifestyle recommendations are unwillingness, difficulty adhering to diets different from the rest of the family, lack of time for exercise, other illnesses and unfavourable weather conditions (Serour et al, 2007).

Two lifestyle factors shown to effectively reduce blood pressure include exercise and diet (Miller et al, 2002). For example, there is much evidence showing that the risk of long term disease and co-morbid conditions will decrease when adhering to nutritional recommendations (e.g., low fat, high fruit and vegetable diet) provided that the disease or condition is modifiable by diet (Krauss et al, 2000). Forty two percent of all adults in a nationally conducted study who reported a history of diabetes, cardiovascular disease, dyslipidemia or hypertension had poor diets and were not exercising regularly (Neuhouser et al, 2002).

Communication is very important in assisting patients to adhere to treatment regimens. Information about hypertension and the treatment thereof determines patient motivation and understanding. This gives the patient purpose and helps them to see the importance of adherence to treatment (Jokisalo et al, 2002).

There are very few studies demonstrating effective long-term adherence to medications and behaviour change. Therefore, new strategies are needed to identify successful methods to help patients adopt and maintain healthy practices (Munro et al 2007, Atreja et al 2005 and Haynes et al, 2002).

Methods to implement and sustain adherence must ensure that patients' overestimation of adherence does not occur. Reasons for overestimation can include patients' difficulty with remembering the details of when and how to take medication and also that they prefer to please practitioners and therefore want to avoid confrontation with health workers (Haynes et al, 2002).

Treatment regimens that are very complex will affect adherence and must be kept as simple and clear as possible if adherence is likely to be achieved. It is important to remind patients of their appointments by phoning patients who have missed appointments to ensure optimal follow-up and re-iterating the importance of adherence every time patients visit an institution. Health care professionals must use these methods to monitor adherence to treatment regimens as they improve effectiveness, practicality and efficiency of patient care. It may also be important to get the family involved for extra support, if the patient consents to this (Miller et al, 2002 and Stewart et al, 2005). Heneghan et al (2006) also emphasized how reminder packing of medications is a simple and effective way of improving adherence to treatment regimens. Therefore, for both lifestyle modification and medication-taking, regimens should be practical and fit in with the patient's normal daily activities (Miller et al 2002).

There are minimal studies on sustaining lifestyle modification behaviours, indicating a great need for further research in this area (Moore et al, 2008). It is important to note that if patients see their adherence to regimes is time- and money-saving and is largely beneficial, this may help sustain adherence and improve prolonged lifestyle modification (Brunenberg et al, 2007).

In conclusion, health care professionals often underestimate the problem of nonadherence in their patients. If a healthcare professional is unable to detect nonadherence, it is impossible for him or her to correct the problem. Measurement of adherence is an important part of assessing the effectiveness of interventions (Miller et al, 2002). From previous studies, we already know that for hypertensive overweight adults already on antihypertensive medication, a comprehensive lifestyle intervention can substantially lower blood pressure and improve blood pressure control (Heneghan et al, 2006). However, as mentioned above, further research is necessary to develop methods to help patients adopt and maintain these lifestyle interventions.

Problem Statement

Poor adherence to lifestyle interventions and medication-taking poses a problem universally. However, there are interventions to help patients adhere to treatment regimens and in turn, lower the risk of cardiovascular disease by decreasing blood pressure. These interventions need to be investigated further. Change in risk factors as a result of a lifestyle modification adherence tool in patients with chronic hypertension is not clear and will be further investigated in this study.

Question

What is the effect of a lifestyle modification adherence tool on risk factors in patients with chronic hypertension compared to usual management?

Aim

To determine the effect of a lifestyle modification adherence tool in patients with chronic hypertension and compare this with usual management.

Objectives

1. To compare the changes in:

- Blood pressure
- Waist-hip ratio
- Weight and body mass index
- Blood glucose, cholesterol, triglycerides, high density lipoprotein (HDL) and low density lipoprotein (LDL) levels
- Exercise Capacity

between two experimental and one control group at baseline and after a six month intervention using a lifestyle modification tool 2. To determine the sustainability of the intervention three months after the intervention is concluded.

Hypothesis Statement

- H₀: There will be no change in risk factors as a result of this intervention.
- H₁: There will be a change in risk factors as a result of this intervention.

<u>Chapter 2 – Literature review</u>

2.1 Introduction

This review includes an understanding of adherence and how we can improve adherence to hypertension regimens. This is achieved by first discussing the prevalence of hypertension both internationally and locally; gaining an understanding of how it is presently controlled and discussing which factors affect the adherence to such regimens.

2.2 Epidemiology

2.2.1 Definition of hypertension

Hypertension is defined according to the World Health Organization-International Society for Hypertension as being a blood pressure greater than or equal to 140/90mmHg (Guidelines Subcommittee, 1999). The South African Hypertension Guideline 2003 update (Milne and Pinkney Atkinson, 2004) describes that changing the definition of hypertension from 165/95mmHg to 140/90mmHg has resulted in another three million individuals being added to the hypertension population and that this has huge consequences regarding the available resources for hypertension care in South Africa (WHO, 2005). The South African Hypertension Guidelines 2006 use the internationally accepted definition of hypertension as a blood pressure greater than or equal to 140/90mmHg (JNHGWG, 2006)

2.2.2 Global statistics

Universally, hypertension causes approximately 7.1 million deaths per annum and its prevalence is 950 million people globally (Lawes et al, 2004 and Seedat, 2007). It was estimated that by 2010, 1.2 billion people would be suffering with hypertension worldwide (WHO, 2005).

Hypertension is associated with cardiovascular disease (CVD) which, according to WHO (2005), is the world's number one cause of death for 17 million people each year. Globally, 60% of CVD load and approximately 50% of coronary heart disease is due to hypertension (Seedat, 2007). Overweight and obesity also contribute as risk factors and according to WHO (2005), 1.6 billion people are overweight and 400 million adults are obese globally (risk factors will be discussed in section 2.3). WHO (2005) also states that this is due to factors such as globalization, urbanization and population ageing as well as poverty and stress (also discussed later).

2.2.3 Sub-Saharan statistics

Hypertensive induced morbidity and mortality is increasing in sub-Saharan Africa. In 2000, hypertension in Sub-Saharan Africa accounted for 41.6 million males and 38.2 million females (Seedat, 2007). In sub-Saharan Africa, blood pressure control and prevention is largely hindered by lack of resources, economic pressure, poor healthcare systems, inaccessibility to appropriate medications and unhealthy behaviours (Seedat, 2007). Implementation of appropriate lifestyle interventions and cost-effective methods of providing quality care and resources to impoverished and under-developed areas will help in attaining better blood pressure control for patients with hypertension (Mensah,

2008) as long term drug therapy is not affordable for every hypertensive patient (Seedat, 2007).

2.2.4 South African statistics

The Demographic and Health Survey on Hypertension in South African adults by Steyn et al. (2001) shows that 21% of South Africans are hypertensive (Rayner and Schoeman, 2009 and Steyn et al, 2001). Data received from registers in Gauteng's four largest hospitals showed that hypertension is the sixth most frequently diagnosed condition. Although this information was only taken from four hospitals, it is also important to state that hypertension is often "under-diagnosed and under-reported" (GDoH, 2007). This report also states that, in Gauteng, hypertensive heart disease is the 17th single cause of mortality in males and the eighth single cause of mortality in females (GDoH, 2007). Steyn et al (2001) state that the proportion of patients with hypertension who are receiving treatment and controlling their hypertension is 67%. This figure may not be

accurate though, as only patients producing medicine containers were counted as receiving treatment which exaggerates their level of control. It is important to find ways to treat this major problem in South Africa through lifestyle modification and other non-pharmacological and cost-effective ways in order to decrease morbidity and mortality resulting from ineffective treatment of hypertension (Steyn et al, 2001). A study by Steyn et al (2008) determined which specific groups of people are at higher risk for hypertension and poor blood pressure control in South Africa (discussed below).

2.2.4.1 Gender statistics

Hypertension rates in men and women are 20.9% and 21.2% respectively (age-adjusted rates to South African population). It was also shown that women were more aware of their condition than men, and a higher percentage of women than men were being treated with antihypertensive medications. Women were also shown to control their blood pressure better than men (Steyn et al, 2001). Men who are 45 years and younger are poorly aware of hypertension control and treatment and they seldom attend health institutions (Steyn et al, 2001).

2.2.4.2 Rural vs. Westernization statistics

Steyn et al (2001) state that almost 50% of the population in 2001 was rural but with westernization of the black population, hypertension prevalence rates are expected to increase with time.

Rural black people have a lower prevalence of hypertension compared to urban black people (Steyn et al 2008, 1991 and Seedat, 2009, 2007, 1982). This is due to westernization of black people which was seen first and more often in men as women were confined to rural areas for much longer. Rural black men were therefore exposed to urban areas earlier resulting in them adopting poor eating habits and becoming less physically active. Therefore western lifestyle habits have been shown to predispose the black population to hypertension (Steyn et al 2008, 1991 and Seedat, 2009, 2007, 1982). In a study on a Zulu population a higher prevalence of hypertension was found in urban as opposed to rural Zulus. This may be due to urban Zulus being more exposed to factors commonly associated with hypertension such as poorer and more stressful lifestyles (many children to support and unfavourable working environments) and habits such as smoking and alcohol consumption (Seedat 2009, 2007, 1982).

2.2.4.3 Poverty vs. wealth statistics

Wealthier groups have a higher prevalence of hypertension but are able to control it better than poorer groups with hypertension (Steyn et al, 2008). The literature also shows that in populations which are disadvantaged, the prevalence of hypertension and cardiovascular disease is higher (Ahluwalia et al, 1997 and Seedat, 2007). Over 80% of CVD deaths worldwide have occurred in middle to low income countries (Seedat, 2007). In South Africa, high unemployment rates are linked with poverty, lack of education, stress, family difficulties and obesity (Stewart et al, 2005). Higher education is associated with lower prevalence of hypertension (Steyn et al, 2008). It is also noted that patients with hypertension on medical aids are more likely to control blood pressure better than those who are utilizing public services. This may not necessarily be due to poor adherence but largely due to the lack of appropriate service delivery to these patients (Steyn et al, 2008).

2.2.4.4 Age statistics

Older groups are more adherent in controlling blood pressure and taking medications regularly than younger groups. This is of great concern as younger individuals exposed to hypertension for longer develop associated complications such as eye and kidney damage amongst other complications (Steyn et al, 2008).

The burden of hypertension not only in our country but around the globe brings us to question why it is so highly prevalent and difficult to control. It is therefore important to discuss factors affecting the control of high blood pressure.

2.3 The risk factors for the development of hypertension and CVD

Lifestyle modification becomes an important treatment alternative where the risk of developing hypertension is lower or even in conjunction with antihypertensive medication. A recent study by Murray et al (2003) highlights the importance of lifestyle and drug therapy in lowering the risk of CVD by as much as 50% in both developed and underdeveloped regions.

Lack of physical activity, obesity, excessive alcohol consumption and an incorrect diet (high sodium and fat content) contribute to hypertension and CVD (JNC-7, 2003, JNHGWG, 2006, Appel et al, 2003, Ramsay et al, 1999 and Steyn, 2008).

Some of the major risk factors for hypertension include:

2.3.1 Smoking

Smoking is a major risk factor in the development of cardiovascular disease and development of hypertension (JNHGWG, 2006).

2.3.2 Dyslipidaemia

Total cholesterol greater than 6.5mmol/l; low density lipoprotein greater than 4mmol/l or; high density lipoprotein less than 1mmol/l in men and less than 1.2mmol/l in women are major risk factors in the development of cardiovascular disease (JNHGWG, 2006).

2.3.3 Diabetes

Diabetes mellitus in men older than 55 years and women older than 65 years of age increases the risk of cardiovascular disease in hypertension (JNHGWG, 2006).

2.3.4 Positive family history of early onset of cardiovascular disease

The risk of cardiovascular disease is elevated in men younger than 55 years and women younger than 65 years of age where there is a positive family history of early onset of cardiovascular disease (JNHGWG, 2006).

2.3.5 Abdominal obesity

Waist circumference should be less than or equal to 102cm in men and less than or equal to 88cm in women. Obesity is associated with a noticeably high occurrence of hypertension (Leenen et al, 2010). By introducing ways to decrease obesity in hypertensive patients, we will also reduce the prevalence of hypertension.

When looking at the risk factors for hypertension, it is necessary to immediately initiate treatment of patients with CVD, target organ damage (TOD) and those with systolic blood pressure (SBP) greater than or equal to 180mmHg or diastolic blood pressure (DBP) greater than or equal to 110mmHg. However, in the absence of TOD and associated clinical conditions, the level of blood pressure at which to begin medication treatment is debatable. (JNHGWG, 2006). Refer to Appendix G for further understanding of risk stratification (JNHGWG, 2006).

2.4 The control of blood pressure

In 2000 in South Africa only 7% of black males and 15% of black females with hypertension had controlled blood pressure (Seedat, 2007 and Steyn et al, 2001). It is difficult to control blood pressure in patients who have already been diagnosed with hypertension (Alhuwalia et al, 1997). This may be because patients who have been taking antihypertensive medications chronically and attending clinics for long may have reached a certain blood pressure level already, whereas patients who are newly diagnosed may achieve better blood pressure control with interventions other than medication-taking (Stewart et al, 2005). Patients know whether their blood pressure is high, normal or low, but still knowledge of their diagnosis and medication alone does not appear sufficient in controlling blood pressure (Alhuwalia et al, 1997). Methods to control blood pressure will be discussed below in detail.

2.4.1 The South African Hypertension Guideline 2006

2.4.1.1 Objective

The objective of the South African Hypertension Guideline 2006 is to provide an accessible, evidence-based and holistic approach to the management of hypertension in both private and public sectors (JNHGWG, 2006).

2.4.1.2 Blood pressure measurement

Blood pressure measurement must be accurately performed. Despite the importance of performing this task, many health care professionals do not measure blood pressure correctly (JNHGWG, 2006).

2.4.1.3 Sustainable management of hypertension

The Department of Health and the South African Hypertension Society find it unacceptable that many patients are suffering with the consequences of poorly managed hypertension (JNHGWG, 2006). Medication-taking and lifestyle modification are two cost-effective ways to control hypertension (Murray et al, 2003 and JNHGWG, 2006). Lifestyle modification should be initiated with every hypertensive patient immediately. This is discussed below under section 2.4.2.

2.4.1.4 Patient education

The South African Hypertension Guideline 2006 emphasizes the importance of educating the patient and communicating effectively with the patient. Patients must experience a mutual relationship which will allow them to become actively involved in the management of their condition (JNHGWG, 2006). However, this is discussed later with factors affecting adherence to treatment regimes.

2.4.2 Control in specific risk factors

2.4.2.1 Body mass index

The BMI must be maintained between 18.5 and 24.9kg/m². Similarly, the JNC-7 (2003) states that management guidelines in terms of lifestyle modification include maintaining a BMI (body mass index) of <25 or reducing a BMI of >25 in obese patients (JNC7, 2003).

2.4.2.2 Salt intake

Sodium intake should be less than 2400mg per day (equivalent to less than one teaspoon of salt). Processed and tinned foods, amongst others, are high in sodium content and should be avoided. Salt intake should be limited by removing salt from the table or reducing salt use when cooking (JNC7, 2003, Appel et al 2003 and JNHGWG, 2006). The use of lemon juice and herbs is encouraged in order to make food tastier (JNHGWG, 2006).

2.4.2.3 Alcohol consumption

Alcohol intake should be reduced to no more than two units per day (JNC7, 2003 and Maheswaran et al, 1992). More specifically, only two units per day for men and one unit per day for women and small men (JNHGWG, 2006).

2.4.2.4 Smoking

Smoking has been associated with increased prevalence of microalbuminuria, defined as a urinary albumin excretion of 30-300mg/day (Ukena et al, 2010). Microalbuminuria is an indicator of systemic vascular damage (Gerstein et al, 2001). Ceasing to smoke or use any tobacco product is necessary as it lowers the risk of microalbuminuria (Ukena et al, 2010). Replacement therapy is available if needed (JNHGWG, 2006 and JNC-7, 2003).

2.4.2.5 Exercise

A meta-analysis shows that progressive resistance exercise is efficient in slightly reducing both systolic and diastolic resting blood pressure (Kelley et al, 2000) and another meta-analysis shows that aerobic exercise lowers blood pressure (Whelton et al, 2002). Exercising regularly (3-5 times per week for at least 30min per session) will reduce risk of developing hypertension and CVD (JNC7, 2003 and Appel et al 2003). Moderate intensity exercise (40% - 60% of peak oxygen consumption) is sufficient and exercise may be continuous or occur in bouts throughout the day. The effects of exercise are most beneficial and effective when begun after not exercising at all. However, exercise should not be initiated until after initial consultation and treatment has taken place (JNHGWG, 2006).

2.4.2.6 Diet

The "Dietary Approach to Stop Hypertension" (DASH) diet has been shown to be effective and is critical in preventing high blood pressure (Milne and Pinkney Atkinson, 2004, JNHGWG, 2006, Sacks et al, 2001, Appel et al 2003 and JNC-7, 2003). The DASH principles include increasing fruit and vegetables and low fat dairy products; and high-fibre wholegrain products, poultry, fish and nuts; reduce salt, sugary foods and beverages, saturated fat and red meat and only 1-2 beverages per day containing caffeine (Miller et al, 2002).

2.4.3 Difficulties in controlling hypertension

2.4.3.1 Non adherence to Hypertension Guidelines

A cross-sectional study by Rayner and Schoeman (2009) discussed the reasons for poor blood pressure control by selecting patients with hypertension from 15 selected general practices throughout South Africa. Although complex, one reason for poor blood pressure control may be due to physicians not managing patients with high blood pressure according to the hypertension guidelines despite awareness of persistently raised blood pressure. The study shows that 61.2% of patients with hypertension achieved blood pressure control below 140/90 mmHg. However, according to the hypertension guidelines a better target for patients with high cardiovascular risk is less than or equal to 130/80 mmHg (JNHGWG, 2006). The Hypertension Guidelines have been discussed in detail above.

2.4.3.2 Management of health care service

A major factor in controlling blood pressure is attributed to the care provided by the health professional and the structures in place to allow optimal care. In Africa, due to social difficulties and poverty, poor detection and control of hypertension is evident (Seedat, 2007). In public health institutions in South Africa, both human and material resources are limited. There is high turnover of staff which disrupts continuity of care (Katz et al, 2009 and Steyn et al, 2008).

Studies have shown that frequent visits to healthcare providers do not necessarily improve blood pressure control (Hyman et al, 2001 and Berlowitz et al, 1998) and that clinical inertia may contribute to poor blood pressure control (Phillips et al, 2001). Clinical inertia is defined by Phillips et al (2001) as the ineffective implementation of effectively researched and useful practices into the clinical setting – "recognition of the problem, but failure to act" (Phillips et al, 2001). A reason for clinical inertia may include health care practitioners' overestimation of the care they provide (Phillips et al, 2001) when they are not practicing in accordance with hypertension guidelines (Hyman

et al, 2000). This is shown to be true in South African hospitals too (Daniels et al, 2000) and Southern African Hypertension Society Executive Committee, 2000). This difference between evidence-based practice and actual practice may be due to practitioners not possessing adequate educational knowledge, training or background in order to be effective in making clinical decisions (Phillips et al, 2001 and Katz et al, 2009) or not having the means to manage patients effectively (Katz et al, 2009). In a study by Katz et al (2009), a Chronic Disease Outreach Programme was used to improve the health care structures and provide support to primary health care nurses in and surrounding Soweto. The programme enabled early detection of patients with chronic disease and in supporting nurses- therefore improving risk factor control. However, it was limited by resources and poor follow-up. The health team felt frustrated, overworked and underpaid. Within the health care team there was a high turnover of staff who were generally poorly educated concerning chronic disease (Katz et al, 2009). Limited resources within the public healthcare system were also acknowledged in another study done in a South African hospital but there are ways to manage patients by designing a programme which takes this limitation into account (Stewart et al, 2005). This programme involves including healthcare practitioner and a family member through telephonic intervention, in conjunction with exercise and education (Stewart et al, 2005). This will be discussed in more detail later.

2.4.3.3 Misinterpretations by health care practitioners

Poor blood pressure control is often treated by changing medications or dosages of medications when the underlying problem is really poor adherence to regimens. This is

expensive and fruitless as patients' blood pressure will not improve if they are not taking their prescribed medicines (Heisler et al, 2008). This study shows that health professionals' decisions to intensify medications was hardly affected by whether patients were adherent to their blood pressure medications or not. This may be due to time limitations or lack of equipment in the form of an electronic medical record programme in clinics or institutions.

2.4.3.4 Health belief model

One patient-centred approach involves the Health Belief Model which suggests that a person takes actions regarding their health by firstly, depending on how susceptible they feel towards an illness; secondly, depending on how severe they perceive the illness is; thirdly, whether the suggested action is beneficial for them and lastly, a prompting should occur to trigger the health behaviour (King, 1982). An older study shows the effects of health belief on adherence to treatment for hypertension. In this study, patients who found it easier to comply with the regimens and who felt more independent and in control adhered better to treatment (Kirscht and Rosenstock, 1977).

In order for change to take place, Miller et al (2002) and Atreja et al (2005) state that the patient must feel at risk by not modifying behaviour (perceived susceptibility), feel that the condition is of great importance (perceived severity), feel they will improve if they adopt the behaviour (perceived benefits), possess ways in which they might overcome the negativity of the condition (perceived barriers) and feel they have the necessary ability to make the positive change (self-efficacy) (King, 1982).

Participation and support of patients in research studies creates feelings of positivity toward health behaviour change (Cohen et al, 2005). Further research is needed to identify what motivates patients to participate in research but some reasons may include good communication, perceived benefit from participation and their interest in the subject being researched (Raftery et al, 2008).

2.4.4 Potentially effective programmes

2.4.4.1 Preventative measures

Strategies to improve and prevent CVD and therefore reduce hypertension in Sub-Saharan Africa include improving incentives and recognition of health care workers and to engage them in preventative measures and educational programmes and for health care workers to realize the value of cost effectiveness therein (Seedat, 2007 and Bosworth, 2008). These strategies seem difficult to achieve in South Africa but involvement of political leaders and mass media may assist in initiating such strategies (Seedat, 2007). However, education on its own is not shown to improve the control of blood pressure and must be used in conjunction with programmes described below (Glynn et al, 2010, Hennessy et al, 2006 and Márquez Contreras et al, 2005).

Heisler et al (2008) suggest equipment in the form of electronic data linking to patient biomedical data to proactively identify patients with poor blood pressure control (Heisler et al, 2008). However, this may not be feasible in South African public hospitals due to lack of budget available to implement and maintain such equipment.

2.4.4.2 Management according to Hypertension Guidelines

In order to improve control of blood pressure, treatment should be compatible with hypertension guidelines in that a stepped approach to anti-hypertensive medication is administered in conjunction with risk reduction (Glynn et al, 2010, Hennessy et al, 2006 and Márquez Contreras, 2005). The results of not treating according to hypertension guidelines is clinical inertia (discussed above) and it has been shown to occur in South African hospitals (Stewart et al, 2005, Hyman et al, 2000, Philips et al, 2001, Daniels et al, 2000 and Southern African Hypertension Society Executive Committee, 2000)

2.4.4.3 Lifestyle modifications

According to the South African Health Review 2005, lifestyle diseases were responsible for 38% of all deaths in South Africa (Seedat, 2007 and Health Systems Trust, 2006). Lifestyle modification in conjunction with appropriate medication dosages is necessary to create a comprehensive and optimal programme to achieve blood pressure control and in turn, lower cardiovascular morbidity and mortality (Rayner and Schoeman, 2009 Bosworth et al, 2008 and Cobb et al, 2006). Other studies show that methods to encourage lifestyle modification as discussed under section 2.4.2 are beneficial in assisting to gain blood pressure control (Glynn et al, 2010, Hennessy et al, 2006 and Márquez Contreras, 2005). Health professionals must understand and address lifestyle behaviour modification and pharmacology in order to gain effective blood pressure control (Heisler et al, 2008, JNC-7, 2003 and JNHGWG, 2006).

Effective blood pressure control can be implemented only if patients are willing to adhere to treatment regimes and modify lifestyle in terms of exercising regularly, eating correctly, taking medicines as prescribed and reducing alcohol consumption where necessary (Maheswaran et al, 1992).

2.4.4.4 Reminders

There should be follow-up to ensure lifestyle behaviour has commenced and is being sustained (Heisler et al, 2008, JNC-7, 2003 and JNHGWG, 2006). Bosworth et al (2008) stated that enhancing blood pressure control needs to be methodically addressed by improving the ability to understand, remember and comprehend (Bosworth et al 2002, 2005 and 2008).

There are various methods of reminding patients to adhere to treatment regimens:

• Telephonic reminders

Positives of telephonic reminders

Bosworth et al (2008) investigated an individually tailored behavioural intervention administered by a nurse via telephone. Nurses used laymen's term as opposed to medical terminology when conducting telephone calls and questions were tailored to suit the subject's individual needs. According to Bosworth et al (2008), this prevents unnecessary and irrelevant information being asked which is ultimately time-saving and cost-effective. Although thought to be difficult to implement in South Africa due to language barriers, it has been found that most people do own cell phones and literature has shown that, in South Africa, telephonic and cell phone reminders assist in improving cardiovascular risk factor modification (Stewart et al, 2005). Others studies also show that telephone and mail reminders assist in bettering patient adherence to hypertension regimens (Márquez Contreras et al, 2005 and Stewart et al, 2005) and may improve blood pressure control (Márquez Contreras et al, 2005).

Negatives of telephonic reminders

When using telephonic reminders for research purposes, one limitation may include the unavoidable trust that must be placed on subjects to report back truthfully (Bosworth et al, 2008). Telephonic reminders may take time if there are many patients to phone and thus requires commitment to carry them out (Márquez Contreras et al, 2005).

• Internet and SMS reminders

Positives of internet and SMS reminders

Short message service (SMS) by cellular phones and web-based programmes have been shown to significantly lower blood pressure amongst other risk factors (Park et al, 2009). In this study, subjects in the intervention group underwent an eight week programme which included individually tailored lifestyle advice on exercise, diet, medication alteration and body mass levels. Subjects were trained on how to enter their data on the internet which enabled them to send their self-assessed blood pressure, weight and medication alteration information to the researcher electronically. This allowed the researcher to then respond to the subject with correction and further advice on how to modify behaviour accordingly.

According to Park et al (2009), reasons for the reduction in blood pressure amongst other risk factors may include the regular communication with subjects and individually tailored programmes which may have motivated the subjects to more eagerly adhere to lifestyle modification.

Negatives of internet and SMS reminders

The study did have some limitations and may not be applicable in all settings as many people do not have access to the internet (Park et al, 2009). This may also be the case in South Africa where, due to poverty, lack of education and poor socio-economic status (Stewart et al, 2005 and Steyn et al, 2008) patients may not have access to the internet or even know how to make use of the internet.

• Other reminder devices

Microelectronic devices such as medication boxes and alarms help patients to remember to take their medicines. These have been shown as effective measures to organize and improve adherence to treatment regimens (Shroeder et al, 2004 and Cramer, 1998) and are discussed under section 2.5.5.1.

A recent review by Glynn et al (2010) stated that reminders, whether postal or electronic, were related to improved follow-up and control of patients with hypertension but not their blood pressures. There are other studies which show that phone calls and reminders assist in improving adherence to treatment regimens. These studies indicate that both postal and telephonic appointment reminders are effective in overcoming missed appointments and these methods are relatively inexpensive (Haynes et al, 2002, Yusuf et al, 2000 and Macharia et al, 1992). Telephonic reminders are shown to be slightly more effective than postal reminders (Márquez Contreras et al, 2005). The telephonic reminder system will likely be more effective than the postal reminder system though such studies

have not been conducted in South Africa. This is because many patients live in informal settlements and do not have access to a proper postal service.

2.4.4.5 Patients ability and efforts

Patients are also responsible for controlling their own blood pressure and they must be willing to adhere to treatment regimens in order for effective blood pressure control to occur. (Maheswaran et al, 1992). Despite the poor lifestyle of patients in South Africa, it is possible to change behaviour if the patient is willing to take responsibility for their own health (Stewart et al, 2005).

2.5 Adherence to treatment regimes

2.5.1 Definition of adherence

Márquez Contrereas et al (2005) define adherence as "the degree to which patients follow the guidelines or instructions provided by the physician or health personnel in terms of the recommended lifestyle habits and prescribed drug treatment – with fully reasoned acceptance of such instructions on the part of the patient, i.e. without submissive connotations" (Márquez Contreras et al, 2005, page 151). The term 'adherence' is used interchangeably with the term 'compliance' in the literature; however, compliance is more suggestive of the health professional making decisions as opposed to the term adherence, which suggests that the patient plays a role in the decision-making process (Lutfey et al, 1999). Research shows that when patients are made aware of their nonadherence and the consequences thereof, adherence improves (Burnier, 2000).

2.5.2 Medication adherence and lifestyle modification

Adherence to prescribed medications is low but adherence to lifestyle modification is even lower (Haynes et al, 2002). Other studies also show adherence to lifestyle modifications when compared to medication –taking in patients with chronic hypertension to be challenging (Gohar et al, 2008 and Miller et al, 2002). This may be because it is much easier to take a tablet regularly than to change eating and exercise habits or to stop smoking. However, this leads to poor disease outcomes and therefore has large implications for quality and length of life and financial implications (Marian et al, 2002). Patient adherence includes behaviour modification and not just medicationtaking (Haynes et al, 2002, Gohar et al, 2008 and Miller et al, 2002) but behaviour modification is attainable and when used in conjunction with medication can help to lower cardiovascular risk factors (Sol et al, 2008 and Wadden, 2005). Therefore, it is necessary to find ways to improve adherence to treatment regimens in order to improve blood pressure. (Gohar et al, 2008).

2.5.3 Lifestyle modification adherence

As discussed under the section "the control of blood pressure", health care professionals must use lifestyle modification methods such as the Dietary Approach to Stop Hypertension (DASH) diet, reduce sodium intake and exercise to monitor adherence to treatment regimens as they improve patient care (Miller et al, 2002).

2.5.3.1 Exercise

Adherence to exercise is a problem and further research is needed to identify ways to improve adherence to exercise programmes (Whelton et al, 2002). Significant decreases in systolic and diastolic blood pressure (amongst other risk factors) were observed in patients aged 50-65 years when participating in an unsupervised home-based walking programme (Tully et al, 2005). The programme consisted of a 30 minute, brisk walk five days a week and information on how much time was spent walking and how many steps were taken were recorded in a diary. Tully et al (2005) comments on a report made just prior to this study by the Chief Medical Officer for England (2004) which stated that people find it very difficult to translate their exercise advice into a behaviour pattern to suit their lifestyle. According to Tully et al (2005), adherence was 90.3%, which was measured as a percentage of the number of minutes walked in comparison to the number of minutes prescribed by the protocol. This may be due to easily available resources and accessibility as well as being accustomed to the environment. The subjects were also allowed to choose whether they would prefer to walk the entire 30 minutes or do several sessions to make up the 30 minutes. The improved adherence to the home-based programme may be attributed to individualization of the programme to suit the subject's daily lifestyle better. No change was found in the control group. This is supported by Burke et al (2009) who state that a tailored approach encourages a better patientpractitioner relationship by taking into account the attitudes, preferences, goals and routines of individual patients.

2.5.3.2 Eating habits

The literature shows that patients find it difficult to adhere to a diet different from the rest of the family and do not follow recommended dietary requirements such as the DASH diet described above (Serour et al, 2007 and Miller et al, 2002). It is known that weight reduction due to poor eating habits and lack of exercise (discussed above) is immensely difficult to achieve and remains a large concern in patients with hypertension and cardiovascular disease (Frolich, 2002). It is especially difficult to achieve good eating habits in South Africa due to poverty, poor knowledge of healthy eating habits, unemployment and difficulty maintaining healthy lifestyles in poor socio-economic areas (Stewart et al, 2005).

2.5.4 Difficulties experienced with adherence to treatment regimes

Enthusiasm and sustained adherence to a healthy lifestyle is challenging for patients (Cobb et al, 2006) and the literature provides a comprehensive view on why adherence is so difficult to achieve (discussed below).

It is difficult and time consuming to achieve long term adherence but it is worthwhile and ultimately cost effective (Haynes et al, 2002) as is shown in one older article (Logan et al, 1981) and may also be cost-effective for patients themselves (Brunenberg et al, 2007). For example, failure to exercise (Miller et al, 2002) or lack of time for exercise (Serour et al, 2007) affects adherence negatively, which in turn will result in further non-adherence.

2.5.4.1 Keeping appointments

Patients who keep appointments and are motivated are more likely to adhere better to lifestyle modification. Missing appointments is correlated with lower adherence rates to prescribed regimens (Gordis et al 1969, JNC7 2003 and Miller et al 2002). A study by Saunders in 1983 included visits to the homes of 75 non-adherent patients between 18 and 21 months after the patient's first visit in order to establish why the patient had not returned for the next appointment. Five of the 75 (7%) had died, 16 (21%) were not available to converse and 54 (72%) were interviewed. The most common reasons, according to the 54 interviewed, for not returning regularly included not remembering that they were told they have high blood pressure and must return (14 patients), they went away from home (7 patients), they could not get sick leave (6 patients), they felt they did attend regularly (5 patients) and they had unfavourable side effects from the drugs (4 patients). Two patients received regular treatment at another institution. Earlier findings show that reminders are effective in helping patients adhere to appointments and ultimately improve blood pressure control (Haynes et al, 2002, Atreja et al, 2005, Yusuf et al, 2000, Macharia et al, 1992, Stewart et al 2005, Márquez Contreras et al, 2005, Khalil et al, 1997 and Miller et al, 2002).

The complications of attending treatments and appointments can affect patients' non adherence to therapy. Difficulties experienced from lack of transport, fear of risky surroundings, unfavourable weather conditions (Serour et al, 2007), waiting in long queues (Macdonald et al, 2002) and scheduling appointments contribute to the current stresses of patients' lives (Ahluwalia et al, 1997 and JNC7, 2003).

2.5.4.2 Complexity of regimes and retaining information

Complexity of the treatment regimes will affect adherence (Atreja et al, 2005). Subjects retain information short term but methods to retain information long term need to be further researched (Cuspidi et al, 2001). In a South African hospital, a 24 week educational programme was shown to be effective in improving subjects' knowledge on hypertension and even more so when telephonic and family support was given (Stewart et al, 2005). However, it was also shown that subjects needed further education every few months in order to retain the knowledge (Stewart et al, 2005). This study by Stewart et al (2005) is a randomised controlled study which reveals important information pertinent to the current study and which takes place in a similar setting with similar subjects from a poor socioeconomic background.

2.5.4.3 Medication side effects

Unfavourable drug side effects and a shortage of drugs may be considered as being another reason for poor adherence to treatment (Jokisalo et al 2002, Shaw et al 1995, JNC7 2003, and Khalil et al 1997). Adverse drug effects may be alleviated with improved patient-physician communication which will be discussed later (Weingart et al, 2005). Weingart et al (2005) show that only two thirds of patients in their study discussed symptoms with the doctor and that factors which may influence report-back included embarrassment, prior experience and opportunity given to report back about adverse effects.

2.5.4.4 Patient perception of health services

Another reason for non-adherence to treatment regimens in patients with hypertension includes problems encountered at health care centres as well as problems related to the patients themselves. Nine out of ten hypertensive patients had identified both health care system-related problems and patient-related problems (Jokisalo et al, 2002). Patients who perceived problems related to the health care system (such as poor follow-up by health centres), were almost four times more likely to be non-adherent. Furthermore, the patients perceiving problems related to patients were twice as likely to be non-adherent (Jokisalo et al, 2002).

2.5.4.5 Patient knowledge and understanding

Patient education was shown as ineffective when used alone as an intervention in improving adherence to hypertension regimens (Glynn et al, 2010, Hennessy et al 2006 and Márquez Contreras et al, 2005). Motivational and multifaceted methods need further evidence to support whether they improve treatment adherence (MacDonald et al, 2002). Literature shows that limited knowledge on hypertension and health education in general negatively affects adherence to treatment regimens (Serour et al, 2007 and Khalil et al, 1997). Research has been consistent for a long time in demonstrating that the understanding a patient has of their condition is positively correlated to their adherence to treatment regimens, and this is related to the amount and type of information given. (Atreja et al, 2005, Burgoon et al, 1987 and Hall et al, 1988).

Adherence may also be confounded by misconceptions leading the patient to adopting behaviour which may or may not be beneficial in lowering risk factors. An example of this is found in Haynes study in 2002 where a patient with diabetes and heart complications drank two to three litres of cranberry juice daily due to believing cranberry juice assists in preventing heart disease. The patient was not aware of the effect cranberry juice would have on his blood glucose levels (Haynes et al, 2002).

2.5.4.6 Patient attitude and motivation

Unwillingness to follow advice from the health care professional results in poor adherence to treatment regimens (Serour et al, 2007) and patients must be motivated by a goal and possess confidence in order to maintain a changed and healthier lifestyle. Therefore, it may be important to allow the patient to choose their own goals as this will motivate them to reach their goals. Other stresses and obstacles such as family problems or financial pressure will affect adherence negatively (Serour et al, 2007). Therefore, it is important to get other medical allied disciplines involved to ensure the patient is treated holistically. (Sol et al, 2008).

2.5.4.7 Patient quality of life

Poor quality of life also negatively affects adherence to treatment regimens (Serour et al, 2007). Patients may not want to express their concerns regarding personal stresses and may overestimate their adherence to treatment regimens. Reasons for overestimation could include that patients find it difficult to remember the details of when and how to take medication and also that they prefer to please practitioners and therefore want to avoid confrontation with health workers (Haynes et al, 2002).

2.5.5 Methods to improve adherence to treatment regimes

2.5.5.1 Reminders

Calling patients to remind them about treatments and contacting them by telephoning them as soon as they do not arrive assists largely in improving adherence to treatment regimens. Patients who miss appointments show the worst form of non-adherence as it is the initial sign that they are totally dropping out of treatment. This procedure may be time consuming, but not costly and has proved to be very effective in helping patients follow treatment regimens and re-iterates the importance of adherence every time the patient visits the institutions (Haynes et al, 2002, Yusuf et al, 2000 and Macharia et al, 1992).

According to Park et al (2009), the reasons for the reduction in blood pressure amongst other risk factors may include the regular communication with subjects and individually tailored programmes which may have motivated the subjects to more eagerly adhere to lifestyle modification. This study and section on reminders was discussed above in more detail.

In short-term regimens (less than 2 weeks), clear instructions must be given to achieve adherence to treatments. On the other hand, improving adherence to long-term regimens requires organizing information about the regimens and the importance of adhering to it, implementing reminders to ensure no missing of appointments (Haynes et al, 2002). Heneghan et al (2006) emphasize how reminder packing of medications is a simple and effective way of improving adherence to treatment regimens. According to a review by Shroeder et al (2004), successful reminders may include daily drug reminder charts (Gabriel et al, 1977), packaging reminders (Skaer et al, 1993), telephone reminders as discussed above and electronic medication aid caps (McKenney et al, 1992).

2.5.5.2 Simplifying information

Patients tend to adhere to treatments which are more convenient and less complex (Serour et al, 2007 and Miller et al, 2002). Therefore, for both lifestyle modification and medication-taking, regimens should be practical and fit in with the patient's normal daily activities. One review shows the most effective method to improve adherence to hypertension treatment in patients in an ambulatory setting is by simplifying dosage regimens as adherence is affected by the complexity of the treatment regimens (Shroeder et al, 2004). Other methods reviewed included patient education and patient motivation, support and reminders which will be discussed separately. If a treatment requires large amounts of time and change, it is most likely it will not be adhered to. Patients adhere better to treatments which coincide well with current lifestyle, routine and belief. However, this may frequently occur as a problem as many patients with chronic diseases often require huge lifestyle modification as opposed to changing one or two lifestyle aspects. (Haynes et al, 2002, Miller et al, 2006 and Atreja et al, 2005). This may also create feelings of negativity towards themselves, the regimens and the health professional which ultimately results in further non-adherence. This may be solved by ensuring that treatment regimens are recorded in a simplified yet attractive manner in order to create feelings of positivity and self-efficacy towards the treatment (Haynes et al, 2002).

2.5.5.3 Physician-patient communication

It is important to listen to the patient's problem before trying to come up with a management strategy. Previous studies show that physicians interrupt their patients on average 18 seconds after they have begun talking (Beckman and Frankel, 1984). Many patients also do not always disclose all the necessary information to physicians due to poor patient-physician relationships. In addition to this, cultural differences and language barriers may contribute to further communication problems. This occurs especially in minority and multicultural populations (Park et al, 2009, Weingart et al, 2005, Betancourt et al, 1999). Sound communication between the patient and the health care team results in improved adherence to regimens and poor communication results in poor adherence and outcome (Burnier et al, 2000 and Barrier et al, 2003). Barrier et al (2003), discusses how two words 'What else?' can improve physician-patient communication.

Three aspects of a medical interview are gathering information, building a relationship and educating the patient and these occur concurrently.

- Gathering information should be patient-centred and the patient should be allowed and encouraged to share all problems to gain a holistic understanding instead of interrupting the patient after the first complaint. Once patients have finished expressing their problems, it is important for the physician to summarize the problems back to the patient in order to show and ensure physician understanding.
- Building relationships involves being aware of verbal and non-verbal cues the patient is giving. The mnemonic PEARLS assists in relationship building:
 Partnership (the patient is not alone in this), Empathy (physician understands what the patient is going through), Apology (physician is apologetic for the

patient's inconveniences such as long queues), **Respect** (for the patient's struggles), **Legitimization** (recognizes that the frustration is representative of many) and **Support** (the physician will not desert the patient).

3. Educating the patient involves identifying their current perspective in order to gain knowledge on how to individually improve those perspectives for improved adherence and results (Barrier et al, 2003).

2.5.5.4 Patient-practitioner relationship

The practitioner-patient relationship is of the utmost importance as it is necessary to understand the complexity of the patients' personal characteristics, social, psychological and cultural background in order to improve patient adherence to treatment regimens. It is important for the practitioner to remember that patients are not clients, but rather complex beings who have consulted them in a personal manner. Issuing or instructing a patient to follow treatment regimens will often result in poor adherence but discussing with the patient treatment that best suits the patients' social, psychological, cultural and personal lifestyle will result in improved and sustained adherence to treatment regimens. This may be time-consuming but will save time when considering long-term application as patients will adhere to treatment regimens better and in turn, will not need consultation as regularly due to a decrease in complications and improved health status (Lutfey and Wishner, 1999 and Atreja et al, 2005). This challenges us to take time to investigate patients' belief, traditions and cultures when attempting to implement interventions for lifestyle modification as knowledge in itself will not be effective (Miller et al, 2002).

2.5.5.5 Shared decision-making

In the past, patients had very little part in deciding the treatment regimes they would need to adhere to. In a study by Davis et al (2003), shared decision-making and risk communication resulted in better understanding of the decisions made. This would need to be further researched to find whether these methods of shared decision-making and risk communication help patients adhere better to treatment. This would assumingly seem to be true, as patients have a better knowledge and understanding of their condition when it is explained to them, resulting in adherence to regimes due to their 'perceived benefit'. In this study, some subjects felt they gained better understanding of their condition than in usual consultations. In addition to the above, it is ethically acceptable to involve patients in decision-making processes as opposed to the previous approach where the health care professional made all the decisions. Shared decision-making is difficult to implement. The shared decision-making (SDM) model integrates four strategies to overcome this difficulty through approaching patients diseases differently and coming to terms with living with chronic illness, communicating with the patient in terms of the difficulties they encounter and are not managing successfully, then reflecting mutually on these difficulties and gaining shared understanding of the difficulties and lastly encouraging independent reflection in order for patients to solve the problems (Zoffman et al, 2008). Communication is therefore of the utmost importance in assisting patients to adhere to treatment regimens. Information about hypertension and the treatment thereof determines patient motivation and understanding (Jokisalo et al, 2002). This gives the patient purpose and helps them to see the importance of adherence to treatment.

2.5.5.6 Family/spousal support

Improving adherence to long-term regimens requires ensuring support from family and friends and giving rewards or recognizing patients for efforts to adhere to treatment. (Haynes et al, 2002). Support is key in improving adherence to behaviour modification. It may be important to get the family involved for extra support, if the patient consents to this (Miller et al, 2002). It has been found that strong social support contributes to the initiation of weight loss and maintenance thereof (Burke et al 2009, Wilde and Garvin, 2007 and Verheijden et al, 2005). Social support can be divided into two aspects namely structural and functional. Structural social support refers to the availability of family, friends, spouses and groups (Cohen et al, 2000). Functional social support relies on how the patient perceives support and depends on their character and expectation (Cohen et al, 2000 and Yopp Cohen et al, 1988). Regular group meetings may also improve adherence to self-monitoring programmes (Burke et al, 2009). Behaviour modification can take place when lifestyle information regarding diet, exercise and encouragement is provided through social support (Cohen et al, 2000 and Bovbjerg et al, 1995). Supervised exercise programmes used in conjunction with education and telephone calls have shown to decrease blood pressure, weight and cholesterol (Gordon et al, 2002) and increase adherence to treatment regimes by creating a supportive environment with family, healthcare practitioner and patient (Stewart et al, 2005).

Support can also affect adherence to treatment regimens negatively as it has also been shown that, in patients who were not positive towards behaviour modification, spouses may have been unhelpful and unsupportive (Burke et al, 2009 and McLean et al, 2003).

2.5.5.7 Diaries and self-monitoring methods

Diaries have been used effectively in medical research and are discussed in detail in this section.

Cohen et al (2005) analyzed diary content from patients and professionals over a 16 month period in response to implementing interventions for health projects. Some of these interventions included interactive educational programmes based on motivational interviewing ; practice protocols to identify overweight and obesity; goal setting with patients; decision support tools to assist clinicians in providing patient tailored counseling and integrated behaviour change from clinicians such as phone calls and routine visits.

Five areas are highlighted in connection with health behaviour change. Four of these areas are discussed below:

Firstly, patients and practitioners respond well to additional resources or interventions to promote lifestyle modification; secondly, support and training from health professionals toward patients or each other create positive feelings toward health behaviour change. Thirdly, adapting tools and techniques is difficult and time consuming and may not be worth it as these resources are valuable. For example, using web-based programmes may be time-consuming without access to fast internet or maintaining telephones and personal digital assistants (PDA) could be expensive and unachievable in a public hospital setting such as the one used in this study. Fourthly, changing routines also require changes that some health practitioners are not convinced are valuable in improving lifestyle modification. (Cohen et al, 2005).

Self-monitoring is another method which may improve adherence to treatment regimens (Carels et al, 2005). Self-monitoring is defined as enhancing self-awareness through self examination, regular measurement and recording of intended behaviour (Wilde and Garvin, 2007). Self-monitoring is affected by a person's feelings, motivation, attitudes and propensity toward it (Burke et al, 2009). Burke et al (2008) shows that adherence to self-monitoring deteriorates with time, but there is significant correlation between achieved weight loss and the amount of time of self monitoring (Burke et al 2008, Yon et al 2007 and Wadden et al 2005). A study by Goldstein et al (1996) compared two strategies of teaching, namely, the use of a home monitoring programme- one in a clinical setting and another in a Patient Learning Center (PLC). This study shows that patient adherence to a home monitoring programme is 30% greater when taught in a PLC compared to a clinical setting. This may be due to the fact that a PLC provides a structured patient educational programme in a quiet, unrushed environment as opposed to a clinical setting where noisiness and interruption occur. Subjects were also able to practice the use of the home monitoring programme and attend a free review session to ensure they had the skills to effectively use the programme on their own at home. The PLC also allowed for application of individual needs, schedules and personal style of learning. However, this study by Goldstein et al (1996) did have limitations in the fact that the sample size appears to be small and a sample size calculation is not evident and the study was not truly randomized. Still, there is valuable information which may assist in improving adherence to home monitoring programmes and hereby improving blood pressure control. In order for this to be effective, a quiet and peaceful environment is needed to teach patients how to use the programme. It may be difficult to develop such

programmes in the South African setting. This is because in South African public institutions high patient loads daily, long queues and inadequate work space often creates a very noisy and busy environment for both staff and patients.

Positives of paper diaries

Paper diaries may be used to improve adherence to treatment (van Berge Henegouwen, 1999 and Verbrugge, 1980) by motivating patients as it is a visible reminder and also by causing patients to comply as they know it will be reviewed by the physician on the next visit. Arrigo et al (2008) show that, in patients one year post cardiac rehabilitation, using a paper diary and three month group sessions almost doubled patients' adherence to exercise compared to patients who did not receive the diary or group sessions. This was found to correlate with adherence to medication-taking and reduction in nicotine usage. Verbrugge (1980), in an old study, states that diaries also assist in understanding the individual variations in health behaviour of the patient holistically.

Negatives of paper diaries

However, recording on paper diaries for research purposes is often inaccurate as information can be falsified due to "parking lot compliance". Parking lot compliance occurs when patients sincerely forget to record or may not have the diary at the time when recording must take place, which leads to further inaccuracy as patients may record retrospectively to make up for missed recordings (Bolger et al, 2003). This defeats the purpose of the diary as it is meant to create changed behaviour at the time of the intended recording (Burke et al, 2008 and Bolger et al, 2003). Without incentives for adherence,

recording is often not completed in paper diaries (Hufford et al, 2002, Stone et al, 2003, Burke et al, 2008, Verbrugge, 1980 and Burke et al, 2009).

Positives of personal digital assistants

Personal Digital Assistants (PDA) compared to paper diaries may improve adherence to dietary regimens as they can provide instant individualized feedback and reminders to encourage compliance (Beasley et al, 2008).

Negatives of personal digital assistants

However, PDA's may be difficult and complex to use especially for patients not familiar with this technology. Patients should use home monitoring tools which suit their lifestyle and skills (Yon et al, 2007). PDA's may be difficult to implement on a large scale in South Africa as they are expensive and this study was conducted in a first world country namely, the USA.

Subjects using a paper diary compared to an electronic diary have found both easy to use and transport (Hufford et al, 2002).

2.6 Conclusion

In conclusion, health care professionals often underestimate the problem of nonadherence in their patients. If a healthcare professional is unable to detect nonadherence, it is impossible for them to correct the problem. In this literature review, it is shown that the prevalence of hypertension worldwide and locally is problematic. In addition to this, controlling blood pressure in patients with hypertension and other cardiovascular risk factors has proven difficult. Adherence to medication-taking and furthermore lifestyle modification is poor and there are many factors which influence the level of adherence to treatment regimens both positively and negatively. Despite the massive amount of literature relating to this topic, further research is necessary to develop methods to help patients adopt and maintain these lifestyle interventions.

Chapter 3 – Method

3.1 Introduction

This chapter describes precisely how the study was performed, what sample size was needed, who qualified to take part in the study and how results were analyzed.

3.2 Study Design

The study design was a quantitative, longitudinal randomized control trial consisting of two experimental and one control group.

3.3 Participants

Participants at the Hypertension Clinic at Helen Joseph Hospital in Johannesburg, South Africa were sampled consecutively and then randomized using computer generated randomization and concealed allocation. This was undertaken by the research assistant.

3.3.1 Inclusion criteria

- Aged 40yrs 65yrs;
- Diagnosed with chronic hypertension (defined as blood pressure greater than 140/90 for more than 24 hours- Brecklin et al, 1998);
- New patients (at the Hypertension Clinic for the first time).

3.3.2 Exclusion criteria

- Previous history of severe and prevailing illness/ surgery or disability;
- Patients on medication other than diabetic & antihypertensive drugs.

3.3.3 Sample Size

In order to measure a blood pressure change of 4-6mmHg SD(\pm 4) at a significance level of p=0.05, a sample size of 30 per group was powered at 90% (Stewart et al, 2005). Accordingly, the sample size consisted of 90 participants divided equally into 30 control participants and 60 experimental participants. A 15% dropout and 15% non-adherence was included in the sample size calculation.

3.3.4 Ethical Consideration

Ethical clearance was obtained from the Committee for Research on Human Participants (Protocol number: M080521). Clearance form can be found in Appendix A. Permission was granted for the study to be done at Helen Joseph Hospital and participants were informed of the study (Appendix B) and signed informed consent (Appendix C) before participating in the study. All participants still received the usual treatment at the Hypertension Clinic.

3.4 Lifestyle Modification Adherence Tool

The adherence tool was in the form of a diary (van Berge Henegouwen, 1999 and Arrigo et al 2007). Each day there was new information related to hypertension that was to be read, suggestions for specific progressive exercises to do on the day, reminders on what to eat and what not to eat (drawn up by the dietician in the clinic according to GDoH, healthy eating plan) and a question on whether medication was taken for that day. A column was present on each page to tick when an activity was completed. Recorded in the diary were the dates when the therapist called the participant to follow-up on the progress made (once a month). Three diary pages are attached (Appendix D) (Soul City Magazine).

3.5 Variables / Outcome Measures

The independent variable was the Lifestyle Modification Adherence Tool (LMAT). Dependant variables included blood pressure (primary outcome measure), cholesterol, waist-hip ratio, weight and body mass index, glucose level and exercise capacity (measured using the standard six minute walk test).

Demographic data was also collected using a questionnaire on the participant's first visit. These included sex, race, educational level, annual income, cardiovascular risk factors and exercise information (Appendix E).

3.5.1 Procedure for measuring blood pressure

Blood pressure was measured before and immediately after the six minute walk test. For this reason, this is discussed with the procedure for measuring exercise capacity.

3.5.2 Procedure for measuring exercise capacity

Exercise capacity was measured using the six minute walk test (Borg, 1982 and Guyatt et al, 1985). Participants began the procedure by having their resting blood pressure tested in sitting with the left and right arm resting at shoulder height. A calibrated digital sphygnomometer was used to measure blood pressure and heart rate of the participant at rest. A 20m measurement was marked using a tape measure measured against a calibrated rod and marked out with beacons on the floor of the hypertension clinic. The

participants were instructed to walk as fast as possible between the beacons for six minutes. If they needed to rest, benches were available next to the measured 20m strip. Every 30 seconds, the researcher said "You are doing well, keep it up". Immediately after the test, participants had their blood pressure and heart rate tested on the left arm only and in the sitting position (Borg, 1982). The normal precautions for exercise testing (American College of Sports Medicine, 1991) were taken (see Appendix F). After the test the distance walked and the Rating of Perceived Exertion were measured (Borg, 1982).

3.5.3 Procedure for measuring waist circumference

The tape measure was measured against a calibrated 150cm length rod. A mirror with grid lines was placed against a wall. The grid lines ensured that the tape measure was horizontal around the waist and was assessed with a carpenter's level to ensure that the lines were perfectly horizontal. After checking the above, participants were asked to remove all clothing around the waist (except very light underwear) and loosen tight clothing. The participants were then asked to stand next to the mirror, feet slightly apart, attempting to distribute weight evenly on both feet. The assessor stood to the side of the participant and firmly held the measuring tape around the participants' waist at the level halfway between the lower rib margin and the iliac crest- just above the umbilicus (Visscher et al, 2001), making sure the tape was horizontal with the grid lines. The participants were asked to breathe in and out and the measurement was taken when the participants had breathed out. This prevented any inaccurate measurement due to the

participants contracting their abdominal muscles or holding their breath. The measurement was recorded to the nearest millimetre.

3.5.4 Procedure for measuring hip circumference

The preparation and procedure was as for waist circumference except the participants removed clothing around the hip and the measurement was taken around the hip at the level of the greatest circumference around the buttocks (Visscher et al, 2001).

3.5.5 Procedure for measuring weight

A digital scale was calibrated. A carpenter's level was used to ensure that the floor was level. The participants were asked to remove all clothing, except for light underwear, and to step onto the scale with feet slightly apart distributing their weight as evenly as possible. The final reading on the scale was recorded.

3.5.6 Procedure for measuring height

The wall tape measure was measured using a calibrated 150cm length rod. A carpenter's level was used to ensure the floor was level. A weighted string was used to ensure the tape measure was vertical against the wall. The participants were asked to stand relaxed with their back against the tape measure on the wall and the height was recorded to the nearest millimetre.

<u>3.5.7 Procedure for measuring glucose levels</u>

Glucose and cholesterol were measured in the hospital blood room. The participants were asked to sit on a chair and the laboratory assistant took blood from either the right or the left arm. The results were received from the laboratory the next Monday and recorded according to the laboratory print-out.

3.6 Familiarization with Outcome Measures

Prior to undertaking the main study, the researcher familiarised herself with taking all measurements and ensuring all precautions as described in section 3.5 above.

3.7 Procedure

3.7.1 Groups

The study consisted of three groups, two experimental and one control group.

All three groups underwent the usual treatment in the Hypertension Clinic. This consisted of a weekly Friday Clinic from 9:00 - 10:00 and involved education about hypertension and exercise (given by the physiotherapist at the clinic) and an aerobics class lasting 20 minutes with music (by the physiotherapist at the clinic). Lastly, patients were given a chance to ask questions while files were signed.

3.7.1.1 Group 1 (experimental group 1):

Experimental group one (EG1) received the Lifestyle Modification Adherence Tool as well as a once-a-month telephone call from the research assistant.

3.7.1.2 Group 2 (experimental group 2):

Experimental group two (EG2) received only a once-a-month telephone call from the research assistant.

3.7.1.3 Group 3 (control group):

The control group (CG) received the standard treatment at the clinic.

3.7.2 First stage (development of diary)

Nursing staff were informed of the study and assisted in ensuring new patients were referred for assessment. Research assistants familiarized themselves in the clinic. The adherence tool was developed and prepared by the researcher during this time.

3.7.3 Telephone Call

Every telephone call to a participant was guided by the same conversation:

- Greeting
- How are you doing?
- How is the medication, diet and exercise programme going?
- Are you managing to complete and adhere to the daily activities?
 - Are you doing the daily exercises?
 - If not, is there a problem?
 - Are you taking the advice on eating?
 - If not, is there a problem?
 - Are you reading the tips everyday?

• If not, is there a problem?

- Do you have any questions about the medication, diet and exercise programme?
- Statement of encouragement
- Statement that if the participant needs to ask any questions, they may phone her (the research assistant).
- End phone call

3.7.4 Second stage (treatment intervention and data collection)

New participants were sampled consecutively as they arrived in the clinic. In the physiotherapy room the participants were informed about the study and invited to participate by the researcher. If they were willing to participate, they signed informed consent (See Appendix C).

The participants were questioned and then had their blood pressure, weight and body mass index, waist-hip ratio, glucose level, cholesterol level and exercise capacity tested (as discussed above) by the researcher on the same day of arrival in the clinic. The researcher then recorded the results on a data collection sheet (See Appendix E).

The research assistant then randomly assigned patients to one of the three groups using a process of concealed allocation. Participants who were in experimental group one (EG1) received the LMAT from the research assistant, who explained how to use the diary and explained that the diary must not be shared or shown to other patients in the clinic and that all questions about the diary must be directed to her only. The research assistant also followed the participants up telephonically once a month for a period of six months (six phone calls per patient). Participants in experimental group two (EG2) received a once a

month telephone call only. A second research assistant was trained to stand-in for the research assistant in times when she was not available.

After six months, variables were measured again (blood pressure, waist-hip ratio, weight and body mass index, glucose level, cholesterol level and exercise capacity) by the researcher and recorded on a different data collection sheet. The researcher was blinded to group allocation and to the results of previous measures. Participants were blinded to results of baseline data.

A follow-up period of three months with no intervention (patients kept using tool independently) took place and the variables were once again measured by the researcher. The participants' files revealed the frequency of check-ups and number of exercise classes attended and this was recorded at six months and nine months again.

3.8 Statistical Analysis

The significance of the study was set at p=0.05. A Students t-test (independent) was used to compare variables between groups at baseline. The Pearsons Chi Square test was used to compare and analyze non parametric data at baseline.

Change in blood pressure, waist-hip ratio, weight and body mass index, glucose levels and exercise capacity between control and intervention groups was established using an ANCOVA.

Pairwise t-tests were used to compare p-values between groups one and two; one and three and; two and three.

STATISTICA was the statistical package used.

Chapter 4 – Results

4.1 Introduction

In this chapter, the results of the differences in demographic data as well as the risk factors between the three groups at month 0, month 6 and month 9 are illustrated. The results of weight, body mass index, waist/hip ratio, blood profile, blood pressure and distance are explained and a flow diagram is included to illustrate the flow of patients through the study.

4.2 Baseline characteristics of participants

From August 2008 to September 2010, 90 patients, who met the inclusion criteria, signed consent to participate in the study. There were 24 (26.67%) males and 66 (73.33%) females. Concealed randomization resulted in 30 per group, that is, 30 experimental group one (EG1) participants, 30 experimental group two (EG2) participants and 30 control group (CG) participants. The groups were similar at baseline with regard to age, sex, race, annual income, risk factors and exercise intensities and frequencies. Table 4.2a below shows basic demographic characteristics of participants at baseline.

Characteristics	Groups at baseline								
	EG 1	EG 2	EG 3						
	m (SD)	m (SD)	m (SD)						
Age	54.8 (±8.75)	53.27 (±9.44)	54.2 (±10.65)	0.71					
	EG 1	EG 2	CG 3						
	n=30 (%)	n=30 (%)	n=30 (%)						
Sex				0.41					
• Male	7 (23.33)	6 (20.00)	11 (36.67)						
• Female	23 (76.67)	24 (80.00)	19 (63.33)						
Race				0.69					
• White	4 (13.33)	2 (6.67)	3 (10.00)						
• Black	16 (53.33)	18 (60.00)	18 (60.00)						
Indian/Coloured	10 (33.33)	10 (33.33)	9 (30.00)						
Educational Level				0.04					
• Grade 7 or less	7 (23.33)	10 (33.33)	11 (36.67)						
• Grade 8–Grade 10	17 (56.67)	6 (20.00)	8 (26.67)						
• Grade 11- Grade 12	5 (5.56)	13 (14.44)	10 (33.33)						
• Tertiary	1 (1.11)	1 (1.11)	1 (1.11)						
Annual Income			•	0.25					
 ≥ 120 000 	1 (3.33)	0 (0.00)	0 (0.00)						
 80 000 ≤ 120 000 	0 (0.00)	1 (3.33)	3 (10.00)						
• $50\ 000 \le 80\ 000$	1 (3.33)	0 (0.00)	0 (0.00)						
• $30000 \le 50000$	4 (13.33)	3 (10.00)	0 (0.00)						
• $20000 \le 30000$	1 (3.33)	2 (6.67)	4 (13.33)						
• $15000 \le 20000$	2 (6.67)	4 (13.33)	6 (20.00)						
 ≤ 15 000 	1 (3.33)	4 (13.33)	1 (3.33)						
Not employed / Pensioner	20 (66.67)	16 (53.33)	16 (53.33)						

 Table 4.2a Baseline characteristics of participants (n=90)

The table above shows that most participants' educational levels were between Grade 8 and Grade 10 with the majority of these being experimental group 1 participants. Most participants were also not employed or were pensioners, again with the majority of these participants being in experimental group 1.

Cardiovascular risk factors		p-value						
	EG 1	Groups at baselin EG 2	CG 3	1				
	n=30 (%)	n=30 (%)	n=30 (%)					
Presence of risk factors			·					
• Stroke	3 (10.00)	5 (16.67)	3 (10.00)	0.78				
Heart problems	7 (23.33)	9 (30.00)	10 (33.33)	0.77				
• Eye problems	16 (53.33)	20 (66.67)	17 (56.67)	0.64				
• Diabetes	5 (16.67)	6 (20.00)	4 (13.33)	0.94				
Renal problems	3 (10.00)	1 (3.33)	3 (10.00)	0.69				
• High cholesterol	8 (26.67)	7 (23.33)	1.00					
Smoking	4 (13.33)	2 (6.67)	5 (16.67)	0.61				
Drinking alcohol	6 (20.00)	5 (16.67)	1.00					
• Exercise	23 (76.67)	23 (76.67)	26 (86.67)	0.95				
Number of times exercised per wee	ek			0.20				
• Once	3 (13.64)	0 (0.00)	1 (3.85)					
• Twice	3 (13.64)	1 (4.35)	4 (15.38)					
• Three	4 (18.18)	9 (39.13)	7 (26.92)					
• Four	2 (9.09)	3 (13.04)	0 (0.00)					
• Five	1 (4.55)	4 (17.39)	6 (23.08)					
• More than five	9 (40.91)	6 (26.09)	8 (30.77)					
Time spent on exercise								
• < 10 minutes	3 (13.04)	0 (0.00)	1 (3.85)					
• 10 minutes	1 (4.35)	3 (13.04)	3 (11.54)					
• 15 minutes	3 (13.04)	3 (13.04)	4 (15.38)					
• 20 minutes	3 (13.04)	2 (8.70)	3 (11.54)					
• 30 minutes or more	13 (56.52)	15 (65.22)	15 (57.69)					
Type of exercise				0.13				
Walking	9 (37.50)	6 (25.00)	13 (50.00)					
• House / Garden work	3 (12.50)	1 (4.17)	4 (15.38)					
Aerobics	2 (8.33)	1 (4.17)	1 (3.85)					
• Other	0 (0.00)	4 (16.67)	1 (3.85)					
Combination	10 (41.67)	12 (50.00)	7 (26.92)					

Table 4.2b Baseline cardiovascular risk factors of participants (n=90)

The table above shows that many participants reported the presence of eye problems above other risk factors. Large percentages of participants also reported that they exercise, and of these participants, most reported exercising more than five times per week, for 30 minutes or more and do a combination of exercises. This may be due to overestimation discussed in section 2.5.4.7 where patients overestimate adherence to regimens in order to please practitioners and avoid confrontation (Haynes et al, 2002).

4.3 Flow of participants through study

Participants came for assessments at baseline, six months and nine months. There was a dropout of 16 % (n= 15) between month 0 and month 6. Between month 6 and month 9 there was only a further 2% (n=2) who dropped out. Reasons for this included participants' phones not working and therefore not being able to contact them, participants moved away from the area or refused re-assessment. Figure 4.3 demonstrates the progression of participants through the study.

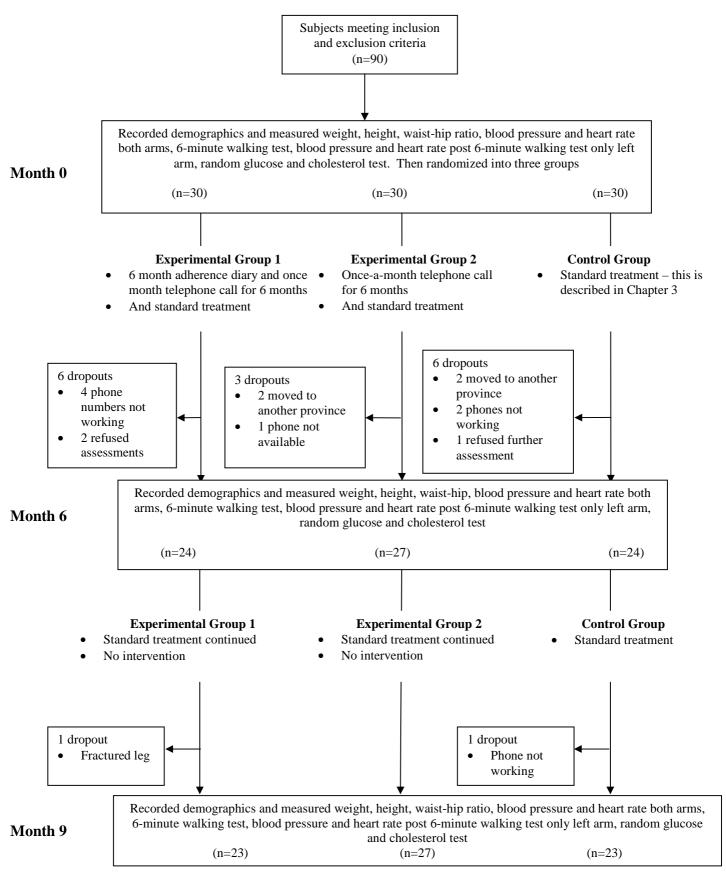


Figure 4.3 Flow of participants through study

4.4 Results of Intervention

Data for variables are presented and tabulated under four headings namely weight, body mass index (BMI) and waist/hip ratio; blood profile; blood pressure and; walking distance.

4.4.1 <u>Weight, BMI and Waist/Hip ratio</u>

Table 4.4.1 illustrates the weight, BMI and waist/hip ratio.

Outcome	Groups									Differences between groups							
	Month 0			Month 6			Month 9			Differences between groups 0 – 6 months			Differences between groups 0 – 9 months				
	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	p-Val (p)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	p-Val (p)
Weight (kg)	83.01 (21.39)	79.67 (16.64)	78.09 (18.73)	84.91 (20.44)	80.53 (16.82)	79.30 (17.23)	83.24 (19.01)	80.96 (17.25)	79.37 (17.90)	2.08 (6.12)	0.83 (2.75)	0.13 (4.61)	0.27	2.29 (7.03)	1.25 (2.89)	-0.02 (5.41)	0.32
BMI (kg/h ²)	32.67 (8.34)	31.55 (7.50)	30.52 (7.73)	33.08 (8.00)	31.9 (7.38)	30.53 (7.36)	32.51 (7.60)	32.07 (7.60)	30.45 (7.69)	0.80 (2.38)	0.32 (1.09)	0.30 (1.78)	0.25	0.87 (2.69)	0.49 (1.14)	-0.02 (2.12)	0.30
Waist/Hip	0.86 (0.08)	0.87 (0.07)	0.85 (0.08)	0.86 (0.07)	0.88 (0.09)	0.86 (0.08)	0.86 (0.07)	0.87 (0.07)	0.85 (0.09)	-0.01 (0.04)	0.01 (0.05)	0.01 (0.04)	0.06 0.04* (1&2) 0.04* (1&3)	-0.01 (0.04)	0.00 (0.03)	0.00 (0.03)	0.35

Table 4.4.1. Mean(SD) of weight, BMI and Waist/hip ratio of groups at month 0, 6 and 9 and the difference between groups at month 0-6 and month 0-9

* Pairwise t-tests revealing significant differences between two groups

4.4.1.1 Weight

There were no statistically significant differences in changes in weight between month 0 and month 6 (p= 0.27) and between month 0 and month 9 (p= 0.32) between the three groups. Weight increased in all three groups between month 0 and month 6. Weight, therefore, did not improve in any of the groups.

4.4.1.2 BMI

There were no statistically significant differences in changes in BMI between month 0 and month 6 (p=0.25) and between month 0 and month 9 (p=0.3) between the three groups. Weight increased in all three groups between month 0 and month 6 and decreased only in the control group between month 0 and month 9.

4.4.1.3 Waist/hip ratio

The pairwise test showed that a significant difference in reduction in waist/hip ratio was found between experimental groups 1 and 2 (p=0.04) and between experimental group 1 and the control group (p=0.04) during month 0 and month 6 (see Table 4.4.1). This change shows that waist/hip ratios decreased in experimental group 1 significantly more than the other two groups in the first six months.

4.4.2 Blood profile

Table 4.4.2 below illustrates the blood profile.

Outcome	Groups										Difference between groups							
	Month 0			Month 6			Month 9			Differences between 0-6 months				Differences between 0-9 months				
	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	p-Val (p)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	p-Val (p)	
Glucose (mmol/l)	5.50 (2.24)	6.22 (3.48)	5.58 (1.78)	5.23 (1.21)	5.95 (3.19)	5.26 (1.14)	4.82 (1.15)	6.13 (3.20)	5.13 (1.15)	-0.41 (2.02)	-0.39 (3.27)	-0.15 (1.12)	0.71	-0.88 (2.49)	0.25 (2.85)	0.30 (1.42)	0.15 0.05* (1&2)	
Cholesterol (mmol/l)	4.98 (1.07)	5.08 (1.31)	4.93 (1.24)	4.91 (1.07)	4.69 (1.11)	5.00 (1.06)	4.64 (1.04)	4.69 (1.20)	4.77 (0.86)	-0.10 (0.67)	-0.37 (1.09)	0.10 (0.94)	0.19 0.07* (2&3)	-0.39 (0.88)	-0.37 (0.87)	0.05 (0.99)	0.36	
Triglycerides (mmol/l)	1.55 (0.65)	1.65 (1.23)	1.32 (0.53)	1.58 (0.63)	1.53 (1.06)	1.54 (0.82)	1.56 (0.74)	1.58 (1.08)	1.18 (0.60)	0.02 (0.36)	-0.16 (0.63)	0.24 (0.59)	0.11 0.04* (2&3)	-0.07 (0.58)	-0.12 (0.57)	-0.11 (0.46)	0.67	
HDL (mmol/l)	1.17 (0.35)	1.19 (0.26)	1.10 (0.27)	1.37 (1.50)	1.19 (0.24)	1.08 (0.22)	1.17 (0.34)	1.19 (0.25)	1.04 (0.21)	0.26 (1.56)	-0.01 (0.16)	-0.01 (0.12)	0.51	0.03 (0.21)	0.00 (0.14)	0.01 (0.14)	0.68	
LDL (mmol/l)	3.10 (0.88)	3.11 (1.06)	3.01 (1.04)	3.42 (0.80)	2.78 (0.85)	3.20 (0.84)	2.74 (0.76)	2.73 (0.77)	3.20 (0.67)	-0.01 (0.65)	-0.30 (0.95)	0.22 (0.99)	0.07 0.03* (2&3)	-0.39 (0.83)	-0.33 (0.84)	0.09 (0.85)	0.03 0.02* (2&3) 0.02* (1&3)	

Table 4.4.2. Mean(SD) of blood profile of groups at month 0, 6 and 9 and the difference between groups at month 0-6 and	l month 0-9
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*Pairwise t-tests revealing significant differences or trends towards significance between two groups

4.4.2.1 Glucose

There were no statistically significant differences in changes in glucose between month 0 and month 6 (p=0.71) and between month 0 and month 9 (p=0.15) between the three groups. However, the pairwise test revealed that the glucose levels of experimental group 1 decreased significantly in comparison to experimental group 2 between month 0 and month 9 (p=0.05).

4.4.2.2 Cholesterol

There were no statistically significant differences in changes in cholesterol between month 0 and month 6 (p=0.19) and between month 0 and month 9 (p=0.36) between the three groups. Between month 0 and month 6, however, a pairwise test revealed that cholesterol in experimental group 2 decreased, showing a trend towards significance in comparison to the control group, whose cholesterol increased (p=0.07).

4.4.2.3 Triglycerides

A pairwise comparison showed a statistically significant difference between experimental group 2 and the control group where experimental group 2 showed a decrease and the control group showed an increase in triglycerides (p=0.04) between month 0 and month 6. Experimental group 2 was the only group to show decreases in triglycerides between month 0 and month 6 but all groups had shown a decrease between month 0 and month 9 (no significant differences between groups during this period though).

4.4.2.4 High density Lipoprotein

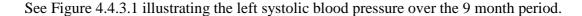
No statistically significant differences in changes were noted between month 0 and month 6 (p=0.51) and between month 0 and month 9 (p=0.68) between the three groups. However, experimental group 1 shows the greatest rise in HDL compared with other groups between both month 0 and month 6 and between month 0 and month 9.

4.4.2.5 Low density lipoprotein

A pairwise comparison shows that LDL was significantly reduced in experimental group 2 compared with the control group (p=0.03) between month 0 and month 6. The same comparison also shows that LDL was significantly reduced in experimental group 1 (p=0.02) compared with the control group and between experimental group 2 and the control group (p=0.02) between 0 and 9 months.

4.4.3 Blood Pressure

4.4.3.1 Left systolic blood pressure



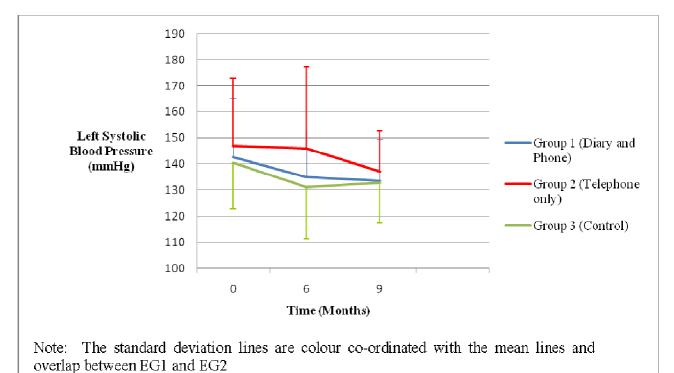


Figure 4.4.3.1 Mean left systolic blood pressure of groups over 9 month period

*Note: Left systolic blood pressure values at baseline were 142.67mmHg (Group 1), 146.87mmHg (Group 2) and 140.40mmHg (Group 3); values at month 6 were 135.04mmHg (Group 1), 146.04mmHg (Group 2) and 131.13mmHg (Group 3); values at month 9 were 133.65mmHg (Group 1), 137.07mmHg (Group 2) and 132.78mmHg (Group 3).

There were no statistically significant differences in changes in left systolic blood pressure between month 0 and month 6 (p= 0.34) and between month 0 and month 9 (p= 0.83) between the three groups. However, left systolic blood pressure decreased in all groups between month 0 and month 6 and between month 0 and month 9. Experimental

group 2 shows the largest decrease of $11.08(\pm 28.83)$ compared with other groups between month 0 and month 9.

4.4.3.2 Left diastolic blood pressure

See Figure 4.4.3.2 illustrating the left diastolic blood pressure over the 9 month period.

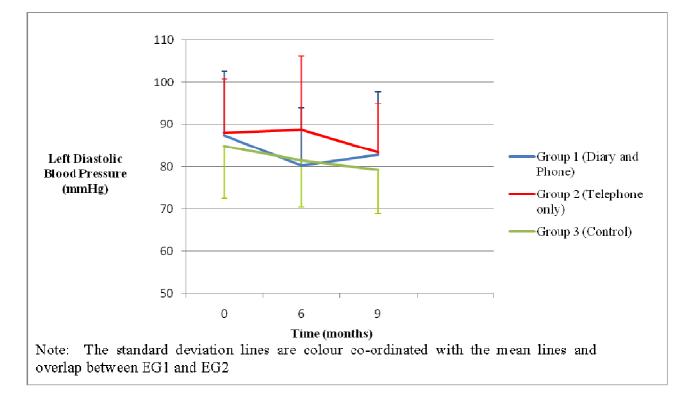


Figure 4.4.3.2 Mean left diastolic blood pressure of groups over 9 month period

*Note: Left diastolic blood pressure values at baseline were 87.40mmHg (Group 1), 88.03mmHg (Group 2) and 83.93mmHg (Group 3); values at month 6 were 80.38mmHg (Group 1), 88.70mmHg (Group 2) and 81.46mmHg (Group 3); values at month 9 were 82.83mmHg (Group 1), 83.41mmHg (Group 2) and 79.22mmHg (Group 3).

There were no statistically significant changes in differences in left diastolic blood pressure between month 0 and month 6 (p=0.26) and between month 0 and month 9

(p=0.62) between the three groups. However, left diastolic blood pressure decreased in all groups between month 0 and month 6 with the greatest decrease shown in experimental group 1. All groups also showed a decrease in left diastolic blood pressure between month 0 and month 9. Although left diastolic blood pressure increased between month 6 and month 9 in experimental group 1, an overall decrease is noted over the nine month period for all three groups.

4.4.3.3 Right systolic blood pressure

See Figure 4.4.3.3 illustrating the right systolic blood pressure over the 9 month period.

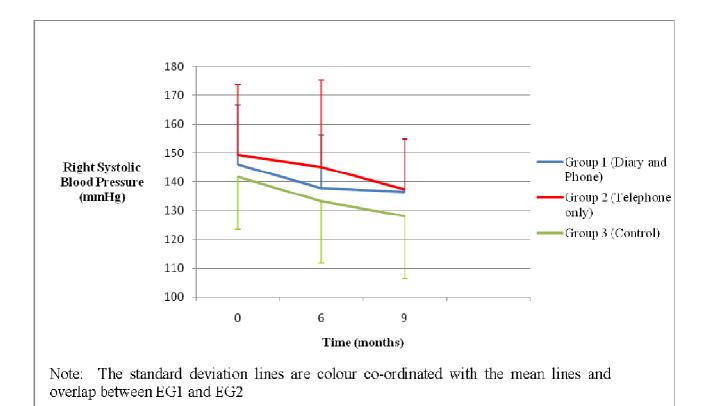


Figure 4.4.3.3 Mean right systolic blood pressure of groups over 9 month period

*Note: Right systolic blood pressure values at baseline were 146.04mmHg (Group 1), 149.34mmHg (Group 2) and 141.17mmHg (Group 3); values at month 6 were 137.75mmHg (Group 1), 145.26mmHg

(Group 2) and 133.33mmHg (Group 3); values at month 9 were 136.43mmHg (Group 1), 137.40mmHg (Group 2) and 128.09mmHg (Group 3).

There were no statistically significant changes in differences between groups in right systolic blood pressure between month 0 and month 6 (p=0.76) or between month 0 and month 9 (p=0.37). All groups showed a decrease in blood pressure though between month 0 and month 6 as well as between month 0 and month 9.

4.4.3.4 Right diastolic blood pressure

See Figure 4.4.3.4 illustrating the right diastolic blood pressure over the 9 month period.

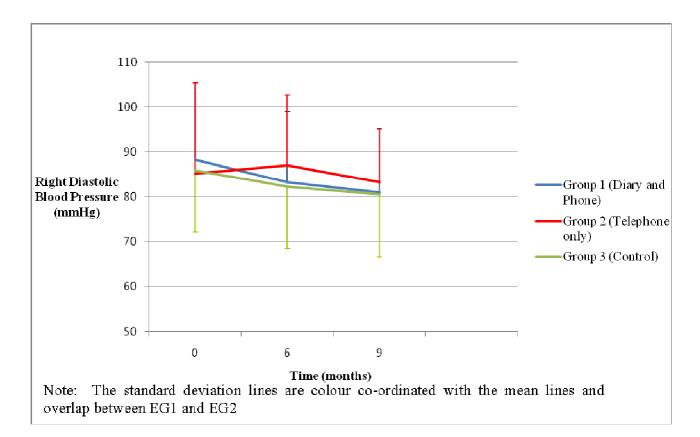


Figure 4.4.3.4 Mean right diastolic blood pressure of groups over 9 month period

*Note: Right diastolic blood pressure values at baseline were 88.33mmHg (Group 1), 85.22mmHg (Group 2) and 85.93mmHg (Group 3); values at month 6 were 83.25mmHg (Group 1), 87.04mmHg (Group 2) and 82.25mmHg (Group 3); values at month 9 were 80.96mmHg (Group 1), 83.28mmHg (Group 2) and 80.57mmHg (Group 3).

There were no statistically significant changes in differences between groups in right diastolic blood pressure between month 0 and month 6 (p=0.39) and between month 0 and month 9 (p=0.83). However, decreases in right diastolic blood pressure were noted in experimental groups 1 and the control group between month 0 and month 6 and in all groups between month 0 and month 9. Once again, experimental group 2 shows the greatest decrease between 6 and 9 months in comparison with other groups. As with the

previous figures, blood pressure of experimental group 1 has decreased between month 0 and month 6 but decrease slows between month 6 and month 9, however, still showing the greatest overall decrease over nine months as compared to other groups.

4.4.4 Distance walked in the six minute walking test

Table 4.4.4 illustrates the distance walked in the six minute walk test.

Outcome	Groups										Difference between groups							
	Month 0			Month 6			Month 9			Differences between 0-6 months				Differences between 0-9 months				
	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	p-Val (p)	EG1 m(SD)	EG2 m(SD)	CG m(SD)	p-Val (p)	
Distance (m)	462.81 (65.97)	446.00 (101.08)	472.52 (65.45)	453.09 (93.77)	473.79 (74.07)	469.53 (113.88)	473.54 (66.89)	471.98 (66.60)	479.22 (74.02)	-1.17 (73.40)	14.57 (44.51)	-2.69 (106.15)	0.70	19.29 (44.71)	12.36 (41.51)	1.81 (63.13)	0.69	

Table 4.4.4. Mean(SD) of distance walked during six minute walk test of groups at month 0, 6 and 9 and the difference between groups at month 0-6 and month 0-9

There were no statistically significant differences in distance walked between month 0 and month 6 (p= 0.7) and between month 0 and month 9 (p= 0.69) between the three groups. However, the greatest increase in distance occurred in experimental group 2 (14.57m) between month 0 and month 6 and in experimental groups 1 (19.29m) and 2 (12.36m) between month 0 and month 9. The control group did not show much change over the nine month period.

4.5 Conclusion

These results are now discussed in chapter 6.

<u>Chapter 5 – Discussion</u>

5.1 Introduction

In this chapter, the results of weight, BMI and waist/hip ratio; blood profile; blood pressure and, distance walked in the six minute walk test are discussed. Weight, BMI and waist/hip ratio are discussed in terms of eating and exercise habits associated with stress, poverty, poor education, time constraints, lack of self control and fast food availability. Glucose, cholesterol, triglycerides and lipoproteins are discussed under blood profile. Blood pressure results are discussed and related to the South African Hypertension Guideline 2006 (JNHGWG, 2006) and results of distance walked and the six minute walk test (Borg, 1982) are also discussed. Lastly, telephone call and diary reminders are discussed in relation to results obtained.

5.2 Blood Pressure

Published research shows that it is very difficult to control blood pressure in hypertensive patients (Heisler et al 2008, Stewart et al 2005, Alhuwalia et al 1997 Hyman et al 2001 and Berlowitzet al 1998, Rayner and Schoeman 2009, Philips 2001). Although changes in blood pressure were not significant, reductions in blood pressure were noted in all three groups at six and nine months. The blood pressures of experimental group one show the greatest decrease in blood pressure of the three groups in the first six months but the decrease slowed between six and nine months and at nine months the group had lower blood pressure than at baseline. The blood pressures of experimental group two show minimal change in the first six months but the blood pressures dropped more than

the other groups between six and nine months and were also below baseline levels at nine months. Lastly, the blood pressures of the control group showed a decrease in the first six months but less than the diary group and then minimal decrease and even a slight increase in blood pressure taking place from six to nine months but still resulting in the nine month blood pressures being lower than baseline blood pressures.

When comparing the blood pressure results of the three groups with the South African Hypertension Guidelines 2006 (JNHGWG, 2006), these blood pressures dropped to below the internationally accepted definition of hypertension values (BP \geq 140/90 mmHg) and systolic blood pressures dropped by the recommended 4-9mmHg (physical activity) and 2-8mmHg (dietary sodium reductions) in all groups except experimental group two at six months which only dropped 2.11mmHg (±23.71) (JNHGWG, 2006). This is therefore a clinically worthwhile change in blood pressure in all three groups. In a similar way, Stewart et al (2005) also found no significant changes in blood pressure but patients were able to modify some cardiovascular risk factors in a supported environment. However, the participants in the study done by Stewart et al (2005) were not new to the clinic such as the participants in this study. New patients who have not undergone treatment in a chronic hypertension unit previously would be expected to respond better to treatment than those patients who have been attending the unit for a long period of time (JNHGWG, 2006). Appel et al (2003) showed significant reductions in blood pressure when implementing lifestyle modification. However, the settings and sample sizes of the study by Appel et al (2003) cannot be compared with this study as it included 810 patients from four clinical centres. Some of the reductions in blood pressure

discussed above were large but were not significant due to the large standard deviations of these blood pressure measurements.

The above interpretation suggests that the fact that all patients were new to the clinic and being medicated explains the initial drops in blood pressure. These results may suggest that the intervention in experimental group one was effective in the first six months as this is when the greatest drops in blood pressure occurred, although these drops were not significant. When the diary intervention was withdrawn after six months, the blood pressures reductions slowed down, suggesting that the diary and telephone reminders may have had a positive effect. Experimental group two shows the greatest improvement only between six and nine months with smaller change in blood pressures in the first six months. This suggests the telephonic reminders may take effect on blood pressure only after six months. The interventions may show a trend of sustained improvement but an even longer follow up may be necessary.

Medication did not change in participants unless the participant was experiencing unfavourable side effects which occurred in only a few of the participants.

5.3 Weight, BMI and Waist/Hip ratio

As with this study, research has been consistent in showing that despite implementing lifestyle modification it is very difficult to reduce weight and BMI in participants and to maintain these changes (Beasley et al 2008, Stewart et al 2005, Shay et al 2009 and Burke et al 2009). The waist/hip ratio in experimental group one was found to be significantly reduced compared with other groups. This is a positive result as waist/hip

ratios give an indication of central or abdominal obesity and have been shown to be better indicators of cardiovascular disease due to obesity than BMI (Yusuf et al, 2005). These results indicate that the diary and telephone calls in experimental group one may have positively influenced the waist/hip ratios and therefore may help in reducing CVD in participants such as these.

Discussed below are eating and exercise habits and the various reasons why it may have been difficult to achieve reduction in weight and BMI in participants.

5.2.1 Eating

Discussed below are possible reasons why eating habits may have prevented participants from losing and maintaining healthy weights and BMI.

5.2.1.1 Stress

Higher stress levels are associated with urbanisation and poor dietary habits (Seedat, 2000 and Poulter et al, 1985 as cited by Seedat, 2007). Urban lifestyles can often lead to unhealthy eating patterns which worsen hypertension. Malan et al (2008) show that patients have difficulty adjusting from a rural to an urban lifestyle and this change has become a cardiometabolic risk. Despite this, eating correctly is not a priority for people when the burden of unemployment, poverty and disease are overwhelming. Patients seen at chronic clinics in public hospitals in South Africa often present with very stressful situations. Patients may present with more than one condition or often have family members who are also chronically ill and experiencing the same diagnoses. This places increased levels of stress on patients who are overwhelmed with many problems which

they feel they cannot rectify. In an overview by Bjorntorp (2001), evidence suggests that stress is linked to neuroendocrine responses which can result in increased food intake and decreased physical activity, leading to abdominal obesity. Stress is also known to cause hypertension (Steyn et al, 2008 and Stewart et al, 2005).

When considering the above literature, it is worthwhile to attempt reducing stress in patients. It is important to be aware of the stress patients are undergoing and to assist them in understanding how important it is to treat the cause of the problem and not the symptoms. Seeing a psychologist and a social worker may help, but can also add further stress as it is just one more appointment the patient needs to accommodate. Stewart et al (2005) show that participants with chronic hypertension in an intervention group were able to decrease their stress significantly better than control group participants where intervention included participants and a family member receiving once a month telephone calls as added support. Patients may feel that added support such as a telephone call may help them to reduce stress and know they are cared for.

5.2.1.2 Poverty

The massive socio-economic problem we face in South Africa affects the eating habits of patients. Studies have shown that hypertensive patients with a low socioeconomic status have poorly controlled blood pressure and that blood pressure control increases with wealth (Steyn et al, 2008 and Seedat, 2009). As with this study, Stewart et al (2005) show that clinically significant blood pressure change is not achieved and reasons may include that most participants were earning less than R15 000 per annum, were unemployed or poorly educated. With many patients being poor and unemployed it

becomes difficult to advise on healthy eating, which is often surprisingly expensive to maintain. Stewart et al (2005) also states that poverty in South Africa makes it very difficult to choose food wisely. Patients purchase inexpensive foods which are often high in saturated fat and low in protein and nutrients. The recommended DASH (Dietary Approaches to Stop Hypertension) is hindered by poverty and cultural factors (Douglas et al, 2003). There are many children to feed and in the African culture single parents are often also caring for children who are not their own. This obligates a mother to cook large amounts of inexpensive and unhealthy food to ensure all are fed. As a result, children become malnourished and obese. In addition to this, fresh fruit and vegetables perish quickly and many people living in informal settlements do not have the means and transport to frequently buy such food for themselves and their families or even store such food due to their living circumstances. This results in buying food which is high in preservatives and carbohydrate, but low in proteins and vital nutrients needed to maintain a healthy body and mind.

Seedat (2007) states that despite appropriate dietary recommendation, food remains inaccessible and unaffordable for poor people in developing countries such as South Africa (Seedat, 2007). Healthy food must be accessible and attainable to all in order to prevent and control chronic diseases (JNHGWG, 2006). Furthermore, fresh foods and foods prepared as naturally as possible should be available at inexpensive prices to the consumer as these foods require minimal ingredients and labour to prepare and are healthier to eat.

5.2.1.3 Poor education

Literature shows that poor education leads to poor blood pressure control (Steyn et al, 2005 and Steyn et al, 2008). The majority of participants participating in this study had an educational level of Grade 10 or lower. Poorly educated patients may become obese where their knowledge regarding the consequences of obesity and other diseases is lacking. Research has been consistent for a long time in demonstrating that the understanding a patient has of their condition is positively related to their adherence to treatment regimens, and this is related to the amount and type of information given. (Atreja et al, 2005, Burgoon et al, 1987 and Hall et al, 1988). It is therefore important to educate patients regarding obesity and how to lose or manage weight effectively. However, as was the case with some participants in this study, patients are generally poorly educated and reading and writing or even understanding what is being verbally portrayed, may be difficult to achieve.

5.2.1.4 Cultural misconceptions

Misconceptions may also lead patients to adopting behaviour which may or may not be beneficial (Haynes et al, 2002) where knowledge is lacking. For example, one of the participants in this study expressed that obesity in women is an attractive quality to her husband and is encouraged in her culture. Johnson et al (2003) states that obesity in the African culture has, for a long time, portrayed an African woman as a good provider, wealthy, fertile, voluptuous and prepared for survival in case of food shortage. Johnson et al (2003) also states "In an unpublished interview regarding obesity and African-American women conducted with African-American men (ages ranging from 45-65) in July 2002, the men all agreed that "real" black men love their women between sizes 14-20". Education on the consequences of such obesity need to be conveyed in an appropriate but sensitive manner.

5.2.1.5 Time constraints

The literature shows that patients do not follow recommended dietary requirements as it is difficult to prepare a special diet different from what the rest of the family eats (Serour et al, 2007 and Miller et al, 2002). Healthy eating is often time consuming and convenience foods may contain many unhealthy ingredients. Cooking food from basic ingredients is often not done as it is much easier and quicker to buy pre-cooked, tinned and processed foods which cook very quickly or can be heated in a microwave. People seem to eat more convenience foods and still have less time which results in a vicious cycle of unhealthy living with no time for exercise either. Urbanisation (Seedat, 2000 and Poulter et al, 1985) has resulted in busier city lifestyles and buying cheap, unhealthy fast food is less time consuming than preparing a meal.

5.2.1.6 Lack of self control

As discussed previously, it is very difficult for patients to modify lifestyle behaviour and sustain such behaviour with enthusiasm (Cobb et al, 2006). Most patients who are obese are used to eating without inhibition. People often respond to 'feelings' and do not stop to consider wiser options before consuming the nearest, quickest food option. Unfortunately, it seems as if the media play a largely promotive and unhelpful role by advertising how good certain (unhealthy) foods make us feel. Satisfaction is immediate

and consequences are not even considered. Health care professionals must make patients aware of false advertising regarding unhealthy foods and educate patients concerning helpful outcomes expected with consumption of healthy foods, even if these rewards are not immediate. Diets such as the DASH include varieties of foods which are low in fat and high in fibre and are effective in preventing and controlling high blood pressure (Miller et al, 2002, Milne and Pinkney Atkinson, 2004, JNHGWG, 2006, Sacks et al, 2001, Appel et al 2003 and JNC-7, 2003). However, it is only possible to change behaviour if the patient is willing to take responsibility for their own health (Stewart et al, 2005). Patients must be willing to exercise self control by choosing healthy foods over unhealthy food in order to improve eating habits and in turn, reduce their weight.

5.2.1.7 Wide availability of fast food today

Fast food is available for most people in South Africa. This appears to pose a constant temptation to individuals who find it hard to weigh up the benefits of buying fresh ingredients to cook a healthy meal compared to a quick stop for a meal they would enjoy immediately. At public hospitals in Johannesburg, patients are participanted to trolleys of unhealthy snacks and pre-packed fried foods while waiting at the pharmacy for their cholesterol medicines! These foods are very difficult to avoid when patients wait in queues for long periods of time and become hungry, tired and frustrated. Research is consistent in finding that the stress of long queues and poor management at healthcare facilities must be dealt with in order to improve blood pressure control and change cardiovascular risk factors (Stewart et al 2005, Heisler et al 2008 and JNC-7 2008).

5.2.2 Exercise

Exercise was encouraged in participants in all three groups but only discussed telephonically with the two experimental groups and included in the Lifestyle Modification Adherence Tool (LMAT) of experimental group 1. This section will be discussed in detail under Section 5.5 but below are some reasons why participants may not have exercised:

5.2.2.1 Safety and poverty

Some patients in this study felt unsafe going for walks and did not have the equipment they needed to exercise indoors. Many do not have gardens to work in, live in informal settlements and have too many family members to look after to worry about exercising. As mentioned previously in section 5.2.1.2, poverty and lack of resource available negatively affects adherence to treatment regimens and therefore also prevents patients from losing weight, exercising and, in turn, improving blood pressures.

5.2.2.2 Self discipline

Discussed above in section 5.2.1.5, patients must be willing to discipline themselves to exercise. Behaviour change and therefore, weight loss cannot occur if the patient is not willing to make healthier lifestyle choices (Stewart et al, 2005). However, added support and reminders in the form of a telephone call to the participant and a family member once a month have been shown to improve exercise capacity (Stewart et al, 2005).

5.4 Blood Profile

5.3.1 Glucose

Although not significant, reductions in glucose did occur in all groups with the greatest reduction occurring in experimental group one. It is important to remember that all groups were exposed to exercise and diet information which forms part of the usual care in the clinic, whereas intervention group one possessed a diary with added information on eating and exercise. All participants were new patients to the hypertension clinic and may not have previously been educated or exercised and according to the South African Hypertension Guidelines 2006 the greatest effect of exercise is seen when patients adapt from being sedentary to moderately active (JNHGWG, 2006). Positively, the diary intervention group's glucose continued to show the greatest drop until nine months which indicates that the diary may have had lasting effects. Mean glucose dropped to normal levels in all three groups, but then glucose levels were not exceptionally high at baseline (See table 4.3.2).

5.3.2 Cholesterol

Although not significant, the two experimental groups showed a decrease in cholesterol and the control group showed an increase in cholesterol over the first six months. These results highlight the positive trend towards significance shown in both intervention groups in reducing hyperlipidaemia by using a diary and receiving a telephone call once a month. However, it is important to note that cholesterol was sustained but did not improve in the telephone intervention group between month six and month nine when no telephone calls were made. This suggests the diary is effective during the follow up period after six months as cholesterol continued to drop until nine months, but that the telephone group did not improve without the constant telephonic reminders. As with the glucose results, the greatest improvement in cholesterol was noted in experimental group one. Miller et al (2002) also showed a drop in cholesterol due to comprehensive lifestyle intervention, although, the cholesterol means were much higher in the study by Miller et al (2002) compared to this study.

5.3.3 Triglycerides

The significant decrease of triglycerides in experimental group two compared with the control group at six months could be due to the above factors discussed. It is unsure why experimental group one's triglycerides did not decrease. One reason may include that the diary group were given dietary guidelines similar to the DASH (Sacks et al, 2001 and GDoH healthy eating plan), which is high in carbohydrate and may have prevented a reduction in triglycerides in this group whereas this diet was not given specifically to the telephone intervention group. These findings are similar to findings of Miller et al (2002) where it is suggested that the reason triglycerides did not decrease or increase significantly in the intervention group may be balanced by the consumption of the DASH diet and exercise. Braun (2010) states that taking medications alone does not eliminate the risk of developing cardiovascular disease and recurrent cardiovascular events. It is important to include lifestyle intervention (healthy eating and physical activity) into the regimes in order to achieve lowered triglyceride and non-HDL cholesterol levels (Braun, 2010). It is important to note, however, that triglycerides were not measured in a fasting state.

5.3.4 HDL and LDL

Although not significant, the improvement in HDL in experimental group one shows that the diary intervention may be effective in raising HDL. This may be due to the daily reminders in the diary to exercise. This increase was sustained at nine months too. The significant decrease in LDL in experimental group two at six months and both intervention groups at nine months also indicates positive change in adherence to the diary and telephone reminders especially since an increase is noted in the control groups at both six and nine months for LDL. In a meta-analysis, Kelley et al (2004) showed findings similar with decreases in LDL but different with regards to no changes in HDL when examining the effect of walking on lipids. Miller et al (2002) also found significant decreases in LDL when implementing a comprehensive lifestyle modification programme. When considering the literature mentioned above, the results of this study suggest that the telephone reminders and diary content may have caused this significant improvement in LDL in the two intervention groups.

5.5 Distance Walked

Exercise tolerance improved but not significantly in experimental group two at six months and in both experimental groups at nine months, showing a trend towards significance in both experimental groups. This suggests that the telephone calls and diaries were helpful in promoting regular exercise. However, in comparison to Stewart et al (2005), the distances improved considerably less in this study. Other studies have also shown that home-based exercise programmes improve exercise capacity in patients

(Tully, 2005) and self kept diaries of physical activities (Arrigo et al, 2008) and telephone calls (Hanssen et al, 2007) improves adherence to exercise. It is possible that if patients had been encouraged more during the six minute walk test, they may have walked further. This is despite having been encouraged to walk as fast as possible at the start of the test. However, the standard protocol of only one encouraging statement per lap was followed (Borg, 1982). Research encourages motivated communication between the health care provider and the patient in the form of a trustworthy and empathetic relationship. Motivation improves the control of blood pressure and adherence to regimens (Cobb et al, 2006 and JNC-7, 2003).

5.6 Telephone call and diary reminders

It is shown that patients tend to forget what was said if not constantly reminded (Haynes et al, 2002 and Marquez Contreras et al, 2005) and this trend was seen in this study. The telephone calls created a caring and helpful environment. However, some participants also reported avoiding telephone calls and conversation at times when they had not adhered to their lifestyle modification programme. It also gave the participant the freedom to understand reasons for non-adherence which were otherwise not possible without telephonic communication. For example, one participant communicated to the research assistant that she was not sure she can go on with the LMAT as her husband was causing substantial amounts of stress in her home, which hindered her ability to effectively follow the LMAT. The participant did not disclose why this was the case, but perhaps time spent on lifestyle modification, food preparation, nature of exercise or even cultural factors as discussed previously played a part in preventing her adherence to the intervention.

In South Africa, it is important to give material in the language spoken at home by the patient and family as this will encourage adherence and may also allow the family to encourage adherence if the material is well understood. Perhaps the diary should not only have been translated into English and Afrikaans, but also into isiZulu and Setswana too. However, an unpublished MSc research report shows that Zulu speaking patients preferred to read in English (Grebe, 2009). This is supported by the JNC-7 which states that interventions at public health level are accepted by the community when their implementation is diverse in terms of race, culture, religion and social factors (JNC-7, 2003).

When looking at the above factors it is important to understand that each patient presents with a different reason for not adhering to treatment regimens. Perhaps it may be beneficial to tailor each treatment individually according to the patient as opposed to developing one general treatment regime for all.

Adherence is very difficult to achieve and research has shown this consistently (Haynes et al 2002, Heisler et al 2008, Cobb et al 2006, Steyn et al 2008 and Brunenberg et al 2007) especially in South Africa when considering poor socioeconomic and financial implications discussed at length above (Seedat, 2007, Seedat, 2009, Steyn et al, 2001, Katz et al, 2009 and Stewart et al, 2005).

5.7 Limitations

The area where the six minute walking test was performed is a very busy and noisy area in the clinic, due to it being a thoroughfare to the doctors' rooms and the cardiac clinic. Also, exercise classes with music take place simultaneously. This may have limited the distances walked as there were sometimes patients and staff in the way of the participant performing the walking test and the researcher often had to attempt to keep the area clear. However, this lack of space is common in public hospitals in South Africa such as the one used in this study. Another limitation includes the few failed blood specimens due to incorrect blood samples taken by the laboratory for participants' blood profile. This was only realized when the results were available a few days after the participants' blood had been taken and participants could not come back to the hospital immediately due to reasons pertaining to transport and occupational limitations.

Chapter 6 – Conclusion and Recommendations

6.1 Conclusion

Blood pressure did not improve significantly with the implementation of this lifestyle modification adherence tool and telephone call or only a telephone call once a month. However, there was a positive change in blood pressure, blood profile, waist/hip ratios and distances walked with significant changes in intervention groups for triglycerides, LDL and waist/hip ratios. No positive change was noted in weight.

6.2 Clinical Recommendations

The effectiveness of the LMAT may be improved by asking the participants to bring the diary in on each visit for checking or also by including less information in the diary. Patients with chronic hypertension must always be referred to the hypertension clinic as soon as possible after diagnosis. Long queues and waiting times need to be reduced to improve adherence and prevent the overwhelming situation patients are faced with when coming for appointments. A multi-disciplinary team approach amongst health practitioners in the clinic must be adopted in order to optimize patient treatment.

6.3 Recommendations for Future Studies

The use of short message service (SMS) via cellular phone need to be investigated and may assist in furthering knowledge and understanding towards improving adherence in patients with chronic hypertension and associated risk factors. Tailoring specific programmes for individual patients to improve adherence may also warrant further investigation.

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Appendices