

THE USE OF HERBAL MEDICINE IN A RETAIL / COMMUNITY PHARMACY

by

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DECLARATION

I, Moraba Mhlanga, declare that this Research Report is my own, unaided work. It is being submitted for the Degree of Master of Science at the University of the Witwatersrand, Johannesburg. It has not been submitted before for any degree or examination at any other University.

_____ day of _____ 20_____ in _____

To my husband Thami P. It's the simple things that make life beautiful with you. In your arms we find security and belonging. Your hands generously provide for our basic needs and extravagant wants. Thank you for pushing me beyond my limits, for your everyday encouragement and for reminding me that I can overcome anything. Thank you again for always keeping the faith even when I'm in doubt.

AND

To our children Agape N, Tafadzwa M, Thami Jr and Tlhalefo B. You guys remain our biggest blessing and achievement to date. You are the laughter that never leaves my heart and my loyalties that will never fade. Love always.

ABSTRACT

Introduction: Despite the availability of thoroughly tested conventional medicines today, complementary and alternative medicines have persistently continued to be practiced globally, in spite of limited supportive evidence of their quality and effectiveness in treating diseases. This study aimed at assessing the patterns, as well as perceptions of herbal medicine use among adult patients with regard to their reasoning, associations, outcome and health concerns in a retail pharmacy.

Method: This was a two-phase cross sectional study that first determined the most preferred herbal products that patients used from the pharmacy's database sales. In phase 2, participants were recruited based on their purchases of the preferred products that were determined in phase 1, and were interviewed using a 35-item questionnaire. Only participants who used the preferred products were included in the study. The study obtained ethical approval and all participants gave written consent.

Results: Five different herbal products with the highest sales in March and April 2018 were the most preferred products by participants. One hundred and six participants, with or without chronic conditions, took part in the study and their main reasons were dissatisfaction with conventional medicine's effectiveness as well as side effects. Although 80% believed that herbal medicines were generally safe for use, less than 30% believed that they were more effective than conventional medicine hence more than 50% preferred the combination of both. Although healthcare givers were not popular sources of information on herbal therapy, 80% of participants believed that doctors and pharmacists must prescribe and dispense herbal products regularly. The overall perception on herbal therapy was positive, with a composite score of 83%, calculated as the summation of 5-Likert scale ranking.

Conclusion: The results of the study showed a general positive attitude towards herbal medicine use. Herbal medicine was thought to improve therapeutic outcome, treat the side effects of orthodox medicine; and improve quality of life. Although participants acknowledged that herbal medicines may not be registered for any specific ailment, they believed that they work and had an added benefit to their health.

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LIST OF ABBREVIATIONS

CAM – Complementary and Alternative Medicine

WHO – World Health Organization

USA – United States of America

HIV – Human Immunodeficiency Virus

AIDS – Acquired Immunodeficiency Syndrome

NHP – Natural Health Product

MHRA – Medicine and Healthcare Regulatory Agency

TCM – Traditional Chinese Medicine

EU – European Union

MCC - Medicine Control Council

FDA – Federal Food Drug and Cosmetics

DSHEA – Dietary Supplement Health and Education Act

SARS – Severe Acute and Respiratory Syndrome

Chapter 1: Introduction

Herbal medicines have been widely used across the world to address symptoms and the well-being of patients with different diseases including amongst others, pain, constipation, diabetes, high blood pressure, compromised immune system (1). The current trends in the pharmacy indicate that there are some patients who prefer to use natural remedies over conventional medicines to treat their ailments. Some of these patients however, combine both herbal and pharmaceutical medicines (2).

Herbal products are made from many different and connected parts of the plant, such as the roots, stems, leaves, flowers, fruits and seeds, which may be raw or processed (3). According to the World Health Organization (WHO), herbal medicines are medicines prepared from one or more herbs or parts of plants such as the roots, bark, seeds, fruit and/or leaves providing human health benefits. In certain traditions, materials of inanimate or animal origin may also be present (4).

Under current regulations, which in most countries are non-existent or less developed than conventional medicines (5), herbal products are classified as food and thus the makers of these products can therefore produce, advertise and sell herbal medicines without demonstrating their quality, welfare and efficacy; as is required with conventional medicines. Most of the people who use these products believe that being derived from plants; they are non-toxic and thus safe (3). This notion is very often false as drug-herb interactions between conventional medicines and herbal products have been reported. It was found that patients taking herbal medicines containing *G. biloba*, *P. ginseng* and others, in combination with conventional medicines, are at risk of experiencing herb-drug interaction due to the fact that these products affect pharmacokinetic and pharmacodynamic properties of prescribed medicines (6), (12,13)

Herbalism (phytotherapy) is the study or practice of using herbs as medicine. It is acknowledged by modern medicine as alternative therapy, because the practice of herbalism is not founded on proof collected using scientific technique (7).

The principles or procedures for which herbal medicines are used are often guided by attitudes, behaviors or convictions which are influenced by circumstances that affect a person's welfare, habitat and geographic area within which it developed (8). The common belief, however, is a complete, integrated approach to life, a balanced mind, body and the environment and it is believed that herbal medicine use has an emphasis on a person's health and not on disease. In general terms, herbal medicinal use focuses on the patient as a whole and not on the disease from which the patient suffers (9).

The most common reasons for using herbal medicine is that it is more affordable, diminishes concerns about adverse effects and allows greater public access to health information (10). Moreover, herbal medicines are generally perceived as natural and safe for consumption anytime (11).

Whether we know or understand the reasons behind the use of it, many people use herbal medicines which forms an integral part of their health care, and it is a flourishing global commercial business (9). A study conducted in 1990 in the USA found that people spent an estimated US\$13.7 billion on alternative therapies. This had doubled by 1997, with the expenditure of herbal medicines increasing faster than any other alternative therapy (14). A study that was conducted in 2002, 2007 and 2012 which looked at the herb and supplement use among USA adults, found that a staggering 40 million people in the US use herbs and supplements (24).

Herbal medicine use is seen all over the world for different conditions. In 2003, Chinese herbal medicine played a significant role in relieving the symptoms of severe acute respiratory syndrome (SARS) in China (15). In Africa, natural health products are taken especially in combination with orthodox medicines in the treatment of HIV/AIDS (16). Herbal medicine use is also very common in Europe and in many developed countries, with essential oils, herbal extracts or herbal teas sold in pharmacies with conventional medicines (17).

More than two centuries ago, morphine, which is used today as a potent pain reliever, was produced from opium extracted from the seeds of the poppy, *Papaver somniferum*. This discovery proved that plants

played an important role in the manufacturing of many drugs and conventional medicines that are used today (18). This approach was intensified by the discovery of penicillin (19). Many other discoveries include the cardiac stimulant, digoxin, from foxglove (*Digitalis purpurea*); salicylic acid, a precursor of aspirin derived from willow bark (*Salix*spp), reserpine, an antihypertensive agent from *Rauwolfia*spp and anti-malarial agent quinine from Cinchona bark (19, 20). More than 60% of cancer therapeutics is based on natural products (21).

This study was aimed at determining the patterns of herbal medicine use among adult patients with or without chronic conditions in a retail pharmacy of Pimville in Soweto. Using in depth interviews, the study looked at the different products that patients preferred to use, how they used them, for which conditions patients used these herbal products and the perceptions of participants on herbal medicine use. This study also evaluated the perception of participants on the need for doctors and pharmacists prescribing and dispensing herbal medicines regularly, as well as the need for thorough testing of herbal products before they are made available for consumption. This will hopefully help health care providers understand complementary and alternative medicine (CAM) practice, because many of the patients they treat use alternative medicines.

RESEARCH QUESTION

What are the patterns of herbal medicine use among adult patients, male and female above the age of 18 years with or without chronic diseases in a retail or community pharmacy?

AIM

The aim of this study was to gain a better understanding of herbal medicinal use from a patients' perspective, through the use of questionnaires and interviews.

OBJECTIVES

- 1, To retrospectively determine the most commonly used herbal medicine products
- 2, To determine the indications for these commonly used products
- 3, To determine if any of these products are used in combination with other prescribed conventional medicines or not
- 4, To determine patients' perceptions concerning herbal medicinal use

Chapter 2: Literature review

2.1 Use of herbal medicines

Herbal medicines have been widely used as remedies for treatment, as well as prevention of multiple ailments for years by people from different cultural and traditional beliefs and backgrounds. The first registered records of herbal medicine use go back about 5000 years in China (22). An ancient medical system, Ayurveda, which is still practiced in India, dates back many centuries (23). Research shows that there is an increase in complementary and alternative medicine use especially in the treatment of chronic diseases around the world (26). In 1997, a staggering 15 million people took prescription medicines in combination with herbal remedies (14).

WHO confirms that more than 80% of the populations in some Asian and African countries rely on herbal medicine for their primary health care (8). A study that investigated the patterns of herbal medicine use among US adults using 2002, 2007 and 2012 National Health Interview Surveys (NHIS) found that at least 40 million USA adults used herbs and supplements in 2012 (24). In another related study carried out in 2007 in the USA, it was found that almost 40% of adults had used complementary and alternative medicine (CAM) therapy in the past year (25).

From research that has been completed thus far, one can conclude that there is a widespread use of herbal medicines for different conditions, including the use by cardiac patients. A study by Pinar (2017), found that a greater proportion of cardiac patients used herbal medicinal supplements, but most of these patients neglected to inform their physicians about their CAM use (27). Although evidence shows that there is a high rate of patients using CAM, few of these patients discuss their experiences of herbal medicine use with their healthcare providers (28). It is vital that health care givers encourage patients to open up about their CAM use, in order to monitor the outcome and management of their diseases (29). This is also aggravated by the fact that physicians fail to obtain a history of herbal medicine use from their patients and often overlook adverse effects that may be associated with herbal supplements (12).

It is important that people should report their use of herbs and nutritional supplements to their healthcare givers so as to minimize potential herb-drug interactions, especially if these supplements are taken with conventional medicines (30). Previous research suggest that patients believe that physicians disapprove of the use of alternative medicine and as a result they choose not to disclose their use of alternative medicines and instead look for sources of information elsewhere (31).

There are many different reasons why we see an increased in CAM use among patients. One of the main reasons is that people believe that herbal medicines been made from plants, are natural and therefore safe, which is not necessarily true as herbal medicines do carry risks and can be harmful to consumers (32). The majority of people who use herbal medicines find these alternatives to be in harmony or agreement with their values and beliefs towards health and life in general (33). In a study that examined how attitudes towards CAM influence its use, it was found that people, who attributed health to personal behavior and beliefs, reported an increased use in alternative medicine use (34).

Most people use herbal medicines for health promotion, supplements and as treatment for chronic conditions. The usage of these remedies, however, is seen to increase when patients do not get relief of symptoms from conventional medicines. This is true in the case of advanced cancer and cases of new infectious diseases (1). The treatment scope of herbal medicine is large. These may include asthma, pre-menstrual syndrome, chronic fatigue, eczema, constipation etc. Alternative medicine use is higher among patients with chronic diseases such as diabetes, hypertension and hyperlipidemia (35). Herbal remedies may also be used for their supposed anti-inflammatory, antispasmodic or immune boosting properties (36).

2.2 Types of herbal medicines used in the pharmacy

Introduction

Herbal medicines are naturally occurring, plant-derived substances that are used to treat illnesses. They exist in different formulations such as teas, powders, tablets, creams, lotion, solutions and essential oils.

People all over the world use herbal medicines as part of their treatment in combination with conventional medicine or as mono-therapy. The most commonly used herbal medicines are:

- Jigsaw, which contains *Aloe* as its main active ingredient
- Procydin, which contains grapeseed oil, (*Vitis*)
- Pharmaton, which contains Ginseng
- Ngoma corrective contains Ladys mantle and *Smilax campestris*
- Ngoma we nzalo has Wild Yam as the main active ingredient
- *Echinacea*, which is contained in many of the preparations for cold.
- Modul8 which contains *Silicea* and *Conium maculatum*
- Moringa which is a good source of proteins, vitamins and amino acids.

2.2.1 *Aloe*–Jigsaw

Aloe has been used as a traditional medicine as far back as 2200BC. It plays a role in the management of health because of its anti-oxidant, anti-tumor and anti-inflammatory properties. It plays a role in curing diseases through modulation of various biological and genetic activities e.g. its anti-microbial activity is through the rupturing of bacterial cell wall (37). It is used for constipation, colic, skin diseases including fungal infections (38). It is also used in the treatment hypertension and diabetes mellitus (39). It has also found its use in the treatment of urinary problems in Trinidad and Tobago (39). According to the label provided on its container, Jigsaw contains *Aloe ferox* and is widely used in the pharmacy to treat constipation and sore joints. It is said to increase peristalsis and to affect the absorption of water. The recommended therapeutic dose is a sip (25ml) of Jigsaw daily. It is not to be taken during pregnancy.

Common side effects of *Aloe* include hypoglycemia, stomach pain and cramps, diarrhea, low potassium, weight loss and muscle weakness. It should not be given to pregnant and breastfeeding women (93).

2.2.2 Grape(*Vitis*)seed oil - Procydin

Procydin, containing grape seed (*Vitis*) oil, has been proven to have anti-inflammatory, cardio-protective, antimicrobial and anti-cancer properties (40). It also has anti-oxidant properties. The highest anti-oxidant capacity is found in grape seeds. The biological mechanism behind the anti-oxidation of grape seed is associated with the removal of free radicals. This influences the functioning of the immune system. Grape- seed oil also has anti-cancer properties (40). Procydin is used in the pharmacy mainly as an immune booster. It is also to improve blood circulation as well as to normalize blood pressure and blood cholesterol. According to the instructions on the label, the dosage of procydin is a capsule twice daily, taken with food.

Side effects of grape seed may include headache, itchy scalp, dizziness and nausea. People who are allergic to grapes should not use grape seed extract. It could interact with medicines like blood thinners, such as aspirin, therefore grape seed oil is not recommended in people with bleeding disorders. It is also not recommended for pregnant and breastfeeding women (92).

2.2.3 Ginseng - Pharmaton

A study by Lee & Kim in 2014 has shown that ginseng enhances the cardiovascular system through the improvement of blood circulation, vasomotor tone and regulation of the lipid profile, and thus has a good effect on cardiovascular disease. More research is still required to assess its safety (41). Ginseng, a powerful anti-oxidant, is well known as an immune booster thereby enhancing resistance to microbial attacks (42). It has also shown to have efficacy against stress related conditions such as depression. It was used in the past to protect the nervous system and is also effective in the improvement of memory and concentration (43). It is also used in the treatment of fatigue although research has shown that efficacy in the treatment of chronic fatigue with ginseng has not been demonstrated or observed (44).

Concomitant use of ginseng with warfarin results in reduced prothrombin time (67) and when Ginkgo is used with anti-platelets, anticoagulants or anti-thrombotics, the risk of bleeding increases. Siberian

ginseng interferes with digoxin assay, resulting in increased levels of digoxin. Continuous use of Echinacea may result in hepatotoxic effects of statin, niacins or amiodarone (67).

2.2.4 Lady's Mantle – *Alchemilla*sp (Ngoma Corrective)

These plants have a wide use in traditional medicine for the treatment of various gynecological ailments such as irregular menstrual cycle. They have been shown to have anti-oxidant and anti-inflammatory properties (45). Lady's mantle has also been proven to have anti-viral properties against orthopoxviruses (*vaccinia* virus and *ectromelia* virus) (46). In our pharmacies and health shops, this plant species is contained in an herbal product known as Ngoma Corrective which is used by female patients for pre-menstrual problems, dysmenorrhea, amenorrhea, lack of sexual desire.

2.2.5 Wild yam – *Dioscorea**villosa* (Ngoma Wenzalo)

Wild yam has found its use in treating menopausal symptoms. It has metabolic/endocrine activity such as estrogen-like or progesterone-like activity, because of the presence of small amount of phytosterols such as *diosgenin* (47). Known side effects of wild yam include nausea, vomiting, diarrhea and headache. It should not be taken by patients with gallbladder problems and rheumatoid arthritis (47). These plants are contained in herbal preparations like Ngoma Corrective and Wenzalo (which simply means 'that which assist in fertility') in many pharmacies and are used by women to treat infertility and gynecological problems such as amenorrhea.

2.2.6 *Smilax campestris* – *Smilacaceae* (Ngoma corrective)

It is widely used in Brazil for its anti-inflammatory properties (48). It has antifungal properties against *Candida* and *Cryptococcus* yeast (49). In South Africa, it is found in Ngoma Corrective, a natural product used in the treatment of premenstrual problems as well as infertility.

Smilax might cause stomach irritation when used in large amounts. It is contraindicated in pregnancy and breastfeeding, as well as in asthma and kidney disease (94).

2.2.7 *Vitex agnus*

It is used for female reproductive conditions, although further research is still recommended on this product. It has beneficial influence on premenstrual mastalgia and on pre-menstrual syndrome (50). The study by Van Die MD et al suggests that, *vitex* is beneficial in the treatment of premenstrual syndrome, premenstrual dysphoric disorder and latent hyperprolactinaemia (51). Uncommon side effects include upset stomach, itching, rash, acne and weight gain. Some women notice a change in menstrual flow when they start taking vitex (51).

2.2.8 *Ipecacuanha–Carapichea ipecacuanha*

It was used in gastric emptying to induce vomiting in poisoned patients, although there is no evidence from prior studies that support that ipecac improves the outcome in poisoned individuals. It was also used to treat bronchitis associated with croup in children. It was used as an expectorant to thin mucous and make coughing easier. Ipecac is now rarely used (52). *Ipecacuanha* is contained in herbal medicine product known as Modul8 which is used in the pharmacy as an immune booster, analgesia, anti-inflammatory and as a mineral supplement. The recommended dosage for Modul8 is 10 drops under the tongue daily. When an overdose of ipecac is taken, the following side effects might be experienced: diarrhea, fast or irregular heartbeat, stomach pain or cramps, nausea and vomiting, troubled breathing as well as weakness and aching of the muscles (52).

2.2.9 *Silicea*

It is believed to have a role in collagen synthesis, stimulate the immune system, bone mineralization and reduces the risk of atherosclerosis (53). It can also be used in the treatment of gastrointestinal (GIT) symptoms. *Silicea* gastrointestinal gel improves GIT disorders (54). When given for prolonged period of time, patients may experience shortness of breath, chest pains or respiratory failure. These normally occur after 5-10 years of exposure to *Silicea* (53).

2.2.10 *Conium maculatum* – *Apiaceae* sp

It is believed to have anti-cancer properties although more research is still required to further prove and substantiate this fact (55). Toxic doses of this product, however, have serious complications which can lead to death (55, 56). These complications include rapid breakdown of muscle tissue and release of muscle tissue byproducts into the blood, rapid heart rate followed by a decreased heart rate, loss of speech, paralysis, unconsciousness, lung, heart and kidney failure, followed by death (56)

2.2.11 *Echinacea*

Echinacea is found mainly in Eastern and Central North America and has three species which are all used as herbal medicines. These species have decongestant properties and are therefore used in pharmacies mainly in the treatment of influenza infection such as common cold, bronchitis, upper respiratory infections and some inflammatory conditions (57). It is also used to strengthen the immune system as well as to prevent infections (57). In the pharmacy, the trade name of the product that is sold is known as A. Vogel Echinaforce and it contains *Echinacea angustifolia*. Some side effects of *Echinacea* have been reported such as bad taste, stomach pain, sore throat, dry mouth, numbness of the tongue, difficulty sleeping, joint and muscle aches. Medicines that interact with *Echinacea* include caffeine and immunosuppressant. Midazolam interacts with *Echinacea*, which might increase the side effects of midazolam (95).

2.2.12 *Moringa oleifera* Lam – Moringa powder

Moringa, which belongs to the *Moringaceae* family, is a good source of protein, vitamins, amino acids, beta carotene and various phenolics. Various parts of this plant have cardiac and circulatory stimulating properties; possess antipyretic, antiepileptic, diuretic, anti-inflammatory, anti-hypertensive, antioxidant, anti-diabetic, antibacterial, antiviral, hepatoprotective as well as antitumor properties (58).

Moringa bark can cause uterine contractions and may interfere with fertility. It may also increase the risk of liver and kidney damage. It may also lower blood glucose and blood pressure (58).

2.3 Adverse effects of herbal medicines

One major problem with herbal preparations is that they can cause serious adverse effects especially when used in combination with other over-the-counter or prescription medicine as many of them remain untested and their use are poorly monitored or not monitored at all (59). The possibility of herb-drug interaction is made worse by the fact that most patients do not report their use of herbal medicines to their health care givers (28). This could potentially increase the likelihood that a doctor would unknowingly prescribe conventional medicine that may interact with herbal preparations that patients use.

Safety remains a big issue with herbal medicine use, it is therefore imperative that relevant stakeholders in medicine control such as the regulatory authorities put up measures to protect the public by making sure that only safe and high quality herbal products are made available to the public (60).

St John's wort which is used to treat anxiety, sleep disorder and depression has been proven to interact with a number of prescription medicines. St John's wort has a potential to cause serious adverse effects because of its effect on drug metabolism. Being a potent inducer of cytochrome P450 enzymes, CYP3A4, CYP2C9 and CYP1A2, it interferes with drugs metabolized by these isozymes. It interferes with the absorption of cyclosporine and oral contraceptives (28).

Herbal anxiolytic, kava, has been reported to cause liver failure, gastrointestinal complaints, restlessness and allergic skin reaction (61). When taken as mono-therapy at recommended doses, kava is well tolerated, thus serious adverse effects has been shown at incorrect doses in combination with benzodiazepines (62). Ingestion of methyl salicylate (oil of wintergreen) which is used to relieve musculoskeletal aches and pains has been shown to cause severe pulmonary edema, seizures and even death especially in patients with renal failure (63).

The use of multiple medications, herbs or supplements has a high risk of causing adverse complications especially in the elderly (14). According to a study in older adults with an average age of 71 years, one in six older adults is at risk of experiencing major drug-drug or drug-herb interactions since concurrent use of interacting medicines has increased (64,68).

There is however insufficient monitoring and recording of adverse effects associated with herbal medicinal use (65). Many adverse effects of herbal medicines may be caused by poor quality of raw materials. The meticulous application of Good Agricultural and Collection Practices (GACP) and Good Manufacturing Practices (GMP) would minimize these issues (66).

2.4 Laws and regulations of herbal medicines

Despite a continuous increase in the number of people using herbal medicines all over the world, the registration and regulation of traditional medicine still present challenges in many countries (8). In USA herbal supplements are regulated by the Federal Food Drug and Cosmetics (FDA) not as drugs but as food. Herbal medicines fall into a category of dietary supplements. In 1994, in America, the congress passed the Dietary Supplement Health and Education act of 1994 (DSHEA). Under the DSHEA, manufacturers of herbal medicines were not required to obtain pre-market approval by the FDA before making their products available to the consumers. Instead, the FDA bore the burden for showing that a product was unsafe before it could take action to prohibit its sale. Unlike pharmaceuticals which must undergo years of clinical testing before approval by the FDA, dietary supplements and herbs are not subject to tests before they can be made available for consumption. Manufacturers of these supplements are even allowed to make certain statements about the supplement's effects on health and overall well-being of consumers. Where they are limited from making a "disease claim"; they cannot state that a supplement can be used to "cure or treat". While the manufacturers must have substantiated for these statements, they were not required to have them evaluated by the FDA before using them for marketing purposes (69).

A regulation that does not allow vigorous testing of dietary supplements and herbal medicines before they are released into the market for consumption can potentially permit low quality and contaminated products to end up in the hands of consumers causing more harm than good. Based on the ingredients supplied on the label, a healthcare giver may offer their assistance to consumers on how to use the supplements. The biggest challenge is that these products are sold everywhere and the consumers only get information from the marketers of these products, which always promise good quality and efficacy. This can potentially increase the risk for adverse events especially if taken in combination with other medicines.

December 2006, however, saw the Dietary Supplement and Nonprescription Drug Consumer Protection Act (S.3546) signed into law, which requires the FDA to collect data on adverse effects experienced with the use of herbal preparations. Manufacturers of natural supplements must, according to this law, report information to the FDA concerning adverse reactions reported to them by the public. This regulatory requirement begins to address long recognized safety concerns over dietary supplement use (70).

Although the WHO estimates that 80% of the population in Asia and Africa depend on traditional/herbal medicines for their primary health needs, and despite the fact that the use of herbal medicines is a highly profitable business around the world with estimated annual income of USD 5 billion in Europe (2003-2004), USD 14 billion in China (2005) and USD 160 million in Brazil (2007), national policies and regulations are inadequate in many countries simply because of differences in definitions and categorization (8).

In Europe, only products that have been assessed by the Medicine and Healthcare products Regulatory Agency (MHRA) would be allowed into the markets for sale. Manufacturers of these products will have to prove beyond doubt that their products are manufactured under strict quality control and assurance standards, must be free from contamination and must contain a consistent and clearly marked dose. In order for these products to be considered as herbal medicines, they must have been in use for the past 30

years. Fifteen years of this usage must have been within the European Union (EU). These products would only be approved for minor ailments like cough and cold, aches and pains or sleep disorders. Product information will include possible side effects and interactions with other drugs and list all herbal ingredients, including vitamins or minerals (71).

In China, Chinese herbal products are governed by the State Food and Drug Administration (SFDA) and can be registered as functional food or drugs. Drugs in China are not just chemical drugs but also traditional medicines. The Drug Administration Law of the People's Republic of China is the law in China that ensures drug quality and safety to protect the health of the people and their rights and interests in the use of drugs. Drugs are generally assessed for safety, efficacy and quality. Both Traditional Chinese Medicine (TCM) and natural traditional medicinal products follow the national drug and provincial standards (72).

With a history of more than 2000 years, Traditional Chinese Medicine (TCM) plays a vital role in health care in China. It is for this reason that China adopted a law on TCM to give it a bigger role in the medical system. According to the new law, government must set up TCM institutions in public hospitals, as well as mother and child centers. All TCM practitioners must undergo continuous education and pass the relevant tests in order to continue practicing. This new law puts TCM and Western medicine on equal footing in China and emphasizes the TCM and Western medicine must learn from each other in order to complement each other (73).

For a long time, herbal medicine was sold in South Africa without regulation. In 2016, the Minister of Health published amendments of the Medicine and Related Substance Act 101 of 1965 providing for the regulation of CAMs by the then Medicine Control Council (MCC). This motivation for the regulation was a need to ensure safety, quality and efficacy of CAM to protect the public. CAM used in homeopathy, naturopathy, phytotherapy, osteopathy, and aromatherapy are included in a new category of regulated medicines called Category D, which must be appropriately labeled. Any products not registered with the

MCC must carry a label declaring ‘This medicine has not been evaluated by the Medicine Control Council. This medicine is not intended to diagnose, treat, cure or prevent any disease.’ All CAM products containing banned substances such as apiol or kava, which are potentially toxic must be withdrawn. All manufacturers of CAM must be licensed. The objective of these new regulations is to ensure that good quality herbal products are made available to the consumers in an effort to reduce hazardous interactions (74).

2.5 Role of pharmacists in herbal medicine use

One of the biggest challenges in herbal medicinal use facing healthcare givers is that they lack general knowledge of natural herbal products (NHP), as well as how they are used. Pharmacists are not required to be experts on natural health products, but must have a basic knowledge on these products (75). This is necessary in order to give sound advice on herbal medicinal use. Additional training on herbal medicine is necessary to ensure that pharmacists are better equipped on the type of products that are sold in their pharmacies, as well as an understanding on how and when to use them. As custodians of medicines, evidence suggests that patients are more likely to trust pharmacists when seeking information and advice about NHPs than any other health care professional (76).

Pharmacists’ responsibilities vary among jurisdictions, but all of them have a responsibility to dispense prescription medicines to consumers. It is, unclear however, when it comes to their roles in respect of natural/herbal medicines. According to the Federal Food and Drugs Act, natural/herbal products are not considered drugs and therefore must be available without a prescription (76). Previous studies have proven that because pharmacists do not recognize NHPs to be the same as conventional medicines, they are generally less knowledgeable about NHPs as compared to conventional medicines (77, 78). Many of the pharmacy stakeholders believe that their main responsibility in the use of NHPs was safety monitoring. They described that pharmacists’ role with respect to NHPs should be similar to that of OTC,

to monitor the products for safety thus identifying and preventing adverse events and drug interactions (75).

A study conducted by Basheti et al in 2014 explored the opinions of pharmacists and herbalists on herbal medicine use and receiving herbal medicine education, found that many of the pharmacists who took part in the study believed that they should be experts in herbal medicine use so as to give sound advice and counseling to their patients who buy herbal products from their pharmacies. Pharmacists showed interest in attending courses on herbal medicine use at pharmacies in order to improve their ability to serve their patients (79). Many consumers believe that pharmacists have knowledge on herbal medicinal use and therefore among healthcare givers, consumers are more likely to approach a pharmacist for help when making decisions on the use of herbal medicinal products (80).

In another related study which explored pharmacists' knowledge and perceptions about herbal medicines, it was found that more than 70% of pharmacists believed that herbal medicines is efficient and safe for use and also acknowledged the benefits of including herbal medicines into conventional medicine practice. However, many of them admitted to having very little knowledge on herbal remedies especially drug-herb interactions (81). Poor level of pharmacists' background and knowledge on herbal medicines might result in poor patient counseling on herbal therapy especially regarding their safety and potential interactions with conventional medicine (81).

Pharmacists are more likely to have some knowledge about the uses of herbal products, but have little knowledge on drug interactions, adverse drug effects and precautions of herbal medications. The opposite is true though about pharmacists with continuing education on herbal medications. They have sound understanding of interactions that might occur with herbal medicine use, as well as their adverse effects (82). It has also been proven through a study in Kuwait that pharmacists have a good knowledge about the uses of selected herbal products, but very little knowledge on the side effects and adverse effects of these

products (83). It is for this reason that pharmacy training programs in this area of practice are required to enable pharmacists to reach their full potential in giving a service to their patients.

The progressive use of herbal medicine among communities led to the Northeast Louisiana University School of Pharmacy in the United States developing a course called Herbal Remedies, which aims to train pharmacy students in the area of herbs as self-selected over-the-counter products. Emphasis about this course is mainly placed on the use of herbal products by the public as alternative therapies, the safety and efficacy of herbs and on the role of pharmacist in counseling consumers on the correct way of using herbs (84).

Conclusion

Although there is sufficient proven evidence of adverse effects and interactions with herbal medicine use, many people around the world continue to use herbal/ natural medicine to treat ailments. Evidence suggests that the use of herbal medicine is generally increasing. There are many different herbal products sold in pharmacies and many people use them daily for many different health conditions. Since patients might take herbal medicine with other conventional medicine, it is important that they reveal this information to their healthcare givers. It is equally important that the healthcare givers have some knowledge of this kind of alternative therapy in order to advise their patients on the side effects and the potential adverse effects and/ or drug-herb interactions that may appear with combination treatment.

Chapter 3: Method

3.1 Study setting and design

This was a two-phase cross-sectional study that was carried out in Pimville Square Pharmacy, a retail/community pharmacy located in the township of Pimville in Soweto. The pharmacy is registered with South African Pharmacy Council with license number Y52277 and opened its doors in January 2002. The study was conducted over a period of three months, May, June and July 2018.

3.2 Study sampling

For Phase 1, five of the most sold/purchased herbal products were first identified from the pharmacy's database and were considered to be the most preferred herbal products that patients used. For Phase 2, recruitment of participants focused on those above the age of 18, male and female with different educational backgrounds, with or without chronic conditions using any of the preferred herbal products as part of their treatment or supplementation. Participants, who took part in the study, were chosen at the point of sale of any of the products that were identified as the most preferred products in phase 1. Only participants who themselves used these products for whatever reason, were invited to take part in the study. Participants participated on their own initiative and were eager to participate in the data collection of the study.

3.3 Data collection

Data was collected in two phases. Phase 1 was done retrospectively to find out which were the most commonly used herbal products amongst participants at the time of this study. Data of all herbal medicine purchases was collected from the pharmacy's database between the months of March and April 2018 in an effort to determine the most preferred herbal products amongst patients. From these recorded sales, five of the most purchased herbal products were selected as most preferred by patients.

During Phase 2, data was collected by the researcher over a three-month period between May and July 2018 through interviews using a questionnaire consisting of both close and open-ended question-response formats where participants needed to explain and substantiate their answers regarding the use of herbal medicine (see Appendix A and B).

The different conditions for which participants have used herbal medicines have been categorized as follows:

Category I: Hypertension, Diabetes, Hyperlipidemia

Category II: Arthritis, Gout, Painful joints

Category III: Irregular periods, Painful periods, Infertility

Category IV: Asthma, COPD, Rhinitis

Category V: Heartburn, Constipation, Supplements

The data collection included the participants' age, gender, level of education and whether or not they had chronic conditions. If they were diagnosed with chronic conditions, participants were requested to disclose the conditions, treatments, dosages, directions of use of their medicines as well as the duration that they have been on prescribed medicines. Participants were also required to confirm if their conditions improved or worsened since they were started on chronic medicines.

With regard to herbal medicines during data collection, the researcher wanted to know exactly what herbal products participants used and for what conditions. The participants were prompted to explain how they used the products and if they felt any changes to their health since they started using the herbal products. The main questions were open-ended, such as 'how do you take this particular herbal product and for what condition'; as well as 'have you noticed any changes to your health since you started using this product? Please specify.' Participants were questioned on the clinical outcome they experienced with

using these products as well as complications and challenges they may have encountered. They were also asked about herbal and pharmaceutical medicine combination preferences; as well as their perceptions, regarding the use of herbal medicine. The interviews took place in the pharmacy, at the point of sale of any of the five most preferred herbal products. These interviews were conducted privately in an office within the pharmacy away from distractions. The questionnaire and interviews lasted approximately 20 to 30 minutes.

3.4 Data analysis

Data was analyzed using Stata Statistical Software version 14 (StataCorp.2015). Data is presented with definitive statistics tables of numbers and proportions as well as composite perception score. The associations between participants' gender, age, level of education and their conditions and the perceptions of herbal medicines were obtained employing Pearson's Chi-square. The composite perception score was determined as the aggregate of 5-Likert scale ranking for perception-related questions. Results ranked from 1 (strong negative perception) to 5 (strong positive perception). The accepted average point of 33 was approved where mean composite perception score >33 was taken to be a general positive perception while mean composite perception score <33 was assumed to be negative. Significant association and influence were assumed at $P < 0.05$.

Different diseases were also categorized and grouped together during analysis, mainly according to participants' similar choice of herbal products for treating those diseases and in case where two or more similar diseases were found to have been diagnosed in one participant, those conditions were grouped e.g. participant with a confirmed diagnosis of gout who also had arthritis. In such a case gout and arthritis were grouped together. This categorization and grouping is elaborated in detail during the results of the study.

3.5 Validation of study instrument

To establish rigor, an interpretative phenomenological approach was used in the study. The emphasis for using this technique was to gain an understanding of the thinking and behavior of participants as perception (85). The researcher considered the credibility of each interview. To avoid bias, the researcher focused on reflexive consideration and each participant was shown their results at the conclusion of each interview.

3.6 Human Ethics

Ethical approval was obtained from Ethics Committee of the University of the Witwatersrand in accordance with their guidelines and a clearance certificate with reference number M170725 was issued in September 2017 (Attachment). Each participant was adequately informed about the nature and purpose of the study before information was obtained from them. Questionnaires and interviews were only conducted anonymously after obtaining informed consent of participants (Appendix D)

The participants were also assured that they were free to terminate the interview at any time they wished to and that the information obtained from them would not affect their treatment in the future.

Participants, who did not have a clear understanding of what the study was about, were excluded from it, especially those who did not want to disclose their conditions and/or treatments.

Chapter 4: Results

4.1 Phase 1

4.1.1 Most commonly used herbal products in a retail pharmacy

At the time of the study, there were about 25 different herbal products available in stock and the pharmacy had on average 290 sales of herbal medicines in a month. In March 2018, there were at least 316 sales of

different herbal products. There was a slight decline in April with 258 sales. Table 1 below shows the five most sold/purchased herbal products and their quantities for the months of March and April 2018.

Table 1: Five commonly used herbal products in a retail pharmacy

Herbal product (Trade Name)	Quantity sold (March)	Quantity sold (April)	Total	Price	Contents
Moringa Powder 200g	23	19	42	R119.00	<i>Moringa oleifera</i> 100g Vit C: 12% of RDA Protein2g Vit B2:11% of RDA Vit A: 9% of RDA Vit B6: 19% of RDA Iron: 11% of RDA Mg: 8% of RDA
Jigsaw700ml	21	19	40	R79.00	<i>Aloe ferox</i> 150mg
Procydin60 capsules	22	15	37	R139.00	<i>Vitis</i> (Grapeseed)70mg
Ngoma Corrective 500ml	18	18	36	R89.00	<i>Vitex agnus</i> 0.12ml <i>Smilax utilis</i> 0.12ml <i>Alchemilla vulgaris</i> 0.12ml <i>Dioscorea villosa</i> 0.12ml Siberian ginseng0.12ml
Modl8 50ml	14	17	31	R175.00	<i>Aconitum napellus</i> DH 20 <i>Arsenicum album</i> DH18 <i>Carapichea</i> DH16ipe <i>cacuanha</i> DH13 <i>Silicea</i> DH20 <i>Conium maculatum</i> DH17

Although there were many different herbal products that were purchased and used daily from the pharmacy, the researcher looked at only five products that had the most sales (during the months of March and April) and invited and interviewed qualifying participants who consented to take part in the study. It was also noted that during the course of the study from May to July2018, however, product

preference shifted slightly from the list that was compiled from the pharmacy's database in the months of March to April, as another product which was not part of the five 'most commonly used products', suddenly became popular amongst patrons within the pharmacy. The product was A. Vogel Boldocynara (*Cynara scolymus*) and this product is said to assist in promoting the function of the liver and the gallbladder. The product received good media advertising, which could have attributed to its high demand. It did not replace any of the five preferred product because it was not similar to any of the five products that were investigated. This observation shows that as more and more herbal products are manufactured and made available to the market and advertised, people will try them and only those that prove to be effective to patients will remain in the market.

The researcher was interested by one participant in particular who, although eligible to take part in the study, refused to give consent, citing that she was worried that the study would discredit the use of herbs as she was aware that most healthcare givers did not approve of herbal medicines.

4.2 **Phase 2**

4.2.1 Demographics of participants

A total of 119 participants who were eligible to take part in the study were invited, but only 106 completed the questionnaire and the interview. Of those who took part, 50 (47%) were males and 56 (53%) were females.

Table 2: Participants' demographics

Parameter	Demographic group	No. of participants n=106	% Frequency
Gender	Male	50	47
	Female	56	53
Age			
	18-30 years	35	33
	31-40 years	28	27
	41-50 years	18	17
	51-60 years	14	13
	61-100 years	11	10
Level of education	Primary	21	20
	Secondary	57	54
	Tertiary	28	26
	Illiterate	0	0

Participants' demographic parameters are shown in Table 2. The mean age and standard deviation (SD) was 39.3 ± 14.06 with the median of 37.5. The majority of the participants 35 (33%) were between the ages of 18 and 25. Many of them 28 (27%) fell within 31 and 40 years of age. The minimum number of participants 11 (10%) were above the age of 61. The different age categories of patients are shown in Table 2. The participants' level of education was also different. The majority of participants (54%), only had secondary level of education.

4.2.2 Conditions for which participants have used herbal medicines

Sixty six (62%) participants had chronic conditions and were on conventional/pharmaceutical medicinal treatment, while 40 (38%) did not have any chronic disease.

In total, 23 participants who bought Procydin capsules were invited to participate in the study and completed the interview and the questionnaire. Twenty four participants used Jigsaw, 22 participants took Moringa powder while 19 and 18 participants used Ngoma Corrective and Modul8 respectively. All of these products contained information on their labels on how they were to be used and for which conditions, but it was noted in the study that many participants used them as they wished and not necessarily in accordance with their labels. Some of the participants tried other herbal products before that were not similar to what they used when the study was conducted.

Conventional and herbal medicine treatment for the different conditions seen in the pharmacy

Of the 23 participants who took Procydin, 6 (26%) used it in the treatment of hypertension, 3 (13%) used it for diabetes, 1 (4%) used it for painful joints. The remaining 13 (57) participants took procydin as supplement to strengthen their immune system and to increase their energy levels.

For high blood pressure, participants took Amloc 10mg daily; enalapril 10mg and indapamide 2.5mg daily; Prexum plus 5mg daily; Losar plus 100mg daily; hydrochlorothiazide 25mg daily; Bilacor 5/6.25mg daily, respectively. Although the manufacturer's dosage recommendation for Procydin is 'one

capsule taken twice daily', participants who used it for category I conditions took it only occasionally. They took it for a week or two and then stopped and continued with their prescribed medicines. They would then continue whenever they felt they needed. They had periods of rest because they believed that herbal medicines are effective enough to stabilize them even when they do not take them daily.

For diabetes, participants took Diagluclide MR 30 twice daily, Glycomin 5mg and Glucophage 850mg twice daily; Novomix insulin flexpen 32iu daily, respectively. For painful joints, they were prescribed Celebrex 200mg taken daily.

Moringa powder was used mainly as an anti-inflammatory in the treatment of asthma, painful joints, chronic obstructive pulmonary disease (COPD) and was also preferred in participants with hypertension and diabetes. Eight participants (36%) used Moringa in treating pulmonary diseases, 4 (18%) used it in the treatment of arthritis, 10 (41%) used Moringa to treat hypertension that exist with diabetes and high cholesterol. Of the 10 participants who used Moringa for treatment of hypertension, only 3 (14%) used it daily while 7 (32%) used it only occasionally, every second or third day, because they feared that their blood pressure would drop too low.

Participants with pulmonary diseases, asthma and COPD, managed the symptoms of their ailments with Asthavent only when necessary to relief tightness in the chest, Beclate and Foxair were used to prevent attacks. Occasionally Prednisone 5-30mg per week would be given for acute attacks

Jigsaw, containing *aloe* concentrate, was also used as an anti-inflammatory and to improve bowel movement. Seven (29%) of participants used Jigsaw to treat arthritis. Two (8%) used Jigsaw in treating hypertension and the remaining 15 (71%) used it to treat constipation. Jigsaw was taken daily, a sip everyday by all participants who used it.

Modul8, were popular as supplements and immune boosters. One (6%) of participants used Modul8 to treat conditions such as hypertension, diabetes and hyperlipidemia. Ten drops of Modul8 placed under the

tongue, was taken daily by participants who used it, when used as an immune booster. The one participant who used to treat hypertension, used it every other day.

Ngoma Corrective was used amongst female participants for many gynecological problems such as irregular and painful menstruation as well as to treat infertility. They tried conventional medicines before with little relief.

Different conditions for which participants used herbal medicine, as well as the quantities of each herbal product are shown in shown in table 3.

Table 3: Different conditions that participants treated with herbal medicine

Condition	Frequency n=106	Percentage	Herbal product preference
Category I: Hypertension, Diabetes and Hyperlipidemia	22	21	Procydin = 9 Moringa = 10 Modul 8 = 1 Jigsimur = 2
Category II: Arthritis, Gout, Painful joints	13	12	Procydin = 1 Moringa = 5 Jigsimur = 7
Category III: Irregular periods, Painful periods, Infertility	19	18	Ngoma Corrective = 19
Category IV: Asthma, COPD, Rhinitis	11	10	Moringa = 8 Modul8= 3
Category V: Heartburn, Constipation, Supplements	41	39	Procydin = 13 Jigsimur = 15 Modul8 = 13

These conditions were categorized as such because the majority of participants 13 (59%) and 5 (23%) with high blood pressure had diabetes and hyperlipidemia, respectively. Participants with confirmed and unconfirmed diagnosis of arthritis or gout, who complained of painful joints, seemed to have a similar choice of herbal product to treat their condition. All participants 19 (100%) who complained of painful and irregular periods as well as infertility, used one common herbal product to alleviate or treat their conditions. Of the participants who were diagnosed with asthma and COPD, 7 (64%) also had allergic rhinitis. Twenty two (54%) of participants who used herbal medicines as supplements and to treat heartburn and constipation, complained that these conditions as well as weakened immune systems were from the use of pharmaceutical medicines and that they were using herbal treatment to counteract these side effects and to boost their immune systems.

4.2.3 How participants used herbal medicine in the pharmacy

Seventeen (77%) participants in Category I took their herbal medicines only when necessary. The 77% was made up of 39% Procydin, 32% Moringa and 6% Modul8. These participants used their herbal medicine occasionally because they worried that their high blood pressure, blood sugar and cholesterol might go too low, as they were also taking their prescribed medicines. Although they used herbal medicines, they acknowledged the fact that their pharmaceutical treatment is important in the treatment of their conditions. One participant stated that “sometimes when I’m stressed, my blood pressure does not seem to be controlled by my conventional medicine alone. I find that during such periods when I combine my prescribed tablets with herbal treatment, I get an added benefit to my treatment, therefore I only take herbal treatment when I feel really tense”. To avoid excessive lowering of blood pressure or glucose level, 13 (59%) of participants took their herbal products only occasionally.

Of the participants with Category II conditions, 7 (54%) experienced severe heartburn and inflamed stomach lining from taking non-steroidal anti-inflammatory drugs (NSAIDs) to relieve the pain. They then took antacids to relieve the discomfort but found that they suffered with constipation as a result.

Although they still continued taking conventional treatment despite the side effects, 10 (77%) took Jigsimur tonic, a sip every day not only to relief the pain but to treat constipation also.

All 19 (100%) participants with Category III conditions used Ngoma Corrective, taken ¼ cup daily for seven consecutive days every month. Nine (47%) participants experienced relief of symptoms while 10 (53%) had not seen any change when the study was conducted. The participants took Ngoma Corrective for a period between two and eighteen months. Of the nine participants who took this product, 5 noticed a reduction in their dysmenorrhea within the first month of treatment, and all five participants still used the product at the time of the study. Four participants confirmed to getting relief after three months of starting on the treatment. The 53% of participants, who did not see any positive result on the product, had been using the product for over three months. Six of those, used it to treat their 'infertility' while the remaining four used it for irregular periods and dysmenorrhea.

Seven (64%) participants with Category IV conditions preferred Moringa powder as their herbal treatment of choice, because they believed that it possessed anti-inflammatory properties to help relieve congestion. They took a spoonful of the powder daily.

Nineteen (46%) participants in Category V, who used herbal medicine as supplements, took it daily. They attributed their strong immunity, increased exercise tolerance and a general sense of well-being to herbal medicinal usage. Eleven (10%) participants in Category V complained of constipation and heartburn from the use pharmaceutical medicines. One participant explained that "several years ago I had severe stomach pains for which doctors at the hospital gave me Lansoloc 30mg. Although this relieved the pain, it also gave me constipation. I take Jigsimur solution every second day to improve my bowel movement".

Although a total of 26 (24.53%) of participants did not experience any change in their conditions while using herbal products during this study, they continued to use them regularly with the hope that they will eventually get relief of their symptoms. Of the 26 participants who said that their health was not really

improved by herbal, 10 (9.43%) used Ngoma Corrective, 6 (5.6%) used Moringa powder, 4(3.8%) Procydin and 6 (5.6%) used Modul8.

4.2.4 Combination of herbal medicine with pharmaceutical treatment

Many of the participants 67 (63%) took their herbal medicine in combination with pharmaceutical treatment while 39 (37%) took herbal medicine as mono-therapy. While those who combined both the treatments understood that conventional therapy is imperative in their treatment of chronic conditions, 55% of participants also believed that herbal medicine work and the combination had added benefit in their whole treatment. Thirty nine (37%) participants preferred taking their herbal products as mono-therapy. The researcher's assumption was that this could have been due to the fact that all of these participants did not have any chronic conditions and were therefore not taking any form of pharmaceutical medicine. Only one participant, although never been diagnosed with a chronic condition, occasionally (weekly) took NSAIDs to relief painful joints. It is possible that these participants were occasionally taking conventional medicine although it was never confirmed. They only disclosed that they took herbal medicine alone and not in combination with any other medicine.

Almost two thirds of the participants 66 (63%) used herbal medicines from recommendations, mostly from people they know like family members and work colleagues who had experiences with the use of herbal medicines. Thirty (28%) participants obtained information on herbal medicinal use from radio, television and newspaper adverts while the remaining 10 (9%) participants got recommendations from their healthcare practitioners (doctors and pharmacists). Healthcare givers were not popular when it came to giving information on herbal medicine use. This is because in this study, less than 10% of healthcare givers could only give recommendations on herbal medicine use. The researcher's assumption was that, healthcare givers do not really believe that herbal medicines could have any benefit to the treatment of ailments, or that they do not have extensive knowledge on how they are used.

4.2.5 Participants' perception on the use of herbal medicine

Participants' perceptions/opinions on the use of herbal medicines are shown in Table 4.

Table 4: Participants' perception regarding herbal medicinal use

Perception	Strongly agree	Agree	Neutral	Disagree	Strongly disagree	Composite perception score
Herbal medicine is safer than pharmaceutical medicine	4(4%)	82(78%)	12(11%)	8(7%)	0	Agree: 82% Neutral: 11% Disagree: 7%
Herbal medicine is more effective than pharmaceutical medicine	3(3%)	26(25%)	32(30%)	45(42%)	0	Agree: 28% Neutral: 30% Disagree: 42%
Herbal medicines should only be sold in licensed pharmacies	6(5%)	60(57%)	4(4%)	35(33%)	1(1%)	Agree: 62% Neutral: 4% Disagree: 34%
Combination of herbal medicine and pharmaceutical medicine is better	4(4%)	54(51%)	6(6%)	39(36%)	3(3%)	Agree: 55% Neutral: 6% Disagree: 39%
Doctors and pharmacists must prescribe and dispense herbal medicine often	4(4%)	85(81%)	3(3%)	12(11%)	1(1%)	Agree: 85% Neutral: 3% Disagree: 12%
Herbal medicine is less expensive than pharmaceutical medicine	1(1%)	36(34%)	7(7%)	58(54%)	4(4%)	Agree: 35% Neutral: 7% Disagree: 58%
Herbal medicine should contain package insert listing all possible side effects	4(4%)	99(93%)	2(2%)	1(1%)	0	Agree: 97% Neutral: 2% Disagree: 1%
Preference of herbal medicine over pharmaceutical medicine	5(5%)	30(28%)	27(25%)	42(40%)	2(2%)	Agree: 33% Neutral: 25% Disagree: 42%
Adverts of herbal medicine have an impact on the choice of herbal product	9(9%)	22(21%)	28(26%)	46(44%)	0	Agree: 30% Neutral: 26% Disagree: 44%
Although I take herbal medicine, I consider pharmaceutical medicine to be more effective	7(6%)	55(52%)	19(18%)	23(22%)	2(2%)	Agree: 58% Neutral: 18% Disagree: 24%

An overwhelming majority of participants (82%) believed that herbal medicines are generally safe for use. Only 7% did not agree with this notion while 11% remained undecided on whether herbal medicine is safe or not. Although the majority of participants agreed that herbal medicine is safe, only 28% believed that herbal medicine is more effective than pharmaceutical medicine. Based on participants' perception on these questions, one can conclude that public trust on the effectiveness of conventional therapies remains high. Sixty two percent of participants agreed that herbal medicines should be sold in licensed pharmacies.

With regard to the combination of herbal medicine with pharmaceutical medicine question, 55% of participants agreed that the combination works better. This was especially seen in participants with chronic conditions such as hypertension, diabetes, hyperlipidemia, asthma, COPD, gout and arthritis who were already taking pharmaceutical treatment. They understood that the herbal products they used were not registered for the conditions they had and therefore it was imperative for them to continue taking their conventional treatment. However, 39% disagreed with this notion while 6% percent of participants were undecided.

An overwhelming majority of participants (85%) believed that doctors and pharmacists should prescribe and dispense herbal medicines frequently. Fifty six (53%) believed that a single herbal product can cure more than one ailment and instead of doctors prescribing many different conventional therapies to an individual with different conditions, they could be given a single herbal product that would address all conditions at once. Fifty eight (58%) percent of participants did not agree that herbal medicine is less expensive. In fact they believed that conventional treatment was far cheaper than the herbal products they used.

Although they believed that herbal medicines was generally safe for consumption, almost all participants (97%) agreed that these herbal products should come with package inserts listing all possible side effects and interactions just as it is done with pharmaceutical medicine.

Only 33% of participants preferred herbal medicinal use over pharmaceutical treatment. Twenty five percent (25%) of participants remained undecided while 42% did not prefer herbal over conventional medicine. Although participants in this study chose to use herbal medicine, whether as mono-therapy or in combination with pharmaceutical medicines, 58% still considered pharmaceutical medicines to be more effective than herbal medicine, 18% remained undecided while 24% did not agree with this notion. Adverts of herbal products did not seem to have much impact on participants' choice of herbal products. Only 30% of participants believed that advertisements of herbal products assisted them in choosing the products they used and 44% did not agree while 26% were not really clear how they went about choosing one herbal product over the other.

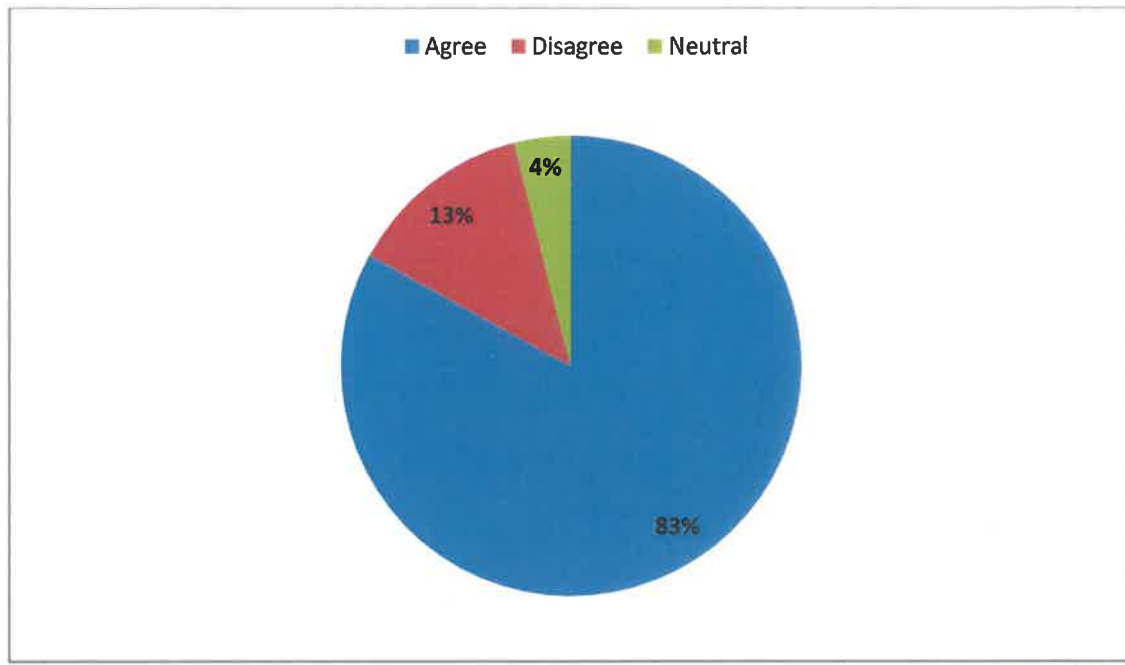


Figure 1: Overall participants' perceptions on herbal medicine use as depicted on a pie chart

Association between participants' age, gender, level of education and conditions and their perceptions of herbs medicines.

Pearson's Chi-square analysis was done in an effort to reveal any common interest between participants' demographics variables and their perceptions of herbal medicines. The effect of participants' age, gender, level of education and their conditions on the perception of herbal medicines were determined. Assuming significant association at $P \leq 0.05$, there was no significant association between gender and the opinion that herbal medicine is safer or more effective than pharmaceutical medicines. There was a significant influence ($P=0.02$) between gender and the perception that herbal medicine is less expensive than conventional medicine. Thirty two female participants disagreed with the belief that herbal medicine is less expensive than conventional medicine while seven female participants remained undecided. Twenty

nine male respondents disagreed that herbal medicines were less expensive while the remaining 19 respondents agreed with the notion that herbal medicine were indeed less expensive. However, this was not the case with the age of participants. There was a significant association ($P=0.04$) between age and participants' perception that herbal medicine is more effective than pharmaceutical medicine. There were no significant association between age and gender of participants and the perception that doctors and pharmacists should prescribe and dispense herbal medicine more often. There was no association between age and gender of participants and the opinion that herbal medicine must contain package insert listing all possible adverse effects.

There was no significant association between participants' level of education and the perceptions that herbal medicine is safer or more effective than conventional medicine. There was however, little evidence of association ($P=0.058$) between level of education and the perception that combination of herbal and pharmaceutical medicine is better. As with age and gender, there was no influence between level of education and the opinion that doctors and pharmacists should prescribe and dispense herbal medicine more often. The analyses showed that there was no significant association between participants' gender, age and their level of education and the perception that adverts of herbal medicine have an impact on participants' choice of herbal products.

Unlike gender and level of education, there was a significant association ($P=0.048$) between the perception that herbal medicine is safer than pharmaceutical medicine and participants' conditions. A significant association ($P=0.026$) was also seen between participants' condition and the opinion that herbal medicine is more effective than conventional medicine. There was significant association ($P=0.033$) between participants' conditions and the belief that herbal medicines should only be sold in licensed pharmacies. There was evidence of significance ($P=0.051$) between participant condition and the opinion that adverts of herbal medicine have an impact on participants' choice of herbal medicine. There was however, no association between participant's condition and the opinion that herbal medicine is less

expensive than pharmaceutical medicine. The P value for gender and overall participants was 0.073 and that of level of education was 0.922.

4.3 Discussion

Five herbal products (in months of March and April), with the most sales were investigated in this study. It was noted during the process of data collection from May to July that product preference shifted from the list that was compiled from the pharmacy's database, as another product known as A. Vogel Boldocynara suddenly became popular amongst the customers. This could have been due to vigorous media advertising that the product received.

During this study the researcher has learned that the general feeling of many participants, 57%, was that pharmaceutical medicines treat identified diseases while herbal medicines restore a patient's physical functions, thus treating a person as a whole to produce a sense of harmony and well-being. Table 3 of the different conditions for which participants used herbal medicines, on page 28, refers. Thirty nine (39%) participants in category V conditions believed that herbal medicines counteracted the side effects that they experienced with their prescribed medicines. The 18% of participants, who used herbal medicines for conditions in category III conditions, have tried treatment of their ailments with conventional medicines, with little relief of their symptoms. A study was done previously where it was found that the common philosophy in herbal medicine use is a holistic approach to life, equilibrium of the mind, body and environment, and an emphasis on health rather than on disease (9). Thirty nine (39%) generally preferred herbal medicines because they believed that conventional medicine may have severe side effects while herbal medicines, because of their 'natural state', has few or no side effects.

Thirty nine (39%) participants believed that herbal medicines not only improved their conditions, but had a positive effect on their immune systems. Some participants reported that they experienced an improvement in exercise tolerance and that they did not easily get sick since they started taking herbs. This was especially seen in patients who were taking their herbal medicines, Procydin and Modul8, as

supplements. The one participant (6%), who took Modul8, who was also taking conventional hypertension and cholesterol treatment; and four participants (17%) with hypertension and diabetes, on prescribed medicines, also reported the same fact. All of the participants (39%) in category V conditions attributed their good health to herbal medicine use. Their belief was that one herbal product was able to cure more than one ailment hence a person with multiple chronic diseases would be found taking a single herbal product for all of his/her chronic diseases. Forty three (43%) participants acknowledged that herbal medicines would still be necessary in their lives even if they did not have any chronic disease. With reference to Table 3 on page 28, all participants in categories I (hypertension, diabetes, hyperlipidemia); category II (arthritis, gout, painful joints) and category IV (asthma, COPD, rhinitis), even though they took herbal medicines, they continued taking their prescribed conventional medicine.

Before a decision to use herbal medicines was taken, some participants visited conventional clinics for treatment of their conditions but did not really experience complete healing of their conditions. They still experienced symptoms and were never stabilized even on pharmaceutical medicines. Most, however, preferred to combine both herbal and pharmaceutical medicines because conventional medicines have been thoroughly tested and are prescribed and dispensed at the right doses. Although a patient may not be stabilized at such a dosage, pharmaceutical medicines were still considered safer to use than herbal medicine which although 'natural', may still be toxic if used incorrectly. Participants acknowledged that herbal medicines may not be as safe to use, hence they recommended that manufacturers of these products must provide information on the dosage, direction of use and every possible side effects just as it is done with pharmaceutical medicine. Although the dosages and directions of use were provided on the labeling of these herbal products, nothing was mentioned on the possible side effects.

Thirty nine (39%) of the participants in this study took herbal medicines to relieve disease symptoms and to boost their immune systems. Some of the herbal products used, such as *Aloe*, have a laxative effect and therefore participants who used such products felt that their bodies were clean because their stomachs ran regularly. They believed that herbal medicines are able to get rid of the pharmaceutical medicines that

they take daily, especially in cases of chronic diseases. They believed that increased bowel movement they experienced with *Aloe*, interferes with absorption of prescribed medicines. They fear that conventional medicines, despite having been tested, cause more harm than good in the body and therefore the use of herbal medicine assist in managing the damaging adverse effects that may arise with pharmaceutical medicine use. This perception that conventional medicines cause more harm than good, favors herbal medicine use greatly (86).

Participants believe that herbal medicines are restorative medicines. A qualitative study conducted in the USA in 2014, reported that after receiving CAM treatment, patients generally feel more hopeful, experience empowerment and spiritual benefits (87). This belief that herbal medicines are not cures has encouraged patients to combine their herbal medicines with conventional medicines. This is especially true in patients with chronic diseases. This, however, has a potential of herb-drug interactions (88). A number of participants preferred taking their herbal products periodically with resting periods in between because they believed that they are effective enough to stabilize their conditions even if they do not take them daily. Hence they do not worry much about adverse effects, as compared to pharmaceuticals which must be taken on a day to day basis. Some, however, took herbal medicines occasionally because they worried that their blood pressure would drop too low. However, not every participant experienced the so called 'positive effects' on herbal treatment, whether as mono-therapy or in combination with conventional medicine. They used herbal medicines on advice they received from family and friends but reported that they did not see or feel any difference with herbal medicinal treatment.

Remarkably most of the participants conceded that doctors and pharmacist should prescribe and dispense herbal medicines regularly. A study that looked at the doctors' attitudes towards the use of herbal medicines in Nigeria, reported that although a high proportion of doctors were inclined to the use of herbal medicines, they believed that the level of research into herbal medicines was insufficient and that the level of education for herbal medicine practitioners was also inadequate (89). In another study, healthcare providers acknowledged that they know little about alternative medicine and are therefore

encouraged to further improve their CAM knowledge and stop being skeptical about CAM use as the patients they take care of often use alternative medicines (90). The more doctors open up to their patients about CAM; they will understand what remedies their patients are using (91). Contrary to the belief that herbal medicinal products are inexpensive (10), in this study most participants believed that CAM can be more expensive than conventional medicines. This could have been due to the fact that they collected their chronic medicine for free from clinics and had no idea how much they really cost. Regardless of this fact, they still chose to use herbal medicines, because they believed that they do not cause any harm to them but that they were good to take.

Most of the participants in this study preferred to get their supply of herbal products from pharmacies. This is encouraging as the consumers of herbal medicine will have more interactions with pharmacists who would be able to counsel patients further on the correct use of these products in order to minimize the risk of interactions with other products that patients could be taking. This will also ensure that only safe and high quality products are sold to the consumers. Data from the study show that the endorsement of herbal products is based on marketing through adverts by manufactures as well as from family and friends (word of mouth advertising). Despite insufficient evidence with regard to the safety or efficacy of herbal products, general promotion and advertisement of herbal products in the media and uncorroborated health care claims increase their demand (69).

The fact that almost all participants in the study agreed that the herbal products they use should contain package inserts with all possible side effects listed, confirms that the public would benefit from the testing of these products before they are released into the market. Vigorous scientific testing, thorough research on safety, quality and efficiency should be motivated and carried through before products are made available to the general public.

Chapter 5

5.1 Conclusion

The result of this study demonstrates a positive attitude by participants towards herbal medicine usage. Patients perceive herbal medicine as natural and therefore safe for consumption without worrying about toxicity as compared to conventional therapies. Participants in this study also believed that herbal medicines improve their quality of life and give them the sense of wellbeing. They also believe that herbal therapies are able to reverse the side effects of conventional medicines. The main origins of information on herbal products were from family, friends and advertisers. Healthcare givers were not popular source of information. The majority of participants would, however, prefer to have doctors and pharmacists prescribing and dispensing herbal medicines regularly. The participants, who were involved in this study, did not complain about any side effects or interactions with herbal medicines they were using. They believed that herbal medicines were effective, hence they purchased it regularly. The group that did not experience any relief of symptoms also did not complain about side effects or interactions. They only complained that they did not see any changes to their health since they started treatment with herbal medicines.

5.2 Study Limitations

The location of the study site meant that all participants who took part in the study were of similar racial group, cultural beliefs as well as similar socio-economic background and thus the researcher did not get any perspective from people of different racial and cultural beliefs. A time constraint was also another limitation. Thirteen participants terminated the interview in the middle of it because it was taking too long to complete. Although they promised to return later to complete the questionnaire, they never did and were therefore eliminated from the survey. Although the study sample was not small, the researcher believes that a much bigger sample may have exposed greater deviations in herbal medicine perceptions.

The researcher acknowledges that the selection criteria were biased towards participants who would have a positive attitude towards the herbal medicine products as they were purchasing and using them.

5.3 Recommendations

Whether healthcare givers are aware or not, many of the patients they care for use alternative therapies daily, as mono-therapy or in combination with conventional medicines. The time has come for healthcare givers to take a stand and become interested in the usage of these forms of alternative therapies through continuous learning/education in order to gain a full understanding of the roles and impact that these alternative therapies may have in the lives of those they care for.

Medical and pharmacy schools might also assist their students through training by introducing curriculum courses on CAM usage in an effort to benefit their students in learning these types of therapies as they will surely encounter these in their careers. Pharmacists as the custodian of medicines must have a clear understanding of these therapies in order to give sound advice especially because many patients purchase their herbal products from their pharmacies.

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Appendix I: Patient Demographics

Age: 18 – 25 ☐ 26 -30 ☐

31 – 35 ☐ 36 - 40 ☐ 41 - 50 ☐

51 - 70 ☐

Gender: Male ☐ Female ☐

Level of Education

Primary Education ☐ Secondary Education ☐ Tertiary Education ☐ Illiterate ☐

Chronic Conditions

Have you ever been diagnosed with any Chronic Disease? Yes ☐ No ☐

If yes, please specify your diagnosis and treatment

Condition:

Treatment: Medicine, Dosage and Directions

How long have you been on this treatment?

Since you started on this treatment, how are you doing? Has your condition improved?

How often do you go for regular check-ups?

Herbal Treatment

Name of herbal product

How do you take it?

For what condition do you take this product?

For how long have you been taking this product?

Have you noticed any changes to your health since you started using herbal medicine?

Please specify.

Do you prefer taking this herbal product with your chronic medicine?

Please explain why?

Was this product recommended to you by anyone?

If not, please explain how you chose this product over other products.

Would you recommend this product to others?

Appendix B: Data Extraction Sheet (Perceptions)

Perceptions regarding the use of herbal products (tick the relevant box)

Question	Strongly agree	Agree	Neutral	Disagree	Strongly Disagree
Herbal medicine is safer than pharmaceutical medicine					
Herbal medicine is more effective than pharmaceutical medicine					
Herbal medicine should only be sold in licensed pharmacies					
Combination of herbal and pharmaceutical medicine is better					
Doctors and pharmacists should prescribe and dispense herbal medicines regularly					
Herbal medicine is less expensive than pharmaceutical medicine					
Like with pharmaceutical medicine, herbal medicine must contain package inserts listing all possible side effects					
Do you prefer herbal medicine over pharmaceutical medicine					
Adverts of herbal medicine help patients decide which products to use					
Although I take herbal medicine, I consider pharmaceutical medicine to be more effective					
Herbal medicine should be tested to ensure safety before released onto the market					

Appendix C

Participant Information Sheet

Research Title: The Use of Herbal Medicine in a Community or Retail Pharmacy

Principal Investigator: Moraba Mhlanga

Research Site: Pimville Square Pharmacy (Y52277). Shop no 4 Pimville Shopping Centre

Before you decide whether or not you wish to participate in the study, it is important for you to understand why the research is being conducted and what it will involve. Please take the time to read the following information carefully.

The purpose of the study is to determine the use of herbal medicine in the pharmacy. This will be achieved by finding out what patients prefer to use, for which conditions and if they combine these herbal products with other medicines or not. The beliefs of the patients concerning the use of herbal medicine will be looked into in this study.

This study will involve interaction with patients through interviews. It will also involve going through the pharmacy's database, point of sale computer, to see which products are purchased by patients regularly.

1. What is the purpose of the study?

The purpose of the study is to determine the patterns of herbal medicine use in the pharmacy.

2. Why have I been invited to participate in this study?

You are eligible to participate in this study because you have purchased and are using herbal medicine that has been identified as one of the preferred products that patients use.

3. What if I don't want to take part in this study?

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

4. How is this study being paid?

This study has no sponsor and therefore there will not be any remuneration to patients participating in it.

5. How will my confidentiality be protected?

I, as the researcher will know your name and will know whether or not you are participating in this study. Any identifiable information that is collected about you in connection with this study will remain confidential and will be disclosed only with your permission, or except as required by law. Only the researcher named above will have access to your details and results.

6. What happens with the results?

In any publication, information will be provided in such a way that you cannot be identified. Results will be provided to you, if you wish.

7. What should I do if I want to discuss this study further before I decide?

When you have studied this information, the researcher, Moraba Mhlanga, will discuss it with you and answer any questions you may have. You are also welcome to take this information away with you and discuss with your family, friends, treating doctor or any other person you choose. If you would like to know more at any stage, please do not hesitate to contact Moraba Mhlanga on 073 246 3805 or mmhlanga71@gmail.com

Thank you for taking time to consider this study. If you wish to take part, please sign the attached consent form. This information sheet is for you to keep.

Appendix D

Consent form

Informed Consent Department of Pharmacy; Research Project Title: The Use of Herbal Medicine in the Pharmacy

On I voluntarily consented to participate in the above named study by being interviewed by Moraba Mhlanga for her Master's research paper through Wits University. The study is specifically looking at the use of herbal /natural products in the pharmacy and I am a participant in this study to give my view of the use of herbal/natural medicine as a patient.

The results of the study will be used for Moraba Mhlanga's research paper. My participation in this interview was voluntary. I could choose not to answer or to skip any of the questions, could ask questions and/or could end the interview at any stage. This interview will be kept strictly confidential. Moraba Mhlanga can be contacted with any questions at 073 246 3805 or at mmhlanga71@gmail.com. Her supervisor at Wits University is Prof Andries Gous whom can be contacted at andries.gous@smu.ac.za



R14/49 Ms M Mhlanga

**HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
CLEARANCE CERTIFICATE NO. M170725**

NAME: Ms M Mhlanga
(Principal Investigator)
DEPARTMENT: School of Therapeutic Sciences
Department of Pharmacy
Medical School

PROJECT TITLE: The use of herbal medicines in a community/retail pharmacy

DATE CONSIDERED: 28/07/2017

DECISION: Approved unconditionally

CONDITIONS:

SUPERVISOR: Professor AGS Gous

APPROVED BY:

Professor CB Penny, Co-Chairperson, HREC (Medical)
19/09/2017

DATE OF APPROVAL:

This clearance certificate is valid for 5 years from date of approval. Extension may be applied for.

DECLARATION OF INVESTIGATORS

To be completed in duplicate and ONE COPY returned to the Research Office Secretary on 3rd floor, Phillip V Tobias Building, Parktown, University of the Witwatersrand, Johannesburg.

I/We fully understand the conditions under which I am/we are authorised to carry out the above-mentioned research and I/we undertake to ensure compliance with these conditions. Should any departure be contemplated from the research protocol as approved, I/we undertake to resubmit to the Committee, I agree to submit a yearly progress report. The date for annual re-certification will be one year after the date of convened meeting where the study was initially reviewed. In this case, the study was initially reviewed in July and will therefore be due in the month of July each year. Unreported changes to the application may invalidate the clearance given by the HREC (Medical).

Principal Investigator Signature

Date

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES