PERIODONTAL STATUS IN RELATION TO SEVERITY OF RHEUMATOID ARTHRITIS AMONG PATIENTS ATTENDING THE KENYATTA NATIONAL HOSPITAL

HUSSEIN MUHOLO MUCHUKA

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UNIT OF PERIODONTOLOGY/COMMUNITY AND PREVENTIVE DENTISTRY

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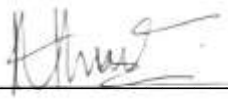
DECLARATION

I declare that this is my original work and has not been presented for the award of a degree in any other university.

Signature:  Date: ____24/11/2023_____

HUSSEIN MUHOLO MUCHUKA

V60/7162/2017

SUPERVISOR'S APPROVAL

I, Dr. Hussein Muholo Muchuka, hereby submit this thesis for examination with the approval of my supervisors,

Dr Wetende Andrew

BDS, MDS (Nrb), FADI, FPFA

Lecturer, Department of Dental Sciences, Periodontology/Community and Preventive Dentistry Unit, University of Nairobi

Signature: _____ Date 30/11/2023

Dr. Matu Nelson

BDS (Nrb), MSc. Dent, (UWC), FPFA, FICD

Senior Lecturer, Department of Dental Sciences, Periodontology/Community and Preventive Dentistry Unit, University of Nairobi

Signature: _____ Date 24/11/23

Dr. Bernard Mua

BDS (Nrb), MPH (Nrb), MBA (St Paul's), PgDip (Nrb)

Senior Lecturer, Department of Dental Sciences, Periodontology/Community and Preventive Dentistry Unit, University of Nairobi

Signature: _____ Date 24/11/2023

DEDICATION

To the Almighty God be the glory; for His infinite love and mercy

To my wife, Munawar, my daughters Lamia and Aimal and my son Zayyan for their perseverance and support throughout my study.

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ABBREVIATION AND ACRONYMS

ACR	American College of Rheumatology
Anti-CCP	Anti-cyclic citrullinated peptide antibodies
BDS	Bachelor of Dental Surgery
BPE	Basic Periodontal Examination
CDAI	Clinical Disease Activity Index
CRP	C-reactive Protein
DAS-28	28 Joint Disease Activity Count
DMARD	Disease Modifying Antirheumatic Drug
ESR	Erythrocyte Sedimentation Rate
EULAR	European League against Rheumatism
FADI	Fellow of the Academy of Dentistry International
FPFA	Fellow of the Pierre Fauchard Academy
HCQ	Hydroxychloroquine
KNH	Kenyatta National Hospital
KNH_UoN ERC	Kenyatta National Hospital and UoN Ethical and Research Committee
MCP	Metacarpophalangeal Joint(s)
MHC	Major Histocompatibility Complex
MTX	Methotrexate
PAS	Patient Activity Scale
PGA	Patient Global Assessment
PI	Principal Investigator

PIP	Proximal Interphalangeal Joint(s)
RA	Rheumatoid Arthritis
RAPID3	Routine Assessment of Patient Index Data 3
RF	Rheumatoid Factor
ROPC	Rheumatology Outpatient Clinic
SDAI	Simplified Disease Activity Index
SJC	28-Joint Swollen Joint Count
SPSS	Statistical Package for Social Sciences
SSZ	Sulphasalazine
TJC	28-Joint Tender Joint Count
UON	University of Nairobi
VAS	Visual Analogue Scale
WHO	World Health Organization

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ABSTRACT

Background: Periodontal disease prevalence is high globally as well as in Kenya affecting about 80% of the population. Rheumatoid arthritis prevalence in Kenya was estimated to be about 4.3 million people in 2018. Both periodontal disease and rheumatoid arthritis being multifactorial complex diseases, have similar aetiopathogenetic mechanisms of chronic inflammation and bone destruction. Periodontal and rheumatoid diseases lead to significant morbidity, with periodontal disease (PD) eventually causing tooth loss and loss of masticatory function, while RA leads to loss of joint function and mobility. Together, development of both diseases brings considerable consequences for public health and for the quality of life of affected individuals.

Study Objective: To investigate the status of periodontal disease and relate it to the severity of rheumatoid arthritis in patients attending the Rheumatoid Outpatient Clinic (ROPC) at Kenyatta National Hospital (KNH).

Setting: Rheumatoid Outpatient Clinic at the Kenyatta National Hospital.

Study design: A hospital-based descriptive cross-sectional study.

Study participants: The study participants were patients above 18 years of age who were already diagnosed with rheumatoid arthritis and visiting the Rheumatology Outpatient Clinic (ROPC)

Materials and methods: Eighty-six (86) participants who fitted the inclusion criteria were recruited into the study by using non probability convenient sampling method. Rheumatoid arthritis (RA) disease activity was determined using Clinical Disease Activity Index (CDAI). Oral hygiene was assessed using Turesky et al modified Quigley Hein Plaque Index (TQHPI) while gingival status determination was carried out using (Loe and Silness,1963). Periodontal examination was based on the Basic Periodontal Examination (BPE). Bio-data and social demographic information was obtained through a questionnaire. Severity of rheumatoid arthritis was assessed using Clinical Disease Activity Index (CDAI) by simple summation of the number of tender joints and swollen joints from the 28-joint

count pattern, the patient's global assessment of disease activity and the provider/physician global assessment of disease activity.

Data Management and Analysis: Data collected were coded and entered into a computer. Cleaning of the data was done thereafter it was subjected to analysis using SPSS Version 23.0 for Windows (SPSS Inc Illinois, Chicago, USA). Obtained results are presented in the form of text, frequency diagrams, graphs tables, pie charts among others.

Results: A total of 86 cases was included in the study. The age ranged from 18 – 82 with a mean age of 52.17 (±16.19 SD), a median of 55 and a mode of 45 years. Majority, 60 (69.8%) had moderate to severe gingival inflammation while 26 (30.2%) had mild gingival inflammation Also, according to CDAI, the majority of patients had moderate to severe rheumatoid arthritis disease activity. There was no association found between the status of periodontal disease and the severity of rheumatoid arthritis. (t 0.70 p 0.49)

Conclusion:

The study did not find any association between periodontal disease and the levels of rheumatoid arthritis disease activity in patients already diagnosed with rheumatoid arthritis.

Recommendations

Based on the findings of this study, the following was recommended.

a. Known RA arthritis patients need periodontal examination and treatment where necessary.
b. To determine the timing of these two diseases and effect of periodontal disease on severity of rheumatoid arthritis, longitudinal studies and more research is required.

CHAPTER ONE

1.0 INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION

Periodontitis is an inflammatory disease affecting tooth supporting- structures as a result of host-microbial interactions[1]. It is initiated by the accumulation of plaque in the gingivodental area as well as bacteria that potentiate destruction of these tooth supporting structures. However, majority of the harm is by activation of immune inflammatory response[2]. Genetic factors and environmental factors including oral hygiene have also been shown to be responsible for the progression of periodontal disease. In Africa, an increase in oral diseases has been typified by the increased prevalence of periodontal disease[3]. In most African countries including Kenya, studies done on adults indicate an increase in the prevalence of periodontal diseases[3]. A study conducted by Kaimenyi J in 2004 indicated a higher prevalence of periodontal diseases among adults of Kenyan origin[4]. Kenya National Oral Health Survey Report 2015 shows a high prevalence of gingivitis, a constitute of periodontal disease, to be 98.4% in male adults while in female adults it is 97,7%. Presently, monitoring periodontal status mainly involves measurement of clinical attachment loss by use of a periodontal probe[5]. Other methods such as the use of standardized radiographs and subtraction images have been employed albeit less frequently.

Rheumatoid arthritis (RA) is an auto-inflammatory disease that affects joints leading to synovitis and functional disability among other symptoms. The estimated worldwide prevalence of this disease was around 1% by the year 2012 [6]. Recently, early stages of RA can be diagnosed using the 2010 American College of Rheumatology (ACR)/European League Against Rheumatism (EULAR) RA classification criteria which has played a significant role in early intervention and consequently minimizing structural damages to the joints as a result of active disease. Disease

activity in RA is largely assessed using either Clinical Disease Activity Index (CDAI) or Simplified Disease Activity (SDAI) indices both being compatible with the Disease Activity Score-28 (DAS 28) [7].

Periodontal and rheumatoid diseases lead to significant morbidity, with periodontal disease(PD) eventually causing tooth loss and loss of masticatory function, while RA leads to loss of joint function and mobility[8].

Rheumatoid arthritis (RA) and periodontitis are both chronic inflammatory diseases sharing potential mechanisms including histopathology and demography. Several studies reviewed the relationship between both diseases considering epidemiological aspects, mechanical periodontal treatment, inflammatory mediators, oral microbiota, and antibodies involved where a lot of similarities were observed [9]. Although the pathogenesis of RA is unclear, the mechanisms for its development are closely associated with the pathogenesis of PD. It is suggested that its development involves activation of the complement system which is also significant in the progress of PD. Susceptibility of both diseases to genetic and environmental factors such as smoking further emphasizes the close relationship between PD and RA.

This study aimed to determine the relation between periodontal status and severity of rheumatoid arthritis among patients visiting the rheumatology clinic at KNH Teaching and Referral Hospital. The findings from this study could be used to develop management strategies focusing on early intervention for both periodontal disease and rheumatoid arthritis.

1.2 LITERATURE REVIEW

1.2.1 Periodontal disease

Periodontal disease is a chronic inflammatory disease of tooth-supporting structures. The advanced form of periodontal disease is characterized by loss of the periodontal ligament and destruction of the surrounding alveolar bone. It eventually causes tooth loss and has been considered one of the two biggest threats to oral health [10].

As a multifactorial inflammatory disease, PD is associated with dysbiotic plaque biofilms and characterized by progressive destruction of the structures that support the tooth.[11] Uncontrolled form of PD may result in tooth loss and disability consequently leading to loss of function. The nature of periodontitis is that it has both destructive and quiescence stages. The active stage is where continuous destruction of bone and loss of clinical attachment occurs, largely referred to as periodontal disease activity [5]. Moreover, tooth loss has an impact on quality of life[12]. This is demonstrated by higher scores in an oral Impact Profile Instrument (OHIP-14). The OHIP-14 consists of 14 questions that assess seven dimensions: functional limitation, pain, psychological discomfort, physical disability, psychological disability, social disability and incapacitation.[13]

1.2.2 Measure of disease activity in periodontal disease

The most commonly used method of checking periodontal disease activity has been clinical probing attachment level measurements. The cemento-enamel junction (CEJ) is used to calculate loss of clinical attachment since this junction usually represents the true normal level of connective tissue attachment. The CEJ, therefore, provides a reliable static landmark from which measurements are done[5]. At present, monitoring periodontal health status involves measuring pocket depths by probing. Increasing probing depths have been associated with periodontal disease activity[14].

Alternatively, use of Basic Periodontal Examination has (BPE) has been widely used in place of clinical attachment loss to screen for periodontal diseases. BPE was introduced in 1986 to act as a simple and rapid tool to help dentists screen for periodontal diseases in adults. A study by Tugnait et al in 2004 found that its use had been adopted by the majority of clinicians during both new patient and recall examinations; reported use being 91% and 84% of the time, respectively[34].

1.2.3 Rheumatoid Arthritis

Rheumatoid arthritis being a chronic auto inflammatory disease has a high prevalence worldwide despite being looked at as a minor disease[6]. This joint disease causes hard tissue damage that often leads to functional disability. Early diagnosis therefore becomes key in the prevention of severe outcomes such as high disease activity, increased serum levels of the autoantibodies coupled with early joint damage. Treatment of RA involves measuring disease activity with composite indices, applying a treatment-to-target strategy, and use of conventional, biological and new non-biological disease-modifying anti-rheumatic drugs (DMARDS). The use of disease-modifying antirheumatic drugs (DMARDs) aims to reverse the symptoms of the disease, reduce the progression of joint damage, and consequently improve the quality of life of patients. The conventional synthetic DMARDs include methotrexate, sulfasalazine, and leflunomide; the available tumor necrosis factor inhibitors (adalimumab, etanercept, and infliximab), the T cell costimulation inhibitor (abatacept), the anti-B cell agent (rituximab), and the interleukin-6 receptor blocking monoclonal antibody are included in biological DMARDs[51].

1.2.4 Measures of Disease Activity in Rheumatoid Arthritis

Rheumatoid arthritis being a disease that causes pain and disability, many measures have been taken to monitor its progress, among them being the development of Modified Disease Activity

Score(DAS) which included more comprehensive joint counts.[7] Since the 1950's many attempts have been made to improve RA disease activity monitoring. A multi-step process was employed to come up with about 6 recommended disease activity measurement tools.[15] These include Patient Activity Scale(PAS), PAS II, Routine assessment of patient index data (RAPID)3, Clinical Disease Activity Index(CDAI), Simplified Disease Activity Index(SDAI) and Disease Activity Score(DAS-28).[16] All the six give a continuous range of values that help in the categorization of the disease activity as low, moderate, high and clinical remission. Application of these categories is significant in treatment planning and implementation of the ACR recommendations for the treatment of RA.[15]

ACR/ European League Against Rheumatism (EULAR) and the WHO have provided a set of data that is to be used in measuring disease activity of RA for both clinical and research purposes. The disease activity is derived from addition of scores from tender and swollen joints, patient and physician's global assessment of disease activity and sometimes use of blood tests such as the CRP or the ESR. A total of 28 joint counts are assessed. These joints are 10 proximal interphalangeal (PIP) and 10 metacarpophalangeal (MCP) joints of the hands, 2 wrists, 2 elbows, 2 shoulders and 2 knees.

1.2.5 Clinical Disease Activity Index (CDAI)

At the rheumatology clinic in Kenyatta National Hospital, Clinical Disease Activity Index (CDAI) and Simplified Disease Activity Index (SDAI) are methods both used in assessment of disease activity. In this study CDAI will be the measure preferred because of its ease of use since it does not involve use of the laboratory composite tools (ECR and CRP). In fact, some studies have shown ECR and CRP tests to be having little or no effect on the overall disease activity.[17],[18]

A study conducted by Ndirangu et al at this same facility investigated the congruency of use of these methods of assessing disease activity as a clinical routine in KNH. They found conformity showing no significant difference in whichever method selected.[19] Laboratory measure such as the anticitrullinated peptide antibodies (ACPA) seems to be costly to these patients. Therefore, exclusion of laboratory parameters in CDAI makes it a suitable method for use in this study due to limited financial capability of patients visiting KNH. CDAI was also found to be more stringent in defining remission.

1.2.6 Relationship between Periodontitis and Rheumatoid arthritis

PD and RA do share several similarities including pathogenesis, risk factors and epidemiological associations.[20]

In developed countries, studies indicate that the occurrence and severity of periodontitis are higher among subjects with RA, showing a positive correlation between these inflammatory diseases.[21] Other studies show a close association of periodontitis with RA and some other conditions such as glaucoma, lateral sclerosis, osteoarthritis by demonstrating similar characteristics of proceeding with bursts of activity.[5]

In high-income countries, previous studies have shown that the occurrence and severity of periodontitis is higher among individuals with RA hence showing a positive correlation between the two diseases.[22] [23] However, these studies focused mainly on bringing out the relationship between PD and RA. Severity of periodontal disease was focused on without consideration for disease activity in RA.

Among the commonest pathogens in chronic periodontitis is porphyromonas gingivalis. It is reported to produce a unique bacterial enzyme, p gingivalis peptidyl-arginine deiminase (PPAD) that converts arginine residues in proteins to citrulline. Alteration of protein structure by citrullination means that PPAD could be involved in deregulation of the host's signaling network and immune evasion causing autoimmunity against citrullinated proteins thus contributing to the development of RA.[24]

Periodontitis has been hypothesized to play a role in the initiation of RA via an increased production of citrullinated proteins within the tooth supporting structures. These in turn induce autoantibodies as the environment is filled with neutrophils that express peptidylarginine deiminase 4(PAD-4). Presence of this citrullinated histone H3 in diseased periodontium supports a role for periodontitis in generation of antigens which will be targeted by anti-citrullinated protein antibodies(ACPA).[25]

On pathological relationship, Hao et al used mouse models to demonstrate pathological features between the two diseases. These include deregulated cytokine production, increase in immune cell infiltration, increased expression of Toll-like receptors(TLRs) and enhanced osteoclast activity with bone resorption.[26]

Effects of periodontal treatment on anti-CCP IgG and Porphyromonas Gingivalis peptidylargine deiminase (anti PPAD) IgG responses and expression of peptydylarginine deiminase-4 (PAD-4) were evaluated with the results showing an improvement in the disease activity of RA, as well as the periodontal inflammation and destruction post periodontal treatment.[27] Same findings were observed in other studies which looked at effects of periodontal treatment on severity of RA and serum inflammatory markers in the same patients.[27]

In RA patients, periodontitis is a significant predictor of anti-citrullinated peptide antibodies(ACPA), which partly explains the higher RA disease activity scores of individuals whose symptoms in terms of periodontitis seem to be severe.[28]

CHAPTER TWO

2.0 PROBLEM STATEMENT, JUSTIFICATION AND STUDY OBJECTIVES

2.1 Statement of the Problem

Rheumatoid arthritis is not only associated with morbidity but also an increased risk of mortality.[24] This autoimmune disease is associated with progressive disability and often being accompanied by systemic complications and socio-economic costs. Periodontal disease on the other hand has a high local and global oral health burden. PD often leads to teeth loss that eventually impacts on the quality of life of individuals. Therefore, presence of both diseases concurrently has detrimental effects where the quality of life and an individual's ability to perform daily activities including oral hygiene is majorly impaired.

2.2 Justification of the Study

In the developed countries, studies continue bringing out the different pathogenic linkages, and possible treatment modalities between periodontal disease and rheumatoid arthritis. Mainly the emphasis has been on showing the relationship without specific consideration on relationship of PD and disease activity of RA. In sub-Saharan Africa, and particularly in Kenya, little is known about this link and the benefits associated with treating both diseases concurrently. This research is therefore aimed at studying the relationship between PD and disease activity of RA in the country. This will provide baseline data that will help with the management of both periodontal disease and rheumatoid arthritis in the country.

2.3 Objectives

2.3.1 Main Objective

To investigate the periodontal health status and relate it to the severity of rheumatoid arthritis in patients attending the Rheumatoid Outpatient Clinic (ROPC) at Kenyatta National Hospital. (KNH)

2.3.2 Specific Objectives

i. To assess the periodontal health status of patients attending the ROPC at KNH.

ii. To determine the levels of rheumatoid arthritis disease activity in patients attending the ROPC using Clinical Disease Activity Index (CDAI).

iii. To correlate periodontal health status with the levels of rheumatoid arthritis disease activity.

Table 2.1: Study variables

Variable	Measurement
Socio-demographic variables	
1.Age	Number of years
2.Gender	Male or Female
3.Occupation	Type of occupation.
4.Education	Level of education
5.Marital status	Married/Single
Independent Variables	
1.Gingival health status	Gingival index (Loe and Silness-1963)
2.Periodontal status	Basic Periodontal Exam (British society of Periodontology 2011)
Dependent Variable	
1.Disease activity in RA(CDAI)	1.Remission 2.Minimal 3.Moderate, 4.High
Confounding variables	
1.Oral hygiene(Plaque score)	Poor, Fair, Good, Excellent
2.Disease- modifying anti rheumatic drugs (DMARDS)	1.Methotrexate(MTX) 2.Hydroxycholoroquine(HCQ) 3.Sulfasalazine(SSZ) 4.Leflunomide
3.Other drugs	1.Steroids 2.NSAID 3.Biologic DMARDs

CHAPTER THREE

3.0 MATERIALS AND METHODS

3.1 Study Design

This study was a hospital based descriptive cross-sectional study based at Kenyatta National Hospital.

3.2 Study Area

The study was carried out at the Rheumatology outpatient clinic (ROPC) as well as the dental clinic at Kenyatta National Hospital (KNH), Nairobi. KNH is the largest national referral hospital in Kenya with a bed capacity of 1800 serving patients from Nairobi and its environments as well as patients referred from all over the country specifically for more specialized care. The ROPC in KNH is held weekly on Thursday afternoon where all out-patients with rheumatologic diseases such as RA, osteoarthritis, systemic lupus erythematosus etc. are reviewed and followed up. The clinic is run by consultant rheumatologists and physicians from KNH and UON, assisted by post-graduate residents from Internal medicine department. The periodontal examination was however carried out within KNH at the dental clinic which is a few meters from the rheumatology clinic.

3.3 Study Population

The study population consisted of patients already diagnosed with rheumatoid arthritis visiting the rheumatology clinic at Kenyatta National Hospital between the months of August 2020 and April 2021.

3.4 Inclusion Criteria

2. All the patients who gave written consent to participate in this study.
3. Patients diagnosed to have RA and fulfills the 2010 American College of Rheumatology-European League Against Rheumatism (ACR-EULAR) criteria for RA. (Appendix 7)
4. Patients aged 18 years and above

3.5 Exclusion Criteria

1. Non-consenting patients
2. Patients who do not meet the ACR-EULAR criteria for RA
3. Diabetes and hypertensive patients with non-compliancy to their treatment modalities
4. Persons under the age of 18 years
5. Patients with fever with/without other COVID-19 infection symptoms.

3.6 Sample size determination

Sample size was calculated based on Kish and Leslie formula for cross sectional studies as shown below[x].

$$n = \frac{z^2 p(1-p)}{c^2}$$

n = desired sample size

z = confidence level at 95% (standard value of 1.96)

p = estimated prevalence of HAQ-DI (0.5 assuming maximum variability)

c = margin of error at 5% (standard value of 0.05)

Therefore,

$$n = \frac{1.96^2 \text{ X } p(1-p)}{0.05^2}$$
$$n = 384$$

The calculated sample size for a population more than 10,000 was 384. However, the average number of patients visiting the clinic at the time of study was 9 patients per week giving a total of 108 patients for the three months of data collection.

Using the correction formulae for a population of less than 10,000[x]

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

Where,

n_0 = desired sample size for population > 10,000

N = estimate of population size (108)

n = desired sample size for population < 10,000 = 86

Hence a total sample size of **86** participants were enrolled into the study.

3.7 Sample selection and procedure

Non probability convenient sampling method was used to recruit participants. A preliminary visit to the ROPC clinic at KNH revealed at least 9 rheumatoid arthritis patients were being attended to every Thursday of the week.

3.8 Data collection

Calibration

Data collection was carried out by the principal investigator who was calibrated by one of the supervisors (NM) and a rheumatologist physician (EN). Kappa values for inter examiner difference were calculated for BPE (0.8) which was considered good enough for the study. For intra examiner variability, repeated examination of every 10th participant to adjust for intra-examiner errors was done.

The process began with reviewing files of patients attending the ROPC thereafter files of patients with a documented diagnosis of RA were selected. Participants who met at least four of the seven ACR-EULAR criteria were subjected to the inclusion and exclusion criteria. Those found eligible were duly informed of the study and a written consent obtained from them. Data from the selected patients was collected using both questionnaire and physical examination of the patients. Triaging of participants was done by the nurses at the rheumatology clinic. Patients with signs of fever with or without other Covid 19 symptoms were sent for further management.

The principal investigator interviewed the participants and duly completed the questionnaire on biodata. At any point, the participants were free to ask for clarification on any question that was not clear to them.

Clinical examination included recording tender and swollen joints at the ROPC with the help of rheumatology specialist (EN). The principal investigator carried out a physical examination on the study patients specifically, counting and summation of the number of tender and/or swollen joints in the 28-joints standard pattern to determine the disease severity using the CDAI score (**Appendix** 10). Oral clinical examination was however done at the dental clinic within KNH.

Standards of protecting personal data were followed. Only the serial numbers were used to identify subjects in the questionnaire and examination form.

3.8.1 Data collection tools

A screening form (appendix 4) was used to identify study participants who fit in the inclusion criteria.

Biodata and social demographic information was obtained through a short questionnaire (appendix 9) by the principal investigator

Tender or swollen joint counts as recorded in CDAI form (appendix 10)

3.8.2 Data on disease activity of Rheumatoid arthritis

Since the study used CDAI to determine the disease activity scores, patient and the provider composite tools were used to calculate the CDAI by simple summation of the number of tender joints and swollen joints from the 28-joint count pattern, the patient's global assessment of disease activity and the provider/physician global assessment of disease activity. Disease activity scores were categorized as follows:

1. Remission ≤ 2.8
2. Low >2.8 and ≤ 10
3. Moderate >10 and ≤ 22
4. High > 22

3.8.3 Oral Hygiene Assessment

Oral hygiene was assessed using Turesky et al Modified Quigley Hein Plaque Index(TQHPI)[29] (Appendix 8). Plaque score was done first to avoid disrupting it while doing the gingival examination since running the probe along the gingival margin or probing the pocket depths disrupts plaque accumulation.

3.8.4 Gingival Health

The Gingival Index (Loe and Silness, 1963) was used for the assessment of the gingival condition and recorded qualitative changes in the gingiva. It scored the marginal and interproximal tissues separately on the basis of 0 to 3.

The bleeding was assessed visually by running the probe gently along the wall of soft tissues of the gingival sulcus, waited for 30 seconds before inspecting the gingiva for areas of bleeding.

The scores of the four areas of the tooth were summated and divided by four to give the gingival index for the tooth. The GI for the individual was obtained by adding the values of each tooth and dividing by the number of teeth examined. Results were tabulated as follows:

0.1-1.0 = mild inflammation;

1.1-2.0 = moderate inflammation

2.1-3.0= signifies severe inflammation (Appendix 8).

3.8.5 Periodontal Health Assessment

Data on periodontal status was collected by basic periodontal examination (BPE). All the present teeth were included in the examination apart from the 3rd molars. BPE was used not only for screening of periodontal diseases but the codes generated also provides recommendations for its management, including advice, treatment and recall periods.

1. The dentition was divided into 6 sextants upper right (17-14), upper anterior (13-23) upper left (24-27), lower right (47-44) lower anterior (43-33) lower left (34-37).
2. All teeth in each sextant are examined with exception of third molar unless 1st or 2nd molars are missing
3. For a sextant to qualify for recording, it must contain at least two teeth

4. A WHO probe was used. This has a ball end 0.5 mm in diameter and a black band from 3.5mm to 5.5mm, light probing force used between 20-25 grams
5. The probe was passed around all teeth in each sextant. All sites should be examined to ensure that the highest score in the sextant is recorded before moving on to the next sextant.

This index integrates gingival inflammation, presence of calculus and overhanging margins and pocket depth to determine a particular score for a given sextant see (Appendix 8)[30]

3.8.6 Infection control

Precautions were taken to protect the participants, the principal investigator and other users of the clinic from the risk of cross infection.

Disinfection of the dental chair before sitting the participant was done. The principal investigator used clean gloves and facemasks during examination. Due to the COVID pandemic, the principal investigator and research assistant donned new gowns, headgear and eyewear. Temperatures of the patients were taken and those found with fever with or without other symptoms of COVID were excluded from the study. They were however referred for definitive test results and management at the COVID 19 department at KNH.

Each study participant wore disposable bib and disposable plastic tumblers for mouth rinsing.
Sterile instruments in a sterile dental instrument tray were used for clinical evaluation.
Waste disposal was done according to hospital guidelines and the used instruments and trays were taken to the central sterilization to prepare them for the next clinical session.

3.8.7 Reliability and Validity

Several measures were put in place to ensure that assessment tools produced stable, consistent and credible results. A pilot phase was carried out on six participants with the help of rheumatology consultant.to ascertain the validity and reliability of questionnaires, clinical examination forms and instruments. Reliability tests were done using a pilot phase of the instruments and materials used by the examiner. All measurements were carried out by the principal investigator. Intra examiner reliability was carried out through double evaluation of every 10th patient. The principal investigator was calibrated by the supervisors who are consultants in periodontology and a rheumatology physician. Cohen's kappa score was used to calculate both inter-examiner and intra-examiner reliability. A score of 80% was accepted for inter examiner reliability.

3.8.8 Data Analysis and Presentation

Data collected was coded and entered into a computer. Cleaning of the data was done thereafter subjected to analysis using SPSS Version 23.0 for Windows (SPSS Inc Illinois, Chicago, USA). Continuous data such as age was summarized in terms of means and standard deviations. Categorical data was presented in terms of frequency distributions, bar charts and pie charts.

Bivariate relationships between variables in the study was assessed using Spearman's correlation test rho (ρ), to identify statistically significant relationships between variables of interest. In this case, periodontal health status vs rheumatoid arthritis disease activity. In the final level of analysis, all variables that were statistically significant were correlated with the dependent variables using ordinal regression analysis. The level of statistical significance was set at $p<0.05$, for all statistical tests.

3.8.9 Ethical Consideration

Ethical approval was obtained from the from KNH-UON-ERC Research and Standards Committee. (Appendix 12).

Approval to conduct the study was obtained from the Head of Clinical Services, Internal Medicine Department. A voluntary written consent was sought from the participants as proof of their willingness to participate in the study.

3.8.10 Study Benefits

As part of the benefits, participants got periodontal health education and the knowledge on the progress of rheumatoid arthritis which was of help in management of the disease. Patients who needed emergency treatment were attended to while those who needed further periodontal management were referred to the school of dental sciences for treatment. Until the results of this study, there wasn't any local study correlating periodontal disease with rheumatoid arthritis.

3.8.11 Limitations

Due to the COVID 19 pandemic, there was restricted movement of people countrywide. This led to closure of the ROPC clinic. Sequentially data collection period took much longer than expected. The closure might have interfered with patients' adherence to medications and other treatment modalities.

CHAPTER FOUR

4.0 RESULTS

4.1 Socio-demographic Data

A total of 86 participants were included in the study. Of the 86, 48 (55.8%) were females while 38 (44.2%) were males. The age of the participants ranged between 18 – 82 years with a mean of 51.7 years (± 16.7 *SD*). The males were slightly older with a mean of 52.3 years (± 18.2 *SD*) compared to females with a mean of 51.0 years (± 14.8 *SD*). The difference was however non-statistically significant ($t(84) = 0.349$, $p = 0.728$

Table 1. Socio-demographics characteristics of the participants (n = 86).

Characteristics		*n*	*%*
Age (Years)	*< 30*	10	11.6
	31-40	12	14.0
	41-50	14	16.3
	51-60	20	23.3
	61-70	19	22.1
	>70	11	12.8
Gender	*Male*	38	44.2
	Female	48	55.8
Education	*<= Primary*	32	37.2
	>= Secondary	54	62.8
Occupation	*Unemployed*	12	14.0
	Employed	74	86.0

4.2 Oral hygiene status

Oral hygiene status of the participants was assessed using plaque score. The plaque score ranged between 0.5 – 5.0 with a mean of 2.1 (± 0.9 *SD*) showing that every participant had some degree of plaque deposits on teeth surface. The scores were grouped into two categories and tested against various variables for association (Table 2). Majority, 47 (54.7%) had fair to poor hygiene status while 39 (45.3%) had good oral hygiene status.

Table 2. Plaque score (oral hygiene status) among participants against socio-demographics (n = 86).

Characteristics			Plaque score			
			< 2	*>= 2*		
		n (%)	*n (%)*	*n (%)*	X^2	*p*
Age (Years)	*< 50*	34 (39.5)	15 (17.4)	19 (22.1)	0.034	0.85
	>= 50	52 (60.5)	24 (27.9)	28 (32.6)		
Gender	*Male*	38 (44.2)	16 (18.6)	22 (25.6)	0.289	0.60
	Female	48 (55.8)	23 (26.7)	25 (29.1)		
Education	*<= Primary*	32 (37.2)	15 (17.4)	17 (19.8)	0.048	0.83
	>= Secondary	54 (62.8)	24 (27.9)	30 (34.9)		
Occupation	*Unemployed*	12 (14.0)	6 (7.0)	6 (7.0)	0.122	0.73
	Employed	74 (86.0)	33 (38.4)	41 (47.7)		

Oral health status: Good=plaque score < 2 Fair/Poor= plaque score > 2

4.3 Gingival Inflammation (Gingivitis)

The degree of gingival inflammation was assessed using the gingival index. The gingival index ranged between 0.1 – 3.0 with a mean of 1.1 ($\pm$ 0.6 SD) showing that every participant had some degree of gingivitis. Majority, 60 (69.8%) had moderate to severe gingival inflammation while 26 (30.2%) had mild gingival inflammation. Summary of gingival inflammation among participants in (Table 3).

Table 3. Gingival index (gingival inflammation) among participants against socio-demographics (n = 86).

Characteristics			Gingival index			
			<= 1	> 1		
		n (%)	n (%)	n (%)	X^2	p
Age (Years)	< 50	34 (39.5)	11 (12.8)	23 (26.7)	0.120	0.73
	>= 50	52 (60.5)	15 (17.4)	37 (43.0)		
Gender	Male	38 (44.2)	13 (15.1)	25 (29.1)	0.511	0.48
	Female	48 (55.8)	13 (15.1)	35 (40.7)		
Education	<= Primary	32 (37.2)	9 (10.5)	23 (26.7)	0.107	0.74
	>= Secondary	54 (62.8)	17 (19.8)	37 (43.0)		

Gingivitis index: Mild=1,Moderate/Severe >1

4.4 Periodontitis

The presence or absence of periodontitis and the severity thereof was assessed and graded according to treatment needs. Majority, 51 (59.3%) of the participants did not require periodontal treatment or required oral hygiene instructions while 35 (40.7) required oral hygiene instructions and removal of plaque retentive factors. The association between BPE and education was statistically significant (X^2 = 5.107, p = .024). The associations of BPE and participants' characteristics are summarized in (Table 4).

Table 4. Basic Periodontal Examination (BPE) among participants against socio-demographics (n = 86).

Characteristics		n (%)	BPE <= 1 n (%)	BPE 2 n (%)	X^2	p
Age (years)	< 50	34 (39.5)	6 (7.0)	28 (32.6)	9.453*	0.01
	>= 50	52 (60.5)	5 (5.8)	47 (54.7)		
Gender	Male	38 (44.2)	21 (24.4)	17 (19.8)	0.460	0.50
	Female	48 (55.8)	30 (34.9)	18 (20.9)		
Education	<= Primary	32 (37.2)	14 (16.3)	18 (20.9)	5.107*	0.02
	>= Secondary	54 (62.8)	37 (43.0)	17 (19.8)		
	Yes	22 (25.6)	13 (15.1)	9 (10.5)	0.001	0.98

BPE: No need for periodontal treatment/ Oral hygiene instructions=1, OHI, removal of plaque retentive factors=2

Association of plaque score and other clinical characteristic.

Correlation of oral health and clinical characteristics among participants elicited statistically significant associations for plaque scores, gingival scores and periodontitis (Table 5).

Table 5: Association of oral health and clinical characteristics among participants

Plaque scores	n (%)	Coefficient, r	p
Gingival index	86 (100)	0.345**	.001
BPE	86 (100)	0.309**	.004

Pearson correlation coefficient (r) was used.

4.5 CDAI

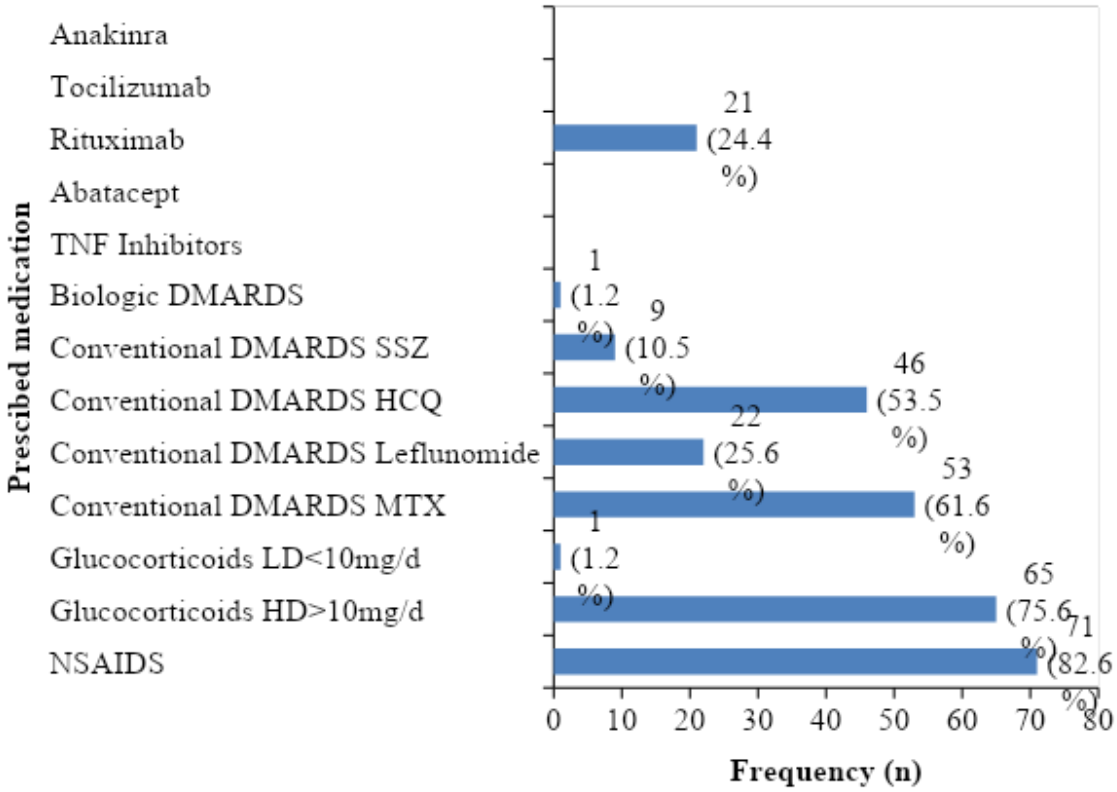
The degree of CDAI grading was assessed using the CDAI score. The majority of individuals exhibited moderate to severe joint inflammation (Table 6).

Table 6. Comparison of CDAI scores against socio-demographics of participants (n = 86).

Characteristics		*n (%)*	*M*	*SD*	*95% CI* *Lower*	*Upper*	*df*	*t*	*p*
Age (Years)	*< 50*	34 (39.5)	26.3	14.2	-9.4	2.5	84	*-1.15*	0.26
	>= 50	52 (60.5)	29.7	13.1					
Gender	*Male*	38 (44.2)	27.1	12.0	-8.2	3.6	84	-0.78	0.44
	Female	48 (55.8)	29.4	14.7					
Education	*<= Primary*	32 (37.2)	30.8	13.6	-2.1	9.9	84	*1.31*	0.20
	>= Secondary	54 (62.8)	26.9	13.5					
Occupation	*Unemployed*	12 (14.0)	32.8	14.4	-3.3	13.5	84	*1.21*	0.23
	Employed	74 (86.0)	27.7	13.4					
	No	27 (31.4)	32.7	14.1					

The participants' RA diagnosis age ranged between 2 – 46 years with a mean of 10.1 years (± 9.4 *SD*). The females had a slightly higher RA diagnosis age with a mean of 10.5 years (± 9.8 *SD*) compared to males with a mean of 9.6 years (± 8.9 *SD*). The difference was however non-statistically significant ($t(84) = 0.424$, $p = 0.673$).). Figure 1 below summarizes the prescription of medication among participants.

Figure 1. Prescribed medications among participants



4.6 CDAI and Plaque

In individuals with good or fair degree of plaque severity (oral health status), the CDAI scores were relatively low (Figure 1). An increase in severity of plaque correlated with increase in CDAI scores. There were no outliers in the CDAI scores among oral health status.

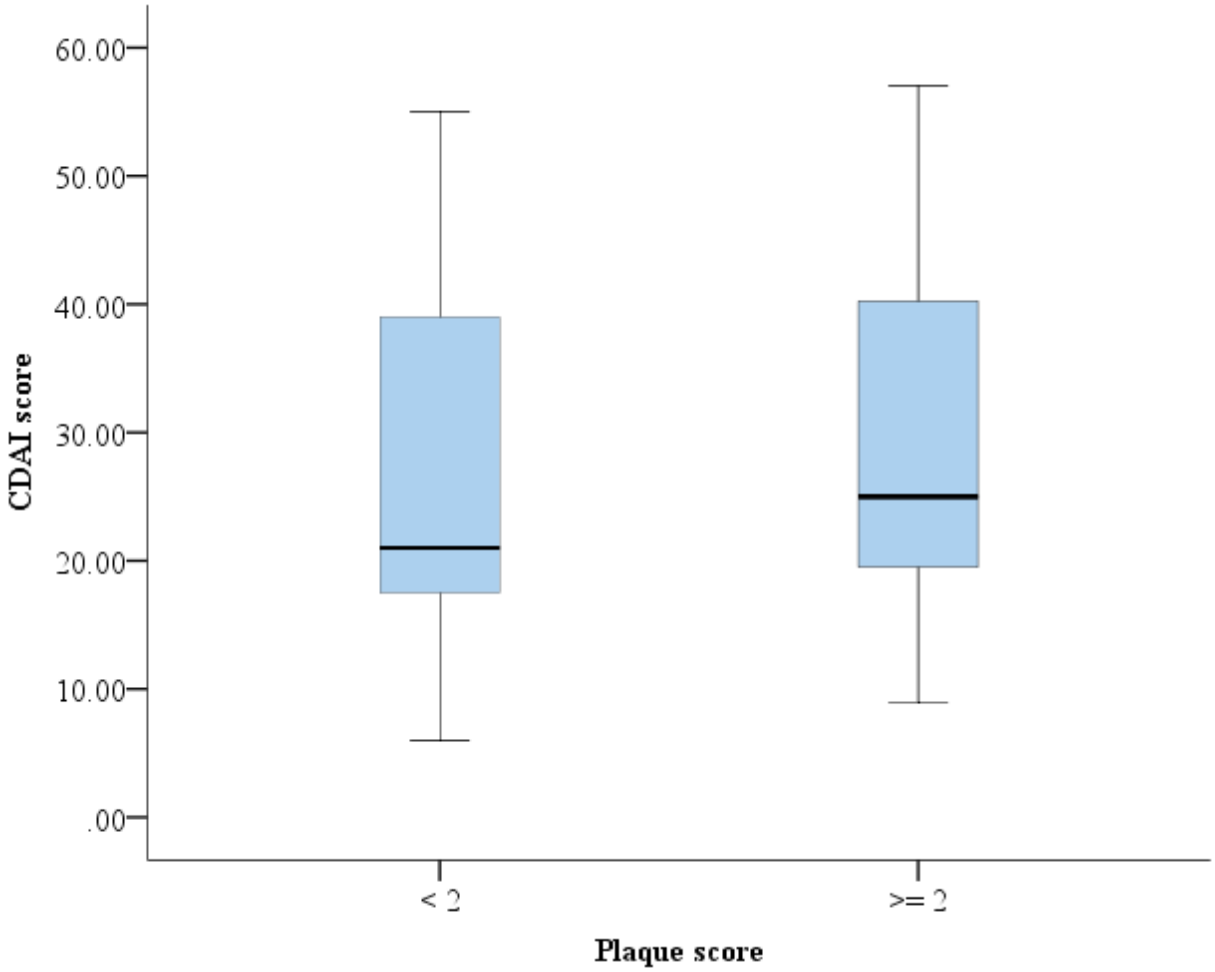


Figure 2. Box plot showing spread of CDAI scores among oral health status of participants.

4.7 CDAI and Gingival Inflammation

In individuals with mild degree of gingival inflammation, the CDAI scores were relatively low (Figure 2). An increase in gingival inflammation correlated with a significant increase in CDAI scores. A Pearson Correlation Coefficient r showed a non-statistically significant association between CDAI and Gingival Inflammation (r=0.120, p=.271).

There were no outliers in the CDAI scores among oral health status.

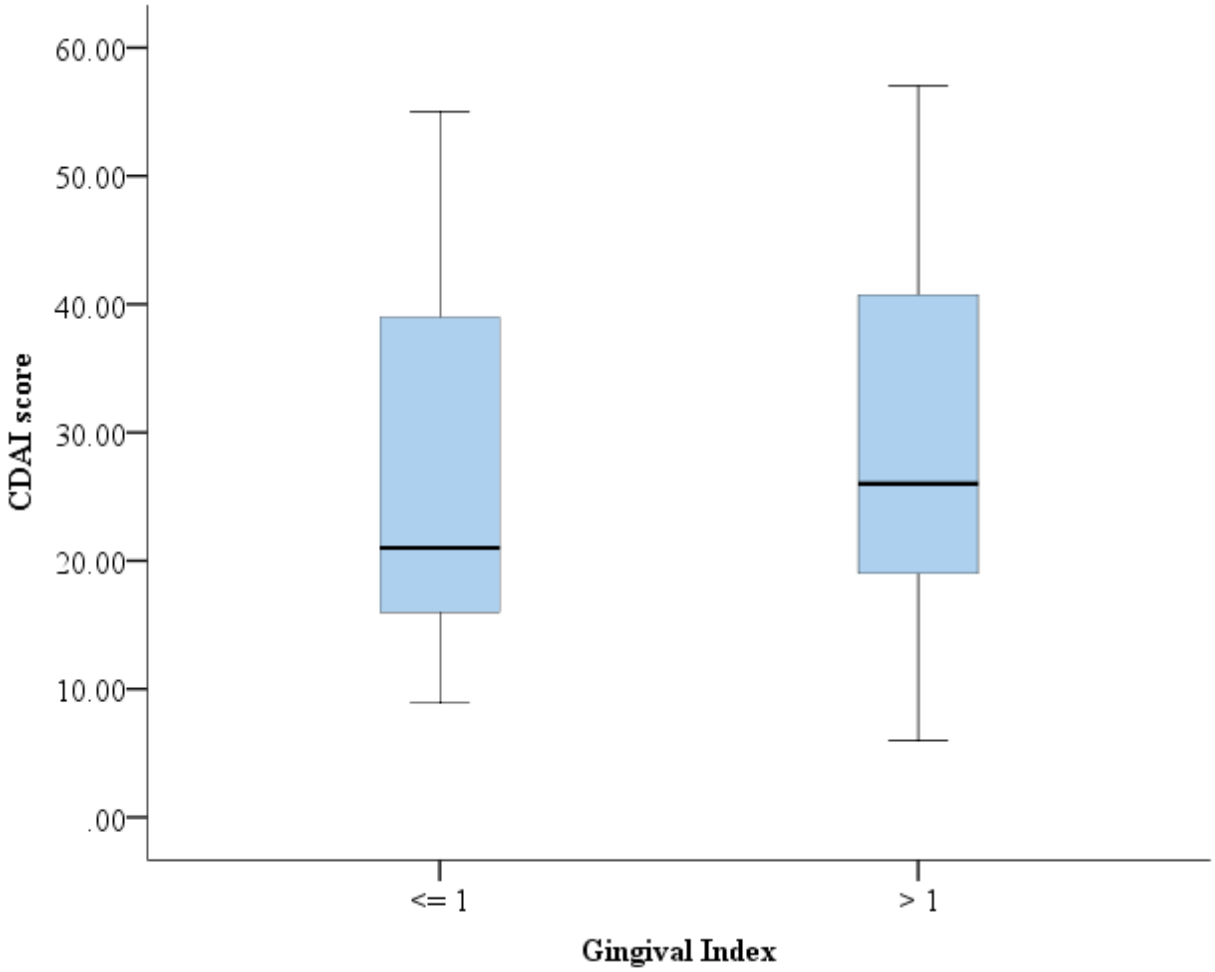


Figure 3. Box plot showing spread of CDAI scores among gingival inflammation of participants.

4.8 CDAI and Basic Periodontal Examination (BPE)

In individuals with who did not need periodontal treatment or oral hygiene instructions, the CDAI scores were slightly higher than scores for individuals who needed OHI or plaque retentive factors (Figure 3).

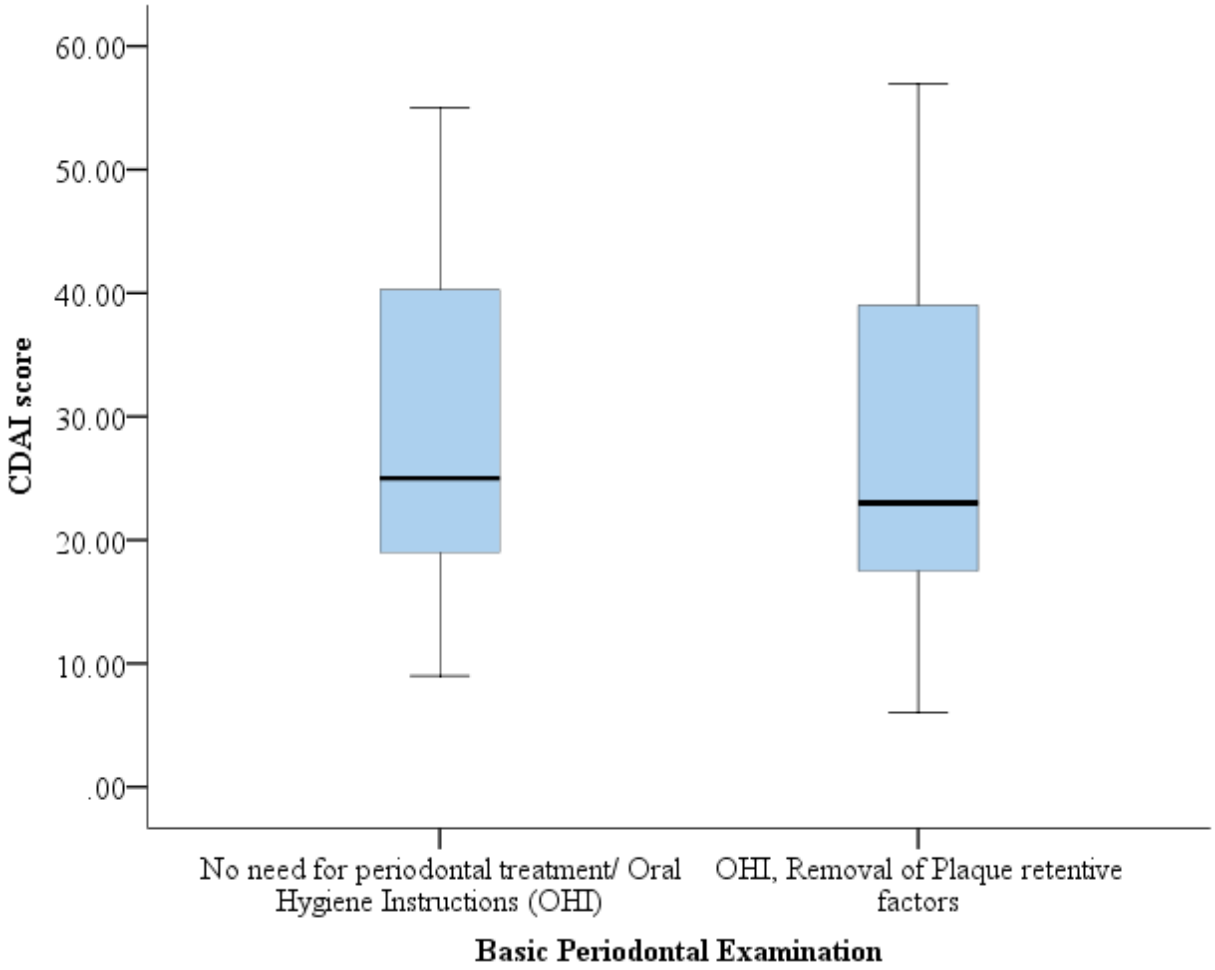


Figure 4. Box plot showing spread of CDAI scores among periodontal treatment needs of participants.

Table 7. Comparison of CDAI scores by clinical characteristics of participants (n = 86).

Characteristics		n (%)	M	SD	95% CI Lower	95% CI Upper	df	t	p
Oral health status	*< 2*	39 (45.3)	27.6	14.4	-7.3	4.5	84	-0.47	0.64
	>= 2	47 (54.7)	29.0	12.9					
Gingival inflammation	*<= 1*	26 (30.2)	26.4	14.3	-9.2	3.5	84	-0.91	0.37
	> 1	60 (69.8)	29.2	13.2					
BPE	*No need for treatment/ Oral Hygiene Instructions*	51 (59.3)	29.2	13.3	-3.9	8.0	84	0.70	0.49
	OHI, Removal of plaque	35 (40.7)	27.1	14.0					

Majority, 50 (58.1%) had low to moderate activity while 36 (41.9%) had high activity. The associations of CDAI and participants' characteristics are summarized in (Table 6).

Table 8. Correlation of CDAI grading with demographic characteristics of participants.

Characteristics		n (%)	CDAI Low/ Moderate n (%)	CDAI High n (%)	X^2	p
Age (Years)	*< 50*	34 (39.5)	22 (25.6)	12 (14.0)	0.10	0.32
	>= 50	52 (60.5)	28 (32.6)	24 (27.9)		
Gender	*Male*	38 (44.2)	25 (29.1)	13 (15.1)	1.64	0.20
	Female	48 (55.8)	25 (29.1)	23 (26.7)		
Education	*<= Primary*	32 (37.2)	15 (17.4)	17 (19.8)	2.66	0.10
	>= Secondary	54 (62.8)	35 (40.7)	19 (22.1)		
Occupation	*Unemployed*	12 (14.0)	6 (7.0)	6 (7.0)	0.38	0.54
	Employed	74 (86.0)	44 (51.2)	30 (34.9)		

A Pearson product-moment correlation was run to determine the relationship between CDAI and various variables. There was a mild, positive correlation between CDAI, age, plaque scores and gingival scores (Table 9).

Table 9. Correlation between CDAI scores with demographic and clinical characteristics of participants.

Characteristics	*n (%)*	*Correlation Coefficient, r*	*p*
Age (Years)	86 (100)	0.13	0.25
Plaque score	86 (100)	0.01	0.93
Gingival score	86 (100)	0.12	0.27
BPE	86 (100)	-0.04	0.72

CHAPTER FIVE

5.0 DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Socio-demographics

The age of participants ranged from 18 – 87 with a mean age of 52.17. Other studies done on this population had a similar mean age[31,32]. This is most likely due to the fact that rheumatoid arthritis often develops between the third and fifth decade of life.

In this study, there were more female participants than male participants. This is consistent with two earlier studies on rheumatoid arthritis conducted in this population.[33,32]. This might be explained by the fact that most connective tissue illnesses tend to affect females more severely than males[34]. The results of this study also support the assertion made by Thompson et al. (2016) that patients who are female had superior health-seeking behavior than patients who are male[35]. It further supports the notion that female sex hormones and rheumatoid arthritis susceptibility may be related, as stated in the literature[36]. Low levels of such hormones during menopause increase the chance of experiencing an early onset of rheumatoid arthritis[36]. However, there is compelling evidence that a deficiency of estrogen influences how severe periodontitis is since it results in worse periodontal parameters[37].

Majority of participants had primary education (36,8%) and secondary education (41.3%). These levels of education might be correlated to the economic situation of these patients. Patients with tertiary level of education and better economic levels tend to seek services from private practitioners as opposed to Kenyatta National hospital, a public hospital. According to a 2014 study by Ilhaji et al, individuals' health seeking behavior was significantly influenced by their education levels among other things[38].

5.2 Gingival health

The degree of gingival inflammation was assessed using the gingival index (Loe and Sillness 1963). The gingival scores of the participants showed that every participant had either mild, moderate or severe gingival inflammation. Every participant had gingival inflammation with majority having between moderate to severe gingival inflammation in both genders. These findings are in agreement with the Kenya National Oral Health Survey of 2015[39].

Greater plaque scores among study participants were also associated with higher gingival scores. According to current literature, pathogenic subgingival plaque is the primary cause of gingival inflammation, so the more plaque there is, the more severe the gingival inflammation is likely to be[40].

Positive correlations were observed between education levels and gingival score that were statistically significant. Individuals with higher levels of education presented with lower degree of inflammation. A study by Peeran et al 2015 demonstrated that education level plays a role in oral hygiene practices. This reinforces the importance of oral hygiene education in reducing prevalence of periodontal diseases.

5.3 Periodontal status

Periodontitis was assessed using Basic Periodontal Examination definitions. The removal of the plaque-retentive factor and the necessity for oral hygiene instructions were more important for participants in older age groups, according to the statistically significant relationship between Basic Periodontal Examination and age. Plausible explanations for increased severity with increasing age in periodontal diseases is as a result of longer duration of exposure to risk factors

over the years such as periodontopathic bacteria, decreased manual dexterity hence compromised plaque control and undiagnosed concurrent systemic diseases[41].

5.4 Clinical Disease Activity Index (CDAI) of Rheumatoid arthritis

A comparison of the CDAI grading showed that majority of the patients had moderate activity followed by high activity. There were no patients with remission. This is an indicator that there is need for a tighter control of disease activity.

When comparing the morbidity of periodontal disease in individuals with rheumatoid arthritis and osteoarthritis, Dissick A et al. did a study that is essentially identical to this one in 2010. The Health Assessment Questionnaire (HAQ) and the Painful and Swelling Joint Count Condition Activity Scores 28 (DAS 28) were used to assess the severity of the rheumatoid arthritis (RA) disease. C-Reactive protein (CRP) was however added as an extra consideration for gauging the severity of the RA illness. They also came to the conclusion that there was no relationship between periodontal disease and the severity of the rheumatoid arthritis disease.

5.5 Disease Modifying-Antirheumatic Drugs(DMARDs)

All the rheumatoid arthritis patients in this study used DMARDs and some type of anti-inflammatory drug for a long period of time and these drugs might protect periodontal tissues from destruction. Based on this, less periodontal destruction would be expected. Thus, the finding of greater periodontal disease extent and/or severity among patients using these anti-inflammatory medications can be interpreted as indication of the strength of the effect of rheumatoid arthritis or of a predisposing genetic trait on periodontal disease pathogenesis, which is supported by the findings of a recent study[42].

The use of disease-modifying antirheumatic drugs (DMARDs) aims to reverse the symptoms of rheumatoid arthritis, reduce the progression of joint damage, and consequently improve the quality of life of patients[43]. The conventional synthetic DMARDs include methotrexate, sulfasalazine, and leflunomide; the available tumor necrosis factor inhibitors (adalimumab, etanercept, and infliximab), the T cell costimulation inhibitor (abatacept), the anti-B cell agent (rituximab), and the interleukin-6 receptor blocking monoclonal antibody are included in biological DMARDs[44]. These medications may be associated with glucocorticoids (GC) or nonsteroidal anti-inflammatory drugs (NSAIDs). Most of the patients in this study were on NSAIDs and actually reported progress in their disease activity. Probably because of the ease of availability of NSAIDs and the fact that the costs are not prohibitive. The long-term, low-dose glucocorticoid and NSAIDs therapy were shown to reduce joint symptoms, pain, and other systemic manifestations[45,46].

Although these benefits are present, the long-time treatment with GC and methotrexate decreased immune response and promoted oral changes, such as candidiasis, periodontitis, and oral ulceration besides impaired saliva secretion[47]. Indeed, literature demonstrates that patients on corticosteroids exhibit higher levels of candidiasis, clinical attachment loss, and probing pocket depth[48]. These aspects, at least in part, may contribute to the worse periodontal status of these rheumatoid arthritis patients.

Although immunosuppressive drugs such as NSAIDs and DMARDs may interfere in the progression of periodontitis, it was not possible to exclude individuals who used such drugs. These drugs are routinely used by the majority of RA patients, and were considered as one possible mechanism for the association of RA and periodontitis.

5.6 Relationship between periodontal status and rheumatoid arthritis disease activity

This study found no association between rheumatoid arthritis disease activity and periodontal disease. Research demonstrating the various distinctions between periodontal disease and rheumatoid arthritis are probably just as numerous as studies demonstrating their association. In addition to concluding that both diseases share a common pathophysiology, common comorbidities such as bacterial, genetic, and environmental variables that affect their progression as well as many common proinflammatory factors also suggest a potential reciprocal influence between periodontal disease and rheumatoid arthritis[49]. The severity of rheumatoid arthritis was not shown to be correlated with periodontal disease in this study, in contrast to the findings of the other studies. This might be explained by the study's use of a modest number of participants.

Periodontal disease and rheumatoid arthritis both have osteoclasia and increased inflammatory cytokines[50]. According to this theory, periodontal disease is a chronic inflammatory condition with an autoimmune component that is brought on by inflammation-mediated processes.

Only two participants were recorded to be smoking and hence had no statistical significance in this study. However, smoking is a major environmental factor for RA since it induces production of antibodies[24].

The Oral Status and Rheumatoid Arthritis (OSARA) study found that periodontal disease affected 94% of outpatients with rheumatoid arthritis, as indicated by an oral health examination. 46% of rheumatoid arthritis patients had periodontal disease that was classified as severe. Patients with rheumatoid arthritis not only had a more severe periodontal disease, but it has also been suggested that periodontal disease may be one of the clinical manifestations of rheumatoid arthritis. The severity of these two illnesses, however, was not correlated in their study.

In a recent study[50], it was examined how treating periodontitis affected those with rheumatoid arthritis. These data are imprecise, though, and may be biased due to the conflicting compliance between the required regular follow-up for rheumatoid arthritis patients and oral care. Each of these studies, however, concentrated on how periodontal therapy affected how severe the rheumatoid arthritis illness was. The influence of medication was less the focus of this investigation than the periodontal health of these patients who had earlier been diagnosed with rheumatoid arthritis.

In this study, the use of NSAIDs and other DMARDs that target specific molecular events associated with acute and chronic inflammation, have significant potential to alter clinical outcomes for both RA and periodontal disease. Hence therefore were considered to be significant confounders.

5.7 Conclusion

Based on the findings of this study, the following was concluded.

a. The majority of participants exhibited moderate to severe gingival inflammation.
b. The study did not find any association between periodontal disease and the levels of rheumatoid arthritis disease activity in patients already diagnosed with rheumatoid arthritis.

5.8 Recommendations

Based on the findings of this study, the following was recommended.

a. Although the study did not find any association between rheumatoid arthritis disease activity and periodontal disease, patients with known rheumatoid arthritis should be examined for any periodontal disease activity and treated appropriately and vice-versa.
b. Longitudinal studies and additional study are needed to ascertain the timing of these two illnesses and the impact of periodontal disease on the severity of rheumatoid arthritis.

5.9 Conflict of interest

The study was carried out for scientific purposes as well as for partial fulfillment for the award of Masters of Dental Surgery Periodontology at the University of Nairobi and as such all the cost involved was solely met by the principal investigator. There was no related conflict of interest.

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APPENDICES

APPENDIX 1: CONSENT FORM

KNH-UoN/ERC/FORM/IC01

UNIVERSITY OF NAIROBI (UoN)
COLLEGE OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity (254-020) 2726300
Ext 44355

KNH-UoN ERC

Email: uonknh_erc@uonbi.ac.ke

Website: http://www.erc.uonbi.ac.ke

Facebook: ttps://www.facebook.com/uonknh.erc

Twitter: @UONKNH_ERC
ttps://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL (KNH)

P O BOX 20723 Code 00202

Tel: 726300-9

Fax: 725272

Telegrams: MEDSUP, Nairobi

PARTICIPANT INFORMATION AND CONSENT FORM

FOR ENROLLMENT IN THE STUDY

Title of Study: INVESTIGATION OF THE PERIODONTAL STATUS AND SEVERITY OF RHEUMATOID ARTHRITIS IN PATIENTS ATTENDING KENYATTA NATIONAL HOSPITAL.

Principal Investigator: DR. HUSSEIN M MUCHUKA

University of Nairobi, School of dental Sciences

Introduction:
I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research,

what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research: I) Your decision to participate is entirely voluntary
ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO
This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

WHAT IS THIS STUDY ABOUT?
The researchers listed above are interviewing and clinically evaluating individuals diagnosed with rheumatoid arthritis. The purpose of the interview is to find out **association between periodontal disease and the severity of rheumatoid arthritis in patients attending the rheumatoid outpatient clinic at Kenyatta National Hospital.** Participants in this research study will be asked questions about their oral habits, disease activity perception and thereafter clinically evaluated for the severity of both periodontal and rheumatoid arthritis.

There will be approximately **106** participants in this study chosen by a method in statistics called consecutive random. We are asking for your consent to consider participating in this study.

WHAT WILL HAPPEN IF YOU DECIDE TO BE IN THIS RESEARCH STUDY?

If you agree to participate in this study, the following things will happen:

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 30 minutes. The interview will cover topics such as personal and identification details, oral hygiene practices. Questions about any other illnesses that you suffer from will be asked.

After the interview has finished, evaluation of your mouth will be done the principal researcher as well as the count of your painful joints done in conjunction with the other researchers.
We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include: follow up and provision of further treatment if necessary depending on the findings.

ARE THERE ANY RISKS, HARMS DISCOMFORTS ASSOCIATED WITH THIS STUDY?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a

code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

ARE THERE ANY BENEFITS BEING IN THIS STUDY?

You may benefit by receiving free dental check-up. We will refer you to a hospital for care and support where necessary. Also, the information you provide will help us better understand the association between periodontal disease and severity of rheumatoid arthritis in our country. This information is a contribution to science and formulation of policy in the country.

WILL BEING IN THIS STUDY COST YOU ANYTHING?

It will not cost you anything.

WILL YOU GET REFUND FOR ANY MONEY SPENT AS PART OF THIS STUDY?

You will not need to spend any money in this research, but in case you spend money, you will be refunded.

WHAT IF YOU HAVE QUESTIONS IN FUTURE?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page.

For more information about your rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

WHAT ARE YOUR OTHER CHOICES?

Your decision to participate in research is voluntary. You are free to decline participation in the study and you can withdraw from the study at any time without injustice or loss of any benefits.

CONSENT FORM (STATEMENT OF CONSENT)

Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study:	**Yes**	**No**
I agree to have (define specimen) preserved for later study:	Yes	No
I agree to provide contact information for follow-up:	Yes	No

Participant printed name: _____

Participant signature / Thumb stamp _____ **Date** _____

Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Researcher 's Name: **DR. HUSSEIN M MUCHUKA** **Date**: _____

Signature_____

Role in the study: Principal Investigator

For more information, contact

1. Dr Hussein M Muchuka

School of dental sciences, University of Nairobi.

Cell phone number – 0718614699

Email address- muholomuchuka@gmail.com

2. Dr Wetende Andrew

Lecturer, School of Dental sciences, College of Health sciences, University of Nairobi

Cell phone number- 0721585820

Email address-drwetende@gmail.com

3. Dr Matu Nelson

Senior Lecturer, School of Dental sciences, College of Health sciences, University of Nairobi

Cell phone number –0722793909

Email address – nkmatu@yahoo.com

4. Dr Benard Mua

Cell phone number - 0722278295,

Lecturer, School of Dental sciences, College of Health sciences, University of Nairobi

Email address- benard.mua@uonbi.ac.ke

KNH/UON-ERC: Tel- 020 726300-9, email address- uonknh_erc@uonbi.ac.ke

from 08:00 am to 05:00pm, Mon - Fri

APPENDIX 2: CONSENT FORM (KISWAHILI)

KNH-UoN/ERC/FORM/IC01

UNIVERSITY OF NAIROBI (UoN)
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Facebook: ttps://www.facebook.com/uonknh.erc

Twitter: @UONKNH_ERC
ttps://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL (KNH)

P O BOX 20723 Code 00202

Tel: 726300-9

Fax: 725272

Telegrams: MEDSUP, Nairobi

FOMU YA RIDHAA

SAMPULI YA RIDHAA YA MTU MZIMA YA USAJILI WA UTAFITI

Mada ya Utafiti:

UHUSIANOKATI YA UGONJWA YA UFIZI NA UKALI WA JONGO LA RHEUMATOID KWA WAGONJWA WANAOHUDHURIA HOSPITALI KUU YA KENYATTA.

Mkuu wa uchunguzi na uhusiano wa taasisi: Daktari Hussein M Muchuka

Chuo kikuu cha Nairobi

Wachunguzi wenza na uhusiano wa taasisi: Haihusiki

Utangulizi:

Ningetaka kukueleza kuhusu utafiti unaofanywa na watafiti ambao wametajwa hapo juu. Lengo la fomu hii ya ridhaa ni kukuwezesha kufanya uamuzi wa iwapo utashiriki katika utafiti au la. Kuwa mwepesi wa kuuliza swali lolote kuhusiana na lengo la utafiti, nini hufanyika iwapo utashiriki kwenye utafiti huu, hatari na manufaa ya utafiti, haki yako kama mtu aliyejitolea kwa

hiari na jambo jingine lolote kuhusiana na utafiti au fomu hii ambalo halijaeleweka. Baada ya kuyajibu maswali yako vilivyo, waweza kuamua kushiriki kwenye utafiti au kutoshiriki. Mchakato huu unafahamika kama 'ridhaa inayofahamika'. Pindi tu utakapoelewa na kukubali kuwa kwenye utafiti, nitaomba ulinakili jina lako na kutia sahihi kwenye fomu hii. Yafaa uelewe sharia za kawaida ambazo hutumiwa na washiriki wote katika utafiti wa kimatibabu: i) Uamuzi wako wa kushiriki ni wa hiari kabisa ii) Waweza kujiondoa kwenye utafiti wakati wowote bila kupatiana sababu ya kufanya hivyo. Iii) Kukataa kushirikio kwenye utafiti hakutaathiri wajibu uanaopaswa kutekeleza katika kituo hiki cha afya ama vituo vinginevyo. Tutakupa nakala ya fomu hii kwa ajili ya rekodi zako

Naweza kuendelea? NDIO / LA

Utafiti huu umeidhinishwa na hospitali ya Kitaifa ya Kenyatta-Kamati ya maadili na utafiti Chuo Kikuu Cha Nairobi, Nambari ya itifaki. _____

Utafiti huu unahusu nini?

Utafiti huu unanuwia ku**tathmini uhusiano kati ya ugonjwa ya ufizi na makali ya jongo la rheumatoid kwa wagonjwa wanaohudhuria hospitali kuu ya Kenyatta.** Habari nitakazopata ni sehemu ya utafiti wangu wa tasnifu ambayo ni sehemu ya ukamilifu wa shahada ya uzamili katika afya ya meno.

Nitashiriki vipi?

Nitakuuliza maswali kuhusiana na unayofahamu kwenye afya ya kinywa. Nitafanya vipimo kadhaa kwa viungo vyako kutathmini kiwango cha makali. Kisha nitaangalia kinywa chako na niyanakili nitakayoyaona. . Uchunguzi utafanywa kwa kutumia vifaa safi na hakuna shurutisho litakalofanywa.

NI NINI KITAKACHOFANYIKA IWAPO UTAAMUA KUWEKO KWENYE UTAFITI?

Iwapo utakubali kushiriki kwenye utafiti, mambo yafuatayo yatafanyika:

Utahojiwa na mtu ambaye amepitia mafunzo katika mahali pa siri ambapo utaweza kuyajibu maswali. Mahojiano hayo yatachukuwa yapata muda wa dakika thelathini. Mahojiano hayo

yatahusisha mada kama vile uchungu kwa viungo vyako, usafi kinywani na ufahamu wa usafi kinywani na jinsi ya kufanya usafi huo.

Tutakuuliza utupe nambari ya simu ambayo tutatumia kuwasiliana iwapo tutahitajika kufanya hivyo. Ukikubali kutupa nambari ya simu itatumiwa tu na watafiti katika utafiti huu na kamwe haitapewa mtu mwingine yeyote. Sababu yetu kuchukua nambari yako ya simu ni ili tuweze kuwasiliana nawe iwapo data itapotea.

JE, KUNA HATARI ZOZOTE AU MADHARA YANAYOHUSISHWA NA UTAFITI HUU?

Utafiti wa kimatibabu una uwezo wa kusababisha hatari za kisaikolojia, katika mahusiano, hisia na kimwili. Yafaa tujaribu tuwezavyo kupunguza hatari hizo. Hatari moja ambayo yaweza kutokea ni ukosefu wa siri. Yote utakayotuambia yatabaki kuwa siri.Tutatumia kodi fulani kukutambua katika tarakilishi iliyo na neno la siri. Data na nakala zetu zote tutazifungia kwa kabati. Hata hivyo, hakuna chombo cha kuhifadhi siri yako ambacho ni salama kabisa na huenda mtu akafumbua kwamba ulishiriki katika utafiti na apate habari kukuhusu.

Aidhaa kujibu maswali kwenye mahojiano huenda kukawa kugumu kwako. Iwapo kuna maswali hutaki kujibu waweza kuyaacha. Una haki ya kukataa mahojiano au swali lolote litakaloulizwa kwenye mahojiano.

Inawezekana liwe ni jambo la aibu kwako kufanyiwa uchunguzi. Tutahakikisha ya kwamba yote hayo yatafanyiwa mahali pa siri. Hali kadhalika watakaofanya mahojiano ni watu wenye weledi na ujuzi. Huenda usihisi vizuri wakati wa kukaguliwa kinywani. Pakitokea ya kwamba umejeruhiwa, umekuwa mgonjwa au shida nyingine inayohusiana na utafiti huu imetokea piga nambari utakayoona mwishoni mwa nakala hii haraka iwezekanavyo. Wahudumu watakutibu magonjwa madogo madogo au wakutume kwingineko iwapo itahitajika kufanya hivyo

KUNA MANUFAA YOYOTE KATIKA UTAFITI HUU?

Huenda utafaidika kwa kupata uchunguzi wa mdomo bila malipo. Tutakutuma hospitalini iwapo utahitajika matibabu zaidi. Habari hiyo itachangia ufahamu katika sayansi na kuelewa uhusiano uliopo kati ya ugonjwa wa ufizi na makali ya jongo la rheumatoid.

JE KUWEPO KATIKA UTAFITI HUU KUTAKUGHARIMU CHOCHOTE?

HAPANA

UTARUDISHA PESA ZOZOTE UTAKAZOTUMIA KATIKA UTAFITI?

Hakuna jambo lolote litakalokupelekea wewe kutumia pesa, lakini iwapo pesa zako zitumike,utaregeshewa .

IWAPO UKUMBANE NA MASWALI SIKU ZA USONI

Iwapo utakuwa na maswali Zaidi kuhusu utafiti huu tafadhali piga simu au utume arafa kwa nambari iliyoko mwishoni mwa nakala hii ili kuwasiliana na wahudumu wetu.

Kwa habari Zaidi kuhusu haki yako kama mshiriki wa utafiti waweza kuzungumza na katibu/Mwenye kiti, Hospitali ya Kitaifa ya Kenyatta-Kamati ya maadili na utafiti Chuo Kikuu cha Nairobi, Nambari ya simu 2726300 Ext. 44102 Barua pepe:uonknh_erc@uonbi.ac.ke.

Wahudumu watakulipa hela zako ukishatumia nambari hizi iwapo mawasiliano yatahusu utafiti

CHAGUO LAKO LINGINE NI LIPI?

Uamuzi wako wa kushiriki katika utafiti huu ni wa hiari.Una ruhusa ya kukataa kushiriki katika utafiti na waweza kujiondoa katika utafiti bila hasara yoyote na bila kukiukwa kwa haki yako.

FOMU YA RIDHAA

Kauli ya mshiriki

Nimeisoma fomu hii ya ridhaa ama nimesomewa ujumbe. Nilipata fursa ya kujadiliana kuhusu utafiti huu na mtafiti. Maswali yangu yamejibiwa kwa lugha ambayo naielewa. Nimeelezewa manufaa na hatari ziliwepo. Naelewa kuwa ushiriki wangu kwa utafiti huu ni wa hiari na naweza kujiondoawa wakati wowote. Nimekubali kwa hiari kushiriki katika utafiti huu.

Naelewa juhudi zitafanywa ili kuuhifadhi habari yangu wa kibinafsi.

Kwa kutia sahihi fomu hii ya ridhaa, sijaiacha haki zangu kisheria kama mshiriki katika utafiti.

Nimekubali kushiriki katika utafiti huu:	**Ndio**	**La**
Nimekubali kupigwa eksirei ya mdomo:	Ndio	La
Nimekubali kupeana nambari za simu ili nifuatiliwe:	Ndio	La

Jina la mshiriki lililochapishwa:

_____

Sahihi ya mshiriki / alama ya kidole _____Tarehe _____

Kauli ya mtafiti

Mimi, ambaye nimetia sahihi, nimetoa maelezo kamili kuhusiana na utafiti huu kwa mshiriki ambaye ametajwa hapo juuna naamini ya kwamba mshiriki ameelewa na akatoa ridhaa yake kwa hiari.

Jina la mtafiti: Dr. Hussein M Muchuka **Tarehe**: _____

Sahihi _____

Kazi yake katika utafiti: Mkuu wa uchunguzi

Kwa habari zaidi zungumza na,

1. Dr. Hussein M Muchuka
   Shule ya kisayansi ya meno, Chuo Kikuu Cha Nairobi, Nambari ya simu: 0718614699.
   Email: muhulomuchuka@gmail.com
   Msimamizi mkuu
2. Dr Wetende Andrew
   Shule ya kisayansi ya meno, Chuo Kikuu Cha Nairobi
   Nambari ya simu: 0721585820
   Email: drwetende@gmail.com
3. Dr Matu Nelson
   Shule ya kisayansi ya meno, Chuo Kikuu Cha Nairobi,
   Nambari ya simu: 0722793909,
   Email: nkmatu@yahoo.com

4. Dr Mua Benard

   Shule ya kisayansi ya meno, Chuo Kikuu Cha Nairobi

   Nambari ya simu: 0722278295

   Email: mua.benard@uonbi.ac.ke

Katibu/ Mwenyekiti,

Hospitali ya Kitaifa ya Kenyatta-Kamati ya maadili na utafiti Chuo Kikuu Cha Nairobi,

Nambari ya simu. (254-020) 2726300-9

Barua pepel: uonknh_erc@uonbi.ac.ke.

Kutoka saa mbili mpaka saa kumi na moja, juma moja mpaka ijumaa.

APPENDIX 3: INTERVIEWER'S STATEMENT

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

INTERVIEWER: …… SIGNATURE: …….

DATE: ……

APPENDIX 4: SCREENING QUESTIONNAIRE

Serial No: _____

Study Date: _____

1. AGE OVER 18 YEARS:

YES, ☐ NO ☐

FOR OFFICIAL USE ONLY

RECRUITED?

YES ☐ NO ☐

Interviewer's Name: _____

Signature: ..... Date: _____

APPENDIX 5: PLAQUE INDEX. TURESKY MODIFICATION OF QUIGLEY-HEIN INDEX

Score	Criteria
0	No plaque
1	Isolated areas of plaque at gingival margin
2	Thin band of plaque at gingival margin(<1mm)
3	Plaque covering up to 1/3 of the tooth surface
4	Plaque covering between 1/3 and 2/3 of the tooth surface
5	Plaque covering ≥ 2/3 of the tooth surface

APPENDIX 6: GINGIVAL INDEX (LÖE AND SILNESS, 1963)

Score	Criteria
0	Normal gingiva/ absence of inflammation
1	Mild inflammation: slight change in color and slight edema. No bleeding on probing
2	Moderate inflammation: redness, edema, and Bleeding on probing
3	Severe inflammation: marked redness and edema, ulceration and tendency toward spontaneous bleeding

APPENDIX 7: PERIODONTAL EXAMINATION

Basic Periodontal Examination (BPE)

Score	Criteria
0	No pockets >3.5 mm, no calculus/overhangs, no bleeding after probing (black band completely visible)
1	No pockets >3.5 mm, no calculus/overhangs, but bleeding after probing (black band completely visible)
2	No pockets >3.5 mm, but supra- or sub gingival calculus/overhangs (black band completely visible)
3	Probing depth 3.5-5.5 mm (black band partially visible, indicating pocket of 4-5 mm)
4	Probing depth >5.5 mm (black band entirely within the pocket, indicating pocket of 6 mm or more)
*	Furcation involvement

Clinical form

Plaque Score: Turesky Modification of quigley-Hein-1970 (0-5)

Tooth	16		12		24		36		32		44	
Surface	F	L	F	L	F	L	F	L	F	L	F	L
Score												
Total score						Average score						

Gingival Score- Löe and Silness, 1963 (o-3)

Tooth	16		12		24		36		32		44	
Surface	F	L	F	L	F	L	F	L	F	L	F	L
Score												
Total score						Average score						

Basic Periodontal Examination (BPE)

Tooth	1st sextant		2nd sextant		3rd sextant		4th sextant		5th sextant		6th sextant	
Surface	F	L	F	L	F	L	F	L	F	L	F	L
Score												
Total score						Average score						

APPENDIX 8: 2010 ACR-EULAR CLASSIFICATION CRITERIA FOR RHEUMATOID ARTHRITIS.

		Score
Joint involvement	1 large joint (shoulder, elbow, hip, knee, ankle)	0
	2-10 large joints	1
	1-3 small joints (MCP, PIP, Thumb IP, MTP, wrists)	2
	4-10 small joints	3
	>10 joints (at least 1 small joint)	5
Serology	Negative RF and negative ACPA	0
	Low-positive RF and low-positive anti-CCP antibodies (≤3 times ULN)	2
	High-positive RF or high-positive anti-CCP Antibodies (>3 times ULN)	3
Acute-phase	Normal CRP and normal ESR	0
	Abnormal CRP or abnormal ESR	1
Duration of Symptoms	<6 weeks	0
	≥6 weeks	1

Note: This is a newer classification criterion aimed at identifying patients with a high likelihood of evolving into a chronic disease with persistent synovitis and joint damage and hence would benefit from early introduction of DMARDs.

A score of ≥6 fulfills the requirement of a definite RA.

APPENDIX 9: PATIENT QUESTIONNAIRE

1. Date…….
2. Age (Years)…….
3. Patient NO…….
4. At what age was RA first diagnosed? --------
5. Have you had any surgery related to RA?
6. Do you have any relations (blood) who have /or have had RA?
7. Have you ever had/tried any?

   (a) Physiotherapy ☐

   (b) Alternative treatment for your rheumatoid?

   ☐
8. What prescribed medication are you currently having?

   ☐

   a) NSAIDS

   b) Glucocorticoids

   ☐

   HD >10mg/d

   LD <10mg/d ☐

   c) Conventional DMARDS

   ☐

   - MTX
   - Leflunomide ☐
   - HCQ ☐
   - SSZ ☐

   d) Biologic DMARDS

   ☐

- TNF-α Inhibitors

Specify…….

- Abatacept ☐
- Rituximab ☐
- Tocilizumab ☐
- Anakinra ☐

9. What level of education did you attain?

a) No formal education ☐

b) Primary ☐

c) Secondary ☐

d) College/University

-degree ☐

-diploma ☐

10. What is your current daily occupation.....?

11. What is your major source of income.....?

APPENDIX 10: CLINICAL DISEASE ACTIVITY INDEX (CDAI)

Clinical Disease Activity Index (CDAI)

Joint	Left		Right	
	Tender	Swollen	Tender	Swollen
Shoulder				
Elbow				
Wrist				
MCP 1				
MCP 2				
MCP 3				
MCP 4				
MCP 5				
PIP 1				
PIP 2				
PIP 3				
PIP 4				
PIP 5				
Knee				
Total	Tender:		Swollen:	

Patient Global Assessment of Disease Activity

Considering all the ways your arthritis affects you, rate how well you are doing on the following scale:

Very Well	O 0	O 0.5	O 1.0	O 1.5	O 2.0	O 2.5	O 3.0	O 3.5	O 4.0	O 4.5	O 5.0	O 5.5	O 6.0	O 6.5	O 7.0	O 7.5	O 8.0	O 8.5	O 9.0	O 9.5	O 10	Very Poor

Your Name_____ **Date of Birth** _____ **Today's Date** _____

Provider Global Assessment of Disease Activity

Very Well	O 0	O 0.5	O 1.0	O 1.5	O 2.0	O 2.5	O 3.0	O 3.5	O 4.0	O 4.5	O 5.0	O 5.5	O 6.0	O 6.5	O 7.0	O 7.5	O 8.0	O 8.5	O 9.0	O 9.5	O 10	Very Poor

How to Score the CDAI

Variable	Range	Value
Tender joint score	(0-28)	
Swollen joint score	(0-28)	
Patient global score	(0-10)	
Provider global score	(0-10)	
Add the above values to calculate the CDAI score	**(0-76)**	

CDAI Score	Interpretation
0.0 – 2.8	Remission
2.9 – 10.0	Low Activity
10.1 – 22.0	Moderate Activity
22.1 – 76.0	High Activity

APPENDIX 11: TURNITIN REPORT

TO SEVERITY OF RHEUMATOID ARTHRITIS AMONG PATIENTS ATTENDING THE KENYATTA NATIONAL HOSPITAL RHEUMATOLOGY CLINIC.

ORIGINALITY REPORT

13%	10%	14%	11%
SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

PRIMARY SOURCES

1	Submitted to University of Nairobi Student Paper	6%
2	paperity.org Internet Source	3%
3	www.scirp.org Internet Source	2%
	Internet Source	1%
5	www.thieme-connect.com Internet Source	1%
6	www.scielo.br Internet Source	1%

DR. WE

Exclude quotes On
Exclude bibliography On
Exclude matches

APPENDIX 12: ERC REPORT

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

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/253

10th August 2020

Dr. Hussein Muholo Muchuka
Reg. No.V60/7162/2017
Dept. of Periodontology/Community and Preventive Dentistry
School of Dental Sciences
College of Human Sciences
University of Nairobi

Dear Dr. Muholo

RESEARCH PROPOSAL – INVESTIGATION OF THE PERIODONTAL STATUS IN RELATION TO THE SEVERITY OF RHEUMATOID ARTHRITIS AMONG PATIENTS ATTENDING THE KENYATTA NATIONAL HOSPITAL RHEUMATOLOGY CLINIC (P244/04/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 10th August 2020 – 9th August 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect 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.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website**http://www.erc.uonbi.ac.ke**

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Dental Sciences, UoN
The Chair, Dept. of Dept. of Periodontology/Community and Preventive Dentistry, UoN
Supervisors: Dr. Wetende Andrew, Dept.of Periodontology/Community and Preventive Dentistry, UoN
Dr. Matu Nelson, Dept.of Periodontology/Community and Preventive Dentistry, UoN
Dr. Benard Mua, Dept.of Periodontology/Community and Preventive Dentistry, UoN