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DEVELOPING A PATIENT DECISION AID FOR COMPLEMENTARY TRADITIONAL MEDICINE USE BY HYPERTENSIVE PATIENTS AT RED CROSS CLINIC, HARARE

BY

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Abstract

Non-communicable diseases burden including hypertension has led to a further rise in the use of complementary traditional medicine globally and regionally. The aim of the paper was to explore the prevalence and determinants of CTM use by patients with hypertension attended to at the Red Cross Clinic in Harare and to design a patient decision aid so as to influence safe and effective use. An analytic cross sectional survey was conducted with a sample of 300 participants selected from adults with hypertension accessing care at Red Cross Clinic. Fifteen key informants were selected for review of the Patient Decision Aid developed. The Ottawa Decision Support Framework was used for decision aid development and the Andersen socio-behavioural model for assessing determinants of Complementary Traditional Medicine use. Of all participants, 63.1% of the respondents seen at Red Cross Clinic reportedly used complementary alternative traditional medicine for the control of hypertension at some point in time. Of those who used CTM, 98.3% utilised herbal products for BP control, whilst 17.4% use exercise, 14.6% use body, mind control methods and 1.1% use manipulation methods. The major sources of herbal products were the backyard garden (68.0%) and local market place (67.4%). Identified determinants of Complementary Traditional Medicine use were; cost relative to conventional medicine (odds ratio=23.9; p-value <0.001), perceived safety odds ratio=47.8, p-value<0.001) and presence of co-morbidities (odds ratio=0.5, pvalue= 0.007). All of the clients (100%) highlighted that the aid made decision making about hypertension management easier. All the practitioners were of the opinion that use PtDA was a cost effective way of helping patients make decisions. Forty percent of practitioners felt that use of the PtDA may cause/result in more harm than benefit. The majority of hypertensive patients seen at Red Cross Clinic utilised complementary traditional medicine with the CTM of choice being herbal medicines. Determinants of CTM use were health factors such as cost of CTM and perceived safety of CTM modalities. The PtDA designed was generally accepted by both patients and health practitioners, however respondents highlighted need for its further development and public education of CTM use. Regulation regarding the use off and sell of Complementary Traditional Medicine by regulatory authorities is recommended because it is crucial for safe utilisation by patients.

Key words: Complementary Traditional Medicine; Hypertension; Patient Decision Aid

Declaration

I declare that this dissertation is my original work except where sources have been cited and acknowledged. The work has never been submitted, nor will it ever be submitted to another university for the award of a degree.

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List of Abbreviations

AUREC Africa University Research, Ethics Committee

BP Blood pressure

CDC Center for Disease Control

CBD Central business district

CAM Complementary and Alternative Medicine

CTM Complementary traditional medicine

CATM Complementary and alternative traditional medicine

CI Confidence interval

DM Diabetes mellitus

GoZ Government of Zimbabwe

LMICs Low to middle income countries

MCAZ Medicines Control Authority of Zimbabwe

NCD Non-communicable disease

ODSF Ottawa Decision Support Framework

PtDA Patient decision aid

QALYs Quality adjusted life years

SPSS Statistical Package for the Social Sciences

SSA Sub-Saharan Africa

DALYs Disability adjusted life years

TCM Traditional and complementary medicine

TCAM Traditional complementary and alternative medicine

THM Traditional herbal medicine

USA United States of America

WHO World Health Organization

ZRCS Zimbabwe Red Cross Society

Definition of Key terms

Complementary traditional medicine: Wide ranging health care practices which are not part of a country's conventional medicine and have not been fully integrated into mainstream health care system.

Hypertension: Elevated blood pressures beyond the set limits and is characterised by progressive cardiovascular damage.

Traditional medicine: The sum total of all knowledge and practices, whether explicable or not, used in diagnosing, preventing and eliminating physical, mental or societal imbalances.

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CHAPTER 1 INTRODUCTION

1.1 Introduction

The rise in prevalence of non-communicable diseases (NCDs) including hypertension is likely to lead to an increased utilisation of complementary traditional medicine (CTM) (Asfaw Erku & Basazn Mekuria, 2016). Hypertension is defined as elevated blood pressures beyond the defined blood pressure values and is characterised by progressive cardiovascular damage (Yano, Reis, Colangelo, Shimbo, Viera, Allen & Lloyd-Jones, 2018). Globally there is estimated to be around 1.13 billion people living with hypertension and approximately two thirds are living in low to middle income countries (LMICs) (WHO, 2019). Hypertension contributes 3.7% of the total disability adjusted life years (DALYs) worldwide (Wong, Kassab, Mohamed, & Qader, 2018).

The global trends for hypertension show an increased prevalence as of 2010 when compared to 2000 particularly for Sub-Saharan Africa (SSA) (Mills *et al.*, 2016). In SSA, the prevalence of hypertension in 2000 for men was 20.9% and for women it was 20.3%, whereas in 2010 these figures stood at 36.9% and 36.3% for men and women respectively (Mills *et al.*, 2016). Hypertension is the most common non-communicable disease (NCD) in Zimbabwe and prevalence of blood pressure (BP) above 140/90mmHg is 23.2% (GoZ, 2005).

Complementary traditional medicine is defined as a wide ranging health care practices which are not part of a country's conventional medicine and have not been fully integrated into mainstream health care system (*WHO*, 2019) and it is used in conjunction with conventional medicine health practices. The World Health Organization (WHO),

defined traditional medicine as "the sum total of all knowledge and practices, whether explicable or not, used in diagnosing, preventing and eliminating physical, mental or societal imbalances" (Duru, Diwe, Uwakwe, Duru, Merenu, Iwu, & Ohanle, 2016). According to the WHO (2019), there is currently a renewed interest in CTM.

Traditional and complementary medicine (TCM) use worldwide is increasing and focus is moving beyond just looking at the products used but to also include practices and professionals. Safe and effective CTM is critical in ensuring universal access to health care (WHO, 2013). In China and in some other parts of the world, there is increasing convergence between conventional medicine and CTM (Yuan, Ma,Ye, & Piao, 2016). There is a growing interest in CTM and globally it is widely utilised as demonstrated in World Health Organisation's global report on traditional and complementary medicine (WHO, 2019).

Global rates of traditional medicine use in hypertensive patients is between 8% and 40%, with the majority of patients using it as complementary medicine (Asfaw Erku & Basazn Mekuria, 2016). The prevalence of complementary traditional medicine use in the Sub-Saharan Africa (SSA) general population is on average 58.2% (James, Wardle, Steel, & Adams, 2018). There is a paucity of articles on the prevalence of CTM use in Zimbabwe, however one study by Chingwaru & Vidmar, (2016) carried out in Bindura found the prevalence in the general population to be 60%. It was however the aim of the study to determine the prevalence of CTM use in hypertensive patients seen at Red Cross Clinic and to identify determinants of use.

1.2 Background of the Study

Complementary traditional medicine use in patients with chronic conditions is gaining popularity for various reasons including perceived safety, accessibility and acceptability

(Ibrahim, Hassali, Saleem, & Al Tukmagi, 2016). Due to the increase in use of CTM in chronic patients including hypertensive patients, the World Health Organisation (WHO) is advocating for safe and rationale as well as appropriate use of CTM by both clients and clinical practitioners (WHO, 2013).

In Zimbabwe, the Government has prioritised the management of NCDs including hypertension in the National Health Strategy because of the high prevalence rates of hypertension in the country (Basopo & Mujasi, 2017). It was noted that patients that were treated by practitioners with knowledge of CTM had reduced costs of care and also had better outcomes as compared to those managed by practitioners with no knowledge of CTM practices (WHO, 2013).

It has been noted that hypertensive patients used CTM and they utilise a wider variety of complementary alternative medicine modalities (Mbizo *et* al., 2018). CTM is valuable and it is possible to effectively manage diseases by combining conventional medicine and traditional medicine (Yuan, Ma, Ye, & Piao, 2016). In order to effectively achieve this synergistic and comprehensive treatment approach, there is need for research to determine the context specific factors that influence the use of CTM (WHO, 2013).

The need for CTM by the community has gradually been increasing over time and the World Health Organization (2013) in the strategic document for Complementary and Traditional Medicine advocated for ensuring safe and effective use of CTM by understanding how and why individuals opt for its use. This will allow for integrated use of CTM and conventional medicine particularly in primary care health set ups and more so when managing chronic non-communicable diseases.

The Africa WHO regional office developed a strategy that was endorsed by African countries which aims to promote traditional complementary and alternative medicine (TCAM) use in African health systems. There is need for health workers to appreciate TCAM as an integral part of population health seeking behavior in order to safe guard patients' well-being (James, Wardle, Steel & Adams, 2018). There is an increasing understanding among both patients and practitioners on the need to increase medical practitioner's knowledge on CTM and to integrate it into routine medical practice but around 50% of physicians were unfamiliar with resources on CATM that are evidence based (Patel, Kemper & Kitzmiller., 2017).

Though WHO notes a high proportion of people in SSA utilise Traditional Complementary Alternative Medicine, there is little research on the area within the region (James, Wardle, Steel & Adams, 2018). According to knowledge of the researcher, there is no study in Zimbabwe and one done at a private clinic in Harare to determine factors that influence the use of CTM in hypertensive patients. The purpose of this study was to generate evidence on factors influencing complementary traditional medicine use and the CTM practices in hypertensive patients at Red Cross Clinic and thus creating a local profile for CTM patients.

1.3 Statement of the Problem

The increasing burden of non-communicable diseases (NCDs) including hypertension will most likely lead to a further rise in the use of complementary traditional medicine (James et al., 2018) and this trend has been established globally and regionally. Even though CTM is a critical component of healthcare management and prevention of chronic diseases, it is often underestimated particularly by healthcare professionals (WHO, 2019). 60% of the population in Bindura utilizing complementary and

alternative traditional medicine (CATM). There are reduced disclosure rates of 70% on the use of CTM in hypertensive patients which may lead to ineffective management of hypertension (Asfaw Erku & Basazn Mekuria, 2016).

Some herbal medicines such as garlic leaves, and coriander leaves have been shown to lead to adverse effects such as kidney damage (Yang *et al.*, 2018). CATM users had poor adherence to anti-hypertensive drugs than non-CATM users (Kretchy, Owusu-Daaku & Danquah, 2014) and this negatively affects the control and management of hypertension. An understanding of factors leading to use of CTM by hypertensive patients in Zimbabwe is limited. The same is true for Red Cross Clinic patients, despite a number of reports by medical personnel that some hypertensive patients reported using herbal medicine for BP control. It was however the aim of this paper to explore the prevalence and determinants of CTM use by patients with hypertension attended to at the Red Cross Clinic in Harare to influence safe and effective use.

1.4 Research Objectives

1.4.1 Research Aim

The aim of the research was to develop a patient decision aid (PtDA) to guide Complementary Traditional Medicine use in hypertensive patients managed at Red Cross Clinic during 2021.

1.4.2 Research Objectives

The objectives were to:

- determine the usage of CTM by hypertensive patients treated at Red Cross clinic;
- ii. examine the determinants of CTM use in hypertensive patients treated at Red Cross Clinic;

- iii. identify CTM practices in patients with hypertension treated at Red CrossClinic;
- iv. develop a patient decision aid for hypertensive patients utilising CTM.

1.5 Research questions

- i. What is the prevalence of CTM use among hypertension patients at Red Cross Clinic?
- ii. What factors determine use of complementary traditional medicine by hypertensive patients?
- iii. What are complementary traditional medicines practices in hypertensive patients seen at Red Cross use?

1.6 Justification of the Study

In Zimbabwe there is a paucity of studies on the use of CATM in the general population and none on the use of CTM in patients with hypertension. Research is critical in the formulation of policy and for implementing robust mechanism for regulation of CTM use and African countries including Zimbabwe have been shown to lack regulatory mechanisms (*WHO*, 2019). It is also critical for health workers and policy makers to have an understanding of the practices in use and prevalence of CTM as this will inform a country's hypertension management protocol (Kretchy, Owusu-Daaku, & Danquah, 2014).

Patients on CTM being managed by practitioners with knowledge on complementary traditional medicine have better treatment outcomes than those managed by physicians who have zero knowledge (WHO, 2013). It is therefore this paper's aim to generate evidence on determinants of CTM use and the prevalence of CTM amongst hypertensive

patients to enable health practitioners at Red Cross Clinic to effectively manage clients and improve patient satisfaction and outcomes.

1.7 Delimitation of the Study

The study only focused on hypertensive patients seen at Red Cross clinic already on treatment and excluded newly diagnosed patients not yet on treatment for hypertension. The Red Cross clinic is located in the central business district (CBD) of the capital city Harare. The third element of the Ottawa Decision Support Framework which looks at decision outcome was not be part of this current research. The study did not pilot test the patient decision aid that was be developed.

1.8 Limitation of the Study

This study was carried out at a private clinic in the capital city, which mostly caters for those in the low socio-economic strata and this meant results may not be generalised to the entire population. There is minimal research in literature on some of the more common herbal medicines used in the context of Zimbabwe.

CHAPTER 2 REVIEW OF LITERATURE

2.1 Introduction

The use of complementary traditional medicine in patients with NCDs is increasing globally and its use is higher in low to middle income countries (James *et al.*, 2018). There is a need to safe guard patient safety by providing sufficient information which will aid clients in decision making. Health care providers should accept that clients may hold different views from health workers regarding treatment and even hold the rights to refuse medicine (Volk, Llewellyn-Thomas, Stacey & Elwyn., 2013). Therefore practitioners must come up with ways to assist in the decision making process of clients by providing them with adequate and appropriate information.

2.2 Theoretical Framework

Ottawa Decision Support Framework (ODSF) is the most widely used and implemented framework (Ng, Mathers, Bradley & Colwell, 2014). The ODSF is a conceptual framework that consists of the theories that include expected utility theory, decisional conflict theory and social support theory. The ODSF postulates that by identifying client's decisional needs, a patient decision aid (PtDA) can be used to provide decision support to patients. This aids patients in making an informed decision about their health which leads to a better health outcome (Ng, Mathers, Bradley & Colwell, 2014).

ODSF helps practitioners and researchers in assisting patients in decision making process by evaluating their needs and providing decision support (Hoefel *et al*, 2020). There are three elements of the ODSF framework and these are decisional needs, decisional outcomes and decision support as illustrated in the diagram below:

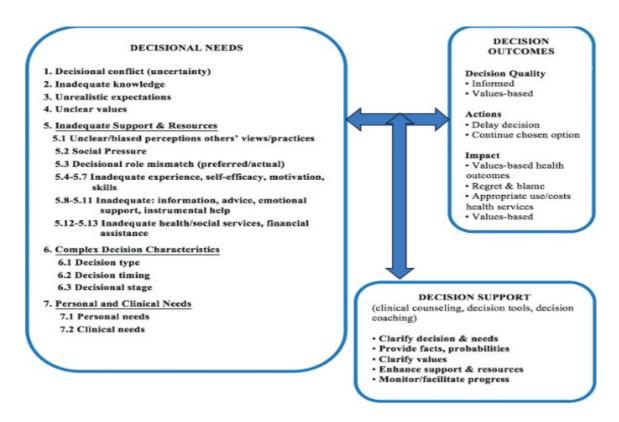


Figure 1 - Ottawa Decision Support Framework: Hoefel et al., (2020).

The first element of decisional needs looks at assessing the determinants of decision making and these include inadequate knowledge on treatment option, unrealistic expectations and lack of support and resources (Hoefel *et al*, 2020). The decision support element seeks to provide relevant information including through decision tools thus aiding in quality decision making (Hoefel *et al*, 2020). The third element looks at evaluating the success of PtDA in improving decision quality as well as outcomes of the intervention (Hoefel *et al*, 2020).

To have an understanding of the personal and clinical needs (assessment of determinants) in the decisional needs element that influence the use of CTM in hypertensive patients, the Andersen's socio-behavioural model for health service use will be utilised (Shewamene, Dune & Smith, 2020). The framework has three components which are predisposing characteristics, need factors, and enabling resources as illustrated below:

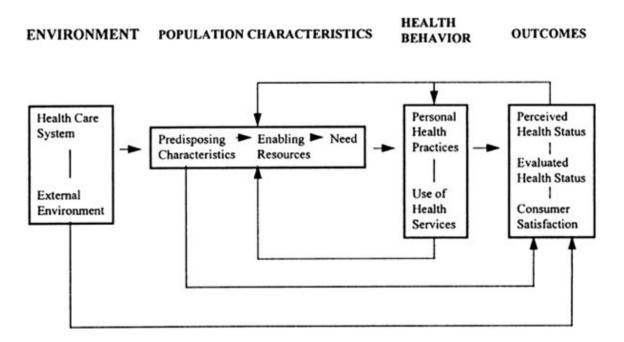


Figure 2 - Andersen socio-behavioural model

Predisposing factors include the socio-demographic characteristics, need factors are the patient health related factors such as comorbidities and enabling factors includes the cost of health services (Roberts, Esponda, Krupchanka, Shidhaye, Patel & Rathod, 2018).

2.3 Relevance of the Theoretical framework to the study

The ODSF can assist medical practitioners in assessing patients' decision-making requirements, provide custom designed decision support and evaluate the impacts of their treatment interventions (Doull *et al*, 2006). Various PtDA which are condition specific can be formulated using the Ottawa Decision Support Framework and these can

be practitioner administered or client self-administered (O'Connor, Jacobsen, & Stacey, 2002). The Andersen's socio-behavioural model assists in understanding the determinants of health care service use (Shewamene, Dune & Smith, 2020) and thus aids in design of a context specific PtDA.

2.3.1 Patient decision aid contents

A patient decision aid (PtDA) is defined as a tool that is designed to help clients during decision making by providing information regarding possible benefits and harms of a particular treatment option (Stacey *et al.* 2017). According to 2009 NICE guidelines, during care a medical practitioner must appreciate patient autonomy and accept decisions they make regarding their preferred treatment options (Horne, Cooper, Wileman, & Chan, 2019).

In order for clinicians to develop a relevant patient decision aid, it is critical to understand the trends in decision making about a particular treatment and factors influencing the choices (Ng, Mathers, Bradley & Colwell, 2014). Therefore, the contents of a PtDA is dependent on the context in which it is developed.

2.3.2 CTM use amongst hypertensive

Hypertension has been shown to contribute 4.5% to the global burden of disease and most patients have been shown to use CAM to manage it. However, there are variations in recorded prevalence of Complementary and Alternative Medicine (CAM) use across countries (Asfaw & Basazn, 2016).

In the United States of America (USA), a cross sectional survey of participants of the National Health Interview survey study was carried out by the Center for Disease Control (CDC) in 2012 (Mbizo *et al*, 2018). From the results, 29.5% of those surveyed

reported that they use of CATM and 28.3% of clients with hypertension used CATM. During a study by Ibrahim, Hassali, Saleem & Al Tukmagi (2016) done in Baghdad the capital city of Iraq, 73.3% of those interviewed reported that they used complementary and alternative medicine to control their blood pressure.

The rates of CATM medicine use in Africa have been reported by the World Health Organisation to be high (WHO, 2013). James, Wardle, Steel & Adams (2018) conducted a study on Traditional and Complementary Alternative Medicine (TCAM) use in SSA and prevalence in the general population averaged 58.2% and in patients with hypertension the range of TCAM use was between 19.5% and 67.8%. The prevalence of complementary traditional medicine use in SSA was recorded as 54.9%.

At the two teaching hospitals in Ghana, the prevalence of CATM use was recorded as 19.5% (Kretchy, Owusu-Daaku & Danquah., 2014). A study was carried out by Ayele, Tegegn, Haile, and Belachew, Mersha & Erku (2017) which looked at CATM use among elderly patients with chronic diseases at a teaching hospital in Ethiopia and showed that 74% of the elderly with chronic diseases used CATM. Asfaw & Basazn (2016) did a study in Gondar Ethiopia at a referral hospital and they recorded 67.8% prevalence of CATM use in hypertensive patients. Of the CATM users in the above study, 75.3% utilised traditional medicine together with conventional medicine.

In Capetown South Africa, 37.1% of patients with chronic diseases used concurrently traditional herbal medicine (THM) and prescription medicine and this was seen most in hypertensive patients (Hughes, Aboyade, Beauclair, Mbamalu & Puoane, 2015). In Zimbabwe there are limited studies looking at CAM use both in the general population and in patients with hypertension. One study in Zimbabwe was done by Chingwaru &

Vidmar (2016) and they demonstrated a 60% prevalence of CTM use in the general population in Bindura Zimbabwe.

2.3.3 The determinants of CTM use in hypertensive patients

The use of Complementary and Alternative Traditional Medicine (CATM) reflects the local values of individuals and the socio-religious makeup of a society (Kretchy, Owusu-Daaku & Danquah, 2014). Therefore, determinants of CTM use are influenced by the social, cultural, religious and economic environments of individuals.

Relative cost of CTM

The cost of antihypertensive medication and that of CTM modalities influences the uptake of CTM in blood pressure management. The high costs associated with the purchase of hypertensive drugs was shown to influence decision to use CTM in patients with high blood pressures (Kretchy, Owusu-Daaku & Danquah, 2014). In a study to evaluate patients' knowledge, attitudes and perceptions of hypertension patients regarding CTM benefits as well as rate of disclosure to health workers at Al-Karama Hospital in Iraq's capital city of Baghdad, one of the most common factors cited as influencing decision to use CTM was its low cost (Ibrahim, Hassali, Saleem, & Al Tukmagi, 2016). According to James, Wardle, Steel & Adams (2018), cost of TCAM was a factor that influenced use of TCAM.

Socio-demographic characteristics

The issue of CTM being relatively cheap may likely explain the higher uptake of CTM in individuals from low socio-economic environments. The socio-demographic characteristics of individuals who used TCAM in hypertension were those of low socioeconomic status and those from rural areas (James, Wardle, Steel & Adams, 2018).

Those with higher education levels were shown to be 44% less likely to use THM (Hughes, Aboyade, Beauclair, Mbamalu & Puoane, 2015). The odds of a patient using complementary and alternative traditional medicine was shown to be 2.9 times more in the rural population than in urban populations (Aljawadi, Khoja, AlOtaibi, Alharbi, Alodayni, AlMetwazi, & Khoja, 2020).

On gender there is conflicting evidence regarding which sex predominantly uses CTM. Socio-demographic characteristics of individuals who used TCAM in the management of hypertension were males (James, Wardle, Steel & Adams, 2018) but according to an article by Mbizo *et al* (2018) females were more likely to use complementary traditional medicine than males.

There was no relationship demonstrated between education, marital status and employment status with use of THM (Hughes, Aboyade, Beauclair, Mbamalu & Puoane, 2015). Local traditions and religious beliefs were also identified as influencing the decision to use CTM (Ibrahim, Hassali, Saleem, & Al Tukmagi, 2016).

Health related factors

Health service related issues and disease related factors influence decision to use CTM in patients with hypertension.

Safety of medication plays an important role in influencing decision to utilise complementary traditional medicine and in an article by Kretchy, Owusu-Daaku & Danquah (2014), a history of side effects from anti-hypertensive medication influenced the decision to use CATM. Respondents from a study in Bindura highlighted that they opted for CTM because they perceived it to be safer than conventional drugs

(Chingwaru & Vidmar, 2016). This view was also highlighted by study participants who used CTM in a study by Ibrahim, Hassali, Saleem, & Al Tukmagi (2016).

Disenchantment with conventional health services may influence decision to utilise CTM and this was highlighted by Ayele, Tegegn, Haile, Belachew, Mersha & Erku (2017) were respondents noted that one of the factors that influenced their decision to use CATM was lack of satisfaction with conventional medicine as well as the perceived effectiveness of CATM in disease control. A lack of satisfaction with conventional health services emanates from easy accessibility of TCAM and the unavailability of conventional drugs plus difficulty in accessing health care services (James, Wardle, Steel & Adams, 2018). Respondents in Bindura viewed that CTM service providers offered better services than conventional medicine service providers and this influenced decision to use CTM (Chingwaru & Vidmar, 2016).

Complications associated with hypertension and presence of another disease may influence the decision to take up CTM. The presence of comorbidity was shown to be associated with use of CATM in hypertensive patients (Ayele, Tegegn, Haile, Belachew, Mersha & Erku, 2017). The above observation tallied with results of a study by Mbizo *et al* (2018) which showed that patients with hypertension, Diabetes mellitus (DM) and obesity had higher rates of CATM use. Presence of a disease complication in hypertension such as a stroke was a determinant for CAM use (Asfaw & Basazn, 2016).

2.3.4 CTM practices in patients with hypertension

The general public utilizes CTM as part of their health choices and there is a need to integrate CTM into mainstream healthcare so as to ensure safe use which is effective. It is therefore critical to understand how, why, when and how people utilise CTM to control hypertension (WHO, 2013).

The most common TCAM used in Africa was biological based for example herbal medicines (James, Wardle, Steel & Adams, 2018). In Ethiopia the commonest CATM method which was being used was herbal medicine at 50.4% (Ayele, Tegegn, Haile, Belachew, Mersha & Erku, 2017). Most common CATM used in Saudi Arabia was herbal products at 25.4% (Aljawadi, M. H., Khoja, A. T., AlOtaibi, A. D., Alharbi, K. T., Alodayni, M. A., AlMetwazi, M. S., & Khoja, T. A., 2020). In study carried out by Hughes, Aboyade, Beauclair, Mbamalu & Puoane, (2015), the major source of herbal medicines was the local herbal market which was followed by personal backyard gardens.

Disclosure rates are low and this has been attributed to various reasons in different publications. Results from a study by Kretchy, Owusu-Daaku & Danquah (2014) showed that 70% of study participants did not disclose to health professionals that they use CATM and this was attributed to a fear of the reaction by health workers and that they were not asked about it during consultation. In another study, 83% of TCAM users did not disclose use to health workers. The reasons that were offered for non-disclosure were the negative attitudes by health workers towards TCAM and their lack of understanding regarding TCAM use (James, Wardle, Steel & Adams, 2018). According to Asfaw & Basazn (2016), amongst the users of CATM, as much as 70.2% highlighted that they did not disclose use to health workers.

2.4 Conclusion

The various studies in literature have shown that the prevalence of CTM use in hypertensive patients varies across countries and the determinants influencing its use varies between studies. The common finding in all studies is that disclosure rates are higher.

CHAPTER 3 RESEARCH METHODOLOGY

3.1 Introduction

The following chapter looks at the research methodology of the study, which includes the research design, research site, sample and data-collection instrument. In this chapter, information on study participants, including inclusion criteria into the study and how participant sampling was done. Research design used is described and the methods that were used in analysing the data are also described in this chapter.

3.2 The Research Design

Research design can be described as the overall plan for data collection and analysis carried out in a manner that is relevant to the research objectives (Akhtar, 2016). This was an analytic cross sectional study and it offers the advantage that it is relatively cheap, easy to conduct and offers valuable information on CTM use in hypertensive patients treated at Red Cross Clinic (Aggarwal & Ranganathan, 2019). The objectives of the study were to describe and identify the prevalence of CTM use in hypertension, the determinants of CTM and the patterns of CTM use in patients with hypertension.

During the study the researcher was measuring the outcome of interest which is the use of CTM in hypertensive patients and the exposures at the same time. The exposures that were evaluated are the determinants of CTM use which are socio-demographic characteristics, health related factors and the cost of healthcare. Cross sectional studies offer the advantage of being relatively inexpensive and findings can be useful for public health planning (Levin, 2006).

3.3 Population and Sampling

The study population is defined as a group of individuals with similar characteristics who are the focus of the evaluation (Hu 2014). The study population were adult hypertension patients who were being treated at the Red Cross Clinic in Harare. Study participants that were included in the research were patients diagnosed with hypertension and on at least one antihypertensive drug, who were 18 years and above. Pregnant women and newly diagnosed hypertension patients were excluded from the study. Pregnant women were excluded from the study due to ethical reasons associated with potential risk to the fetus. Newly diagnosed hypertension patients

were also excluded because they were less likely to have commenced either conventional medicine or CTM.

Convenience non-random sampling was utilised for the study sample because it held the advantage of easy accessibility of study participants at a particular point in time and was relatively simple to carry out (Taherdoost, 2016). The study participants were selected consecutively (consecutive consenting participants) from hypertension patients who presented at Red Cross Clinic for treatment.

The minimum sample size for the study was determined by using the prevalence of hypertension according to 2005 ZimStepwise survey (23.2%) and a confidence interval of 95% (Kretchy, Owusu-Daaku, & Danquah, 2014). The Cochrane formula,

 $n = Z^2 \frac{p(1-p)}{e^2}$, at 5% sampling error was used to determine the sample size (Kasiulevičius, Šapoka, & Filipavičiūtė, 2006). The minimum sample for this study was calculated as 274.

Maximum sample was calculated as follows, $274 \div Rr$ where 274 is minimum sample size calculated above and Rr is response rate. According to literature, response rates for interviewer administered questionnaire was between 70% and 80% (Wagenaar, 2005). For the study we assumed 75% as the response rate and thus a maximum sample size of 365. For the purposes of the study a sample size of 300 participants was chosen based on the average number of patients seen per month at the clinic.

For the purposes of this study, a review panel of 15 key informants with five expert health care professionals and ten hypertensive patients who were already using CTM to control hypertension (O'Connor & Jacobsen, 2003) were used and these were

purposively sampled. The purpose of the review panel was to establish acceptability of the patient decision aid that was developed.

3.4 Data collection instruments

A structured questionnaire was used to collect data and it is defined as a data collection tool with predetermined answers for respondents to choose from (Harris, & Brown, 2010) and this was an interviewer administered questionnaire. The questionnaire was administered by nurses acting as research assistants and they were trained by the researcher.

A systematic review of the literature was carried out to identify all the necessary information which needs to be incorporated into the CTM-hypertensive patient decision aid and identify effects of the identified CTM methods on blood pressure control as well as associated adverse effects (Ng, Mathers, Bradley & Colwell, 2014). The PtDA for this study contains information on options available to the patient which are CTM and conventional drugs, adverse effects of each option and need for communication with health workers (O'Connor & Jacobsen, 2003).

The PtDA developed was subjected to a review by health care practitioners and hypertensive patients (Dowding, Swanson, Bland, Thomson, Mair, Morrison & Niven, 2004). The review of the acceptability of the PtDA was done through an interviewer administered questionnaire developed from the Ottawa review tool (O'Connor & Jacobsen, 2003).

3.5 Pretest

A pilot study is defined as a study preceding the main study with a small sample or pretesting of data collection tools (Connelly, 2008). One of the objectives was to

evaluate the adequacy of the data collection tools and training of research assistants (Connelly, 2008). The pilot study also enabled the researcher to test for reliability of the questionnaire (Bolarinwa, 2020).

Reliability is defined as the degree to which a data collecting tool results can be replicated (Mohajan, 2017). The site for the pilot study was at Red Cross Clinic in Harare. The sample size for the pretesting of the questionnaires was 10% of study sample size (Hertzog, 2008), that is 30 participants. The pilot allowed researcher to clarify issues of consent and also correct numbering on question 17 as option 3 was captured as question 18.

3.6 Analysis and Organisation of Data

Data that was collected for the purposes of this study was kept by the researcher in a locked file cabinet and only the researcher had access to the data. The data was coded and entered into excel and analysis was done using Statistical Package for the Social Sciences (SPSS) version 17. Primary data collected was entered into SPSS from coded data in excel for analysis and generating of descriptive statistics. Categorical data was analysed and described using proportions whereas continuous data was described using medians. Regression analysis was utilised in assessing the determinants of CTM use in different groups of patients with hypertension.

3.7 Ethical Considerations

Approval from the Zimbabwe Red Cross Society (ZRCS) senior management was sought and approval granted by the Operations Director. University approval was sought through Africa University Research, Ethics Committee (AUREC). Informed consent is a critical component of the research process (Cho, Magnus & Wilfond, 2015) and it was sought from participants by administering a written consent form to each identified

participant and they were notified that they were free to withdraw at any time from participation without penalty.

Consent forms were designed both in English and Shona to cater for non-English speaking individuals. To cater for the illiterate, the consent form was read out to them and explained by research assistants after which the participants were asked to consent through using a thumb print or an X. Confidentiality of participants was ensured to guarantee safety and anonymity of study participants (Surmiak, 2018) through use of a separate interview room. No names were put on the questionnaires and responses together with informed consent forms were locked and stored away for safe keeping.

All participants in the study were subjected to Covid-19 screening upon entry into the clinic as was done for every client. The screening included a temperature check and a brief history to identify potential cases. All participants were only allowed to enter with a face mask on. The research assistants, were also subjected to a temperature check daily and those with suspected symptoms of Covid-19 would get a Covid-19 antigen test as per company policy and were not allowed to interact with participants until medically cleared. Hand washing and sanitization facilities were provided at the clinic.

3.8 Information dissemination plan

The researcher produced hard and soft copies which may be accessed by students and researchers at the Africa University library. A presentation of the findings on the review of the PtDA was shared with ZRCS Clinic Director and staff. Other platforms that the researcher utilised to disseminate data to healthcare practitioners are platforms organised by Zimbabwe Medical Association.

Reporting results of a study is a key ethical component of a research. Two systems were put in place to ensure that those who would want the results of the study would access them. The researcher's Whatsapp number was provided to all study participants for follow up on results. Participants who may want access to results of the study were asked to leave their phone numbers and notifications would be sent when results were available both as softcopies and as hardcopies at the Red Cross clinic. The results summary sheet for patients was short and written in layman's language. Participants were informed that the results will be available after completion of the researcher's study at most beginning of January 2022.

3.9 Conclusion

This analytic cross sectional research study led to the development of a patient decision aid by identifying determinants of CTM and the practices in the context of patients with hypertension being managed at Red Cross Clinic.

CHAPTER 4 DATA PRESENTATION AND ANALYSIS

4.1 Introduction

The chapter details the results and presentation of the study results. Three hundred participants were involved in the study however, 18 responses were omitted in the data analysis procedure due to the fact that they were considered invalid as they did not have corresponding signed consent forms. All questionnaires were manually coded, data entered into excel and was analysed in SPSS.

4.2 Data presentation and analysis

4.2.1 Sociodemographic data

The majority of respondents were female 192(70.0%) compared to males 84(30.0%). The age group that had the highest frequency was those above 50 years with 47% and the one with the least frequency was the 18 to 30 age group at 9% of the respondents. Seventy-six percent 212(76.0%) of the respondents resided in urban areas, with 68(24.0%) residing in rural areas. One hundred and twenty-nine (47.0%) of the respondents were educated up to tertiary level, whilst 71(26.0%) up to primary level and 74(27.0%) up to secondary level. The total number of responses varied due to non-response on some of the questions. Table 1 below highlights the various demographic characteristics in relation to CTM usage for BP control;

Table 1 - Socio-demographic characteristics and CTM use

	Traditional_medic to control hypert	_
	No (%)	Yes (%)
Age		
18-30 years	4(1.42)	20(7.12)
31-40 years	33(11.74)	29(10.32)
41-50	24(8.54)	40(14.23)
Above 50	43(15.30)	88(31.32)
Sex		
Male	31(11.23)	53(19.20)
Female	70(25.36)	122(44.53)
Education_level		
Primary	33(12.04)	38(13.87)
Secondary	27(9.85)	47(17.15)
Tertiary	41(14.96)	88(32.12)
Employment_status		
Unemployed	42(15.11)	74(26.62)
Self-employed	23(8.27)	44(15.83)
Formally-employed	39(14.03)	56(20.14)
Place_of_residence		
Urban	81(28.93)	131(46.76)
Rural	23(8.21)	45(16.07)

4.2.2 Blood pressure control

Blood pressures for each of the respondents was measured as part of the questionnaire and table 2 highlights the findings;

Table 2 - Mean BP recordings

Group Statistics

	Traditional_medicine_t o_control_hypertension	N	Mean	Std. Deviation	Std. Error Mean
Systolic BP	Yes No	176 104			
Diastolic BP	Yes No	176 104			

The mean systolic blood pressure (sBP) for those using CTM was 162mmHg with standard deviation of 18.344 and the mean diastolic blood pressure (dBP) was 102mmHg, with a standard deviation of 69.330. Whereas the mean sBP for those who do not use CTM was 161mmHg and the dBP was 97mmHg. The mean pressures recorded were tested to evaluate if there was any significant difference in the blood pressures for the two populations, an independent T-test was done at 95% confidence level as shown;

H0: $\mu 1 = \mu 2$ ("the two population means are equal")

H1: $\mu 1 \neq \mu 2$ ("the two population means are not equal")

Table 3 - Independent T-test for differences in the mean

Independent Samples Test

		Levene's T Equality of V					t-test for Equalit	y of Means		
			P-					Std. Error		ence Interval of fference
		F	value	Т	Df	p-value	Mean Difference	Difference	Lower	Upper
Systolic BP	Equal variances assumed	2	6 .105	.3	278	.744	.854	2.612	-4.288	5.997
	Equal variances not assumed			.3	168.175	.763	.854	2.827	-4.727	6.436
Diastolic BP	Equal variances assumed		5 .502	.8	278	.417	5.59659	6.88017	-7.94726	19.14044
	Equal variances not assumed			1.0	197.162	.301	5.59659	5.39381	-5.04037	16.23356

The results in table 3 above indicate that all the p-values (0.744, 0.763, 0.417 and 0.301) are above alpha (0.05) and therefore, there is no significant difference in the mean blood pressures between those who use CTM and those who do not use CTM.

4.2.3 CTM use amongst hypertensive patients treated at Red Cross clinic

Out of the 282 respondents, 63.1% of the respondents indicated that they utilised complementary alternative traditional medicine for the control of hypertension whilst 36.9% did not use CTM.

4.2.4 The determinants of CTM use in hypertensive patients treated at Red Cross Clinic

Forward Selection (Conditional) was utilised and it is a stepwise variable selection procedure were variables are sequentially entered into the model. The variable considered for entry into the equation is the one with the largest significance of the score statistic. This variable is entered into the equation only if it satisfies the criterion for entry. If the first variable is entered, the independent variable not in the equation that has the largest significance of the score statistic is considered next. The procedure stops when there are no variables that meet the entry criterion.

From the Omnibus Tests of model Coefficients, all steps in the forward stepwise logistic regression the p-value were less than 0.0001 (<0.05) and thus the model was significant at all steps of the model. Using the Forward Stepwise (conditional) as can be seen from the table 3 below; at step 1, one variable that is question 15 found to be statistically significant at 5% significant level, and as at the second step another variable was added

and at the fourth which is the step which was performed, four variables were found to be statistically significant as shown in table 4 below:

Table 4 - Stepwise selection for significant variables

Variables in the Equation

		В	S.E.	Wald	Df	Sig.	Exp(B)
Step 1 ^a							
	CTM_is cheaper_than_conventio nal_medicine	4.140	.503	67.679	1	.000	62.800
	Constant	-2.549	.464	30.143	1	.000	.078
Step 2 ^b							
	CTM_is_safer_than_con ventional_medication	3.859	.756	26.092	1	.000	47.435
	CTM_cheaper_than_con ventional_medicine	3.033	.542	31.341	1	.000	20.762
	Constant	-2.710	.491	30.413	1	.000	.067
Step 3°							
	Cormobid conditions	620	.230	7.258	1	.007	.538
	CTM_is_safer_than_con ventional_medication	3.947	.761	26.871	1	.000	51.775
	CTM_cheaper_than_con ventional_medicine	2.935	.560	27.525	1	.000	18.830
	Constant	-2.150	.528	16.604	1	.000	.117
Step 4 ^d							
	Place_of_residence	1.264	.590	4.589	1	.032	3.541
	Cormobid conditions	637	.235	7.350	1	.007	.529
	CTM_is_safer_than_con ventional_medication	3.868	.763	25.713	1	.000	47.841
	CTM_cheaper_than_con ventional_medicine	3.175	.607	27.394	1	.000	23.932
	Constant	-3.846	1.011	14.470	1	.000	.021

A logistic regression model allows us to establish a relationship between a binary outcome variable and a group of predictor variables and for this study the model is highlighted below;

$$\operatorname{Log}\left(\frac{p}{1-p}\right) = -3.846 +$$

1.26 place of residence – 0.637 cormorbid conditions + 3.686 CTM safety + 3.175 CTM cost

4.2.5 CTM practices in patients with hypertension treated at Red Cross Clinic

The majority of clients who utilise CTM at Red Cross clinic (78.7%) notify their health service provider of their CTM use. Of those that do not disclose their CTM use, a majority 23(60.5%) highlighted that the reason is that health workers do not actively ask clients, the remainder 15(39.5%) do not disclose due to the fear of being reprimanded by health workers. Of those participants who use CTM, 98.3% (175) utilise herbal products for BP control, 17.4% use exercise, 14.6% use body, mind and 1.1% use manipulation methods. A majority acquire their herbal products from backyard garden (68.0%) and local market place (67.4%).

4.2.6 CTM use patient decision aid

4.2.6.1 Development of the PtDA

We carried out a comprehensive review of the literature using suitable keywords such as 'hypertension', 'complementary and alternative traditional medicines', 'benefits', 'adverse events' and 'herbal' on the search engines of PubMed, BMJ, Google Scholar and Research Gate in the month of July and August 2020 during the current COVID-19 pandemic and assessed mortality data. The decision aid was developed from information found from 16 articles. Antihypertensive medication that was searched against was the ones that patients responded as using and these were grouped into drug classes for

searching literature. The herbal drugs used to develop the PtDA are some of the most common used by hypertensive patients as specified in literature. Part of the patient decision aid that was designed is shown below;

PURPOSE

The purpose of the aid is to promote informed decision making by providing research data on CTM.

ADVICE TO THE PATIENT

- <u>I.</u> Though some anti-hypertensive effects have been demonstrated, it is worth noting that there remains need for more robust research (Randomised control studies) for longer duration.
- <u>II.</u> Some of the CTM modalities have been shown to have adverse effects and absence of safety profile does not imply absence of side effects but rather lack of research.
- <u>III.</u> Effective safe doses have not been well established for most CTM and some have been shown to interact with antihypertensive drugs.
- IV. For the patient's safety it is important that use of CTM is notified to the doctor/nurse.
- V. The patient should regularly monitor and record BPs at home and take note of any potential side effects of CTM.

Who is the decision aid meant for?

> Hypertensive patients who are using CTM or contemplating the use of CTM.

Figure 3 - Part of the designed PtDA

4.2.6.2 Evaluation of the PtDA

The PtDA was reviewed by both health practitioners and hypertensive patients seen at Red Cross Clinic.

Patient review results

For the review, 10 clients participated by answering questions through as questionnaire. Seventy percent (70%) of the clients who reviewed the PtDA, rated the information on the benefits of CTM as good whilst 20% felt it was fair and 10% as excellent. Majority of the clients, 60% felt the information on side effects was good. On the information

regarding evidence about CTM, 50% were of the opinion that the evidence was good, whereas 10% highlighted the evidence was poor.

The majority (90%) of respondents felt the length of the decision aid was just right and 10% highlighted it was too short. On the amount of information provided, 80% felt the information was just right, whilst 20% were of the opinion the information was too little. 60% of the clients felt that the presentation was balance and 40% felt it was slightly balanced. All of the clients (100%) highlighted that the aid makes decision making about hypertension management easier.

With regards to opinion of what the best feature of the PtDA, 50% felt the PtDA was easy and precise, 40% felt the table on herbs was best feature as people use herbs without full understanding of effects and 10% did not offer a response. The clients were asked on way to improve the decision aid and their responses were as follows: 20% felt more information should have been provided on side effects, 30% highlighted the need to translate into other languages, 40% had no suggestions for improvement and 10% felt there was a need for health education of patients with hypertension on CTM.

Practitioner review

Five practitioners were chosen for participation and their fields of practice are as follows; General Practitioner from Red Cross, Pharmacists, Urologist and two Primary care practitioners. The majority (60%) of practitioners interviewed felt the best feature of the PtDA was tables on effects of CTM on BP and conventional drugs. Ten percent (10%) highlighted that the provision of a list of references was the best feature. Regarding recommendations, 40% were of the opinion that more information was needed on conventional medicine for balance. One of the respondents highlighted the need to add doses and frequency of herbal medicines highlighted. The remainder 40% were of the opinion that more needs to be done in raising public awareness.

All of the respondents (100%) felt the PtDA was easy to use. Sixty percent of the respondents were of the opinion that the strategy of using a PtDA is better at helping patients make decisions on CTM whereas 40% were neutral in their opinion. All the practitioners agreed or strongly agreed that use PtDA was a cost effective way of helping patients make decisions. Sixty percent were neutral and 40% disagreed with the notion that use of the PtDA may cause/result in more benefit than harm. A majority (60%) felt the strategy would complement their daily work.

4.3 Discussion and interpretation

4.3.1 Blood pressure control

Analysis of the results through an independent t-test showed that there was no significant difference in the mean blood pressures between those who use CTM and those who do not use CTM.

4.3.2 Determinants of complementary traditional medicine use

In the stepwise regression variable 15 was the strongest predictor of CTM use with p-value <0.0001 and was used in step one. The model continuously added variables 14, 10 and 8 as they also significantly affected model fit. Model terminated at step four because other variables were not significant predictors of CTM use. Therefore according to the analysis, cost of conventional medicine, perceived safety, presence of a chronic disease and place of residence significantly influenced decision to use CTM.

Results of the study show that those who felt that CTM was cheaper than conventional medicine were 23.9 times likely to use CTM than those who felt it was expensive and this was significant with p-value <0.0001. The odds of using CTM was 47.8 times higher in those who felt CTM was safer than conventional medicine as compared to those who felt it was not safe and this was significant with p-value <0.0001. The

analysis highlighted that use of CTM was 0.54 times less likely in those who had other chronic diseases (co-morbidities) than in those who had no co-morbidities and was statistically significant with p-value <0.007. The odds of using CTM was 3.54 times higher in those who reside in rural areas when compared to those in urban areas, though there was no significant difference with p-value of 0.32.

4.3.3 Patient Decision Aid review

The key findings are that clients (100%) felt that the decision aid assisted them in decision making concerning BP control. There we concerns raised by patients that the PtDA needed to be translated into local languages. Practitioners agreed with notion that the decision aid was good at aiding patient decision making, and majority disagreed with the statement that the PtDA may cause more benefit than harm.

4.4 Summary

The study results of the study show that 63.1% of Red Cross clients with hypertension have used CTM for BP control with majority (78.7%) using herbal remedies. There were four factors identified in the study that influence use of CTM and these are cost of CTM, perceived safety of CTM, presence of comorbidities and a resident in the rural areas. However, place of residence did not have a statistically significant association with use of CTM.

CHAPTER 5 SUMMARY, CONCLUSIONS AND RECOMMENDATIONS

5.1 Introduction

In this chapter, the researcher provides a summary of the main study findings and relating them to previous literature findings. The researcher also identifies limitations of the study and makes recommendations to the medical practice, health training and

regulatory authorities in Zimbabwe. The discussion on the research will be outlined according to the study objectives.

5.2 Discussion

5.2.1 The usage of CTM by hypertensive patients treated at Red Cross clinic

According to the results of this study, 63.1% of the respondents seen at Red Cross Clinic use complementary alternative traditional medicine for the control of hypertension. These findings are consistent with other studies done prior. Chingwaru & Vidmar (2016) demonstrated that 60% of the general population in Bindura Zimbabwe use CTM. In another study done by James, Wardle, Steel & Adams (2018) on TCAM use in SSA showed the prevalence of TCAM use was between 19.5% and 67.8% in patients with hypertension. Statistically there was no difference in BP control between those who use CTM and those who do not use CTM.

5.2.2 The determinants of CTM use in hypertensive patients treated at Red Cross Clinic

In literature there have been varying factors identified that influence the use of CTM for disease control. Findings from this study show that the cost of conventional medicines, perceived safety of CTM and place of residence significantly influenced decision to use CTM. Being from the rural population influenced the use of CTM though not significant and results are similar to those by Aljawadi *et al* (2020) showing a 2.9 times odds of using CTM in the rural population.

A study by Mbizo *et al* (2018) had similar results which showed that patients with hypertension, Diabetes mellitus (DM) and obesity had higher rates of CATM use but in this study, the findings were that presence of co-morbid conditions led to lower rates of CTM use. In this study there was no link between education, marital status and

employment status with use of CTM and these findings are similar to a study by Hughes, Aboyade, Beauclair, Mbamalu & Puoane (2015).

5.2.3 CTM practices in patients with hypertension treated at Red Cross Clinic Some of the findings of this study are similar with other studies, whilst some are in conflict with some in literature. Majority of clients who utilise CTM at Red Cross clinic (78.7%) disclose CTM use. However, results from a study by Kretchy, Owusu-Daaku & Danquah (2014) showed that 70% of study participants did not disclose to health professionals that they use CATM.

Of those that do not disclose their CTM use, 15(39.5%) do not disclose due to the fear of being reprimanded by health workers and this was one of reasons offered in a study in Sub-Saharan Africa by James, Wardle, Steel & Adams (2018). A majority in the study who used CTM utilise herbal products for BP control and these findings are similar to those in literature. In study carried out by Hughes, Aboyade, Beauclair, Mbamalu & Puoane, (2015), the major source of herbal medicines was the local herbal markets and personal backyard gardens. The researcher's study had similar results as a majority acquired their herbal products from backyard garden and local market place.

5.2.4 Patient decision aid for hypertensive patients utilising CTM at Red Cross Clinic The key findings is that all participants felt that the decision aid was key in assisting them in decision making and this is similar to previous studies that highlight the benefits of decisions aids for patients. Practitioners agreed with notion that the decision aid was good at aiding patient decision making, however a majority felt currently it may cause more harm than good and there is need for further development and patient education.

5.3 Study Conclusions

The study has shown that a majority of hypertensive patients seen at Red Cross Clinic utilised complementary traditional medicine use with the CTM of choice being herbal medicines. The main determinants of CTM use were health factors such as cost of CTM and perceived safety of CTM modalities. The PtDA designed was generally accepted by both patients and health practitioners, however respondents highlighted need for its further development and public education of CTM use.

5.4 Implications of the study

The results of the study have shown that a majority of clients at Red Cross Clinic (63.1%) use CTM to control BP and thus there is need for regulatory authorities in the country to move in and ensure the safety of the population. For doctors practicing at Red Cross clinic, the study highlights the need to actively seek information on whether clients use CTM as this has a bearing on BP control as well as potential life threatening adverse effects.

5.5 Recommendations

- Develop guiding regulations/Regulation of street vendors and some herbal shops selling herbal medicines by the Medicines Control Authority of Zimbabwe MCAZ.
- ii. Health education by MCAZ and MoHCC on the use of alternative complementary traditional medicine.
- iii. Introduction on CTM courses in universities and colleges for health professionals undergoing training by MoHCC and Ministry of higher and tertiary education.

5.6 Suggestions for further research

The following are areas the researcher suggests as further research areas:

- I. Study on whether there is a difference in BP between those using CTM and those not using CTM in a randomized control study.
- II. To find out the effectiveness of the PtDA on CTM in decision making about hypertension control and whether it improves control of BP.

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APPENDICES

Appendix A: Patient Decision Aid for Patients

PATIENT DECISION AID TOOL - COMPLEMENTARY TRADITIONAL

MEDICINE (CTM) IN HYPERTENSION

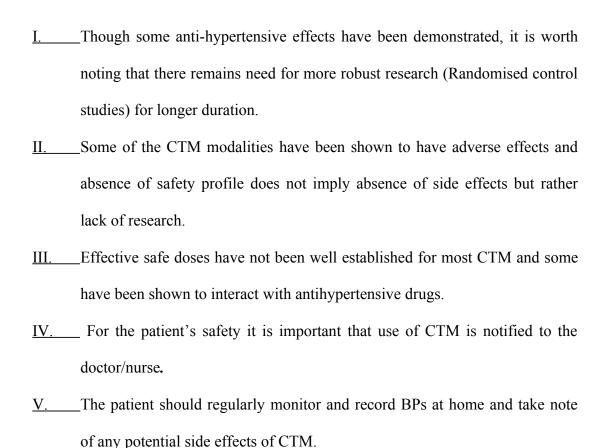
CTM is defined as any form of treatments for example herbs that are not western (conventional) medication and these are used together with conventional medicines to treat diseases. Some studies have shown effectiveness of CTM in lowering BP however, the evidence is limited regards to their effectiveness, efficacy and safety. Some herbal

drugs have been shown to have serious side effects such as kidney and liver failure. It is therefore important to notify health workers if you use CTM because non-disclosure poses risk of unsafe use and ineffective control of hypertension.

PURPOSE

The purpose of the aid is to promote informed decision making by providing research data on CTM.

ADVICE TO THE PATIENT



Who is the decision aid meant for?

➤ Hypertensive patients who are using CTM or contemplating the use of CTM.

CTM AND BP MEDICATION

The table below shows CTM methods that have been shown to have effects on lowering BP and their potential side effects as illustrated in literature:

TABLE 1 – CTM on BP and their side effects

CTM	Effects on BP	Potential side effects		
Coriander – seed	Lowers BP by dilating	Allergic reactions, nay		
powder, leaves	blood vessels, diuresis	damage liver function		
	(no clinical trials)			
Sweet lemon – fruit	Lowers BP	Allergic dermatitis,		
		discolouration of teeth,		
		contraindicated in		
		pregnancy		
Garlic (Allium sativum)	Lowers BP by causing	Gastritis, Antithrombotic		
	relaxation of vascular	effects,		
	smooth muscle	Allergic dermatitis		
Marula – stem bark	Lowers BP by relaxing			
	blood vessels			
Sweet prickly pear -	Lowers BP			
leaves				
Avocado – leaves	Lowers BP			
Transcendental	Lowers BP through			
meditation (strong	mind and body			
evidence)	relaxation			
Vitamin C (strong	Lowers BP by diuresis,			
evidence)	dilation of blood vessels			

Beetroot juice (strong	Lowers BP by dilating	Potential to cause cancers	
evidence)	blood vessels	(limited evidence)	
Yoga (weak evidence)	Lowers BP		
Ginger	Lowers BP (No	Heartburn, diarrhea,	
	significant evidence)	arrhythmia(in animals)	
Black jack (Bidens pilosa	Lowers BP (No clinical	No studies in humans on	
L)-leaves	trials)	side effects available	
		(toxicity in rats observed)	

Table 2 below shows drugs that are affected by certain CTM drugs;

TABLE 2 – CTM/DRUG INTERACTIONS

CTM	Conventional Drug interactions
Ginko leaf tablet	Amlodipine
Rosella	НСТ
St John's Wort	Reduced effect on some antihypertensives (calcium
	channel blockers e.g Nifedipine)
Ginseng and licorice	Affect diuretics (eg HCT, indapamide)
Ginger	Potentiate antiplatelet effects of nifedipine
Garlic	Warfarin – increase risk of bleeding
Black jack	No known interactions (no studies)

NB: FOR SAFE AND EEFECTIVE USE OF T IS ADVISED THAT YOU NOTIFY

YOUR TREATING HEALTH WORKER IF YOU PLAN ON OR ARE ALREADY

USING CTM!!!!!!

For further reading please see articles below;

- Talha, J., Priyanka, M., & Akanksha, A. (2011). Hypertension and herbal plants. *Int Res J Pharm*, 2(8), 26-30.
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Appendix B – Patient Decision Aid for Physicians

COMPLEMENTARY TRADITIONAL MEDICINE (CTM) IN HYPERTENSION

PATIENT DECISION AID TOOL

INTRODUCTION

CTM is defined as any form of treatments for example herbs that are not western (conventional) medication and these are used together with conventional medicines to treat diseases (*World Health Organization*, 2019). Though they are widely utilised, there

is limited evidence regards to their effectiveness and some have been shown to have serious side effects such as kidney failure (*Yang et al., 2018*). Majority of patients with hypertension use complementary traditional medicine but do not disclose to treating medical practitioners, which poses a risk of unsafe use and ineffective control of hypertension. Currently in Zimbabwe there are no regulatory guidelines on use of CTM in hypertension as is the case in some countries like China which has successfully integrated traditional medicine and conventional medicine.

PURPOSE

The purpose of the aid is to promote informed decision making by providing research data on traditional medication. Though some anti-hypertensive effects have been demonstrated, it is worth noting that there remains need for more robust research (Randomised control studies) for longer durations (*Talha, Priyanka & Akanksha, 2011*). Some of the CTM modalities have been shown to have adverse effects and absence of safety profile does not imply absence of side effects but rather lack of research. Effective safe doses have not been well established for most CTM and some have been shown to interact with antihypertensive drugs. For the patient's safety it is important that use of CTM is notified to the doctor/nurse (*Asfaw Erku & Basazn Mekuria, 2016*). The patient should regularly monitor and record BPs at home and take note of any potential side effects of CTM.

Who is the decision aid meant for?

➤ Hypertensive patients who are using CTM or contemplating the use of CTM.

CTM and their effects

TABLE 1 – ANTIHYPERTENSIVE IN CTM IN OTHER CONTEXTS

CTM	Effects on BP	Side effects
Coriander – seed	Antihypertensive	Photosensitivity, Liver
powder, leaves	antioxidant, vasodilator	damage, allergic
	(no clinical trials)	reactions
Sweet lemon – fruit		Allergic dermatitis,
	Antihypertensive	discolouration of dental
		plaque, contraindicated
		in pregnancy
Garlic (Allium	Antihypertensive, vascular	Gastritis, Antithrombotic
sativum)	smooth muscle relaxation	effects,
		Allergic dermatitis
Marula – stem bark	Antihypertensive,	
	vasorelaxant	
Sweet prickly pear -	Antihypertensive	
leaves	J1	
Avocado – leaves	ANTIHYPERTENSIVE	
Transcendental	Antihypertensive	
	(relaxation)	
evidence)	(Totaxation)	
Vitamin C (strong	Antihypertensive, diuresis,	
evidence)	vasodilation	
Beetroot juice (strong		Potential carcinogenic
		Č
evidence)	vasodilation	due to high formation
		of N-nitroso compounds
		(limited evidence)

Yoga (weak evidence)	Antihypertensive	
Ginger	Antihypertensive-No	Heartburn, diarrhea,
	significant evidence	arrhythmia(in animals) –
Black jack (Bidens	antihypertensive effects -	No toxicology studies in
pilosa L)-leaves	No clinical trials	humans (acute toxicity
		in rats)

CTM-DRUG INTERACTIONS

TABLE 2 – INTERACTIONS IN OTHER CONTEXTS

CTM	Conventional Drug interactions
Ginko leaf tablet	Increase T1/2 of Amlodipine
Rosella	Increase Cmax and volume distribution of HCT
St John's Wort	Reduced effect on some antihypertensives (calcium channel blockers)
Ginseng and licorice	Diuretics (eg HCT, indapamide)
Ginger	Potentiate antiplatelet effects of nifedipine
Garlic	Warfarin – increase risk of bleeding
Black jack	Unknown interactions (no studies)

For further reading find following articles:

Al Disi, S. S., Anwar, M. A., & Eid, A. H. (2016). Anti-hypertensive herbs and their mechanisms of action: part I. *Frontiers in pharmacology*, *6*, 323.

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Appendix C: Questionnaire for CTM use in hypertension

Patient questionnaire: For complementary traditional medicine use in hypertension patients

INTRODUCTION

My name is Tapiwa Terence Chiworeka registration number 182580, a final year Masters of Public Health student with Africa University. I am carrying out a study on: THE DEVELOPMENT OF A PATIENT DECISION AID FOR COMPLEMENTARY TRADITIONAL MEDICINE USE BY HYPERTENSIVE PATIENTS AT RED CROSS CLINIC. The study is quite relevant because hypertension is prevalent and use complementary traditional medicine is on the rise in Zimbabwe and there is very little

information currently existing in Zimbabwe. The outcome of the research is expected to be useful in improving the care of patients with hypertension who utilise complementary traditional medicine (CTM) in managing hypertension. Results from this study will be used for academic purposes only. Could you please spare some time (around 20 minutes) for questionnaire completion. **SECTION B: Clinical Data** 1. $BP = \underline{\hspace{1cm}} /\underline{\hspace{1cm}} mmHg$ SECTION A: Objective 1 - Determine the prevalence of CTM use amongst hypertensive patients treated at Red Cross clinic. 2. Do you use traditional medicine to control your hypertension? No Yes 3. If yes how do you use it to manage your hypertension? As alternative medicine As complementary medicine SECTION B: Objective 2 - To examine the determinants of CTM use in hypertensive patients treated at Red Cross Clinic. Socio-demographic data 4. Age: 18 - 30 years 30 - 40 years 40 - 50 years > 50 years 5. Sex: Male **Female** 6. Education level: **Primarv Secondary Tertiary** Self-Employed Formally-

7. Employment status: Unemployed

Employed

8. Place of residence: Urban
Hypertension history
9. How many years have you been on treatment for hypertension?
< 1year
10. Do you have any other chronic diseases?
Yes Unknown Unknown
11. Have you ever had side effects from anti-hypertensive drugs?
Yes No
12. Have you suffered any complications of Hypertension in the past?
Yes No
13. Family history of hypertension?
Yes No
Complementary Traditional Medicine Use
14. Do you consider CTM to be safer than conventional medication?
Yes No
15. Are CTM cheaper than conventional medicine?
Yes No
16. Do you inform your doctor/nurse that you use CTM to manage hypertension?
Yes No
17. If no what are the reasons for non-disclosure?
Health workers do not ask
Fear of what the health will say
Lack of knowledge regarding CTM by health workers

SECTION C: Objective 3 - Assess the trends of CTM use in patients with hypertension treated at Red Cross Clinic.

18. What complementary traditional medicine do you use to control hypertension?

•	Herbal (ginger, garlic, black jack etc.)		
•	Exercise		
•	Manipulative (chiropractor, etc.)		
•	Mind – body (meditation, prayer etc.)		
19. Where d	o you normally get CTM medicines?		
Garde	n local Market place	Pharmacy	Herbal shop
20. What co	nventional antihypertensive are you on?	•	

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Appendix D: Health practitioner's review questionnaire of the patient decision aid developed

Health practitioner questionnaire: For complementary traditional medicine use in hypertension patient decision aid review

INTRODUCTION

My name is Tapiwa Terence Chiworeka registration number 182580, a final year Masters of Public Health student with Africa University. I am carrying out a study on: THE DEVELOPMENT OF A PATIENT DECISION AID FOR COMPLEMENTARY TRADITIONAL MEDICINE USE BY HYPERTENSIVE PATIENTS AT RED CROSS

CLINIC. The study is quite relevant because hypertension is prevalent and use complementary traditional medicine is on the rise in Zimbabwe and there is very little information currently existing in Zimbabwe. The outcome of the research is expected to be useful in improving the care of patients with hypertension who utilise complementary traditional medicine (CTM) in managing hypertension. Results from this study will be used for academic purposes only. Could you please spare some time (around 25 minutes) for questionnaire completion.

The following questions will be asking about your perceptions on the Patient decision aid (PtDA) on CTM use in hypertension that you have been assigned.

ITEM	Strongly	Disagree	Neutra	Agree	Strongly
	disagree		1		agree
It will easy for me to	1	2	3	4	5
use					
The results of the	1	2	3	4	5
decision aid will be					
easy to see					
This strategy better at	1	2	3	4	5
helping patients make					
decisions on CTM in					
hypertension					
The use PtDA is a cost	1	2	3	4	5
effective way of					
helping patients make					

decisions					
Using PtDA will save	1	2	3	4	5
me time					
Use of a PtDA is a	1	2	3	4	5
reliable way of helping					
patients make					
decisions about CTM					
and hypertension					
There is a high	1	2	3	4	5
probability that using					
this strategy may					
cause/result in more					
benefit than harm					
This strategy	1	2	3	4	5
compliments my usual					
approach					

1.	In your opinion, what was the best feature of the patient decision aid and why

2.	What suggestions do you have to improve the decision aid?

Appendix E: Patient's review questionnaire for the patient decision aid developed Patient questionnaire: For complementary traditional medicine use in hypertension patient decision aid review

INTRODUCTION

My name is Tapiwa Terence Chiworeka registration number 182580, a final year Masters of Public Health student with Africa University. I am carrying out a study on: THE DEVELOPMENT OF A PATIENT DECISION AID FOR COMPLEMENTARY TRADITIONAL MEDICINE USE BY HYPERTENSIVE PATIENTS AT RED CROSS CLINIC. The study is quite relevant because hypertension is prevalent and use complementary traditional medicine is on the rise in Zimbabwe and there is very little

information currently existing in Zimbabwe. The outcome of the research is expected to be useful in improving the care of patients with hypertension who utilise complementary traditional medicine in managing hypertension. Results from this study will be used for academic purposes only. Could you please spare some time (around 25 minutes) for questionnaire completion.

Kindly indicate your preference by ticking in the boxes provided.

1.	Please rate each section by selecting one of the option given to show what you
	think about the information provided by the decision aid
	Benefits of CTM: poor fair good excellent
	Side effects of CTM: poor fair good excellent
	Evidence about CTM: poor fair good excellent
2.	The length of the decision aid was (select one)
	Too short
3.	The amount of information was (select one)
	Too little information Too much information Just right
4.	Was the presentation balanced?
	No Slightly Yes
5.	Do you find this Aid makes decision making about hypertension management
	easier?
	Yes No

W]	nat suggestions do you have to improve the decision aid?
W]	nat suggestions do you have to improve the decision aid?
W]	nat suggestions do you have to improve the decision aid?
W]	nat suggestions do you have to improve the decision aid?
W I	nat suggestions do you have to improve the decision aid?
W I	nat suggestions do you have to improve the decision aid?
W I	nat suggestions do you have to improve the decision aid?
W]	nat suggestions do you have to improve the decision aid?
W]	nat suggestions do you have to improve the decision aid?

Appendix F: Consent form for CTM use survey

Complementary traditional medicine use: INFORMED CONSENT

My name is Tapiwa Chiworeka registration number 182580 a final year Master's in Public Health student from Africa University. I am carrying out a study on THE DEVELOPMENT OF A PATIENT DECISION AID FOR COMPLEMENTARY TRADITIONAL MEDICINE USE BY HYPERTENSIVE PATIENTS AT RED CROSS CLINIC.I am kindly asking you to participate in this study by filling in the questionnaire provided.

Purpose of the study:

The purpose of the study is to develop a decision aid to be utilised by patients with hypertension who use Complementary Traditional Medicine. You were selected for the study because you are patient on treatment for high blood pressure. You are one of the 300 participants to be involved in the study.

Procedures and duration

If you decide to participate you will be asked to answer a set of questions through a questionnaire. It is expected that this will take about 20 minutes.

Risks and discomforts

There are currently no anticipated risks from participating in this research.

Benefits and/or compensation

There will be no compensation for participation in this study.

Confidentiality

Participants will remain anonymous and any information that is obtained in the study that can be identified with the participant will not be disclosed without your permission. Names and any other identification will not be asked for in the questionnaires.

Voluntary participation

Participation in this study is voluntary. If you decide not to participate in this study, your decision will not affect how you will be managed at Red Cross Clinic. If you chose to participate, you are free to withdraw your consent and to discontinue participation without penalty.

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

Authorisation If you have decided to participate in this study pelow as an indication that you have read an above and have agreed to participate.	-
Name of Research Participant (please print)	Date
Signature of Research Participant or legally auth	norised representative
If you have any questions concerning this study	or consent form beyond those answered

If you have any questions concerning this study or consent form beyond those answered by the researcher including questions about the research, your rights as a research participant, or if you feel that you have been treated unfairly and would like to talk to someone other than the researcher, please feel free to contact the Africa University Research Ethics Committee on telephone (020) 60075 or 60026 extension 1156 email aurec@africau.edu

Name of Researc	ner	
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Appendix G: Consent form for Patient decision aid review

Review of Patient decision aid: INFORMED CONSENT

My name is Tapiwa Chiworeka registration number 182580 a final year Master's in Public Health student from Africa University. I am carrying out a study on THE DEVELOPMENT OF A PATIENT DECISION AID FOR COMPLEMENTARY TRADITIONAL MEDICINE USE BY HYPERTENSIVE PATIENTS AT RED CROSS CLINIC.I am kindly asking you to participate in this study by answering question in a questionnaire.

Purpose of the study:

The purpose of the study is to develop a decision aid to be utilised by patients with hypertension who use Complementary Traditional Medicine. You are one of the 15 participants to be involved in the study.

Procedures and duration

If you decide to participate you will be asked to answer a set of questions through an interviewer administered questionnaire. It is expected that this will take about 30 minutes.

Risks and discomforts

There are currently no anticipated risks from participating in this research.

Benefits and/or compensation

There will be no compensation for participation in this study.

Confidentiality

Participants will remain anonymous and any information that is obtained in the study that can be identified with the participant will not be disclosed without your permission. Names and any other identification will not be asked for in the questionnaires.

Voluntary participation

Participation in this study is voluntary. If you decide not to participate in this study, your decision will not affect how you will be managed at Red Cross Clinic. If you chose to participate, you are free to withdraw your consent and to discontinue participation without penalty.

Before you sign this form, please ask any questions on any aspect of this study that is unclear to you. You may take as much time as necessary to think it over.

Suthorisation Syou have decided to participate in this study please sign this form in the space provide elow as an indication that you have read and understood the information provided pove and have agreed to participate.	
Name of Research Participant (please print)	Date
Signature of Research Participant or legally authors If you have any questions concerning this study or by the researcher including questions about the participant, or if you feel that you have been treas someone other than the researcher, please feel feel	consent form beyond those answered research, your rights as a research ted unfairly and would like to talk to
Research Ethics Committee on telephone (020) 6 aurec@africau.edu Name of Researcher	

Appendix H: CTM use patient consent form (Shona)

Complementary traditional medicine use: INFORMED CONSENT

Zita rangu ndinonzi Tapiwa Chiworeka registration number 182580 mudzidzi we Master's in Public Health student PaAfrica University. Ndiri kuita tsvakurudzo inonzi "THE DEVELOPMENT OF A PATIENT DECISION AID FOR COMPLEMENTARY TRADITIONAL MEDICINE USE BY HYPERTENSIVE PATIENTS AT RED CROSS CLINIC." Ndinokumbira mupinde mutsvakurudzo kuburikidza nekupindura mibvunzo mishoma shoma yandinayo.

Chinangwa chetsvakurudzo ndechekuti tigadzire chirongwa chinobatsira vanhu vanorwara nechirwere cheBp vanoshandisa mimwe mishonga isiri yemuchipatara. Masarudzwa pavanhu mazana matatu kuti mupinde mutsvakurudzo. Mukasarudza kupinda mutsvakurudzo muchabvunzwa mibvunzo uye inotarisirwa kutora maminitsi makumi maviri.

Hapana njodzi yamunotarisirwa kusangana nayo kuburikidza nekupinda mutsvakurudzo ino. Hapana mubairo wamunowana kana muchinge mapinda mutsvakurudzo ino.

Zita renyu nezvimwe zvingaite kuti muzivikanwe hazvisi kuzoiswa mumapepa etsvakurudzo ino uye muongorori wetsvakurudzo ndiye oga ane mvumo yekuona mhinduro dzamunenge mapa. Hapana mhinduro dzenyu dzinoiswa paruzhinji kana musina kutendera.

Hamumanikidzwe kupinda mutsvakurudzo uye mune mvumo yekusarudza kuti hamusi kuda kupinda mutsvakurudzo isati yatanga kana yave pakati kana mava kunzwa kusasununguka nemimwe mibvunzo. Kuramba kwenyu kupinda mu tsvakurudzo hakukanganise mabatirwo enyu pano paclinic.

Musati maisa sainecha yenyu pabepa, sunungukai kubvunza mibvunzo yamungange munayo. Torai nguva yamunoda kuti munyatsonzwisisa pamusoro petsvakurudzo. Kana muchinge mabvuma kupinda mutsvakurudzo ndinokumbira muise sainecha yenyu kuratidza kuti manzwisisa pamusoro petsvakurudzo uye mabvuma kupinda mutsvakurudzo.

Name of Research Participant (please print)	Date	
Signature of Research Participant or legally authoris	sed representative	

Signature of Research Participant or legally authorised representative

Kana mune mimwe mibvunzo pamusoro petsvakurudzo ino, kana kuti muchinzwa kuti mambunyikidzwa kuburikidza ne tsvakurudzo ino uye mune munhu wamungade kutaura naye pamusoro pezvazvo asiri muridzi wetsvakurudzo, sunungukai kubata Africa University Research Ethics Committee pa number dzinoti (020) 60075 or 60026 extension 1156 kana kutumira email pa <u>aurec@africau.edu</u>

Name of Researcher	·
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Appendix I: Patient PtDA review consent form (Shona)

Review of Patient decision aid: INFORMED CONSENT

Zita rangu ndinonzi Tapiwa Chiworeka registration number 182580 mudzidzi we Master's in Public Health student PaAfrica University. Ndirikuita tsvakurudzo inonzi "THE DEVELOPMENT OF A PATIENT DECISION AID FOR COMPLEMENTARY TRADITIONAL MEDICINE USE BY HYPERTENSIVE PATIENTS AT RED CROSS CLINIC." Ndinokumbira mupinde mutsvakurudzo kuburikidza nekupindura mibvunzo mishoma shoma yandinayo.

Chinangwa chetsvakurudzo ndechekuti tigadzire chirongwa chinobatsira vanhu vanorwara nechirwere cheBP vanoshandisa mimwe mishonga isiri yemuchipatara. Masarudzwa pavanhu gumi nevashanu kuti mupinde mutsvakurudzo.

Mukasarudza kupinda mutsvakurudzo muchabvunzwa mibvunzo iyo inotarisirwa kutora maminitsi makumi matatu.

Hapana njodzi yamunotarisirwa kusangana nayo kuburikidza nekupinda mutsvakurudzo ino. Hapana mubairo wamunowana kana muchinge mapinda mutsvakurudzo ino.

Zita renyu nezvimwe zvingaite kuti muzivikanwe hazvisi kuzoiswa mumapepa etsvakurudzo ino uye muongorori wetsvakurudzo ndiye oga ane mvumo yekuona mhinduro dzamunenge mapa. Hapana mhinduro dzenyu dzinoiswa paruzhinji kana musina kutendera.

Hamumanikidzwe kupinda mutsvakurudzo uye mune mvumo yekusarudza kuti hamusi kuda kupinda mutsvakurudzo isati yatanga kana yave pakati kana mava kunzwa kusasununguka nemimwe mibvunzo. Kuramba kwenyu kupinda mu tsvakurudzo hakukanganise mabatirwo enyu pano pachipatara.

Musati maisa sainecha yenyu pabepa, sunungukai kubvunza mibvunzo yamungange munayo. Torai nguva yamunoda kuti munyatsonzwisisa pamusoro petsvakurudzo.
Kana muchinge mabvuma kupinda mutsvakurudzo ndinokumbira muise sainecha yenyu kuratidza kuti manzwisisa pamusoro petsvakurudzo uye mabvuma kupinda mutsvakurudzo.
Name of Research Participant (please print) Date
Signature of Research Participant or legally authorised representative
Kana mune mimwe mibvunzo pamusoro petsvakurudzo ino, kana kuti muchinzwa kuti mambunyikidzwa kuburikidza ne tsvakurudzo ino uye mune munhu wamungade kutaura naye pamusoro pezvazvo asiri muridzi wetsvakurudzo, sunungukai kubata Africa University Research Ethics Committee pa number dzinoti (020) 60075 or 60026 extension 1156 kana kutumira email pa <u>aurec@africau.edu</u>
Name of Researcher