

UNIVERSITY OF NAIROBI, FACULTY OF HEALTH SCIENCES DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS

UTILIZATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE BY PATIENTS WITH RHEUMATOLOGICAL DISEASES IN KENYATTA NATIONAL HOSPITAL

DR. KISMAT.M. JUMA H58/34179/2019 MBCHB, UoN

A DISSERTATION SUBMITTED IN PARTIAL FULFILMENT FOR
THE DEGREE OF MASTER OF MEDICINE IN INTERNAL
MEDICINE AT THE UNIVERSITY OF NAIROBI

STUDENT'S DECLARATION

I hereby confirm that this dissertation is my own work and has not been presented for a degree at any other institution.

Dr. Kismat M. Juma

Internal medicine resident

Department of Clinical Medicine and Therapeutics
University of Nairobi

Signature: Date: 23rd Novembr. 2023.

DEDICATION

I dedicate this work to my late grandmother who never stopped believing in me. I also dedicate this book to my mum who has been my most profound inspiration and always pushes me to reach for the star.

APPROVAL OF SUPERVISORS AND CHAIRMAN OF THE DEPARTMENT

This dissertation has been submitted with our approval as the supervisors and the chairman form the Department of Clinical Medicine and Therapeutics, Faculty of Health Sciences, University of Nairobi

SUPERVISORS:	
Prof. G. Omondi Oyoo	
Associate Professor	
Consultant Physician and Rheumatologist	
Department of Clinical Medicine and Therapeutics, U	niversity of Nairobi.
Signature Date Date	
Dr.Eugene K. Genga	
Senior Lecturer	
Consultant Physician and Rheumatologist	
Department of Clinical Medicine and Therapeutics, U	niversity of Nairobi.
Signature	
Date 17 [111]	
Dr. Enoch O. Omonge	
Senior Lecturer	
Consultant Physician and HIV specialist	
Department of Clinical Medicine and Therapeutics, U	nit of Clinical Pharmacology
University of Nairobi	

Signature

CHAIRMAN OF THE DEPARTMENT:
Prof. E. O. Amayo
Chairman
Consultant Physician and Neurologist
Department of Clinical Medicine, and Therapeutics
University of Nairobi SITY OF NAIROBI Signature SE OF HEALTH SCIENCES Signature SE OF HEALTH SCIENCES
Signature CON SE OF HEALTH SCHERAPEUTICS

Date

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LIST OF ABBREVIATIONS AND ACRONYMS

CAM - Complementary and Alternative Medicine

DMARDs - Disease-Modifying Anti-Rheumatic Drugs

MD- Medical Doctor

NSAIDs - Non-Steroidal Anti-Inflammatory Drugs

NAFKAM - Norway's National Research Centre in Complementary and Alternative

Medicine

NCCAM - National Centre for Complementary and Alternative Medicine

NIH- National Institute of Health

HCQ- Hydroxychloroquine

KNH- Kenyatta National Hospital

ICAMQ - International Complementary Alternative Medicine Questionnaire

OA- Osteoarthritis

RA - Rheumatoid Arthritis

RD- Rheumatological Diseases

SF-36- Short Form 36 Health Survey Questionnaire

SLE - Sýstemic Lupus Erythematosus

SPSS- Statistical Package for Social science

TNF- Tumour Necrosis Factor

TwHF- Tripterygium wilfordii Hook F

WHO- World Health Organization

UON - University of Nairobi

Vit B6 - Vitamin B6

Vit C - Vitamin C

Vit D - Vitamin D

Vit E- Vitamin E

DEFINITION OF KEY TERMS

Complementary and Alternative Medicine - a broad domain of resources that encompasses health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the domain health system of a particular society and culture in a given period. CAM includes resources that are perceived by the users as associated with positive health outcomes.

CAM -user – A person who has utilized herbal medicine, dietary supplements, or self-care techniques within the last year.

ABSTRACT

Background: The utilization of complementary and alternative medicine (CAM) has increased in recent times, especially among patients with rheumatic diseases, particularly those experiencing pain and mobility limitations. CAM use poses potential risks such as drug interactions and challenges in adhering to conventional medicine.

Objective: This study aimed to determine the prevalence of CAM use and evaluate the reasons and determinants of CAM use among patients with rheumatological diseases who attended the rheumatology outpatient clinic at Kenyatta National Hospital.

Research design and method A cross-sectional descriptive study was conducted among 151 patients with a confirmed diagnosis of rheumatic diseases at the rheumatology outpatient clinic in KNH. Patients were selected using a consecutive sampling technique. Data was collected using the self-administered NAFKAM International - CAM-Questionnaire (I-CAM-Q) to determine the prevalence and main reasons for CAM use, and the SF-36 questionnaire to determine the quality of life. Both tools have been validated.

Results: The prevalence of CAM use was 55.6%. The most commonly used CAM modalities were vitamins/minerals (94%), praying for health (80.9%), and herbs/herbal products (69%). The main reason for CAM use was to improve well-being, followed by its use as an alternative/co-medication due to the high cost of conventional medicine. The least common reason was dissatisfaction with conventional medicine. There were no significant sociodemographic determinants of CAM use; however, an association was observed between the quality of life of CAM users and non-CAM users.

Conclusion: CAM use was observed in more than 50% of the study participants, highlighting a significant prevalence. It is plausible that these individuals had pre-existing severe conditions, which led them to explore CAM as an additional approach to managing their health. Alternatively, the use of CAM may have interfered with their adherence to conventional medication, potentially contributing to the experience of more severe disease. Healthcare professionals should be vigilant in identifying CAM usage and assessing whether it is the preferred treatment choice over conventional medicine for patients, in order to provide objective information.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background Information

Rheumatological diseases are a group of disorders that affect the musculoskeletal, arthritic, and connective tissue systems. These disorders include conditions such as rheumatoid arthritis, systemic lupus erythematosus, systemic sclerosis, ankylosing spondylitis, psoriatic arthritis, osteoarthritis, fibromyalgia, gout, and vasculitides. They are characterized by pain, which often results in restricted range of motion and function in one or more parts of the musculoskeletal system(1). This can lead to decreased productivity, significant disability, and reduced quality of life(2).

Conventional therapies for rheumatological diseases usually involve non-steroidal anti-inflammatory drugs (NSAIDs), disease-modifying anti-rheumatic drugs (DMARDs), and biologics(3). However, some patients do not respond well to these treatments and therefore seek other forms of therapy, such as complementary and alternative medicine(4).

Complementary and alternative medicine (CAM), according to the National Institute of Health (NIH) definition, encompasses a range of diverse medical and healthcare systems, practices, and products that are currently not classified as part of conventional medicine. Complementary medicine refers to a non-mainstream approach used in conjunction with conventional medicine, whereas alternative therapy involves a non-mainstream approach used instead of conventional medicine. Conventional medicine is the practice of medicine by individuals with medical doctor (MD) degrees and their allied health professionals, including physical therapists, psychologists, and registered nurses (5).

In certain countries, these terms are employed interchangeably with the expression "Traditional Medicine," a concept defined by the World Health Organization (WHO) as the totality of knowledge, skills, and practices derived from various cultures' theories, beliefs, and experiences, whether formally articulated or not. Traditional Medicine is utilized for the preservation of health, as well as in the prevention, diagnosis, enhancement, or treatment of both physical and mental illnesses (6).

The global prevalence of CAM usage in rheumatological conditions is a widespread concern. Studies have reported varying rates of CAM use, ranging from 22% to 96%, depending on the country, culture, and type of rheumatological condition as illustrated in Table 1.

Generally, the utilization of CAM is more widespread in countries with limited accessibility to conventional medical care or in cultures where CAM is widely accepted.

In developing countries, herbal medicine is the most commonly used CAM modality, while in developed countries, dietary supplements and mind-body practices are popular.

Factors that influence CAM use in rheumatological conditions include patient demographics, disease severity, perceived effectiveness of CAM, and satisfaction with conventional medical care. Patients who are older, female sex, have a lower educational background, and experience more severe illness are more prone to engage in CAM usage. (7).

It is worth noting that there is a lack of standardization in the definition and classification of CAM, which makes it difficult to compare studies from different regions. Additionally, the regulation and safety of CAM vary widely across countries, which poses challenges for patients, healthcare providers, and policymakers.

According to the 2019 global burden of disease study, rheumatological disorders constitute a significant contributor to disability.(8). Patients with these disorders often rely on medication that may not always provide complete symptom relief, leading them to consider alternative therapies in addition to conventional treatments.

Despite the potential adverse effects of CAM and the risk of interactions with conventional medications, many patients with rheumatic conditions fail to disclose their CAM usage to their healthcare providers. The majority of CAM modalities lack official certification, leaving uncertainty about what is backed by evidence and officially endorsed (9).

To our knowledge, there have been no prior investigations into the utilization of CAM among individuals with rheumatological conditions in Kenya. Consequently, the objective of this study was to assess the prevalence of CAM usage among patients with rheumatic diseases and understand the reasons for its utilization at the rheumatology outpatient clinic in Kenyatta National Hospital.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Terminology

The term "Complementary and Alternative Medicine" has evolved, and "Integrative Medicine" is increasingly used to refer to these practices. In the past, CAM was formally called "quackery" and was ridiculed(9). However, attitudes have changed, and the scientific community has become more accommodating, particularly after the founding of the office of Alternative Medicine at the National Institutes of Health (NIH) in 1992. The program was initially called the National Center for Complementary and Alternative Medicine (NCCAM) and subsequently renamed the National Center for Complementary and Integrative Health.

2.2 Definition

There is no standard definition of CAM in existing literature. The National Center for Complementary and Alternative Medicine (NCCAM) of NIH defines CAM as "a group of diverse medical and healthcare systems, practices, and products that are not presently considered to be part of conventional medicine"(10). The NCCAM stated in 2002 that when non-mainstream approaches are utilized alongside conventional medicine, it is termed complementary medicine; however, when non-mainstream approaches are employed instead of conventional medicine, it is referred to as alternative medicine (5).

The definition of CAM has changed over time. Earnest et al described CAM as "a diagnosis, treatment, and/or prevention that complements mainstream medicine by contributing to a common whole, satisfying a demand not met by orthodox or diversifying the conceptual framework of medicine" (11). Eistenberg et al depicted CAM in 1993 as "interventions neither taught widely in medical schools nor generally available in hospitals" (12).

The NCCAM's modified definition and description of CAM states that "Complementary and alternative medicine (CAM) is a broad domain of resources that encompasses health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the domain health system of a particular society and culture in a given period. CAM includes resources that are perceived by the users as associated with positive health outcomes. Boundaries within CAM and between the CAM domain and the domain of the health system are not always sharp and fixed"(13).

This definition is expansive, capturing the breadth and nature of CAM usage, being driven by patients, encompassing practices perceived to confer health benefits, and allowing for potential evolution.

It acknowledges the fluidity of the "conventional" medicine definition across time and regions, avoids assuming the adoption of proven practices, and permits the ongoing assessment of CAM.

This study embraces the NCCAM's definition of CAM due to its inclusivity, which mirrors the comprehensive nature of CAM use. The chosen definition avoids excluding common practices from the research agenda, prioritizes a patient-centered approach, and acknowledges the potential for evolution.

2.3. Domains of CAM

NCCAM 2000 has proposed a classification system that can be used to organize the field (13). It divides CAM modalities into five groups:

- a) Alternative medical systems
- **b)** Mind -body interventions
- c) Biological based treatment
- d) Manipulative and body -based methods
- e) Energy therapies

2.3.1 Alternative medical system

A classification that incorporates practices developed independently of conventional medicine. Examples of such systems encompass traditional Chinese medicine, Ayurvedic medicine, homeopathy, and naturopathy (13).

2.3.2 Mind- body interventions

This encompasses practices that are hinged on the human mind but have an impact human body and physical health. They include meditation, prayer, and mental healing (13).

2.3.3 Biological based therapies

Comprises of herbal products, specialized diets, and other natural products such as minerals, hormones, and biologicals (13).

2.3.4 Manipulative and body -based methods

Encompasses therapies that entail the movement and manipulation of the body, with chiropractic being a prominent example in this category. Body-based therapy includes practices like massages. (13).

2.3.5 Energy therapies

Involve manipulating and applying energy fields to the body, based on the postulation that energy fields exist within the body. While the experimental proof of the existence of these biofields is lacking, several therapies, such as qi gong and therapeutic touch, incorporate these principles (13).

2.4 Epidemiology

In 1990, a nationwide study revealed that 2.5% of adults in the United States were using herbal medicine (14). Subsequently, a later survey showed a significant increase, with 12.1% of American adults stating that they had used herbal medicine in the previous year, marking a fivefold growth. The primary factor contributing to this substantial rise was the passage of the Dietary Supplement Health Education and Education Act (DSHEA) by Congress in 1994. This legislation permitted manufacturers to market herbal products without having to demonstrate their safety and efficacy beforehand. As per the World Health Organization (WHO), approximately 70-80% of patients in developed nations utilize at least one form of complementary and alternative medicine (CAM) (15).

According to the 2012 National Health Interview Survey (NHIS) regarding complementary and alternative medicine (CAM), 17.7% of individuals in the United States had employed natural products, encompassing herbal and other non-botanical supplements, during that year. CAM use was found to be more common in chronic conditions than in life-threatening medical disorders (16).

Herman and colleagues conducted research on CAM use in various rheumatic diseases in the US, finding a prevalence rate of 65%. The highest use of CAM was for oral supplements, specifically glucosamine and chondroitin (34%), followed by mind-body therapy (29%) and vitamins and minerals (16%) (17). Another study by Chatfield and colleagues in Australia revealed a CAM use prevalence rate of 94% among patients with ankylosing spondylitis, with 71 out of 74 participants reporting previous or current CAM use. Of these, 44 (72%) used dietary CAM, and 27 (36%) sought treatment from a CAM practitioner during the study.

Out of the people who use CAM, 56% did not observe significant improvements. Those who use CAM are more likely to be female and had a higher education level compared to non-CAM users (18).

Ramus and colleagues carried out a study in Mexico to ascertain the prevalence of CAM utilization among individuals with rheumatological conditions, discovering it to be approximately 83%. Those patients who had engaged in CAM over the past twelve months exhibited lower educational levels and slightly higher disability, as evaluated through the modified health assessment questionnaire. (19).

In Sweden, E. Kleinberg conducted a study on the utilization of CAM in patients with rheumatic diseases and estimated the prevalence of CAM use to be 65%, with women being the most common users. CAM use was linked to parameters indicating poor mental and physical health, as measured by the SF-36. Additionally, CAM use was associated with limited use of immunomodulatory drugs (20). Another study by Hasan Ulusoy and colleagues in Turkey estimated the use of CAM in rheumatic disease patients at 46%. The most commonly used forms of CAM were dietary modifications (26%) and body-based practices (16.4%). Of the users, 26% reported satisfaction with the benefits of CAM, while 73.5% perceived it as useless. Most patients using CAM were encouraged by their relatives and the media, whereas only 13% used CAM after being recommended by their physicians (21).

Research conducted in Saudi Arabia on the utilization of complementary and alternative medicine (CAM) among individuals with rheumatoid arthritis (RA) showed that 70.7% of the participants integrated at least one form of CAM into their treatment, with herbal medicine being the most commonly employed type. The study also demonstrated that the level of education, income, and duration of illness were important factors that impacted the usage of CAM (22).

The prevalence of CAM use is expected to be higher in Africa due to the availability of Traditional Medicine practice. More than 80% of Africa's population relies on traditional healing modalities, including herbal remedies, for medical management and health maintenance. The proportion of traditional health practitioners to the population in Africa is 1:500, whereas the ratio of medical doctors to the population is 1:40,000 (6). A study conducted in Nigeria showed a prevalence of CAM for musculoskeletal pain at 96.8%. The most common CAM used was herbal therapy and massages at 83% and 81%, respectively(23).

Studies have been conducted in Kenya on cancer patients and individuals with type 2 diabetes mellitus. Matheka et al. observed a rise in the utilization of CAM among diabetic patients, which poses a public health concern due to the potential adverse effects associated with its concurrent use. The prevalent forms of CAM in Kenya included herbal medicine, dietary

supplements, prayer, and relaxation techniques. The main reason why patients used CAM was dissatisfaction with and inaccessibility of conventional medicine (24).

In another study by Ong'udi and colleagues at Kenyatta National Hospital, the prevalence of CAM use by cancer patients was found to be relatively low at 14% compared to other countries. The most used form of CAM was herbal medication, with patients hoping to cure their disease(25).

The use of CAM was not influenced by age, gender, marital status, or education level. Many patients did not experience the expected benefits of CAM and did not inform their doctors as they did not consider it important (25).

There is a lack of research on the use of CAM among rheumatic patients in Kenya. While numerous studies have demonstrated an increase in CAM usage globally, obtaining reliable data on the prevalence of CAM use within specific diagnostic groups remains difficult.

The prevalence of CAM use in a given patient population ranges from 25% to 50%, but the percentages can vary greatly depending on the region and timeframe of measurement. The discrepancy in data is largely due to the lack of a standardized definition of CAM. Some surveys include prayer and relaxation techniques as part of CAM, while others do not.

As a result, CAM usage varies from 11% to 72% in the same patient group, depending on the definition used (26). Additionally, there is no consistent method for measuring CAM use.

To address these discrepancies and improve cross-country comparisons, a standardized tool called the International Complementary and Alternative Medicine Questionnaire (ICAM-Q) was developed in 2006(27). The questionnaire has since been validated, translated and adapted to various languages and countries(28)(29). It has been used to estimate the rate of CAM use in patients with diabetes, inflammatory bowel diseases, and multiple sclerosis. The ICAM-Q has been used in countries such as France (30), Germany (31), Iran (32), the United States (33), Argentina (34), Japan (35), Taiwan (36), and Korea (37).

Research by Quandt et al has shown that the ICAM-Q is effective in replacing local and regional methods to allow for cross-study comparisons of CAM use (33). However, a study by Ealdley et al in 2012 found that the ICAM questionnaire may produce biased estimates of CAM use in certain populations (29). Despite this limitation, the ICAM questionnaire remains a common tool for comparing CAM use across different populations and will be used in this study.

Table 1:Prevalence of CAM use in rheumatological disease demonstrated in previous studies.

Reference	Country	Diagnosis	Methods	CAM use previous 12 months (%)	Ever used CAM (%)	Questionnaire
Herman et al (17)	USA	Various RD	Face to face interview		90%	Structured Questionnaires
Chatfield et al (18)	Australia	Ankylosing spondylosis arthritis	Telephone administered questionnaire		95%	Structured Questionnaire
Cesar Ramos- Remus et al (19)	Mexico	Various RD	Face to face interview	68%	83%	Semi- Structured Questionnaire
E klingberg et al (20)	Sweden	Various RD	Questionnaire		65%	Structured Questionnaires
Hasan Ulusoy et al (21)	Turkey	Various RD	Face to face interview		46%	Semi- Structured Questionnaire
Mbada et al (23)	Nigeria	Musculoskelet al pain	Self- administered questionnaire	83%	96%	Semi- Structured Questionnaire
Fautrel et al (38)	Canada .	Arthritis	Telephone survey	22%		Semi- Structured Questionnaire
Fleming et al (39)	USA	Patients with chronic pain treated in primary care	Face to face interview	44%		Semi- Structured Questionnaire
Buchbinder et al (40)	Australia	Rheumatoid arthritis	Telephone administered questionnaire	73%		Unstructured Questionnaire
Rao et al (41)	USA	Various RD	Telephone survey		63%	Semi- Structured Questionnaire

None of these studies used the I-CAM questionnaire.

Table 2:Studies on CAM use in Kenya (Different population)

Author	Population	Prevalence	Type of CAM used	Reason for use
Matheka et al (24)	Diabetes mellitus	80%	Herbal, prayer relaxation	Dissatisfaction and inaccessibility of conventional medicine
Ong'udi et al (25)	Cancer patients	14%	Herbal medication	To cure illness
Karaki et al (42)	Cancer patients	46%	Spiritual therapy and herbal	Improve health

2.5 Determinants influencing the utilization of Complementary and Alternative Medicine (CAM).

Patients with rheumatological diseases often seek alternative approaches to complement or supplement conventional medical treatments.

Reasons for CAM Use in Rheumatological Diseases:

- Symptom management: Patients grappling with the debilitating symptoms of rheumatological diseases, such as pain, inflammation, and stiffness, often seek relief beyond conventional treatments. CAM therapies example mind-body practices like yoga, have been reported to provide symptom relief and improve physical function in these patients (43)
- Dissatisfaction with conventional medicine: Some patients may express dissatisfaction
 with the outcomes or side effects of conventional medical treatments for
 rheumatological conditions. CAM offers an alternative or complementary approach,
 addressing perceived gaps in conventional care (3).
- 3. Holistic approach and well-being: CAM therapies emphasize a holistic view of health, considering physical, mental, emotional, and spiritual well-being. Patients often turn to CAM to enhance their overall well-being, reduce stress, and improve their quality of life. Mindfulness, meditation are examples of CAM modalities that have demonstrated positive effects on well-being and psychological outcomes in rheumatological patients (43).
- 4. Cultural and personal beliefs: Cultural or personal beliefs and preferences can play a significant role in CAM utilization among patients with rheumatological conditions. CAM therapies aligned with traditional or cultural practices may resonate with patients' values and beliefs, leading them to explore these modalities (44).

It is important to consider the risks associated with CAM use, such as the lack of scientific evidence, potential for delayed or inadequate treatment, and risks of adverse effects and interactions. Health care workers need to inquire about CAM use to provide comprehensive patient care, ensure patient safety, and offer education and guidance regarding evidence-based CAM options. ICAM-Q has been chosen as the questionnaire tool for this study to identify the primary reasons for CAM utilization among patients with rheumatological diseases. It is important to note that the ICAM-Q has its limitations as it only includes three reasons, and participants are asked to select only one main reason. These reasons encompass using CAM to improve well-being, dissatisfaction with medical care, or the high cost of conventional medicine. Similar studies conducted in Kenya have explored these reasons and found them to be the primary motivations for CAM use among patients. For instance, in the case of cancer patients, CAM was predominantly used with the hope of curing the disease or providing symptomatic relief(25). On the other hand, diabetic patients reported dissatisfaction with and limited access to conventional medicine as their primary reason for turning to CAM (34). By utilizing the ICAM-Q questionnaire in this study, we aim to determine the main reasons behind CAM utilization among patients with rheumatological diseases. This research will provide valuable insights into the specific motivations driving patients to seek CAM and contribute to the existing body of knowledge on CAM use in rheumatological conditions.

2.6 Complementary and alternative remedies used by patients with rheumatological diseases.

Therapies with limited and inadequate or inconsistent evidence

A) Herbal remedies

Several herbal remedies have been tested for their potential benefits in treating arthritis and musculoskeletal diseases. However, there is no convincing and reproducible evidence that supports the use of any herbal therapy as a safe, effective, and clinically significant treatment for patients with rheumatic diseases. An example of a herbal remedy with potential benefits for rheumatoid arthritis is the alcohol extract of Tripterygium wilfordii Hook F (TwHF), a Chinese herbal remedy that has been found to have immunosuppressive properties. Well-designed randomized trials have demonstrated that Tripterygium wilfordii Hook F (TwHF) can offer clinical benefits to patients with rheumatoid arthritis (RA), exhibiting noninferiority to methotrexate.

Furthermore, studies have indicated that the combination of TwHF and methotrexate is more effective than using either treatment alone. However, additional research is needed to further investigate the mechanism behind TwHF's anti-inflammatory effects. It should be noted that the use of TwHF may be limited due to its cost and potential adverse effects (45).

Supplementation with turmeric was found to be beneficial in treating lupus nephritis when used in combination with standard care in a small randomized trial (46). Similarly, green tea extract was found to improve disease activity and fatigue in patients with systemic lupus erythematosus in a randomized trial (47). However, the efficacy of these herbal remedies still needs to be confirmed by further studies in humans.

Some herbal preparations, such as Eazmov, Gitadyl, and ginger extract, have been promoted as treatments for osteoarthritis, but there is currently no convincing evidence to support their use (48).

- B) Ayurveda Ayurveda is an ancient Indian medical system utilizing a variety of practices. Two Ayurveda mixtures, borage, garlic, phytodolor and selenium have been studied, but analytical reviews have not considered satisfactory evidence of efficacy (49).
- C) Diet and nutritional therapies-Dietary therapies do not play role in therapy for patients with chronic inflammatory arthritis, osteoarthritis, or systemic autoimmune rheumatic disease due to lack of evidence to support the efficacy of food, diet, or nutritional therapy for patients with these conditions (50)

Here are some exceptions:

- In gouty arthritis, dietary composition and specific foods and drinks are well established as risk factors for hyperuricemia, incidental gout, or symptomatic flares of acute gout.
- Diet rich in fish or fish oil supplement (vegetable oil) or that were "healthy" have provided marginal clinical benefit to patients, compared to normal diet.
- **D)** Supplements- Glucosamine is naturally found in the body as an amino sugar. It is a precursor for cartilage component and several studies have been carried out in osteoarthritis. It is acquired as glucosamine sulphate and glucosamine hydrochlorides. Studies in animal models: glucosamine sulphate has been shown to repair damaged cartilage and decrease inflammation. However, studies of glucosamine in patients with rheumatoid arthritis reported fruitless effect on diseases activity but noted to reduce pain in patients. (51)(43)

E) Vitamins- A balanced diet is important for providing essential vitamins that are necessary for good health. One such vitamin is Vitamin D, which is primarily produced when the skin is exposed to sunlight. In some parts of the UK, there may be a deficiency of Vitamin D. It plays a crucial role in calcium and bone metabolism, which is especially important for rheumatic conditions like rheumatoid arthritis, as there is a correlation with osteoporosis, falls, and fractures. If a deficiency of Vitamin D is identified, it should be treated adequately by medical practitioners, as simply supplementing with doses may not be sufficient to correct the deficiency (43).

Vitamin B6 is an enzyme cofactor and is an important regulator of protein metabolism. It is found in different forms, including pyridoxine from plants and pyridoxal and pyridoxamine from animal tissues, which are converted into the active metabolite pyridoxine-5-phosphate (PHP). Patients with rheumatoid arthritis have been found to have lower levels of Vitamin B6 compared to healthy individuals, which has been linked to cytokine overproduction like tumor necrosis factor (TNF) (52)(53).

Although an increased dose of Vitamin B6 has been found to improve inflammatory conditions, there has been no significant effect on disease activity (52). Patients can tolerate supplementation well, but overdosing may have adverse effects.

Free radicals are associated with inflammatory processes that can lead to tissue destruction. Vitamins C and E are antioxidants that are used in the treatment of inflammatory conditions like rheumatoid arthritis. Vitamin E is found in plant oils like sunflower and corn oil. Studies conducted in patients with rheumatoid arthritis (RA) have demonstrated a potential reduction in pain with the use of vitamins C and E. However, it is important to note that many of these studies have been deemed inadequate in terms of their methodology and findings (54).

Selenium is an essential trace element and functions as a cofactor for antioxidant enzymes such as glutathione peroxidase. It has been observed that patients with rheumatoid arthritis (RA) tend to have lower levels of selenium compared to the general population. However, studies on selenium supplementation in RA have not shown conclusive efficacy. While selenium is generally well-tolerated, it is important to note that high toxic doses of selenium can potentially lead to adverse effects (54).

2.7 The American College of Rheumatology (ACR) position statement on CAM

The American College of Rheumatology (ACR) acknowledges the interest in complementary and alternative medicine (CAM) among those with arthritis and believes that healthcare providers should be informed about CAM modalities and able to discuss them with patients.

The ACR supports scientific evaluation of CAM modalities and the integration of those proven to be safe and effective through rigorous clinical trials. However, caution should be exercised with modalities that have not been studied scientifically, and patients should be warned of the potential harm that can come from unproven therapies. Healthcare practitioners should be proactive in inquiring about patients' use of CAM(4).

2.8 Problem statement

According to the World Health Organization (WHO), many patients in developed countries utilize at least one form of complementary and alternative medicine (CAM), and this number is expected to be even higher in Africa due to the reliance on traditional healing methods (43). However, there is a shortage of reliable data and information regarding CAM use in developing countries. In Kenya, studies have been conducted on CAM use in cancer and diabetes mellitus patients, but there is lack of reliable data on CAM use in patients with rheumatic diseases (RD). Despite the high prevalence of CAM use, patients often do not disclose its use to physicians, resulting in many doctors being unaware of their patients' CAM utilization. It is important to note that the use of CAM carries risks such as potential drug interactions and treatment deferral. This study aims to address the knowledge gap by assessing the prevalence of CAM use among patients with rheumatic diseases and investigating the reasons and determining factors behind CAM utilization. The findings of this study will contribute to a better understanding of the trends surrounding CAM use. Healthcare practitioners can anticipate CAM use and develop strategies to enhance patient compliance with standard treatments.

2.9 Research Question

What is the magnitude of complementary and alternative medicine use in patient with rheumatological diseases on follow up at the KNH?

2.10 Objectives

2.10.1 Broad objective

To determine the prevalence of complementary and alternative medicine use and its determinants in patients with rheumatological diseases in KNH.

2.11 Specific objectives

2.11.1 Primary objectives

- a) To determine the prevalence of complementary and alternative medicine use among patients with rheumatological diseases in Kenyatta National Hospital, rheumatology clinic
- b) To establish the main reason of Complementary and alternative medicine use among patients with rheumatological diseases in KNH, rheumatology clinic

2.11.2 Secondary objective

a) To identify the determinants of Complementary and alternative medicine use among patients with rheumatological diseases in KNH.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study design

A cross-sectional descriptive study on the utilization of CAM in rheumatic patients in Kenya at Kenyatta National Hospital

3.2 Study site

The research took place at Kenyatta National Hospital, a teaching and referral hospital located in Nairobi, Kenya. This hospital comprises 22 specialty clinics, including the rheumatology clinic, which operates on Tuesday and Thursday afternoons. New patients receive care from consultant rheumatologists from both KNH and the University of Nairobi, while follow-up patients are attended to by internal medicine residents from the University of Nairobi in consultation with the rheumatologists.

3.3 Study setting

The investigation was based on a self-administered questionnaire, in which patients participated after their appointment with a physician or rheumatologist. The estimated time required to respond to the questionnaire was approximately 15-20 minutes.

3.4 Study population

Case definition

Rheumatic disease patient – A patient with a rheumatologist confirmed diagnosis of a RD as documented in the file

3.4.1 Inclusion criteria

Patients > 18 years on follow up in the rheumatology clinic

3.4.2 Exclusion criteria

Patients who do not consent

3.5 Sample size determination

The sample was determined using fisher's formula for sample size for one proportion (prevalence) studies defined as:

$$n_0 = \frac{Z_{1-\frac{\alpha}{2}}^2 p(1-p)}{d^2}$$

Where.

 $Z_{1-\frac{\alpha}{2}}^2$ = the level of significance assumed to be 95% equivalent to 1.96 z-score value p= the expected proportion assumed to 46% (turkey study on ever use of CAM)(21) d= the margin of error assumed to be 5%

Since the number of RD patients in the rheumatology clinic is less than 10,000, as it's an inflammatory RD clinic. The calculated sample size, was adjusted for finite population correction using a population of 250 using the formula:

$$n = \frac{n_0}{1 + \frac{(n_0 - 1)}{N}}$$

Where N is the finite population

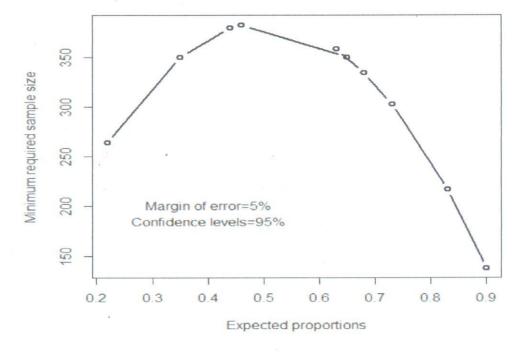


Figure 1:Sample size determination

Assumption of 46% prevalence of ever CAM use among various rheumatic diseases in Turkey (21), Calculated sample size of 382 and adjust for the finite population of 250 participants sample size required for the study will be 151.

3.6 Sampling technique

Participants for this study were recruited using consecutive sampling. The principal investigator, along with two trained research assistants (registered clinical officers), attended the rheumatology clinic on their designated clinic days.

All patients with a diagnosis of a rheumatological disease, who met the inclusion criteria, were recruited in the order of their arrival and given the opportunity to participate in the study. This process was repeated until the desired sample size was achieved.

3.12 Study variables

3.12.1 Independent variables

- i. Sociodemographic:
 - Age-recorded as the number of years documented in the file or reported from the date of birth.
 - Sex- categorized as male or female.
 - Marital status recorded as single, married, divorced, or widowed.
 - Level of education the highest level of education the patients has attained.
- ii. Related to rheumatic disease:
 - a) Type of rheumatic disease,
 - Rheumatoid arthritis,
 - Systemic lupus erythematosus,
 - Fibromyalgia,
 - Osteoarthritis,
 - Other rheumatologic conditions e.g., gout, scleroderma, Sjogren syndrome
 - b) Duration of disease Time interval from the date of confirmed diagnosis to the last follow-up
 - c) Treatment modality: Defined as the current drug use, duration, and dosage. Drugs are classified as NSAIDS, DMARDS and antimalarials.
 - d) Quality of life assessed by the SF-36 questionnaire.

3.12.2 Outcome variables

The use of CAM and the pattern of usage

ICAM-Q questionnaire will be used to evaluate the use of CAM.

- a) Prevalence of CAM use
- b) Type of CAM used.
- c) Reason for CAM use

3.9 Study instruments

A data collection sheet was used to document patients' details and characteristics including.

3.9.1 Demographic and clinical characteristic of study population

This following information was obtained from the patient's file.

- i. Age in years
- ii. Sex
- a) Female
- b) Male
- iii. Duration of treatment in years
- iv. Duration of follow up in Rheumatology clinic.
- v. Level of education.
- vi. Diagnosis
 - a) Rheumatoid arthritis (RA)
 - b) Systemic lupus erythematosus (SLE)
 - c) Osteoarthritis (OA)
 - d) Fibromyalgia
 - e) Others

This was followed by structured questionnaire, the I-CAM-Q and SF36.

3.9.2 International CAM questionnaire

The ICAM questionnaire was developed to measure the use and patterns of complementary and alternative medicine (CAM) by researchers at the National Research Centre in CAM of the University of Tromso, Norway. It was first published in 2009 and has since been validated and translated to many different languages and countries. The self-administered questionnaire has four sections on visiting healthcare providers, CAM prescribed by physicians, use of herbal medicine and dietary supplements, and self-practice. Survey participants furnish details about their utilization over the preceding 12 months ,their main reason for CAM therapy, and whether it was helpful(28). Permission to use the questionnaire was obtained. See in appendix

3.9.3 Quality of life

The Short Form Health Survey (SF-36) was used to evaluate the quality of life among patients. This survey comprises 36 questions addressing various dimensions of quality of life and overall health. It evaluates eight health concepts:

- i. Limitation in physical activities because of health problems
- ii. Limitation of social activities due to physical or emotional problems
- iii. Limitation in usual role activities because of physical health problems
- iv. Bodily pain
- v. General mental health (psychological and well-being)
- vi. Limitation in usual role activities because of emotional problems
- vii. Vitality (energy and fatigue).
- viii. General health perception

The subscale and summary scores range from 0 to 100, where 100 signifies the highest level of health, and zero reflects the poorest perceived health. A cut-off of 50 was utilized to categorize the quality of life as either good or poor.

3.8 Data collection

The following steps were followed;

- The files of all patients attending the rheumatology clinic were screened to confirm the diagnosis of RD by the rheumatologist.
- II. The patient's age was assessed to determine their eligibility for providing consent.
- III. The patients were identified by their names as recorded in the file after being examined by either the registrar or the rheumatologist.
- IV. The study was explained to the patients to obtain their consent.
- V. The principal investigator administered a structured screening proforma.
- VI. The recruited patients in the study were provided with the ICAM questionnaire and SF36 questionnaire to complete in either English or Kiswahili.
- VII. Tags were placed on the patient's file to indicate the date of their visit, ensuring avoidance of duplicate sampling.

3.10 Quality assurance

Throughout the study, the hospital's established protocol and standard operating procedures were strictly followed. The research tools utilized in the study have been validated in different languages and implemented globally. The SF-36 has been utilized in previous studies conducted at KNH. The ICAM-Q and SF-36 were translated into Kiswahili using a professional translation service located in Nairobi. The translation was conducted through the forward and back translation method, and permission was obtained from the copyright owners before the translation process commenced. Attached in appendix.

3.13 Data management and statistical analysis

3.13.1 Data handling

Data from questionnaires was collected during visits to the rheumatology clinic. Details of the rheumatological condition i.e., specific type of the disease, duration of diseases, current medication was retrieved from file. Completed data were locked in a secure cabinet by the PI for analysis.

3.13.1 Data analysis

The data was entered and managed in Microsoft Excel 2016 spreadsheet, and the cleaned data was exported to SPSS version 24.0 for statistical analysis. The study population characteristics were described by summarizing socio-demographic and clinical features percentages for categorical data, and median and interquartile range (IQR) for continuous variables.

The prevalence of complementary and alternative medicine (CAM) use was determined and presented as a frequency and percentage of all rheumatological patients included in the study. The results of the SF-36 were analysed according to established norm-based standards for the survey. The sum of scores for all subscales was categorized into good and poor health-related quality of life using a 50% cut-off. The association between categorical variables, including CAM use, socio-demographic and clinical features, as well as health-related quality of life (HRQoL), was assessed using the chi-square test. The difference in age in years between users and non-users of CAM was assessed using Wilcoxon rank sum test which is non-parametric equivalent of independent t-test. The data were presented in tables and graphs, with statistical significance set at p < 0.05 wherever applicable.

3.14 Ethical consideration

The research was undertaken following approval from the Department of Clinical Medicine and Therapeutics at the University of Nairobi (UON) and the KNH/UON Scientific and Ethical Review Committee, with the approval number P669/08/2022, as indicated in the attached letter in the appendix. Comprehensive written and verbal explanations of consent were provided to the study participants. Before enrolment, patients were informed about the study's objectives and purpose in a language, convenient for them. Participants were reassured that their involvement was voluntary, and there would be no repercussions for those choosing not to participate. Stringent measures were implemented to maintain patient confidentiality, and all collected information was securely stored under lock and key.

4.0 CHAPTER FOUR: RESULTS

4.1 Patients recruitment

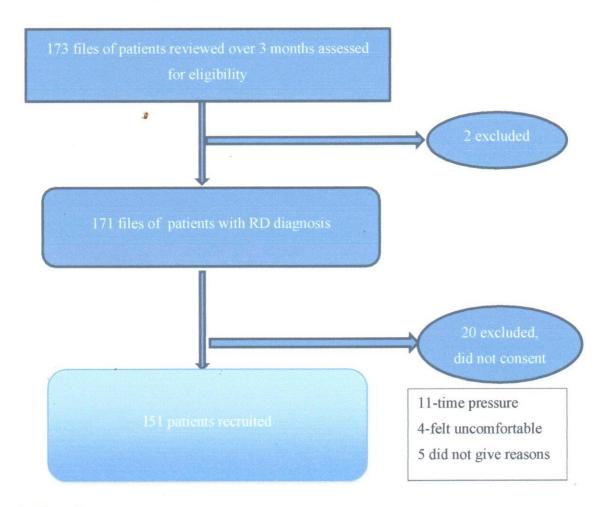


Figure 1: Flow chart

4.2 Socio-demographic characteristics

The majority were females (87.4%; n=132). The median age in years was 45.0 (IQR: 31.5-56.5), with most of the patients in the 40-49 age group (21.2%; n=32), followed by the 50-59 and over 60 age groups at 19.9% and 19.2% respectively. In terms of marital status, 61.6% (n=93) were married, 30.5% (n=46) were single, while the rest were either divorced or widowed. Over forty-one percent (n=62) of the patients were unemployed at the time of the study, and 34.4% (n=52) were employed. A total of 74% of the study participants had completed post-primary education, as shown in Table 3.

Table 3: Socio-demographic characteristics of the respondents

Characteristic	Frequency (%) N = 151
Sex	-
Female	132 (87.4)
Male	19 (12.6)
Age in years, Median (IQR)	45.0 (31.5 – 56.5)
Categories of ages (years)	
>18 -20	9 (6.0)
20-29	26 (17.2)
30-39	25 (16.6)
40-49	32 (21.2)
50-59	30 (19.9)
60+	29 (19.2)
Marital status	
Divorced	5 (3.3)
Married	93 (61.6)
Single	46 (30.5)
Widowed	7 (4.6)
Occupation	
Employed	52 (34.4)
Unemployed	77 (51.0)
Retired '	22 (14.6)
Level of education	-
Primary	38 (25.2)
Secondary	85 (56.3)
Tertiary	28 (18.5)

4.3 Clinical characteristics

The most common type of rheumatological disease (RD) was rheumatoid arthritis, affecting 38.4% of individuals (n=58), followed by systemic lupus erythematosus at 36.4% (n=55). Osteoarthritis and other rheumatologic conditions were present in 13.9% (n=21) and 11.3% (n=17) of individuals, respectively. The median duration of RD disease was 4.0 years (IQR: 1.5-6.0), with many having the disease for a duration between 1-4 years (Table 4).

Table 4: Clinical characteristics of the respondents

Clinical Characteristics	Frequency (%) N = 151
Type of Rheumatology, n (%)	
Rheumatoid arthritis	58 (38.4)
Osteoarthritis	21 (13.9)
Systemic Lupus erythematosus (SLE)	55 (36.4)
Other rheumatologic conditions e.g., gout, scleroderma, Sjogren syndrome	17 (11.3)
Duration of the disease (years), Median (IQR)	4.0 (1.5 – 6.0)
Duration of illness, n (%)	
<1	3 (2.0)
1-4	84 (55.6)
5-10	50 (33.1)
> 10	14 (9.3)

The most frequently prescribed drug for symptomatic pain relief was NSAIDs, with 66.2% of individuals (n=100) receiving this treatment. Hydroxychloroquine and steroids were the next most prescribed drugs, with 57.6% (n=87) and 51.0% (n=77) of individuals receiving these treatments, respectively. Cyclosporine (0.7%; n=1) and leflunomide (5.3%; n=8) were the least commonly used drugs. Additional medications that were prescribed included methotrexate, azathioprine, and mycophenolate, as shown in Figure 2.

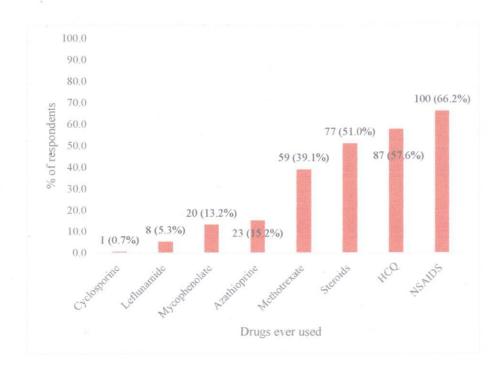


Figure 2:Types of treatments ever used by the respondents.

4.4 Prevalence of Complementary Alternative Medicine use in patients with RD

Out of the 151 studied patients ,84 patients had used CAM in the last 12 months.

The prevalence of using CAM among the RD patients was 55.6% (95%CI: 47.3% to 63.7%).

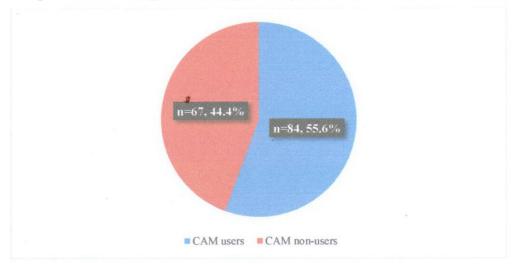


Figure 3: Prevalence of CAM use in rheumatological disease patients

4.4.1 Types of CAM used by respondents.

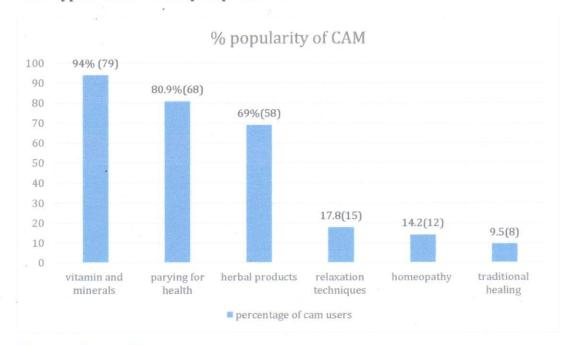


Figure 4: Type of CAM used by the respondents.

In a sample population of n=151, 84 individuals used CAM. The most commonly used method among the CAM users was vitamins and minerals, accounting for 94% of the CAM users (n=79). Herbal remedies were also popular, 69% of the CAM users (n=58).

Praying for health was practiced by approximately 81% of the CAM users (n=68). Relaxation techniques were employed by 14% of the CAM users (n=12). Similarly, both homeopathy and traditional healing methods were used by approximately 14% and 10% of the CAM users, respectively (n=12 and n=8). These results are summarized in Figure 4. Multiple responses were allowed, allowing individuals to select more than one CAM method, which could result in overlap between the different practices.

4.5 Main reason for CAM use as per the ICAM-Q

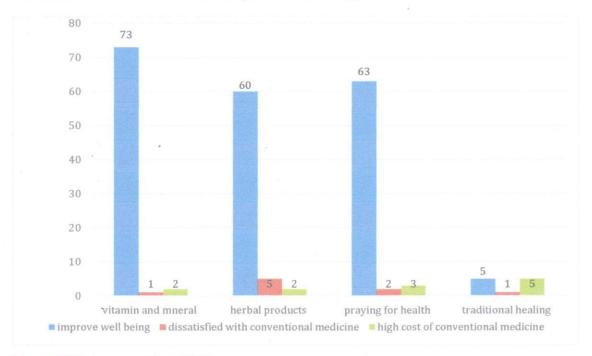


Figure 5 Main reason for CAM use

Majority of the patients used CAM to improve wellbeing as highlighted in figure 5

4.6 Perceived Benefit of CAM Used by respondents.

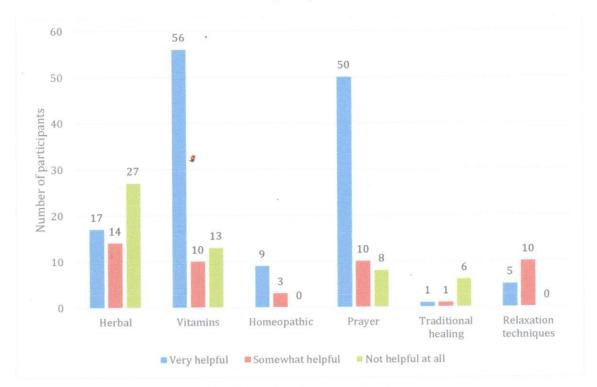


Figure 6: Perceived benefit of CAM use by the respondents

Among those who used herbs/herbal medicine and traditional healing methods the majority found them not helpful for their health. In most patients who used vitamins and prayer the majority reported the products/practices very helpful in improving their health (Figure 6).

4.7 Source of information on CAM

The main source of information was relatives at 55.6% (n=84), 37.7% (n=57) heard about CAM from friends, 18.5% (n=28) from radio/tv, 11.9% (n=18) from CAM practitioners, whereas 3.3% (n=5) heard from others. (Figure 7).

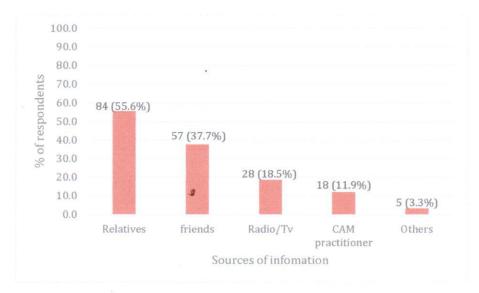


Figure 7: Sources of information on CAM

4.8 CAM providers visited by the respondents.

Figure 8 shows the list of CAM providers visited in the last 12 months, 27% n=27 visited herbalist, whereas only two each visited homeopath and acupuncturist respectively. Herbalist and spiritual healers were visited by 15.0% (n=27) and 14.4% (n=26), respectively.

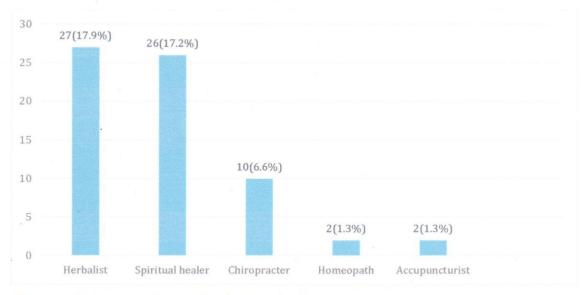


Figure 8: Health provider visited in the last 12 months.

4.9 Determinants of CAM use

Stratification of CAM and demographic and clinical characteristics as shown in Table 5 and 6 respectively. Overall, there was no significant difference in the demographic and clinical characteristics between CAM-users and non-users.

Table 5: Socio-demographic characteristics of the respondents by status of CAM use

	Classification			
Variable **	Non-CAM Users N = 67 ¹	CAM Users, N = 84 ¹	p-value ²	
Gender, n (%)			0.20	
F	56 (83.6)	76 (90.5)		
M	11 (16.4)	8 (9.5)		
Age in years, Median (IQR)	48.0 (34.0 – 56.0)	43.5 (29.0 – 57.0)	0.45	
age group, n (%)			0.87	
< 20	4 (6.0)	5 (6.0)		
20-29	9 (13.4)	17 (20.2)		
30-39	12 (17.9)	13 (15.5)		
40-49	13 (19.4)	19 (22.6)		
50-59	15 (22.4)	15 (17.9)		
60+	14 (20.9)	15 (17.9)		
Marital status, n (%)			0.89	
Divorced	2 (3.0)	3 (3.6)		
Married	42 (62.7)	51 (60.7)		
Single	19 (28.4)	27 (32.1)		
Widowed	4 (6.0)	3 (3.6)		
Occupation, n (%)			0.10	
Employed	26 (38.8)	26 (31.0)		
Unemployed	24 (35.8)	38 (45.2)		
Retired	13 (19.4)	9 (10.7)		
Level of education, n (%)			0.51	
Primary	15 (22.4)	23 (27.4)		
Secondary	37 (55.2)	48 (57.1)		
Tertiary	15 (22.4)	13 (15.5)		
¹ Median (IQR) or Frequency (%)				

Table 6: Clinical characteristics of the respondents by status of CAM use

,	Classification			
Variable	Non-CAM users	CAM Users	P-value	
Type of Rheumatology, n (%)			0.55	
Rheumatoid arthritis	22 (32.8)	36 (42.9)		
Osteoarthritis	10 (14.9)	11 (13.1)		
Systemic Lupus erythematosus (SLE)	28 (41.8)	27 (32.1)		
Other rheumatologic conditions e.g., gout, scleroderma, Sjogren syndrome	7 (10.4)	10 (11.9)		
Duration of the disease (years), Median (IQR)	4.0 (2.0 – 6.0)	4.0 (1.0 - 6.0)	0.76	
Duration of illness, n (%)			0.62	
<1	2 (3.0)	1 (1.2)		
1-4	40 (59.7)	44 (52.4)		
5-10	19 (28.4)	31 (36.9)		
> 10	6 (9.0)	8 (9.5)		
¹ Frequency (%)				
² Pearson's Chi-squared test; rank sum test.				

4.10 Quality of life in CAM users

Among the 84 patients who were CAM users 52(61%) patients had poor quality of life (P<0.001) this was statistically significant.

Table 7: Quality of life in CAM users

	HRQoL Classification as assessed by SF-36				
Variable	Poor (SF36 Score <50) , N = 76 ¹	Good, (SF36 Score >50) N = 75 ¹	p- value ²		
CAM, n (%)			0.001		
CAM Non-users	24 (31.6)	43 (57.3)			
CAM Users	52 (68.4)	32 (42.7)			
¹ Frequency (n)					
Pearson's Chi-squared test					

5.0 CHAPTER FIVE: DISCUSSION

5.1 Discussion

The study was conducted with the aim of determining the prevalence of CAM (Complementary and Alternative Medicine) use among RD (Rheumatological Diseases) patients, the main reason for use, and its determinants. In this study, 55.6% of patients with rheumatological diseases (RDs) reported using complementary and alternative medicine (CAM).

Similar findings have been reported in previous studies conducted in various countries. The percentage of rheumatology patients using CAM varies widely, from 22% to 95%, depending on the study. For example, a Canadian study found that 22% of arthritis patients had used CAM in the past year(38), while an Israeli study reported that 42% of patients with defined RDs attending rheumatology clinics had used CAM(56). A Swedish study found that 65% of RD patients had used CAM at least once in their lives(20), while 70% of Australian RA patients had used CAM therapies. In the United States, 92% of RD patients had used CAM methods for their arthritis. A study on CAM use among patients with ankylosing spondylitis in Australia reported that 95% of patients had used CAM at some point(18). In Mexico, the estimated prevalence of CAM use was 83%(19), while in Turkey it was 46%(21). A study in the Middle East found a prevalence of 67%(22). In Nigeria, the prevalence of CAM use in patients with musculoskeletal pain was 96%, with herbal therapy and massages being the most common modalities(23).

The varying frequency of CAM use in different studies may be due to cultural differences, availability of CAM providers, advertisements in the lay press, or different study methodologies. For instance, some studies used self-administered questionnaires with telephone or mail contact, while others conducted face-to-face interviews. Additionally, some studies focused only on specific diseases or used self-definition of rheumatic diseases, while others used physician-based diagnosis and assessment.

The lack of consistency in the definition of CAM and its specificity with regards to what can be considered as a CAM modality. In this study, prayer was considered as a form of CAM, while other studies considered it not.

Our finding of a high prevalence of CAM use in RD could be due to the lack of regulation of CAM products in Kenya, as these products are readily available. Another possibility is the fact that WHO endorses CAM use combined with ease of access patients use it.

The main reason of CAM use of in this study was to improve well-being. ICAM -Q questionnaire was used to determine the main reason for CAM used. Our tool is limited as it only had three reasons and participant were only to choose one main reason. The reasons included use of CAM to improve well-being or because one was dissatisfied with medical care or high cost of conventional medicine In Kenya, these were the main reasons as to why they used CAM. For example, cancer patients reported using CAM mainly in the hope of curing their disease or for symptomatic relief (24), while diabetic patients cited dissatisfaction with and inaccessibility of conventional medicine as the main reason for CAM use (34).

A significant amount of information regarding CAM was obtained from relatives. However, the study did not determine the primary source of information on CAM use, which could potentially influence patients' decisions to utilize CAM. It should be noted that relatives may not necessarily be medical practitioners and may lack expertise in the field. As a result, the information provided by relatives may have an impact on patients' perceptions and decisions. Patients may trust information from their relatives more due to personal connections and familiarity. However, it is important to consider that patients should rely on evidence-based information and professional knowledge by healthcare workers.

To ensure accurate and reliable information, it is advisable for patients to consult reputable sources, such as healthcare professionals, scientific research, and reliable CAM resources, when considering CAM options. This approach can help minimize potential misinformation and ensure informed decision-making regarding CAM use.

There was no significant difference in demographic characteristics between CAM-users and non-users, and it is use is not influenced by age, gender, education level, or employment status. Similar study findings were revealed in a previous study done in Kenya on cancer patients (25). However an association between CAM use, female sex, lower level of education and older age has been shown in other studies from different countries(17) (18) (39).

The usage of CAM in Kenya seems to be influenced more by cultural factors rather than demographics, as the association between CAM and female gender, education level, and age appears to be a widespread phenomenon globally (25).

Our study identified an association between quality of life and CAM use. This finding was statistically significant, indicating a meaningful relationship between these variables. It is plausible to assume that individuals in the CAM user group were facing challenges in managing their illness and had more severe disease, which likely motivated them to explore additional avenues, such as CAM, to address their condition.

Alternatively, these patients may have chosen to rely on CAM as a preference over prescribed conventional medications. It is important to note that our study did not specifically investigate medication adherence. However, it is plausible that some patients may have opted for CAM instead of adhering to their prescribed conventional medication regimen.

Several studies have highlighted the phenomenon of non-adherence to conventional medication among CAM users (44)(55). These findings suggest that some patients who utilize CAM may not adhere to their prescribed conventional medication protocols. This could be due to various factors, including personal beliefs, perceived efficacy of CAM, or dissatisfaction with conventional treatments. Due to the high prevalence of CAM use, healthcare professionals should engage in open and non-judgmental communication with their patients.

5.2 Conclusion

In summary, our study highlights the significant utilization of CAM among RD patients, with vitamin and mineral supplements, faith-based practices, and herbal medicine being the most commonly used modalities. Notably, no significant associations were found between CAM usage and specific demographic or clinical factors. However, individuals with a lower quality of life demonstrated a higher prevalence of CAM use. The primary motivation for CAM utilization was the pursuit of improved overall well-being. These findings emphasize the need for further research to investigate the effectiveness and safety of different CAM modalities in this population and their impact on quality of life. The study results provide valuable insights for healthcare providers, who can now inquire about CAM use due to its high prevalence among RD patients. This enables them to deliver comprehensive care by considering potential interactions or contraindications with conventional treatments and ensuring patient safety. Additionally, healthcare providers can play a vital role in educating patients about evidence-based CAM options, potential risks, and reliable sources of information.

5.3 Recommendation

a) Healthcare provider should inquire and educate patients on CAM use

Healthcare providers, particularly those in rheumatology clinics, should actively inquire about CAM use during patient visits. It is important to have open and non-judgmental discussions with patients, gathering information about the specific CAM modalities they are utilizing. This enables healthcare providers to have a comprehensive understanding of the patient's treatment plan, including potential interactions or contraindications with conventional therapies. Furthermore, healthcare providers should take on the role of educating patients about evidence-based CAM options, potential risks, and reliable sources of information. This empowers patients to make informed decisions regarding CAM use and fosters a collaborative approach to their healthcare.

b) Evaluation and regulation of CAM use

Government agencies in Kenya should take steps to evaluate and regulate the use of CAM. This involves conducting thorough assessments of CAM modalities, their safety, efficacy, and potential interactions with conventional treatments. Government agencies can establish guidelines and standards for CAM practitioners, ensuring that they adhere to ethical practices and provide evidence-based care. By implementing regulatory measures, patients can have access to reliable and standardized CAM options, reducing the risk of misinformation or harm.

c) Follow-up studies on CAM use

Further research is necessary to evaluate the effects of CAM use on disease activity and its impact on RD management.

Long-term follow-up studies can assess the effectiveness of different CAM modalities in managing symptoms, improving quality of life, and influencing disease outcomes. These studies can provide valuable insights into the role of CAM as a complementary approach in RD management, helping healthcare providers and patients make informed decisions about incorporating CAM into their treatment plans.

5.4 Limitations

- a) Recall Bias: The study may be susceptible to recall bias, which refers to the inaccuracy or distortion of participants' recollection of past events or experiences. In the context of CAM use, participants may have difficulty accurately remembering and reporting their specific CAM modalities. This can lead to inaccurate data and potentially affect the overall findings and conclusions of the study.
- b) Single-Center Study: Another limitation is that the study was conducted at a single center, which may limit the generalizability of the findings. The study's sample may not fully represent the diverse population of RD patients, as it is limited to a specific geographic location or healthcare setting. The findings may be influenced by local practices, healthcare resources, and patient demographics specific to that center. To enhance the generalizability of the results, future studies should aim for multi-center collaborations involving different regions, healthcare settings, and patient populations to capture a broader representation of RD patients.

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APPENDICES

Appendix I: Patient Information and Information Consent Form

Should you agree to participate in the study you will:

Sign a consent form and participate in a survey

- ii. Fill in a questionnaire administered by the principal investigator after your consultation by the rheumatologist
- iii. Answer questions about your personal information i.e. age, gender, marital status, level of education. Information regarding your disease will be obtained and verified from your medical records. Your response will be filled into the study questionnaire
- iv. Be asked if you have used any complementary and alternative medicine (a group of diverse medical and health care system, practices, products that are not presently considered to be part of conventional medicine), and the reasons for using the modality of treatment and if you experienced any benefit. Questions will be guided by a questionnaire which is standardized to enquire about complementary and alternative medicine internationally.
- v. Be asked about your functional status by assessing how the disease impacts your life and daily activities. Your response will be filled in the study questionnaire.

Participation in the study

- i. Is voluntary
- ii. You are free to terminate the interview and withdraw from the study at any time.
- iii. You will not be victimized if you refuse to participate in the study
- iv. You are free to ask any question before enrolment or at any given time during the study
- v. All the information collected will remain confidential

Purpose of study

The main objective is to find out the prevalence of CAM use and the perceived benefit of patients using CAM. This will provide data on the determinants on the usage of CAM in patients with rheumatic diseases and result to a better understanding of the trends in the CAM use in Kenya. The results will be published in a medical journal and used for academic purposes.

Duration

The study will be over a period of 3 months period at the rheumatology clinic. Each participant will be enrolled once. It will take approximately 20 minutes of your time.

Risks and cost incurred

There will be no delay and interference of care during your clinic visit. Covid -19 protection measures will be in place as per hospital policy. No cost will be incurred by the participants.

Confidentiality

Medical research has the potential to introduce psychological, social, emotional, and physical risks. Efforts will be put in place to minimize the risk. One potential risk of being in the study is loss of privacy. We will use a code number to identify you in a password-protected computer database and will keep all our paper records in a locked file cabinet.

Participants Benefit

The information you provide will help us understand CAM usage in patients with rheumatic diseases in Kenya.

Compensation

There will be no monetary compensation for participation in this study.



Informed Consent

I have read and understood the above information /I am unable to read and have had the above information dictated for me in a language I understand

I understand that participation in this study is of my free will and is voluntary and there will be no compensation for doing so. I also understand that I have a right to withdraw from the study at any point and refuse to answer question I am uncomfortable with within the questionnaire.

I understand that my information and data will be kept confidential.

I agree to participate in this research study:

(Tick where appropriate)

Date:/.......

I freely agree to participate in this study, and I have not given up any of the legal rights I have as a participant in a research study.

YES NO

Participant's signature:

Researchers signature:



Principal Investigator's /Research assistant's statement: I have explained all the above to the potential participant clearly and concisely in a language that he/she understands.

Principal Investigator: Signature:



Whom to contact:

If you have any queries during the study, you may contact any of the following Principal Investigator:

Dr. Kismat Juma

University of Nairobi

College of health sciences.

Department of Clinical Medicine and therapeutics

Tel: 0726532531

Email: kismatjm@gmail.com

Supervisors:

Prof. Omondi Oyoo

Associate Professor,

Department of Clinical Medicine and Therapeutics

Consultant Physician and Rheumatologist

University of Nairobi

Tel: 020-27254552

Email: george.oyoo@uonbi.ac.ke

Dr Eugene Kalman Genga

Consultant Physician and Rheumatologist

Senior lecturer

Department of Clinical Medicine and Therapeutics

University of Nairobi

Tel: 0723596189

Email:ekalman@uonbi.ac.ke

Or

Kenyatta National Hospital/University of Nairobi-Ethics and Research Committee

College of Health Sciences

Telephone: (+254-020) 2726300-9, extension 44355

P.O Box 19676-00202, Nairobi. Email: uonknh_erc@uonbi.ac.ke



Appendix II: Screening Questionnaire

Participants study number:	Hospital No:
Study Date:	
1. Consent /Assent Given: Yes [].	No []. If yes proceed to 2
2. Age above 18 years: Yes [].	No []. If yes proceed to 3
3. For official use only	
Recruited? Yes [].	No [.]
Interviewers Name:	
Signature:	Date:
	30 NOV 3022
	2022

Appendix III: Study Proforma (English)

	Study Date:
Socio-demographic D:	ata
a) Sex: M[] F[]
b) Age:[]	[] Months
c) Marital sta	atus: Married []. Single []. Divorced []. Widowed []
d) Occupatio	n[]
1.	Employed 2.Unemployed 3.Retired 4.others
e) Education	Level []
	Drimory 2 Secondary 2 University (college 4 Others
1.)	Primary 2. Secondary 3. University /college 4. Others
Clinical Data	Frinary 2. Secondary 3. University/conege 4. Others
Clinical Data	
Clinical Data Type of rheumato	logy disease [].
Clinical Data Type of rheumato l= Rheumatoid ar	ology disease []. thritis 2=fibromyalgia. 3= Osteoarthritis,
Clinical Data Type of rheumato I= Rheumatoid ar 4=Systemic Lupus	ology disease []. thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e.
Clinical Data Type of rheumato I= Rheumatoid ar 4=Systemic Lupus	ology disease []. thritis 2=fibromyalgia. 3= Osteoarthritis,
Clinical Data Type of rheumato I = Rheumatoid ar 4=Systemic Lupus gout, scleroderma,	ology disease []. thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e.
1. Clinical Data a) Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis	clogy disease []. thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome
1. Clinical Data a) Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis c) Have you been on	thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome sease from the onset of diagnosis: [] years [.] Months
Clinical Data Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis	thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome sease from the onset of diagnosis: [] years [.] Months treatment with these drugs?
1. Clinical Data a) Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis c) Have you been on Drugs NSAIDS	thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome sease from the onset of diagnosis: [] years [.] Months treatment with these drugs?
1. Clinical Data a) Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis c) Have you been on	thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome sease from the onset of diagnosis: [] years [.] Months treatment with these drugs?
1. Clinical Data a) Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis c) Have you been on Drugs NSAIDS Steroids HCQ Methotrexate	thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome sease from the onset of diagnosis: [] years [.] Months treatment with these drugs?
1. Clinical Data a) Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis c) Have you been on Drugs NSAIDS Steroids HCQ Methotrexate Leflunamide	thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome sease from the onset of diagnosis: [] years [.] Months treatment with these drugs?
1. Clinical Data a) Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis c) Have you been on Drugs NSAIDS Steroids HCQ Methotrexate eflunamide Mycophenolate	thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome sease from the onset of diagnosis: [] years [.] Months treatment with these drugs?
1. Clinical Data a) Type of rheumato 1= Rheumatoid ar 4=Systemic Lupus gout, scleroderma, b) Duration of the dis c) Have you been on Drugs NSAIDS Steroids HCQ Methotrexate	thritis 2=fibromyalgia. 3= Osteoarthritis, s erythromatosus (SLE) 5= Other rheumatologic conditions e. , Sjogren syndrome sease from the onset of diagnosis: [] years [.] Months treatment with these drugs?

Appendix IV: Study Proforma (Kiswahili)

Appendix III	: Profoma ya Uta	fiti			
Namba ya Utafi	ti:		Tarehe y	a Utafiti:	
Data ya K	isosholojia ya Dei	mografia			
a)	Jinsia: ME[]	KE	[]		
b)	Umri: [*]	Miezi [1		
c)	Hali ya Ndoa: Ndo	oa []Mse	eja []. Mtalaka	[]. Mjane []	
d)	Kazi []				
	1. Nimea	jiriwa 2.Sina	Ajira 3.Mstaafu	4. Nyingine	
e)	Kiwango cha Elin				
	1. Shule y	ya Msingi 2. Se	kondari 3. Chuo	Kikuu/Chuo 4. N	vingine
1. Data y	a Kitabibu				
a) Aina ya	Ugonjwa wa bari	idi yabisi []			
1= Bari	di Yabisi 2=fib	romyalgia. 3	= Ugonjwa wa nev	va,	
4=Ugor	ijwa wa Lupus (S	(LE) 5= M	aradhi mengine ya	a baridi yabisi e.g	., ugonjwa wa jongo
skleroda	ama, Ugonjwa wa	Sjogren			
b) Muda v	wa ugonjwa kuai	nzia ulipobain	ika kwamba uko	nao: Miaka []	Miezi [.]
c) Je, umo	ekuwa ukitumia	dawa hizi?			
Dawa		Ndiyo []	Hapana []	Muda	
NSAIDS		0 8			
Steroids					
Hydroxychlo	roquine				
Methotrexate					
Leflunamide					
Mycophenola	ite				
Azathioprine			Contracto	SELECTION OF SELEC	17-12-11
Cyclosporine					
				same eletti	STREET, STREET
d) Chanzo cha k	rumwambia mgor	ijwa atumie ma	tibabu saidizi au n	nbadala []	
1=Ndug	gu 2= marafiki	3 = Televisher	ni /redio. 4. Mhud	umu wa CAM 5.0	vingine
0				1/2/	
Certified	as true translat	tion of		NA NA	0 8 CEC 2027
	he original			*	
SIGNED	March .			110	1211

Appendix V : Questionnaire (English)

	COMPLEMEN	nternational OMMENDED TARY AND Self-Adm	ALTERNAT	Version	nay be attended to	
	Yes		ate the main rea		saw the provider	How helpful was it for you to see this provider?
Have you seen any of the following providers in the last 12 months?	Number of times you saw this provider in the last 3 months?	For an acute iliness/condition, one that lasted less than one month	To treat a long-term health condition (one that lasted more than one month) or its symptoms	To improve well-being	Other (Please specify the other reason)	(Check only one) Very Somewhat Not at all Don't know
Physician						-0000
Chiropractor						_0000
Homeopath '						_0000
Acupuncturist						_0000
Herbalist						_0000
Spiritual	пп					
healer Specified option:						_0000
Other (please specify):	00_					
Other (please specify):	00_					_0000
	***		39		30	NOV 2022

2. Complementary treatments received from physicians (MDs)

If you have not seen a physician in the past 12 months, please go to question

complementary, as well as conventional treatments

	Yes	Please indicate	How helpful was it to receive treatment from the physician			
Have you received any of the following complementary reatments from a physician in the last 12 months?	Dissatisfied with medical care	High cost of conventional medicine	To improve well-being	Other (Please specify the other reason)	(Check only one) Very Somewhat Not at all Don't know	
Manipulation	00_					0000
Homeopathy	00_					0000
Acupuncture	00_					0000
Herbs .	00-					
Spiritual healing						
Specified option:	00_					
Other (please specify):	00_					
					ATA V	
					30 NOV	
			40			03

3. Use of Herbal Medicine and Dietary Supplements, including tablets, capsules and liquids. How helpful did you find this product? (Check only ons) Do you cuttently use this product? Please indicate the <u>main</u> reason that applies to your <u>last</u> use (Check only one). For each category below, please list up to three products you have used in the last 12 months. Somewhat High cost of conversional medicine Other (Please specify) To improve well-being Dissatisfied with medical care Not at all Yes Don't know Hertis/Herbal Medicine Vitamins/Minerals Homeopathic remedies Other Supplements 30 NOV 2022 41

4. Self Help Practices

	Yes	Please indicate the <u>main</u> reason that applies to your <u>fast</u> use of the self-help practice (Check only one).					
Have you used any of the following self- help practices in the last 12 months?	Number of times you used this practice in the last 3 months?	Dissatisfied with medical care	High cost of conventional medicine	To improve well-being	Other (Please specify the other reason)	(Check only one) Very Somewhat Not at all Don't know	
Meditation	00_					0000	
Yoga	00_					0000	
Relaxation techniques						0000	
Visualization						0000	
Attended traditional healing ceremony	00,					0006	
Praying for own health	00_					0006	
Specified option:	00_						
Other (please specify):	00_					0000	

Source: Quandt SA, Verhoef MJ, Arcury TA, Lewith GT, Steinsbekk A, Kristoffersen AE, Wahner-Roedler DL, Fønnebø V. Development of an international questionnaire to measure use of complementary and alternative medicine (I-CAM-Q). J Altern Complement Med. 2009 Apr;15(4):331-9. doi: 10.1089/acm.2008.0521.



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Appendix VI: Questionnaire (Kiswahili)

App	endix II: Hojaji ya Uchunguzi wa Awali				
Namba	ı ya Mhusika:	Namba ya Hospitali:			
Tarehe	ya Utafiti:				
	3				
1.	Kibali /Amekubali: Ndiyo [].	Hapana []. Ikiwa amekubali nenda kwenye 2			
2.	Umri usiopungua miaka 18: Ndiyo [].	Hapana []. Ikiwa Ndiyo nenda 3			
3.	Kwa matumizi rasmi tu				
	Amesajiliwa? Ndiyo [].	Hapana [.]			
Jina la	Anayehoji:	,			
Sahihi	·	Tarehe:			

Certified as true translation of the ariginal SIGNED......



Appendix VII: Questionnaire (Kiswahili)

Hojaji ya CAM ya Shirika la Kimataifa la NAFKAM (I-CAM-Q): IMEIDHINISHWA KWA TAFITI ZA TIBA SAIDIZI NA TIBA MBADALA (CAM)—

Toleo la Kujijibia

 Kutembelea wahudumu wa afya: Matibabu ya matatizo ya afya yanaweza kutolewa na wahudumu wasaidizi au wahudumu wa kawaida wa afya

Je, umewahi kutafuta huduma za afya	Ndiyo Hapana	Tafadhali taja	mhudur	mara ya m nu huyu moja tu).	wisho kumtembelea	Je, mhudumu huyu alikuwa wa msaada gani kwako? (Chagua moja tu)
kutoka kwenye wahudumu wafuatao katika kipindi cha miezi 12 iliyopita?	Je, ni mara ngapi ulienda kumwona mhudumu huyu katika kipindi cha miezi 3 iliyopita?	Kwa ajili ya ugonjwa hali/ugonjwa mbaya uliodumu chini ya mwezi mmoja	Kutafuta matibabu ya maradhi/hali sugu (ugonjwa uliodumu kwa kipindi cha zaidi ya mwezi mmoja) dalili zake	Kubores ha hali yangu ya afya	Nyingine (Tafadhali taja hiyo sababu nyingine)	Sana Kiasi Hata Kidogo Sijui
Daktari						
Daktari wa Viungo	00_					
Homeopath	00_					
Daktari wa Tiba ya Sindano	00_					
daktari wa Mitishamba	00_					
Mpiga Ramli	00_					
Aina Iliyotajwa	00_					0000
Mwingine (Tafadhali Taja):	00_					0000

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2. Matibabu mbdala uliyopata kutoka kwa madaktari (MDs)

. Ikiwa hujatembelea daktari katika kipindi cha miezi 12 iliyopita, tafadhali nenda kwenye swali la 3.

Baadhi ya madaktari hutoa huduma saidizi sambamba na matibabu ya kawaida

	Ndiyo	Tafadhali taja	and the same of th		wisho kumtembelea	Je, mhudumu huyu
Je umetembelea mhudumu yeyeote kati ya wafuatao katika kipindi cha miezi 12 ilivooita?	Hapana Ni mara ngapi ulitembele a mhudumu huyu katika			mu huyu moja tu)		alikuwa wa msaada gani kwako? (Chagua moja tu)
	kipindi cha miezi 3 iliyopita?	Kwa ajili ya ugonjwa hali/ugonjwa mbaya uliodumu chini ya mwezi mmoja	Kutafuta matibabu ya maradhi/hali sugu (ugonjwa uliodumu kwa kipindi cha zaidi ya mwezi mmoja) dalili zake	Kubores ha hali yangu ya afya	Nyingine (Tafadhali taja hiyo sababu nyingine)	Sana Kiasi Hata Kidogo Sijui
Ushawishi						
Homeopathi	00_					
Tiba ya Kudunga Mwili						
Miti Shamba						0000
Upiga Ramli	00_					0000
Nyingine (tafadhali taja):						0000



Kwa kila aina iliyopo hapa	Ndiyo Je, unatu	Tafadhali taja sabab mara ya mwisho uli			Je, mhudumu huyu alikuwa wa msaada gani kwako?
chini, tafadhali taja bidhaa tatu ulizotumia katika kipindi cha miezi 12 iliyopita.	mia bidha a hizi <u>hivi</u> sasa?	Kwa ajili ya ugonjwa hali/ugonjwa mbaya uliodumu chini ya mwezi mmoja	Kutafuta matibabu ya maradhi/hali sugu (ugonjwa uliodumu kwa kipindi cha zaidi ya mwezi mmoja) dalili zake	Kuboresh a hali yangu ya afya	(Chagua moja tu) Sana Kiasi Hata Kidogo Sijui
Mitishamba					
Vitamini/Ma	dini				
Homeopathi	Tale S				
,					
0					

3. Matumizi ya Dawa za Mitishamba na Virutubisho Mbadala, ikiwa ni pamoja na tembe, vidonge na virutubisho vya kunywa

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4. Mbinu za Kujitibu

e e	Ndiyo Hapana Ni mara ngapi	Tafadhali taja s		okufanya uj moja tu)	itibu mara ya mwisho	How helpful did you find this self –help practice? (Chagua moja tu)
Je, umetumia mbinu yoyote kati ya zifuatazo ya kujitibu katika kipindi cha miezi 12 iliyopita?	ulitumia mbinu hizi za kujitib i katika kipindi cha miezi 3 iliyopita?	Kwa ajili ya ugonjwa hali/ugonjwa mbaya uliodumu chini ya mwezi mmoja	Kutafuta matibabu ya maradhi/hali sugu (ugonjwa uliodumu kwa kipindi cha zaidi ya mwezi mmoja) dalili zake	Kubores ha hali yangu ya afya	Nyingine (Tafadhali taja hiyo sababu nyingine)	Sana Kiasi Hata Kidogo Sijui
*						
Yoga						
Mbinu za Kutulia	00_					0000
Kujenga Taswira	00_					
Kuhudhuria Sherehe za Tiba . za Kitamaduni						
Kuomba kwa ajili ya afya yako						
Nyingine Iliyotajwa						0000
Nyingine (Tafadhali taja):	00_					

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Appendix VIII: SF-36 Questionnaire (English)

Patients Study No:

o 1- Excellent o 2- Very good				
o 4- Fair				
o 5- Poor		tels in general m	ow?	
2. Compared to one year ago, how would ye		nth in general n		
o 1- Much better now than one	year ago			
o 2- Somewhat better now than	one year ago			
o 3- About the same				
o 4- somewhat worse now than	one year ago			
The following items are about activities you	might do duri			
The following items are about activities you now limit you in these activities? If so, how	might do durin			
The following items are about activities you now limit you in these activities? If so, how 3. Vigorous activities, such as running,	might do duri	Yes, limited a little (2)	No, not limited at all (3)	
The following items are about activities you now limit you in these activities? If so, how 3. Vigorous activities, such as running, lifting heavy objects, participating in	might do during much? Yes, limited	Yes, limited	No, not limited	
The following items are about activities you now limit you in these activities? If so, how 3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports 4. Moderate activities, such as moving a table, pushing a vacuum cleaner,	might do during much? Yes, limited	Yes, limited	No, not limited at all (3)	
The following items are about activities you now limit you in these activities? If so, how 3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports 4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf 5. Lifting or carrying groceries	might do during much? Yes, limited	Yes, limited	No, not limited at all (3)	W 2
The following items are about activities you now limit you in these activities? If so, how 3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports 4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf 5. Lifting or carrying groceries 6. Climbing several flights of stairs	might do during much? Yes, limited	Yes, limited	No, not limited at all (3)	W 202
The following items are about activities you now limit you in these activities? If so, how 3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports 4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf 5. Lifting or carrying groceries 6. Climbing several flights of stairs 7. Climbing one flight of stairs	might do during much? Yes, limited	Yes, limited	No, not limited	W 202
The following items are about activities you now limit you in these activities? If so, how 3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports 4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf 5. Lifting or carrying groceries 6. Climbing several flights of stairs 7. Climbing one flight of stairs 8. Bending, kneeling, or stooping	might do during much? Yes, limited	Yes, limited	No, not limited at all (3)	W 202
The following items are about activities you now limit you in these activities? If so, how a limit you in these activities? If so, how limit you in these activities? If so, how a lifting heavy objects, participating in strenuous sports 4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf 5. Lifting or carrying groceries 6. Climbing several flights of stairs 7. Climbing one flight of stairs 8. Bending, kneeling, or stooping 9. Walking more than a mile	might do during much? Yes, limited	Yes, limited	No, not limited at all (3)	W 202
The following items are about activities you now limit you in these activities? If so, how 3. Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports 4. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf 5. Lifting or carrying groceries 6. Climbing several flights of stairs 7. Climbing one flight of stairs 8. Bending, kneeling, or stooping	might do during much? Yes, limited	Yes, limited	No, not limited at all (3)	W 202

During the past 4 weeks, have you had any of the following problems with your regular daily activities as a result of your physical health?	our work or Yes	other
	0.1	0.2
13. Cut down the amount of time you spent on work or other activities	01	02
14. Accomplished less than you would like	01	02
15. Were limited in the kind of work or other activities	01	02
16. Had difficulty performing the work or other activities (for example,		7.
it took extra effort)		

During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or

anxious)?	Yes	No
17. Cut down the amount of time you spent on work or other activities	0.1	02
18. Accomplished less than you would like	01	02
19. Didn't do work or other activities as carefully as usual	01	02

- 20. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?
 - o 1- Not at all
 - o 2-Slightly
 - o 3- Moderately
 - o 4- Quite a bit
 - o 5- Extremely
- 21. How much bodily pain have you had during the past 4 weeks?
 - o 1-None
 - . o 2- Very mild
 - o 3- Mild
 - o 4- Moderately
 - o 5- severe
 - o 6- very severe
- 22. During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?
 - o I- Not at all
 - o 2- A little bit
 - o 3- Moderately
 - o 4- Quite a bit
 - o 5- Extremely



These questions are about how you feel and how things have been with you during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the past 4 weeks:

	All of the time (1)	Most of the time (2)	A good bit of the time (3)	Some of the time (4)	A little of the time (5)	None of the time (6)
23. Did u feel full of pep?						
24. Have you been a very nervous person?						
25. Have you felt so down in the dumps that nothing could cheer you up?						
26. Have you felt calm and peaceful?						
27. Did you have a lot of energy?						
28. Have you felt downhearted and blue?						
29. Did you feel worn out?						
30. Have you been a happy person?						
31. Did you feel tired?	Part 1					d Salas

32. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives, etc.)?

- o 1- All of the time
- o 2- Most of the time
- o 3- Some of the time
- o 4- A little of the time
- o 5- None of the time



Appendix IX: SF-36 Questionnaire (Kiswahili)

	3	F-36 HOJAJI		
JINA:		Ref. Dkt :	Та	rehe:
# Utambulisho:		Umri:		Jinsia: Me/KE
Tafadhali jibu maswa	ali yote 36 ya Uta	fiti wa Afya, kwa uam	inifu na bila k	cusumbuliwa na mtu
yeyote.				
AFYA KWA UJUML	A:			
1.Kwa ujumla, je un	aweza kusema	afya yako ni:		
C _{1.Bora Kabisa}	2.Nzuri Sana	C _{3.Nzuri} C	4.Sawa	5.Mbaya
2.Je, unaweza kuse	ma afya yako ik	oje kwa ujumla, ukilir	nganisha na	mwaka mmoja
C 2. C 3.	Imeimarika kidog Iko vilevile Ni mbaya kidogo	ukilinganisha mwaka u go ukilinganisha na mw ikilinganishwa na mwa ilinganishwa na mwaki	vaka uliopita	O & CEC 2022
UGUMU WA KUFAN	YA SHUGHULI:			
Yafauatayo ni maele	zo kuhusu shugh	uli mbalimbali ambazo	unaweza ku	ıfanya katika siku ya
kawaida. Je, kwa sas	sa hali yako ya af	fya inakuzuia kufanya :	shughuli hizi'	? Na ikiwa ni hivyo, kwa
kiasi gani?				
3.Shughuli zinazotu michezo ya mazoez		gi, kama kukimbia, k	ubeba vitu v	vizito, kucheza
_1.Ndiyo, Imenizuia	sana	C _{2.Ndiyo, Imenizuia}	Kiasi	3.Hapana, Haijanizuia
4.Shughuli zinazotu	umia nguvu was	tani, kama vile kusoç	jeza meza, k	susogeza mtambo wa
kufyonza uchafu, k	ucheza kwenye	kumbi au kucheza go	ofu.	
C _{1.Ndiyo} , Imenizuia	a sana	C _{2.Ndiyo} , Imenizuia	Kiasi	3.Hapana, Haijanizuia
			SI	the original GNED

5.Kuinua au kubeba vitu unavyonunua dukani.

1.Ndiyo, Imenizuia sana

2.Ndiyo, Imenizuia Kiasi

3.Hapana, Haijanizuia

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6.Kupanda vidato vya safari nyin	gi za ngazi	
C _{1.Ndiyo} , Imenizuia sana	C _{2.Ndiyo} , Imenizuia Kiasi	3.Hapana, Haijanizuia
7.Kupanda vidato vya safari moja	a ya ngazi	
1.Ndiyo, Imenizuja sana	C _{2.Ndiyo,} Imenizuia Kiasi	3. Hapana, Haijanizuia
8.Kuinama, kupiga magoti, au ku	chuchuma	
C ₁ .Ndiyo, Imenizuia sana	C _{2.Ndiyo} , Imenizuia Kiasi	3.Hapana, Haijanizuia
9.Kutembea zaidi ya maili moja		
	C _{2.Ndiyo} , Imenizuia Kiasi	3.Hapana, Haijanizuia
10.Kutembea Mtaa Mmjoa		
1.Ndiyo, Imenizuia sana	C _{2.Ndiyo, Imenizuia Kiasi}	3.Hapana, Haijanizuia
11.Kutembea hatua chache		
1.Ndiyo, Imenizuia sana	2.Ndiyo, Imenizula Kiasi	3.Hapana, Haijanizuia
12.Kuoga au kuvaa nguo		
C1.Ndiyo, Imenizuia sana Haijanizuia	C _{2.Ndiyo} , Imenizuia Kiasi	C _{3.Hapana,}
MATATIZO YA AFYA YANAYOO!	NEKANA.	
Katika kipindi cha wiki 4 zilizopita, u		vafuatavo katika kazi vako
au shughuli zako za kawaida za kili		
		TS SOLUTION
13.Kupunguza muda unaotumia	kufanya kazi	Sale
C _{1.Ndiyo}	-2.Hapana	0 6 CEC 2017
14.Ulifanya kazi kidogo ikilingan	ishwa na wakati mwingine	dox 75457 - 101-00 #
C _{1.Ndiyo}	2.Hapana	Contract
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15.Ulipata changamoto ya aina ya kazi au shughuli nyingine ulizofanya

1.Ndiyo

C_{2.Hapana}

16.Ulipata wakati mgumu kufanya kazi au shughuli nyingine (kwa mfano, ulitumia nguvu

zaidi)

C_{1.Ndiyo}

2.Hapana

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MATATIZO YA AFYA YA HISIA:

Katika kipindi cha wiki 4 zilizopita, je umepata matatizo yoyote kati ya yafuatayo katika kazi yako ay shughuli nyingine zako za kawaida kutokana na matatizo ya hisia (kama vile mawazo na wasiwasi?

17.Kupunguza muda uliotumia kufanya kazi au shughuli nyingine							
C _{1.Ndiyo}	C _{2.Hapana}						
18.Ulifanya kazi kidogo kuliko r	na siku zingine						
C _{1.Ndiyo}	C _{2.Hapana}						
19.Hukufanya kazi au shughuli	nyingine kwa makini kama	a ilivyo kawaid	à				
C _{1.Ndiyo}	C _{2.Hapana}						
SHUGHULI ZA KIJAMII:							
20.Matatizo ya hisia yaliingilia shug	huli zako za kawaida za kijami	i na ndugu, mara	afiki, majirani au				
makundi mengine?							
C _{1.Hata Kidogo} C _{2.Kiasi}	C _{3.Wastani}	C _{4.Mbaya}	C _{5.Mbaya} Sana				
MAUMIVU:							
21.Je, ulipata maumivu kiasi gani ka	atika kipindi cha wiki 4 zilizopi	ta?					
C1.Hakuna C2.Kidogo Sana	3.Kidogo C3.Wastani	C _{4.Mbaya}	C _{5.Mbaya} Sana				
22.Katika kipindi cha wiki 4 zili:	zopita, je maumivu yaliathi	iri kazi yako kv	va kiasi gani (ikiwa				
ni pamoja na kazi za nje na kaz	i za nyumbani)?						
1.Hata Kidogo 2.Kidogo	3.Wastani 4.K	liasi	_5.Mabaya sana				
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NGUVU NA HISIA:

Maswali haya yanahusu hisia zako na hali yako kwa ujumla katika kipindi cha wiki 4 zilizopita.

Tafadhali toa jibu ambalo ni sahihi linaloelezea hisia zako kwa kila swali.

22	1 111	115-1	-1 -	and in	-			9
۷۵.	UH	րու	si n	1CI	an	ga	ш	u :

1. Wakati wote	2.Mara nyingi
3 Kiasi	4. Wakati mwingine
5 Kiasi Kidogo	6 Hata Mara moja
uwa na wasiwasi wowote?	

24.Je, umewahi k

Wakati wote	2 Mara nyin	gi
3 Kiasi	4. Wakati mwi	ngine
5.Kiasi Kidogo	6. Hata Mar	a moja

25.Umewahi kujisikia mnyonge na kukosa furaha kabisa?

5. Kiasi Kidogo

	 1.Wakati wote 	 2.Mara nyingi
	3 Kiasi	4. Wakati mwingine
	5 Kiasi Kidogo	6. Hata Mara moja
26.Umewa	ahi kuwa mtulivu na mwenye amani	?
	1. Wakati wote	2 Mara nyingi
	3 Kiasi	4 Wakati mwingine

27. Ulikuwa na ari na nguvu nyingi?

1 Wakati wote	- 2 Mara nyingi		
3 Kiasi	4 Wakati mwingine		
5 Kiasi Kidooo	6 Hata Mara moia		

6 Hata Mara moja

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20. Omejisikia kuvunj	ika moyo na mwenye nu	Lumir	
	C1.Wakati wote	2.Mara nyingi	
2	C _{3.Kiasi}	C4.Wakati mwingine	
C	5.Kiasi Kidogo	C 6.Hata Mara moja	
3			
29.Umejisikia kuchol	ka kabisa?		
	C ₁ .Wakati wote	2.Mara nyingi	
	C _{3.Kiasi}	4.Wakati mwingine	
C	5.Kiasi Kidogo	6.Hata Mara moja	
30.Umekuwa mtu mv	venye furaha?		
b) .	C1.Wakati wote	2.Mara nyingi	
	C _{3.Kiasi}	4.Wakati mwingine	
C	5.Kiasi Kidogo	6.Hata Mara moja	
31.Ulihisi uchovu?			
	_1.Wakati wote	2.Mara nyingi	
ă .	C3.Kiasi	4.Wakati mwingine	
C	5.Kiasi Kidogo	6.Hata Mara moja	
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SHUGHULI ZA KIJAMII:

32.Katika kipindi cha wiki 4 zilizopita, ni muda gani ambao matatizo yako ya kiafya yako na hisia zilitatiza shughuli zako za kutangamana na jamii (kama kutembelea ndugu, marafiki, nk.)?

1 Muda wote
2.Mara nyingi
3.Wakati mwingine

4.Muda kidogo

5.Hakuna hata mara moja

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AFYA KWA UJUMLA:		
33.Ukizingatia kauli hizi, ni k	wa kiasi gani ni kweli tunapoz	ungumzia afya yako?
Huwa ninaugua sana kuliko v	watu wengine	
1.Ukweli kabisa	Mara nyingi ni kweli	C _{3.Sijui}
3		
4.Mara nyingi si kweli 5.Ni ud		go kabisa
34.Nina afya nzuri kama	watu wengine	
1.Ukweli kabisa C2.I	Mara nyingi ni kweli	C _{3.Sijui}
4.Mara nyingi si kweli	C _{5.Ni uon}	go kabisa
35.Naona afya yako itak	uwa mbaya zaidi	
C _{1.Ukweli kabisa} C _{2.1}	Mara nyingi ni kweli	C _{3.Sijui}
C4.Mara nyingi si kweli	C _{5.Ni uon}	go kabisa
36.Afya yangu ni nzuri k	abisa	
C _{1.Ukweli kabisa} C _{2.I}	Mara nyingi ni kweli	C _{3.Sijui}

5.Ni uongo kabisa

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4.Mara nyingi si kweli



Appendix X: Certificate of Translation



COMMUNICATING THE ESSENCE
Corporate Events – Translations – Conferences

Seamless Events Solutions

Upper Hill, Duplex Apartments, Suite No. 60

P.O Box 75457-00200, Nairobi, Kenya.

Tel: +254 720475518

+254 732474271

E-Mail: info@seamevents.com Website: www.seamevents.com

06.12.2022

TO WHOM IT MAY CONCERN

CERTIFICATE OF TRANSLATION

We certify that the documents

- 1. ICAM -Questionnaire
- 2. SF -36 Questionnaire

Were translated by Seamless Events Solutions from English to Swahili

We further certify that the enclosed translated documents are a true reflection of the documents provided to us by **Dr. Kismat Juma** for translation.

Yours Faithfully,

JAMES GACHARA NDIRITU BUSINESS LEAD

We work hard, deliver and love it!

Appendix XI: Letter of Authorization to Use Medical Records

Kismat M. Juma

H58/34179/2019

University of Nairobi

College of health sciences,

Department of clinical Medicine and therapeutics

Date

To.

Head of department, health Management information systems,

Kenyatta National Hospital.

REF: Request for authorization to use health records in the conduction of a study

I am a resident currently undertaking a master's degree in internal medicine at the University of Nairobi.

I kindly request for authorization to use medical records for purposes of conduction of a study: utilization of complementary and alternative medicine in patients with Rheumatic diseases at Kenyatta National Hospital. This is in partial fulfilment of the requirement for my degree of Master of Medicine in Internal medicine.

Thank you.

Yours sincerely,

Dr. Kismat Juma

Appendix XII: Departmental Approval



Tel.: 2726300/2726450/2726550

Fax: 2725272

Email: knhadmin@knh.or.ke

Ref: KNH/HOD-MED/37/VOL.II/61

Date: 2nd December 2022

Dr. Kismat Juma Reg.No. H58/34179/2019 Faculty of Health Sciences, Dept. of Clinical Medicine and Therapeutics

Dear Dr. Kismat,

RE: APPROVAL TO CONDUCT A STUDY AT THE KNH MEDICINE DEPARTMENT

Following approval by the KNH/UON-Ethics & Research Committee for your research proposal and subsequent filing of the study registration certificate, this is to inform you that authority has been granted to collect data in Medicine Department, on your study titled "Utilization of complimentary and alternate medicine by patients with rheumatological diseases in Kenyatta National Hospital."

By a copy of this letter, DCN - Medical Services is informed and requested to facilitate.

You will also be required to submit a report of your study findings to the office of the undersigned after completion of your study.

W AV KOND 01129010

Dr. Kinoti Ndege HOD, MEDICINE

DCN - Medical Services

Vision: A world class patient-centered specialized care hospital

0

150 9001: 2015 CERTIFIED

Appendix XIII: Study Registration Certificate

KNH/R&P/FORM/01



KENYATTA NATIONAL HOSPITAL P.O. Box 20723-00202 Nairobi

Tel.: 2726300/2726450/2726565 Research & Programs: Ext. 44705 Fax: 2725272

Email: knhresearch@amail.com

Study	Registration Certificate
1. Name of the Principal Investigat	
2. Email address: Number	gm-11-(0m Tel No. 0726132131
5. Contact person (if different from	P1)
4. Email address:	Tel No.
5. Study Title	
by pale to will be pile	temponentry and allinether modere spectralogyed discuss in togethe be conducted Diportmoly of medition
6. Department where the study will (Please attach copy of Abstract)	be conducted Deper modeliere
7. Endorsed by KNH Head of Depart	ment where study will be conducted.
	Signature Park Date 12-2011
8. KNH Light Ethics Research Commit (Please attach copy of ERC approv	the approved study comb
9. 1 Kismed June . findings to the Department when	commit to submit a report of my study e the study will be conducted and to the Department of Medical
Signature SKL	Date 131 Del 2022
10. Study Registration number (Dept/I (To be completed by Medical Rese	Number/Year) 7669 354/ 351 2022 arch Department)
41. Research and Program Stamp	0.5 DEC 2022
All studies conducted at Kenyatta Nati Research and investigators <u>must comm</u>	onal Hospital must be registered with the Department of Medical nit to share results with the hospital.

Appendix XIV: KNH/UoN-ERC Letter of Approval



UNIVERSITY OF NAIROBI FACULTY OF HEALTH SCIENCES P O BOX 19676 Code 00202 Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC

Email: uonknh ero@uonbi.ac ke Website: http://www.erc.uonblac.ke Facebook https://www.facebook.com/uoriknih.erc Twitter: @UONHNH_ERC https://twitter.com/UONHNH_ERC

Ref: KNH-ERC/A/495

Dr. Kismat M Juma Reg. No. H58/34179/2019 Dept. of Clinical Medicine & Therapeutics Faculty of Health Sciences University of Nairobi

3 0 NOV 2022

KENYATTA NATIONAL HOSPITAL

P O BOX 20723 Code 00202

Telegrams: MEDSUP, Nairobi

30th November, 2022

Tel: 726300-9

Fax: 725272

Dear Dr Juma.

RESEARCH PROPOSAL: UTILIZATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE BY PATIENTS WITH RHEUMATOLOGICAL DISEASES IN KENYATTA NATIONAL HOSPITAL (P669/08/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is P669/08/2022. The approval period is 30m h November 2022 - 29m November 2023.

This approval is subject to compliance with the following requirements:

- Only approved documents including (informed consents, study instruments, MTA) will be used.
- All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC
- Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of
- Any changes, anticipated or otherwise that may increase the risks or affected safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH-UoN ERC within 72 hours.
- Clearance for export of biological specimens must be obtained from relevant institutions.
- Submission of a request for renewal of approval at least 60 days prior to expiry of the approval VI. period. Attach a comprehensive progress report to support the renewal.
- Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC

Utilization of Complementary And Alternative Medicine By Patients With Rheumatological Diseases In Kenyatta National Hospital

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APPROVAL OF LEAD SUPERVISOR AND CHAIRMAN OF THE DEPARTMENT

Prof. G. Omondi Oyoo
Associate Professor
Consultant Physician and Rheumatologist
Department of Clinical Medicine and Therapeutics, University of Nairobi. Signature Date
Prof. E. O. Amayo
Chairman
Consultant Physician and Neurologist
Department of Clinical Medicine, and Therapeutics
University of Nairsbiy OF NAIROBI COLLEGE S AFALTH SCIENCES Signature ARTMENT OF CLARGE MERIDIA STATE APPENTICS.