

FEASIBILITY AND ACCEPTABILITY OF A CONTEXTUALISED PHYSICAL ACTIVITY AND DIET INTERVENTION FOR HYPERTENSION CONTROL IN A RURAL ADULT POPULATION OF SOUTH AFRICA

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A thesis submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, South Africa and to the School of Sport, Exercise, and Health Sciences, Loughborough University, Loughborough, United Kingdom, in fulfilment of the requirements for the degree of Doctor of Philosophy.

October, 2024

DECLARATION

I, Kganetso Sekome, declare that this thesis is my own, unaided work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, South Africa, and to Loughborough University, United Kingdom. It has not been submitted before for any degree or examination at any other university.

Kganetso Sekome

Name of candidate

Signature of candidate

DEDICATION

Dedicated to everyone diagnosed with hypertension



Image credit: <https://stpsupport.nice.org.uk/cvd-prevention-hypertension/index.html>

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I am because you are. The completion of this PhD is deeply rooted in the African philosophy of Ubuntu and follows the worldview of South Africa's Nguni language expression "Umntu ngumuntu ngabantu" which translates to "a person is a person through other people". I am deeply grateful to the following people:

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ABSTRACT

Introduction:

Over half the population of adults from rural South Africa are hypertensive. Most strokes and ischaemic heart diseases in rural and remote South Africa are because of hypertension, which is a modifiable risk factor. Apart from pharmaceutical treatment, lifestyle changes such as increasing physical activity and reducing dietary salt have been strongly advocated for the control of hypertension. Despite the known benefits of physical activity and diet modifications for hypertension control, adults in rural South African settings still have high levels of uncontrolled hypertension. There is a lack of culturally sensitive, community-based, lifestyle interventions to control hypertension among rural South African adult populations. We designed, implemented, and evaluated a contextual intervention which recommends adjusting daily routine physical activity and dietary behaviour of adults with hypertension - HYPHEN (*HY*pertension control using *PH*ysical activity and *dIE*t in a rural *coN*text). This study aims to evaluate the feasibility and acceptability of HYPHEN in a rural South African community setting.

STUDY ONE

Methodology: The first study involved establishing a profile of the frequency, intensity, duration, and domain (work or non-work) of self-reported physical activities of rural South African adults living with hypertension. Four hundred and twenty-nine adults diagnosed/self-report with hypertension aged 40 years and above completed the International Physical Activity Questionnaire Long-Form (IPAQ-LF) via telephone interview.

Results: Fifty eight percent of participants were women of which 44% were in paid/unpaid work, while 64% of men were in paid/unpaid work. Men reported greater (duration and frequency) vigorous physical activity at work compared to women. Walking frequency as mode of transport was higher for working men and women compared with those not in work. Women reported high frequency of moderate-intensity physical activity inside the house and outside the house compared to men. Non-working men and women spent more time sitting during the week compared to their working counterparts.

Conclusion: Sex, work status, and gender roles are related to physical activity among hypertensive adults living in rural South Africa. Further exploration of socioeconomic and cultural factors influencing physical activity in rural African populations is required so that appropriate contextual interventions can be developed and evaluated.

STUDY TWO

Methodology: The second study was a qualitative study to explore the social and cultural beliefs, perceptions and practices regarding physical activity and diet as a hypertension control intervention for adults living in a rural sub-district in South Africa. Nine focus group discussions were conducted with hypertensive adults using a semi-structured interview guide.

Results: Participants had a lack of knowledge about blood pressure values. Perceived causes of hypertension were related to psychosocial factors such as family and emotional-related issues. Physical activity practices were influenced by family and community members' attitudes and gender roles. Factors which influenced dietary practices mainly involved affordability and availability of food. To control their hypertension, participants recommend eating certain foods, emotional control, taking medication, exercising, praying, correct food preparation, and performing house chores.

Conclusion: Lifestyle interventions to control hypertension for adults in a rural South African setting using physical activity promotion and dietary control must consider the beliefs related to hypertension control of this population.

STUDY THREE

Methodology: The third study was the design of a contextualised physical activity and diet intervention using behaviour change models. The intervention comprised of three components: a structured group education session, individualised physical activity education, and individualised dietary education over a period of 10 weeks. Participants were recruited via telephone.

Results: Feasibility parameters included recruitment of 30 participants with a self-report hypertension diagnosis over one week, 80% participants retained to completion, 80% engaged with weekly monitoring calls. Acceptability was assessed qualitatively via face-to-face interviews to explore perceived expectations, benefits, motivation, and barriers concerning the intervention. Fidelity parameters included measures of adherence, dosage, quality of intervention delivery, and participant responsiveness. Secondary measures included blood pressure, body mass index, waist- hip ratio, urinary sodium, accelerometer-measured physical activity, and 24-hour diet recall.

Conclusion: This study offers a person-centred, sociocultural approach to hypertension control through adaptations to physical activity and dietary intake. This study will determine whether HYPHEN is feasible and acceptable and will inform changes to the protocol/focus that could be tested in a full trial.

STUDY FOUR

Methodology: The fourth study sought to evaluate the feasibility and acceptability parameters of HYPHEN.

Results: The evaluation demonstrated high level of feasibility, acceptability, and fidelity. Thirty (100% of target) participants were successfully recruited over two days, 28 (93%) participants were retained, and 28 (93%) provided complete data. Qualitative data demonstrated high acceptability. Fidelity measures demonstrated that adherence was high, dosage of intervention lasted as planned, no deviation was observed from the planned educational content, and all participants engaged with weekly telephonic calls.

Conclusion: Although deemed feasible and acceptable, some amendments are required to the intervention procedures that were carried out before a full trial can be rolled out.

Implications

This study provides the first known evaluation of a contextualized physical activity and diet intervention for hypertension control in rural South Africa. This study shows that a contextually developed intervention for hypertension control has a promise of success if rolled out in a larger trial.

Trial registration: Pan African Clinical Trial Registry (pactr.samrc.ac.za) PACTR202306662753321. Retrospectively registered on 29 June 2023.

Keywords: High blood pressure, nutrition, rural, IPAQ, lifestyle change.

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LIST OF ABBREVIATIONS

AIDS	- Acquired Immunodeficiency Syndrome
ART	- Antiretroviral Treatment
BCT	- Behaviour Change Technique
CARTA	- Consortium for Advanced Research Training in Africa
CONSORT	- Consolidated Standards of Reporting Trials
COVID	- Coronavirus Disease
DALYS	- Disability Adjusted Life Years
DASH	- Dietary Approaches to Stop Hypertension
FGD	- Focus Group Discussion
FITT	- Frequency Intensity Time Type
HAALSI	- Health and Aging in Africa, a Longitudinal Study of an Indepth community
HDSS	- Health and Demographic Surveillance Site
HPT	- Hypertension
HYPHEN	- HYpertension control using PHysical activity and diEt in a rural coNtext
HIV	- Human Immunodeficiency Virus
HREC	- Human Research Ethics Committee
HRQOL	- Health Related Quality of Life
IM	- Intervention Mapping
IPAQ	- International Physical Activity Questionnaire
IPAQ-LF	- International Physical Activity Questionnaire – Long Form
INDEPTH	- International Network for the Demographic Evaluation of Populations and Their Health
LMIC	- Low- and Middle-Income Countries
MRC	- Medical Research Council
MVPA	- Moderate-to Vigorous Physical Activity
NCD	- Non-Communicable Disease
NiDS	- National income Dynamics Study
NRF	- National Research Foundation
PA	- Physical Activity
PEH	- Post Exercise Hypotension
RCT	- Randomized Controlled Trial
SADHS	- South African Demographic and Health Survey
TB	- Tuberculosis
WHO	- World Health Organization

CHAPTER 1

1. INTRODUCTION

1.1 BACKGROUND

Non-communicable diseases (NCDs) are on the rise in rural and urban South Africa (Moraga & Collaborators, 2017; Nojilana et al., 2016). Projections from the World Health Organization (WHO) show that by 2030, NCDs will be the biggest cause of death in the African region (Nojilana et al., 2016). The burden of NCDs is expected to increase due to factors such as the reduction of HIV/AIDS related mortality because of the roll-out of antiretroviral therapy (ART). Non-communicable diseases are classified as one of the South African quadruple burden of disease (Bradshaw et al., 2019). Hypertension is a risk factor for cardiovascular and cerebrovascular diseases such as heart attacks and strokes. Cardiovascular and cerebrovascular diseases are reported to be higher in rural areas compared to urban areas of South Africa (Ntuli et al., 2015; Sekome, 2018). Hypertension, stroke and ischaemic heart disease are amongst the most common NCDs causing many premature adult deaths in South Africa (Ntuli et al., 2015).

Raised blood pressure, defined as systolic blood pressure higher than 139 mmHg or diastolic blood pressure higher than 89 mmHg, remains the leading global risk factor for cardiovascular and kidney diseases (Zhou et al., 2021). Hypertension is the leading modifiable risk factor for cardiovascular disease and premature death worldwide (Burnier & Egan, 2019; Mills et al., 2020). Over the past decade, the prevalence of hypertension has increased worldwide, especially in low- and middle-income countries (LMICs). Reports suggest that 31.1% of adults (1.39 billion) worldwide had hypertension in 2010 (Mills et al., 2020). This reported prevalence was higher in LMICs (31.5%, 1.04 billion people) than in high-income countries (28.5%, 349 million people) (Mills et al., 2020). In 2010 alone, raised blood pressure (hypertension) caused an estimated 9.4 million deaths worldwide (World Health Organization, 2013).

In 2013 at the World Health Assembly, the World Health Organization adopted a global NCD target of a 25% reduction in the prevalence of raised blood pressure by 2025 according to national circumstances (World Health Organization, 2013). South Africa does not have adequate consistent surveillance data to track the reduction in prevalence of hypertension. For example, the South African Demographic and Health Survey (SADHS) outlined in the strategic plan document for the prevention and control of NCDs 2013-2017 only reports on national prevalence of hypertension from 1998 – 2008. The trend shows an increasing prevalence highlighting the need for urgent interventions. There is a shift in hypertension prevalence from predominantly

high prevalence for younger men (<45 years old) to high prevalence for older women (45 years and older) in both surveys conducted in 1998 and 2008 (figure 1.1). The National income Dynamics Study (NiDS) in 2010 wave 2 reported a national prevalence of 69.8% for adults aged 45 years and above (Day et al., 2014). Of these, only 27,5% had treatment coverage and only 22.5% had their blood pressure controlled. There has not been any data published by the National Department of Health since the 2013 – 2017 NCD strategic plan document.

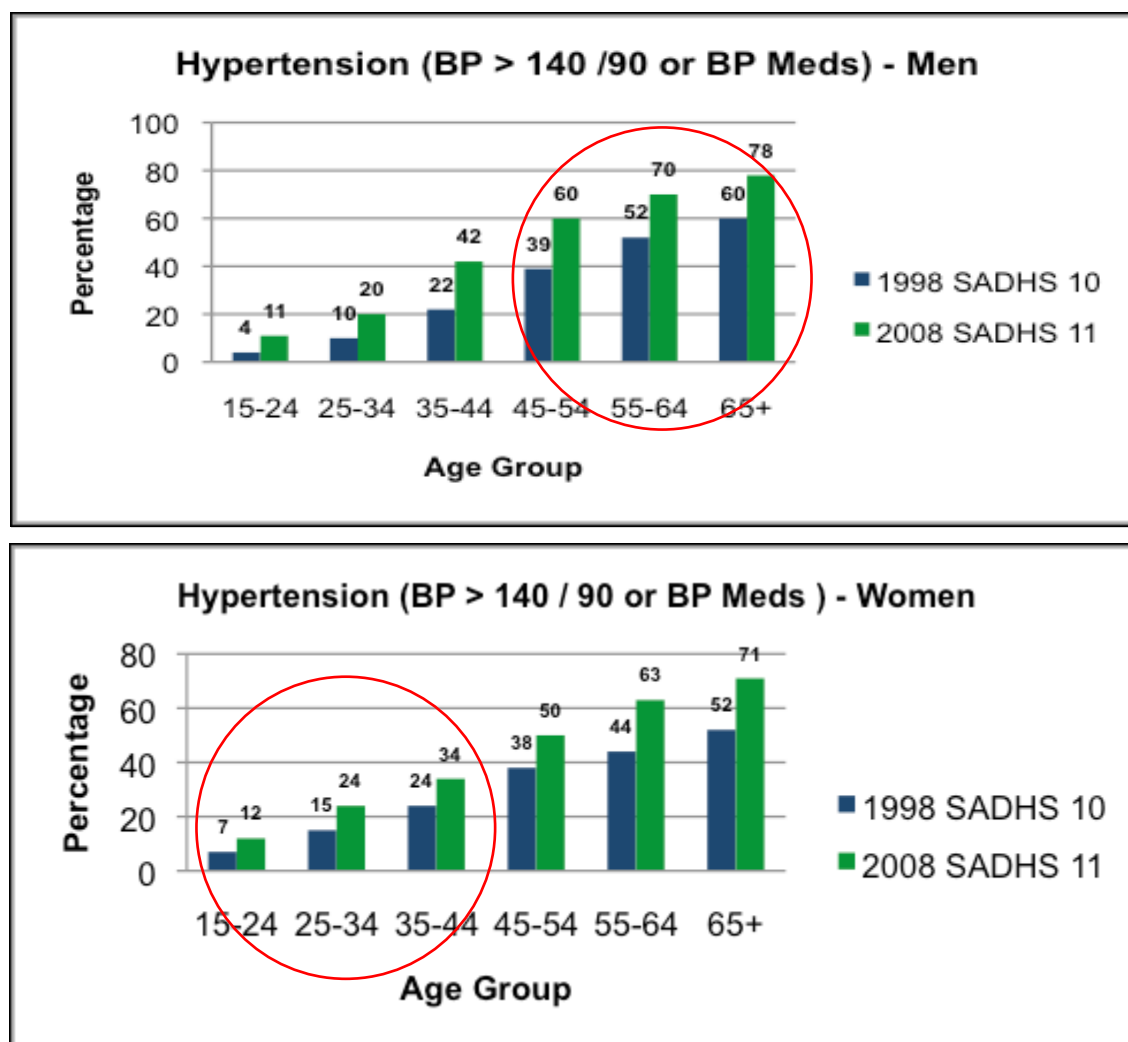


Figure 1.1: Hypertension National Prevalence for Men and Women 1998 – 2008.
Adapted from (National Department of Health, 2013)

Raised blood pressure accounted for 7% of global disability-adjusted life years (DALYs) and 34.5 million NCD death rates in 2010 (Lim et al., 2012; Moraga & Collaborators, 2017), highlighting hypertension as a major public health concern globally. In the early 2000, hypertension resulted in an estimate of 9% of all deaths and >390 000 DALYs in South Africa

(Bradshaw et al., 2007). In addition, 50% of all strokes and 42% of ischaemic heart diseases in South Africa were because of hypertension.

The most cited national prevalence of hypertension among older adults in South Africa is 77.3% in 2008 for a sample of adults aged 50 years or older (Peltzer & Phaswana-Mafuya, 2013). In 2014, Lloyd-Sherlock and colleagues reported a South African hypertension prevalence of 77.9% amongst older adults aged 50 and above (Lloyd-Sherlock et al., 2014). These numbers can be attributed to factors such as ageing of the population, rapid urbanization, diet and lifestyle changes, and an increase in psychosocial issues (Ibrahim & Damasceno, 2012). The prevalence in rural South Africa is reported to be 41% in Limpopo (Dikgale Health and Demographic Surveillance Site) (Ntuli et al., 2015) and 40% in Mpumalanga (Agincourt Health and Demographic Surveillance Site) (Thorogood et al., 2014). This is higher than infectious chronic diseases such as the reported 19.4% prevalence of HIV/AIDS in these rural settings (Gómez-Olivé et al., 2013). Limpopo and Mpumalanga are two of the nine provinces of South Africa (figure 1.2). Out of the nine provinces, Limpopo, KwaZulu-Natal, Eastern Cape, Mpumalanga, and North West were classified as rural provinces (Conradie et al., 2022; Gaede & Versteeg, 2011).

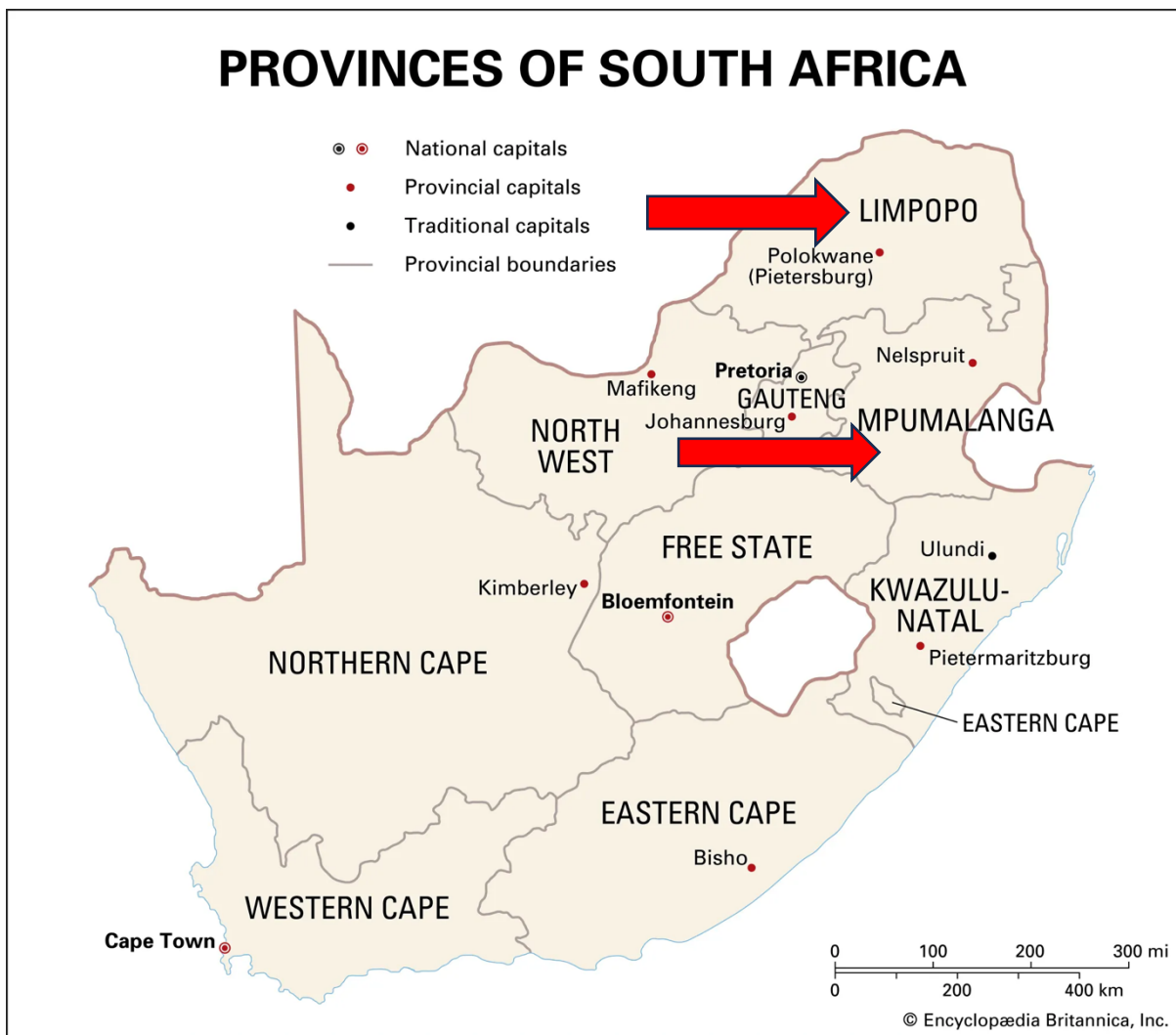


Figure 1.2: Provinces of South Africa (adapted from:
<https://www.britannica.com/place/South-Africa/Local-government>. (Accessed 10 April 2024)

The high prevalence of hypertension in rural areas is a concern due to factors such as poorly organized health care systems, intermittent drug supply, as well as shortage of health care workers (Rispel et al., 2019; Sekome, 2018; Zihindulai et al., 2018). Some of the reported sociodemographic risk factors for hypertension in LMICs are obesity or overweight, being married, older age group, low level of education, and use of alcohol (Ahaneku et al., 2011; Ibrahim & Damasceno, 2012; Williams et al., 2013). Research in a rural South African community by Ntuli and colleagues however, reported that there was no significant association between BMI and hypertension – they attributed this to the declining use of dietary salt among their study population regardless of the increase in obesity (Ntuli et al., 2015). Their study confirmed that

being married, having lower levels of education and falling within an older age group are the most common correlates risk factors in a rural population.

With reference to measures for controlling hypertension, a reduction in salt and caloric intake, and increase in physical activity are the widely recommended therapeutic approaches to help meet national hypertension targets (Bertram et al., 2012; He et al., 2013; Lin et al., 2014). The most recent South African NCD strategic plan document (National Department of Health, 2013) sets out two goals for the control of hypertension, goal six and seven. In goal six: the aim is to reduce the prevalence of people with raised blood pressure (through lifestyle and medication) and in goal seven the aim is to increase the prevalence of physical activity (defined as 150 minutes of moderate-intensity physical activity per week, or equivalent).

People 40 years and older in rural Agincourt subdistrict of Mpumalanga seem to be aware of their blood pressure levels (awareness rate of 64.4%) and many of them (89.3%) are on medication treatment; however, the level of control remains low (45.8%) (Gómez-Olivé et al., 2017; Jardim et al., 2017). When considering the overall hypertensive population and not only those who were aware of the condition, the number of patients receiving pharmacological treatment dropped to 49.7%. The overall control rate verified among treated and untreated hypertensive participants was 22.8% (Jardim et al., 2017). Awareness of blood pressure status was greater in females age ≥ 60 years; higher socioeconomic status, literacy and physical limitation.

Adults living in rural areas of South Africa are usually involved in manual labour that varies from low levels of vigorous-intensity to high levels of moderate- and low-intensity (Oyeyemi et al., 2016). Shackleton explains the value that forests and dry woodlands provide adults living in rural areas with an opportunity to walk for wood collection (C. M. Shackleton et al., 2007; S. E. Shackleton & Hebinck, 2018). Many women in rural South African communities are involved in housework and yardwork, and in most aspects of farming (Cook, 2007). Activities performed by females in rural Limpopo which also includes walking as a means of transport are not performed at intensities associated with the recommended international guidelines for moderate-vigorous physical activity (MVPA) compared to urban areas of South Africa (Cook, 2007).

A recent intervention aimed to control raised blood pressure in rural South African adults engaged with older people at points of pension collection in the Agincourt sub-district of Mpumalanga Province (Lloyd-Sherlock et al., 2018). At these points, older people were given information about hypertension, measuring blood pressure, referral to primary care services, and

providing a monthly supply of low sodium salt (Lloyd-Sherlock et al., 2018). This intervention demonstrated high acceptance of the low sodium salt and a high engagement with the hypertension education. Though provision (and subsequent consumption) of low sodium salt can be successful in lowering high blood pressure, the financial commitment might not be sustainable (Hernandez et al., 2019). A high level of dependence on antihypertensive medication is also observed (Jardim et al., 2017) which is not always successful due to deficiencies in the health system and patient's non-adherence to medication (Kayima et al., 2013). Physical activity volume of adults in rural areas is generally high, but the intensity is very low (Craig et al., 2013). Culturally appropriate interventions that are cost-effective and evidence-based for the primary and secondary prevention within populations and health services need to be tested. A conceptual framework that takes into account factors that influence a person's health outcomes is proposed to guide this project.

1.2 **CONCEPTUAL FRAMEWORK**

Physical activity and dietary practices are a function of the interaction between the individual and their social and physical environment. The conceptual framework for this thesis is adopted from (Wilson & Cleary, 1995) and further revised by (Ferrans et al., 2005). According to this framework, the biological-symptom-functional status complex is directly influenced by both individual and environmental characteristics and together they influence the general perceptions of health and overall Health Related Quality of Life (HRQOL). The understanding of contextual factors when designing health intervention encourages a bio-psycho-social and person-centred approach to healthcare and promotes a multidimensional view of a person's health (Allan et al., 2006; Snyman et al., 2016).

With regards to hypertension, the characteristics of the adult (individual) such as their beliefs and practices regarding physical activity and diet could have an impact on their biologic-symptom-functional status complex. Environmental characteristics that could impact this complex may include the rural nature of the area in which they live, their livelihood, as well as availability of farming activities and health services. These personal and environmental characteristics together have an influence on the adult's health perception as well as their overall quality of life. This thesis approach seeks to use the environment where the individual lives to control the individual's hypertension. For example, it is known that rural communities have easy access to farming opportunities which enhances good diet and increases physical activity. Also, water is usually fetched from communal taps which requires long distance walking and improves upper body strength. The study outlined in this thesis will contribute to understanding the facilitators or barriers to controlling hypertension at the individual level and then design,

implement, and evaluate an intervention that considers individual and environmental characteristics.

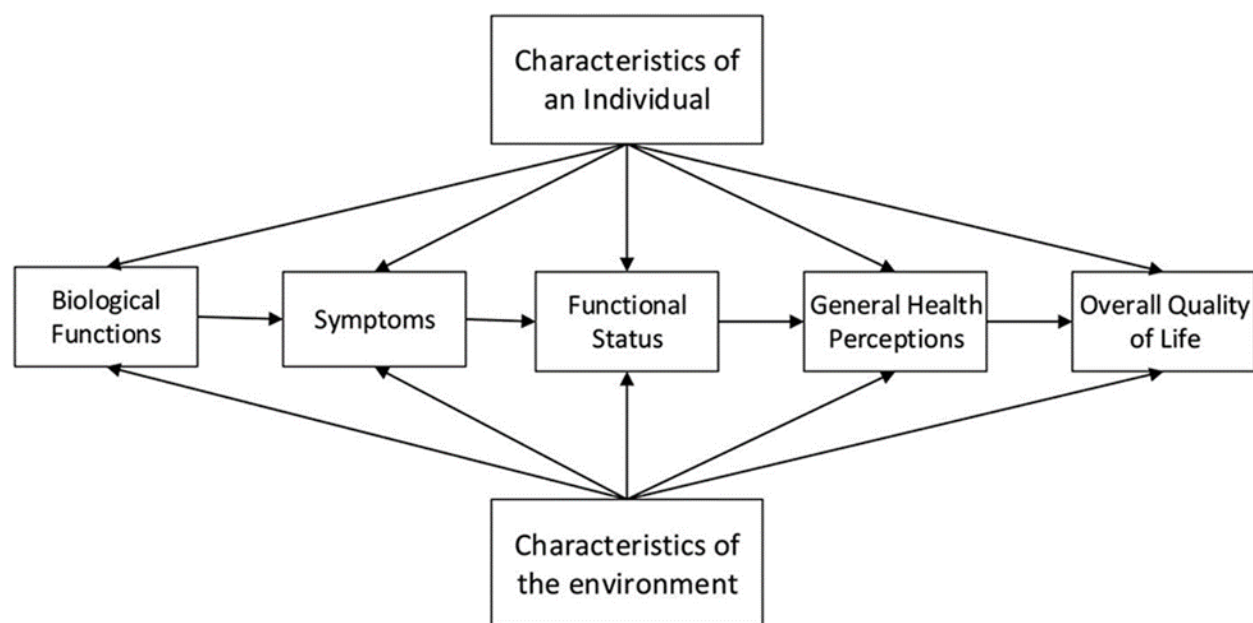


Figure 1.3: Health Related Quality Of Life (HRQOL) framework: adopted from
(Ferrans et al., 2005; Wilson & Cleary, 1995)

1.3 PROBLEM STATEMENT AND STUDY JUSTIFICATION

With the increasing access to pharmacological treatment for chronic communicable diseases in rural areas, such as Tuberculosis (TB) and Human Immunodeficiency Virus (HIV), populations are living to older ages with higher risk of acquiring NCD and hence increasing the burden from NCDs. In South Africa, research has not explored the daily lifestyle-embedded activities regarding physical activity and diet for rural adults and hence there is a lack of interventions designed to consider the reality of this population (Craig et al., 2013). Existing health promotion interventions do not consider the cultural and social beliefs and practices that influence diet and physical activity (Gómez-Olivé et al., 2018). These interventions that have been tested to control raised blood pressure and other NCDs through physical activity have been focused on monitoring and increasing the number of steps taken a day (Cook, 2007; Gómez-Olivé et al., 2018; Roos et al., 2014). Moreover, interventions that have focused on diet have been providing diet advice that is usually not affordable or not accepted by the rural adults (Faber & Wenhold, 2012; Temple et al., 2011).

Adults in rural South Africa are involved in everyday manual labour but this is performed at low intensity and is not adequately profiled (Oyeyemi et al., 2016a). There is a dearth of data to describe the types and intensity of lifestyle-embedded physical activities that adults perform in rural South Africa (Minnaar et al., 2016). This has resulted in a shortage of contextually relevant physical activity and lifestyle modification interventions tailored to control raised blood pressure in this population (Bertram et al., 2012; He et al., 2013; Lin et al., 2014).

The standard care for controlling hypertension is pharmacological treatment and general health advice from the health care provider (Lloyd-Sherlock et al., 2014). There is a high dependence on antihypertensive medication that is currently being observed (Jardim et al., 2017), this is however not always enough on its own to control hypertension. To be effective; a reduction in salt and caloric intake, and an increase in physical activity are the widely recommended therapeutic approaches to help meet national hypertension targets (Bertram et al., 2012; He et al., 2013; Lin et al., 2014). There is a gap for new interventions to test the feasibility of socially and culturally appropriate diet and physical activity recommendations for hypertension control. Also, in order to change behaviour of a population, one needs to better understand the contextual realities at play that may influence a specific behaviour.

This study will be, to the author's knowledge, the first intervention focusing on adjusting lifestyle-embedded physical activity and dietary practices among hypertensive adults in a rural South African population. If successful, this study may inform future interventions that might contribute to global and national targets such as the World Health Assembly non-communicable disease target to lower the prevalence of raised blood pressure by 25% by 2025 compared with its country-specific 2010 level (World Health Organization, 2017). Nationally, Goal six and Goal seven of the South African NCD strategic plan is to reduce the prevalence hypertension and to increase the prevalence of physical activity respectively (Day et al., 2014).

1.4 **RESEARCH QUESTIONS**

- a) What is the profile of lifestyle-embedded physical activity among adults living with hypertension in rural Agincourt, South Africa.
- b) What social and cultural beliefs about physical activity and diet in a rural adult South African population influence behaviour change for the control of hypertension?
- c) What physical activity and diet adjustments can be made to the daily routine of adults living in rural Agincourt to control raised blood pressure?
- d) Is a contextualised physical activity and diet intervention for the control of hypertension in adults from a rural subdistrict feasible and acceptable?

1.5 THESIS AIM AND OBJECTIVES

1.5.1 Aim

The aim of this thesis was to design, implement, and evaluate the feasibility and acceptability of a contextually appropriate physical activity and diet intervention for the control of hypertension in adults living in rural Agincourt, South Africa.

1.5.2 Objectives

- a) To establish the profile of weekly physical activity using a self-reported long form questionnaire amongst hypertensive adults living in rural Agincourt.
- b) To explore the social and cultural beliefs, perceptions and practices regarding physical activity and diet in hypertensive adults living in rural Agincourt.
- c) To develop and implement a contextually appropriate educational intervention programme for the control of hypertension in adults living in rural Agincourt
- d) To determine feasibility, acceptability, and fidelity of a contextually appropriate educational intervention programme for the control of hypertension in adults living in rural Agincourt.

1.6 STUDY SITE AND POPULATION

This study will be conducted in Bushbuckridge sub-district in Mpumalanga province where the Agincourt Health and Demographic Surveillance System (HDSS) has been running since 1992. The HDSS is run by the MRC/ Wits Rural Public Health and Health Transitions Research Unit. The Agincourt HDSS covers an area of 450km² with 115 000 individuals (approximately 52 000 older than 18 years) living in approximately 20 000 households distributed in 31 villages (Goudge et al., 2018; Jardim et al., 2017; Thorogood et al., 2014). The prevalence of hypertension in this study site for the adult population varies from 40% in 2010 (Thorogood et al., 2014), 57% in 2012 (Gómez-Olivé et al., 2013), and 58.4% in 2016 (Jardim et al., 2017).

The Health and Aging in Africa: A Longitudinal Study of an INDEPTH (International Network for the Demographic Evaluation of Populations and Their Health) community in South Africa (HAALSI) is a cohort of 5059 adults aged 40 years and above within the Agincourt HDSS (Gomez-Olive et al., 2018) will be used as a sampling frame. The prevalence of hypertension in this cohort is 57% (n= 2843), defined as self-reported medication of hypertension or systolic ≥ 140 mm Hg or diastolic ≥ 90 mm Hg. The prevalence is divided as 1227 males (54,3%) and 1616 (61,3%) females.

CHAPTER 2

2. LITERATURE REVIEW

2.1 INTRODUCTION

The aim of this study is to design, implement, and evaluate the feasibility and acceptability of a contextualised physical activity and diet intervention for the purpose of controlling hypertension of adults living in rural Agincourt, South Africa. Literature concerning physical activity and dietary practices of both urban and rural adults and how these contribute to the control of hypertension is reviewed. The purpose of this chapter is to review and discuss literature that has addressed hypertension control in order establish the status of evidence and the gap in knowledge of hypertension in rural South Africa.

The scope of this literature review begins with global and local epidemiological data about non-communicable diseases and hypertension. In particular it looks at epidemiology of hypertension and the determinants of hypertension. The pathophysiology of hypertension is described with a focus on the neurohormonal, renal, metabolic, and vascular factors that regulate blood pressure. Studies that describe the non-pharmacological management strategies of hypertension are described including physical activity and dietary approaches. Studies related to barriers and facilitators to physical activity and diet are discussed with a focus on the daily routine of African adults living in rural settings. Various methods of collecting data in public and population health studies are discussed to provide an overview of methods that were used to collect data for this thesis.

2.2 SEARCH METHODS

Search engines utilized for this literature review included: PubMed, Scielo, NCBI, Clinical Key, CINHALL, and Google Scholar. The literature included in this review is predominantly from 2010 to 2024. There is, however, literature from previous years explaining concepts that have been published in relatively older studies. Only studies published in English were included. The author utilized a Mendeley referencing software which was used to manage references.

2.3 GLOBAL BURDEN OF HYPERTENSION

Over 1.2 billion people have hypertension worldwide and more than half of people with hypertension are not receiving treatment (Mills et al., 2020). The prevalence of hypertension is estimated to increase to 1.5 billion people worldwide by the year 2025, thus making hypertension a global public health crisis (Guwatudde et al., 2015). The continued increase in the prevalence

of hypertension is attributed to aging and population growth, lack of physical activity and poor dietary intake. Hypertension is identified as a worldwide public health challenge due to its effects on mortality and disability adjusted life years (Mills et al., 2020; Moraga & Collaborators, 2017).

Hypertension was associated with increased risk of all-cause mortality and 17 out of 67 causes of death (Aune et al., 2021). Majority of these deaths were due to septicemia, infectious diseases, Diabetes Mellitus, circulatory diseases, hypertensive heart disease, and ischaemic heart disease. A global study reported that the number of deaths because of systolic blood pressure of $\geq 110 - 115$ mmHg was 10.7 million while systolic blood pressure of ≥ 140 mmHg was 7.8 million (Forouzanfar et al., 2017). Forouzanar and colleagues (2017) described that deaths due to increased systolic blood pressure were attributed to ischaemic heart diseases, ischaemic strokes, and haemorrhagic strokes. A study by (Feigin et al., 2017) further emphasized that ischaemic heart disease was the most common cause of death worldwide (14.8% of all deaths) and the second most common cause of disability (6.1% of DALYs from all causes) in 2013, followed by stroke which accounted for 11.8% of all deaths and 4.5% of DALYs from all causes. Hypertension was identified as the leading contributor to developing stroke and ischaemic heart disease.

A pooled analysis which studied hypertension trends from 200 countries pooled 1479 studies which measured blood pressure of 19.1 million adults (Zhou et al., 2017). The analysis found that low- and middle- income countries; especially those in Africa, South Asia, and Southeast Asia report higher prevalence rates than high-income countries; especially those in North America and Europe (Zhou et al., 2017). The reasons for these disparities have been attributed to differences in access to healthcare, lifestyle, social, and genetic factors. Predictive analysis intimates that the number of hypertension-related deaths before the age of 70 will occur in low- and middle- income countries (Egan et al., 2019).

In addition to international and regional differences in the prevalence of hypertension; differences by age, gender, and ethnicity have been observed globally (Riaz et al., 2023). Hypertension becomes more prevalent as people age; this is due to normal physiological changes that occur when people age such as changes in blood vessel flexibility and general cardiovascular health (Riaz et al., 2023). However, hypertension can also affect younger people mostly due to lifestyle factors such as inactivity and obesity (Singh et al., 2012). Prevalence rates as high as 19% in an American population younger than 32 years have been reported (Chiolero et al., 2013) and this is mainly due to unhealthy lifestyle habits (Carey, Muntner, et al., 2018a). It has been reported in a recent systematic review that unhealthy lifestyle habits from a younger age can translate to poor lifestyle habits in adulthood hence contributing to the high burden of chronic diseases in adult years (Meher et al., 2023).

For people in different age groups, differences of hypertension prevalence vary by gender. During early adult years, men have an increased likelihood of getting hypertension than women (Ferrari et al., 2013). Although this trend varies across different populations, many regions have reported high prevalence in young men than women. For example, a study conducted in the United States found that the prevalence

of hypertension in younger men was 45% while it was 35% for younger women (Ong et al., 2008). Young adult men (<40 years) in the African region also had a higher prevalence rate of 23% while women of the same age band were 20%. Some of the reported reasons why hypertension prevalence is higher in younger men than women is smoking and alcohol use which is observed in men (Ogah & Rayner, 2013; Wang et al., 2006). In a recent South African study, however, the prevalence of hypertension was similar between older women and men, however the risk factors differed across sex. For example, the alcohol and tobacco consumption were higher in men than women, but the levels of obesity were higher in women than men (Peer et al., 2021). This demonstrates the influence of alcohol and tobacco as a risk factor for hypertension in men regardless of age, while obesity is highlighted as a risk factor for older African women.

As both genders age, women have an increased prevalence than men due to menopause (Ferrari et al., 2013). Menopause causes hormonal changes, in particular there is a drop in oestrogen levels during menopause. Oestrogen is a hormone which helps to maintain blood pressure levels due to its vasodilatory effects and is known to decline during menopause (Coylewright et al., 2008). The decline in oestrogen causes an impairment in vasodilation and increases vascular resistance, causing hypertension (Coylewright et al., 2008; Manson & Bassuk, 2005). In addition to its vasodilation effects, oestrogen is responsible for sodium and fluid balance and its reduction further predisposes women to developing hypertension (Modena, 2014).

The burden of hypertension has been reported in multiple South African regions of different age and gender. Risk factors of developing hypertension has also been noted amongst urban and rural south African adults. Other factors that have been attributed to the development of hypertension are differences in socioeconomic, cultural variables and healthcare access (Benjamin et al., 2018).

2.4 LOCAL BURDEN OF HYPERTENSION

The latest South African hypertension practice guideline published by the South African Hypertension Society reported that 30.4% of South African adults have hypertension (Seedat et al., 2014). This guideline was published a decade ago and the prevalence has since changed but not updated by the guideline. Studies have been conducted for different South African populations but may not be representative of national statistics. For example, a study conducted in a rural adult population of 451 South Africans reported a hypertension prevalence of up to 60% (Jongen et al., 2019) with 27.4% of men and 26.1% of women hypertensive (Gaziano et al., 2017). The study was conducted in a cohort of adults aged 18 years and above who attended the Ndlovu Research Centre in Elandsdoorn, Limpopo. Participants in the study were also asked about their awareness and treatment of hypertension. The results show that only 14% of participants had good knowledge of hypertension. The risk factors to developing hypertension were identified as poor nutritional status and lack of recreational physical activity, both due to poverty.

Another recent cross-sectional study was done in rural and semi-urban communities of Limpopo province (Mphekgwana et al., 2020). The study assessed the prevalence of hypertension using the MEDIC

Pharmacists Choice Blood Pressure Monitor and risk factors of hypertension using the INTERHEART Risk Score tool amongst 1106 rural and 1187 semi-urban adults aged 18 years and above. The results showed that the prevalence of hypertension was 21% for all adults and there was no gender difference. In both studies the main contributing factors to developing hypertension were identified as physical inactivity and unhealthy eating behaviours characterised by a high salt diet. It has also been found that age above 50 years, multimorbidity (obesity, diabetes, other cardiovascular diseases), and westernized diet increased the likelihood of a hypertension diagnosis (Jongen et al., 2019; Mphokgwana et al., 2020; Sharma et al., 2021).

For urban populations of South Africa such as the Western Cape province, the pooled prevalence has been reported at 38.9% (Peer et al., 2021). This prevalence was mainly associated with alcohol consumption especially amongst the male population. The Western Cape government has reported that alcohol abuse is a major crisis and is the highest in South Africa, with as much as 43% of pregnant women reporting alcohol consumption during pregnancy (Herrick, 2012; May et al., 2014). Due to the differences in risk factors for hypertension in rural and urban South Africa, approaches to hypertension control should be targeted at the specific context.

Awareness/non-awareness of blood pressure status has been reported to affect control of the condition (Al Duraihim et al., 2019). In a rural district in Mpumalanga province there is a high level of awareness and an even higher number of people on pharmacological treatment; however, the condition is still not under control (Gómez-Olivé et al., 2017; Jardim et al., 2017). The reported predictors of blood pressure awareness were being female, older age, high educational status, experiencing limitations in physical function, and being employed.

In uMgungundlovu, a district in the rural province of KwaZulu-Natal a study was conducted amongst 7303 Black South Africans (hypertension prevalence = 44.4%) across three different municipalities which explored the awareness and control of hypertension amongst adults of differing education statuses (Madelá et al., 2023). The results, which are in contrast with other rural districts in South Africa (Gómez-Olivé et al., 2017; Jardim et al., 2017; Ntuli et al., 2015) showed that adults with no education had a better understanding and were more knowledgeable regarding hypertension compared to those who had little to high education. These results were explained by people with no educational background being the likely targeted recipients of public health interventions and had better health seeking behaviour than those who had higher educational background. The results were also similar to a South African household survey of 1847 adults (hypertension prevalence = 43%) where the authors argued that adults with low education had frequent interactions with public health interventions and had more visits to primary health care services (Ware et al., 2019). The low control of hypertension amongst adults with a higher educational background in uMgungundlovu district was explained by the adults' limited time to access health care services as a result of their high job demands. The high prevalence of hypertension in South Africa and the low levels of control results in increased financial spending from the government (Kohli-Lynch et al., 2022).

The financial burden of hypertension in South Africa is a concern due to the deficiency of the health systems to deal with a high disease burden (Mills et al., 2020). The health system in South Africa is two-tiered with approximately 85% of the country's population utilizing state/public healthcare services (Mayosi et al., 2012; Senkubuge & Mayosi, 2012). This means that only 15% have access to private health facilities in the form of health insurance, out-of-pocket payment, or hospital plans. Some of the contextual characteristics that affects access to health services for hypertensive people in South Africa includes ethnic or residential segregation, poverty, literacy levels, and socio-economic factors (Kandala et al., 2021). While South Africa remains one of the most unequal countries in the world, there has been rapid urbanization and income growth which has resulted in a shift in lifestyle and dietary changes, and stress amongst most South Africans, worsening the burden from hypertension.

A study in South Africa investigated the financial burden of hypertension on the country (Kohli-Lynch et al., 2022). It was found that a large amount of the country's health care budget is spent on the screening, diagnosing and treatment of hypertension which is costing South Africa US\$2.79 billion annually. Type 2 diabetes annual healthcare cost is US\$160 million, smoking annual health care cost is US\$2.54 billion and alcohol abuse amounts to US\$2.27 billion. Thus, the overall hypertension spending is taking up a large portion of the healthcare budget.

2.5 **PATHOPHYSIOLOGY OF HYPERTENSION**

Hypertension can be classified as either primary or secondary. Around 95% of hypertensive patients are classified as primary hypertension and only 5% as secondary hypertension (Laurent et al., 2002). Primary hypertension, also known as essential hypertension, occurs without an obvious cause while secondary hypertension occurs due to an underlying health condition. Many physiological mechanisms are involved in maintaining a normal blood pressure. If any derangement of these physiological mechanisms occurs, it could play a role in the development of primary hypertension (Delacroix et al., 2014; Laurent et al., 2002).

Hypertension is characterized by an increase in systemic blood pressure above 139/89mmHg (Burnier & Wuerzner, 2015). The increase in blood pressure is caused by multiple factors which differ across different ages, ethnic group, and sex. The mechanisms leading to increased blood pressure involve a variety of neurohormonal, renal, metabolic, and vascular factors. One of the physiological mechanisms involved is the cardiac output and peripheral resistance. These specific mechanisms are important factors which maintain normal blood pressure. When there is a sympathetic dysfunction in the body, there is an increase in cardiac output which causes the development of hypertension (Delacroix et al., 2014). Physical activity, especially aerobic exercise works to lower cardiac output and blood pressure by lowering heart rate, improving heart efficiency, decreasing stress response, and improving vascular function (Astorino et al., 2017; Haslam et al., 2011). Therefore, in order to accommodate the change in blood pressure and for the body to maintain homeostasis, the peripheral vascular resistance is required to increase which is the body's natural physiological response (Beevers et al., 2001; Delacroix et al., 2014).

Another physiological mechanism which affects the control of blood pressure is the renin-angiotensin system (Santos et al., 2012). Renin is secreted when there is a reduction in salt intake as well as when the sympathetic nervous system is stimulated. Renin is responsible for converting angiotensinogen to angiotensin I which is then converted to angiotensin II in the lungs by the angiotensin converting enzyme. Angiotensin II is a vasoconstrictor and this causes an increase in blood pressure. Angiotensin II is also responsible for the release of aldosterone which produces risen blood pressure by increasing the sodium and water retention in the body (Beevers et al., 2001; Delacroix et al., 2014). High sodium intake can lead to dysregulation of the renin-angiotensin system, contributing to hypertension. Moreover, excessive sodium intake leads to increased blood volume and fluid retention, which in turn increases cardiac output and places greater demand on the cardiovascular system (Chamarthi et al., 2011; Weidemann et al., 2015). It is therefore important that people with hypertension focus on lowering dietary sodium intake in order to maintain regulation of the renin-angiotensin system (Drenjančević-Perić et al., 2011).

The vasoactive system is another system which is essential for the control of blood pressure. Nitric oxide is produced by the arterial and venous endothelium which diffuses through the vessel walls into the smooth muscle resulting in vasodilation. The atrial natriuretic peptide, a hormone secreted by the atria of the heart, responds to an increase in blood volume. It is responsible for increasing the sodium and water excretion from the kidney. Any dysfunction in this system results in fluid retention and hypertension (Beevers et al., 2001; Delacroix et al., 2014). Regular physical activity, a healthy diet following the principles of Dietary Approaches to Stop Hypertension (DASH), weight management to normal Body Mass Index, stress reduction, smoking cessation, and alcohol reduction can positively influence the vasoactive system in both men and women with hypertension and can lower blood pressure to normal (Chobanian et al., 2003).

Blood pressure and sodium homeostasis work together to stabilize blood pressure through the pressure-natriuresis mechanism (Guyton, 1990). According to this mechanism, hypertension occurs when the kidneys require an increase in blood pressure higher than normal to maintain extracellular fluid volume within normal limits (Baek & Kim, 2021). The increase in blood pressure causes a defect of the pressure-natriuresis mechanism and sodium excretion is not regulated. Other important endocrine factors such as the renin-angiotensin-aldosterone system, prostaglandins, and nitric oxide can create defects of the pressure-natriuresis mechanism to either higher or lower set values (Ivy & Bailey, 2014).

The important contribution of the kidneys in hypertension development was tested in a study by Rettig & Grisk, (2005) who experimented on rats. In their study, they cross-transplanted a kidney of a hypertensive rat to a normotensive rat and this led to the development of hypertension on the normotensive rat. Conversely, they transplanted the kidney of a normotensive rat into a hypertensive rat and this eliminated hypertension showing that blood pressure actually follows the kidneys (Rettig & Grisk, 2005).

While the majority of hypertensive patients suffer from primary hypertension, about 5% have secondary hypertension which usually has an underlying and potentially reversible cause (Charles et al., 2017). The

cause of secondary hypertension varies by age and is more common in children than adults (Charles et al., 2017). Secondary hypertension tends to have a sudden onset with an acute rise of blood pressure from previously normal readings and should always be considered in the presence of suggestive signs and symptoms (Viera & Neutze, 2010). People who are diagnosed with secondary hypertension usually have certain health conditions or are taking medicines; these health conditions can include adrenal gland tumours, blood vessel problems present at birth, kidney disease, obstructive sleep apnoea, and thyroid problems. Examples of medicines which can cause secondary hypertension are cough and cold medicines, certain analgesics, contraceptive pills, cocaine and amphetamines (Puar et al., 2016). It is also possible to present with high blood pressure just by having your blood pressure checked, a phenomenon known as white-coat hypertension (Franklin et al., 2013).

2.6 STRATEGIES USED TO CONTROL HYPERTENSION.

Pharmacological as well as non-pharmacological interventions have been widely recommended to control hypertension (Carey et al., 2018). In South Africa, the 2021 national user guide on the prevention and treatment of hypertension in adults at the primary health care level recommends that upon diagnosis of hypertension, the adult must be given education on the risk factors and co-morbidities before initiating drug therapy (National Department of Health South Africa, 2021). The emphasis of the guide is that management of hypertension is not simply about administering of medication. After educating about the condition and associated risk factors, the health provider needs to provide the patient with lifestyle modification advice and then prescribe medication.

Similar recommendations are made in India where it is recommended that pharmacological management should be initiated only after the patient has been educated regarding lifestyle modifications (Gupta & Guptha, 2010). In India, however, it is recommended that patients with elevated blood pressure should first try lifestyle modifications before initiating drug therapy (Parati et al., 2022). In South Africa drug therapy and lifestyle modification advice are initiated at the same time. Factors such as cardiovascular risk, patient's age, and other co-morbidities should be considered when patients are initiated on drug therapy for hypertension (Makukule et al., 2023).

A large body of growing evidence advocates the role of dietary salt, potassium, alcohol, and body mass index in blood pressure control (Nguyen et al., 2013; O'Shaughnessy, 2006). The PREMIER clinical trial for the control of hypertension randomized free-living hypertensive adults into three groups: behavioral modification (weight loss, increased physical activity, reduced sodium and alcohol intake), behavior plus DASH diet, and "advice only" as a comparison group for six months (Appel et al., 2003; McGuire et al., 2004). There were significant systolic and diastolic blood pressure improvement in the behavior plus DASH diet group which showed that limiting salt to <6g/day, moderating alcohol consumption to <2 units/day for men and <1 unit/day for women, weight loss if BMI is greater than 25 kg/m², exercise, and a DASH diet rich in 20-30 mmol/day of potassium can decrease systolic blood pressure of 10 to 15 mmHg over a period of six months.

Fruits and vegetables are encouraged to assist with the control of hypertension as they generally seen to contain a high potassium level and therefore individuals can acquire a higher potassium intake through fruits and vegetables compared to that of supplements (Gupta & Guptha, 2010). Alcohol reduction to the recommended units (Svetkey et al., 2003) has been shown to decrease the systolic blood pressure by 3.3mmHg and the diastolic blood pressure by 2.0 mmHg. In addition to reducing alcohol intake, people with hypertension should stop tobacco smoking (Carey et al., 2018).

In the South African context and other countries such as India, Congo, and Tanzania there are two types of tobacco use: smokeless tobacco and smoking tobacco (Loh et al., 2023; Mehrotra et al., 2019; Yadav et al., 2020). Smokeless tobacco is common amongst women and there have been debates about the effect of smokeless tobacco on the cardiovascular system as there is a belief that smokeless tobacco is harmless (Peltzer et al., 2001). Smokeless tobacco is in the form of snuff and the basic ingredients are tobacco and other plant leaves (Peltzer et al., 2001; Reddy et al., 2014). Specific data on the prevalence of smokeless tobacco use amongst South African women is not available, however, a prevalence of 12.4% has been reported in South African high school learners (Reddy et al., 2014). The use of smokeless tobacco is more prevalent in rural areas and is associated with certain cultural groups as they use it for cultural practices in some communities (Peltzer et al., 2001).

Studies have demonstrated that there is an increased risk of stroke for people who use smokeless tobacco compared to non-smokers (Hergens et al., 2007). Mortality due to cardiovascular diseases has been reported by other authors to be higher among people who use smokeless tobacco compared to non-tobacco smokers (Wennberg et al., 2007). There is lack of data that compares the effects of smokeless tobacco versus tobacco smoking on chronic illness; however, tobacco smoking has been strongly associated with lung conditions due to the chemical properties related to burning. The chemical composition of both forms of smoking is similar, therefore, smokeless tobacco cannot be used as a strategy to stop tobacco smoking.

Another strategy to assist with the control of hypertension is weight management (Aronow, 2017; Kurukulasuriya et al., 2008). There is a direct relationship between an increase in body weight and the development of hypertension which is extensively published worldwide (Aucott et al., 2005; Jiang et al., 2016; Kurukulasuriya et al., 2008; Leggio et al., 2017; Seravalle & Grassi, 2017). People with hypertension should aim to maintain body weight within body mass index of less than 25 kg/m² (Gupta & Guptha, 2010). Obesity and hypertension are independent global public health problems, and hypertension seems to be the most commonly occurring co-morbidity amongst obese people, especially visceral obesity (Kurukulasuriya et al., 2008). It is therefore expected that hypertensive obese people have increased rates of cardiovascular-related morbidity and mortality. For the South African rural adult population, being obese has been associated with low literacy levels (Kimani-Murage et al., 2011; Kruger et al., 2005). Some factors that hinder interventions towards weight loss in the South African population include very few

obese and overweight people view themselves as overweight (Cois & Day, 2015). Obese and overweight women do not want to lose weight even though they may know the health consequences of excess weight, women with a slightly increased body mass index appear as attractive to the community, and being slightly overweight is associated with affluence (Cois & Day, 2015; Puoane et al., 2002).

Although lifestyle changes have been demonstrated worldwide to contribute to the control of hypertension and other cardiovascular diseases, these may only have short-term impact due to individual and contextual challenges (Bowen et al., 2019; Oliveros et al., 2020; Sebire et al., 2018; Terragni et al., 2018). It is therefore essential for lifestyle interventions to consider environmental factors and build healthy public policies that enable individuals to make lifestyle decisions that will have a longer lasting impact.

2.7 LIFESTYLE MODIFICATIONS IN HYPERTENSION CONTROL

2.7.1 Physical Activity

The 2020 World Health Organisation recommendations for physical activity for adults state: “all adults should undertake 150-300 minutes of moderate-intensity, or 75-150 minutes of vigorous-intensity physical activity, or some equivalent combination of moderate-intensity and vigorous-intensity aerobic physical activity, per week, for health benefits” (Bull et al., 2020). This dose-response relationship between physical activity and health has, however, been challenged by public health researchers as not feasible in community settings due to its threshold messaging (Segar et al., 2020). Multiple studies recommend regular participation in physical activity even if it is of low to moderate intensity for health benefits (Alpsoy, 2020; Herbert et al., 2020; Tsukita et al., 2022; You et al., 2018). However, a recent systematic review shows that higher levels and intensity of physical activity are likely associated with lower risk of developing hypertension and other cardiovascular diseases (Cleven et al., 2020). Segar and colleagues (Segar et al., 2020) reviewed the WHO 2020 recommendations for physical activity and concluded that the new guidelines provide an opportunity to communicate simple, scientifically supported concepts and messages that are easy to understand, easy to remember, and able to be put into practice across different contexts and populations. The main message should not be memorising the exact physical activity dose, but rather regular participation in physical activity of increasing intensity.

Regular aerobic physical activity has been demonstrated to provide significant reduction in blood pressure and overall reduced risk of cardiovascular diseases (Diaz & Shimbo, 2013). An exercise prescription update which reviewed existing recommendations with emerging research reports that on days when physical activity of moderate-vigorous intensity is performed, the blood pressure reading is lower than on days when not performed (Pescatello et al., 2015). This is due to a physiological response known as post exercise hypotension (PEH) whereby there is an immediate decrease in blood pressure by 5-7mmHg and this decrease is usually sustained for up to 24 hours post exercise (Pescatello et al., 2015). A narrative review of PEH suggests that blood pressure should be assessed for 20 minutes after exercise in order to observe a decrease in blood pressure (de Brito et al., 2019).

As previously described, most hypertensive individuals are overweight or obese (Kurukulasuriya et al., 2008), so participating in regular physical activity allows these individuals to expend energy which may facilitate weight loss (Lyznicki et al., 2001; Seravalle & Grassi, 2017). When assessing the recommended time frame for physical activity of hypertensive people, individuals should achieve at least 150 minutes or more of exercise per week (Bull et al., 2020). A recent systematic review which evaluated the effect of different types of aerobic exercise on individuals with and without hypertension has shown that aerobic exercises performed in shorter bouts but done throughout the day also facilitates reduction in blood pressure (Esmailian et al., 2023). Physical activity for shorter bouts of light to moderate intensity interspersed throughout the day results in PEH for the remainder of the day (de Brito et al., 2019).

Further recommendations for hypertensive people speak about the frequency, intensity, time and type (FITT) prescription principles which state that aerobic exercises should be done preferably every day and it should be coupled with dynamic resistance exercises 2-3 times in the week (Pescatello et al., 2015). Both the aerobic exercises as well as the dynamic resistance exercises should be of moderate intensity (60% - 80% one repetition maximum). Aerobic exercises should last for 30-60 minutes per day if it is done continuously or else it should be done in 10-minute durations and should make up the 30-60 minutes in the day while the dynamic resistance exercises should consist of 2-3 sets of 10-12 repetitions. This should make up 150 minutes or more per week. Aerobic exercises could include jogging, walking, cycling, and swimming while the dynamic resistance exercises could include body weighted exercises, free weighted exercises, resistance band or machine weighted exercises (Pescatello et al., 2015).

A population-based survey of 6636 adult participants in the United States evaluated the years of life gained from light intensity physical activity (del Pozo Cruz et al., 2021). In the study, a mean follow-up of 11 years was conducted, and the results showed that participants with low, medium, and high light-intensity physical activity had a predicted life expectancy of 53.92, 58.16, and 58.44 years. The results suggested significant years of life gained from medium and high levels of light-intensity physical activity of 2.89 and 3.07 years. Given the low prevalence of moderate-to-vigorous physical activity in populations such as South Africa, light-intensity physical activity may extend life expectancy and provide health benefits for reduction of high blood pressure.

Another form of light intensity exercise which has been shown to cause a reduction in blood pressure amongst mild hypertensive adults is Tai Chi Chuan exercises which were tested in 12 weeks randomized controlled trial (Tsai et al., 2003). Tai Chi Chuan exercises are slow, smooth, gentle exercises aimed at loosening joints, stretching muscles, and promoting circulation (Lan et al., 2008). Examples are arm swings, waist rotations, and gentle stretches. Thirty minutes of Tai Chi Chuan exercises, three times a week at an intensity of 64% of maximal heart rate were performed. The trial demonstrated that after a 12-week programme of implementing the Tai Chi Chuan exercises, participants showed a decrease in systolic blood pressure by 15.6 mmHg and a decrease in diastolic blood pressure by 8.8 mmHg. The Tai Chi Chuan was shown to be effective within community settings as the exercises do not require any equipment

or technology and it also has a positive effect on cardiorespiratory function. With an increase in exercise, there is increase in perspiration where sodium is lost. Increased perspiration causes a decrease in tonic sympathetic nerve activity which causes a decrease in hypertension (Baker, 2019).

In addition to performing light-intensity exercises, public health interventions must also focus on encouraging people to sit less and move more. Rural areas of South Africa are currently experiencing environmental and demographic shifts characterised by an aging population which tends to move less, urbanisation of public and workspaces which encourage physical inactivity, and a higher proportion experiencing frailty and reduced physical function (Ragie et al., 2020). Emerging physical activity strategies which focus on changing patterns of sedentary behaviour may have the potential to lower the prevalence of hypertension.

A large-scale observational study by (Diaz et al., 2017) found that both total sedentary time and prolonged uninterrupted sedentary bouts were associated with an increased risk for all-cause mortality, after controlling for moderate-vigorous physical activity and traditional cardiovascular risk factors. Similar findings were reported in a population-based cohort study of Australian adults, concluding that greater amounts of sitting time and prolonged uninterrupted sitting were associated with waist circumference, body mass index, cholesterol, triglycerides, 2-hour postload glucose, and plasma glucose. Due to the growing body of evidence reporting on the cardiovascular and metabolic risk factors of too much sitting, leading health agencies have acknowledged the need to provide health messaging that change sedentary behaviours.

In a systematic review and meta-analysis, Lee and Wong (2015) examined the associations of time spent in sedentary behaviours with blood pressure in both adults and children. Of the 28 studies included in the meta-analysis (8 longitudinal and 20 cross-sectional), 10 assessed sedentary behaviour via accelerometry, and the remainder used self-report measures (i.e. television/ screen viewing time, sitting time, or both). Results from this meta-analysis revealed that for each hour increase in self-reported sedentary behaviour, there was an associated small increase in systolic and diastolic BP of 0.06 (95% CI, 0.01– 0.11) and 0.20 (95% CI, 0.10–0.29) mmHg, respectively. Additionally, for each hour increase in sedentary behaviour, there was a 2% elevation in risk for hypertension (odds ratio, 1.02; 95% CI, 1.003– 1.03). Interestingly, no statistically significant associations were observed when sedentary time was assessed via accelerometry, although systolic BP trended at 0.10 (95% CI, –0.001 to 0.21; $P=0.06$) mmHg (Lee & Wong, 2015). These discrepancies between the self-report and device-based exposure measures suggest either differences in measurement variability, validity, and reliability (for both the sedentary behaviour exposures and the resting blood pressure outcomes), poorer compliance with the use of the accelerometers or that the disparity in timing of office blood pressure measurements in relation to the active/sedentary behaviours may also be important.

2.7.1.1 Physical activity considerations for rural population

While international guidelines are very clear on the recommendation about the frequency of weekly physical activity, recent findings from systematic reviews and meta-analyses evidence has challenged this threshold-centred messaging as it may create an unnecessary barrier to those who might benefit greatly from simply becoming more active (Warburton & Bredin, 2017). In their systematic review, a dose-response relationship between physical activity and health status was examined (Warburton & Bredin, 2017). Majority of studies reviewed revealed a nonlinear relationship between physical activity and health outcomes with most benefits observed at lower doses of physical activity (i.e. moving from an inactive position to a more active position). The benefits increased more with higher volumes of physical activity. This may be important for adults living in rural areas of South Africa who are usually involved in manual labour work that is of low intensity (Oyeyemi et al., 2016). All that may be required is for them to increase the intensity of their current physical activities.

A national South African survey reported that 57% of South African adults were not physically active and being from a rural settlement reduced the likelihood of engaging in vigorous physical activity (Mlangeni et al., 2018). Physical activity of moderate-vigorous intensity was associated with having a higher education and higher socioeconomic status. Interventions in the South African context which focuses on increasing physical activity based on usual daily routine are required. Such interventions must first understand factors which influence physical activity participation in the context of the environment (Diaz & Shimbo, 2013; Minnaar et al., 2016; Pelletier et al., 2022; Tusso, 2015).

Health promotion to reduce the prevalence of hypertension should promote physical activity as an adjunct to pharmacological treatment for effective control (Bolin et al., 2018). The focus should be on getting people to become more active in order to get the best benefits for improved health status. In rural areas, adults are involved in everyday walking as means of transport (Cook, 2007), promoting brisk walking amongst these people can have positive health benefits as proved in a review that brisk walking for 20minutes a day provides 30% - 40% reduced risk of myocardial infarction (Manson et al., 1999). A narrative review on the evidence of health benefits of regular physical activity also advocates for getting people from low intensity tasks to moderate-vigorous intensity tasks, the threshold-centred messaging should be avoided as it can be a barrier for those who have not been regularly active (Warburton et al., 2006).

While the evidence suggesting that physical activity is a strong recommendation to lower blood pressure in hypertensive adults is globally accepted, it is not sufficient on its own (Verma et al., 2021). Guidelines recommends that pharmaceutical therapy combined with lifestyle changes of physical activity and dietary intake are the gold standard (Seedat et al., 2014; World Health Organization, 2021). When it comes to dietary recommendations for hypertensive adults, the globally recommended approach is the Dietary Approaches to Stop Hypertension.

2.7.2 Diet/Nutrition

The Dietary Approach To Stop Hypertension (DASH) has been proven overtime in multiple trials to be effective in reducing blood pressure (Appel et al., 2006; Challa et al., 2022; Guo et al., 2021). The DASH diet promotes the dietary inclusion of fruits, vegetables, lean meat, dairy products and micronutrients while advocating for a decrease in sodium intake and processed foods as these are shown to cause hypertension (Appel et al., 2006). Individuals following the DASH diet should typically include the following into their diet: five servings of fruits and vegetables per day, seven servings of carbohydrates per day which include green leafy vegetables, whole grain products, beans and legumes as well as fruits which contain a low glycaemic index. The diet also includes two servings of low-fat dairy product and lean meat per day and lastly nuts and seeds should be consumed two to three times within the week (Challa et al., 2022).

Individuals following the DASH diet are encouraged to consume healthy fats which prevent inflammation such as flaxseed oil, olive oil, avocado oil, hempseed, fish oil and nuts (Appel et al., 1997, 2006; Sacks et al., 2001). The DASH diet also encourages individuals following the diet to increase their consumption of items which are high in potassium, calcium and magnesium as these add in muscle relaxation and prevent endothelial dysfunction. Items which are rich in potassium include oranges, bananas and spinach. Calcium rich items include green leafy vegetables and dairy products while magnesium rich products include whole grains, nuts, seeds and green leafy vegetables (Challa et al., 2022).

In a randomized controlled trial, 412 participants of various backgrounds in the United States were randomly assigned to either a typical daily diet or the DASH diet. (Sacks et al., 2001). In all subgroups (men, women, blacks, non-blacks, hypertensive, non-hypertensive) the DASH diet group had significantly lowered blood pressure. The effects were even greater in the black population (systolic reduction of 6.9 and diastolic reduction of 3.7 mmHg). When analysing results for hypertensive individuals vs non-hypertensive, the results were striking and showed significant improvements in the hypertensive individuals (systolic reduction of 3.5 and diastolic reduction of 2.2 mmHg) (Sacks et al., 2001).

While the DASH diet has been unarguably the gold standard to reducing high blood pressure, compliance still remains low (Appel et al., 1997; Sacks et al., 2001). In the rural South African context there is a high poverty rate and a low intake of dairy products, fruits, and vegetables which makes adoption of the DASH diet unrealistic among the poor (Rose & Charlton, 2002). Street vendors and supermarkets in rural South African communities usually only stock full-cream dairy products, fatty snacks such as 'vetkoek' (fried dough) and cheap fatty meat such as 'russians' (sausage), with very few fruits and vegetables (Kruger et al., 2005). Fatty foods are very common in rural South Africa because they are ready-to-eat, cheap, and require no effort from the consumer to prepare. These include French fries, fried liver, deep-fried fish, russian sausage, tripe, cow's head, cow's feet, chicken feet, heads and eggs (Kruger et al., 2005). A staple in the rural South African population is bread, which provides the highest content of non-discretionary sodium (41-73%) (Charlton et al., 2005). Interventions aiming at dietary changes for rural South Africans

should identify affordable, culturally acceptable, and sustainable approaches in order to enhance compliance. One of the proposed strategies to reducing hypertension in this population is to target sodium content in processed and everyday consumed food (Williams et al., 2003).

The World Health Organization (WHO) recommends less than 5000mg/day (<5g/day) of sodium intake, which is equivalent to just under a teaspoon (WHO, 2020); however, amongst hypertensive patients this should be even lower. By reducing the sodium intake in one's diet, it does not only assist with the reduction in blood pressure but has a beneficial effect on the cardiovascular system as well as the vascular system (Williams et al., 2003). Of all the dietary recommendations made for hypertensive people, salt intake is the most amenable to change. Most rural South African communities hold several social gatherings which encourages overeating due to abundance of food. Such food usually contains high fat and energy, and no one considers the health status of the consumers. Nevertheless, the message for dietary changes to hypertensive adults should be to limit salt intake to as low as possible and to prepare own food as often as they can. Lowering dietary salt and increasing daily physical activity are only two examples of non-pharmacological interventions in hypertension management, many other lifestyle approaches exist and should be recommended where applicable.

2.7.3 Other Interventions

Although the focus of this study is dietary and physical activity adjustments, there are other proven interventions which are recommended to assist with hypertension control such as stress management, meditation, yoga, and getting adequate sleep. These interventions are acknowledged and will be reviewed briefly as they are not the focus of this study.

Stress management has been recommended as an adjunct to blood pressure control (Fu et al., 2020). A study on breathing control by (Grossman et al., 2001) assigned adults with uncontrolled hypertension to either a treatment group or a control group. Both groups were subjected to listening to 10 minutes of music every evening for 8 weeks. The treatment group received a Breathe with Interactive Music device (BIM) while the control group listened passively with a Walkman. A significant reduction in blood pressure was noted amongst the treatment group. The control group showed a very slight reduction in blood pressure. The study demonstrated the effect of slow music as a stress reliever on blood pressure (Grossman et al., 2001). Slow and regular breathing has been shown to play an important role in reduction of blood pressure probably due to the stimulation of the vagus nerve which activates the parasympathetic nervous system (Grossman et al., 2001).

Another intervention described to assist with stress management is meditation (Ponte Márquez et al., 2019). Meditation is conducted by an instructor while participants are seated with their eyes closed and meditate for 20 minutes twice every day (Fu et al., 2020). Meditation has been shown to be more effective in reducing stress amongst African American individuals who present with carotid atherosclerosis

compared to that of health education (Castillo-Richmond et al., 2000). Meditation, however, might not be as applicable in a rural South African setting due to unavailability of meditation instructors in the setting.

Yoga was also recommended as a stress-reducing intervention (Fu et al., 2020). A study was conducted in a primary health care setting in Southern Sweden which looked at the effects of yoga on blood pressure and quality of life (Wolff et al., 2013). The study concluded that providing patients with a short yoga home programme for 30 minutes, three times per week is beneficial in the reduction of blood pressure and improves quality of life. This home programme has to be implemented together with taking the anti-hypertensives as prescribed by the doctor/physician. Getting adequate sleep of at least 6 hours has also been recommended to assist in blood pressure regulation (Hwang et al., 2015). Shortened sleep of 5 hours or less causes a maintenance in the waking state which stimulates the sympathetic nervous system and causes an increase in nighttime blood pressure.

Physical activity, diet, and stress management amongst others (weight management, smoking cessation, alcohol reduction) are recommended worldwide in the fight against hypertension and other cardiovascular diseases (World Health Organization, 2013). These recommendations may apply differently to different contexts, therefore, a tendency of “one size fits all” should be avoided.

2.8 CONTEXTUAL CONSIDERATIONS IN LIFESTYLE MODIFICATIONS.

Contextual considerations may play a crucial role in designing effective lifestyle modifications for hypertension control. These considerations involve understanding the unique circumstances, preferences, and challenges faced by individuals and communities and tailoring interventions accordingly. Some key contextual considerations include cultural background, socioeconomic factors, built environment, health literacy, family and social support, workplace and community setting, technology, and digital health (Kirmayer & Jarvis, 2019; Rimando, 2015; Ring et al., 2018). Considering these factors allows policy makers, health workers, and public health practitioners to design interventions that are culturally sensitive thereby eliminating barriers to public health interventions.

In a study to investigate the barriers to physical activity participation in Kuwait, 240 randomly selected hypertensive adults who visited a primary health care facility for treatment follow-up were given a questionnaire (Al SAIRAFI et al., 2010). Only 35% of participants conducted the exercises as advised by the treating clinician. When investigating why most hypertensive individuals did not exercise even though they were advised to, 51.1% of them stated that they ‘cannot spare time’ for exercise. Another 19.6% of individuals stated that they ‘lacked the desire’ to perform exercise and 12% stated that they were ‘not convinced of its benefits’. Further barriers to exercise by hypertensive adults in Africans were explored in a qualitative study by Rimando, (2015) who reported that individuals lack motivation to leave their homes to exercise, others stated that they live alone and there is no one to assist them with their exercise while many individuals admitted that they were just lazy and they lived a sedentary lifestyle because they stayed at home all day. Other individuals in the same study commented that they were fearful of injuring

themselves and they stated that they have pains which also prevent them from exercising (Rimando, 2015).

Another study conducted in public health care in Kosovo Europe, identified reasons as to why patients with hypertension did not perform physical exercises and it was noted that most individuals chose walking in their neighbourhood as the means of exercise (Bytyci Katanolli et al., 2022). They stated that the sidewalks are usually very crowded, and they are unable to walk on the road due to the traffic. They also noted that there was not adequate lighting on the roads which meant that once they returned home from work, they were unable to undertake exercise. They expressed that having to go further away to exercise required more time and effort which means that they were less likely to exercise. Individuals from the study also complained of the dense traffic within their respective areas as they expressed that due to the high traffic flow it was unsafe for them to exercise, and the sidewalks were too crowded with people and cars and therefore they were unable to exercise. Individuals also noted that they have low energy levels and high levels of stress which prevented them from exercising. It was also noted that individuals from the study did not necessarily have the support and motivation from friends and family to exercise (Bytyci Katanolli et al., 2022).

With regard to dietary changes, many individuals complain that they are unable to follow the dietary changes due to unaffordability of fresh food and vegetables. Other individuals noted that culturally they have a very poor diet, and it is very difficult to change in old age (Wexler et al., 2009). Other individuals expressed that they were unable to perform their exercises and stick to their diet due to lack of support from their family and friends (Devkota et al., 2016).

A review of research literature on whether adapting interventions improves retention to the intervention and outcome effectiveness found that adapting interventions to the local cultural contexts can increase retention by up to 40% (Kumpfer et al., 2002). Similar findings were reported in a meta-analysis which found that culturally adapted health promotion interventions had greater outcomes and impact than standard “fit-for-all” interventions (Soto et al., 2019). For health promotion interventions aimed at hypertensive adults in rural South Africa, it has been noted as crucial to understand the determinants of behaviour change and social context, and apply the necessary behaviour change models in order to improve retention, and eventually outcomes (Sekome et al., 2024a). Multiple research methodologies were applied in the health promotion intervention development.

2.9 METHODOLOGICAL CONSIDERATIONS

2.9.1 Introduction

Researchers in the field of public health are usually concerned with shedding light on the influence of the determinants of health (Bromley et al., 2015). These factors can range from genetic, environmental, and social (Chalub et al., 2016). The aim of public health research is to generate knowledge and use it to propose interventions and policies, based on scientific evidence, to help improve health and well-being,

and reduce health inequalities (Bromley et al., 2015). As in most research in health and social sciences, public health research usually focuses on two types of research, namely, qualitative, and quantitative research (Isaacs, 2014). This thesis utilized a combination of quantitative and qualitative research approaches to develop and then test the feasibility and acceptability of modifications to lifestyle (namely physical activity and diet) on blood pressure among hypertensive rural adults. The two types of research and how they were applied in this thesis are described below.

2.9.2 Qualitative Research Approach

Qualitative research methodology enables researchers to explore social and behavioural issues related to public health that are not achievable with quantitative methods (Isaacs, 2014; Mykhalovskiy et al., 2018). Qualitative research is useful when the research focuses on complex issues such as human behaviour and unmet needs. There are three identified circumstances where qualitative research is usually utilized: i) to study the social, cultural, economic, and political factors that influence health and disease; ii) to examine interactions between various stakeholders in an issue of public health importance; iii) to explore how people and their communities interpret health and disease (Mykhalovskiy et al., 2018). In-depth Interviews and focus group discussions are the most common methods of data collection in qualitative research.

2.9.2.1 In-depth interviews

For this thesis, in-depth interviews were conducted with selected participants in order to understand the social and cultural beliefs of the participants about barriers and facilitators to physical activity and diet behaviour (Sekome et al., 2024a). This method of data collection started gaining growth in the 1980s as a method of qualitative educational research and now it is generally agreed that interviewing is a key method of data collection (Granot et al., 2012; McNair et al., 2008). One of the recommendations from a study by Tausch & Menold, (2016) which was a key consideration for this thesis is that participants preferred to be recruited for the interviews face-to-face rather than in writing. The main aim of this thesis is to test an intervention that considers the felt beliefs of the community members therefore it is important to gather information about their feelings through face-to-face interviews.

Some of the reported strengths of in-depth interviews which motivated the choice of this method is their ability to provide detailed insights into participants' thoughts, allowing for a deeper understanding of personal and social issues (Knott et al., 2022). This type of data collection method also allows the researcher to be flexible in the questions they ask, allowing exploration of more topics as the conversation unfolds, which leads to unexpected findings. In-depth interviews provides the researcher an opportunity to probe, especially in a community where the study participants may be shy to provide elaborate responses (Della Porta, 2014; Knott et al., 2022; Matyas, 2020; Scanlan, 2020). A few weaknesses are also identified with in-depth interviewing, the major one for consideration was interviewer bias. This study utilised local research assistants and necessary measures had to be put in place to avoid bias. Conducting in-depth interviews can be labour-intensive hence the use of trained research assistants. In addition to the

lengthy fieldwork, analysing in-depth interview data is complex and requires significant time and resources (Matyas, 2020). Another consideration is that participants may sometimes struggle to recall specific information and provide socially desirable responses (Knott et al., 2022). In addition to collecting data through in-depth interviews, focus group discussions needed to be conducted to understand shared feelings about the thesis topic from community members with shared interests.

2.9.2.2 Focus group discussions

Focus group discussions were chosen to collect opinions from community members for this thesis. This method was chosen due to its ability to elicit information that can be applied to developing recommendations for a broader community with shared interests (Muijeen et al., 2020). The use of focus groups as a research method in market research, originated in the 1940s in the work of the Bureau of Applied Social Research at Columbia University (Stewart & Williams, 2005). There is more to focus group discussions than merely collecting similar data from many participants at once (Colucci, 2007). Group interactions allow for participants to share diverse perspectives and insight that may otherwise not be discovered through one-on-one interactions. Researchers also can observe how different group members of different gender and age interact with each other on a particular topic. On the topic of hypertension, physical activity, and dietary practices, men and women might have different values and gender roles; a mixed focus group discussion can be a platform to uncover this phenomenon. Focus group discussions can also stimulate ideas. Participants can build on each other's ideas with the guidance of the moderator who will probe participants (Colucci, 2007). Much of the debate around focus group discussions has been around how many people should be in the group as well as the composition of people in the group (Reid & Reid, 2005). Gill and colleagues recommend that the optimum number of people in a focus group should be six to eight participants and suggests that researchers should always over-recruit as there is a common possibility of up to two non-attendees (Gill et al., 2008).

The outcome of this thesis is to produce and assess an intervention to control hypertension. Therefore, it needs to consider how community members view their health and what they think would be the best approach for an intervention in the context of their environment.

The sampling frame for the focus groups of this thesis was a cohort of adults diagnosed with hypertension from a defined community, aged 40 years and above (Gomez-Olive et al., 2018). It is recommended that pre-existing groups be used to sample participants as they may be easier to recruit, have shared experiences and enjoy a comfort and familiarity which facilitates discussion or the ability to challenge each other comfortably (Keane et al., 2012). Focus group discussions were therefore better suited to collect data on shared interests for this thesis in adjunct to in-depth interviews. In addition to the two qualitative methods, quantitative approaches were also employed.

2.9.3 Quantitative Research Approach

Quantitative research generally requires the development of a hypothesis that frequently comes from social theory (Choy, 2014). With quantitative research, decisions need to be made about the type of case or samples to select how to measure relevant factors and what research techniques such as questionnaires or experiments to be employed (Sukamolson, 2007). Quantitative methods are frequently designed to precisely estimate population parameters and measure the association between biologic, social, environmental, and behavioral factors, and health conditions to define the determinants of health and disease and, ultimately, to understand causal pathways (Choy, 2014).

2.9.4 **Cross-Sectional Community Surveys**

Community surveys have gained popularity as a research method of understanding more about a particular community (Mackenzie & Knipe, 2006). Two cross-sectional surveys were conducted with hypertensive adults for this thesis. Firstly, the profile of physical activity that the community engages in through a questionnaire was investigated, then secondly a design and an evaluation of the intervention to assess its feasibility and acceptability was conducted. Although these surveys can be structured either qualitatively or quantitatively, the decision to conduct them quantitatively was based on the research questions under investigation (Sukamolson, 2007).

The researcher used an interviewer-administered approach when conducting questionnaires so that the participants can be asked questions in their home language. This approach is in line with methods followed in a study which aimed at comparing data between two physical activity measures (Oyeyemi et al., 2016). The researchers collected quantitative data from a cohort of elderly participants in South Africa. In their study, they noted the importance of conducting surveys in the participants' home language especially if the participants are of older age and low literacy levels as seen in the cohort used for this thesis (Gomez-Olive et al., 2018). Similar to recommendations from in-depth interviews conducted by other researchers, (Oyeyemi et al., 2016) also utilized and recommended recruiting community members through door-to-door visits. One method of data collection which they used in their study was inviting the participants to a central clinic for completing the questionnaires.

During data collection of some parts of this thesis, the world was facing a COVID-19 pandemic (Rothan & Byrareddy, 2020) and data collection approaches had to be amended to meet guidelines for reducing COVID-19 transmission (Melnick & Darling-Hammond, 2020). For example, quantitative surveys to collect data on physical activity were conducted telephonically instead of door to door. The main advantages of conducting the study telephonically were a wider reach and cost saving (Maffioli, 2020). Conducting the questionnaire via the phone allows the researcher to contact more people in one day compared to the number of people that could be reached if traveling. This allowed the researchers to obtain the required sample size faster. Due to the lack of travel expenses, this method of data collection saved us costs as only airtime costs were involved. Further implications of COVID-19 on data collection are discussed within each study on this thesis.

2.10 CONCLUSION

This literature review outlined previous research conducted within the scope of the study on hypertension prevention and management outlined in this thesis. It has shown the effectiveness of previous interventions as well as knowledge gaps that need to be filled. This review has shown that there is a lack of culturally sensitive community-based, lifestyle interventions to control hypertension among rural South African adult populations. In order to change behaviour of a population, one needs to better understand the contextual realities at play that may influence a specific behaviour. The studies outlined in this thesis will offer a person-centred, sociocultural approach to hypertension control through adaptations to physical activity and dietary intake. The following chapter outlines a protocol which was followed to design the behaviour change intervention and was published in *Pilot and Feasibility Studies*.

CHAPTER 3

3. STUDY PROTOCOL

3.1 PUBLICATION DETAILS

This chapter is presented as a publication of the thesis protocol. The protocol was published with *Pilot and Feasibility Studies*. The journal is open access and the publication is presented as is without amendments. Table 3.1 presents information about the journal.

Table 3.1: Journal Information where the Protocol was Published

Title of publication	Feasibility and acceptability of a contextualised physical activity and diet intervention for the control of hypertension in adults from a rural subdistrict: a study protocol (HYPHEN)
Authors	Sekome, K., Gómez-Olivé, F.X., Sherar, L.B., Esliger, D.W., Myezwa H.
Journal name	Pilot and Feasibility Studies
Journal publisher	Springer Nature
ISSN	2055-5784
Impact factor	1.7
Year published	2024
Volume	10
DOI number	https://doi.org/10.1186/s40814-024-01456-w

3.2 AUTHOR CONTRIBUTIONS

Table 3.2 outlines the contributions to the publication made by each author according to the Contributor Roles Taxonomy (CRediT) laid out by (Allen et al., 2019).

Table 3.2: Author Contributions to Paper One

	Sekome	Gómez-Olivé	Sherar	Esliger	Myezwa
Conceptualization	✓	✓	✓	✓	✓
Project administration	✓				
Methodology	✓	✓	✓	✓	✓
Initial data analysis	✓				
Writing – original draft	✓				
Writing – reviewing and editing	✓	✓	✓	✓	✓
Visualization	✓	✓	✓	✓	✓
Supervision		✓	✓	✓	✓
Funding acquisition	✓				

3.3 ASSOCIATED DOCUMENTATION

The documentation associated with this publication are included as appendices and are labelled:

- Appendix 1: Ethical clearance certificate from University of the Witwatersrand Human Research Ethics Committee
- Appendix 2: local provincial department of health research and ethics committee clearance
- Appendix 3: local district department of health research and ethics committee clearance
- Appendix 12: published paper one – Pilot and Feasibility Studies

3.4 PUBLISHED ARTICLE: FEASIBILITY AND ACCEPTABILITY OF A CONTEXTUALISED PHYSICAL ACTIVITY AND DIET INTERVENTION FOR THE CONTROL OF HYPERTENSION IN ADULTS FROM A RURAL SUBDISTRICT: A STUDY PROTOCOL (HYPHEN).

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Number of tables: 7

Number of figures: 1

Abstract

Introduction: In rural and remote South Africa, most strokes and ischaemic heart diseases are as a consequence of hypertension, which is a modifiable risk factor. The widely recommended therapeutic approaches to control hypertension are through physical activity and diet modifications. However, there is a lack of culturally sensitive community-based, lifestyle interventions to control hypertension among rural African adult populations. We designed an intervention which recommends adjusting daily routine physical activity and dietary behaviour of adults with hypertension. This study aims to evaluate the feasibility and acceptability of HYPHEN in a rural community setting.

Methods: We aim to recruit 30 adult participants with a self-report hypertension diagnosis. A one-arm, prospective design will be used to assess the feasibility and acceptability of recruitment, uptake, engagement, and completion of the 10-week intervention. Recruitment rates will be assessed at week 0. Intervention uptake, engagement, and adherence to the intervention will be assessed weekly via telephone. Blood pressure, body mass index, waist-hip ratio, urinary sodium, accelerometer measured physical activity, and 24hour diet recall will be assessed at baseline and at 10-weeks. Qualitative semi-structured interviews will be conducted at 10 weeks to explore feasibility and acceptability.

Discussion: This study offers a person-centred, sociocultural approach to hypertension control through adaptations to physical activity and dietary intake. This study will determine whether HYPHEN is feasible and acceptable and will inform changes to the protocol/focus that could be tested in a full trial.

Trial registration number: PACTR202306662753321.

Key words: High blood pressure, nutrition, rural, South Africa.

Introduction

The World Health Organization projects that in the African region, by 2030, non-communicable diseases (NCDs) will be the biggest cause of death (Alwan, 2011). The relative burden of NCDs is expected to increase as both HIV/AIDS related mortality declines with the roll-out of antiretroviral therapy and the region continues to experience the rapid urbanization of communities (Zhou et al., 2017). Hypertension, stroke, and ischaemic heart disease are amongst the most common NCDs causing premature deaths among adults living in South Africa (Ntuli et al., 2015). Over half of strokes and ischaemic heart disease in South Africa are caused by hypertension and these cardiovascular and cerebrovascular diseases are reported to be more prevalent in rural areas compared to urban areas (Ntuli et al., 2015).

The high prevalence of hypertension in South Africa will likely result in increased mortality and morbidity in rural compared to urban areas due, in part, to poorly organized health care systems, intermittent drug supply, and shortage of health care workers (Rispel et al., 2019; Sekome, 2018; Zihindulai et al., 2018). Reduced salt and caloric intake and increase in physical activity are the widely recommended therapeutic approaches to meeting national hypertension targets (Bertram et al., 2012; He et al., 2013; Lin et al., 2014).

There is a paucity of research that provides a profile of daily physical activity practices of rural South African adults living with hypertension. A study by Oyeyemi and colleagues (Oyeyemi et al., 2016b) assessed physical activity for rural South Africans using short versions of physical activity subjective assessment which does not provide information about the domain of physical activity (transportation, job, leisure, and housework) performed each day. Another study using a short version physical activity questionnaire by Smart Mabweazara (Smart Mabweazara et al., 2019) in the general population concluded that adults in rural Western Cape engaged in more physical activity than urban adults from the same province. A further study by Tomaz and colleagues (Tomaz et al., 2020) assessed physical activity for middle-aged and older rural adults and recommended that physical activity interventions should be targeted for adults from the age of 40 years in order to provide health benefits earlier in life.

Available literature on dietary practices of rural South African adults have provided successful intervention recommendations for hypertension but the recommendations are not sustained in the long run. For example, a study by Charlton and colleagues (Charlton et al., 2008) provided recommendations of food replacement which participants could not afford due to high unemployment rates in rural South Africa and the fact that recommended food was not part of the participants' daily diet (Geza et al., 2022). Another study by Najam and colleagues (Najam et al., 2023) reported that adults in rural South Africa have good nutrition knowledge but this did

not translate into regular healthy nutrition practices. The literature on physical activity and diet practices for rural South African adults points to a need to have better understanding of the sociocultural influences so that interventions targeting the control of hypertension can consider the realities of this population.

To the authors' knowledge there are no interventions to test whether adaptations in physical activity and diet focusing on a contextualised structured health promotion approach could lower high blood pressure in a rural South African adult population with hypertension (Cook, 2007; Gómez-Olivé et al., 2018). There is a need for studies to investigate the feasibility of implementing such interventions. A contextualised intervention is one that is adapted to the local context of the target population and informed by the population needs. Many adults in rural South Africa are involved in daily manual labour as part of their activities of daily living but this is performed at low intensity and is not well documented (Oyeyemi et al., 2016b). Common manual labour activities reported by adults living in rural South Africa include walking for wood collection, different aspects of farming, yard work, walking as a means of transport, and housework. These activities are not adequate to paint a full picture of the daily routine practices of rural adults and need further exploration (Cook, 2007; C. M. Shackleton et al., 2007). There is lack of information regarding the type, frequency, and intensity of physical activities performed by rural South African adults. Moreover, many diet based interventions are usually not affordable due to high costs or not accepted by the rural adults due lack of availability and contextual considerations, hence the need for tailor-made interventions that consider the contextual realities of the population (Faber & Wenhold, 2012; Temple et al., 2011).

We followed a systematic process to design an evidence and theory-informed contextualised 10-week physical activity and diet intervention which recommends adjusting routine physical activity and diet practices for the control of hypertension using the Intervention Mapping (IM) protocol (Bartholomew et al., 2001) – HYPHEN (HYpertension control using PHysical activity and diEt in a rural coNtext). Intervention Mapping is used as a planning approach to develop theory- and evidence-based health promoting intervention programs. Intervention Mapping has been suggested as a useful and effective tool to further improve the development and application of theories to promote nutrition and physical activity (Brug et al., 2005). The tasks in the IM protocol are iterative with the program planner revisiting previous steps throughout the process so that all objectives, outcomes, and determinants are addressed. This process allows for the development and delivery of the intervention to be replicated

Aim and objectives.

The aim of this study is to implement and evaluate the feasibility and acceptability of a contextually appropriate educational program for hypertension control in adults from a rural South African population.

The primary objectives of the study are:

- a) To present the social and cultural beliefs, perceptions and practices regarding physical activity and diet which influenced the development of an intervention for the control of hypertension in adults living in rural South Africa.
- b) To implement a contextually appropriate educational intervention programme for the control of hypertension using physical activity and diet.
- c) To determine feasibility of the intervention through assessing recruitment, retention, and attrition rates, intervention uptake, engagement, adherence to the intervention, completion, and the evaluation measures.
- d) To determine acceptability of the intervention through individual interviews.
- e) To assess fidelity of intervention delivery using a checklist centered around the behaviour change techniques.

The secondary objective of the study is:

- a) To present descriptive statistics data on health-related indicators (blood pressure, physical activity, diet consumption, body mass index, urine sodium, and waist-hip ratio) before and after the intervention.

Methods

Study design

This feasibility study will be a one-arm community based, prospective study. Feasibility and acceptability of recruitment, the intervention (HYPHEN), and associated outcome measures will be assessed using a mixed-method approach.

Study site and population

This study will be conducted at Bushbuckridge sub-district in Mpumalanga province where the Agincourt Health and Demographic Surveillance System (HDSS) has been running since 1992. The Agincourt HDSS covers an area of 450km² with 116 000 individuals (approximately 52 000 older than 18 years) living in approximately 20 000 households distributed in 31 villages (Goudge et al., 2018; Jardim et al., 2017; Thorogood et al., 2014). We will sample adults aged 40 years and above within the Agincourt HDSS from the Health and Aging in Africa: A Longitudinal Study of an INDEPTH (International Network for the Demographic Evaluation of Populations and Their Health) community in South Africa (HAALSI) (Gomez-Olive et al., 2018). The prevalence of

hypertension in this sub-district for people aged 40 years and above is 57%, defined as a self-reported diagnosis of hypertension (systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg) or self-reported taking medications for hypertension control (Gomez-Olive et al., 2018).

Sample size

A study which provides guidance on conducting feasibility studies by Tickle-Degnen (Tickle-Degnen, 2013) states that feasibility studies are not expected to have large sample sizes as they do not need to power statistical null hypothesis testing. However, Arian and colleagues (Arian et al., 2010) in their review of current best practice state that the sample size of feasibility studies should be adequate to estimate critical parameters such as recruitment rate. An overall sample size of 30 has been recommended by Lancaster, Dodd, & Williamson (Lancaster et al., 2004). We will aim to recruit 30 participants at the beginning of the intervention.

Patient identification, consent process and ethical considerations.

Eligible participants will be invited telephonically via the Agincourt HDSS from a cohort of adults with hypertension. The details of the study will be explained through a telephone call and if the adult demonstrates interest, a household visit will be conducted to provide further information, answer any questions, and obtain written informed consent to participate. The study has received the necessary ethical clearance from the University of the Witwatersrand Human Research Ethics Committee (clearance number: M 210282) and the local Provincial Department of Health Research and Ethics Committee (clearance number: MP_202106_001). We do not anticipate any adverse events to occur because of participating in this intervention therefore no data monitoring committee will be required. Participants already taking anti-hypertensive medications will continue this treatment as usual.

Inclusion criteria

- Ages 40 years and older.
- Self-reported diagnosis of hypertension or self-reported taking medications for hypertension control.
- Lived in the district study setting for minimum six months prior to start of intervention.

Exclusion criteria

- Dependent on wheelchairs for mobility

Preparation procedures

The primary author will train three research assistants on the entire protocol of the study including questionnaire administration, anthropometric measurements, and education of the participants.

Intervention

The intervention will comprise of three components: a structured group education session, individualised physical activity education, and individualised dietary education over a period of 10 weeks (table 3.3 – table 3.5). The duration of the intervention was informed by recommendations from similar studies (Eldridge et al., 2016; Mailhot et al., 2020). The three components of the intervention were informed by a needs assessment from (Sekome et al., 2024b) and other unpublished data (chapter 4 of this thesis). The first part of the needs assessment established the profile of physical activity levels of hypertensive adults in the rural sub-district. Results found that males reported more vigorous physical activity than females at work. Females reported high frequency of moderate-intensity physical activity inside and outside the house. The second part explored the sociocultural perceptions about physical activity and dietary practices which influences behaviour change for the control of hypertension in adults from the rural sub-district (Sekome et al., 2024b). Some key findings included a lack of variety in the daily consumed diet, and the usual diet was mainly influenced by affordability and availability. Physical activity practices were mainly influenced by community perceptions of age and gender-related roles.

The design of the intervention was under-pinned by the COM-B model by Michie, Van Stralen, and West (Michie, Van Stralen, et al., 2011) (figure 3.1). The model identifies three factors that need to be present for any behaviour to occur – Capability, Opportunity, and Motivation. Capability is defined as the individual's psychological and physical capability to engage in the activity concerned. The capability includes having the necessary knowledge and skills. Opportunity is defined as all the factors external to the individual and prompt or make the behaviour possible. Motivation is defined as brain processes that energize and direct behaviour, it includes habitual processes, emotional responding, as well as analytical decision-making. Potential influence between components in the model can occur, for example, opportunity and capability can influence motivation (Figure 3.1).

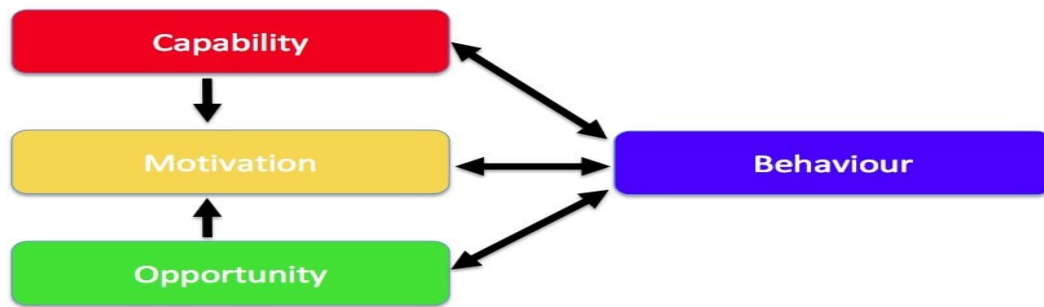


Figure 3.1: COM-B Model of Behaviour Change (Michie, Van Stralen, et al., 2011)

Intervention component one: structured group education

Participants of the intervention will be invited to a common location in small groups (of between six to ten). The main focus of the group education will be to enhance capability through shaping knowledge and skills to engage in the proposed intervention. The trained research assistants will deliver the education using a printed educational pamphlet. Some topics to be covered in the discussion (informed by a contextual need assessment) will include knowledge about what causes hypertension and normal blood pressure values, knowledge on ways to control blood pressure such as reducing salt intake and increasing physical activity, awareness of social triggers/barriers such as cooking for the family, awareness and correction regarding common myths. The group education is expected to last up to 90 minutes per session.

Intervention component two: individualised physical activity education

Participants who attended the group education session will be visited at their home by a trained research assistant to provide individual education on physical activity. Capability will be enhanced by first asking the individual to set goals by identifying the physical activities which they perform as part of their daily routine from a list (informed by a needs assessment). The research assistant will educate the participant on how to adapt performance of the physical activities. This may include changing positions (from sitting) when performing activities, increasing pace of usual active daily tasks, and avoiding sedentary behaviour. Opportunity will be enhanced by emphasizing the importance and benefits of moderate to high intensity physical activities on hypertension control. Participants will be motivated by weekly telephone calls where they will be asked to indicate which activities they were able to achieve that week and encouraged where they fall short. The research assistant will keep record of everyone's weekly performance so that feedback and motivation can be enhanced during weekly telephone feedback.

Intervention component three: individualised dietary education

To enhance capability, individual education on how to make dietary changes will be provided on the same visit as the physical activity education. The research assistant will provide education on food items which contains high sodium content from the participant's usual diet, education on reduction of salt consumption and high salt spices, finding alternative options for food with lower sodium content (for example brown bread instead of white bread), limiting cooking salt to one teaspoon per day, and removing salt from the table during meals. Opportunity for consuming healthier food items will be enhanced by encouraging habitual consumption of self-grown vegetables and naturally growing wild herbs which participants already have access to in their communities. Participants will be motivated through weekly monitoring calls where they will be asked to list which dietary adjustments they achieved weekly. The research assistant will keep record of everyone's weekly dietary habits so that feedback and motivation can be enhanced during weekly telephone feedback.

The authors are cognizant of the under-pinning theories that influence behaviour change such as the social cognitive theory (Bandura, 2013). The primary variable of interest in this theory of motivation is self-efficacy, which concerns someone's belief in his/her capabilities to successfully execute necessary courses of action to satisfy situational demands (Bandura, 2013; Bandura et al., 1999). According to Bandura (Bandura et al., 1999), a high expectation of self-efficacy and outcome expectancy leads to greater adherence to a recommended activity (in our case, physical activity and diet adaptations). Alongside the COM-B model, we developed taxonomies of behaviour change techniques (BCTs) (table 1-3) to identify active intervention ingredients and allow for future replication (Michie et al., 2013; Michie, Hyder, et al., 2011). The BCTs are classified using the Behaviour Change Taxonomy (Michie et al., 2013).

The scope and sequence of the intervention is provided on table 4. The intervention will run over a period of Ten weeks. During week zero, baseline individual assessments of blood pressure, body mass index, waist-hip ratio, and urine sample collection will be conducted. Participants will be asked to wear a wrist-worn accelerometer for seven consecutive days. They will also be asked to complete a 24-hour diet recall questionnaire. During week one, participants will be invited to a group education session limited to up to ten participants per group. Participants will be asked to return the accelerometer device during the group session. The research assistants will note down the recruitment rate, intervention uptake, and any reasons for refusal to take up the intervention. Week two of the intervention will consist of individual household visits to provide participants with physical activity and diet education based on set goals, and to provide printed pamphlet of the education components. The research assistants will telephone the participants weekly for monitoring support and motivation. On week Ten, the research assistants will conduct

household visits and re-assess all baseline measurements. Participants will be asked to wear the accelerometer for seven days as a post-intervention measure. Adherence rate, completion rate, follow up rate, and fidelity will be assessed. An exit interview will be conducted to assess intervention acceptability.

Self-monitoring support

Due to reported low literacy levels in the HAALSI cohort (Abrahams-Gessel et al., 2023; Gomez-Olive et al., 2018), self-monitoring support which does not require the participants to read or write will be provided. The trained research assistants will telephone each participant once weekly to ask questions about the participant's identified physical activity and dietary goals. The research assistant will have a copy of each participant's printed intervention and record progress. Participants will be asked to provide personal and alternative contact number. Where a participant cannot be reached via telephone, a household visit will be conducted. The self-monitoring support is also noted as an active behaviour change technique due to its ability to enhance motivation of adhering to an intervention (Michie, Hyder, et al., 2011).

Table 3.3: COM-B Component and Behaviour Change Techniques (BCT) used in the Structured Group Education Session Targeting Hypertension

Model component	Taxonomy Category	BCT	Definition	Finding from needs assessment	Example
Capability	Shaping knowledge	Information about antecedents	Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict performance of the behaviour.	Lack of knowledge about blood pressure and normal blood pressure values Negative influence from community resulting in myths about causes of hypertension.	Knowledge about what causes hypertension and normal blood pressure values Knowledge on ways to control blood pressure such as reducing salt intake and increasing physical activity Awareness of social triggers/barriers such as cooking for the family Awareness and correction regarding common myths

Table 3.4: COM-B Component and Behaviour Change Techniques (BCTs) Targeting Individual's Physical Activity Behaviour

Model component	Taxonomy Category	BCT	Definition	Findings from needs assessment	Example
Capability	Shaping knowledge	Instruction on how to perform a behaviour (identified by the participant) Goal setting (behavior)	Advise or agree on how to perform the behaviour (includes 'Skills training') Set or agree a goal defined in terms of the behavior to be achieved	Most daily activities are performed at low intensities or in sitting positions.	Changing positions (from sitting) when performing activities Increasing pace of usual active daily tasks Avoid sedentary behaviour Identifying a list of usual daily physical activities performed.
Opportunity	Shaping knowledge	Instruction on how to perform a behaviour (identified by the participant)	Advise or agree on how to perform the behaviour (includes 'Skills training')	Some daily activities performed were of moderate to high intensities.	Emphasize the importance and benefits of moderate to high intensity physical activities on hypertension control.
Motivation	Feedback and monitoring	Self-monitoring of behaviour	Establish a method for the person to monitor and record their behavior(s) as part of a behavior change strategy	Lack of motivation to maintain behaviour change recommendations.	Participant to tick which activity(ies) they achieved on a weekly basis

Table 3.5: COM-B Component and Behaviour Change Techniques (BCTs) Targeting Individual's Dietary Behaviour Change

Model component	Taxonomy Category	BCT	Definition	Findings from needs assessment	Example
Capability	Shaping knowledge	Instruction on how to perform a behaviour	Advise or agree on how to perform the behaviour (includes 'Skills training')	Diet is rich in high salt content such as processed food; use of high salt spices for cooking.	Education on high sodium content food items from usual diet.
	Antecedents	Avoidance/reducing exposure to cues for the behavior	Advise on how to avoid exposure to specific social and contextual/physical cues for the behavior, including changing daily or weekly routines		Education on reduction in salt consumption and high salt spices.
		Goal setting	Set or agree a goal defined in terms of the behavior to be achieved		Finding alternative options for food with lower sodium content (for example brown bread instead of white bread). Limiting cooking salt to one teaspoon per day.
Opportunity	Shaping knowledge	Information about antecedents	Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict performance of the behaviour	Habitual consumption of self-grown vegetables and naturally growing wild herbs such as Nkaka, Aloe and Moringa).	Encourage to continue consumption of wild herbs and self-grown garden produce.
Motivation	Feedback and monitoring	Self-monitoring of behavior	Establish a method for the person to monitor and record their behavior(s) as part of a behavior change strategy	Lack of motivation to maintain behaviour change recommendations.	Participants to tick which dietary adjustments they achieved weekly.

Table 3.6: Scope and Sequence of the Intervention

Program components	Sequence			
	Week zero	Week one	Week two (household visit)	Week Ten (household visit)
Group educational program		Group education sessions.		
Individualised physical activity			-Goal setting -Physical activity intervention education. -Provide printed intervention pamphlet.	Final data collection of self-monitoring physical activity tool.
Individualised diet			-Goal setting -Dietary intervention education -Provide printed intervention pamphlet	Final data collection of self-monitoring physical activity tool.
Anthropometric measurements	Baseline individual assessment: - Demographic data -Blood pressure -BMI* -WHR* -Urine sample collection			Follow-up individual assessment -Blood pressure -BMI* -WHR* -Urine sample collection
Physical activity assessment	Baseline accelerometer wear for 7 days	Return accelerometer		Follow up accelerometer wear for 7 days. (collect after 7 days)
Dietary assessment	Nutrition questionnaire– 24HR diet recall			Follow up nutrition questionnaire- 24HR diet recall
Feasibility parameters		-Recruitment rate -Intervention uptake and engagement -Reasons for refusal		-Adherence rate -Completion rate -Follow up rate -Acceptability interview -Fidelity

*WHR = Waist-hip ratio. *BMI= body mass index

Outcomes and criteria for success

In line with the primary objective c) of the study, the criteria adapted for judging the feasibility of progressing to a larger scale evaluation (table 3.7) were initially developed by Avery and colleagues' (K. N. L. Avery et al., 2017). Top Ten tips for guiding the decision to progress from a pilot to a definitive trial and later reproduced by Hynes and colleague (Hynes et al., 2022). The criteria were also discussed by the study authors guided by existing literature.

Table 3.7: HYPHEN Progression Criteria

HYPHEN progression criteria	Go – proceed to larger scale (RCT)	Amend – Proceed with changes	Stop – Do not proceed unless changes possible
Feasibility of participant recruitment – can 30 participants be recruited in one week?	If 30 participants are recruited in one week (100%)	If 15 to 29 participants are recruited in one week (50 to <100%)	If <15 participants are recruited in one week (<50%)
Feasibility of patient retention – can at least 80% of recruited participants be retained till study end?	≥24 (80%) retained	21-24 (70-80%) retained	<21 (70%) retained
Feasibility of engagement – can at least 80% of recruited participants provide complete weekly data	≥24 (80%) engaged	21-24 (70-80%) engaged	<21 (70%) engaged
Feasibility of intervention implementation	Delivery of intervention judged strongly feasible by qualitative data	Delivery of intervention judged feasible by qualitative data	Delivery of intervention judged possibly feasible by qualitative data

Primary feasibility outcome measures

For primary objective a) of the study, nine focus group discussions were conducted as part of the needs analysis process and the outcome is presented in tables 3.3 – 3.5. For primary objective b) of the study, we followed a model of behaviour change as outlined in figure 3.1 and the outcomes are presented in tables 3.3 – 3.5. Primary objective c) will be assessed as per table 3.7.

The feasibility study parameters which will be used to inform the design of a larger HYPHEN intervention trial are outlined in Table 3.6. Demographic data (age, sex, employment status, type of employment) of participants who refuse to participate in the intervention will be recorded as well as their reasons for refusal. Acceptability of the intervention will be assessed using an in-depth semi-structured interviews through a self-developed interview guide. All participants who were recruited will be invited for the interviews including those who did not complete the intervention. The interview topics and questions will focus on pre-determined themes of participants' perceived expectations of the intervention, benefits, motivations, and barriers. These topics will be explored in relation to participants age, sex, and employment status. Participants will also be asked to rate their overall satisfaction with the intervention using a Likert scale (Joshi et al., 2015). Fidelity of intervention delivery will be assessed by the primary author to ascertain whether the field workers provided the intervention as intended using a checklist framed around the intended BCTs (Table 3.8).

Secondary outcome measures

Secondary outcomes which will be assessed are outlined in Table 3.9 and are as follows: i) Blood pressure will be measured using a oscillometry blood pressure monitor; ii) Body Mass Index will be measured using a stadiometer and a portable LED weighing scale; waist/hip ratio will be measured using a rubber tape measure; iv) urinary sodium will be measured by collecting participants urine sample; v) physical activity will be measured using an Axivity AX3 wearable device on the wrist; and vi) diet will be assessed using a 24HR diet recall questionnaire.

Table 3.8: Fidelity of Delivery of Intervention

Definition (Bellg et al., 2004)	Intervention BCTs	Example
Intervention is delivered as intended	Information about antecedents	Facilitator provided education on all identified aspects of physical activity and diet.
	Goal setting	Facilitator identified and made a tick of the participant's goals for physical activity and diet modifications
	Instruction on how to perform a behaviour	Facilitator explained to the participant how to perform identified goals with images on a printed handout.
	Self-monitoring of behaviour	Facilitator followed with each participant weekly and noted with a tick based on participant's responses.
	Avoidance/reducing exposure to cues for the behavior	Facilitator explained with pictures to the participant how to identify and avoid/replace food items with lower sodium salt.

Table 3.9: Secondary Outcome Measure Outline

Variable	Tool used	Manufacturer	Participant position/instruction	Procedure
Blood pressure	Oscillometry blood pressure monitor	OMRON M3 comfort. Japan.	Sitting on a chair with back supported with feet on the ground. Cuff wrapped on upper arm.	Three measurements recorded and the average of the last two will be calculated. (Carey, Whelton, et al., 2018)
Body Mass Index	Portable stadiometer	SECA. Germany.	Standing on the scale with shoes off, no cap or hat worn on head.	Body mass index will be calculated by dividing the participant's weight in kilograms by the participant's height in meters squared. (Lyznicki et al., 2001)
	Portable LED weighing scale	DQUIP, India.	Standing on the scale. Shoes off, no heavy clothing worn, no items in pockets.	
Waist-hip ratio	Rubber Tape measure (centimeters)	n/a	Waist: participant standing shoulder width apart, measuring around participant's waist at the smallest point. Hip: participant standing shoulder width apart, measuring around participant's hip at the widest part.	Waist circumference divided by hip circumference (Dalton et al., 2003)
Urinary sodium	Urine sample	n/a	n/a	On-the-spot urine sample collected in a 300ml container and stored at temperatures of -80 °C in a laboratory upright biomedical freezer. Samples will be analysed in a clinical laboratory which adheres to Good Clinical Laboratory Practice (GCLP) standards. Samples will be tested only for Sodium levels.
Physical activity	Axivity AX3	Axivity Ltd, United Kingdom	Participant to wear the axivity wristwatch and instructed not to remove it.	Device worn on the non-dominant wrist with an adjustable watch strap over seven full days consecutively.
Diet	24HR diet questionnaire	(Vereecken et al., 2008)	Participant asked to recall all food consumed in the past 24 hours.	Record type of food consumed for breakfast, lunch, dinner, and any snack meals.

Data and statistical analysis

Quantitative analysis

A Consolidated Standards of Reporting Trials (CONSORT) flowchart will be used to present the flow of participants throughout the intervention. The CONSORT flowchart will also present reasons for declining participation or withdrawing. Descriptive statistics will be used to present baseline statistics and outcomes of feasibility. Depending on data distribution, mean and standard deviation or median and interquartile range will be described. Pre-post intervention outcome change will be assessed using a paired t-test if data is evenly distributed. If data is unevenly distributed, the Wilcoxon signed-rank test will be used. Confidence interval is set at 95%.

Qualitative analysis

The interviews will be audio-recorded, transcribed verbatim, and analysed using Braun and Clarke's approach to thematic analysis (Braun & Clarke, 2012). An independent transcriber will be employed to perform the transcription, the first author will perform the initial codes and themes and the co-authors will confirm the generated codes and themes. Data will be described narratively. Participants' direct quotations will be provided and will be used to judge whether the participants perceive the intervention to be acceptable. Positive responses from the participants will indicate acceptability (Table 3.7).

Patient and public involvement

In the needs assessment prior to intervention design, stakeholder engagements were undertaken with hypertensive adults exploring their perceptions of sociocultural influences on diet and physical activity. Hypertensive adults were also consulted on their perceived intervention needs and preferred educational approaches before designing the intervention. Local dieticians were consulted about current approaches to hypertension control and learning points from community-based interventions. Community members/the public were also consulted for social issues that are likely to enhance/inhibit success of the intervention. The findings from the various engagements led to the development of the 10-week intervention. The involvement of local research assistants was an important aspect to consider overcoming any trust and cultural issues involved.

Discussion

In this study, we will seek to implement and then test the feasibility of a community-based intervention for hypertensive adults that incorporates the patient's perceptions about their social and cultural beliefs regarding physical activity and dietary practices. This study may lead to recommendations that will assist in the control of high blood pressure particularly for adults in a rural South African or similar population. The results from this study may provide

a novel contribution to the understanding of contextual factors about physical activity, diet, and implementation of interventions for a rural, South African adult population. Data generated from this study will inform the design and implementation of a larger scale intervention of HYPHEN, if appropriate.

List of abbreviations

NCD	: Non-communicable disease
BCT	: Behaviour Change Technique
CONSORT	: Consolidated Standards of Reporting Trials
HDSS	: Health and Demographic Surveillance System
HREC	: Human Research Ethics Committee
IM	: Intervention Mapping

Declarations

Ethics approval and consent to participate.

This study required clearance from two ethical bodies. The first clearance was obtained from the University of the Witwatersrand Human Research Ethics Committee (HREC - Medical) (clearance number: M 210282). The second clearance was obtained from the local Provincial Department of Health Research and Ethics Committee (clearance number: MP_202106_001). Consent considerations and confidentiality of all research data will be adhered to. This study is based on the usual ethical principles, such as every person's right to refuse to participate in the study and to withdraw at any time, as well as respect for all participants and protection of their privacy.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Funding

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Africa) programme. The research is also supported by the National Research Foundation (NRF) Thuthuka (Grant No: 129864). The statements made and views expressed are solely the responsibility of the Fellow. The statements made and views expressed are solely the responsibility of the Fellow.

Author Contributions

All authors have participated in the design of the study. KS drafted the manuscript and all authors read and approved the final manuscript. KS applied for and obtained the grants for the study.

Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Acknowledgements

The authors would like to acknowledge the Agincourt HDSS for allowing the study to access information through their surveillance system.

3.5 CONCLUSION

This chapter presented the study protocol as published in *Pilot and Feasibility Studies*. The following chapter will present the profile of physical activity of hypertensive adults from the study site, presented as a submitted paper to a journal. The profile was obtained through a physical activity questionnaire conducted with hypertensive adults telephonically.

CHAPTER 4

4. PHYSICAL ACTIVITY PROFILE

4.1 PUBLICATION DETAILS

This chapter is presented as a submitted original research publication currently under review. The paper was submitted to *South African Journal of Physiotherapy* on 27th September 2024. The journal is open access. Table 4.1 presents information about the journal.

Table 4.1: Journal Information where the Protocol was submitted

Title of publication	Physical activity profile of hypertensive adults living in rural South Africa
Authors	Sekome, K., Myezwa H., Gómez-Olivé, F.X., Sherar, L.B., Esliger, D.W.
Journal name	South African Journal of Physiotherapy
Journal publisher	AOSIS
ISSN	0379-6175 (PRINT) 2410-8219 (ONLINE)
Impact factor	1.0
Status	Under review

4.2 AUTHOR CONTRIBUTIONS

Table 4.2 outlines the contributions to the publication made by each author according to the Contributor Roles Taxonomy (CRediT) laid out by (Allen et al., 2019)

Table 4.2: Author Contributions to Paper Two

	Sekome	Gómez-Olivé	Sherar	Esliger	Myezwa
Conceptualization	✓	✓	✓	✓	✓
Project administration	✓				
Methodology	✓	✓	✓	✓	✓
Initial data analysis	✓				
Writing – original draft	✓				
Writing – reviewing and editing	✓	✓		✓	✓
Visualization	✓	✓	✓	✓	✓
Supervision		✓	✓	✓	✓
Funding acquisition	✓				

4.3 ASSOCIATED DOCUMENTATION

The documentation associated with this publication are included as appendices and are labelled:

- Appendix 1: Ethical clearance certificate from University of the Witwatersrand Human Research Ethics Committee
- Appendix 2: local provincial department of health research and ethics committee
- Appendix 4: IPAQ questionnaire
- Appendix 5: Information letter for physical activity profile

4.4 UNDER REVIEW: PHYSICAL ACTIVITY PROFILE OF HYPERTENSIVE ADULTS LIVING IN RURAL SOUTH AFRICA

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Abstract

Background: Understanding physical activity behaviours of adults at risk of poor health is important to inform targeted interventions. We profiled the frequency, intensity, duration, and domain (work or non-work) of self-reported physical activities of rural South African adults living with hypertension.

Methods: Data were collected from a cohort of 5059 adults aged 40 years and above living in Agincourt sub-district, Mpumalanga province. A total of 429 adults diagnosed with hypertension completed the International Physical Activity Questionnaire Long-Form (IPAQ-LF) via telephone interview. Data were summarized using means and standard deviations, or medians and interquartile ranges. The Mann Whitney U Test and Krustal-Wallis Rank Test were used to assess physical activity differences by sex and work status. Statistical significance was set at $p < 0.05$.

Results: The mean age of the participants was 65.1 (SD $\pm$ 10.9 years), 58% women and 52% had paid/unpaid work. Men reported greater (duration and frequency) vigorous physical activity at work compared to women ($p = 0.003$ and $p = 0.002$). Walking frequency as mode of transport was higher for working men and women ($p < 0.001$). Women reported higher frequency of moderate-intensity physical activity inside the house ($p < 0.001$) and outside the house ($p < 0.001$) compared to men. Non-working men and women spent more time sitting during the week compared to their working counterparts ($p = 0.009$).

Implications: Contextual factors such as gender roles are related to the physical activity profile of hypertensive adults living in rural South Africa and should be considered when designing specific interventions targeted at improving hypertension control for this population. Study participants met the guidelines for physical activity participation, but this is performed at low intensities, specific interventions should focus on increasing the intensity of physical activity.

Keywords: IPAQ, hypertension, high blood pressure, sedentary

Introduction

Hypertension is a global public health concern which ranks first as a cause of disability-adjusted-life-years worldwide (Carey, Muntner, et al., 2018c). The prevalence of hypertension is on the rise worldwide, especially in low- and middle-income countries, making hypertension a worldwide public health concern (Mills et al., 2020). Data from the World Health Organization show the national prevalence of hypertension in South Africa to be approximately 27.4% for men and 26.1% for women (World Health Organization. GHO, 2015), while a pooled prevalence of up to 60% has been previously reported (Gaziano et al., 2017). For rural areas of South Africa, the highest recently recorded prevalence of hypertension for adults was 52% (Abrahams-Gessel et al., 2023). Hypertension, defined as systolic blood pressure of ≥ 140 mmHg and diastolic blood pressure of ≥ 90 mmHg, is a modifiable risk factor for cardiovascular and cerebrovascular diseases such as heart attacks and strokes which causes premature adult deaths in South Africa (Valenzuela et al., 2021). In comparison with urban areas, rural areas of South Africa have a higher prevalence of cardiovascular and cerebrovascular diseases (Akinyemi et al., 2021; Ntuli et al., 2015). This high prevalence may partly be attributed to the aging population found in rural areas (Kobayashi et al., 2021).

The high prevalence of hypertension against the backdrop of poorly organised health care systems, intermittent drug supply, and shortage of health care workers (Rispel et al., 2019; Sekome, 2018; Zihindulai et al., 2018) is a major concern, consequently, the control of the condition is often left to the patient (Zihindulai et al., 2018). Most hypertensive patients in rural South Africa have focused their management of hypertension on anti-hypertensive medication but this has shown little evidence of effectiveness (Abrahams-Gessel et al., 2023; Jardim et al., 2017; Kayima et al., 2013). Lifestyle approaches in combination with pharmaceutical therapy (Bertram et al., 2012; He et al., 2013; Lin et al., 2014) have been shown to provide optimal control of hypertension (Valenzuela et al., 2021). The widely recommended lifestyle approaches to control hypertension are a reduction in salt and caloric intake, and an increase in physical activity (Bertram et al., 2012; He et al., 2013; Lin et al., 2014).

The positive effects of physical activity on hypertension and cardiovascular diseases have been well documented (Diaz & Shimbo, 2013; Hegde & Solomon, 2015; Ma et al., 2021; Verma et al., 2021). The World Health Organisation recommends that adults with chronic conditions such as hypertension, should do at least 150–300 minutes of moderate-intensity aerobic physical activity; or at least 75–150 minutes of vigorous-intensity aerobic physical activity; or an equivalent combination of moderate- and vigorous- intensity activity throughout the week. Other key elements of the guidance state that they should also do muscle-

strengthening activities at moderate or greater intensity that involve all major muscle groups on 2 or more days a week, and should limit the amount of time spent being sedentary for substantial health benefits (World Health Organization, 2020).

Men and women in rural areas of South Africa generally perceived themselves as being highly active (Malambo et al., 2017) because many are involved in moderate intensity manual labour; however, there are a lack of data on the physical activity of South African adults in rural populations in general and even less knowledge about those that are living with hypertension (Gomez-Olive et al., 2018). Existing literature (Cook, 2007; Gómez-Olivé et al., 2018; Roos et al., 2014) are limited by a single indicator of overall physical activity such as total step count (Roos et al., 2014) and/or self-reported minutes spent in moderate to vigorous physical activity (Gomez-Olive et al., 2018) without consideration of the types of activities undertaken, which is critical for informing tailored interventions.

In order to implement contextually appropriate physical activity interventions that focuses on controlling hypertension, there is a need to better understand the physical activities by sex and work status. Thus, the aim of this study was to provide a profile of the frequency, intensity, duration, and domain of self-reported physical activities over a 7-day period in adults with hypertension from a rural sub-district in South Africa.

Methods

Study design and participants

The study was a cross-sectional, descriptive population-based study of adults aged 40 years and above with a previous diagnosis of hypertension living in Agincourt rural sub-district in Mpumalanga Province, South Africa. Data were collected during October 2021. Due to COVID-19 regulations at the time of data collection, participants were recruited via telephone and consent was obtained verbally. Participants were recruited from the Health and Aging in Africa: A Longitudinal Study of an INDEPTH (International Network for the Demographic Evaluation of Populations and Their Health) community (HAALSI) in South Africa (Gomez-Olive et al., 2018). The HAALSI study is a cohort of 5059 adults aged 40 years and above living in Agincourt sub-district. This cohort was reported to have a hypertension prevalence of 57% at the time of data collection (Gomez-Olive et al., 2018).

Sample size estimation and selection

The inclusion criteria were men and women aged ≥ 40 years, hypertensive (defined by self-reported anti-hypertensive medication use or diagnosed with raised blood pressure of $\geq 140/90$ mmHg) and living in Agincourt sub-district for at least six months prior to the date of data collection. Participants were contacted telephonically using a computer-generated

simple random sampling technique. Based on the hypertension prevalence in the study cohort, to achieve a 95% confidence interval with a 5% margin of error, a minimum sample of 339 participants living with hypertension from the HAALSI cohort were required.

Ethics approval and consent to participate

This study required clearance from two ethical bodies. The first clearance was obtained from the University of the Witwatersrand Human Research Ethics Committee (HREC - Medical) (clearance number: M 210282). The second clearance was obtained from the local Provincial Department of Health Research and Ethics Committee (clearance number: MP_202106_001). This study was based on the usual ethical principles, such as every person's right to refuse to participate in the study and to withdraw at any time, as well as respect for all participants and protection of their privacy.

Method of physical activity assessment

The International Physical Activity Questionnaire Long Form (IPAQ-LF) was used to assess the frequency, intensity, duration, and domain of physical activities as part of everyday lives (C. L. Craig et al., 2003). The IPAQ-LF was initially designed for use with adults up to the age of 69 years old, however, it has also been validated for use in older adults which indicated that although differences between sub-groups were apparent, the use of the IPAQ-LF is not limited to specific subgroups (Cleland et al., 2018; Wanner et al., 2016). The IPAQ-LF comprises a set of five activity domains that seeks to obtain information on (i) job related physical activity, (ii) transportation physical activity, (iii) housework related physical activity, (iv) recreation, sport, and leisure time physical activity, (v) time spent sitting. The IPAQ-LF considers only those physical activities performed within the last 7 days as well as time spent sitting. The frequency is presented as number of days in a week, and the duration is presented as average minutes on a single day for that week. Vigorous intensity physical activities were defined as activities that require hard physical effort and make the participant breathe much harder than normal (IPAQ research committee, 2005). Moderate intensity physical activities were defined as activities that take moderate physical effort and make the participant breathe somewhat harder than normal (IPAQ research committee, 2005). The IPAQ-LF has been shown to have acceptable validity and reliability for the assessment of physical activity among adults of different sex, age, and region (Boon et al., 2010; Wanner et al., 2016). A study conducted in 12 countries, over 14 study sites, showed that the IPAQ-LF had excellent one-week test-retest reliability (pooled $r=0.81$) and acceptable validity (pooled $r=0.33$) when compared with accelerometer-measured physical activity (C. L. Craig et al., 2003). The original version of the IPAQ-LF is available in English (IPAQ research committee, 2005). For our study, data were collected in the participants' first language (Xitsonga) and was interviewer-administered over the telephone by researchers who are fluent in both

English and Xitsonga. The translation process was a three-step back translation method which involved translation of the original questionnaire to Xitsonga by an independent translator, then a second translator translated the Xitsonga version back to English. The primary researcher compared the two documents, and any differences were reconciled with the two translators (Ozolins et al., 2020). No adaptations were made to the original version of the questionnaire.

Procedures

A list of eligible participants was obtained from the HAALSI cohort which contained the participant's basic demographics and contact details using a computer generated simple random technique. We did not stratify the sample by village, sex, or age. Eligible participants were then contacted by three research assistants and the primary author who were trained how to administer the IPAQ-LF. Each researcher received a list of people to contact, and discussions were held at the end of each day to tally the total participants reached on the day until the required sample was obtained. Any reasons for refusal or non-participation were recorded and presented in Figure 4.1. There was no incentive for participating in the study. Data were captured on REDCap and analysed using STATA 16.

Statistical analyses

Categorical variables such as sex, work status, and age were summarized using mean and standard deviation (SD). Due to the uneven distribution of data across physical activity duration and frequency, data were summarized using median and interquartile ranges (IQR). To calculate the differences between the individual types of physical activity from IPAQ-LF between male and female, and work status, the Mann-Whitney U test and Krustal-Wallis rank test were used with a level of statistical significance of $p < 0.05$.

Results

A total of 896 calls were made to recruit participants, and 429 complete responses were included in the final analysis (Figure 3.1). Reasons for exclusion included invalid phone number, voicemail, request to call back later, refused participation, unanswered call, deceased, and other. The mean age of included participants was 65.1 years (SD= ± 10.9 years), 58% (n=250) of the participants were women and 52% (n=225) had paid/unpaid work (Table 3.3). Men who were working were 64.2% while only 44% of women were working.

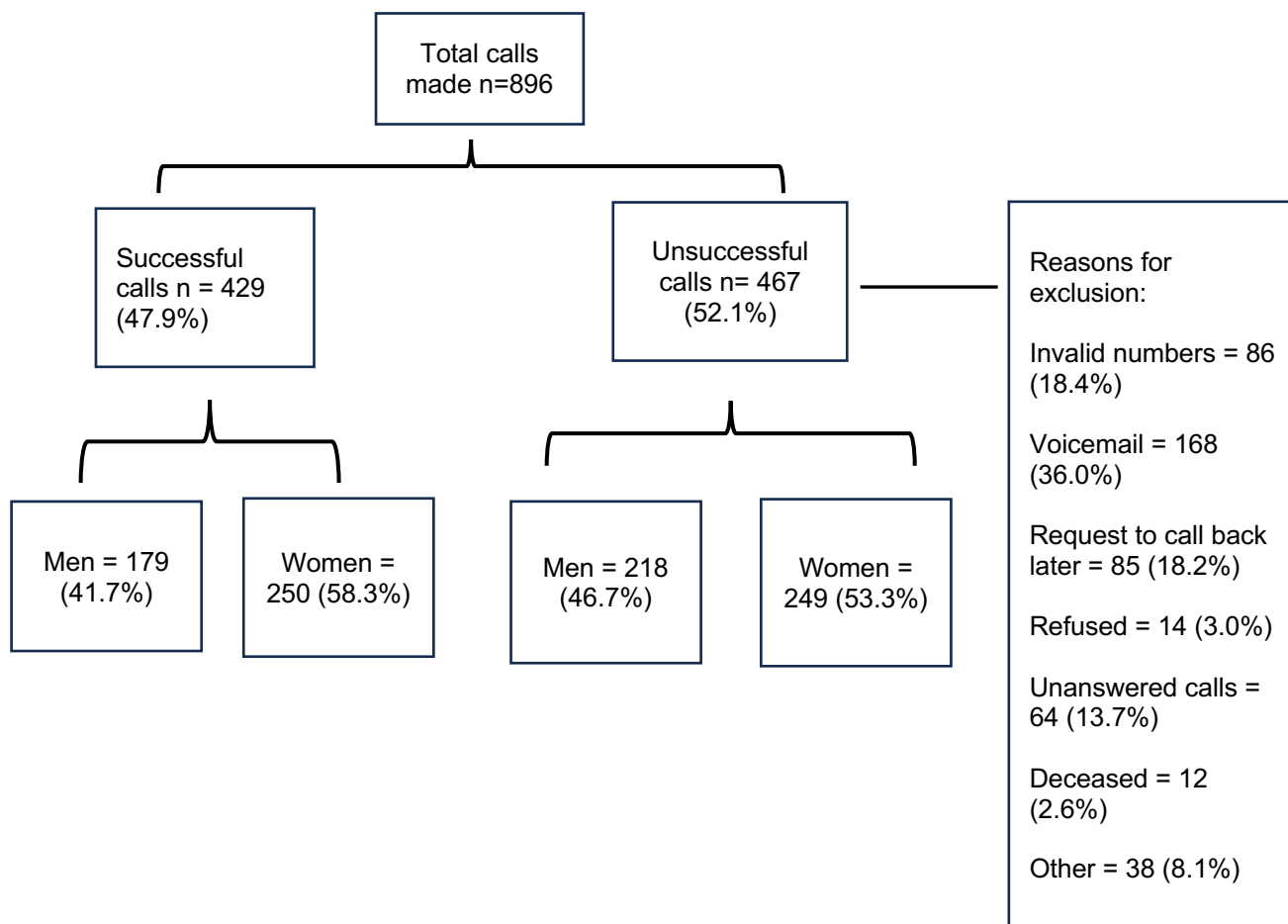


Figure 4.1: Distribution of Included and Excluded Participants

Table 4.3: Demographic Profile of Participants

Variable	n(%)
Age (years)	
40-49	32 (7.5)
50-59	121 (28.5)
60-69	126 (29.4)
70-79	102 (23.8)
80+	48 (11.2)
Mean (SD)	65.1 (± 10.9 years)
Sex	
Men	179 (41.7)
Women	250 (58.3)
Work status	
Men Working	115 (64.2)
Men not working	64 (35.8)
Women working	110 (44.0)
Women not working	140 (56.0)

Total physical activity

Men who are working reported more minutes of total physical activity (547 (315-810), followed by women who are working (495 (360-735), men who are not working (150 (32-306), and women who are not working reported the least amount of physical activity (60-280).

Table 4.4: Total Physical Activity

Variable	Walking (min)	Moderate (min)	Vigorous (min)	Total (min)	Meet / not meet guidelines
Male not working n=64	27 (5-112)	30 (0-120)	0 (0-120)	150 (32-306)	Meet
Female not working n=140	10 (0-40)	105 (37-180)	0 (0-50)	137 (60-280)	Meet
Male working n=115	100 (40-235)	120 (30-210)	210 (60-420)	547 (315-810)	Meet
Female working n=110	60 (32-150)	240 (180-360)	120 (30-210)	495 (360-735)	Meet
Total sample	45 (10-130)	120 (45-240)	60 (0-180)	330 (120-595)	Meet

Work related physical activity

Vigorous intensity physical activity duration as part of work was most commonly reported and was higher for men (median= 240 minutes/day) than women (median= 120 minutes/day); $p=0.003$, with men reporting more days in vigorous physical activity (median= 2 days/week) than women (median= 1 day/week); $p=0.008$. Men also reported more minutes of moderate intensity activity (median= 120 minutes/day) than women (median= 85 minutes/day). Men reported walking a median of 40 minutes/day over a median of 3 days/week while women walked a median of 30 minutes/day over a median of 3 days/week.

Table 4.5: Work Related Physical Activity

PA aspect	Total sample	Sex		P-value
	N= 225	Men n=115	Women n=110	< 0.05
	Median (IQR)			
Vigorous PA (days/week)	2 (0-5)	2 (0-5)	1 (0-3)	0.002
Vigorous PA (mins/day)	180 (120-360)	240 (120-390)	120 (60-240)	0.003
Moderate PA (days/week)	2 (0-5)	2 (0-5)	2 (0-5)	0.475
Moderate PA (mins/day)	120 (60-180)	120 (60-217.5)	85 (60-180)	0.036
Walking (days/week)	3 (2-5)	3 (2-7)	3 (2-5)	0.467
Walking (mins/day)	30 (15-120)	40 (15-120)	30 (15-90)	0.353

PA= physical activity

Transportation related physical activity.

Men and women who were working walked longer (median = 30 minutes/day) than those who were not working ($p<0.001$). The frequency of walking was also higher for men and women who were working (median = 3 days/week) ($p=0.009$). No differences were observed in the duration spent traveling in a motor vehicle between men and women ($p=0.596$); however, working participants travelled in a motor vehicle for more days compared to non-working participants ($p<0.001$). The duration and frequency of travelling by bicycle was low for all participants.

Table 4.6: Transportation Physical Activity

Physical Activity Aspect	Total sample	Work Status by Sex				P value
	N=429	Men		Women		< 0.05
		Working	Not Working	Working	Not Working	
		n=115	n=64	n=110	n=140	
	Median (IQR)					
Motor vehicle (days/week)	0 (0-2)	1 (0-4)	0 (0-2)	1 (0-2)	0 (0-1)	0.001
Motor vehicle (mins/day)	60 (30-120)	60 (30-120)	60 (52.5-150)	60 (30-120)	60 (30-120)	0.596
Bicycle (days/week)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0.388
Bicycle (mins/day)	25 (10-50)	40 (20-60)	30 (15-40)	0 (0-0)	7.5 (5-10)	0.060
Walking (days/week)	2 (1-4)	3 (1-6)	2 (0-5.5)	3 (1-3)	1 (0-2.5)	0.009
Walking (mins/day)	30 (10-60)	30 (15-90)	25 (10-60)	30 (15-45)	15 (10-45)	0.001

Housework, house maintenance, and caring for family.

Men and women reported low volumes of vigorous physical activity while doing housework, house maintenance, and caring for family (median = 0 days/week). Women however, reported more days per week performing moderate-intensity physical activities inside the house compared to men ($p < 0.001$). Women also spent more days performing moderate-intensity household activities outside the house compared to men ($p < 0.001$). The overall duration spent on housework, house maintenance, and caring for family inside and outside the house was 60 minutes/day for both men and women.

Table 4.7: Housework, House Maintenance, and Caring for Family

Physical Activity Aspect	Total sample	Work Status by Sex				P value
	N=429	Men		Women		< 0.05
		Working n=115	Not Working n=64	Working n=110	Not Working n=140	
	Median (IQR)					
Vigorous: heavy lifting, chopping wood, or digging in the garden or yard (days/week)	0 (0-2)	0 (0-2)	0 (0-1)	0 (0-2)	0 (0-1)	0.018
Vigorous: heavy lifting, chopping wood, or digging in the garden or yard (mins/day)	120 (60-180)	120 (60-180)	180 (120-180)	90 (60-165)	60 (60-150)	0.052
Moderate: carrying light loads, sweeping, washing windows, and raking in the garden or yard (days/week)	2 (0-5)	0 (0-2)	0 (0-3)	3 (1-7)	3 (0-6)	0.001
Moderate: carrying light loads, sweeping, washing, and raking in the garden or yard (mins/day)	60 (45-120)	60 (35-120)	60 (30-180)	80 (60-120)	60 (45-120)	0.555
Moderate: washing windows, scrubbing floors and sweeping inside home (days/week)	2 (0-7)	0 (0-1)	0 (0-2)	5 (2-7)	5 (0-7)	0.001
Moderate: washing windows, scrubbing floors and sweeping inside home (mins/day)	60 (40-120)	60 (22.5-105)	60 (30-180)	65 (60-120)	60 (30-120)	0.047

Recreation, sport, and leisure time physical activity

The overall reported recreation, sport, and leisure physical activities was low. No statistical differences by sex and work status were seen. All men and women spent a median of 0 days/week performing recreational, sport, and leisure physical activities.

Table 4.8: Recreation, Sport, and Leisure Time Physical Activity

Physical activity aspect	Total sample	Work Status by Sex				P value
	N=429	Men		Women		< 0.05
		Working n=115	Not Working n=64	Working n=110	Not Working n=140	
	Median (IQR)					
Walking for leisure (days/week)	0 (0-0)	0 (0-1)	0 (0-1)	0 (0-0)	0 (0-0)	0.108
Walking for leisure (mins/day)	60 (30-180)	60 (45-180)	120 (30-180)	90 (60-180)	52.5 (30-180)	0.660
Vigorous leisure: (days/week)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0.948
vigorous leisure: (mins/day)	60 (30-180)	90 (60-120)	60 (30-120)	45 (15 – 80)	60 (30-120)	0.512
Moderate leisure: (days/week)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0 (0-0)	0.140
Moderate leisure: (mins/day)	105 (60-120)	97.5 (75-142.5)	120 (45-210)	60 (40-120)	120 (120-120)	0.603

Time spent sitting.

Men and women who do not work reported spending more time sitting on a weekday (median= 180 minutes/day) compared to those who work (median = 120 minutes/day) (p=0.009). No statistical differences were seen for time spent sitting on a weekend.

Table 4.9: Time Spent Sitting (Work, at Home, while Doing Course Work, and During Leisure Time)

Physical Activity Aspect	Total sample	Work Status by Sex				P value
	N=429	Men		Women		< 0.05
		Working n=115	Not Working n=64	Working n=110	Not Working n=140	
Median (IQR)						
Sitting on a weekday (mins/day)	120 (60-240)	120 (60-180)	180 (62-300)	120 (60-180)	180 (60-300)	0.009
Sitting on a weekend (mins/day)	150 (60-300)	150 (60-270)	180 (60-390)	150 (60-240)	180 (30-300)	0.794

Discussion

This study profiled the frequency, intensity, duration, and domain of self-reported physical activities of rural South African adults with hypertension by sex and work status. We found that, overall, participants in our study self-reported meeting the aerobic component of the international guidelines for total physical activity per week when considering physical activities as part of work, transportation, housework, recreation, and time spent sitting (Bull et al., 2020).

Work-related physical activity

Most studies on physical activity for the rural South African population have been conducted on children and adolescents who are not of employment age (Craig et al., 2013; Micklesfield et al., 2014; Sedibe et al., 2014; Van Biljon et al., 2018). We found higher frequency of physical activity during work (paid or unpaid) for men compared to women which is in-line with the type of employment opportunities found in rural South Africa. Men are usually employed in physical labour jobs such as construction, while women are more likely to be in less active jobs such as self-employment as saleswomen in the formal or informal market (Wilkinson et al., 2017). We also found that the duration of vigorous physical activity at work was higher for men than women, this has face validity as construction work typically involves more time being physically active than selling at the shop or even house-to-house selling (Eveleigh, 2023). Although our study did not ask about the type of employment undertaken by the participants, it is evident that sex differences play a role in physical activity as part of work. In our study, employment referred to paid or unpaid work. The most commonly reported unpaid work by other studies in rural South Africa is subsistence farming which favours the men population more than women (Eveleigh P, 2023), hence the higher frequency and duration of physical activity reported by men versus women. Future physical activity interventions for adults with hypertension may consider targeting increased physical activity for employed women in rural settings.

Transportation and physical activity

Employed men and women in our study spent more days traveling in a motor vehicle. Access to a motor vehicle is associated with driving to the destination as compared to walking and may contribute to enhanced inactivity and/or sedentary (sitting) behaviours (Koohsari et al., 2020; Sugiyama et al., 2020). Although we did not ask participants about ownership of a motor vehicle, it is likely that those who do not own a motor vehicle would rely on walking as means of transport. Interestingly, employed participants reported more days per week and minutes per day walking as means of transport compared to their unemployed counterparts. Some possible reasons for higher walking frequency and duration for employed adults could be that their employment does not require or guarantee motor vehicle ownership, therefore, these individuals could spend most time walking to catch public transport for personal, social and family responsibilities compared to unemployed participants who are likely to spend less time using public motor vehicle transport due to cost challenges (Biernat & Piątkowska, 2017). Walking as a means of transport is generally higher in rural areas due to multiple livelihood and environmental factors (S. E. Shackleton & Hebinck, 2018). People walk to fetch water and firewood, visit friends, social gatherings, and to access shops and supermarkets which are usually within a walking distance or walking to the taxi rank for farther travel (Collinson, 2010; Ragie et al., 2020). There is an opportunity for physical activity interventions in public health to take advantage of the walking opportunities in rural areas to encourage physical activity for hypertensive participants.

Housework, house maintenance, and caring for family

Physical activities such as sweeping, washing, scrubbing floors, and raking in the garden at moderate intensities were higher for women compared to men. This is in line with traditional gender roles in the African society where women resume more responsibilities in taking care of the family and performing housework and house maintenance inside and outside the house (Oyewumi, 2016). Men reported more vigorous physical activity related to housework compared to women, regardless of work status. This finding for housework physical activity reported by men could be linked to gender and sociocultural roles in the household where 'tougher' activities in the household are performed by men (Oyewumi, 2016). Even though men undertake more vigorous intensity housework physical activities than women in this setting, their level of hypertension control still remains lower than women (Jardim et al., 2017). This could possibly be due to other men-associated risk factors such as tobacco smoking, alcohol consumption, and poor dietary habits (Sulaica et al., 2020).

Recreation, sport, and leisure time physical activity

Physical activity duration and frequency related to recreation, sport, and leisure time across both sex and work status was low for our study participants. Rural areas of South Africa lack amenities (Rogerson & Sixaba, 2022) for recreation and do not routinely promote recreational physical activity. As seen in this study, hypertensive adults in a rural South African setting spent a reasonable number of days performing housework and paid/unpaid work physical activity tasks which require physical effort and probably leaving less time to devote to leisure activity.

There appears to be an association between physical activity related to leisure and recreation with age (Stodolska, 2015); with children, adolescents, and youth engaging in more physical activities such as play, swimming, and sports than adults (Spencer & Zembani, 2011). Other authors (Gómez-Olivé et al., 2017) also reported that younger age and higher education contributed to engaging in walking for leisure. The age of our study population could explain why adults in this study are involved in little to no leisure and recreation physical activities. There is an opportunity to explore what extramural activities adults in a rural setting partake in so that interventions to encourage recreation and leisure physical activity can be implemented. The development of rural areas in South Africa (South African Government, 2017) such as building of malls, recreational parks, swimming pools, tarred and paved roads and sidewalks can also be an opportunity to encourage hypertensive adults to participate in physical activity for leisure. Local government should accelerate rural development with a focus on creating recreational opportunities for adults to perform in their leisure time.

Time spent sitting

Overall self-reported sitting time was slightly higher at weekends than during the week. No known study in rural South Africa has explained this phenomenon. A possible explanation for slightly longer weekend sitting time could be that participants have a relatively high physical activity demand of work, personal, and family responsibilities during the week, resulting in people wanting to rest at the weekend. A previous study in rural South Africa (Peltzer & Phaswana-Mafuya, 2012) has attributed longer sitting time to obesity, older age, lack of social cohesion, and physical limitation. Our study included older adults; we did not assess obesity and participants with physical limitations were excluded. In rural areas, adults typically spend their weekend performing activities which require long sitting times such as attending religious gatherings, community social networks, funerals, and other household duties such as washing clothes. Non-working participants reported slightly more sitting time compared to those who work. A report from (Biernat & Piątkowska, 2017) states that women, smokers, and those without full-time employment reported longer sitting time. The phenomenon could not be explained but may be attributed to the fact that employed adults have more responsibilities and less free time than their unemployed counterparts. More information is

required regarding the type of activities hypertensive adults perform on weekends for interventions that aim to target physical activity at the weekend.

Conclusion

The findings of the present study highlight the influence of sex and gender roles, work status, environmental and social factors as determinants of physical activity in a hypertensive rural South African adult population. The concept of gender roles appears to influence the intensity and type of physical activities adults perform in a rural South African setting, particularly regarding work-related and housework-related physical activity. Social influences must also be considered; social expectations tend to be internalized by adult men and women thus adding to the perception that men must perform more strenuous activities than women. This study necessitates a further exploration into the socioeconomic factors influencing physical activity for hypertensive adults in a rural setting so that appropriate contextual interventions can be developed and evaluated.

Strengths and Limitations

This is the first study, to the author's knowledge, to provide physical activity profile of adults with hypertension in Agincourt sub-district. This study provides rich useful data on physical activity participation; however, the study used the IPAQ-LF, which while a validated questionnaire (Boon et al., 2010; Wanner et al., 2016) likely led to error in the measurement associated with inaccurate recall and/or self-report bias (Cleland et al., 2018). Furthermore, we collected data from 32 villages without clustering which has a potential of under- and over-representation from particular villages. Our study also had limited sociodemographic data, such as indicators of socioeconomic status, which would have provided more insight into determinants of physical activity. We collected data during Covid-19 pandemic where movements and human contact were limited. It is possible that the reported physical activity levels might have been influenced by limited movements including the use of public transport during the pandemic.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Author Contributions

All authors have participated in the design of the study. KS drafted the manuscript and all authors read and approved the final manuscript. KS applied for and obtained grants for the study.

Availability of data and materials

Data sharing is available on request.

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The following chapter will provide an exploration of the socioeconomic factors influencing physical activity for hypertensive adults in a rural setting so that appropriate contextual interventions can be developed and evaluated. The chapter will be a qualitative study conducted using focus group discussions with hypertensive adults.

CHAPTER 5

5. QUALITATIVE STUDY

5.1 PUBLICATION DETAILS

This chapter is presented as a published paper. The paper was submitted at *BMC Public Health* on 13 August 2024. The journal is open access and the publication is presented with minor amendments from thesis examiners. Table 5.1 presents information about the journal.

Table 5.1: Journal information where the paper was published.

Title of publication	Sociocultural perceptions of physical activity and dietary habits for hypertension control: voices from adults in a rural sub-district of South Africa.
Authors	Kganetso Sekome, Francesc Xavier Gómez-Olivé, Lauren B Sherar, Dale W. Esliger, Hellen Myezwa
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5.2 AUTHOR CONTRIBUTIONS

Table 5.2 outlines the contributions to the publication made by each author according to the Contributor Roles Taxonomy (CRediT) laid out by (Allen et al., 2019)

Table 5.2 Author contributions to paper two

	Sekome	Gómez-Olivé	Sherar	Esliger	Myezwa
Conceptualization	✓	✓	✓	✓	✓
Project administration	✓				
Methodology	✓	✓	✓	✓	✓
Initial data analysis	✓				
Writing – original draft	✓				
Writing – reviewing and editing	✓	✓	✓	✓	✓
Visualization	✓	✓	✓	✓	✓
Supervision		✓	✓	✓	✓
Funding acquisition	✓				

5.3 ASSOCIATED DOCUMENTATION

The documentation associated with this publication are included as appendices and are labelled:

- Appendix 1: Ethical clearance certificate from University of the Witwatersrand Human Research Ethics Committee
- Appendix 2: local provincial department of health research and ethics committee
- Appendix 6: Interview schedule for qualitative study
- Appendix 7: information letter for qualitative study

5.4 PUBLISHED PAPER: SOCIOCULTURAL PERCEPTIONS OF PHYSICAL ACTIVITY AND DIETARY HABITS FOR HYPERTENSIVE CONTROL: VOICES FROM ADULTS IN A RURAL SUB-DISTRICT OF SOUTH AFRICA

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Type of research: Original research

No of figures: 0

No of tables: 2

Abstract

Background: Over half of adults from rural South Africa are hypertensive. Apart from pharmaceutical treatment, lifestyle changes such as increasing physical activity and reducing dietary salt have been strongly advocated for the control of hypertension. However, the control rates of hypertension for adults in rural South Africa are low. In this paper we explore whether this is due to the recommended lifestyle intervention not aligning with the individual's socio-cultural determinants of behaviour change.

Aim: To explore the social and cultural beliefs, perceptions and practices regarding physical activity and diet as a hypertension control intervention on hypertensive adults living in a rural sub-district in South Africa.

Methods: Nine focus group discussions were conducted with hypertensive adults aged 40 years and above from Bushbuckridge sub-district in Mpumalanga Province of South Africa using a semi-structured interview guide. Each session began with introductions of the discussion theme followed by a short discussion on what the participants know about hypertension and the normal blood pressure readings. Physical activity and dietary habits were then introduced as the main subject of discussion. Probing questions were used to get more insight on a specific topic. A thematic analysis approach was used to generate codes, categories, and themes. A manual approach to data analysis was chosen and data obtained through transcripts were analysed inductively.

Findings: Participants had a lack of knowledge about blood pressure normal values. Perceived causes of hypertension were alluded to psychosocial factors such as family and emotional-related issues. Physical activity practices were influenced by family and community members' attitudes and gender roles. Factors which influenced dietary practices mainly involved affordability and availability of food. To control their hypertension, participants recommend eating certain foods, emotional control, taking medication, exercising, praying, correct food preparation, and performing house chores.

Conclusion: Lifestyle interventions to control hypertension for adults in a rural South African setting using physical activity promotion and dietary control must consider the beliefs related to hypertension control of this population.

Keywords: high blood pressure, hypertension, physical activity, nutrition, lifestyle change.

Introduction

Hypertension is one of the world's most prevalent and modifiable risk factors for cardiovascular and cerebrovascular diseases such as heart attacks and strokes (Parati et al., 2022; World Health Organization, 2013; Zhou et al., 2017). Trends from 1975 to 2015 show that the number of people with hypertension worldwide has doubled from 594 million in 1975 to 1.13 billion in 2015 (Zhou et al., 2017). Reports suggest that 31.1% of adults worldwide had hypertension in 2010, with an estimated 9.4 million deaths (Mills et al., 2020; World Health Organization, 2013). Over the past decade, the prevalence of hypertension has increased worldwide, especially in low- and middle-income countries (LMICs). This reported prevalence was higher in LMICs (31.5%) than in high-income countries (28.5%) (Mills et al., 2020).

Hypertension or high blood pressure is defined as systolic blood pressure higher than 139 mmHg or diastolic blood pressure higher than 89 mmHg (Zhou et al., 2017). The most cited national prevalence of hypertension among older adults in South Africa is 77.3% in 2008 among a sample of adults aged 50 years or older (Peltzer & Phaswana-Mafuya, 2013). In 2014, Lloyd-Sherlock and colleagues reported a South African hypertension prevalence of 77.9% amongst older adults aged 50 years and above (Lloyd-Sherlock et al., 2014). These numbers can be attributed to factors such as ageing of the population, rapid urbanization, diet and lifestyle changes, and an increase in psychosocial issues (Ibrahim & Damasceno, 2012). The prevalence of hypertension in rural South Africa for individuals aged 15 years and above is reported to be 41% in Limpopo (mean age = 44.2 ± 20.9) (Dikgale Health and Demographic Surveillance Site) (Ntuli et al., 2015) and 40% (women), 30% (men) in Mpumalanga (mean age not reported) (Agincourt Health and Demographic Surveillance Site) (Clark et al., 2015). Some of the reported risk factors for hypertension in LMICs are overweight/obesity, being married, older age group, low education, and alcohol consumption (Ahaneku et al., 2011; Hendriks et al., 2012; Ibrahim & Damasceno, 2012; E. A. Williams et al., 2013).

People 40 years and older in rural Mpumalanga seem to be aware of their blood pressure status (awareness rate - 64.4%) and amongst those aware most are on medication for hypertension (89.3%) although the level of control remains low (45.8%). However, the number of people receiving treatment dropped to 49.7% when considering the overall hypertensive population and not only those who were aware of the condition (Jardim et al., 2017).

A longitudinal observational study in rural Agincourt that followed individual adults on usual care for hypertension, found improved rates of hypertension over a four-year follow-up period

(Abrahams-Gessel et al., 2023). Studies for hypertension control using physical activity in South Africa focused on monitoring and goal setting (increasing the number of steps taken a day) (Cook, 2007; Roos et al., 2016). Studies targeting dietary changes for hypertension control have focused on providing advice on diet that is usually not affordable or not accepted by the rural adults (Faber & Wenhold, 2012; Temple et al., 2011). There is one known study in rural Agincourt of South Africa aimed to reduce hypertension through provision of monthly supply of low sodium salt (Lloyd-Sherlock et al., 2018), where participants expressed a challenge with sustainability of this approach because the sodium salt product is not available in local stores. For effective implementation of this recommendation, one must first understand the contextual (personal and environmental) factors regarding salt and calorie intake in this population.

Providing a description of what individual factors contributed to the improved hypertension control rates (Abrahams-Gessel et al., 2023), considering the influences of physical activity performance (Roos et al., 2016.), and understanding the socioeconomic factors contributing to dietary consumption (Faber & Wenhold, 2012; Temple et al., 2011) could yield better hypertension control rates. A recent systematic review concluded that future research in developing countries should consider individual risk perceptions, cultural barriers, and gender when designing interventions for hypertension control (Dhar et al., 2017).

Various personal and/or environmental factors along with the person's level of functioning can influence the uptake of an intervention (Ferrans et al., 2005). For example, physical activity interventions to control hypertension in rural South Africa may be different from other populations more studied due to the daily physical activities in rural South Africa such as walking for wood collection, different aspects of farming, yard work, walking longer distances for daily chores, and housework (Cook, 2007; C. M. Shackleton et al., 2007). Activities are also likely constantly evolving because of urbanization, migration, and an ageing population (Awumbila, 2017; Ibrahim & Damasceno, 2012).

When developing interventions in South Africa to reduce hypertension, there is a need to consider the cultural and social beliefs and practices that influence behaviour of the rural adult population. Both a reduction in salt and caloric intake, and an increase in physical activity are the most extensively recommended lifestyle approaches to help meet national hypertension targets (Bertram et al., 2012; He et al., 2013; Lin et al., 2014). However, promoting change in behaviour of someone through an intervention needs an understanding of the contextual realities at play that influence that person's behaviour. We aimed to explore the social and cultural beliefs, perceptions and practices regarding physical activity and diet from hypertensive adults living in rural South Africa and to explore how these perceptions

may influence future behaviour change. This should inform novel interventions for the control of hypertension in this population.

Methods

Setting

This qualitative study was conducted at Bushbuckridge sub-district in Mpumalanga province South Africa where the Agincourt Health and Demographic Surveillance System (HDSS) has been running since 1992. The HDSS is run by the MRC/ Wits Rural Public Health and Health Transitions Research Unit from the University of the Witwatersrand. The Agincourt HDSS covers an area of 450km² with 115 000 individuals (approximately 52 000 older than 18 years) living in approximately 20 000 households (Kahn et al., 2012). We used as a sampling frame the cohort of 5059 adults aged 40 years and above within the Agincourt HDSS, named the Health and Aging in Africa: A Longitudinal Study of an INDEPTH (International Network for the Demographic Evaluation of Populations and Their Health) community in South Africa (HAALSI) (Gomez-Olive et al., 2018). The prevalence of hypertension in this cohort is 57%, defined as systolic blood pressure ≥ 140 mmHg or diastolic blood pressure ≥ 90 mmHg or self-reported medication of hypertension.

Participation in the physical activity profile study of this thesis was not a requirement to be included in this study. Since we recruited from the same cohort, it is possible that some of the participants might have already participated in the telephonic IPAQ study, but this was not established.

Population selection

Participants for the focus groups were randomly selected from the HAALSI cohort including men and women aged 40 years and above with a diagnosis of hypertension. We chose a random sample because we wanted to observe opinions from a mixed sample (age, gender, awareness of hypertension status). Participants must have been living in Agincourt for the past six months prior to the start of the focus group discussions to ensure that they have adapted to the daily routine of the community. We produced a random list of 150 potential participants, and they were contacted by phone and asked to participate in a focus group on high blood pressure. Participants were interviewed until data saturation required was reached. Participants were contacted by a locally trained research assistant who speaks the local language (Xitsonga), and they were compensated for their participation in the focus group discussion.

Focus group preparation

The focus group interview guide was developed by the first author and reviewed and approved by all co-authors. The focus group guide included questions on physical activity and dietary practices and influences, barriers and enablers of physical activity and dietary approaches, for hypertension control.

Focus group discussions (FGD)

FGDs were facilitated by a locally trained qualitative research assistant. Moreover, the first author and a second locally trained qualitative research assistant were present to co-facilitate. Each FGD included 6 to 9 participants and lasted 45 to 90 minutes. Each session began with introduction of the discussion theme and then followed by a short discussion on what the participants knew about hypertension, the average normal blood pressure reading as well as their awareness of their blood pressure status. Physical activity and dietary habits were then introduced as the main subject of discussion using the focus group guide. Probing questions were introduced to get more insight on specific topics if needed. The FGDs were audio recorded and the co-facilitator documented the discussion during each session. Translation to English and transcription of the audio recorded interviews occurred after each session. The FGD were performed at a private venue in the Agincourt HDSS premises. All participants were fetched from their homes and dropped off after the session.

Trustworthiness of data

We ensured trustworthiness of our data by following the principles of credibility, transferability, dependability, confirmability, and reflexivity (Stahl & King, 2020). To ensure credibility of the data, locally trained qualitative research assistants were employed to conduct the FGDs and transcribe the data. The transcribed FGDs audio data was reviewed by the first author and all co-authors. The first author received feedback from all co-authors on the interview guide ahead of data collection and amendments made when indicated. Throughout the data analysis process, codes were generated and reviewed by three experienced peer qualitative researchers not involved in the research project as well as a senior co-author (HM). Transferability, though limited in qualitative research, was ensured by providing a thick description of the study setting and population selection in this paper to allow for repeatability. Dependability was achieved through inviting qualitative researchers not involved in the research study to view and give feedback on the field notes and initial codes created through a debriefing session. The authors have also kept an audit trail of interview recordings and transcripts. The first author kept a clear focus during the data analysis phase by examining his own judgments, practices, and belief systems regarding the topic of analysis through a reflexive journal which documented the study rationale and methodological decisions. To ensure confirmability, direct excerpts from the interviews are provided under the findings section.

Data analysis

A thematic analysis approach was used to generate codes, themes and categories. All transcripts were analysed using an inductive approach. We employed a manual analysis technique to generate codes, categories, and themes. This process included printing hard copy transcripts, photocopying, line-by-line coding, coding in margins, cutting, cut-and-paste, sorting, reorganising, hanging and arranging colour-coded sticky notes on a large display wall (Bosit, 2003; Maher et al., 2018; Mattimoe et al., 2021) . The five-step approach to qualitative data analysis outlined by (Braun & Clarke, 2012) was followed.

Findings

The analysis of the data revealed eight main themes: i) lack of knowledge of normal blood pressure values; ii) perceived causes of hypertension; iii) variety in daily physical activity practices; iv) limited variety in daily diet; v) ways in which the participants control their hypertension; vi) alternative beliefs for hypertension control; vii) factors that influence their dietary practices; and viii) community influences on physical activity. The themes are presented with their categories and accompanying excerpts from the participants (table 5.3). The daily dietary practices are presented on a separate table to indicate the frequency of consumption (table 5.4).

Table 5.3: Findings from Focus Group Discussions according to Identified Themes, Categories, Codes, and Participants Excerpts

Theme	Category Description	Identified Codes	Participant Excerpt
Lack of knowledge of normal blood pressure values.	Lack of knowledge about normal BP values. Field workers from the studies run by MRC/Wits Agincourt Research Unit had some influence on their knowledge of normal BP values.	No feedback Fieldworker influence	<i>"They (nurses) don't tell us the numbers they only tell us that it is normal or high". FGD7, P2.</i> <i>"They (Agincourt HDSS field workers) do show you the numbers but at the clinic they don't show you". FGD5, P5.</i>
Perceived causes of hypertension.	Family dynamics.	Spousal induced stress, stress caused by children, partner abuse, family conflicts, and family loss due to death.	<i>"Sometimes you find that at home you have a husband and is not treating you very well, even if you can hide it but deep inside from your heart you are worried. We also have children, and they are speaking to us with bad manners, so even if we run away from high blood pressure in that way you can find yourself with high blood pressure". FGD1, P8.</i>
	Emotional causes.	Loneliness, anger, sadness, and worrying too much as the main contributing factors.	<i>"it's caused by thinking a lot, because when you worry too much each and every day about things that is troubling you, and when you worry too much it becomes to the point where your life begins to change and being diagnosed with high blood pressure". FGD1, P8.</i>
	Poor eating habits.	Eating sweet food items, an urbanised diet, cold water consumption, oily and fatty diet, salty and spicy diet, and obesity.	<i>"The food that we eat now is the one which causes us high blood but before we used to eat traditional food and some of those food was very sour and that help us to be healthy. But now we eat modern and some of those food is not good for our health". FGD3, P6.</i>
Variety in physical activity practices	Sedentary activities.	Sewing mat, grinding maize, and ploughing while seated.	<i>"I don't know how to run, I plough while I am sitting on the chair, I grind maize meal while I am sitting on the chair". FGD4, P1.</i>
	Social and cultural activities.	Dancing at church and teaching traditional dancing.	

Theme	Category Description	Identified Codes	Participant Excerpt
	Work/livelihood activities.	Selling at a tuckshop, shop cleaner, sweeping the yard, construction of bricks, cutting poles at the forest, farming work, domestic worker, and ploughing.	
	Household activities.	Wash dishes, cook daily, yard work, and taking care of family.	<i>"I wash clothes or clean the house.... then after I come sweep the yard and make some fire and cook, then I go to work". FGD4, P6.</i>
	Purposeful exercise.	Morning jog, jogging after work, a daily home exercise program, female soccer player, running at soccer field, and stretching daily.	<i>"When I wake up in the morning before I do anything I start by exercising inside the house". FGD4, P8.</i>
	Routine activities.	Fetching firewood from the bush, gardening, running around with children, physical activity health educator, daily ploughing, fetching water with wheelbarrow, and cleaning the yard.	<i>"We teach the elderly people to do physical activities, such as stretching, exercising, playing soccer, and we also practice running with them". FGD1, P8.</i>
	Walking activities.	Herding cows, walking to the bush, walking in the neighbourhood.	<i>"...and then I go outside and sweep the yard. Sometimes I play with my grandchildren, running around with them". FGD4, P3.</i>
	Unstructured physical activities.	Based on daily household needs and general housework	<i>"You have to do activities like walking around then your blood pressure will be reduced. If you sit in one place without moving your blood pressure will rise". FGD1, P5.</i> <i>"When I wake up, I just go around my yard and see what I can do, I clean the yard removing grass, fixing some broken fence. Then after that I rest." FGD9, P6.</i>

Theme	Category Description	Identified Codes	Participant Excerpt
Ways to control hypertension	Emotional control.	Social interactions, reducing stress, avoiding anger, avoiding over-excitement, accepting situations, avoiding stress, and finding ways to manage anger.	<i>"because of our age we think a lot about death, but if you meet other people like as we are here today, we are busy chatting about lot of things and some they do jokes, and we laugh". FGD1, P8.</i>
	Medical control.	Follow the prescribed treatment regime, follow health worker advice, adhere to medication, adhere to doctor's diet advice, avoid medical pluralism, and practice early health seeking behaviour.	<i>"If you are hypertensive don't mix medication, if you are taking high blood pills take them only, don't mix it with traditional medication because the high blood pressure won't be controlled". FGD1, P5.</i>
	Structured exercise routine.	Perform daily exercises, have a daily exercise plan, join a female soccer club, go for a daily jog, increase levels of physical activity at home, increase walking distance, walk daily.	<i>"The only thing that can reduce high blood is to eat Muroho and Nkaka. Nkaka it can reduce the high blood pressure. And also cabbage, if you can get used to chop the cabbage and not add salt just eat it as it is raw, the high blood pressure will be reduced". FGD1, P5</i>
	Dietary control.	Drink tea instead of coffee, avoid spicy diet, avoid salt and spices, avoid oil and fats, increase fruits and vegetables, eat more bitter vegetables, drink water, prepare own meal, avoid sugar, stop spreading bread with margarine, and grow own vegetable.	
	Involvement in house chores.	Increasing gardening work, increasing chores which require exercise, performing daily house chores, and increasing pace of tasks.	

Theme	Category Description	Identified Codes	Participant Excerpt
Alternative beliefs for hypertension control.	Spiritual means.	Prayer, denial and avoidance of diagnosis, and accepting situations.	<i>"Another thing is to accept difficult situation that can cause high blood pressure. Sometimes you have to pray and ask God, you become better". FGD4, P5.</i>
	Ways of preparing food.	Drinking boiled marijuana, drinking aloe boiled in water, drinking warm water with sugar, and drinking water of boiled local trees.	<i>"Indeed, there's this tree that is called Moringa I know it, and even Nkaka I eat it. When I use these things, I can see the difference. Even when I go to the clinic the nurses ask me 'what are you using?'". FGD9, P6.</i>
	Alternative food to consume.	Raw potato, moringa leaves, moringa juice, and Nkaka.	<i>"The other thing that I heard about it is Moringa powder and Moringa juice they said it is helpful to reduce high blood pressure". FGD3, P9.</i>
Factors influencing dietary practices	Lack of diet control.	Eating outside home (such as at a party or funeral), community food project provision, religious influence, not preparing own food, children preference, and donated food.	<i>"Sometimes you find out that you are not at home you visited somewhere and because of hunger you end up eating food that you were not supposed to eat". FGD1, P3.</i> <i>"Another thing is because of some of the food they just buy and give us, when they give you food you won't refuse knowing that there's nowhere you can get food". FGD1, P6.</i>
	Food taste.	Fatty and oily food preferred because it's delicious, Rama margarine makes food taste good, craving for spicy food, "hypertensive" meals are not enjoyable, and participants love bitter vegetables.	<i>"Those who are hypertensive you won't like their food because they don't put salt at all, they just eat like that because they are hypertensive. They don't put oil in their food because they are hypertensive". FGD1, P1.</i> <i>"I can say the food that I am eating at home is the food that I am affording." FGD1, P8.</i> <i>"Another thing at our church we don't eat lot of things that's the reason why I am not eating</i>

Theme	Category Description	Identified Codes	Participant Excerpt
	Food safety, affordability, and availability.	Most vegetables are difficult to access, participant eats whatever is available, there is a lack of money for variety, and the prescribed diet is expensive.	<i>some of the things. If it was not for my church, I would eat anything". FGD8, P4.</i>
Influences of community on physical activity.	Influence of family.	Children see physical activity as punishment and complain that the parent ploughs too much, family viewed the parent as working a lot, children question the reason for daily chores, physical activity tasks were seen as suffering, parents are told by children to sit and rest.	<i>"They are like: what kind of a woman are you always doing the house chores?" FGD1, P1.</i>
	Physical activity seen as a must.	Daily chores are forced by situation, being head of the household, and the chores need to be done.	<i>"Because you are the man of the house there's no way you can rest, a man does not rest". FGD1, P6.</i> <i>"So, I told them who is going to do the work for me because I do this and this, if they (children) work, they do little things and rest". FGD5, P6</i> <i>"Others will say that I love working too much so you don't have to mind them because it can cause you high blood if you want to listen to them" FGD2, P4</i>
	Disregarding opinions from the community.	Neighbours viewed physically active people as working too hard.	

Limited variety in daily diet

The daily dietary practices were categorised into breakfast meals, lunch meals, and dinner meals. These meals are presented in table 2 together with the frequency in which they are consumed. All meal items are consumed for breakfast, lunch meals consist of bread, porridge, soft porridge, vegetables, meat, and tea. For dinner the consumed food items are porridge, vegetables, meat, and tea.

Table 5.4: Daily Meals Consumed by Hypertensive Participants

Meal item	Breakfast	Lunch	Dinner
Bread	✓	✓	✓
Porridge	✓	✓	✓
Soft porridge	✓	✓	
Mageu & Amasi (fermented porridge & milk)	✓		
Vegetables	✓	✓	✓
Wild vegetables	✓		✓
Meat	✓	✓	✓
Tea	✓	✓	✓

Discussion

This qualitative study identified eight major themes relating to hypertensive adults' lack of knowledge of normal blood pressure values, perceived causes of hypertension, variety of PA practices, ways to control hypertension, alternative beliefs for HPT control, factors influencing dietary practices, the influence of community on PA, and limited variety in daily diet. These insights are key to guide interventions on sociocultural considerations when developing strategies to control hypertension from a rural, African lens. Few studies have reported on hypertensive adults' knowledge of normal blood pressure values; however, some studies have investigated knowledge about hypertension as a health condition (Chimberengwa et al., 2019; Hacking et al., 2016; Haricharan et al., 2017; Jongen et al., 2019; Rampamba et al., 2017). Our study found that hypertensive adults have little to no knowledge about high blood pressure normal values, the little knowledge which they have is obtained from ongoing research studies conducted in their community (Kahn et al., 2012). A study in Ghana by Agyei-Baffour (Agyei-Baffour et al., 2018) also reported that knowledge of hypertension was very low in their participants. They reported that those participants who had knowledge about hypertension obtained it from the media, followed by health staff. Our study showed that health staff have very little influence on hypertension education and sharing feedback on measured blood pressure results in this community. Suggestions for health promotion in rural communities from previous studies have included alternates to clinic-based education, such as door-to-door, peer education (teaching the youth who will teach the adult), working with

local church leaders to provide church-based education, and providing education via pamphlet handout and billboards (Jongen et al., 2019).

In almost all our focus group discussions, participants spoke about the influence of poor emotional wellbeing and stress-related factors as causes of elevated blood pressure. They referred strongly to stress induced by family members. This finding is not unique to our study and has been reported by participants in rural KwaZulu-Natal who described that unhappiness and stress were major contributing factors to elevated blood pressure (De Wet et al., 2016). Similarly, Jongen and colleagues (Jongen et al., 2019) identified stress/anxiety as factors that prompt the development of hypertension. The participants in their study (Jongen et al., 2019) reported that fighting with children or spouse or the inability to support the family financially due to unemployment were the major triggers of stress and/or anxiety. There appears to be an unmet need for psychosocial support in rural South Africa.

Regarding the influence of diet as a cause of hypertension, our study participants recognised that high sodium salt consumption, oily and fatty food items, and certain spices can cause hypertension. These risk factors have been reported and confirmed by other studies as contributors to the development of hypertension (Carey, Whelton, et al., 2018; Forman et al., 2009; Jongen et al., 2019). Participants in our study also identified being obese as a cause of hypertension. There is a reported positive relationship between obesity and overweight with hypertension (Aronow, 2017; Kaneva & Bojko, 2023).

Our results highlight the variety of sociocultural and livelihood physical activities adults perform as part of their daily living in this setting. These activities include walking to fetch cows, sweeping the yard, ploughing, and walking to fetch firewood which all have been previously reported by other studies as playing a major part of physical activity involvement for rural adults (Biernat & Piątkowska, 2017; Francis & Webster, 2019; Oyewumi, 2016). It is important to note that most of these reported activities, such as sewing mat while seated, household activities, walking activities, and unstructured activities are defined as sedentary or light/moderate intensity physical activity (Biernat & Piątkowska, 2017). Public health interventions aiming at increasing physical activity for hypertensive adults in a rural population may therefore want to target increasing the intensity of already existing physical activity practices.

Family members of hypertensive adults appeared to often discourage physical activities of high intensities. The participants are told by their family members that doing chores every day is a form of punishment and suffering. However, the participants continue performing these activities due to lack of help. This suggests that most house chores in rural South Africa

are left for the adults, an opportunity which can enhance physical activity participation for health benefits. Indeed, participants recognised that performing daily chores was beneficial to their health because it keeps their heart pumping more blood and this is good to control their blood pressure. It was interesting to note that females are often discouraged from performing chores linked to vigorous intensity physical activities instead of the males. This has been explained by Oyewumi (Oyewumi, 2016) who highlighted the role of gender in household activities. The author explains that adult men are expected to perform more vigorous intensity physical activities at home such as heavy lifting, chopping wood, or digging in the garden and women are expected to perform activities of lower intensity. The influence of gender cannot be ignored when designing public health physical activity interventions for blood pressure control.

Dietary approaches to stop hypertension (DASH) is a globally recommended approach to dietary habits for hypertension control which has been in existence for over 25 years (Appel et al., 1997). The DASH diet is considered the golden standard in high blood pressure control, and it emphasizes foods rich in potassium, protein, fiber, magnesium, and calcium (Steinberg et al., 2017). Such foods may include fruits and vegetables, nuts, beans, whole grains, low-fat dairy, and limiting food high in saturated fat. However, the daily diet consumed by participants in our study indicates lack of variety of different food types. Participant's diet appears mainly rich in starch which is high in carbohydrates as seen by the bread, porridge, soft porridge, and fermented porridge and milk consumed daily.

Our study revealed multiple factors which are linked to the reasons why hypertensive adults in our study setting may not follow the DASH diet recommendations. Lack of control in the type of food eaten because of attending social events like parties and funerals, where there is no choice of food, was a contributing factor. In rural African settings, when attending a social event, it is uncommon to have different meals prepared based on an attendee's dietary recommendations. Although social and community gatherings happen occasionally in rural South African populations, the consumption of unhealthy diet such as high dietary sodium in the long-term can lead to dysregulation of the renin-angiotensin system, contributing to hypertension. Religion was another influence in our study where certain religious groups prohibit eating certain types of food and may promote other types of food and beverages regardless of an individual's health status (Desalegn et al., 2018). In addition, participants reported that the taste of the food played a major role in food choice. They found that unhealthy food items taste better and reported that "hypertensive meals are not enjoyable". Another important contributor to food choice mentioned by our participants and that has been reported in multiple studies was affordability and availability of different, healthier foods (Adeyeye, 2017; Labadarios et al., 2011; Temple et al., 2011).

Due to the high poverty and unemployment rate in rural areas of South Africa, people often eat what is affordable and readily available (Statistics South Africa, 2023). Most families living in poverty purchase larger quantities of less healthy food products compared to smaller healthier substitutes (Jongen et al., 2019). This highlights the importance of considering the local financial context when designing dietary interventions for the control of elevated blood pressure. Charlton and colleagues (Charlton et al., 2008) explain that sometimes the DASH diet is not realistic to people living in rural areas with high unemployment and poverty. They recommend that the best dietary approach to controlling hypertension may be making small adjustments to current daily salt intake instead of advising people to change what they eat. This recommendation is important to consider as it has proven effective in other similar settings (Bertram et al., 2012; Charlton et al., 2021; Ware et al., 2017). In our study setting, it was recently reported that 65% of study participants aged 40-75 years had a mean salt intake of 6g/day (Du Toit et al., 2023). This is higher than the recommended daily salt intake of 5g/day by World Health Organization (Organization, 2012).

Participants in our study were knowledgeable with regards to strategies for controlling hypertension. They mentioned the importance of psychosocial wellbeing, adhering to pharmaceutical treatment, dietary control, and involvement in daily household chores and exercise. These measures have been well documented in literature as effective strategies for hypertension control (Chobanian, 2017; Guwatudde et al., 2015; World Health Organization, 2021). Regarding psychosocial wellbeing, our participants highlight the value of engaging with other people and sharing positive thoughts and having a spiritual connection with higher powers. They expressed that managing stress and anger is important in controlling hypertension. These findings have also been reported by adults in a study by Jongen (Jongen et al., 2019) and in a church-based intervention by Tussing-Humphries (Tussing-Humphreys et al., 2013).

Participants in our study believed that traditional medicine must not be mixed with pharmaceutical/western medicine. This may be attributed to the ongoing research and collaborations between traditional healers in the communities and the research team (WITS HDSS Research and Surveillance System). One important wild herb that adults in our study setting strongly emphasised as assisting in high blood pressure control is *Nkaka* (*Momordica balsamina*), also known as the African Pumpkin. Although it is not a cure for hypertension, this herb is reported to contain high potassium content which is good for hypertension management and it has also been associated to some antiviral activity which it is said could inhibit the replication of HIV-1 (Jandari et al., 2020; Thakur et al., 2009). The leaves are also important source of nutrients having 17 amino acids with adequate mineral composition like

potassium, magnesium, phosphorus, calcium, sodium, zinc, manganese, and iron (Thakur et al., 2009). Participants in our study strongly believe that this herb helps them to control their elevated blood pressure. Some of the participants eat it before their clinic visits to maintain low blood pressure levels. A further study is required to evaluate whether hypertensive adults replace antihypertensive medication with *Nkaka* to lower their high blood pressure. This wild herb could be considered as an important component of dietary education for hypertension control in the area under study; however, further studies are also required to evaluate its effectiveness in lowering elevated blood pressure.

Strengths and limitations

This study provides important in-depth cultural and social contexts to the implementation of public health interventions for adults with hypertension in a rural African setting. It provides a broad description of key determinants of physical activity and dietary considerations that strongly influence rural-based hypertension lifestyle interventions. As limitations we understand that in any focus group discussion, the inclusion of multiple people in one discussion does not guarantee full participation of everyone. For this reason, we probe those participants who seemed to contribute less during the discussions in order to have the most from the group. In addition, all participants included in this study are part of an on-going cohort study on health in older population and have also been involved in other studies which may have influenced their perceptions and knowledge on the topic. This population might be more aware of health issues such as hypertension due to the regular study visits and clinic referrals, and may, therefore, not be representative of the general population. For individuals who declined to participate in our study, we did not ask reasons for non-participation, which creates a potential bias for non-response.

Conclusion

This study provides useful insight for public health community-based interventions on physical activity and dietary sociocultural perceptions to be used when developing hypertension control interventions in rural African settings. We also highlight the need to design context specific interventions which make use of existing daily physical activity and dietary behaviour.

List of abbreviations

DASH : Dietary Approaches to Stop Hypertension

FGD : Focus Group Discussion

HDSS : Health and Demographic Surveillance System

HPT : Hypertension

LMIC : Low- and middle- income countries

MRC : Medical Research Center

PA : Physical Activity

Declarations

Ethics approval and consent to participate.

This study obtained clearance from two ethical bodies. The University of the Witwatersrand Human Research Ethics Committee (HREC - Medical) (clearance number: M 210282) and the local Provincial Department of Health Research and Ethics Committee (clearance number: MP_202106_001). Written informed consent for both participation and audio-recording of the discussion was obtained from each participant. The right to withdraw from the discussion at any point and confidentiality issues were explained to the participants prior to the beginning of each focus group discussion. Respect for all participants and protection of their privacy was adhered to.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

Funding

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Author Contributions

All authors contributed to the design of the study. KS drafted the manuscript and all authors read and approved the final manuscript. KS applied for and obtained the grants for the study.

Availability of data and materials

The datasets used and/or analysed during the current study include only transcripts of the interviews. Deidentified data may be made available from the corresponding author on reasonable request.

Acknowledgements

The authors would like to acknowledge the Agincourt HDSS for allowing the study to access information through their surveillance system. The authors would also like to acknowledge the research assistants for their work with the data collection and to the colleagues of the first author for providing feedback on the coding process during data analysis.

The next chapter will provide an evaluation of HYPHEN. Evaluation measures of feasibility, acceptability, and fidelity were conducted amongst the participants of the intervention.

CHAPTER 6

6. FEASIBILITY AND ACCEPTABILITY EVALUATION

6.1 PUBLICATION DETAILS

This chapter is presented as a submitted original research publication currently under review. The paper was submitted to *International Journal of Hypertension* on 14 April 2024. The journal is open access and the chapter is presented with corrections from thesis examiners. Table 6.1 presents information about the journal.

Table 6.1: Journal Information where the paper was submitted.

Title of publication	Feasibility and acceptability evaluation of a contextualised physical activity and diet intervention for the control of hypertension in adults from rural South Africa (HYPHEN)
Authors	Kganetso Sekome, Francesc Xavier Gómez-Olivé, Hellen Myezwa, Dale W Esliger, Lauren B Sherar
Journal name	International Journal of Hypertension
Journal publisher	Hindawi
ISSN	2090-0384 (Print) 2090-0392 (Online)
Impact factor	1.9
Status	Under review

6.2 AUTHOR CONTRIBUTIONS

Table 6.2 outlines the contributions to the publication made by each author according to the Contributor Roles Taxonomy (CRediT) laid out by (Allen et al., 2019)

Table 6.2: Author Contributions to Paper Four

	Sekome	Gómez-Olivé	Sherar	Esliger	Myezwa
Conceptualization	✓	✓	✓	✓	✓
Project administration	✓				
Methodology	✓	✓	✓	✓	✓
Initial data analysis	✓				
Writing – original draft	✓				
Writing – reviewing and editing	✓	✓	✓	✓	✓
Visualization	✓	✓	✓	✓	✓
Supervision		✓	✓	✓	✓
Funding acquisition	✓				

6.3 ASSOCIATED DOCUMENTATION

The documentation associated with this publication are included as appendices and are labelled:

- Appendix 1: Ethical clearance certificate from University of the Witwatersrand Human Research Ethics Committee
- Appendix 2: local provincial department of health research and ethics committee
- Appendix 9: Intervention copy
- Appendix 10: Data collection measurement sheet
- Appendix 11: Exit acceptability interview guide

6.4 UNDER REVIEW: FEASIBILITY AND ACCEPTABILITY EVALUATION OF A CONTEXTUALISED PHYSICAL ACTIVITY AND DIET INTERVENTION FOR THE CONTROL OF HYPERTENSION IN ADULTS FROM RURAL SOUTH AFRICA (HYPHEN)

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Running head: Evaluation of HYPHEN for hypertension adults.

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Abstract

Background: Despite the known benefits of physical activity and diet modifications for hypertension control, adults in rural South African settings still have high levels of uncontrolled hypertension. Most physical activity and diet interventions for hypertension control of rural adults require financial commitment and are not tailored to suit their contextual needs. This paper outlines an intervention which targets adjusting routine physical activity and diet practices for the control of hypertension in adults from rural South Africa (HYPHEN).

Aim: To evaluate the feasibility and acceptability of HYPHEN for adults aged 40 years and older living with hypertension and in rural north-east South Africa.

Methods: This was a one-arm 10-weeks intervention. Feasibility was measured via assessing recruitment and retention rates. Acceptability was assessed through interviews after the 10 weeks intervention using pre-determined themes of perceived expectations, benefits, motivation, and barriers concerning the intervention. Fidelity was evaluated by intervention adherence, dosage, quality, and participant responsiveness.

Results: Data collected to measure outcomes was complete. Our study demonstrated high level of feasibility, acceptability, and fidelity. Thirty (100% of target) participants were successfully recruited over two days, 28 (93%) participants were retained, and 28 (93%) provided complete data. Qualitative data demonstrated high acceptability with participants reporting that the intervention met their expectations, they benefited from the intervention, were motivated to continue with intervention, and had limited barriers associated with the intervention. Participants suggested possible ways to improve the intervention such as being clear with what the intervention will not provide them. Intervention fidelity was high all three components carried out as planned, minor dosage adjustment, high delivery quality, and 100% participant engagement.

Conclusion: HYPHEN is a feasible and acceptable intervention for hypertension control in rural South Africa and can be rolled out on a full trial. Considerations that are required for the full trial include being clear from the onset about the resources which the intervention shall not provide, for example, food parcels, money to buy food, and exercise equipment.

Trial registration: Pan African Clinical Trial Registry (pactr.samrc.ac.za)
PACTR202306662753321. Retrospectively registered on 29 June 2023.

Keywords: High blood pressure, nutrition, rural, exercise, Agincourt.

Introduction

The benefits of physical activity and dietary modifications for hypertension control have been well documented (Flack & Adekola, 2020; Seedat et al., 2014; World Health Organization, 2020). Evidence suggests that adults with chronic diseases can benefit from increasing their physical activity, including increasing of steps taken per day (Bravata et al., 2007; Richardson et al., 2008), increasing the intensity of daily physical activity (US Department of Health and Human Services, 2018), or simply participating in regular physical activity according to their level of ability (Piercy et al., 2018). The widely recommended dietary approaches to control hypertension are through reduction of dietary sodium salt and adoption of the Dietary Approaches to Stop Hypertension (DASH) diet (Charlton et al., 2021). To be most effective for adults, these interventions should be targeted earlier in life, such as from the age of 40 years (Tomaz et al., 2020).

Despite the proven benefits of physical activity and diet modifications for hypertension control, adults in rural South African settings still have high levels of uncontrolled hypertension (Abrahams-Gessel et al., 2023; Ntuli et al., 2015). Recent data from rural north-east South Africa reports that only 41.3% of adults aged 40 years and above have their hypertension under control (Abrahams-Gessel et al., 2023). Some of the identified challenges for the low control rates in rural South Africa include inadequacies of the health care system, unaffordability issues with the recommended diet, and a poor understanding of the daily physical activity routine of the population (Cook, 2007; Maphumulo & Bhengu, 2019; Steinberg et al., 2017). Other challenges which have been reported globally include low frequency of interaction with health staff, availability of clear clinical guidelines and the unavailability of medicine (Zhou et al., 2021). The low rate of hypertension control for adults in a rural population contributes to economic hardships due to associated costs of accessing the health care system, low doctor-to-patient ratios, and lack of access to health information (Eyinda et al., 2022; Rispel et al., 2019; Sekome, 2018).

Interventions at community level which do not require financial commitment from the hypertensive individual can substantially reduce the burden of hypertension on the individual (Correia et al., 2019). In line with the World Health Organisation recommendations for lifestyle approaches to control hypertension through physical activity and diet (World Health Organization, 2020), rural populations require affordable and/or free tailored interventions that suit their contextual needs. Adults in rural South Africa have been reported to engage in various daily physical activity routines such as walking as means of transportation, walking for wood and water collection, yard work, various aspects of farming, and housework (Cook, 2007; C. M. Shackleton et al., 2007; S. E. Shackleton & Hebinck, 2018). These daily routines are, however, performed at intensities that may not be sufficient to achieve health benefits

(World Health Organization, 2020). The majority of published dietary interventions involve food recommendations which are unaffordable in many rural communities (Charlton et al., 2008). Considering these existing knowledge, the contextualised HYPHEN (**HY**pertension control using **PH**ysical activity and **diEt** in a rural **coN**text) intervention was developed based on the social and cultural beliefs, perceptions and practices regarding physical activity and diet from hypertensive adults in the rural South Africa (Sekome et al., 2024a). The aim of the present study was to evaluate the feasibility and acceptability of HYPHEN for adults in rural South Africa.

Methods

The full protocol for the HYPHEN study has been published elsewhere (Sekome et al., 2024a). We recruited 30 adult participants with a self-report hypertension diagnosis. Feasibility studies do not require a formal power calculation or hypothesis testing as the aim is not to assess intervention effect (Mailhot et al., 2020). Primary outcomes were feasibility, acceptability, and fidelity of delivery. Secondary outcomes were blood pressure, accelerometer-measured physical activity, diet consumption, body mass index, urine sodium, and waist-hip ratio.

Study design

The study was a single-group community-based evaluation which assessed the feasibility and acceptability of a 10-weeks contextualised physical activity and diet intervention for adults with hypertension. Inclusion criteria were aged 40 years and older; a self-reported diagnosis of hypertension and/or currently being on medication for hypertension; and having lived in the study setting for a minimum of six months prior to the start of the intervention.

Setting and population

The study was conducted at Bushbuckridge sub-district in Mpumalanga Province of South Africa where the Agincourt Health and Demographic Surveillance System (HDSS) has been running since 1992. Participants were sampled from the Health and Aging in Africa: A Longitudinal Study of an INDEPTH (International Network for the Demographic Evaluation of Populations and Their Health) community in South Africa (HAALSI) (Gomez-Olive et al., 2018). Participants were contacted via telephone and given a description of the study. Those who expressed interest to participate were then visited at their households for further explanation and to obtain written informed consent to participate.

Participation in the physical activity profile study and the qualitative study of this thesis was not a requirement to be included in the intervention. Since we recruited from the same cohort,

it is possible that some of the participants in this study might have already participated in the telephonic IPAQ study and the qualitative focus group study, but this was not established.

Intervention procedure

Three locally trained field-workers, who are residents of the study setting and are Xitsonga native language speakers, delivered the intervention. The field-workers were trained by the first author including questionnaire administration, anthropometric measurements, and delivery of education to the participants.

Intervention

The intervention comprised three components: structured group education, individualised physical activity education, and individualised dietary education and is described in full elsewhere (Sekome et al., 2024a). The intervention was delivered in Xitsonga language, which is the participants' home language. The structured group education focused on enhancing participants' knowledge and skills by providing explanations about hypertension, its related risk factors and its management. Information pamphlets were given to each participant. Individual household visits were conducted to impart behaviour change techniques which targets participants' individual physical activity and diet. As part of the behaviour change strategy, participants were asked to set individual goals which they wanted to achieve over a ten weeks period. Participants were provided with individualised education on how to make modifications to their daily physical activity and dietary routine. Monitoring of behaviour change and feedback was conducted by the field-workers via weekly telephone calls to monitor participation and engagement throughout the ten weeks intervention. There was no compensation or incentive provided for being part of the intervention, because there was no financial or additional time commitment required from participants for being part of the intervention.

Outcomes

The primary outcomes of interest were the intervention's feasibility, acceptability, and fidelity. The primary outcomes were measured at week one and monitored throughout the intervention. Secondary outcomes were changes in blood pressure, body mass index, waist-hip ratio, urinary sodium, physical activity, and diet intake. The secondary outcomes were all assessed at the beginning of the intervention. All outcomes were assessed again at week 10. We used the criteria developed by Avery and colleagues (K. N. L. Avery et al., 2017) to judge the feasibility of progressing to a larger scale evaluation. This comprised of successful recruitment of 30 participants in one week, $\geq 80\%$ of recruited participants retained, $\geq 80\%$ of recruited participants provide completed weekly data. Acceptability was assessed through interviews at the end of the ten weeks intervention. The interviews explored participants'

perceived expectations, benefits, motivation, and barriers concerning the intervention. Overall satisfaction was rated using a Likert Scale with a rating of 7/10 being considered acceptable satisfaction. Fidelity of the delivery of each component of the intervention was assessed by the primary investigator using the five dimensions of fidelity, namely: adherence, dosage, quality of intervention delivery, participant responsiveness, and program differentiation (An et al., 2020). We assessed all but program differentiation. The reason was because our intervention consisted of a one arm group with no control group to compare differences.

Quantitative analyses

A Consolidated Standards of Reporting Trials (CONSORT) flowchart was used to present the flow of participants. Descriptive statistics were used to measure outcomes of feasibility, acceptability, and pre-post intervention secondary parameters.

Qualitative analysis

Audio-recorded interviews were transcribed and translated from Xitsonga to English by two qualitative locally trained research assistants. Transcripts were analysed manually by the principal investigator for themes relating to acceptability of intervention following Braun and Clarke's approach to thematic analysis (Braun & Clarke, 2012). All co-authors confirmed the codes and themes. Coding was performed deductively according to already pre-determined themes of: perceived expectations, benefits, motivation, and barriers of the intervention (L. Avery et al., 2023).

Results

Participant recruitment

The CONSORT diagram, which presents the flow of participants through the intervention, is presented in Figure 6.1. We produced a random list of hypertensive participants from the HAALSI study to get the required sample. We phoned 66 participants and 33 (50%) were eligible to participate in the study. All adults who were ineligible reported not having hypertension. Of the eligible participants, three declined to participate due to: illness (n=2) and unwillingness to wear accelerometer (n=1). A total of 30 participants were recruited via telephone over two days. One participant contacted the research team three days after recruitment and requested to drop out due to moving house outside the study site for work. A total of 29 (97% of those recruited) participated in the intervention and had complete baseline data. One participant dropped out during week ten due to spousal death and could no longer engage with the research team for follow-up assessments due to cultural reasons. In total, 28 (93%) of the 30 recruited participants completed the intervention and had follow-up assessments. Their characteristics are presented in Table 6.3.

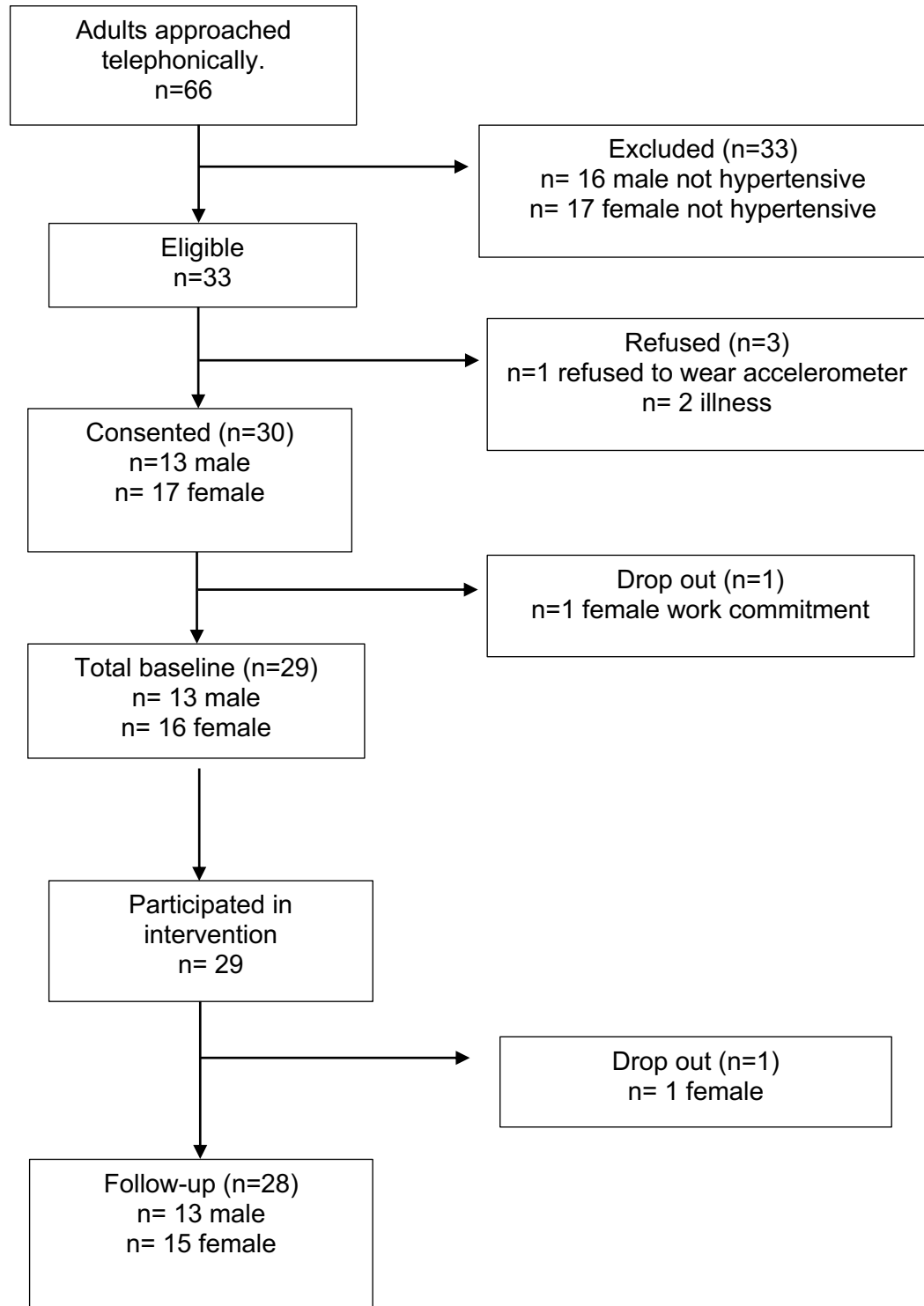


Figure 6.1: CONSORT Diagram

Participants characteristics

The baseline sample (n=29) were more likely to be female (16, 55%), unemployed (28, 97%), lower educated [attended only primary school (19, 66%)], non-smokers (27, 93%), and non-alcohol drinkers (26, 90%). The mean age was 64.9 years. One participant did not complete follow-up assessment.

Table 6.3: Participant Characteristics

Variable	Baseline (N=29)	Follow-up (N=28)
Sex		
Male	13 (45%)	13 (46%)
Female	16 (55%)	15 (54%)
Age		
50-59	10 (35%)	10 (36%)
60-69	12 (41%)	11 (39%)
70+	7 (24%)	7 (25%)
Employment status		
Employed	1 (3%)	1 (4%)
Unemployed	28 (97%)	27 (96%)
Educational level		
Primary education	19 (66%)	18 (64%)
Secondary education	10 (34%)	10 (36%)
Alcohol drinkers	3 (10%)	3 (11%)
Tobacco smokers	2 (7%)	2 (7%)

Primary outcomes

1. Feasibility

A pre-defined progression criteria (K. N. L. Avery et al., 2017) outlined in the study protocol (Sekome et al., 2024a) was used to judge feasibility of progressing to a larger intervention (Table 6.4). We recruited 100% participants in two days, 93% of participants were retained to completion, 93% of participants engaged with weekly telephonic calls, and measurements of all outcome data of feasibility were complete. The overall rating on the Likert scale was 8.6/10 (SD=2.55).

Table 6.4: HYPHEN Progression Criteria

HYPHEN progression criteria	Go – proceed to larger scale (RCT)	Amend – Proceed with changes	Stop – Do not proceed unless changes possible	HYPHEN results
Feasibility of participant recruitment – can 30 participants be recruited in one week?	If 30 participants are recruited in one week (100%)	If 15 to 29 participants are recruited in one week (50 to <100%)	If <15 participants are recruited in one week (<50%)	30 (100%) participants in 2 days
Feasibility of patient retention – can at least 80% of recruited participants be retained?	≥24 (80%) retained	21-24 (70-80%) retained	<21 (70%) retained	28 (93%) participants retained
Feasibility of engagement – can at least 80% of recruited participants provide complete weekly data	≥24 (80%) engaged	21-24 (70-80%) engaged	<21 (70%) engaged	28 (93%) participants engaged.
Feasibility of intervention implementation	Delivery of intervention judged strongly feasible by qualitative data	Delivery of intervention judged feasible by qualitative data	Delivery of intervention judged possibly feasible by qualitative data	Participants quotations very positive. Likert rating 8.6/10

2. Acceptability

Five pre-determined themes were used to judge the acceptability of the intervention: (1) meeting intervention expectations, (2) benefits of the intervention, (3) motivators to continue with intervention, (4) barriers associated with the intervention, and (5) suggestions for improvement.

2.1 Meeting intervention expectations

Most participants expected a reduction in blood pressure from the intervention and they believed that this was achieved but only modestly. However, some participants misunderstood the intervention and expected that the intervention would also provide them with anti-hypertensive pills, food parcels and money to buy healthier food.

- *“Yes it did (meet my expectation) because the level my high blood pressure had decreased a little. I want you to keep on doing what you are doing to us because we are now living good without any complications”. Female, aged 57.*
- *“No, they did not reach my expectation. I was expecting WITS to give me pills after screening me and find that I have high blood pressure and I was also expecting that they will give us some food parcels”. Female, aged 71.*
- *“If you were offering us the food that is in the diet maybe things would be easy for us to stick to the diet. For now, the best thing is not to eat salted food and to eat brown bread because it is something that we can do simple”. Male, aged 70.*

2.2 Benefits of the intervention

Some of the intervention benefits expressed by participants included: reduced night sweats, awareness of blood pressure reading, reduced heartbeat, improved daily activity performance, family involvement, overall health improvement, no body pains, and reduced shortness of breath.

- *“my high blood pressure is no longer troubling me like it used to, I would sweat a lot at night when I am sleeping but now I don’t”. Male, aged 68.*
- *“I did not even know my high blood reading but they (field workers) were able to alert me about it.” Female, aged 68.*
- *“Even my heart beating is no longer that fast as it used to be”. Female, aged 68.*
- *“Taking a long walk was difficult for me but now I am able to take a walk from here in my household to Newington and I can also play with children as well”. Female, aged 68.*
- *“Those that are cooking for us now know that they don’t have to add more salt on our food but a small amount of salt because they now that you told us to follow the diet”. Female, aged 57.*
- *“It took me days to get used to the food but now I am used to it and I am even complaining if they had added much salt on the food”. Male, aged 70.*
- *“I used to sweat at night when I am asleep, feeling pains all over my body and struggling to walk around but ever since with the intervention of diet and physical activity I am able*

2.3 Motivators to continue with the intervention

The participants were motivated to continue with the intervention because they saw a positive health change, were encouraged by receiving weekly calls from field workers, and they had hopes of feeling better as a result of the intervention.

- *“What gave me energy is the education that I got from you, and I was able to reduce salt and also eat fruits and vegetables that I was told to eat. That is what motivated me because I could see a change about my health”.* Female, aged 68.
- *“The phone calls motivated me, because you always call me to check what have I eaten and you also ask that did I do any activities? So that is encouraging us to do it every day”.* Female, aged 68.
- *“What motivated me was the advices, the education you gave us, it gave me hope that if I follow your instructions I will be fine”.* Female, aged 52.

2.4 Barriers associated with the intervention

Some of the challenges expressed by participants during the intervention included difficulty adapting to the recommended diet due to learnt habits (e.g. high salt food intake) and difficulty measuring how much salt to add when cooking for household. The participants alluded to the fact that the diet recommendations were clear but they required a longer duration for them to adapt to making changes in their diet. For physical activity most participants reported no barriers as they said the intervention was embedded into their daily routine activities they were already performing.

- *“When it comes to diet it was very difficult because I was used to eating whatever I want but when I was taught about good diet I had to change and it was difficult, I am doing it because I want my health to be good and my blood pressure to reduce”.* Male, aged 67.
- *“I only had a challenge with salt measurements in food but the rest I did not have any challenges”* Female, aged 68.
- *“There were no challenges because something like going to the field and cleaning my yard is daily routine so I did not have any problem by doing it”.* Female, aged 57.

Suggestions given to improve the intervention included provision of healthy food, starting a community farming project, provision of blood pressure machines, and expanding the intervention to more people in future.

- *“If it was possible, you must open a project where we can go and do our farming where we will plough vegetables like spinach and pumpkins that will always keep us healthy”.* Female, aged 68.
- *“You should give us these (blood pressure) machines because if you take them with you we are not able to know if the level of high blood pressure is stable or I am in danger”.* Female, aged 57.
- *“You must continue to remind us about doing exercises and also motivate us because if you don’t do that we will stop as time goes on”.* Male, aged 67.
- *“You had given us the perfect diet so I don’t think you should add on it or remove something, just keep on implementing it on other participants.* Male, aged 64.

Participants were also asked to rate their overall satisfaction on a Likert scale out of 10. The average rating on the Likert scale was 8.6/10 (SD=2.55). The lowest participant rating was 6 (n=4) while the highest rating was 10 (n= 12). This demonstrated that the intervention was acceptable. Textbox 1 provides supporting quotes for the Likert scale rating.

Textbox 1: Supportive quotes for overall intervention rating using Likert scale.

- *“I rate it 8 to 10 because when there are people who are always reminding you about your health it is good. I used to chase WITS people out of my home but now I welcome them with open arms”.* Female, aged 73.
- *“I would rate it 10, the intervention was great to me. I want the intervention to continue helping our society and I am very much happy with it”.* Female, aged 52.
- *“I will choose 6. I think if we can be taught how to farm and also help us with water because we don’t have water in our community even if we can plough vegetables will not have water to water them.”* Female, aged 55.

3. Intervention fidelity

All four assessed dimensions of fidelity demonstrated that the intervention was delivered as intended. Table 5 outlines the outcomes of the intervention fidelity.

Table 6.5: Fidelity of Delivery of Intervention

Measure of fidelity (An et al., 2020)	HYPHEN study fidelity outcome
Adherence	The three intervention components were carried out as planned with all participants attending the group and individual interventions, complied with weekly monitoring telephonic calls, and were visited at their households at the end of the intervention. During each weekly call, the research assistants asked participants which components of the intervention were achieved for that week and ticked this on the data collection sheet.
Dosage	The group educational interventions were planned for 90 minutes but could be slightly shorter or longer by 15 minutes depending on the level of engagement and participation. They lasted between 75 – 100 minutes. This showed good fidelity. Individual educational interventions were planned for 60 minutes but could be slightly shorter or longer by ten minutes depending on the participant's set goals, they lasted between 60 to 70 minutes which showed good fidelity.
Quality of intervention delivery	Field workers had copies of educational material which they followed for each of the three interventions. There was no deviation from the planned educational material content. The primary researcher who designed the intervention materials was present throughout all interventions to assess the extent to which the materials were delivered as planned and note any deviations.
Participant responsiveness	Participants were telephoned weekly to assess engagement with the intervention. Field workers kept record of participants who refused to engage. 100% participants were called weekly and 100% engaged with the calls
Program differentiation	Not measured

Secondary outcomes

Participants complied with all assessment measured, resulting in complete captured data. The average baseline blood pressure measurement was 139/87mmHg while average follow-up blood pressure was 136/87mmHg (1.02mmHg decrease in systolic blood pressure). Baseline body mass index was 29.34 while follow-up body mass index was 29.48 (0.13 decline). The baseline waist to hip ratio was 0.93, the same as the follow-up (no changes). The baseline urine sodium levels were 90.93 mmol/L and the follow-up was 84.79 mmol/L (6.14 mmol/L decline). Baseline physical activity measurement was 82.33 minutes of moderate-vigorous physical activity (MVPA) per day while follow up was 78.83 minutes of MVPA per day (3.50 minutes of MVPA reduction). All our participants returned the accelerometer devices on day seven (pre and post intervention), although we noticed some errors with the devices during recording which are discussed in the following section. For example, where participants reported wearing the device for full seven days, the device recorded fewer days of physical activity data.

Table 6.6: Baseline and Follow-Up Assessments of Secondary Outcome Measures

Variable	Baseline (N=29)	Follow-up (N=28)
Blood pressure (mmHg)	139/87	136/87
Urinary sodium (mmol/L)	90.93	84.79
Physical activity (min/day)		
MVPA	82.33	78.83
Vigorous physical activity	3.72	1.42
Moderate physical activity	78.61	77.41
Light physical activity	194.01	181.29
Total physical activity	276.34	260.12
Inactive time	770.75	781.57
Body Mass Index (kg/m ²)	29.34	29.47
Weight (kg)	77.01	77.36
Height (m)	1.62	1.62
Waist-hip ratio (cm)	0.93	0.93
Waist (cm)	100.21	99.43
Hip (cm)	107.64	107.26

mmHg= millimetres of mercury, kg= kilograms, m= metre, mmol/L = millimoles per litre, min/day= minutes per day, mvpa= moderate to vigorous physical activity.

Discussion

The aim of our study was to evaluate the feasibility and acceptability of HYPHEN, a contextually relevant physical activity and diet intervention for controlling hypertension for adults aged 40 years and older living in rural north-east South Africa. Our study demonstrated that HYPHEN was feasible and accepted. The design and methods were feasible by showing recruitment in the set time-frame; high intervention adherence, engagement, and retention; and positive feedback during qualitative interviews. The mean score for intervention satisfaction was a Likert scale of 8.6/10. The intervention also demonstrated a promise of success if rolled out on a larger scale trial due to its modest reduction in blood pressure.

Feasibility

During participant recruitment, half of the adults we approached telephonically did not disclose to our fieldworkers their hypertension status, although we recruited a sub-sample of participants in the HAALSI cohort (adults 40+) who had been found to be hypertensive in the last cohort visit in 2022 (Abrahams-Gessel et al., 2023). It is possible that the HAALSI study might have wrongly identified some participants as hypertensive but they were not confirmed as hypertensive when attended the local health facilities. Also, due to its asymptomatic nature, most adults who have been newly diagnosed with hypertension are not aware of being hypertensive (Mothiba et al., 2013). A study in Nepal reported that hypertensive patients who do not feel dizziness and headaches perceive their blood pressure to be normal (Shrestha et al., 2018). This affects efforts towards hypertension control as most

hypertensive adults are not on treatment increasing the mortality and morbidity from the disease especially in rural communities (Jardim et al., 2017; Jongen et al., 2019). Besides denial of diagnosis, only one female participant refused to take part in our study because she did not feel comfortable wearing an accelerometer device on her wrist due to potential for skin irritation. Studies have, however, reported that compliance with wrist-worn accelerometers is high due to lower participant burden and reduced potential for skin irritation (Doherty et al., 2017; Troiano et al., 2014).

Our study demonstrated high feasibility as it met the criteria for “Go – proceed to larger scale” in all four areas of feasibility defined by (Avery et al., 2017). Of all the targeted 30 recruited participants, 28 were retained to completion. One participant dropped out due to relocating to another community outside the study site and our design did not plan following migrants. One other participant dropped out during week nine of the intervention due to cultural reasons as her husband passed away. It is expected for women in some rural South African areas to socially exclude themselves from society for several weeks to months as part of the mourning period (Kotzé et al., 2012; Rosenblatt & Nkosi, 2007), therefore we could not engage with the participant for final follow-up assessments. All the participants who were retained to study completion provided complete data during weekly telephonic monitoring and engaged successfully with the intervention, demonstrating high study feasibility.

Acceptability

Participants in our study expressed two main perceived expectations from the intervention during follow-up interviews. Their first expectation was a reduction in elevated blood pressure, which was modestly achieved. Their second expectation was a supply of antihypertensive medication, healthier food-parcels, and money to purchase food options that are low in sodium salt. It was not the intention of our intervention to provide participants with any supplies of medication, money, or food-parcels. Due to multiple previous and ongoing studies at the study site, participants have been exposed to other studies that have provided incentives and this could have created the expectation that we will also provide incentives. A future, larger scale intervention should make it clear to participants what the intervention will not provide to avoid wrong expectations that could affect participation in the study.

Our study participants considered the intervention to be acceptable due to the perception of a reduction of blood pressure associated symptoms. Participants expressed a reduction in night sweats, reduced irregularity in heartbeat, reduced body pain and reduced shortness of breath. It has been described that some of the commonly reported clinical symptoms of hypertension were headaches, vertigo, chest pain, vision problems, dyspnoea, increased

urinary frequency, nausea, sleep apnoea, irregular heartbeat/palpitation, fatigue and confusion (Adnan et al., 2018). A larger scale intervention of HYPHEN must consider keeping records of participant's clinical history (Adnan et al., 2018), in this way the investigators can assess the effects of the intervention on the patient's physical health. Apart from benefits in clinical manifestation of hypertension, participants in our study expressed the benefits of awareness of blood pressure reading and family involvement.

Our findings that our study participants had challenges to adapt to the recommended changes in diet due to learnt habits of high salt food, and to know and measure how much salt to add when cooking for their household corroborated previous findings elsewhere (Bertoni et al., 2011). We suggest that a future larger scale intervention considers prolonging the intervention to allow for participants to adapt and sustain the recommended changes in diet. Regarding changes in physical activity performance, most participants reported no barriers because the intervention was embedded into their daily routine activities. Our study participants recommended that a future study should target the wider population due to the benefits of the intervention. They also suggested investigators to provide healthy food which can also be through initiating a community farming/gardening project, and provision of blood pressure machines.

Fidelity

Assessment of fidelity of enactment demonstrated that our intervention was carried out as planned, though some slight amendments are recommended for future larger iterations. We recommend that future trials nominate a senior fieldworker, principal investigator, or a co-investigator who was involved from the initial design of the intervention present during educational sessions. This assists in answering certain questions which intervention developers may be able to answer. No major alterations were required regarding the duration of the group and individual educational sessions. The longest group education session was 10 minutes longer than the anticipated time, while the shortest group session was 15 minutes shorter. This was due to the different levels of engagement and participation in each group. Future trials should therefore allow for flexibility with the length of the group sessions. For individual education sessions, the planned duration was 60 minutes and sessions lasted between 60 to 70 minutes. This was because participants set different number of goals, therefore those with more goals needed longer time to discuss them. The length of future trials should also allow flexibility for individual engagements. Participants in our study were very responsive to the weekly calls and they reported that this approach also provided them with motivation to continue with the intervention. We noted that in order for the telephonic calls to occur exactly seven days apart, it is best to have an initial call in the morning. In those

instances that participants could not answer morning calls due to household or personal duties it gave the fieldworkers adequate time to call them back at a later time on the day.

Secondary outcomes

Our study participants complied with all assessment measures with only one participant refusing to take part in the evaluation measures due to possible irritation of wearing the accelerometer device on the wrist. Some of the participants had incomplete recording time on the accelerometer even though they all reported wearing it for seven days as instructed. This could have been due to errors in setting up the device. We recommend to future investigators to first engage with the accelerometer device and use it on general population before the intervention. We assessed dietary intake using the 24HR dietary recall questionnaire, however, data capturing was inconsistent and incomplete and thus excluded from analysis. We recommend piloting the 24HR dietary recall with a sample of adults especially if the data collectors have not used this tool before. Due to its subjective nature, it can be open to interpretation hence resulting in poor data.

During recruitment, some participants were reluctant to wear the accelerometer because they had the assumption that the device is going to monitor their whereabouts as well as video record them throughout the day and night which would infringe on their privacy. Explaining the purpose of the device was important to ensure successful recruitment and compliance. We did not experience any compliance issues with blood pressure measurement, urine sample collection, and anthropometric measures. Some participants, however, mentioned that they would not have been willing to participate in the study if it involved collection of blood samples. Since our intervention was a feasibility study, there was no power calculation to detect pre-post effect of the intervention. We nonetheless assessed pre-post changes which shows some promise of success in blood pressure reduction. A larger powered study should investigate pre-post difference across sex and age of participants.

Conclusion

This was, to the authors' knowledge, the first study in rural South Africa to determine whether adaptations in physical activity and diet based on existing daily routine would be feasible and acceptable by adults for the control of hypertension. Although deemed feasible and acceptable, some amendments are required to the intervention procedures that were carried out before a full trial can be rolled out. Future definite trials should be clear from the onset about the resources which the intervention shall not provide, for example, food parcels, money to buy food, and exercise equipment.

Declarations

Ethics approval and consent to participate.

This study required clearance from two ethical bodies. The first clearance was obtained from the University of the Witwatersrand Human Research Ethics Committee (HREC - Medical) (clearance number: M 210282). The second clearance was obtained from the local Provincial Department of Health Research and Ethics Committee (clearance number: MP_202106_001). Consent considerations and confidentiality of all research data will be adhered to. This study is based on the usual ethical principles, such as every person's right to refuse to participate in the study and to withdraw at any time, as well as respect for all participants and protection of their privacy.

Consent for publication

Not applicable

Competing interests

The authors declare that they have no competing interests.

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Author Contributions

All authors have participated in the conceptualization of the study and data curation. KS performed the initial data analysis and all authors approved the final analysis. KS applied for and obtained the grants for the study. KS was involved in data methodology and project administration. FXG, HM, DE, and LS Supervised the study. KS drafted the original manuscript draft and all authors reviewed and approved the final manuscript.

Availability of data and materials

Data for this study is available on request to the principal investigator.

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The following chapter will provide a discussion by highlighting and integrating key findings from all studies conducted. The chapter will also provide guidance for future research studies, policy guidance, and full clinical trial testing.

CHAPTER 7

7. INTEGRATED DISCUSSION

7.1 INTRODUCTION

Chapter 7 highlights the key findings from each study in relation to the overall study aim and draws on relevant local and global literature. The chapter will also revisit the conceptual framework to identify any lessons learnt that may confirm or add to the conceptual framework. This chapter also provides the strengths, limitations and recommendations emanating from this thesis.

The overall aim of this thesis was to design, implement, and evaluate the feasibility and acceptability of a contextualised physical activity and diet intervention for the control of hypertension of adults living in a rural sub-district in South Africa. This study included multiple methods of data collection conducted to answer six objectives. In summary, objective one was to establish the profile of physical activity of hypertensive adults (aged 40+) living in a rural sub-district of Mpumalanga province, South Africa. Objective two was to explore hypertensive adults' social and cultural beliefs, perceptions and practices regarding physical activity and diet. Objective three was to design and implement a contextually appropriate educational intervention programme for the control of hypertension for the target population. The last three objectives were to evaluate the feasibility (objective four), acceptability (objective five), and fidelity (objective six) of the intervention.

7.2 DISCUSSION

7.2.1 Profile of Physical Activity of Hypertensive adults in Rural Agincourt

Key findings

- Total self-reported median weekly physical activity for all participants was 330 (120-595) minutes.
- Men reported higher frequency and duration of vigorous physical activities at work than women.
- Women reported higher frequency and duration of moderate -intensity physical activity inside and outside the house.

This study revealed information about the frequency, intensity, duration, and domain of self-reported physical activities of adults with hypertension from rural South Africa. The overall median reported duration of physical activity amongst the study participants met the international guidelines for total aerobic physical activity per week. Adults should perform at

least 150 – 300 minutes of moderate-intensity aerobic physical activity; or at least 75 – 150 minutes of vigorous-intensity aerobic physical activity per week (World Health Organization, 2020). The results demonstrate that participants in this study population are generally physically active, therefore, physical activity interventions for this study population should target specific domains of physical activity such as recreation physical activity.

Although the participants' median weekly physical activity met the WHO physical activity guidelines, vigorous physical activity levels did not meet these guidelines (median=60 minutes per week). Men in this study reported greater duration of vigorous physical activity at work compared to women. This finding was related to the type of work (paid or unpaid) men perform compared to women. Women however, reported higher frequency of moderate intensity physical activities inside and outside the house than men. A nationally representative population-based survey study found that only 27% of the population of 26339 South Africans met the guidelines for vigorous physical activity (Mlangeni et al., 2018). The study reported that increasing age and being female were associated with low levels of vigorous physical activity. This could be the case in our study, as we included adults aged 40 years and above, with females reporting lower levels of moderate-vigorous physical activity. Older adults are less likely to engage in vigorous physical activity due to physiological and biological changes and social expectations (Mlangeni et al., 2018). Age-related changes in the dopamine system decreases motivation for movement (Delacroix et al., 2014). The reason why men in our study performed more vigorous physical activity than women could be attributed to gender roles in rural South Africa where men are expected to perform “tougher” activities (Oyewumi, 2016). Age and gender should therefore be considered in physical activity interventions, as suggested by previous studies (Mabweazara et al., 2018; Tusso, 2015). Additionally, the findings of our study necessitated the need to further explore sociocultural perceptions which influence physical activity to design a contextually relevant health promotion programme.

7.2.2 Sociocultural Beliefs, Perceptions and Practices regarding Physical Activity and Diet by Hypertensive Adults in Rural Agincourt.

Key findings

- High sodium diet, oily and fatty food items, and obesity were recognized as causes of hypertension by study participants.
- Eating frequently at social and community events, religion, food taste, affordability, and unavailability of food were cited as reasons for unhealthy eating habits.
- Participants believed that they participate in high levels of physical activity, although many cited activities, such as walking and most household tasks, were of lower intensity and/or sedentary.
- Women were often discouraged by family and community members from performing vigorous intensity physical tasks such as heavy lifting, chopping wood, or digging in the garden.

This study provides a profile of the dietary and physical activity habits of hypertensive adults and revealed the need to consider existing dietary and physical activity behaviours when designing context specific interventions. This finding has been reported by other authors; for example, Charlton et al., (2008) in their RCT concluded that strategies to lower high blood pressure should not ask people to change the food that they eat. The focus should be on making small longer-term adjustments such as finding similar cost food replacements and lowering salt and food seasoning. A contextualised six-weeks physical activity intervention study for HIV positive adults employed local resources, opportunities, and activities of daily living and found significant increase in moderate-vigorous physical activities (Mabweazara et al., 2018). Interventions aimed to increase physical activity especially for adults in a rural community must focus on increasing the intensity of already existing daily tasks, especially for women who seem to be discouraged from performing vigorous intensity tasks. Therefore, for physical activity and diet interventions to be effective, the intervention needs to be responsive to locally available resources and the daily routine behaviour of the individual adult.

Participants in this study are aware that unhealthy food and physical inactivity can elevate blood pressure; however, certain sociocultural and livelihood factors prevented them from achieving dietary and physical activity guideline recommendations. Education about how to make small changes such as food replacements and increasing the pace or position (for example sitting to standing) of daily tasks was implicated as a potential intervention strategy.

Previous studies to lower high blood pressure, increase physical activity and change dietary behaviour have recommended group education where adults meet at a central community structure such as a church or local organization, providing individualised door-to-door education, and providing pamphlets during education which can result in improved intervention uptake (Jongen et al., 2019; Tussing-Humphreys et al., 2013). Our study adopted these recommendations as an approach to the physical activity and diet educational intervention to increase intervention uptake.

7.2.3 Design and Implementation of a Contextualised Educational Intervention Programme for the Control of Hypertension

Key intervention parameters

- COM-B (Capability, Opportunity, and Motivation) model underpinned the intervention design.
- Taxonomies of behaviour change techniques such as self-monitoring of behaviour, goal setting, and information about antecedents were used to identify active intervention ingredients and allow for future replication.
- The intervention comprised of three components: a structured group education session, individualised physical activity education, and individualised dietary education over a period of 10 weeks and were informed from the previous research outlined in this thesis.
- Feasibility parameters included recruitment, retention, and engagement.
- Acceptability parameters included perceived expectations, benefits, motivation, and barriers concerning the intervention.
- Fidelity, whether the structured group education session and individualised education was delivered as planned, was measured.
- Secondary measures included blood pressure, body mass index, waist- hip ratio, urinary sodium, accelerometer-measured physical activity, and 24HR diet recall.

The COM-B model (Michie, Van Stralen, et al., 2011) has been used in multiple health promotion programmes to enhance physical activity participation and dietary changes (Brown et al., 2024; Willmott et al., 2021). A systematic review by Pelletier et al., (2022) on physical activity promotion using the COM-B model in rural care settings reviewed articles mostly involving older adults and people with chronic diseases. Their review found that the most successful intervention strategies which increased physical activity behaviour included the wearing of activity tracker (self-monitoring of behaviour) and monitoring and feedback from trusted sources. Feedback and monitoring for our intervention was provided by locally trained research assistants who can speak the local language.

The COM-B model of behaviour change was key to identifying factors at the personal and environmental level which were important for behaviour change. For example, capability allowed the researchers to assess individual's psychological and physical capability to engage in the activity concerned. The assessment included having the necessary knowledge and skills. Factors such as the amount of knowledge people have about hypertension and identifying knowledge gaps was key. For opportunities, the researcher had to identify all the factors external to the individual that can make the behaviour possible. An opportunity to engage with family members of the individuals was noted as a consideration for future trial. For motivation, the researcher identified brain processes that energize and direct behaviour, it includes habitual processes, emotional responding, as well as analytical decision-making. Contacting the individuals weekly to track participation was reported by individuals as a techniques that enhanced motivation to continue with the intervention. We designed the intervention duration of ten weeks based on recommendations from previous feasibility studies (Eldridge et al., 2016; Mailhot et al., 2020). The main recommendation about the duration of pilot and feasibility studies is that feasibility studies should not be too long as this can result in large financial commitments which could be better utilized in the larger trial. Although it was not the primary aim of this study, we employed secondary outcome measures in order to assess if the intervention offers any promise of success if rolled-out in a larger trial. A previous feasibility and acceptability protocol study has suggested the assessment of secondary outcomes in similar studies as these measures will be the main indicators of success in a larger trial (L. Avery et al., 2023).

7.2.4 **Evaluation of a Contextualised Physical Activity and Diet Educational Intervention Programme for the Control of Hypertension**

Key findings

- Feasibility was high as judged by 100% participant recruitment in the set timeframe, 93% participants retained to intervention completion, and 93% participants engaged with the intervention by providing weekly data.
- High intervention acceptability was demonstrated by qualitative data relating to intervention expectations, benefits, motivators, barriers, and suggestions for improvement.
- Fidelity of delivery was high as demonstrated by adherence, dosage, quality of intervention, and participant responsiveness.
- The evaluation measures were feasible as all primary data collection was complete.
- Regarding secondary data; while all participants wore accelerometers for seven days, missing recorded data was noted during analysis. Data related to dietary recall was also incomplete and not included in analysis.

Our study demonstrated that a contextualised physical activity and diet intervention for rural-dwelling adults is both feasible and accepted. Multiple factors can be attributed to the positive results of our study and have also been reported elsewhere (Bandura, 2004; Charlton et al., 2008; Mabweazara et al., 2018; Tuso, 2015; Webel et al., 2013). Similar to our study, these studies (Mabweazara et al., 2018; Webel et al., 2013) included self-monitoring, goal setting, targeting physical activities that adults perform as part of their usual daily lives, and support strategies such as weekly telephone calls. The inclusion of strategies for overcoming barriers to physical activity participation has also been reported by Bandura (2004) who explains the importance of educating participants on the benefits of health behaviour change and the application of behaviour change theories such as self-efficacy.

Mabweazara included focus group discussions in their design of a contextualised physical activity intervention for HIV positive adult women in rural South Africa to discover participants' preferred exercise activities (Mabweazara et al., 2018). Their group discussions contributed to an increase in total moderate-to-vigorous physical activity by enhancing motivation to physical activity. Indeed, designing interventions guided by a theory of change and an emphasis on understanding how the intervention interacts with the context can result in a positive implementation and scale up particularly for communities with specific contextual needs. Charlton and colleagues have also emphasized the importance of understanding the socioeconomic factors that affect interventions for dietary recommendations in hypertension control (Charlton et al., 2008). For our study, it was important that the diet intervention focused on reduction of sodium salt, oil, fatty foods, and certain spices instead of recommending the DASH diet which is viewed as expensive (Adeyeye, 2017; Labadarios et al., 2011; Temple et al., 2011)

7.3 **CONCEPTUAL FRAMEWORK**

The Health-Related Quality Of Life (HRQOL) conceptual framework adopted from Wilson & Cleary, (1995) and further revised by Ferrans et al., (2005) were used to guide this study. The key determinants of overall HRQOL are the characteristics of the individual as well as the characteristics of the environment (WHO, 2007). This study revealed key individual and environmental characteristics which were important in the design and implementation of a contextualised physical activity and diet intervention. Individual characteristics such as sex differences in the physical activity profile of study participants, knowledge about causes and symptoms of hypertension, preference in food taste, intensity of physical activity performance, motivation to change behaviour, and consumption of wild herbs were all important in the design and implementation of this study's intervention. At the environmental level, an understanding of contextual factors was important to encourage a bio-psychosocial

and person-centred approach as well as promoting a multidimensional view of a person's health (Allan et al., 2006; Snyman et al., 2016). Characteristics which were important in the design and implementation of the intervention at environmental level included availability of food, livelihood (employment type), type of household duties performed, religious affiliation, type of social events and gatherings, affordability of food, and gender roles. Our study has demonstrated the importance of considering contextual factors that act on the individual and the environment level when designing interventions to improve health and health related quality of life (figure 7.1)

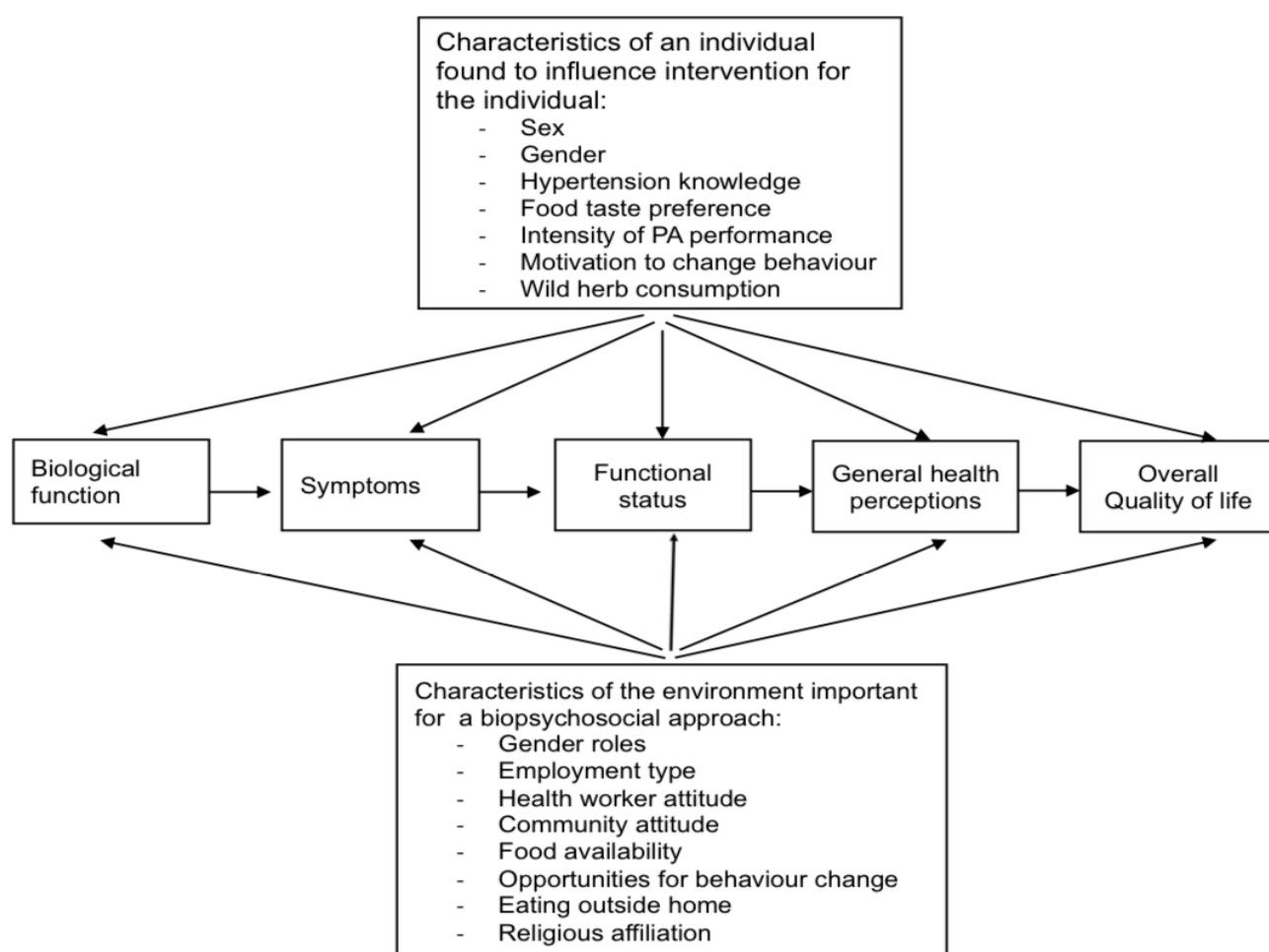


Figure 7.1 Conceptual framework emanating from this study. Adapted from (Ferrans et al., 2005; Wilson & Cleary, 1995)

While this study focused on the HRQOL conceptual framework for intervention design and the larger trial progression criteria by (K. N. L. Avery et al., 2017), other frameworks of implementation science such as the reach, effectiveness, adoption, implementation, and maintenance (RE-AIM) framework can be used to direct future implementation of similar studies (Glasgow et al., 2022) . The RE-AIM framework was developed to improve the adoption and sustainable implementation of evidence-based interventions in a wide range of health, public health, educational, community, and other settings using five key dimensions. Table 7.1 outlines the outcomes of this study and future considerations for a larger trial based on the RE-AIM framework.

Table 7.1 RE-AIM dimensions and considerations for a larger trial.

Dimension	Study findings	Recommendations
Reach (proportion of the target population that participated in the intervention)	We reached 100% of our target population	Have a clear recruitment strategy that will ensure equitable distribution of study participants of study population. Make use of local field workers where possible. Have a strategy to confirm hypertension diagnosis, such as being on medication for hypertension.
Effectiveness (improvement in targeted health indicator)	Effectiveness was a secondary measure in this study. We found overall modest reduction in systolic blood pressure and no changes in diastolic blood pressure.	A larger trial should be conducted over a longer period (minimum six months) to observe any changes in hypertension.
Adoption (proportion settings and intervention agents (people who deliver the intervention), that adopt the intervention.	We recruited three local field workers who were all	Intervention agents must be locally trained and preferably from the study setting. An understanding of contextual factors related to intervention adoption is needed. All intervention materials should be in the local language.
Implementation (extent to which the intervention is implemented as intended in the real world)	We assessed fidelity of enactment and found that the intervention was delivered as intended, with minor adaptations.	Have a clear intervention protocol and set measures of intervention fidelity. Employ an external person for independent verification. This consideration may have high budgetary implications. Ensure sufficient availability of resources (costs and time of implementation).
Maintenance (extent to which a program is sustained 6 months or more after intervention).	This study did not assess maintenance due to it being a feasibility study, however we found 93% retention rate during the intervention.	Assess the proportion and representativeness of people that continue the intervention and reasons for maintenance or discontinuance six months or longer after the intervention. Collaborations with end-users to enhance intervention fit and sustainability. Need strategies for relapse prevention such as ongoing monitoring.

7.4 STRENGTHS AND LIMITATIONS OF THE STUDY

7.4.1 Strengths of the Study

There are several notable strengths to this study. The study provides a broad description of key determinants of physical activity and dietary considerations that may strongly influence rural-based hypertension lifestyle interventions. We employed multiple research approaches to design the study intervention. This included cross-sectional descriptive surveys, focus group discussions, in-depth one-on-one interviews, and a mixed-method approach thus allowing for rich triangulated data on the concepts explored. In addition to the multiple approaches used, our intervention design was also informed by underpinning concepts and theoretical approaches such as behaviour change technique, frameworks, and models as well as using various sources for co-production (hypertensive study participants, health care workers, community members). The use of multiple research approaches, health promotion models, and community needs assessment incorporating relevant key-stakeholders is central to designing effective contextual interventions (Bartholomew et al., 2001; Creswell & Clark, 2017; Edwards & Barker, 2014).

To ensure integrity in meaning, this study was conducted in participants' home language which is XiTsonga. To further enhance trust, we employed locally trained field workers who come from the local villages and who understand the context. This consideration was essential in gathering rich, quality data from study participants as most adults in the study sample could only speak XiTsonga and they could relate with field workers who come from similar backgrounds.

7.4.2 Limitations of the Study

To the authors' knowledge this is the first study to examine whether contextualising physical activity and diet could be a feasible intervention approach to the management of hypertension in adults of a rural South African background. Our study is not without limitations; part of this study was conducted during COVID-19 pandemic which had multiple restrictions to social movement and interactions (Rogerson & Sixaba, 2022). For example, we assessed physical activity profile during a period where movement around communities was restricted. This period could have affected the level of physical activity reported by study participants and therefore the data obtained could not be a true reflection of the usual physical activity of the population. People in rural communities often depend on use of public transport to move from place to place, therefore the time spent using transport could have been underreported due to COVID-19 social restrictions (Wilke et al., 2021).

Although we sampled participants from all 32 villages in Agincourt sub-district, from a cohort of adults aged 40+ years with hypertension. We did not employ any stratification during

participant sampling which might have led to over- or under-representation from certain villages.

- 7.4.3 Our study provides a rich description of the profile of physical activity amongst hypertensive adults in Agincourt, however, the description of dietary habits is limited. We explored the daily dietary habits of hypertensive adults during the focus group discussions, and this provided an overview of what types of food they consume. We then assessed individual dietary profile using the 24HR diet recall during household visits, but this data could not be included in the analysis. We noticed inconsistencies in the capturing of data as well as poor specificity in the recording of food types and portion.

7.5 **RECOMMENDATIONS**

7.5.1 **Research Recommendations**

Our study revealed that physical activity varied by employment. We recommend that future studies that are implementing physical activity educational interventions should ask the employed participant about their type of employment. Understanding the type of employment occupied by people will provide opportunities for contextualising physical activity recommendations with the type of employment. This will also ensure that goal setting for improving physical activity as part of work will be tailored to the type of employment for that individual. For example, people involved in employment that requires prolonged sitting may need interventions that encourages them to get up.

We did not ask our study participants about the presence of co-morbidities as part of criteria to enroll in our study. Future studies should document other co-morbidities which may influence the contextualisation of the intervention provided to the participant. For example, certain dietary and physical activity recommendations to assist in the control of hypertension may encourage the development/worsening of other health conditions such as Diabetes and coronary heart problems.

7.5.2 **Full HYPHEN Clinical Trial Recommendations**

Our study recruited participants from a cohort of adults with a self-reported diagnosis of hypertension (Gomez-Olive et al., 2018). Fifty percent of approached participants for our study reported not to be hypertensive on recruitment. We recommend the full trial to recruit participants who are on medication for hypertension in addition to self-report diagnosis. Some of the participants could have had elevated blood pressure on assessment but not a confirmed diagnosis by a health worker.

The objectives of the intervention should be made clear to participants from the onset to avoid expectations not linked to the intervention goals. For example, some participants in our

study expected the provision of medication, money, or food parcels which was not the intention of our intervention. We recruited participants from a health and demographic surveillance site where multiple other studies are/have been conducted. Some of these interventions have provided participants with incentives and this might have created the expectation that our study will do the same. The provision of medication, money, or food parcels was deemed unnecessary for our study because participants receive medication free of charge from the local health facilities and our study was designed not to require any additional financial commitment from the participants.

The intervention duration can be prolonged to a longer period to allow for participants to adapt and sustain the recommended changes in diet and/or physical activity. There is no clear consensus about the duration of behaviour change intervention, however, a meta-analysis has reported on duration of six months from baseline measurement (Murray et al., 2017). Such changes in behaviour have been maintained up to 15 months.

The educational sessions should involve a nurse practitioner or health promotor knowledgeable on the topic due to unexpected questions that may be raised by study participants. These are mostly questions that may only be answered by individuals who were present from study development.

During the group and one-on-one educational sessions, the time taken to conduct the education varied across all sessions. We had planned a certain timeframe for each session, however, due to various levels of engagement and discussions the time spent varied. We recommend that for the full trial, time allocated for group and one-on-one sessions should be flexible enough to allow for participant engagement, as there should be anticipation of the session being slightly longer or shorter.

Comprehensive training to people who will administer the intervention should be provided about the use of accelerometry devices as well as how to administer the dietary recall questionnaire because we found missing data for these two outcomes. For accelerometry devices, even though participants reported wearing the accelerometry devices for full seven days as instructed, some devices recorded fewer days of physical activity. We accounted reasons for missing data to error with deployment of the device. For dietary recall questionnaire, the research assistants recorded data differently which shows they did not understand the outcome measure. We suggest that training on the administration of the 24h dietary questionnaire should include piloting it on a few adults before the intervention especially if the administrators are not familiar with the tool (Raupach et al., 2012).

Thorough explanation to trial participants about the purpose of the accelerometry device is essential to improve understanding of its use, especially to participants who have never worn a similar device. Our study found that participants were reluctant to wear the accelerometry device if they thought it would track their whereabouts and infringe on their privacy. After thorough explanation they agreed to wear the device.

7.5.3 Policy Recommendations

There are very few opportunities for physical activity performance as part of recreation and leisure for adults in rural areas of South Africa as revealed by the profile of recreation physical activity in our study. The South African local government should accelerate rural development with a focus on creating recreational opportunities for adults to perform on their leisure time.

South Africa has approved the National Health Insurance as part of a strategy to strengthen the health system through universal health coverage. Our study has developed an educational program for people with hypertension which can be used as part of the tools in the package of primary health care for chronic non-communicable diseases. The tool can be used particularly in rural areas such as our study site or similar settings. The educational program can be used in group settings or one-on-one sessions as we have utilized it in our study.

There is a need to expand blood pressure screening beyond the health facilities. There was poor awareness of blood pressure readings by the study participants and the prevalence of hypertension in our study site is on the rise. It should be explored if introducing self-monitoring of blood pressure is feasible and an effective way to increase blood pressure awareness.

The South African government has introduced and implemented a salt reduction policy but the compliance is low especially with local manufacturers and retailers due to limited regulation of the policy. We recommend immediate collaboration between the health sector and local food suppliers for the implementation of salt according to national guidelines especially in daily consumed products such as bread and meat products (in particular as seen in our study: locally produced brown bread and Russian sausage).

7.6 CONCLUSION

This chapter provided a highlight of the key findings from each study in relation to the overall study aim. Study strengths, limitations, and recommendations were made to enhance the management of hypertension for policy, research, and conducting a larger clinical trial. The following chapter will conclude the study.

CHAPTER 8

8. CONCLUSION

The consequences of uncontrolled hypertension can be devastating and often lead to long-term disability or death. For people living in rural areas of South Africa such as Agincourt sub-district, it is important to design interventions that will suit their everyday life. This study followed an iterative process of intervention design that was rooted in the contextual reality of adults in a rural setting. Our study was deemed feasible to conduct a larger trial, although certain amendments are noted before the larger trial can be rolled out.

Our study has highlighted key behaviour change considerations such as co-production, needs assessment, stakeholder engagement, and application of behaviour change techniques. To be effective in behaviour change for physical activity and dietary habits, other aspects that must be considered such as the duration of the intervention and financial commitment were highlighted. Adults with hypertension need to be empowered with the necessary skills to make better health decisions; especially in a rural South African setting where the health system is not fully equipped to provide community health promotion and health education interventions.

The fight against hypertension requires multi-stakeholder involvement. Local retailers need to be involved and willing to oblige with national policies for salt regulation, especially because most people in rural South Africa source their food from local retailers because they are cheaper. Health workers and health promoters in rural South Africa must work together to establish best approaches to implementing physical activity and dietary approaches in their various settings which may be (slightly) different from our study settings.

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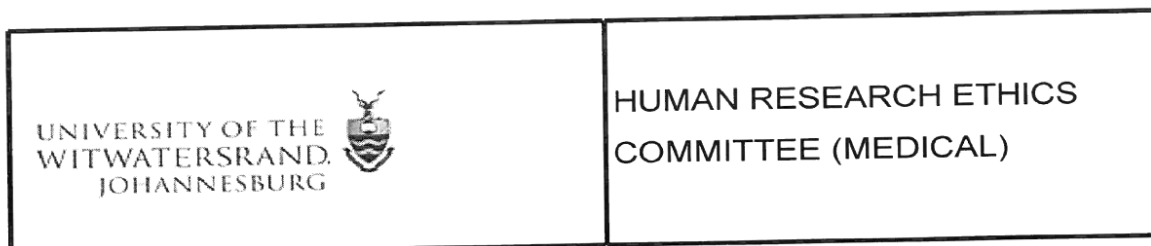
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APPENDIX 1

▪ ETHICAL CLEARANCE CERTIFICATE FROM UNIVERSITY OF THE WITWATERSRAND HUMAN RESEARCH ETHICS COMMITTEE



Office of the Deputy Vice-Chancellor (Research and Innovation)

TO: Mr K Sekome
School of Public Health
Medical School
University

E-mail: Kganetso.Sekome@wits.ac.za

CC: Supervisor: Professors X Gomez-Olivecacas and H Myezwa
<F.Gomez-Olivecacas@wits.ac.za>
and <HREC-Medical Research Office@wits.ac.za>

FROM: Mr Iain Burns
Human Research Ethics Committee (Medical)
Tel: 011 717 1252

E-mail: Iain.Burns@wits.ac.za

DATE: 2021/06/08

REF: R14/49

PROTOCOL NO: **M210282** (This is your ethics application reference number. Please quote it in all enquiries, oral or written, relating to this study.)

PROJECT TITLE: *Implementation of a contextualized physical activity and diet intervention based on community social and cultural beliefs for the control of hypertension in adults living in rural Agincourt, South Africa*

Please find attached the Clearance Certificate for the above project. I hope it goes well and that an article in a recognized publication comes out of it. This will reflect well on your professional standing and contribute to Government funding of the University.



MS\Works2000\Iain0007\Clearescan.wps

APPENDIX 2

LOCAL PROVINCIAL DEPARTMENT OF HEALTH RESEARCH AND ETHICS COMMITTEE



Indwe Building, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
Private Bag X11285, Mbombela, 1200, Mpumalanga Province
Tel I: +27 (13) 766 3429, Fax: +27 (13) 766 3458

Litiko Letemphilo

Departement van Gesondheid

UmnYango WezeMaphilo

Enq: 013 766 3766
Ref: MP_202108_001

Research Permission Letter

MR KGANETSO SEKOME
PRINCIPAL INVESTIGATOR
P O BOX 2
TINTSWALO HOSPITAL
ACORNHOEK, 1360

Dear Mr Sekome

STUDY TITLE: IMPLEMENTATION OF A CONTEXTUALIZED PHYSICAL ACTIVITY AND DIET INTERVENTION BASED ON COMMUNITY SOCIAL AND CULTURAL BELIEFS FOR THE CONTROL OF HYPERTENSION IN ADULTS LIVING IN RURAL AGINCOURT, SOUTH AFRICA

The Mpumalanga Provincial Health Research and Ethics Committee (MPHREC) has approved your research proposal in the latest format you sent, and hereby grant you permission to conduct your research as detailed below.

- Approval Reference Number: MP_202108_001
- Data Collection Period: 20/08/2021 to 30/06/2024
- Approved Data Collection Facilities:

* AGINCOURT CHC

Kindly ensure that conditions mentioned below are adhered to, and that the study is conducted with minimal disruption and impact on our staff, and also ensure that you provide us with a soft or hard copy of the report once your research project has been completed.

Conditions:

- Researchers not allowed to make copies, take pictures of medical records or administer medicine to patients at the facility.
- Kindly notify the facility manager a week **BEFORE** you start with data collection to ensure that conditions are conducive in the facility.
- The **FINAL RESEARCH FINDINGS** must be uploaded on the NHRD website

Kind regards

DR C NELSON
MPHREC CHAIRPERSON
DATE: 05/07/2023



APPENDIX 3

LOCAL DISTRICT DEPARTMENT OF HEALTH RESEARCH AND ETHICS COMMITTEE



No.3, Government Boulevard, Riverside Park, Ext. 2, Mbombela, 1200, Mpumalanga Province
Private Bag X11285, Mbombela, 1200, Mpumalanga Province
Tel: +27 (13) 766 3429, Fax: +27 (13) 766 3458



Litiko Letemphilo

Departement van Gesondheid

UmNyango WezeMaphilo

Letter of Support (To be signed by relevant Senior Managers/Responsibility Managers)

1. Study Details	
1.1 Name of Applicant	Kganetso Sekome.
1.2 Contact Number:	(0) 780118605
1.3 Study Title:	Implementation of a contextualized physical activity and diet intervention based on community social and cultural beliefs for the control of hypertension in adults living in rural Agincourt, South Africa
1.4 Data collection period to undertake the study:	Start: 08/2021 End: 12/2022
1.5 Provide summary of the study, study area, and how data will be collected (your response should not be more than the space provided: Research questions a) What social and cultural beliefs about physical activity and diet in a rural adult South African population influence behaviour change for the control of raised blood pressure? b) What physical activity and diet adjustments can be made to the daily routine of adults living in rural Agincourt to control raised blood pressure? Research Aim The aim of this study is to implement a contextualized physical activity and diet intervention based on community social and cultural beliefs for the control of hypertension in adults living in rural Agincourt, South Africa. Study site and population This study will be conducted at Bushbuckridge sub-district in Mpumalanga province where the Agincourt Health and Demographic Surveillance System (HDSS) has been running since 1992. The HDSS is run by the MRC/ Wits Rural Public Health and Health Transitions Research Unit. The Agincourt HDSS covers an area of 450km² with 115 000 individuals (approximately 52 000 older than 18 years) living in approximately 20 000 households distributed in 32 villages (Thorogood et al., 2014; Jardim et al., 2017; Goudge et al., 2018). The prevalence of hypertension in this study site for the adult population varies from 40% in 2010 (Thorogood et al., 2014), 57% in 2012 (Gómez-Olivé et al., 2013), and 58.4% in 2016 (Jardim et al., 2017). The Health and Aging in Africa: A Longitudinal Study of an INDEPTH (International Network for the Demographic Evaluation of Populations and Their Health) community in South Africa (HAALSI) is a cohort of 5059 adults aged 40 years and above within the Agincourt HDSS (Gómez-Olivé et al., 2018) will be used as a sampling frame. The prevalence of hypertension in this cohort is 57% (n= 2843), defined as self-reported medication of hypertension or systolic ≥ 140 mm Hg or diastolic ≥ 90 mm Hg. The prevalence is divided as 1227 males (54,3%) and 1616 (61,3%) females. Target population: This PhD will only include adult men and women aged 40 years and above. They must be presenting with raised blood pressure (140/90 mm Hg or higher) or currently on medication for hypertension. Participants must be living in Agincourt for the past six months from the start of data collection	

Please note that this letter is not an approval to undertake a study, but a support letter from identified facility/district. i.e. the CEO/District Manager acknowledges to have been consulted on the study

APPENDIX 4

▪ IPAQ QUESTIONNAIRE

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE (October 2002)

LONG LAST 7 DAYS SELF-ADMINISTERED FORMAT

FOR USE WITH YOUNG AND MIDDLE-AGED ADULTS (15-69 years)

The International Physical Activity Questionnaires (IPAQ) comprises a set of 4 questionnaires. Long (5 activity domains asked independently) and short (4 generic items) versions for use by either telephone or self-administered methods are available. The purpose of the questionnaires is to provide common instruments that can be used to obtain internationally comparable data on health-related physical activity.

Background on IPAQ

The development of an international measure for physical activity commenced in Geneva in 1998 and was followed by extensive reliability and validity testing undertaken across 12 countries (14 sites) during 2000. The final results suggest that these measures have acceptable measurement properties for use in many settings and in different languages, and are suitable for national population-based prevalence studies of participation in physical activity.

Using IPAQ

Use of the IPAQ instruments for monitoring and research purposes is encouraged. It is recommended that no changes be made to the order or wording of the questions as this will affect the psychometric properties of the instruments.

Translation from English and Cultural Adaptation

Translation from English is encouraged to facilitate worldwide use of IPAQ. Information on the availability of IPAQ in different languages can be obtained at www.ipaq.ki.se. If a new translation is undertaken we highly recommend using the prescribed back translation methods available on the IPAQ website. If possible please consider making your translated version of IPAQ available to others by contributing it to the IPAQ website. Further details on translation and cultural adaptation can be downloaded from the website.

Further Developments of IPAQ

International collaboration on IPAQ is on-going and an *International Physical Activity Prevalence Study* is in progress. For further information see the IPAQ website.

More Information

More detailed information on the IPAQ process and the research methods used in the development of IPAQ instruments is available at www.ipaq.ki.se and Booth, M.L. (2000). *Assessment of Physical Activity: An International Perspective*. Research Quarterly for Exercise and Sport, 71 (2): s114-20. Other scientific publications and presentations on the use of IPAQ are summarized on the website.

INTERNATIONAL PHYSICAL ACTIVITY QUESTIONNAIRE

We are interested in finding out about the kinds of physical activities that people do as part of their everyday lives. The questions will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. Please think about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

Think about all the **vigorous** and **moderate** activities that you did in the **last 7 days**. **Vigorous** physical activities refer to activities that take hard physical effort and make you breathe much harder than normal. **Moderate** activities refer to activities that take moderate physical effort and make you breathe somewhat harder than normal.

PART 1: JOB-RELATED PHYSICAL ACTIVITY

The first section is about your work. This includes paid jobs, farming, volunteer work, course work, and any other unpaid work that you did outside your home. Do not include unpaid work you might do around your home, like housework, yard work, general maintenance, and caring for your family. These are asked in Part 3.

1. Do you currently have a job or do any unpaid work outside your home?

☐ Yes

☐ No →

Skip to PART 2: TRANSPORTATION

The next questions are about all the physical activity you did in the **last 7 days** as part of your paid or unpaid work. This does not include traveling to and from work.

2. During the **last 7 days**, on how many days did you do **vigorous** physical activities like heavy lifting, digging, heavy construction, or climbing up stairs **as part of your work**? Think about only those physical activities that you did for at least 10 minutes at a time.

_____ days per week

☐ No vigorous job-related physical activity →

Skip to question 4

3. How much time did you usually spend on one of those days doing **vigorous** physical activities as part of your work?

_____ hours per day

_____ minutes per day

4. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the **last 7 days**, on how many days did you do **moderate** physical activities like carrying light loads **as part of your work**? Please do not include walking.

_____ days per week

☐ No moderate job-related physical activity →

Skip to question 6

5. How much time did you usually spend on one of those days doing moderate physical activities as part of your work?
- _____ hours per day
_____ minutes per day
6. During the last 7 days, on how many days did you walk for at least 10 minutes at a time as part of your work? Please do not count any walking you did to travel to or from work.
- _____ days per week
- ☐ No job-related walking → Skip to PART 2: TRANSPORTATION
7. How much time did you usually spend on one of those days walking as part of your work?
- _____ hours per day
_____ minutes per day

PART 2: TRANSPORTATION PHYSICAL ACTIVITY

These questions are about how you traveled from place to place, including to places like work, stores, movies, and so on.

8. During the last 7 days, on how many days did you travel in a motor vehicle like a train, bus, car, or tram?
- _____ days per week
- ☐ No traveling in a motor vehicle → Skip to question 10
9. How much time did you usually spend on one of those days traveling in a train, bus, car, tram, or other kind of motor vehicle?
- _____ hours per day
_____ minutes per day

Now think only about the bicycling and walking you might have done to travel to and from work, to do errands, or to go from place to place.

10. During the last 7 days, on how many days did you bicycle for at least 10 minutes at a time to go from place to place?
- _____ days per week
- ☐ No bicycling from place to place → Skip to question 12

11. How much time did you usually spend on one of those days to bicycle from place to place?
- _____ hours per day
_____ minutes per day
12. During the last 7 days, on how many days did you walk for at least 10 minutes at a time to go from place to place?
- _____ days per week
- ☐ No walking from place to place → *Skip to PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY*
13. How much time did you usually spend on one of those days walking from place to place?
- _____ hours per day
_____ minutes per day

PART 3: HOUSEWORK, HOUSE MAINTENANCE, AND CARING FOR FAMILY

This section is about some of the physical activities you might have done in the last 7 days in and around your home, like housework, gardening, yard work, general maintenance work, and caring for your family.

14. Think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do vigorous physical activities like heavy lifting, chopping wood, shoveling snow, or digging in the garden or yard?
- _____ days per week
- ☐ No vigorous activity in garden or yard → *Skip to question 16*
15. How much time did you usually spend on one of those days doing vigorous physical activities in the garden or yard?
- _____ hours per day
_____ minutes per day
16. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do moderate activities like carrying light loads, sweeping, washing windows, and raking in the garden or yard?
- _____ days per week
- ☐ No moderate activity in garden or yard → *Skip to question 18*

17. How much time did you usually spend on one of those days doing moderate physical activities in the garden or yard?
- _____ hours per day
_____ minutes per day
18. Once again, think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do moderate activities like carrying light loads, washing windows, scrubbing floors and sweeping inside your home?
- _____ days per week
- ☐ No moderate activity inside home → *Skip to PART 4: RECREATION, SPORT AND LEISURE-TIME PHYSICAL ACTIVITY*
19. How much time did you usually spend on one of those days doing moderate physical activities inside your home?
- _____ hours per day
_____ minutes per day

PART 4: RECREATION, SPORT, AND LEISURE-TIME PHYSICAL ACTIVITY

This section is about all the physical activities that you did in the last 7 days solely for recreation, sport, exercise or leisure. Please do not include any activities you have already mentioned.

20. Not counting any walking you have already mentioned, during the last 7 days, on how many days did you walk for at least 10 minutes at a time in your leisure time?
- _____ days per week
- ☐ No walking in leisure time → *Skip to question 22*
21. How much time did you usually spend on one of those days walking in your leisure time?
- _____ hours per day
_____ minutes per day
22. Think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do vigorous physical activities like aerobics, running, fast bicycling, or fast swimming in your leisure time?
- _____ days per week
- ☐ No vigorous activity in leisure time → *Skip to question 24*

23. How much time did you usually spend on one of those days doing vigorous physical activities in your leisure time?
- _____ hours per day
_____ minutes per day
24. Again, think about only those physical activities that you did for at least 10 minutes at a time. During the last 7 days, on how many days did you do moderate physical activities like bicycling at a regular pace, swimming at a regular pace, and doubles tennis in your leisure time?
- _____ days per week
- ☐ No moderate activity in leisure time → Skip to PART 5: TIME SPENT SITTING
25. How much time did you usually spend on one of those days doing moderate physical activities in your leisure time?
- _____ hours per day
_____ minutes per day

PART 5: TIME SPENT SITTING

The last questions are about the time you spend sitting while at work, at home, while doing course work and during leisure time. This may include time spent sitting at a desk, visiting friends, reading or sitting or lying down to watch television. Do not include any time spent sitting in a motor vehicle that you have already told me about.

26. During the last 7 days, how much time did you usually spend sitting on a weekday?
- _____ hours per day
_____ minutes per day
27. During the last 7 days, how much time did you usually spend sitting on a weekend day?
- _____ hours per day
_____ minutes per day

This is the end of the questionnaire, thank you for participating.

APPENDIX 5

▪ INFORMATION LETTER FOR PHYSICAL ACTIVITY PROFILE

PARTICIPANT INFORMATION SHEET FOR TELEPHONIC PHYSICAL ACTIVITY QUESTIONNAIRE

Good day Sir/Madam

My name is _____ I am a fieldworker at WITS Agincourt facilities.

We are conducting research to test an intervention that aims to assist in controlling high blood pressure amongst adults living here in Agincourt. For us to implement this intervention we are also looking into understanding how people in this community spend their daily routine with regards to the physical activities performed daily as well as the diet they consume daily. This information will assist in developing the intervention to control high blood pressure based on principles of physical activity and diet management.

For this part of the study, we are looking at establishing your levels of weekly physical activity and I will be using a questionnaire for this which is called the Long Form physical activity questionnaire. I will ask you about the time you spent being physically active in the **last 7 days**. Please answer each question even if you do not consider yourself to be an active person. You will be asked about the activities you do at work, as part of your house and yard work, to get from place to place, and in your spare time for recreation, exercise or sport.

You will not have direct benefits for being part of this study, but the information gathered will help me understand physical activity levels of people with hypertension so that we can develop an intervention. There are no harms for participating in this study. Participation is voluntary and you have the right to refuse to participate in the study or withdraw from participating in the study at any time. There is no penalty for refusal to participate or withdrawal from the study.

You will not be identified by name or any other personal information. Data will be captured using special identifiers such as numbers and letters, the data will be stored electronically where only the researcher, research assistants, and research supervisors will have access to. When information is presented at the end of the study, you will still remain anonymous to protect your identity and personal information.

Do you agree to participate in our study?

If you have any concerns or questions, please feel free to ask.

APPENDIX 6

▪ INTERVIEW SCHEDULE FOR QUALITATIVE STUDY

INTERVIEW GUIDE

Research topic: Implementation of a contextualised physical activity and diet intervention based on community social and cultural beliefs for the control of hypertension in adults living in rural Agincourt, South Africa.

Research question: What social and cultural beliefs about physical activity and diet in a rural South African population influence behaviour change for the control of raised blood pressure?

Objective: To explore the social and cultural beliefs, perceptions and practices regarding physical activity and diet which may influence the implementation of an intervention for the control of raised blood pressure in adults living in rural Agincourt.

Introduction

Good morning. My name is _____. Thank you all for coming here today. How are you today? I am a field worker working at WITS Agincourt. We are conducting a research project here in Agincourt and surrounding villages to help people reduce their blood pressure and become healthier. In particular we want to understand how people like you spend your day, including what you eat and physical activity that you do. This information will help us to design a programme to help people be more active and eat better. You have been asked to come here today so we can gain insight on how you do things daily in your life and to get your opinions on physical activity and diet.

With your permission, I would like to record this conversation, anything we discuss here is private and confidential and I would like to request that we do not share any information outside this conversation. This discussion will take 45 minutes to an hour.

I am interested in your own experiences. If any of the questions I ask make you uncomfortable, you do not have to answer them. My role as the interviewer is to listen and to respect your point of view. The type of questions that I will ask you will relate to your perceptions about physical activity and diet, practices around physical activity, barriers and facilitators of physical activity and diet modification.

Do you have any questions for me before we begin?

Opening Questions:

1. How long have you lived in in your village?
2. When did you find out you have high blood pressure?
3. Do you know what is the average normal blood pressure reading?
4. What do you know about high blood pressure?

Key Questions (Physical Activity):

1. Please tell me what you think causes (your) blood pressure to be high
2. Could you please take me through a typical day in your life from the moment you get up to when you go to bed
Probe: What do you do everyday that involves movement and/or manual labour?
3. Do you like/enjoy activities that make you sweat and breathe faster?
Probe: why/why not?
4. What do you think someone with high blood pressure should do to reduce their blood pressure?
Probe: What about physical activity or exercise?
5. Do you understand how much physical activity is required for you to achieve health benefits and to keep your blood pressure under normal values?
Probe: are you currently achieving this? Why? Why not?
6. What could motivate/help you to increase your level of physical activity?
7. What is your opinion on increasing the amount or intensity of physical activity (such as walking, housework, yardwork) you do?
8. What do your friends and family think about physical activity?
Probe: Do they support you or hinder you to be more active?
9. Do you think men and women should perform similar types and amounts of physical activities?
Probe: What about those with hypertension?

Key Questions (Diet):

1. Could you please tell me about the types of food you eat on a regular basis?
Probe: can break down the questions into breakfast meals, lunch meals, dinner meals, and snack meals.
2. Please tell me about your use of salt and spices in your diet.
Probe: Do you consume food with both salt and spice? Do you only use one of the two? Why/why not?
3. Also please tell me about your use of oils and fats in your diet.
4. Is your choice of diet influenced at all by your friends and family? If yes, how?
5. What do you know about controlling your blood pressure based on what you eat?
6. Are you following this type of eating habits?
Probe: why? Why not?
7. Is there anything that you feel could prevent you or support you in eating foods that could help you control your high blood pressure?
8. Is there anything that you feel could support you in eating foods that could help you control your high blood pressure?

Besides physical activity and eating healthy, what else do you think helps in controlling high blood pressure?

Closing Questions:

1. What are your opinions about body weight?
2. What is your idea of a normal body weight? Is that the same as a healthy body weight?
3. Would you be willing to change your body weight to help control your blood pressure?

Thank you very much for participating in the focus group. If there are any questions, please feel free to ask me now. If you want to ask any questions outside this group, I will be available.

APPENDIX 7

▪ INFORMATION LETTER FOR QUALITATIVE STUDY

INFORMATION SHEET FOR FOCUS GROUP DISCUSSION

Good day Sir/Madam

My name is _____. I am a research fieldworker at Agincourt research facilities.. We are conducting research to implement an intervention that aims to assist in controlling high blood pressure amongst adults living here in Agincourt. For us to implement this intervention we want to understand how people in this community spend their daily routine with regards to the physical activities performed daily as well as the diet they consume daily. This information will assist in developing the intervention to control high blood pressure based on principles of physical activity and diet management.

For this part of the study, I would like to ask you questions about your social and cultural beliefs, perceptions and practices regarding physical activity and diet which will assist us to design an intervention to control high blood pressure for adults living here in Agincourt. The type of questions that I will ask you will relate to your perceptions about physical activity and diet, practices around physical activity, barriers and facilitators of physical activity and diet modification.

You will form part of a group of people of between eight to twelve adults who live here in Agincourt. These are also adults who were diagnosed with hypertension or are on medication for hypertension. You will not have direct benefits for being part of this study but the information gathered will help me understand physical activity and diet perceptions from people with hypertension so that I can develop an intervention to control the raised blood pressure. There are no harms for participating in this study. Participation is voluntary and you have the right to refuse to participate in the study or withdraw from participating in the study at any time. There is no penalty for refusal to participate or withdrawal from the study.

You will not be identified by name or any other personal information. Data will be captured using special identifiers such as numbers and letters, the data will be stored electronically where only the researcher, research assistants, and research supervisors will have access to. When information is presented at the end of the study, participants will still remain anonymous to protect their identity and personal information. Due to the nature of the group discussion, it is beyond my control to ensure that other members do not share the information discussed but every attempt will be made to explain to participants to keep all information confidential.

If you have any concerns or questions please contact the researcher: Kganetso Sekome
Cell (0780118605). Email (Kganetso.sekome@wits.ac.za).

Signature of participant _____

APPENDIX 8

▪ INFORMATION LETTER FOR INTERVENTION STUDY

INFORMATION SHEET FOR INTERVENTION

Hello,

My name is _____. I am a fieldworker at WITS Agincourt. We are doing a study to help people control their high blood pressure. Can I please speak to _____?

For this part of the study, we are looking for people who know they have high blood pressure or are taking high blood medication. The focus of our study is to provide you with an intervention that aims to help you lower your high blood. It will be in five steps:

1. Step one: We will come to your home on an agreed date to give you a physical activity wristband which will measure how much physical activity you do. You will be asked to wear this for 7 days/one week without taking it off. We will collect it from you after 7 days/one week.
2. Step two: We will invite you to come to WITS Agincourt facilities (we will fetch you) where you will learn about high blood, the causes, and how to manage it. You will be learning in a room with other people who have high blood. The session will be approximately 1hour 30 min. You will be reimbursed for your time.
3. Step three: We will visit your home and provide you with an intervention program that is tailored for you based on what you do and eat everyday. This programme will help you lower your high blood pressure based on making adaptations to your daily routine physical activity and dietary practices. You will be given a pamphlet which will give you ideas on what you can do. During this visit we will measure your blood pressure, your sodium level using urine dipstick, your body weight, height, waist circumference, and you will be asked questions about the food you eat.
4. Step four: We will contact you after five weeks to find out how the programme is going and ask you questions about the food you have been eating.
5. Step five: We will visit your home after 10 weeks (two and half months) to measure your blood pressure, your sodium level using urine dipstick, your body weight, height, waist circumference, and you will be asked questions about the food you eat. We will also ask you questions about how the program was.

Some of the benefits for being part of this study is that you might have better controlled blood pressure. There are no harms for participating in this study. Participation is voluntary and you have the right to refuse to participate in the study or withdraw from participating in the study at any time.

You will not be identified by name or any other personal information. Data will be captured using special identifiers such as numbers and letters, the data will be stored electronically where only the researcher, research assistants, and research supervisors will have access to. When information is presented at the end of the study, participants will still remain anonymous to protect their identity and personal information.

Do you agree to participate? Yes _____ No _____

Signature _____ Date _____

CONTACT DETAILS

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Ethics chair: Professor Clement Penny, 011 717 2301, e-mail (Clement.Penny@wits.ac.za)

Ethics secretary: 011 717 2700/1234, e-mail addresses are Zanele.Ndlovu@wits.ac.za and Rhulani.Mukansi@wits.ac.za

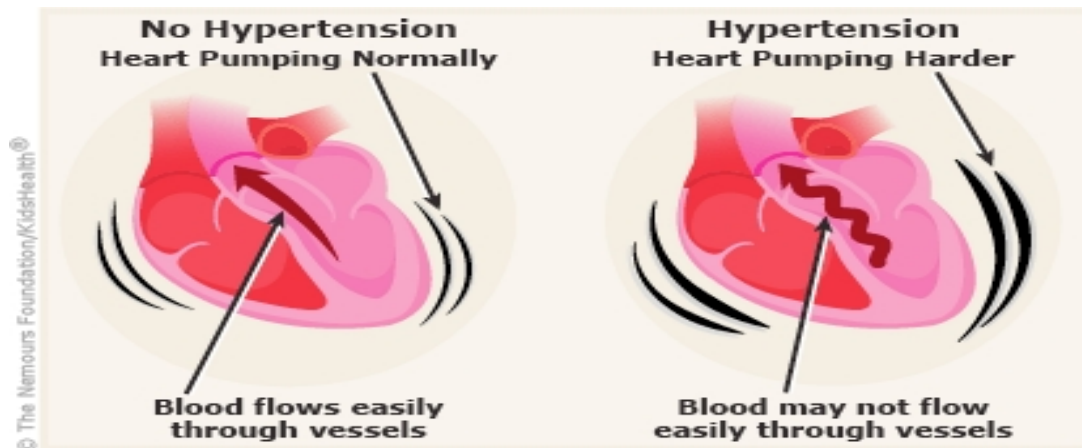
APPENDIX 9

INTERVENTION COPY

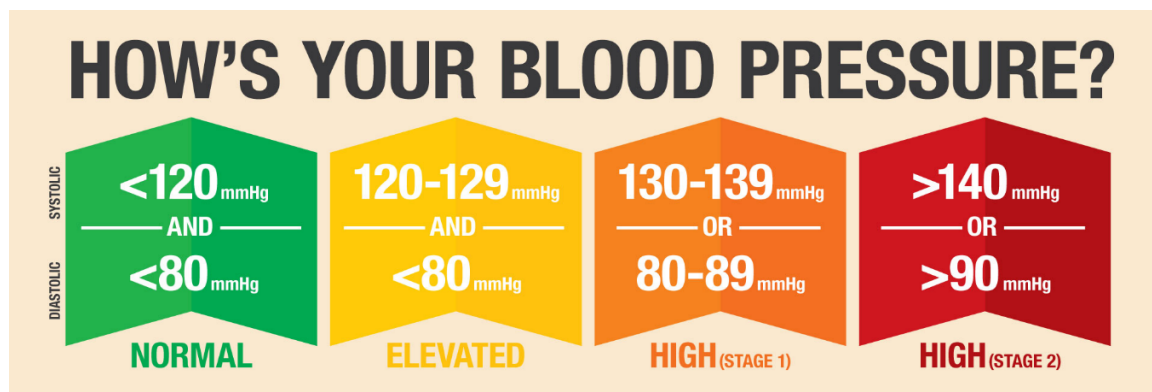
INFORMATION ABOUT HYPERTENSION

What is hypertension?

- High blood pressure, or hypertension, occurs when the force of blood pushing through your vessels is consistently too high.



Blood pressure values.



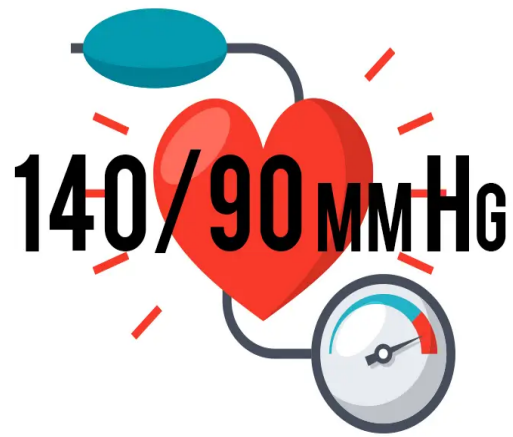
What can cause high blood pressure?



Some common myths about causes of high blood pressure



Diagnosis of hypertension



What can I do to control my high blood pressure?



Some common myths about how to control high blood pressure



TASK	AVOID THIS	DO THIS
Sewing mat		
Ploughing		

Attending church	
Sweeping	

Brick laying



Wood chopping



Farming	 A person wearing a green jumpsuit and a white bucket hat is using a long-handled hoe to work in a field. The field is filled with young green plants growing in rows. In the background, other people are visible working in the field under a blue sky with scattered clouds.
Washing dishes	 Two side-by-side photographs of a woman washing dishes outdoors. She is wearing a yellow short-sleeved shirt and a patterned skirt. In the left image, she is kneeling on a blue plastic stool, washing a pink plate in a white basin. In the right image, she is standing and holding a pink plate, with the white basin still on the blue stool. The background shows a dirt area and some vegetation.

Cooking	
Washing clothes	
Running/ jogging	

Playing soccer



Lifting firewood		
Playing with grandchildren / children	 www.shutterstock.com · 1131775370	 shutterstock

Fetching water with wheelbarrow		
Walking		

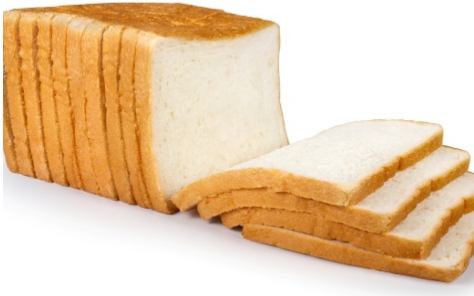
Preparing
maize



Herding kettle



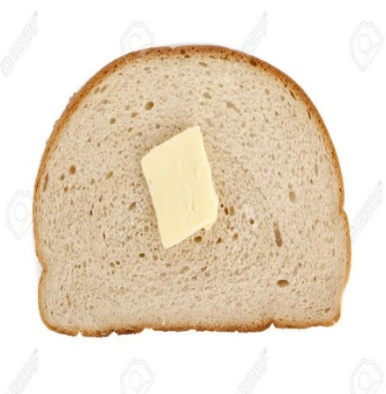
DIETARY ADVICE

AVOID THIS X X X	REPLACE WITH THIS ✓✓✓
	
	
	
	

AVOID THIS X X X



REPLACE WITH THIS ✓✓✓



DASH Eating Plan

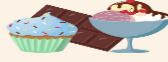
The Benefits: Lowers blood pressure & LDL “bad” cholesterol.



Eat This



Limit This

	Vegetables		Fatty meats
	Fruits		
	Whole grains		Full-fat dairy
	Fat-free or low-fat dairy		
	Fish		Sugar sweetened beverages
	Poultry		
	Beans		Sweets
	Nuts & seeds		
	Vegetable oils		Sodium intake

www.nhlbi.nih.gov/DASH



National Heart, Lung,
and Blood Institute



APPENDIX 10

▪ DATA COLLECTION SHEET

DATA COLLECTION SHEET

Participant ID (surname and initials) : _____
Age : _____
Gender : _____
Employment status : _____
If employed, type of employment : _____
Educational history : _____
Tobacco use frequency p/day : _____
Alcohol use frequency p/week : _____
Number of people living in the household: _____

DAY ONE

Date: _____

- Blood pressure measurement one _____, two _____, three _____
- Urine Sodium measurement _____
- Waist _____, Hip _____, Waist/Hip _____
- Weight _____, Height _____, BMI _____

WEEK 10

Still participating? Yes ☐ No ☐

- Blood pressure measurement one _____, two _____, three _____
- Urine Sodium measurement _____
- Waist _____, Hip _____, Waist/Hip _____
- Weight _____, Height _____, BMI _____

APPENDIX 11

▪ EXIT INTERVIEW GUIDE

EXIT INTERVIEW GUIDE

Name: _____ Age/Date of birth: _____ Gender: _____ Employment status: _____

Aim of the interview: To assess how the participant found the intervention and if they think the intervention can work if it is implemented in the community. Questions will be asked to establish if the participant thinks the intervention was acceptable, appropriate, and feasible.

SECTION 1: EXPECTATIONS

- Please share with me what were your expectations when you joined the intervention from the beginning.

SECTION 2: EXPECTATIONS

- Do you think your expectations that you described were met?
- *Probe:* If YES, how did we successfully meet them?
- *Probe:* If NO, what could have been done to meet your expectations?

SECTION 3: BENEFITS

- Please explain to me what did you gain from this intervention to help with your high blood?

SECTION 4: MOTIVATION

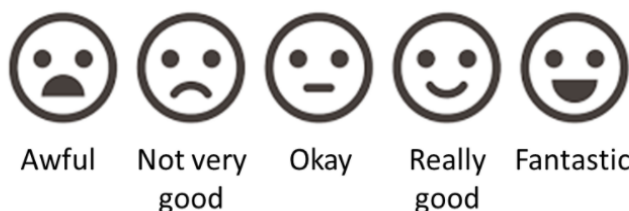
- Please explain to me what gave you the motivation and energy to continue with the diet intervention?
- Please explain to me what gave you the motivation and energy to continue with the physical activity intervention?

SECTION 5: BARRIERS

- Please explain to me what you found challenging with the diet intervention?
- Please explain to me what you found challenging with the physical activity intervention?

SECTION 6: RATING

- From a scale of 1 to 10 how would you rate your satisfaction with the intervention?



SECTION 7: SUGGESTIONS TO IMPROVE INTERVENTION

- What suggestions would you make to improve the diet intervention?
- What suggestions would you make to improve the physical activity intervent

APPENDIX 12

▪ PUBLISHED PAPER ONE – PILOT AND FEASIBILITY STUDIES

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Pilot and Feasibility Studies

STUDY PROTOCOL

Open Access



Feasibility and acceptability of a contextualized physical activity and diet intervention for the control of hypertension in adults from a rural subdistrict: a study protocol (HYPHEN)

Kganetso Sekome^{1,3*} , Francesc Xavier Gómez-Olivé², Lauren B. Sherar³, Dale W. Esliger³ and Hellen Myezwa⁴

Abstract

Introduction In rural and remote South Africa, most strokes and ischaemic heart diseases are as a consequence of hypertension, which is a modifiable risk factor. The widely recommended therapeutic approaches to control hypertension are through physical activity and diet modifications. However, there is a lack of culturally sensitive community-based, lifestyle interventions to control hypertension among rural African adult populations. We designed an intervention which recommends adjusting daily routine physical activity and dietary behaviour of adults with hypertension. This study aims to evaluate the feasibility and acceptability of HYPHEN in a rural community setting.

Methods We aim to recruit 30 adult participants with a self-report hypertension diagnosis. A one-arm, prospective design will be used to assess the feasibility and acceptability of recruitment, uptake, engagement, and completion of the 10-week intervention. Recruitment rates will be assessed at week 0. Intervention uptake, engagement, and adherence to the intervention will be assessed weekly via telephone. Blood pressure, body mass index, waist-hip ratio, urinary sodium, accelerometer-measured physical activity, and 24-h diet recall will be assessed at baseline and at 10 weeks. Qualitative semi-structured interviews will be conducted at 10 weeks to explore feasibility and acceptability.

Discussion This study offers a person-centred, sociocultural approach to hypertension control through adaptations to physical activity and dietary intake. This study will determine whether HYPHEN is feasible and acceptable and will inform changes to the protocol/focus that could be tested in a full trial.

Trial registration number PACTR202306662753321.

Keywords High blood pressure, Nutrition, Rural, South Africa

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Introduction

The World Health Organization projects that in the African region, by 2030, noncommunicable diseases (NCDs) will be the biggest cause of death [1]. The relative burden of NCDs is expected to increase as both HIV-/AIDS-related mortality declines with the roll-out of antiretroviral therapy and the region continues to experience the rapid urbanization of communities [2]. Hypertension, stroke, and ischaemic heart disease are among the most common NCDs causing premature deaths among adults living in South Africa [3]. Over half of strokes and ischaemic heart disease in South Africa are caused by hypertension, and these cardiovascular and cerebrovascular diseases are reported to be more prevalent in rural areas compared to urban areas [3].

The high prevalence of hypertension in South Africa will likely result in increased mortality and morbidity in rural compared to urban areas due, in part, to poorly organized health care systems, intermittent drug supply, and shortage of health care workers [4–6]. Reduced salt and caloric intake and increase in physical activity are the widely recommended therapeutic approaches to meeting national hypertension targets [7–9].

There is a paucity of research that provides a profile of daily physical activity practices of rural South African adults living with hypertension. A study by Oyeyemi and colleagues [10] assessed physical activity for rural South Africans using short versions of physical activity subjective assessment which does not provide information about the domain of physical activity (transportation, job, leisure, and housework) performed each day. Another study using a short version physical activity questionnaire by Smart Mabweazara [11] in the general population concluded that adults in rural Western Cape engaged in more physical activity than urban adults from the same province. A further study by Tomaz and colleagues [12] assessed physical activity for middle-aged and older rural adults and recommended that physical activity interventions should be targeted for adults from the age of 40 years in order to provide health benefits earlier in life.

Available literature on dietary practices of rural South African adults has provided successful intervention recommendations for hypertension, but the recommendations are not sustained in the long run. For example, a study by Charlton and colleagues [13] provided recommendations of food replacement which participants could not afford due to high unemployment rates in rural South Africa and the fact that recommended food was not part of the participants' daily diet [14]. Another study by Najam and colleagues [15] reported that adults in rural South Africa have good nutrition knowledge, but this did not translate into regular healthy nutrition practices. The literature on physical activity and diet practices

for rural South African adults points to a need to have better understanding of the sociocultural influences so that interventions targeting the control of hypertension can consider the realities of this population.

To the authors' knowledge, there are no interventions to test whether adaptations in physical activity and diet focusing on a contextualized structured health promotion approach could lower high blood pressure in a rural South African adult population with hypertension [16, 17]. There is a need for studies to investigate the feasibility of implementing such interventions. A contextualized intervention is one that is adapted to the local context of the target population and informed by the population needs. Many adults in rural South Africa are involved in daily manual labour as part of their activities of daily living, but this is performed at low intensity and is not well documented [10]. Common manual labour activities reported by adults living in rural South Africa include walking for wood collection, different aspects of farming, yardwork, walking as a means of transport, and housework. These activities are not adequate to paint a full picture of the daily routine practices of rural adults and need further exploration [16, 18]. There is lack of information regarding the type, frequency, and intensity of physical activities performed by rural South African adults. Moreover, many diet-based interventions are usually not affordable due to high costs or not accepted by the rural adults due lack of availability and contextual considerations, hence the need for tailor-made interventions that consider the contextual realities of the population [19, 20].

We followed a systematic process to design an evidence and theory-informed contextualized 10-week physical activity and diet intervention which recommends adjusting routine physical activity and diet practices for the control of hypertension using the intervention mapping (IM) protocol [21] — HYPHEN (*H*YPertension control using *P*hysical activity and *d*iEt in a rural coNtext). Intervention mapping is used as a planning approach to develop theory- and evidence-based health promoting intervention programmes. Intervention mapping has been suggested as a useful and effective tool to further improve the development and application of theories to promote nutrition and physical activity [22]. The tasks in the IM protocol are iterative with the programme planner revisiting previous steps throughout the process so that all objectives, outcomes, and determinants are addressed. This process allows for the development and delivery of the intervention to be replicated.

Aim and objectives

The aim of this study is to implement and evaluate the feasibility and acceptability of a contextually appropriate

educational programme for hypertension control in adults from a rural South African population.

The primary objectives of the study are as follows:

- a) To present the social and cultural beliefs, perceptions, and practices regarding physical activity and diet which influenced the development of an intervention for the control of hypertension in adults living in rural South Africa
- b) To implement a contextually appropriate educational intervention programme for the control of hypertension using physical activity and diet
- c) To determine feasibility of the intervention through assessing recruitment, retention, and attrition rates, intervention uptake, engagement, adherence to the intervention, completion, and the evaluation measures
- d) To determine acceptability of the intervention through individual interviews
- e) To assess fidelity of intervention delivery using a checklist centred around the behaviour change techniques

The secondary objective of the study is as follows:

- a) To present descriptive statistics data on health-related indicators (blood pressure, physical activity, diet consumption, body mass index, urine sodium, and waist-hip ratio) before and after the intervention.

Methods

Study design

This feasibility study will be a one-arm community-based, prospective study. Feasibility and acceptability of recruitment, the intervention (HYPHEN), and associated outcome measures will be assessed using a mixed-method approach.

Study site and population

This study will be conducted at Bushbuckridge sub-district in Mpumalanga province where the Agincourt Health and Demographic Surveillance System (HDSS) has been running since 1992. The Agincourt HDSS covers an area of 450 km² with 116,000 individuals (approximately 52,000 older than 18 years) living in approximately 20,000 households distributed in 31 villages [23–25]. We will sample adults aged 40 years and above within the Agincourt HDSS from the Health and Aging in Africa: A Longitudinal Study of an INDEPTH (International Network for the Demographic Evaluation of Populations and Their Health) community in South Africa (HAALSI) [26]. The prevalence of hypertension

in this subdistrict for people aged 40 years and above is 57%, defined as a self-reported diagnosis of hypertension (systolic blood pressure $\geq$ 140 mmHg or diastolic blood pressure $\geq$ 90 mmHg) or self-reported taking medications for hypertension control [26].

Sample size

A study which provides guidance on conducting feasibility studies by Tickle-Degnen [27] states that feasibility studies are not expected to have large sample sizes as they do not need to power statistical null hypothesis testing. However, Arian and colleagues [28] in their review of current best practice state that the sample size of feasibility studies should be adequate to estimate critical parameters such as recruitment rate. An overall sample size of 30 has been recommended by Lancaster, Dodd, and Williamson [29]. We will aim to recruit 30 participants at the beginning of the intervention.

Patient identification, consent process, and ethical considerations

Eligible participants will be invited telephonically via the Agincourt HDSS from a cohort of adults with hypertension. The details of the study will be explained through a telephone call, and if the adult demonstrates interest, a household visit will be conducted to provide further information, answer any questions, and obtain written informed consent to participate. The study has received the necessary ethical clearance from the University of the Witwatersrand Human Research Ethics Committee (clearance number: M 210282) and the local Provincial Department of Health Research and Ethics Committee (clearance number: MP_202106_001). We do not anticipate any adverse events to occur because of participating in this intervention; therefore, no data monitoring committee will be required. Participants already taking anti-hypertensive medications will continue this treatment as usual.

Inclusion criteria

- Ages 40 years and older
- Self-reported diagnosis of hypertension or self-reported taking medications for hypertension control
- Lived in the district study setting for minimum 6 months prior to start of intervention.

Exclusion criteria

- Dependent on wheelchairs for mobility

Preparation procedures

The primary author will train three research assistants on the entire protocol of the study including questionnaire administration, anthropometric measurements, and education of the participants. The summary of the study schedule is outlined in Table 1.

Intervention

The intervention will comprise of three components: a structured group education session, individualized physical activity education, and individualized dietary education over a period of 10 weeks (Tables 1, 2 and 3). The duration of the intervention was informed by recommendations from similar studies [30, 31]. The three components of the intervention were informed by a needs assessment from unpublished data. The first part of the needs assessment established the profile of physical activity levels of hypertensive adults in the rural sub-district. Results found that males reported more vigorous physical activity than females at work. Females reported high frequency of moderate-intensity physical activity inside and outside the house. The second part explored the sociocultural perceptions about physical activity and dietary practices which influence behaviour change for the control of hypertension in adults from the rural sub-district. Some key findings included a lack of variety in the daily consumed diet, and the usual diet was mainly influenced by affordability and availability. Physical activity practices were mainly influenced by community perceptions of age- and gender-related roles.

The design of the intervention was underpinned by the COM-B model by Michie, Van Stralen, and West [32] (Fig. 1). The model identifies three factors that need to be present for any behaviour to occur — Capability, Opportunity, and Motivation. Capability is defined as the individual's psychological and physical capability to engage in the activity concerned. The capability includes having the necessary knowledge and skills. Opportunity is defined as all the factors external to the individual and prompt or make the behaviour possible. Motivation is defined as brain processes that energize and direct behaviour, and it includes habitual processes, emotional responding, and analytical decision-making. Potential influence between components in the model can occur, for example opportunity and capability can influence motivation (Fig. 1).

Intervention component one: structured group education

Participants of the intervention will be invited to a common location in small groups (of between 6 and 10). The main focus of the group education will be to enhance capability through shaping knowledge and skills to engage in the proposed intervention. The trained research assistants will deliver the education using a

printed educational pamphlet. Some topics to be covered in the discussion (informed by a contextual need assessment) will include knowledge about what causes hypertension and normal blood pressure values, knowledge on ways to control blood pressure such as reducing salt intake and increasing physical activity, awareness of social triggers/barriers such as cooking for the family, awareness, and correction regarding common myths. The group education is expected to last up to 90 min per session.

Intervention component two: individualized physical activity education

Participants who attended the group education session will be visited at their home by a trained research assistant to provide individual education on physical activity. Capability will be enhanced by first asking the individual to set goals by identifying the physical activities which they perform as part of their daily routine from a list (informed by a needs assessment). The research assistant will educate the participant on how to adapt performance of the physical activities. This may include changing positions (from sitting) when performing activities, increasing pace of usual active daily tasks, and avoiding sedentary behaviour. Opportunity will be enhanced by emphasizing the importance and benefits of moderate-to-high intensity physical activities on hypertension control. Participants will be motivated by weekly telephone calls where they will be asked to indicate which activities they were able to achieve that week and encouraged where they fall short. The research assistant will keep record of everyone's weekly performance so that feedback and motivation can be enhanced during weekly telephone feedback.

Intervention component three: individualized dietary education

To enhance capability, individual education on how to make dietary changes will be provided on the same visit as the physical activity education. The research assistant will provide education on food items which contains high sodium content from the participant's usual diet, education on reduction of salt consumption and high salt spices, finding alternative options for food with lower sodium content (for example brown bread instead of white bread), limiting cooking salt to one teaspoon per day, and removing salt from the table during meals. Opportunity for consuming healthier food items will be enhanced by encouraging habitual consumption of self-grown vegetables and naturally growing wild herbs which participants already have access to in their communities. Participants will be motivated through weekly monitoring calls where they will be asked to list which dietary

Table 1 COM-B component and behaviour change techniques (BCT) used in the structured group education session targeting hypertension

Model component	Taxonomy category	BCT	Definition	Finding from needs assessment	Example
Capability	Shaping knowledge	Information about antecedents	Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict performance of the behaviour	Lack of knowledge about blood pressure and normal blood pressure values Negative influence from community resulting in myths about causes of hypertension	Knowledge about what causes hypertension and normal blood pressure values Knowledge on ways to control blood pressure such as reducing salt intake and increasing physical activity Awareness of social triggers/barriers such as cooking for the family Awareness and correction regarding common myths

Table 2 COM-B component and behaviour change techniques (BCTs) targeting individual's physical activity behaviour

Model component	Taxonomy category	BCT	Definition	Findings from needs assessment	Example
Capability	Shaping knowledge	Instruction on how to perform a behaviour (identified by the participant) Goal setting (behaviour)	Advise or agree on how to perform the behaviour (includes 'skills training') Set or agree a goal defined in terms of the behaviour to be achieved	Most daily activities are performed at low intensities or in sitting positions	Changing positions (from sitting) when performing activities Increasing pace of usual active daily tasks Avoid sedentary behaviour Identifying a list of usual daily physical activities performed
Opportunity	Shaping knowledge	Instruction on how to perform a behaviour (identified by the participant)	Advise or agree on how to perform the behaviour (includes 'skills training')	Some daily activities performed were of moderate to high intensities	Emphasize the importance and benefits of moderate to high intensity physical activities on hypertension control
Motivation	Feedback and monitoring	Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy	Lack of motivation to maintain behaviour change recommendations	Participant to tick which activity(ies) they achieved on a weekly basis

Table 3 COM-B component and behaviour change techniques (BCTs) targeting individual's dietary behaviour change

Model component	Taxonomy category	BCT	Definition	Findings from needs assessment	Example
Capability	Shaping knowledge Antecedents	Instruction on how to perform a behaviour Avoidance/reducing exposure to cues for the behaviour Goal setting	Advise or agree on how to perform the behaviour (includes skills training) Advise on how to avoid exposure to specific social and contextual/physical cues for the behaviour, including changing daily or weekly routines Set or agree a goal defined in terms of the behaviour to be achieved	Diet is rich in high salt content such as processed food; use of high salt spices for cooking	Education on high sodium content food items from usual diet Education on reduction in salt consumption and high salt spices Finding alternative options for food with lower sodium content (for example brown bread instead of white bread) Limiting cooking salt to one teaspoon per day
Opportunity	Shaping knowledge	Information about antecedents	Provide information about antecedents (e.g. social and environmental situations and events, emotions, cognitions) that reliably predict performance of the behaviour	Habitual consumption of self-grown vegetables and naturally growing wild herbs such as <i>nkaka</i> , <i>Aloe</i> , and <i>Moringa</i>	Encourage to continue consumption of wild herbs and self-grown garden produce
Motivation	Feedback and monitoring	Self-monitoring of behaviour	Establish a method for the person to monitor and record their behaviour(s) as part of a behaviour change strategy	Lack of motivation to maintain behaviour change recommendations	Participants to tick which dietary adjustments they achieved weekly

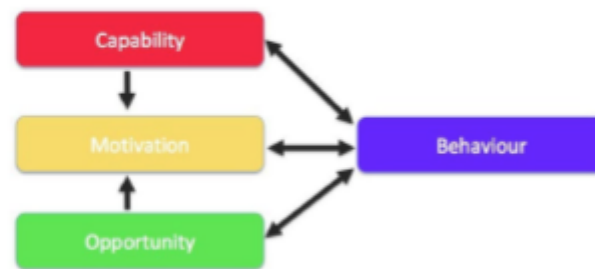


Fig. 1 COM-B model of behaviour change [32]

adjustments they achieved weekly. The research assistant will keep record of everyone's weekly dietary habits so that feedback and motivation can be enhanced during weekly telephone feedback.

The authors are cognizance of the under-pinning theories that influence behaviour change such as the social cognitive theory [33]. The primary variable of interest in this theory of motivation is self-efficacy, which concerns someone's belief in his/her capabilities to successfully execute necessary courses of action to satisfy situational demands [33, 34]. According to Bandura [34], a high expectation of self-efficacy and outcome expectancy leads to greater adherence to a recommended activity (in our case, physical activity and diet adaptations). Alongside the COM-B model, we developed taxonomies of behaviour change techniques (BCTs) (Tables 1, 2 and 3) to identify active intervention ingredients and allow for future replication [35, 36]. The BCTs are classified using the Behaviour Change Taxonomy [36].

The scope and sequence of the intervention are provided in Table 4. The intervention will run over a period of 10 weeks. During week 0, baseline individual assessments of blood pressure, body mass index, waist-hip ratio, and urine sample collection will be conducted. Participants will be asked to wear a wrist-worn accelerometer for seven consecutive days. They will also be asked to complete a 24-h diet recall questionnaire. During week 1, participants will be invited to a group education session limited to up to 10 participants per group. Participants will be asked to return the accelerometer device during the group session. The research assistants will note down the recruitment rate, intervention uptake, and any reasons for refusal to take up the intervention. Week 2 of the intervention will consist of individual household visits to provide participants with physical activity and diet education based on set goals and to provide printed pamphlet of the education components. The research assistants will telephone the participants weekly for monitoring support and motivation. On week 10, the research

assistants will conduct household visits and reassess all baseline measurements. Participants will be asked to wear the accelerometer for 7 days as a post-intervention measure. Adherence rate, completion rate, follow-up rate, and fidelity will be assessed. An exit interview will be conducted to assess intervention acceptability.

Self-monitoring support

Due to reported low literacy levels in the HAALSI cohort [26, 37], self-monitoring support which does not require the participants to read or write will be provided. The trained research assistants will telephone each participant once weekly to ask questions about the participant's identified physical activity and dietary goals. The research assistant will have a copy of each participant's printed intervention and record progress. Participants will be asked to provide personal and alternative contact number. Where a participant cannot be reached via telephone, a household visit will be conducted. The self-monitoring support is also noted as an active behaviour change technique due to its ability to enhance motivation of adhering to an intervention [35].

Outcomes and criteria for success

In line with the primary objective (c) of the study, the criteria adapted for judging the feasibility of progressing to a larger-scale evaluation (Table 5) were initially developed by Avery and colleagues' [38] top Ten tips for guiding the decision to progress from a pilot to a definitive trial and later reproduced by Hynes and colleague [39]. The criteria were also discussed by the study authors guided by existing literature.

Primary feasibility outcome measures

For primary objective a of the study, nine focus-group discussions were conducted as part of the needs analysis process, and the outcome is presented in Tables 1, 2 and 3. For primary objective b of the study, we followed a model of behaviour change as outlined in Fig. 1, and the outcomes

Table 4 Scope and sequence of the intervention

Programme components	Sequence			
	Week 0	Week 1	Week 2 (household visit)	Week 10 (household visit)
Group educational programme	Group education sessions			
Individualized physical activity			• Goal setting • Physical activity intervention education • Provide printed intervention pamphlet	Final data collection of self-monitoring physical activity tool
Individualized diet			• Goal setting • Dietary intervention education • Provide printed intervention pamphlet	Final data collection of self-monitoring physical activity tool
Anthropometric measurements	Baseline individual assessment • Demographic data • Blood pressure • BMI^a • WHR^a • Urine sample collection			Follow-up individual assessment • Blood pressure • BMI^a • WHR^a • Urine sample collection
Physical activity assessment	Baseline accelerometer wear for 7 days	Return accelerometer		Follow up accelerometer wear for 7 days (collect after 7 days)
Dietary assessment	Nutrition questionnaire—24-h diet recall			Follow up nutrition questionnaire—24-h diet recall
Feasibility parameters		• Recruitment rate • Intervention uptake and engagement • Reasons for refusal		• Adherence rate • Completion rate • Follow-up rate • Acceptability interview • Fidelity

^a WHR waist-hip ratio

^a BMI body mass index

Table 5 HYPHEN progression criteria

HYPHEN progression criteria	Go—proceed to larger scale (RCT)	Amend—proceed with changes	Stop—do not proceed unless changes possible
Feasibility of participant recruitment—can 30 participants be recruited in 1 week?	If 30 participants are recruited in 1 week (100%)	If 15 to 29 participants are recruited in 1 week (50 to < 100%)	If < 15 participants are recruited in 1 week (< 50%)
Feasibility of patient retention—can at least 80% of recruited participants be retained until study end?	≥ 24 (80%) retained	21–24 (70–80%) retained	< 21 (70%) retained
Feasibility of engagement—can at least 80% of recruited participants provide complete weekly data	≥ 24 (80%) engaged	21–24 (70–80%) engaged	< 21 (70%) engaged
Feasibility of intervention implementation	Delivery of intervention judged strongly feasible by qualitative data	Delivery of intervention judged feasible by qualitative data	Delivery of intervention judged possibly feasible by qualitative data

are presented in Tables 1, 2 and 3. Primary objective c will be assessed as per Table 5.

The feasibility study parameters which will be used to inform the design of a larger HYPHEN intervention trial are outlined in Table 4. Demographic data (age, sex, employment status, type of employment) of participants

who refuse to participate in the intervention will be recorded as well as their reasons for refusal. Acceptability of the intervention will be assessed using an in-depth semi-structured interviews through a self-developed interview guide. All participants who were recruited will be invited for the interviews including those who

did not complete the intervention. The interview topics and questions will focus on predetermined themes of participants' perceived expectations of the intervention, benefits, motivations, and barriers. These topics will be explored in relation to participants age, sex, and employment status. Participants will also be asked to rate their overall satisfaction with the intervention using a Likert scale [40]. Fidelity of intervention delivery will be assessed by the primary author to ascertain whether the field workers provided the intervention as intended using a checklist framed around the intended BCTs (Table 6).

Secondary outcome measures

Secondary outcomes which will be assessed are outlined in Table 7 and are as follows: (i) Blood pressure will be measured using an oscillometry blood pressure monitor, (ii) body mass index will be measured using a stadiometer and a portable LED weighing scale, (iii) waist-hip ratio will be measured using a rubber tape measure, (iv) urinary sodium will be measured by collecting participants urine sample, (v) physical activity will be measured using an Axivity AX3 wearable device on the wrist, and (vi) diet will be assessed using a 24-h diet recall questionnaire.

Data and statistical analysis

Quantitative analysis

A Consolidated Standards of Reporting Trials (CONSORT) flowchart will be used to present the flow of participants throughout the intervention. The CONSORT flowchart will also present reasons for declining participation or withdrawing. Descriptive statistics will be used to present baseline statistics and outcomes of feasibility. Depending on data distribution, mean and standard deviation or median and interquartile range will be described. Pre- and post-intervention outcome change will be assessed using a paired *t*-test if data is evenly distributed. If data is unevenly distributed, the Wilcoxon signed-rank test will be used. Confidence interval is set at 95%.

Qualitative analysis

The interviews will be audio-recorded, transcribed verbatim, and analysed using Braun and Clarke's approach to thematic analysis [46]. An independent transcriber will be employed to perform the transcription, the first author will perform the initial codes and themes, and the co-authors will confirm the generated codes and themes. Data will be described narratively. Participants' direct quotations will be provided and will be used to judge whether the participants perceive the intervention to be acceptable. Positive responses from the participants will indicate acceptability (Table 5).

Patient and public involvement

In the needs assessment prior to intervention design, stakeholder engagements were undertaken with hypertensive adults exploring their perceptions of sociocultural influences on diet and physical activity. Hypertensive adults were also consulted on their perceived intervention needs and preferred educational approaches before designing the intervention. Local dieticians were consulted about current approaches to hypertension control and learning points from community-based interventions. Community members/the public were also consulted for social issues that are likely to enhance/inhibit success of the intervention. The findings from the various engagements led to the development of the 10-week intervention. The involvement of local research assistants was an important aspect to consider overcoming any trust and cultural issues involved.

Discussion

In this study, we will seek to implement and then test the feasibility of a community-based intervention for hypertensive adults that incorporate the patient's perceptions about their social and cultural beliefs regarding physical activity and dietary practices. This study may lead to recommendations that will assist in the control of high

Table 6 Fidelity of delivery of intervention

Definition [41]	Intervention BCTs	Example
Intervention is delivered as intended	Information about antecedents	Facilitator provided education on all identified aspects of physical activity and diet
	Goal setting	Facilitator identified and made a tick of the participant's goals for physical activity and diet modifications
	Instruction on how to perform a behaviour	Facilitator explained to the participant how to perform identified goals with images on a printed handout
	Self-monitoring of behaviour	Facilitator followed with each participant weekly and noted with a tick based on participant's responses
	Avoidance/reducing exposure to cues for the behaviour	Facilitator explained with pictures to the participant how to identify and avoid/replace food items with lower sodium salt

Table 7 Secondary outcome measure outline

Variable	Tool used	Manufacturer	Participant position/instruction	Procedure
Blood pressure	Oscillometry blood pressure monitor	OMRON M3 comfort, Japan	Sitting on a chair with back supported with feet on the ground. Cuff wrapped on upper arm	Three measurements recorded and the average of the last two will be calculated [42]
Body mass index	Portable stadiometer	SECA, Germany	Standing on the scale with shoes off, no cap or hat worn on head	Body mass index will be calculated by dividing the participant's weight in kilograms by the participant's height in metres squared [43]
	Portable LED weighing scale	DQUIP, India	Standing on the scale. Shoes off, no heavy clothing worn, no items in pockets	
	Rubber tape measure (centimetres)	N/a	Waist: participant standing shoulder width apart, measuring around participant's waist at the smallest point Hips: participant standing shoulder width apart, measuring around participant's hip at the widest part	
Waist-hip ratio			N/a	Waist circumference divided by hip circumference [44]
Urinary sodium	Urine sample	N/a		On-the-spot urine sample collected in a 300-ml container and stored at temperatures of -80°C in a laboratory upright biomedical freezer. Samples will be analysed in a clinical laboratory which adheres to good clinical laboratory practice (GCLP) standards. Samples will be tested only for sodium levels
Physical activity	Activity AX3	Activty Ltd., UK	Participant to wear the activity wristwatch and instructed not to remove it	Device worn on the nondominant wrist with an adjustable watch strap over 7 full days consecutively
Diet	24-h diet questionnaire	[45]	Participant asked to recall all food consumed in the past 24 h	Record type of food consumed for breakfast, lunch, dinner, and any snack meals

blood pressure particularly for adults in a rural South African or similar population. The results from this study may provide a novel contribution to the understanding of contextual factors about physical activity, diet, and implementation of interventions for a rural, South African adult population. Data generated from this study will inform the design and implementation of a larger-scale intervention of HYPHEN, if appropriate.

Abbreviations

NCD	Noncommunicable disease
BCT	Behaviour change technique
CONSORT	Consolidated Standards of Reporting Trials
HDSS	Health and demographic surveillance system
HREC	Human Research Ethics Committee
IM	Intervention mapping

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Authors' contributions

All authors have participated in the design of the study. KS drafted the manuscript, and all authors read and approved the final manuscript. KS applied for and obtained the grants for the study.

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Availability of data and materials

Data sharing is not applicable to this article as no datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate

This study required clearance from two ethical bodies. The first clearance was obtained from the University of the Witwatersrand Human Research Ethics Committee (HREC-Medical) (clearance number: M 210282). The second clearance was obtained from the local Provincial Department of Health Research and Ethics Committee (clearance number: MP_202106_001). Consent considerations and confidentiality of all research data will be adhered to. This study is based on the usual ethical principles, such as every person's right to refuse to participate in the study and to withdraw at any time, as well as respect for all participants and protection of their privacy.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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APPENDIX 13

▪ TURN-IT-IN REPORT

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Regards,

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APPENDIX 14

DISTRIBUTION OF STUDY PARTICIPANTS BY VILLAGE

Village name	Participants obtained	Number of men	Number of women
Agincourt	29	10	19
Belfast	27	14	13
Cunningmore A	14	7	7
Cunningmore B	21	8	13
Croquetlawn	23	8	15
Dumphries A	13	6	7
Dumphries B	18	8	10
Dumphries C	19	7	12
Ireagh A	15	7	8
Ireagh B	20	6	14
Justicia A	16	6	10
Justicia B	24	11	13
Khaya Lami	20	9	11
Kildare A	34	14	20
Kildare B	15	6	9
Lillydale A	34	14	20
Lillydale B	16	9	7
Somerset A	25	10	15
Somerset B	19	7	12
Xanthia	27	12	15
TOTAL	429	179	250

APPENDIX 15: STROBE Statement—checklist of items that should be included in reports of observational studies

	Page No	Recommendation
Title and abstract	54	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	55	Explain the scientific background and rationale for the investigation being reported
Objectives	56	State specific objectives, including any prespecified hypotheses
Methods		
Study design	56	Present key elements of study design early in the paper
Setting	56	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	56	(a) <i>Cohort study</i> —Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <i>Case-control study</i> —Give the eligibility criteria, and the sources and methods of case ascertainment and control selection. Give the rationale for the choice of cases and controls <i>Cross-sectional study</i> —Give the eligibility criteria, and the sources and methods of selection of participants (b) <i>Cohort study</i> —For matched studies, give matching criteria and number of exposed and unexposed <i>Case-control study</i> —For matched studies, give matching criteria and the number of controls per case
Variables	57	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	58	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	58	Describe any efforts to address potential sources of bias
Study size	56	Explain how the study size was arrived at
Quantitative variables	57	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	58	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) <i>Cohort study</i> —If applicable, explain how loss to follow-up was addressed <i>Case-control study</i> —If applicable, explain how matching of cases and controls was addressed <i>Cross-sectional study</i> —If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses

Continued on next page

Results		
Participants	58	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	59	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest (c) <i>Cohort study</i> —Summarise follow-up time (eg, average and total amount)
Outcome data	60	<i>Cohort study</i> —Report numbers of outcome events or summary measures over time <i>Case-control study</i> —Report numbers in each exposure category, or summary measures of exposure <i>Cross-sectional study</i> —Report numbers of outcome events or summary measures
Main results	60 - 65	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	n/a	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	65-68	Summarise key results with reference to study objectives
Limitations	68	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	65-68	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	65-68	Discuss the generalisability (external validity) of the study results
Other information		
Funding	69	Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based

*Give information separately for cases and controls in case-control studies and, if applicable, for exposed and unexposed groups in cohort and cross-sectional studies.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.