QUALITY OF SLEEP IN PATIENTS WITH CHRONIC RHINOSINUSITIS AT KENYATTA NATIONAL HOSPITAL

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A dissertation for submission to the University of Nairobi in partial fulfilment for the award of the degree of Master of Medicine in Otorhinolaryngology-Head and Neck Surgery at the University of Nairobi.

March 2022

DECLARATION

I, the undersigned, hereby declare this dissertation as purely my original work and that it has not been presented for a degree at any other university. Where I have used another person's work, I have carefully acknowledged and referenced.

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ABBREVIATIONS

ARAS-	Ascending reticular arousal system
ASP-	Average Sleep Propensity
CRS-	Chronic Rhinosinusitis
CRsNP-	Chronic Rhinosinusitis without polyps
CRSwNP-	Chronic Rhinosinusitis with polyps
CT-	Computed tomography
ENT-	Ear Nose and Throat
EPOS 2012-	European Position Paper on Rhinosinusitis and nasal polyposis
ESS-	Epworth Sleepiness Scale
FESS-	Functional Endoscopic Sinus Surgery
IL-	Interleukin
κ-	Cohen kappa
KNH-	Kenyatta National Hospital
N95-	Non-Oil 95
NREM-	Non-Rapid Eye Movement
NSF-	National Sleep Foundation
OSA-	Obstructive Sleep Apnoea
PNS-	Paranasal Sinus
PSG-	Polysomnography
PSQI-	Pittsburgh Sleep Quality Index
QoL-	Quality of life
QoS-	Quality of sleep
REM-	Rapid Eye Movement
RSDI-	Rhinosinusitis Disability Index
SARS-CoV-2-	Severe Acute Respiratory Syndrome Coronavirus 2
SNOT-22-	Sino Nasal Outcome Test
SPSS-	Statistical Package for the Social Sciences
TGF-	Transforming Growth Factor
US-	United States
USA-	United States of America
VAS-	Visual Analogue Scale
α-	alpha

β- beta

ABSTRACT

Background: Chronic rhinosinusitis (CRS) is a frequent rhinological disease. Among individuals suffering from it, a common complaint is poor sleep, which can lead to morbidity and mortality.

Objective: To determine the quality of sleep in patients with CRS at Kenyatta National Hospital.

Study Methodology: This was a hospital-based descriptive cross-sectional study. Recruitment was via convenience sampling. It involved adults (≥18 years) with a diagnosis of CRS on follow-up at the Kenyatta National Hospital-Ear, Nose, and Throat clinic. Informed consent was obtained, followed by a history and physical examination. Patients who did not have paranasal sinus computed tomography imaging had nasal endoscopy done. After that, the CRS visual analogue scale, the Pittsburgh sleepiness scale, and the Epworth sleepiness scale questionnaires were completed.

Study Analysis: The results were analysed using version 22 of the Statistical Package for Social Sciences. Independent t-tests were employed to compare continuous data, whereas Fisher's exact test compared categorical variables. The results were presented in tables, graphs, and charts.

Data Results: Eighty-two patients ages 18–71 years met the inclusion criteria. On the Pittsburgh sleepiness scale, 75.6% reported poor sleep, with a mean of 9.2±4.20. It had no correlation with disease severity on the visual analogue scale or computed tomography scan ($p > 0.05$), although endoscopy scores revealed a significant correlation ($p = 0.001$). On the Epworth sleepiness scale, 62.2 % exhibited daytime sleepiness ratings of healthy individuals (0-10). It and the Pittsburgh sleepiness scale had a fair agreement (kappa coefficient = 0.24).

Conclusions: Poor sleep quality affects a significant percentage of CRS patients, and it is significantly associated with disease severity based only on endoscopic scores. A case-control study is recommended to assess if CRS patients have poorer sleep quality than the general population.

1.0 CHAPTER ONE: INTRODUCTION

Sleep is a metabolically active state required by every human being for their bio-psychosocial wellbeing. It is important for memory consolidation, hormone regulation, immunity, and metabolism. Quality of sleep (QoS) is when one feels fulfilled through having good sleep onset, maintenance, adequacy, and a feeling of being revitalized after waking up[1]. Poor sleep, on the other hand, results in poor concentration, impaired memory, inability to learn new tasks, irritability, and poor judgment[2]. Prolonged poor sleep places one at risk of developing type two diabetes mellitus (DM), hypertension, obesity, or depression that can lead to an increase in mortality[3].

Rhinosinusitis is a disease prevalently found in outpatient clinics and is characterized by inflammation of the sinonasal mucosa. It is classified as chronic if the symptoms persist for at least twelve weeks[4,5]. Chronic rhinosinusitis (CRS) not only impacts the nose and paranasal sinuses but also impacts patients' physical, mental, and social wellbeing, with excessive sleep and fatigue being its trademark[6]. Sleep is a domain in most quality of life (QoL) questionnaires, such as the Sinonasal outcome test (SNOT-22) and Rhinosinusitis disability index (RSDI). When compared to other domains in these questionnaires, it is one of the most affected, with 75% of CRS patients reporting poor QoS[7]. Its disruption results in poor QoL and poor functional outcomes[8].

1.1 BACKGROUND

1.1.1 CRS

1.1.1.1 Diagnosis of CRS

The European Position Paper on Rhinosinusitis and nasal polyposis (EPOS) 2012 guidelines state that CRS is present when a patient complains of two or more symptoms, one of which should include nasal blockage or nasal discharge that can be either anterior or posterior. Other symptoms may include facial pain or loss in the sense of smell that has persisted for at least 3 months[4].

Being a clinical diagnosis, its symptoms may overlap with other diseases such as allergic rhinitis and upper respiratory tract infections. Hence, an objective form of diagnosis is required[9]. This includes the use of either a nasal endoscopic examination of the nasal cavity for polyps, mucopurulent discharge, or middle turbinate oedema and or a computed tomography (CT) scan of the nose and paranasal sinus (PNS) to evaluate the osteo-meatal

complex mucosal change[4,10,11]. Findings on endoscopy have grouped CRS as either chronic rhinosinusitis with polyps (CRSwNP) or chronic rhinosinusitis without polyps (CRsNP)[4,12].
As a middle-income country, endoscopes in the outpatient clinic in Kenya are a limited resource; hence, CRS is diagnosed based on symptomatology and radiological findings.

1.1.1.2 Severity of CRS

The severity of the disease can be subjectively assessed by a visual analogue scale or objectively with the use of a nasal cavity endoscopic examination or a CT-scan view of the nose and PNS [11,13].

The visual analogue scale (VAS) is a psychometric tool used by patients to quantify the severity of their symptoms[14]. It is a horizontal ten-centimetre line capped at the extreme ends with words that describe the extremes of a patient's emotions. It consists of a continuum of values with the best emotional states or no symptomatology being on the left while the worst or most severe emotions are on the right. The patient marks on the line the point that best corresponds to their current state based on what is being investigated, for example, pain. The total VAS score classifies the severity of the disease as mild if the score is 3 or below, moderate if it is more than 3 but less than 7, and severe if the score is more than 7, with 10 being the maximum score[4].

Endoscopic examination of the nose using a rigid or flexible endoscope allows one to visually assess the nasal cavity, spheno-ethmoidal recess, and postnasal space[13]. One can identify any anatomical abnormalities that may be a source of nasal obstruction, such as a deviated nasal septum, hypertrophied turbinates, and polyps. Signs of inflammation, such as oedematous middle turbinate, secretions, and crusting, can also be seen. Features seen have been used in the Lund-Kennedy scoring system to score the severity of the disease based on the presence of polyps, discharge, crusting, scarring, and oedema. Scoring in each of the five domains runs from a score of 0 if absent, 1 if mild, and 2 when severe. Each nasal cavity is scored separately, and the total score from both cavities ranges from 0 to 20[15].

Features consistent with CRS, such as mucosal thickening and the amount of sinus opacification on a CT-scan of the nose and PNS, enable one to grade and score the severity of the disease using the Lund-Mackay grading system. Each sinus is awarded a score of 0–2 based on the amount of opacification, while the osteo-meatal complex is awarded a score of 0 or 2 based on the presence of obstruction. The aggregate score ranges from 0 to 24[11,16]. In both the Lund-Kennedy and Lund-Mackay scores, the higher the total scores, the more severe the disease severity.

1.1.2 Sleep

1.1.2.1 Sleep Architecture

Sleep has two phases, namely nonrapid eye movement (NREM) and rapid eye movement (REM). Cycling between the two phases occurs after a 90-minute interval, with NREM forming the bulk (80%) of the sleep cycle. The American Academy of Sleep Medicine divides NREM into 3 stages; N1, N2, and N3 based on polysomnography (PSG) features [(2)]. These stages show an increase in the depth of sleep from N1 to N3[(17)].

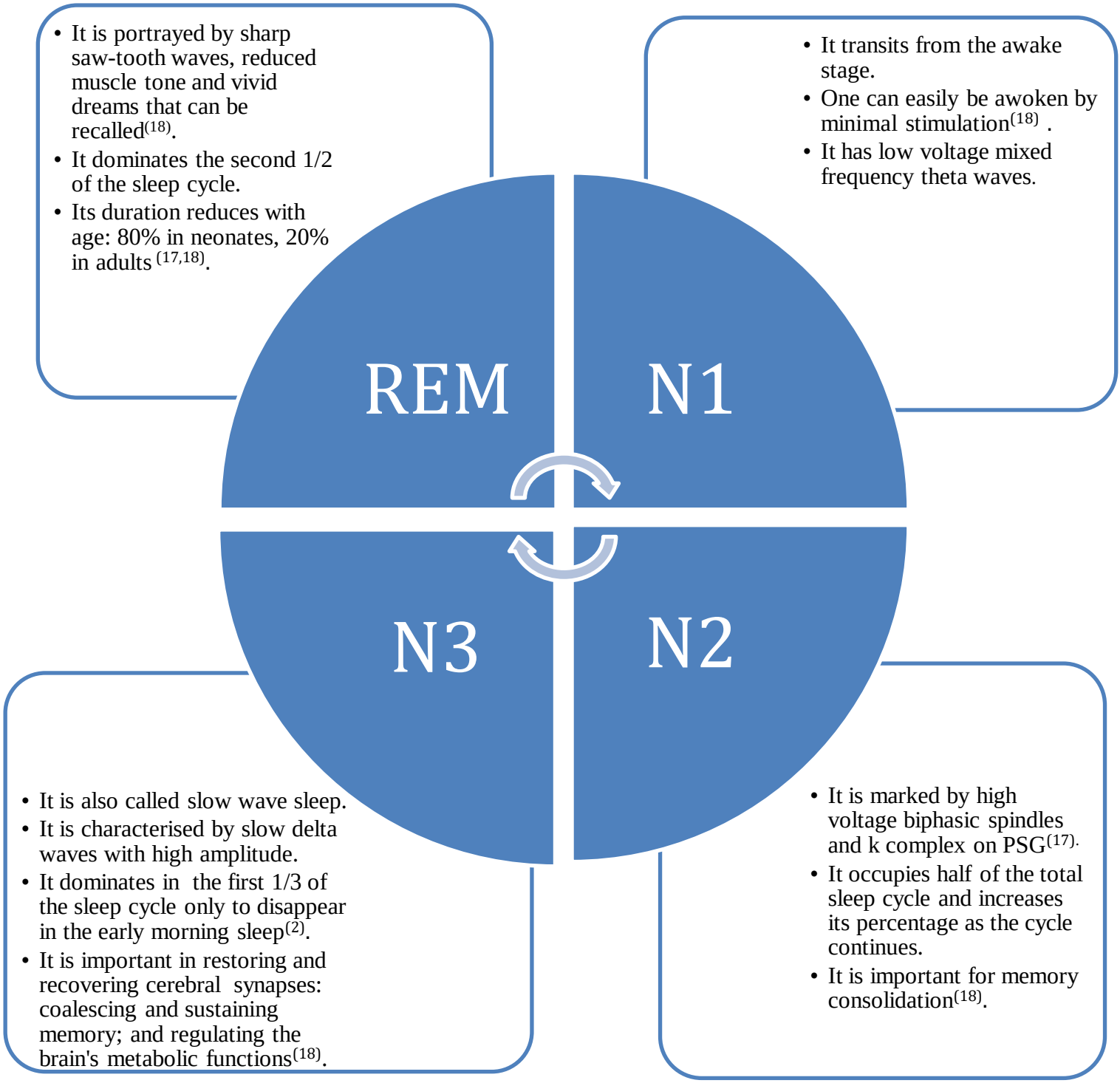

*Figure 1:**Sleep cycle***

1.1.2.2 Sleep physiology

Within the human body, the suprachiasmatic nucleus (SCN) is the internal clock responsible for the rhythmic fluctuations of the sleep-wake cycle. It receives information from the retino-hypothalamic neurons regarding the light and dark cycle in the environment and relays signals to the pineal gland to secrete melatonin that synchronizes the body tissues' circadian rhythm to the environmental cues[2]. The ventrolateral preoptic area (VLPO) in the cortex is responsible for the initiation and maintenance of sleep. It has an indirect relationship with the ascending reticular arousal system (ARAS), with the activity of one leading to inhibition of the other in a flip-flop type of mechanism[18]. The ARAS is composed of a network of subcortical pathways that connect to the cortical activation system and induce wakefulness through various transmitters such as norepinephrine, histamine, serotonin, and many more[17,19]. Adenosine and prostaglandin D2 (PG D2) accumulate during the day, leading to activation of VLPO and the onset of sleep[17,18]. During sleep, GABA and galanin actively inhibit ARAS while the SCN modulates the exchange between wakefulness and sleep. Sleep is also modulated by cytokines such as interleukin-1 beta (IL-1 β) and tumour necrosis factor-alpha (TNF-α) that activate VLPO, inducing NREM sleep[20].

1.1.2.3 Definition of quality of sleep

Quality of sleep (QoS) has been defined by the National Sleep Foundation (NSF) as falling asleep within half an hour or less, awakening for 20 minutes or less after sleep has begun, awakening once or not all per night, and sleeping efficiently for 85% or more of one's sleep while in bed[21]. Poor QoS is due to lifestyle habits such as poor sleep hygiene, stressful life circumstances, or the environment in which one sleeps[2,22].

1.1.2.4 Effect of poor QoS

In chronic inflammatory conditions, poor QoS is a common complaint due to inhibition of sleep-promoting cytokines by inflammatory cytokines such as IL-4, IL-13, and transforming growth factor (TGF)-β[23–27]. Suppression of slow-wave sleep results in peripheral insulin resistance, hence predisposing one to type 2 diabetes mellitus (DM) and hypertension, both of which increase one's risk of cerebrovascular accidents. There is an increase in ghrelin and a reduction in leptin, increasing one's appetite, which is linked to obesity. Suppression of the immune system promotes infection[2,28–30]. Poor cognitive function impairs reaction times, which is especially problematic at work or when driving. This puts one at risk of mishaps that can result in serious harm to oneself or others, as well as death[31,32].

1.1.2.5 Sleep in CRS

Poor sleep is a common complaint in patients with CRS, with various theories having been made on the aetiology of sleep dysfunction amongst them. Some include difficulty in breathing secondary to rhinological symptoms such as nasal obstruction and nasal congestion. Sleep may also be hampered by facial discomfort, depression, and a persistent local inflammatory reaction producing antisomnogenic cytokines[8,33].

1.1.2.6 Assessment of QoS and daytime sleepiness

Various tools can be used for the assessment of QoS both subjectively and objectively. PSG is the gold standard test that can assess QoS objectively. It is, however, expensive and unavailable in most centres. Subjective evaluation is therefore done using validated tools like the Pittsburgh quality index (PSQI) and the Epworth sleepiness scale (ESS), which are the most commonly used[34].

In the PSQI questionnaire, one assesses and rates how their QoS and its disturbance have been in the last four weeks. It contains nineteen items that have been grouped into seven subdomains. These subdomains assess different aspects of sleep, which include quality, extent, latency, interruptions, efficiency, induction by use of pills, or daytime dysfunction. Each item is scored from 0-3 with the aggregate score ranging from 0-21. A score of more than 5 indicates poor quality sleep. It has an internal consistency of 0.83 with a sensitivity of 82% and a specificity of 56.2% and has been validated and translated into different languages for ease of use[35,36].

The ESS questionnaire is a self-administered screening test that gauges one's risk of developing sleep disorders by assessing one's rate of daytime sleepiness. It contains 8 questions for which the respondent must rate from 0–3 their propensity to fall asleep while engaging in different activities[37]. The cumulative score ranges from 0-24, with greater scores indicative of one's risk of suffering from daytime sleepiness. It has been validated and translated into different languages and has an internal consistency of 0.86[38].

2.0 CHAPTER TWO: LITERATURE REVIEW

CRS has a significant negative influence on people's overall well-being. Poor sleep and excessive fatigue are synonymous with patients with CRS, which negatively impacts their quality of life. These symptoms place patients at an increased risk of developing non-communicable disorders such as obesity, DM type 2, hypertension, depression, and accident-related mortalities.

Bengtsson et al. carried out a population-based study in Sweden and found that 90% of the population who suffered from CRS had sleep-related complaints and over 50% of them had excessive daytime sleepiness. Both findings were noted to be directly related to the severity of the disease based on the total number of CRS symptoms one had, but the duration of the symptoms was not reported. When compared to individuals who did not have any sleep issues, these patients were found to consume twice as many sleep medications. Of the CRS symptomatology, nasal obstruction was the greatest complaint, at 89.1%. However, the study did not show the magnitude of its severity or whether it was the cause of the sleep dysfunction. Cigarette smoking was also found in 23.7% of the CRS population and was postulated to induce nasal obstruction secondary to inflammation of the nasal mucosa. However, no relation was found between it and sleep complaints. The patients who had both CRS and persistent allergic rhinitis were found to also have sleep problems with an association odds ratio range of 2.76 to 3.15[39].

Alt et al. found in a multi-centre cross-sectional cohort study that 75% of CRS patients had PSQI > 5, indicating poor sleep and significantly lower quality of life scores on CRS-disease specific QoL survey measures ($p<0.001$). Unlike the Bengtsson study, this study showed that there was no correlation between the severity of the disease based on CT-scan and endoscopy grading scores and the QoS. It also noted that patients with poor sleep had depression as comorbidity, but the study did not show how the findings interacted (synergistic effect or cause-effect relation). The study did, however, have similar findings on the smoking history of CRS patients, but the pathogenesis of poor sleep in those who smoked was not shown[7].

In a case-control study by Alt et al., it was noted that CRS patients had increased daytime somnolence on ESS when they were compared to a control group of people without CRS (9.1 verses 6.5, $p = 0.06$) and poor sleep quality on PSQI (10.1 verses 4.7, $p<0.001$). Using objective instruments (portable sleep device), CRS patients had more awakenings (8.6 versus 6.3) and spent most of the night snoring (24.7 versus 14.6) than controls. The study also reported greater fatigue symptoms amongst CRS patients but did not show if there was any difference in the

sleep complaints based on the presence of polyps or not on endoscopy and what was the probable cause of the sleep dysfunction in the CRS patients[40].

Daniel et al. conducted a prospective study on CRS patients to find out if there was any relationship between pain, depression, and sleep dysfunction. A positive correlation ($R = 0.38–0.61$, $p \leq 0.05$) amongst the three was found. However, the study population was comprised of only 68 CRS patients, with no exclusion of patients based on medications in current use that could influence the results[41].

In De Conde et al.'s multi-centre cohort study among patients with CRS, it was found that 55 out of the 179 patients who had FESS reported worse sleep dysfunction scores on the Sinonasal outcome test (SNOT-22) before treatment that improved after surgery. This was demonstrated by the increase in the number of patients who had low SNOT-22 scores (<20) from 7% to 39% [15]. These findings were replicated in the Rotenberg et al. study that showed that surgery was instrumental in improving sleep after comparing ESS and PSQI values of patients with CRsNP before and after surgery. ESS scores improved from 14.2 to 9.1 while PSQI declined from 10.9 to 5.3. However, the sample size was small, comprising of 53 CRsNP patients in Canada and Singapore who were followed up for half a year post-surgery[42].

Ando et al. sought to find out what symptomatology in CRS was responsible for the sleep impairment in patients who underwent FESS. The results showed that nasal symptoms were the cause, with nasal obstruction being the most culpable (beta coefficient 0.27 $p<0.001$) and nasal discharge (beta coefficient 0.13, $p=0.004$). It also showed the probability of impaired sleep could be anticipated in those with allergic rhinitis and greater endoscopic polyp grading scores with a relative risk of 0.029 and $p=0.034$[43].

In a prospective multi-institutional study, Alt et al. found that after FESS, QoL and QoS significantly improved in patients with only CRS when compared to those with OSA as a comorbid. However, 29.6% of the patients were not compliant with follow-up, so the results could be biased. The patients also did not undergo similar procedures, so one cannot compare which procedure had the greatest effect on QoS[16].

Rassi et al. conducted a prospective observational cohort study of 317 patients post-FESS and found that there was an improvement in the mean scores of the SNOT-22 sleep dysfunction domain from 13.7 to 7.7, $p<0.001$. The FESS procedures included septoplasty and turbinoplasty, which were part of the exclusion criteria in other studies. The findings in this study showed that there was no relation between sleep and the severity of CRS, with a relative risk of 0.083 and $p<0.130$, though there was some degree of impairment of sleep in 78% of the patients[44].

Despite this knowledge, no investigation has been carried out in Kenyatta National Hospital (KNH) or Kenya at large to evaluate the relationship of CRS with quality of sleep.

2.1: STUDY JUSTIFICATION

Patients with CRS have poor QoS, which impacts negatively on their QoL. With this clinical evidence, no scientific research has been carried out on KNH to confirm it. This was the first scientific study done locally to investigate this finding. It aimed at the holistic management of patients with CRS not only in KNH but also in Kenya at large, thus improving their QoL and treatment outcomes.

2.2: RESEARCH QUESTION

What is the QoS in patients with CRS at KNH?

2.3: OBJECTIVES

2.3.1: Main Objective

The main objective was to determine the QoS in CRS patients at KNH.

2.3.2: Specific objective

The specific objectives were:

- **a)** To determine the severity of symptoms in CRS patients at KNH.
- **b)** To assess daytime somnolence of CRS patients at KNH.
- **c)** To assess the QoS in CRS patients at KNH.
- **d)** To correlate the severity of CRS with QoS in patients at KNH.

3.0 CHAPTER THREE: RESEARCH METHODOLOGY

3.1: Study Design

This was a hospital-based descriptive cross-sectional study.

3.2: Study Area

The study was conducted at the Kenyatta National Hospital (KNH)-ENT clinic.

3.3: Study Population

The participants were adults ≥ 18 years old who were on follow-up in the KNH-ENT outpatient clinic with a diagnosis of CRS, having fulfilled the EPOS 2012 criteria with evidence of sinusitis on either endoscopy or CT-scan.

3.4: Study Duration

Following approval by the KNH-UoN Ethics and Research committee, the study was carried out over a two-year period (20 January 2020–19 January 2022).

3.5: Inclusion Criteria

The participants were adults ≥18 years old who had already been diagnosed with CRS as per the EPOS 2012 criteria (appendix IV a), with endoscopy (appendix IV b-1) or CT-scan features of CRS (appendix IV b-2) and had consented to participate in this study.

3.6: Exclusion Criteria

- ∉ Patients who were on treatment for other nasal or paranasal diseases, such as sino-nasal tumours.
- ∉ Patients who were on anxiolytics or hypnotics.
- ∉ Patients who were on analgesics for severe or chronically painful conditions such as fractures, postoperative patients, and chronic migraines.
- ∉ Patients who had been diagnosed with and were on treatment for sleep disorders.
- ∉ Patients who failed to complete the study questionnaires.
- ∉ Patients who worked on the night shift.

3.7: Sample Size Determination

The study used the Krejcie and Morgan formula below to calculate the sample size as follows[45]. El-Beltagy et al. found that 52 of the 100 CRS patients had increased daytime somnolence on ESS ranging from mild to severe[46].

$$n^1 = \frac{X^2\, Np(1-p)}{e^2(N-1)+X^2p(1-p)}$$

n^1 was the sample size with a finite population correction

N was the population size:100

x^2 was a confidence level of 95% with the critical value of 1.96

p was the proportion of the population expected prevalence:52%

e was the precision:0.05

As a result, the study comprised at least 79 participants. For those who chose to drop out of the study or incompletely filled out the questionnaires, a 10% (8) allowance was incorporated.

3.8: Sampling Technique

Sample recruitment was done by a convenience sampling technique until the desired sample size was met.

3.9: Tools

The following tools were used in this study;

1. Sociodemographic data sheet (appendix II)
   This contained a special study identification number, sex, age, medical and social history.
2. A 30 degrees 4.0 mm rigid endoscope
3. Topical decongestant- 10% xylocaine spray
4. Antifog solution-chlorhexidine solution
5. A high-intensity light source
6. Visual analogue scale for CRS (appendix III a) [4]
7. Pittsburgh sleep quality index (appendix III b) [34]
8. Epworth sleepiness scale (appendix III c) [36]

3.10: Coronavirus Precautions

Due to the ongoing severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) pandemic, all precautions were taken to prevent the patient and researcher from acquiring the infection. These included hand sanitizations and donning personal protective equipment such as long-sleeved gowns, surgical masks, Non-Oil 95 (N95) masks, eye goggles, and face visors by the researcher at all encounters. The interviewees were required to sanitize their hands and wear face masks except during the examination. A social distance of two meters was also maintained during the interviews, except during physical and endoscopic examinations. As part of triage,

patients who had temperatures of 37.8 degrees or higher, cough, or difficulty breathing were requested to get tested for the virus. A negative nasopharyngeal swab was required before any endoscopic examination.

3.11: Procedure

In this study, the target population was made up of patients who were 18 years of age or older on follow-up for CRS at the KNH-ENT clinic. The diagnosis of CRS was based on the EPOS 2012 criteria (Appendix IV a). The researcher explained to the patients the nature of the study and those who agreed to participate gave written consent (Appendix I a/b). Thereafter, those who met the inclusion and exclusion criteria proceeded to the next phase of the study. The patients' sociodemographic data was taken, and ENT-head and neck examinations were conducted (Appendix II). For those who had carried CT-scan films of their nose and paranasal sinuses, the principal researcher viewed the films for any radiological evidence of CRS and used the Lund Mackay to score the patients' severity of disease (Appendix IV b-2). The scoring involved assessing the level of opacification in each of the six sinuses located bilaterally from 0 to 2, then summing them up to produce a total score range of 0 to 24. A rigid nasal endoscopic examination was carried out on patients who lacked their scans. This was done with the patient seated in an upright position and applying a topical decongestant (4 drops of xylocaine spray). After 10 minutes, a 4-millimeter, 30-degree nasal endoscope was introduced into the nasal cavity. The first pass was made along the floor of the nose to the nasopharynx, looking at the general anatomy, septum, inferior turbinates, and nasal mucosa. The second pass ran above the inferior turbinate to the middle meatus, then medial to the middle turbinate into the spheno-ethmoidal recess. The third pass was made as the endoscope was being withdrawn and any features of CRS were used in the Lund Kennedy scoring (Appendix IV b-1). Based on nasal mucosal oedema, secretions, and polyps, each nasal cavity was rated separately from 0 to 4, with the final score being added together to give a range of 0 to 20. Following the SARS-CoV-2 pandemic, all patients undergoing an endoscopic procedure were required to have a negative nasopharyngeal swab test for the virus. Thus, rigid nasal endoscopy was carried out in patients diagnosed with CRS who had been admitted for functional endoscopic sinus surgery (FESS). Their examination was carried out while the patients were under general anaesthesia while lying supine 20 degrees in the reverse Trendelenburg position on the theatre table. Their CT Scan films were also viewed by the principal researcher. The patients finally filled in the VAS for CRS (appendix III a), PSQI (appendix III b), and ESS (appendix III c). On the day of their discharge, those who had been hospitalized for FESS filled out the questionnaires.

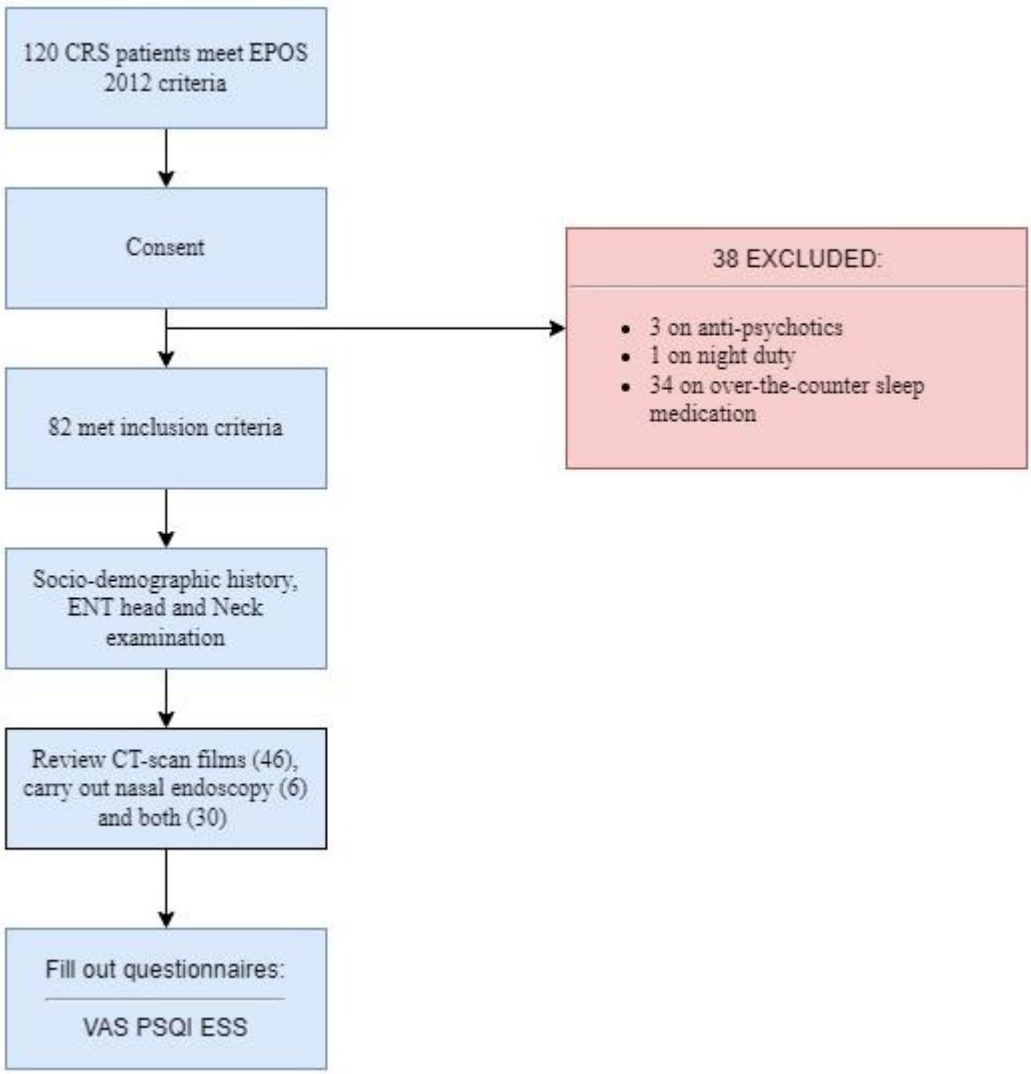

Figure 2:Study procedure flow chart

3.12: Data Management

The data was captured using a data collection sheet. Data was keyed into an excel spreadsheet where it was cleaned for errors and any other inconsistencies. At the end of data collection, the entire database in an Excel spreadsheet was exported into a designed computer database using the Statistical Package for Social Sciences (SPSS) version 22.

3.13: Data Analysis

Data analysis was conducted using SPSS Statistics version 22. The ages were grouped based on the World Health Organization (WHO) age standardization rates. This entailed both descriptive and inferential statistics. We utilized ratings from previous research since there was no validated grading method for the total Lund-Mackay CT scan score and the Lund-Kennedy endoscopic score. The Lund-Kennedy endoscopic total score was rated as normal (0-4), mild

(5-9), moderate (10-14), or severe (15-24) in the Hopkins et al study[47]. Enema et al rated the total Lund-Mackay CT scan score as mild (≤4), moderate (5-7), and severe (≥8)[48]. In descriptive statistics, the characteristics of the participants were expressed in percentages, frequencies, and mean scores. Standard deviation was determined for the continuous variables, for example, the ages of the patients. The categorical variables were analysed by calculating the percentages of participants in each level. Fisher's exact test determined the relationship between the participants' status (that is, CRS status) and their characteristics (age and sex). The student's t-test was used to compare and correlate the scores found in VAS, ESS, and PSQI with the CRS severity total scores gathered from radiological and endoscopy examinations. A p-value of less than 0.05 was used as the level of statistical significance while the multivariate regression model determined the relationship between independent and dependent variables.

3.14: Quality Control

To increase the validity and reliability of the study's findings, quality control was implemented throughout the investigation.

To eliminate bias and misinterpretation of the questions, a pre-test of the structured questionnaires was conducted to clarify grammar and wording. All the interviews and physical examinations were conducted by the principal researcher. For patients who did not understand the wording in the questionnaires, the principal researcher assisted in paraphrasing.

The data gathering tools were double-checked for accuracy, and any missing entries were filled in. Any contradictions in the quantitative and qualitative data were verified, and outliers were corrected.

3.15: Ethical Considerations

This research was carried out after approval from the UoN ENT surgical department and the KNH/UoN ethics and research committee. Each patient received counselling and education before obtaining informed written consent. Patients who declined to give consent were not victimized in any way and continued to receive treatment as prescribed for their condition. Participation in this study did not incur an extra cost for the patient. The patients were identified by the study codes and not by their names or hospital numbers. This was to maintain confidentiality throughout the process of data collection. All the data collection sheets and soft copy data were kept safe by the principal researcher and were not shared with unauthorized persons. Once the study was complete, all the data collection materials were destroyed and discarded. The results of the study will be submitted to the university in the form of a thesis.

The findings of the study will also be shared during presentations in meetings, seminars, conferences, journals, and other scientific forums. Hard copies of the study will be available at the UON department of surgery, the College of Health Science Library, and the ENT department library. A soft copy will also be available on the University of Nairobi online portal (http://erepository.uonbi.ac.ke) for reference and dissemination. As part of the Master of Medicine in Ear, Nose, and Throat surgery partial fulfilment, a manuscript will be prepared and submitted for publication in a journal.

4. CHAPTER FOUR: RESULTS

4.1. Patient distribution based on age and gender

Of the 82 patients recruited into the study, 37 (45.1%) were males and 45 (54.9%) were females, making the male to female ratio of 0.8:1. The patients' ages ranged from 18 to 71, with the median age being 30.

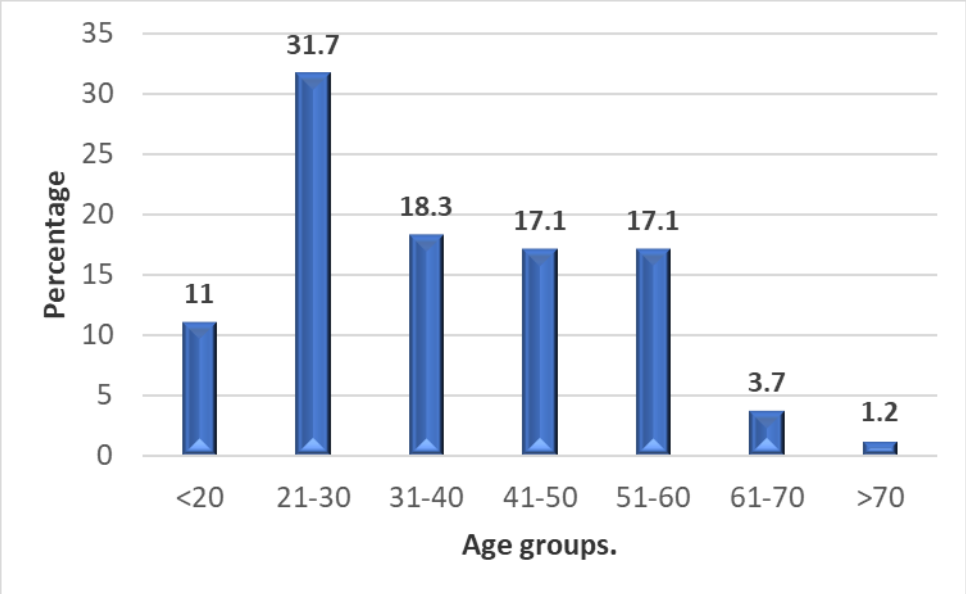

Figure 3: Age Distribution

Patients with CRSsNP were 30 (36.6%), while those with CRSwNP were 52 (63.4%). Table 1 shows the medical and social history of the patients in the study.

Table 1: The medical and social history of the study population

VARIABLE	**YES** **Number(n) (%)**	**NO** **n (%)**
Medical treatment	73(89.0%)	9(11.0%)
Prior FESS	20(24.4%)	62(75.6%)
Alcohol	14(17.1%)	68(82.9%)
Tobacco	1(1.2%)	81(98.8%)

4.2. Quality of sleep-PSQI.

4.2.1. Total and subdomain scores

Of the seven PSQI subdomains sleep efficiency and duration were the most affected, whereas subjective sleep quality and daytime dysfunction were the least affected.

Table 2: PSQI domains

Domain	Mean ± SD	Range
Subjective sleep quality	1.4±0.8	0-3
Sleep latency	1.5±1.0	0-3
Sleep duration	1.7±1.2	0-3
Sleep efficiency	1.7±1.3	0-3
Sleep disturbance	1.6±0.7	0-3
Use of sleeping pills	00	0-0
Daytime dysfunction	1.4±0.9	0-3

The PSQI total score ranged from 2 to 18, with a median of 9 and a mode of 13. Its mean was 9.24±4.20. The PSQI total score of more than 5 indicated poor sleep quality, with 75.6% of patients falling into this category and 24.4% having good sleep (scores <5).

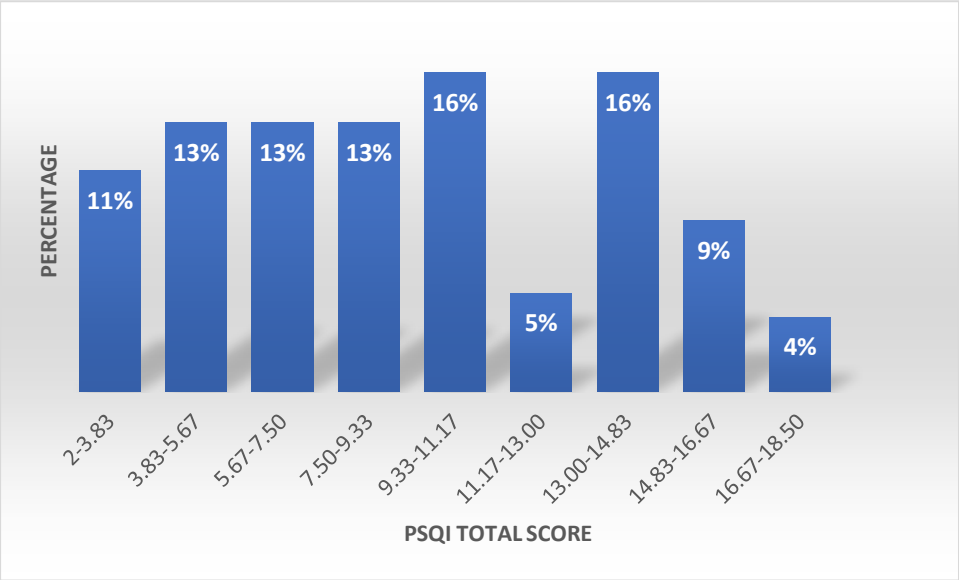

Figure 4:Distribution of PSQI total

4.2.2. Distribution of global PSQI

Despite not being statistically significant, many of the patients had high PSQI total scores, indicating poor sleep. CRSwNP made up 72.6% of the poor sleep category, whereas CRSsNP made up 27.4% (p=0.004).

Table 3: Relating patients' characteristics to quality of sleep

Variable		PSQI total mean ± SD	Good sleep n (%)	Poor sleep n (%)	P-value
Gender	Male	9.2±4.2	9(45%)	28(45.2%)	1
	Female	9.2±4.2	11(55%)	34(54.8%)	
Age	≤20	7.0±3.6	3(15%)	6(9.7%)	0.07
	21-30	9.0±4.5	10(50%)	16(25.8%)	
	31-40	8.6±3.5	3(15%)	12(19.4%)	
	41-50	11.8±4.2	1(5%)	13(21.0%)	
	51-60	9.9±3.3	1(5%)	13(21.0%	
	61-70	8.7±5.1	1(5%)	2(3.2%)	
	>70	3.0	1(5%)	0(0%)	
Medical treatment	Yes	9.4±4.3	17(85%)	56(90.3%)	0.78
	No	7.8±3.6	3(15%)	6(9.7%)	
Prior FESS	Yes	8.6±4.0	6(30%)	14(22.6%)	0.55
	No	9.5±5.3	14(70%)	48(77.4%)	
Alcohol	Yes	10.0±3.3	2(10%)	12(19.4%)	0.5
	No	9.1±4.4	18(90%)	50(80.6%)	
Tobacco	Yes	11.0	0(0%)	1(1.6%)	1
	No	9.2±4.2	20(100%)	51(98.4%)	
CRS	CRSsNP	7.7±3.8	13(65%)	17(27.4%)	0.004
	CRSwNP	10.1±4.2	7(35%)	45(72.6%)	

4.3. Measurement of daytime sleepiness-Epworth Sleepiness Scale (ESS)

Regardless of the patients' characteristics, the distribution of daytime average sleep propensity (ASP) within the study was found to be statistically insignificant.

Table 4: Average sleep propensity distribution

Variable		Average Sleep Propensity				P-value
		Normal (0-10) **n (%)**	Mild (11-12) **n (%)**	Moderate (13-15) **n (%)**	Severe (16-24) **n (%)**	
Gender	Male	23(45.1%)	3(50%)	5(62.5%)	6(35.3%)	0.67
	Female	28(54.9%)	3(50%)	3(37.5%)	11(64.7%)	
Age	≤20	6(14.3%)	1(20%)	0(0%)	2(13.3%)	0.96
	21-30	17(40.5%)	2(40%)	3(50%)	4(26.7%)	
	31-40	9(21.4%)	1(20%)	0(0%)	5(33.3%)	
	41-50	7(16.7%)	1(20%)	3(50%)	3(20%)	
	51-60	2(4.8%)	0(0%)	0(0%)	1(6.7%)	
	61-70	1(2.4%)	0(0%)	0(0%)	0(0%)	
	>70	0(0%)	0(0%)	0(0%)	0(0%)	
Medical treatment	Yes	46(85.2%)	6(100%)	8(100%)	16(100%)	0.55
	No	8(14.8%)	0(0%)	0(0%)	0(0%)	
Prior FESS	Yes	12(23.5%)	3(50%)	2(25%)	3(18.8%)	0.48
	No	39(76.5%)	3(50%)	6(75%)	13(81.2%)	
Alcohol	Yes	8(15.7%)	1(16.7%)	2(25%)	3(17.6%)	0.92
	No	43(84.3%)	5(83.3%)	6(75%)	14(82.4%))	
Tobacco	Yes	0(0%)	0(0%)	0(0%)	1(5.9%)	0.37
	No	51(100%)	6(100%)	8(100%)	16(94.1%)	
CRS	CRsNP	22(43.1%)	1(16.7%)	2(25%)	5(29.4%)	0.52
	CRSwNP	29(56.9%)	5(83.3%0	6(75%)	12(70.6%)	

The majority (62.2%) of those interviewed had normal ESS scores (0-10) as shown in figure 5.

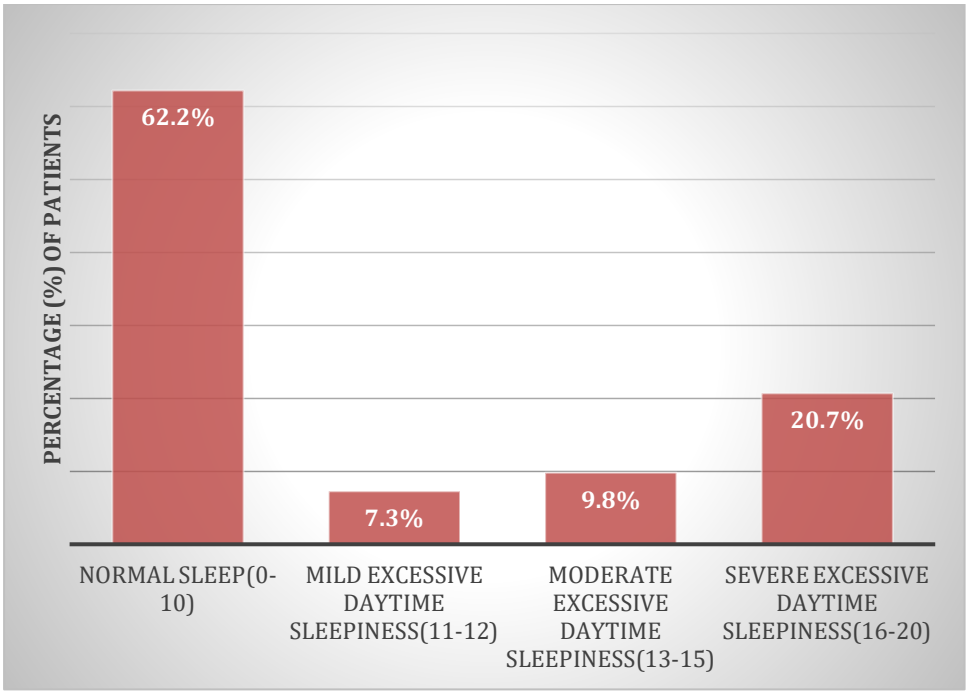

Figure 5: Epworth sleepiness scale score

4.4. Measurement of disease severity

Both subjective and objective measures of disease severity showed that most of the patients suffered from severe disease (VA = 46.3% and CT Scan Lund Mackay = 50.0%, respectively). The mean VAS score was 7.03±2.69, the mean CT scan score was 13.42±8.75, and the mean endoscopic score was 4.86 ±3.72.

***Table 5*: Patients' disease severity**

Measurement	Normal	Mild	Moderate	Severe
VAS	----------	11(13.4%)	33(40.2%)	38(46.3%)
CT Scan	----------	28(36.8%)	10(13.2%)	38(50.0%)
Endoscopy	7(19.4%)	13(36.1%)	11(30.6%)	5(13.9%)

4.5: Disease severity and PSQI

Amongst the different scoring criteria of disease severity, only the Lund Kennedy endoscopy staging correlated with the quality of sleep (p = 0.001) as shown in Table 6 below.

Table 6: Relationship between sleep quality and disease severity

DISEASE SEVERITY		PSQI		P-VALUE
		GOOD	POOR	
1.CT SCAN	Mild	10(13.2%)	18(23.7%)	0.07
	Moderate	3(3.9%)	7(9.2%)	
	Severe	5(6.6%)	33(43.4%)	
2.VAS	Mild	9(11%)	2(2.4%)	0.19
	Moderate	22(26.8%)	11(13.4%)	
	severe	20(24.4%)	18(22%)	
3.ENDOSCOPY	Normal	5(71.4%)	2(6.9%)	0.001
	Mild	0(0.0%)	13(44.8%)	
	Moderate	2(28.6%)	9(31.0%)	
	Severe	0(0.0%)	5(17.2%)	

4.6: Comparison between PSQI and ESS

The PSQI and ESS data were divided into dichotomous groups, with PSQI having good (<5) and poor sleep (>5) and ESS having normal risk of sleepiness (0-10) and excessive daytime sleepiness (11-24). Despite having poor sleep on the PSQI, most CRS patients (64.7%) had a normal risk of sleepiness on ESS.

Table 7: Agreement between PSQI and ESS

		PSQI (Rater 2)		TOTAL
		Good sleep	Poor sleep	
ESS (Rater 1)	Normal risk of sleepiness	18(35.3%)	33(64.7%)	51(62.20%)
	Excessive risk of daytime sleepiness	2(6.5%)	29(93.5%)	31(37.80%)
TOTAL		20(24.39%)	62(75.61%)	82(100%)

The Cohen's kappa coefficient (κ) was calculated using the formula: $k = (p_o – p_e) / (1 – p_e)$.

where:

p_o was the relative observed agreement among raters

p_o:18+29=47(57.32% of the observations)

p_e was the hypothetical probability of chance agreement

p_e= (20*51) +(62*31) =35.9(43.75% of the observations)

The Kappa was found to be 0.24 with the percentage of the agreement being 57.32 and the standard error of kappa being 0.07. The 95% confidence interval ranged from 0.097 to 0.386.

5. CHAPTER FIVE: DISCUSSION, CONCLUSION, AND RECOMMENDATIONS

5.1: Discussion

Sleep is a necessity in life. It is important in the regulation of the body's physiology, immunity, and memory. Its disturbance in both health and disease states has been linked to poor concentration, an increase in daytime drowsiness, and fatigue. It also increases the risk of morbidity and mortality secondary to work or home-related accidents, psychological disturbances such as depression, and the development of non-communicable diseases such as type 2 diabetes mellitus, hypertension, and cerebrovascular accidents[2,32].

A common complaint among patients suffering from chronic rhinosinusitis is poor sleep, increased fatigue, and hypersomnolence in the daytime. In disease-specific quality of life questionnaires such as the Sino-Nasal Outcome Test (SNOT 22), the rhinological and psychological domains are the most affected, followed by sleep dysfunction[16,49,50]. Several studies have been conducted using various sleep validated tools to substantiate these complaints[39,42,51].

The Pittsburgh sleep quality index (PSQI) and the Epworth sleepiness scale (ESS) were used in this study. Total PSQI scores of 5 or more indicated poor sleep, while ESS scores of 11 or more indicated excessive daytime sleepiness. The majority (75.6%) of the patients suffered from poor sleep (9.24±4.2) on the PSQI score. This was regardless of gender, age, or type of treatment (medical or FESS). Other research, such as Fried et al., found that patients with CRS had PSQI ratings of 11.0±4.5 when compared to patients with other rhinological disorders such as rhinitis and nasal septal deviation (6.1±3.7 and 8.6±3.5 respectively)[52]. In a case-control study conducted by Alt et al., PSQI scores were significantly higher in CRS patients (10.1±4.3) than in controls (4.7±2.5; $p < 0.001$)[40]. A multi-institutional cohort study conducted on CRS patients found 75% of them had PSQI scores of > 5, with the mean score being 9.4±4.4, reiterating that CRS patients have poor sleep quality[7].

Our study found that there were significantly more patients with CRSwNP in the poor sleep category than CRSsNP (72.6% vs 27.4%, respectively; p=0.004). This contrasted with the Alt et al study that found no significant difference between those with and without polyps (8.9±4.5 vs 9.6±4.3; $p = 0.179$)[7]. In the sleep domain in the SNOT-20 questionnaire, Schneider et al found there was no difference between those with and without polyps[53]. Patients with

CRSwNP are more likely to have additional inflammatory disorders such as unified airway disease, Samter's triad, and allergic rhinitis that are linked to poor sleep quality. In a study by Nyangaresi et al. at Kenyatta National Hospital on the impact of endoscopic sinus surgery on lung function in patients with chronic rhinosinusitis, polyps were found in 90.9% of the patients, while 18.2% of the CRS patients suffered from asthma[54]. KNH is an academic tertiary referral hospital where patients with severe illnesses are referred to. In addition to associated comorbidities, the large number of CRSwNP (63.4%) who made up our study patients may have contributed to selection bias, leading to the disparity found between our study and other studies.

Although a common complaint in CRS patients is daytime drowsiness, in this study, the majority (62.2%) of the patients had a normal Epworth sleepiness scale. Fried et al investigated several rhinological disorders and their impact on sleep and found that they all had normal ESS scores, despite CRS having the highest score (9.8±4.0) and nasoseptal deviation having the least score (8.9±4.6)[52]. In a case-control multi-institutional investigation, Alt et al found that patients with CRS had a higher ESS (9.1± 5.3) when compared to controls (6.5 ±3.7; $p = 0.006$) but within the normal range[40]. Varendh et al compared preoperative and postoperative ESS ratings and found that they were both within the normal range (7.5 vs 6.0; $p=0.048$), but the risk of daytime sleepiness had decreased postoperatively[51]. This demonstrates that, while CRS patients are more likely to fall asleep throughout the day, their risk is within acceptable normal limits. Patients may also confuse fatigue and daytime somnolence as being the same thing, which is, however, different. Sleep disturbance caused by CRS symptomatology might be the source of fatigue.

The value of the Cohen kappa coefficient was found to be 0.24. This meant that there was a fair agreement between sleep quality and daytime drowsiness(Appendix V)[55]. Other investigations, such as Mondal et al. and Buysee et al., found Pearson correlation coefficients of both ESS and PSQI as 0.13 and 0.16 ($p<0.05$), respectively, indicating slight agreement[34,56]. While both questionnaires are psychometric scales, they assess different aspects of sleep. The PSQI assesses sleep quality as well as daytime dysfunction over the past month, whereas the ESS assesses the risk of falling asleep when engaging in various activities with variable amounts of sleep-inducing potential.

According to this study, a significant number of CRS patients had severe disease on both subjective (VAS-46.3%) and objective (CT scan-50%) assessments. However, neither VAS nor CT Scan severity scores correlated with sleep quality ($p > 0.05$), but endoscopic scores did ($p=0.001$). Alt et al. and Gabriella et al. found no link between disease severity (VAS,

endoscopy, and CT Scan) and sleep quality (P> 0.05)[7,57,58]. The difference between our study results and the other studies may be due to the small number of patients who underwent endoscopic examination, n = 36 (43%), due to the ongoing SARS-CoV-2 pandemic and the high cost of screening for it, hence creating bias.

As one of the chronic inflammatory conditions in the body, the pathophysiology of CRS has been linked to the release of inflammatory mediators such as Interleukin (IL) 4, IL-13, and transforming growth factor-beta (TGF β). These cytokines have a negative influence on the neuronal input-output activity in the sleep centre resulting in a disturbed sleep cycle. Even though it was not statistically significant (p = 0.55), patients in this study with prior FESS reported poor sleep with PSQI-8.6±4.0. Rotenburg et al. found an improvement in the PSQI scores from 10.9±2.8 to 5.3±2.2 after surgery; however, 26.4% still had scores > 5[42]. Alt et al. found an improvement of 2.2 points in CRS patients postoperatively (preoperative PSQI-9.4 to 7.2 postoperatively)[59].FESS may have reduced the disease burden and the cytokine load, improving the patients' sleep, but other factors are yet to be elucidated that can explain the persistent poor sleep.

5.2: Conclusion

Our study demonstrated that, despite having a normal risk of daytime sleepiness, most CRS patients suffer from severe disease symptomatology and poor sleep quality. In contrast to VAS and CT scans, the severity of their disease on endoscopy correlates with their sleep quality. This understanding will help in the patient's overall treatment and quality of life.

5.3: Recommendations

We propose that clinicians evaluate the quality of sleep in individuals with CRS as part of their therapy irrespective of their disease severity. We recommend a case-control study to be conducted to assess whether sleep quality is poorer in CRS patients than in the general population.

More research should be conducted to determine the pathogenesis of poor sleep among patients with CRS which will enable physicians to manage CRS patients in a wholesome manner.

5.4: Limitations

The PSQI questionnaire assessed the patients' sleep in the previous month, so the study suffered from recall bias. Some of the patients had difficulties understanding the wording in the PSQI questionnaire, which required assistance from the principal researcher with its interpretation. Both the PSQI and ESS questionnaires are screening tools. For a definitive

diagnosis, a polysomnogram (PSG) can be carried out. However, within the country, it is an expensive test with limited availability. Due to the current pandemic, patients who required endoscopic evaluation were required to have a negative nasopharyngeal swab for SARS-CoV-2. This was, however, shunned by many patients. Those who took the test did it as part of their preoperative tests.

TIMELINE

TASK	Jan – April 2019	July 2019	Oct 2019 - Jan 2020	Feb2020-Dec 2021	Jan-Feb 2022	Mar 2022
Proposal writing						
Proposal presentation						
Ethics approval						
Data collection						
Data analysis						
Results presentation						

BUDGET

EXPENSES	QUANTITY	UNIT COST EACH (Ksh)	TOTAL COST (Ksh)
PERSONNEL: ∉ Statistician	1	30000	30000
STATIONERY			5000
PRINTING and PHOTOCOPY			10000
SERVICES: ∉ KNH/UON ETHICAL approval ∉ Rigid nasal endoscopy (RNE)	1 6	2000 2650	2000 15900
MISCELLANEOUS EXPENDITURES			10000
TOTAL (Ksh)			72900

The principal researcher catered to the costs from her savings. Six rigid nasal endoscopy examinations were carried out before the COVID 19 pandemic, unlike the 30 patients who had to have a COVID 19 screening test as a prerequisite for their surgery. This was catered for by the patient as part of their preoperative management. Their endoscopic examinations were carried out as part of their surgery.

REFERENCES

1. Kline C. Sleep Quality. In: Gellman MD, Turner JR, editors. Encyclopaedia of Behavioural Medicine. New York, NY: Springer New York; 2013. p. 1808–1818.

2. Medic G, Wille M, Hemels ME. Short- and long-term health consequences of sleep disruption. Vol. 9, Nature and Science of Sleep. Dove Press; 2017. p. 151–161.

3. Beule AG. Epidemiology of chronic rhinosinusitis, selected risk factors, comorbidities, and economic burden. GMS Curr Top Otorhinolaryngol Head Neck Surg. 2015 Apr 10;14(S 01): Doc11.

4. Fokkens WJ, Lund VJ, Mullol J, et al. EPOS 2012: European position paper on rhinosinusitis and nasal polyps 2012. A summary for otorhinolaryngologists. Rhinology. 2012;50(1):1–12.

5. Tan BK, Kern RC, Schleimer RP, et al. Chronic rhinosinusitis: The unrecognized epidemic. Vol. 188, American Journal of Respiratory and Critical Care Medicine. 2013. p. 1275–1277.

6. Alt JA, Smith TL. Chronic rhinosinusitis and sleep: A contemporary review. Int Forum Allergy Rhinol. 2013;3(11):941–949.

7. Alt JA, Smith TL, Mace JC, et al. Sleep quality and disease severity in patients with chronic rhinosinusitis. In: Laryngoscope. 2013. p. 2364–2370.

8. Mahdavinia M, Schleimer RP, Keshavarzian A. Sleep disruption in chronic rhinosinusitis. Expert Rev Anti Infect Ther. 2017 May 4;15(5):457–465.

9. Bachert C, Pawankar R, Zhang L, et al. ICON: chronic rhinosinusitis. World Allergy Organ J. 2014 Dec 27;7(1):1–28.

10. Kolethekkat AA, Paul RR, Kurien M, et al. Diagnosis of adult chronic rhinosinusitis: Can nasal endoscopy predict intrasinus disease? Oman Med J. 2013;28(6):427–431.

11. Abdikadir MH, Obura HO, Nyagah S. Correlation of symptoms and computed tomography scan findings in patients with chronic rhinosinusitis at the Kenyatta National Hospital. East Cent Africa J Otolaryngol Head Neck Surg. 2019; Volume 3(1):14–19.

12. Kato A. Immunopathology of chronic rhinosinusitis. Allergol Int. 2015;64(2):121–130.

13. Rimmer J, Hellings P, Lund V, et al. European position paper on diagnostic tools in rhinology. Rhinology. 2019 May 27; Suppl. 28:1–42.

14. Doulaptsi M, Prokopakis E, Seys S, et al. Visual analogue scale for sino-nasal symptoms severity correlates with sino-nasal outcome test 22: paving the way for a simple outcome tool of CRS burden. Clin Transl Allergy. 2018 Dec 3 ;8(1):1-32.

15. DeConde AS, Mace JC, Ramakrishnan VR, et al. Analysis of factors associated with electing endoscopic sinus surgery. Laryngoscope. 2018;128(2):304–310.

16. Alt JA, DeConde AS, Mace JC, et al. Quality of Life in Patients With Chronic Rhinosinusitis and Sleep Dysfunction Undergoing Endoscopic Sinus Surgery A Pilot Investigation of Comorbid Obstructive Sleep Apnea. JAMA Otolaryngol Head Neck Surg. 2015 Oct 1;141(10):873–881.

17. Carley DW, Farabi SS. Physiology of sleep. Diabetes Spectr. 2016 Feb;29(1):5–9.

18. Brown RE, Basheer R, McKenna JT, et al. Control of sleep and wakefulness. Vol. 92, Physiological Reviews. NIH Public Access; 2012. p. 1087–1187.

19. Barrett KE, Susan M, Scott B, et al. Ganong review of medical physiology. Electrical Activity of the Brain, Sleep-Wake States, & Circadian Rhythms. 26th ed. New York: McGraw-Hill Medical. Vol. 26th. 2019. 619–677 p.

20. Irwin MR, Olmstead R, Carroll JE. Sleep Disturbance, Sleep Duration, and Inflammation: A Systematic Review and Meta-Analysis of Cohort Studies and Experimental Sleep Deprivation. Biol Psychiatry. 2016;80(1):40–52.

21. Ohayon M, Wickwire EM, Hirshkowitz M, et al. National Sleep Foundation's sleep quality recommendations: first report. Sleep Health. 2017;3(1):6–19.

22. Brick CA, Seely DL, Palermo TM. Association between sleep hygiene and sleep quality in medical students. Behav Sleep Med. 2010;8(2):113–121.

23. Fernandes Oliveira E, Nacif SR, Alves Pereira N, et al. Sleep disorders in patients with myasthenia gravis: a systematic review. J Phys Ther Sci. 2015 Jun;27(6):2013–2018.

24. Grabovac I, Haider S, Berner C, et al. Sleep Quality in Patients with Rheumatoid Arthritis and Associations with Pain, Disability, Disease Duration, and Activity. J Clin

Med. 2018 Oct;7(10):336.

25. Ulus Y, Akyol Y, Tander Bet al. Sleep quality in fibromyalgia and rheumatoid arthritis: associations with pain, fatigue, depression, and disease activity. Clin Exp Rheumatol. 29(6 Suppl 69): S92-96.

26. Hussein J. Quality of Sleep and Sleep Disorders in Adult Patients with End-Stage Renal Disease Undergoing Hemodialysis At Kenyatta National Hospital.Mmed dissertation. UON erepository;2017.

27. Orb Q, Orlandi RR, Alt JA. Sleep dysfunction and its association to chronic rhinosinusitis: Updated review. Laryngoscope Investig Otolaryngol. 2017 Apr;2(2):46–52.

28. Rod NH, Vahtera J, Westerlund H, et al. Sleep disturbances and cause-specific mortality: Results from the GAZEL cohort study. Am J Epidemiol. 2011 Feb 1;173(3):300–309.

29. Asif N, Iqbal R, Nazir CF. Human immune system during sleep. Am J Clin Exp Immunol. 2017;6(6):92–96.

30. Hurtado-Alvarado G, Pavón L, Castillo-García SA, et al. Sleep loss as a factor to induce cellular and molecular inflammatory variations. Clin Dev Immunol. 2013 Dec 3; 2013:801341.

31. Uehli K, Mehta AJ, Miedinger D, et al. Sleep problems and work injuries: a systematic review and meta-analysis. Sleep Med Rev. 2014 Feb;18(1):61-73.

32. Pilcher JJ, Morris DM. Sleep and Organizational Behavior: Implications for Workplace Productivity and Safety. Front Psychol. 2020;11:45.

33. Thomas AJ, Orlandi RR, Ashby S, et al. Nasal Obstruction Has a Limited Impact on Sleep Quality and Quality of Life in Patients with Chronic Rhinosinusitis. Laryngoscope. 2016 Sep 1;126(9):1971–1976.

34. Mondal P, Gjevre JA, Taylor-Gjevre RM, et al. Relationship between the Pittsburgh sleep quality index and the Epworth sleepiness scale in a sleep laboratory referral population. Nat Sci Sleep. 2013; 5:15–21.

35. Hashmi AM, Khawaja IS, Butt Z, et al. The Pittsburgh Sleep Quality Index: Validation of the Urdu Translation. J Coll Physicians Surg Pak. 2014 Feb;24(2):123-126.

36. Salahuddin M, Maru TT, Kumalo A, et al. Validation of the Pittsburgh sleep quality index in community dwelling Ethiopian adults. Health Qual Life Outcomes. 2017 Jan 27;15(1):58.

37. Al-Abri M, Al-Hamhami A, Al-Nabhani H, et al. Validation of the Arabic Version of the Epworth Sleepiness Scale in Oman. Oman Med J. 2013;28(6):454-456.

38. Kendzerska TB, Smith PM, Brignardello-Petersen R, et al. Evaluation of the measurement properties of the Epworth sleepiness scale: a systematic review. Sleep Med Rev. 2014 Aug;18(4):321-331.

39. Bengtsson C, Lindberg E, Jonsson L, et al. Chronic rhinosinusitis impairs sleep quality: Results of the GA2LEN study. Sleep. 2017 Jan 1;40(1).

40. Alt JA, Ramakrishnan VR, Platt MP, et al. Impact of chronic rhinosinusitis on sleep: a controlled clinical study. forum Allergy Rhinol. 2019 Jan 1;9(1):16–22.

41. Cox DR, Ashby S, Mace JC, et al. The Pain-Depression Dyad and the Association with Sleep Dysfunction in Chronic Rhinosinusitis. Int Forum Allergy Rhinol. 2017;7(1):56–63.

42. Rotenberg BW, Pang KP. The impact of sinus surgery on sleep outcomes. Int Forum Allergy Rhinol. 2015;5(4):329–332.

43. Ando Y, Chiba S, Capasso R, et al. Risk factors for sleep impairment in adult patients with chronic rhinosinusitis. Auris Nasus Larynx. 2016 Aug;43(4):418–421.

44. Rassi E El, Mace JC, Steele TO, et al. Improvements in sleep-related symptoms after endoscopic sinus surgery in patients with chronic rhinosinusitis. Int Forum Allergy Rhinol. 2016;6(4):414–422.

45. Krejcie, R. V., & Morgan, D. W. Determining sample size for research activities. Educational and Psychological Measurement.1970; 30(3): 607–610.

46. El-Beltagy, Ghita AF, Mady OM, et al. The relation between chronic rhinosinusitis and sleep-disordered breathing. Egypt J Otolaryngol. 2019;35(2):155-161.

47. Hopkins C, Browne JP, Slack R, et al. The Lund-Mackay staging system for chronic rhinosinusitis: How is it used and what does it predict? Otolaryngol - Head Neck Surg. 2007;137(4):555–561.

48. Amodu EJ, Fasunla AJ, Akano AO, et al. Chronic rhinosinusitis: correlation of symptoms with computed tomography scan findings. Pan Afr Med J. 2014 May 10; 18:40.

49. Sitima O.D. Translation and Validation of a Swahili Version of The Sino-Nasal Outcome Test (Snot-22). Mmed dissertation. UON erepository;2020.

50. Adan M.W. The Effect of Isotonic Nasal Saline Irrigation on Chronic Rhinosinusitis Symptoms in Adult Patients at The Kenyatta National Hospital. Mmed dissertation. UON erepository;2020.

51. Värendh M, Johannisson A, Hrubos-Strøm H, et al. Sleep quality improves with endoscopic sinus surgery in patients with chronic rhinosinusitis and nasal polyposis. Rhinology. 2017;55(1):45–52.

52. Fried J, Yuen E, Li A, et al. Rhinologic disease and its impact on sleep: a systematic review. Int Forum Allergy Rhinol. 2021;11(7):1074–1086.

53. Schneider S, Campion NJ, Villazala-Merino S, et al. Associations between the quality of life and nasal polyp size in patients suffering from chronic rhinosinusitis without nasal polyps, with nasal polyps or aspirin-exacerbated respiratory disease. J Clin Med. 2020;9(4):925.

54. Nyangaresi JN. Effect Of Endoscopic Sinus Surgery On Lung Function In Patients With Chronic Rhinosinusitis At Kenyatta National Hospital.Mmed dissertation.UON repository;2021.

55. McHugh ML. Interrater reliability: The kappa statistic. Biochem Medica. 2012 Oct 15;22(3):276–282.

56. Buysse DJ, Hall ML, Strollo PJ, et al. Relationships between the Pittsburgh Sleep Quality Index (PSQI), Epworth Sleepiness Scale (ESS), and clinical/polysomnographic measures in a community sample. J Clin Sleep Med. 2008 Dec 15;4(6):563–571.

57. Alt JA, Sautter NB, Mace JC, et al. Antisomnogenic cytokines, quality of life, and chronic rhinosinusitis: A pilot study. In: Laryngoscope. 2014. p. 107–114.

58. Gabriella CC, Wigati KW, Sutikno B. Correlation Between the Severity of Chronic Rhinosinusitis and Sleep Quality in Adult Patients. Biomol Heal Sci J . 2020 Oct 30;3(2):63–66.

59. Alt JA, Smith TL, Schlosser RJ, et al. Sleep and Quality of Life Improvements after Endoscopic Sinus Surgery in Patients with Chronic Rhinosinusitis. Int Forum Allergy Rhinol. 2014;4(9):693-701.

APPENDICES

Appendix I (a): Consent Explanation

Study number: …….

Study Title: QUALITY OF SLEEP IN PATIENTS WITH CRS AT KENYATTA NATIONAL HOSPITAL

Principle Investigator: Dr. Irungu Anne Nyambura (Postgraduate student in Ear, Nose and Throat surgery, University of Nairobi)

Supervisors: Dr. Joyce Aswani

Dr. Samuel Nyagah

INTRODUCTION

I would like to tell you about a study being conducted by the above-named investigator. The purpose of this consent form is to give you the information you will need to help you decide whether 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 all your questions have been answered 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 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 reference.

May I continue? YES / NO

This study has approval by The Kenyatta National Hospital-University of Nairobi Ethics and Research Committee protocol No. _____

STUDY BACKGROUND

Patients suffering from CRS have been noted to be persistently fatigued and complain of frequent daytime sleepiness and poor quality of sleep at night. This impairs their concentration making them very vulnerable to accidents at work, home, or while driving. Such patients are prone to the consumption of excessive amounts of over-the-counter sleeping medications to aid better sleep. Prolonged poor sleep in CRS patients places them at risk of developing various non-communicable diseases such as type 2 DM, hypertension, and obesity. Various investigations have been done that have found a relationship between poor quality of sleep and CRS.

BROAD OBJECTIVE

The purpose of the interview is to find out the quality of sleep (QOS) in patients suffering from CRS.

STUDY PROCEDURE

If you agree to participate in this study, I will interview you in a private area where you feel comfortable answering questions. It will last approximately 20 minutes. The interview will cover topics such as medical history, medication currently in use, rate the severity of your disease, your sleeping habits over the last one month, and your rate of falling asleep while performing day-to-day activities.

After the interview, those with CT scans of their nose and paranasal sinus will have the films examined. Those without the films will have a rigid nasal endoscopy examination of their nose. I will ask for your telephone number so that I can contact you if necessary. Your contact information will be used only by people working for this study and will never be shared with anyone else. I may need to contact you to disseminate the results or refer you for further treatment in instances where an abnormality is found.

STUDY RISKS, HARM, OR DISCOMFORT

Medical research has the potential to introduce psychological, social, emotional, and physical risks. Efforts should always be put in place to minimize the risks. One potential risk of being in the study is the loss of privacy. Everything you tell me in this study will be treated as confidential. I will give you a code number for identification in a password-protected computer database and will keep all our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be total, so it is still possible that someone could find out that you participated in this study and may find out information about you.

You may feel uncomfortable answering some questions in this interview. In case of such, you have the right to refuse to answer or to skip them.

It may be embarrassing for you to have a nasal endoscopy examination. I will do everything possible to ensure that this is done in private.

You may feel some discomfort when examination of the nose is done, and you may have a small bruise or swelling in your nasal cavity. In case of an injury, illness, or complications related to this study, contact me as soon as possible using the number provided at the end of this document. I will offer treatment for minor conditions or refer you if necessary.

STUDY BENEFITS

You will benefit by receiving free screening for sleep disorders. You will be referred to a hospital for care and support where necessary. Also, the information you provide will help us, as medics, to better understand the effect of CRS on sleep quality. This information is a contribution to science and a guide to the wholesome management of patients with CRS.

STUDY COST AND REFUND

You will not incur any costs when you participate in the study. There will be no monetary benefits for participating in the study.

RIGHT TO WITHDRAW

Your decision to participate in this 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 or had the information read to me in this consent form. I have had the chance to discuss this research study with a study counsellor. 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 at any time. I freely agree to participate in this research study.

I understand that all efforts will be made to keep information regarding my 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 the endoscopy /PNS CT-scan results preserved for later study: Yes No

I agree to provide contact information for follow-up: Yes No

Participant printed name: _____

Participant's 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: _____

Date: _____ **Signature**: _____

Role in the study: _____ [i.e. study staff who explained informed consent form.]

For more information contact_____ at _____ from_____ to _____.

Witness Printed Name (If a witness is necessary, A witness is a person mutually acceptable to both the researcher and participant)

Name _____

Contact information _____

Signature /Thumb stamp: _____

Date: _____

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.

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Appendix I (b): Maelezo ya mshiriki na fomu ya idhini

Nambari ya mshirika: ……. ……

Jina la Utafiti: **QUALITY OF SLEEP IN PATIENTS WITH CRS AT KENYATTA NATIONAL HOSPITAL**

Mchunguzi na uhusiano wa taasisi: Dr. Irungu Anne Nyambura (Mwanafunzi wa uzamili kozi ya sikio, pua na koo, Chuo kikuu la Nairobi)

Wachunguzi wengineo na uhusiano wa taasisi: Dr. Joyce Aswani

Dr. Samuel Nyagah

UTANGULIZI:

Ningependa kukueleza kuhusu utafiti unaofanywa na mtafiti aliotajwa hapo juu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa unayohitaji kukusaidia kuamua kama wataka kuwa mshiriki wa utafiti au la. Una uhuru wa kuuliza maswali yoyote kuhusu madhumuni ya utafiti, kile kinachotokea unaposhiriki katika utafiti huu, uwezekano wa hatari na manufaa, haki yako kama mtu aliyejitolea, na kitu kingine chochote kuhusu utafiti au fomu hii ambayo si wazi. Ukiridhika na majibu ya maswali yote ndipo unaweza kuamua kama wataka kuhusika katika utafiti au la. Utaratibu huu unaitwa 'idhini julishwa'. Baada ya kuelewa na kukubali kuwa katika utafiti huu, nitakuomba uweke ishara ya jina lako kwenye fomu hii. Lazima uelewe kanuni za jumla zinazotumika kwa washiriki wote katika utafiti wa matibabu: i) Uamuzi wako wa kushiriki ni kwa hiari kabisa

ii) Unaweza kujiondoa kutoka utafiti wakati wowote bila kutoa sababu ya wewe kujitoa

iii) Kukataa kushiriki katika utafiti hakutaathiri huduma unazofaa kupewa katika kituo hiki cha afya au vifaa vingine. Tutawapa nakala ya fomu hii ili iwe kumbukumbu yako.

Ninaweza kuendelea? NDIO/ LA

Utafiti huu umepewa ruhusa na Hospitali Kuu ya Kenyatta - Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi, nambari ya itifaki _____

MSINGI WA UTAFITI HUU:

Wagonjwa wanaouguwa ugonjwa wa CRS wamebainika kuwa an uchovu mwingi Kila wakati na hulalamika kuwa na usingizi wakati wa mchana na ubora mbaya wa usingizi wakati wa usiku. Hii huwasumbua sana kuwa kunaingiliana na shughuli za siku kwa siku an pia kuwa

hatarini kubwa kutokana na ajali kazini, nyumbani au wakati wa kuendesha gari. Hii inaongoza wagonjwa kula kiasi kikubwa cha juu cha madawa ya kulala kukabiliana na msaada usingizi bora. Ugonjwa ukizidi muda mrefu wagonjwa wa CRS wanaweza kuuguwa maradhi kama ugonjwa wa sukari, kupanda kwa damu na fetma. Uchunguzi mbalimbali umefanywa ambao wamegundua uhusiano kati ya ubora wa usingizi na CRS.

MADHUMUNI WA UTAFITI HUU

Madhumuni ya mahojiano ni kutafuta/kujua ubora wa kulala kwa wagonjwa wa chronic rhinosinusitis.

ITAKAOFANYIKA KATIKA UCHUNGUZI HUU

Ukikubali kushiriki katika utafiti huu, mambo yafuatayo yatatokea:

Nitakuhoji katika eneo binafsi ambapo unaweza kujibu maswali kwa amani. Mahojiano yatadumu dakika takriban 20. Mahojiano yatapitia mada kama vile historia ya matibabu, utumizi wa madawa ya kulevya, kiwango cha ukali wa ugonjwa wako, tabia yako ya kulala zaidi ya mwezi uliopita na kiwango chako cha kulala wakati unafanya shughuli za siku kwa siku.

Baada ya mahojiano kumalizika, wale walio na CT-scan ya pua na paranasal sinus watanisaidia na filamu hizo. Wale wasio na filamu watachunguzwa pua zao kwa njia ya kamera ‘nasal endoscopy’.

Nitaomba namba ya simu ambayo ninaweza piga ili kuwasiliana na wewe inapohitajika. Ukikubali kunipa nambari yako, itatumika na watu wanaofanya kazi kwa ajili ya utafiti huu pekee yao na haitawai pewa kwa watu wengine. Sababu ya kuhitaji kuwasiliana na wewe ni kukupa matokeo ya utafiti na kukuelekeza kwa matibabu nikipata kesi zozote sumbufu.

HATARI AMA USUMBUFU WOWOTE KATIKA UTAFITI HUU

Utafiti wa matibabu una uwezo wa kuhatarisha mtu kisaikolojia, kijamii, kihisia na kimwili. Juhudi lazima iwe imewekwa ili kupunguza hatari. Moja ya hatari inayoweza kutokea ni kupoteza siri yako. Tutaweka kila kitu unachotwambia kama siri iwezekanavyo. Tutatumia kodi ya nambari kukutambua katika databasi ya tarakilishi iliyolindwa na neno la ficho na kushika kumbukumbu zetu za karatasi zitafungwa katika kabati ya faili itakayofungwa. Hata hivyo, hakuna mfumo wa kulinda siri yako unaoweza kuwa salama kabisa, inawezekana kwamba mtu anaweza kujua ulikuwa katika utafiti huu na anaweza kujua mambo yako.

Pia, kujibu maswali katika mahojiano inaweza kukufanya uwe na wasiwasi. Kama kuna maswali yoyote hutaki kujibu, unaweza wachana nayo. Una haki ya kukataa mahojiano au maswali yoyote wakati wa mahojiano.

Waweza kuwa na aibu tukifaanya mitihani ya 'nasal endoscopy'. Tutafanya kila tunaweza kuhakikisha kwamba hii inafanyika kwa siri. Zaidi ya hayo, mtafiti katika utafiti huu ni mtaalamu na ana mafunzo maalum katika mitihani /mahojiano.

Unaweza sikia usumbufu wakati wa kuangalia puani na unaweza kuwa na chubuko ndogo au uvimbe katika pua lako. Ukipata maumivu, ugonjwa ama matatizo kuhusiana na utafiti huu, wasiliana na mtafiti aliohusika na utafiti huu mara moja ukitumia nambari zilizopeanwa katika mwisho wa waraka huu. Mtafiti aliohusika na utafiti atatibu maumivu ya hali ndogo ama atakuelekeza kwa kupata usaidizi unaohitaji.

FAIDA KATIKA UTAFITI HUU

Unaweza kufaidika kwa kupokea bila malipo habari ya afya juu ya umuhimu wa kulala vyema. Pia utaelekezwa kwa hospitali kwa matibabu na msaada inapobidi.Taarifa utakayotupa itatusaidia kuelewa mchango upi ugonjwa wa CRS unachangia kwa ubora wa usingizi. Habari hii ni mchango kwa sayansi na utatupa mwelekeo wa kutibu wanaougua kutokana na ugonjwa wa CRS.

GHARAMA NA FEDHA KATIKA HARAKATI YA UTAFITI HUU

Hakuna gharama yoyote utakayopata ukiwa katika utafiti huu.Hakuna fedha zozote ambazo utatumia katika utafiti huu.

CHAGUO LINGINE LAKO NI LIPI?

Uamuzi wako wa kushiriki katika utafiti ni hiari. Wewe waweza kukataa kushiriki katika utafiti huu na unaweza kuondoka kutoka utafiti wakati wowote bila udhalimu au kupoteza faida yoyote.

FOMU YA IDHINI (MAELEZO YA MAKUBALIANO)

Kauli ya mshiriki

Nimesoma fomu hii ya idhini ama nimesomewa habari inayoihusu. Nimepewa nafasi ya kujadili utafiti huu na mshauri wa utafiti. Maswali yangu yamejibiwa kwa lugha ninayoelewa. Nimeelezwa hatari na faida husika. Naelewa kwamba ushiriki wangu katika utafiti huu ni wa hiari na naweza kuchagua kujiondoa wakati wowote. Nakubali, kwa uhuru wangu, kushiriki katika utafiti huu.

Naelewa kwamba juhudi zote zitafanywa ili kuweka maelezo kuhusu utambulisho wangu kibinafsi faragha.

Kwa kuweka saini yangu kwa fomu hii ya idhini, sijawachilia haki zozote zangu za kisheria kwa kuwa mshiriki katika utafiti.

Ninakubali kushiriki katika utafiti huu utafiti:	**Ndiyo**	**Hapana**
Ninakubali kuweka (kufafanua sampuli) kwa hifadhi / kuhifadhiwa kwa ajili ya utafiti ya baadaye:	Ndiyo	Hapana
Ninakubali kutoa taarifa za mawasiliano ya kufuatilia:	Ndiyo	Hapana

Mshiriki kuchapishwa jina: _____

Mshiriki sahihi / Thumb muhuri : _____

Tarehe: _____

Kauli la mtafiti

Mimi, aliyetia sahihi hapa chini, nimempa maelezo kamili kuhusu utafiti huu mshiriki aliyetajwa hapo juu na naamini kuwa mshiriki ameelewa kwa hiari na uhuru wake / ridhaa yake.

Jina la mtafiti : _____Tarehe: _____

Sahihi: _____

Wajibu katika utafiti: _____ [*yaani mfanyikazi wa utafiti ambaye alieleza fomu ya ridhaa.]*Kwa maelezo zaidi wasiliana na **_____** katika number **_____** kutoka **_____** hadi **_____**.

Jina la mshuhuda :_____

Nambari ya Mawasiliano:_____

Sahihi/ muhuri: _____

Tarehe: _____

Kwa habari zaidi kuhusu haki yako kama mshiriki wa utafiti unaweza kuwasiliana na:

Katibu / Mwenyekiti,

Hospital Kuu ya Kenyatta -Chuo Kikuu cha Nairobi; Kamati ya Maadili na Utafiti

Namba No. 2726300 Ext. 44102

Bara pepe: uonknh_erc@uonbi.ac.ke.

Mchunguzi wa taasisi:

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Appendix II: Data Collection Form

Study number…… Date: …….

Biodata:

Age (years)……. Sex …….

Medical history

Medical treatment: yes ☐ no ☐(if yes, type) ……

Prior ESS: yes ☐ no☐(if yes, indication) ……

Social history

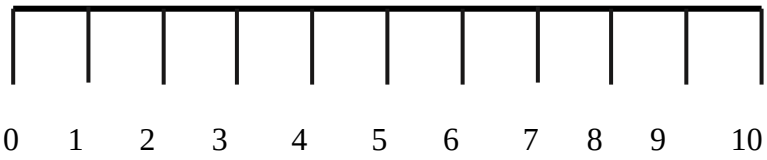
Alcohol intake: yes ☐ no☐(amount per day) ……

Tobacco use: yes ☐ no ☐(number of packs per day) …….

TOOL	**SCORE**
VAS for CRS	
PSQI	
ESS	
LMS **LKS**	

Appendix III (a): Study Tools-Visual Analogue Scale (VAS) for CRS

How troublesome are your symptoms of rhinosinusitis?



0: not troublesome

10: worst thinkable troublesome

Appendix III (b): PSQI

Subject's Initials_____ID#_____Date_____Time_____AM PM

PITTSBURGH SLEEP QUALITY INDEX

INSTRUCTIONS:
The following questions relate to your usual sleep habits during the past month only. Your answers should indicate the most accurate reply for the majority of days and nights in the past month. Please answer all questions.

1. During the past month, what time have you usually gone to bed at night?

   BED TIME _____

2. During the past month, how long (in minutes) has it usually taken you to fall asleep each night?

   NUMBER OF MINUTES _____

3. During the past month, what time have you usually gotten up in the morning?

   GETTING UP TIME _____

4. During the past month, how many hours of actual sleep did you get at night? (This may be different than the number of hours you spent in bed.)

   HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, check the one best response. Please answer all questions.

5. During the past month, how often have you had trouble sleeping because you . . .

a) Cannot get to sleep within 30 minutes

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

b) Wake up in the middle of the night or early morning

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

c) Have to get up to use the bathroom

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

d) Cannot breathe comfortably

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

e) Cough or snore loudly

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

f) Feel too cold

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

g) Feel too hot

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

h) Had bad dreams

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

i) Have pain

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

j) Other reason(s), please describe_____

_____

How often during the past month have you had trouble sleeping because of this?

Not during the past month_____ Less than once a week_____ Once or twice a week_____ Three or more times a week_____

6. During the past month, how would you rate your sleep quality overall?

Very good _____

Fairly good _____

Fairly bad _____

Very bad _____

7. During the past month, how often have you taken medicine to help you sleep (prescribed or "over the counter")?

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

8. During the past month, how often have you had trouble staying awake while driving, eating meals, or engaging in social activity?

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

9. During the past month, how much of a problem has it been for you to keep up enough enthusiasm to get things done?

No problem at all _____

Only a very slight problem _____

Somewhat of a problem _____

A very big problem _____

10. Do you have a bed partner or room mate?

No bed partner or room mate _____

Partner/room mate in other room _____

Partner in same room, but not same bed _____

Partner in same bed _____

If you have a room mate or bed partner, ask him/her how often in the past month you have had . . .

a) Loud snoring

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

b) Long pauses between breaths while asleep

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

c) Legs twitching or jerking while you sleep

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

d) Episodes of disorientation or confusion during sleep

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

e) Other restlessness while you sleep; please describe_____

_____

Not during the past month_____	Less than once a week_____	Once or twice a week_____	Three or more times a week_____

Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: Psychiatry Research, 28:193-213, 1989.

Appendix III (c): ESS

Epworth Sleepiness Scale

Name: _____ Today's date: _____

Your age (Yrs): _____ Your sex (Male = M, Female = F): _____

How likely are you to doze off or fall asleep in the following situations, in contrast to feeling just tired?

This refers to your usual way of life in recent times.

Even if you haven't done some of these things recently try to work out how they would have affected you.

Use the following scale to choose the **most appropriate number** for each situation:

0 = would **never** doze
1 = **slight chance** of dozing
2 = **moderate chance** of dozing
3 = **high chance** of dozing

It is important that you answer each question as best you can.

Situation	**Chance of Dozing (0-3)**
Sitting and reading _____	___
Watching TV _____	___
Sitting, inactive in a public place (e.g. a theatre or a meeting) _____	___
As a passenger in a car for an hour without a break _____	___
Lying down to rest in the afternoon when circumstances permit _____	___
Sitting and talking to someone _____	___
Sitting quietly after a lunch without alcohol _____	___
In a car, while stopped for a few minutes in the traffic _____	

THANK YOU FOR YOUR COOPERATION

Appendix IV (a): EPOS 2012 Criteria for Chronic Rhinosinusitis

Subjective: two or more symptoms, one of which should be either:
○ nasal blockage/obstruction/congestion
○ or nasal discharge (anterior/posterior nasal drip)
♠ ± facial pain/pressure
♠ ± reduction or loss of smell
Objective: either-
1: Endoscopic signs of:
- nasal polyps, and/or
- mucopurulent discharge primarily from middle meatus and/or
-edema/mucosal obstruction primarily in middle meatus and/or
2. CT changes: - mucosal changes within the ostiomeatal complex and/or sinuses

Appendix IV (b): Objective Signs of CRS

1: LUND-KENNEDY SCORE OF ENDOSCOPIC ASSESSMENT

Characteristics	Nasal cavity	
	Right	left
Polyp (0,1,2) Oedema (0,1,2) Secretion (0,1,2) Crusting (0,1,2) Scarring (0,1,2)		
Total		
Note: Polyp: 0-absent; 1-limited to the middle meatus; 2-extending to the nasal cavity Mucosa oedema: 0-absent; 1-mild/moderate oedema; 2-polypoid degeneration Secretion: 0-absent; 1-thin and clear; 2-thick and/or mucopurulent Scarriong:0-absent: 1-mild; 2- severe Crusting: 0-absent; 1-mild; 2-severe		

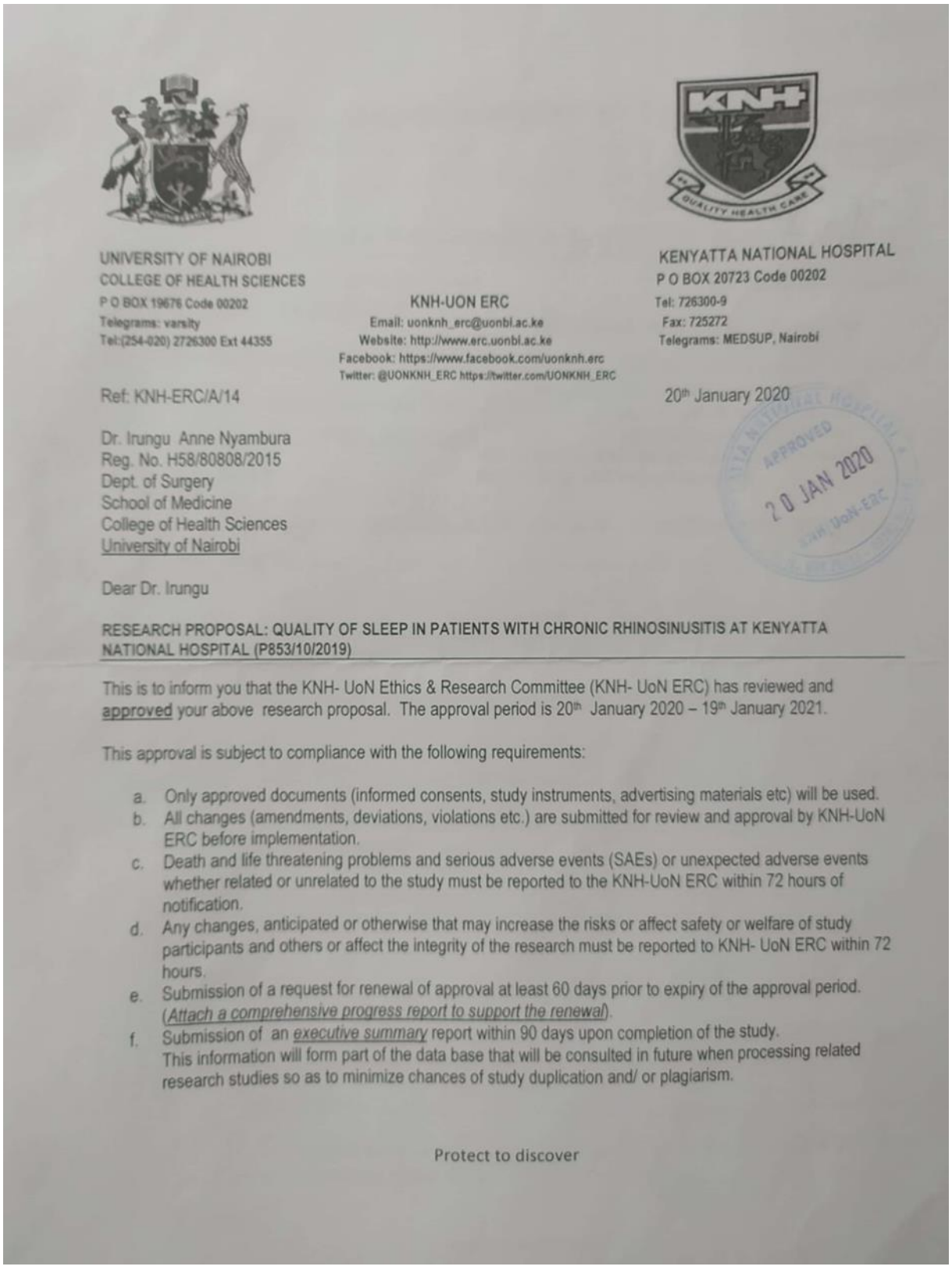
2: LUND-MACKAY SCORE OF CT SCAN

Paranasal sinuses	Right	Left
Maxillary (0,1,2) Anterior Ethmoid (0,1,2) Posterior Ethmoid (0,1,2) Sphenoid (0,1,2) Frontal (0,1,2) Ostio-meatal Complex (0,2) *		
Total		
Note: 0-without abnormalities; 1-partial opacification; 2-total opacification *0-no obstruction; 2-obstructed		

Appendix V: Cohen kappa

Cohen suggested the Kappa result be interpreted as follows: values ≤ 0 as indicating no agreement and 0.01–0.20 as none to slight, 0.21–0.40 as fair, 0.41– 0.60 as moderate, 0.61–0.80 as substantial, and 0.81–1.00 as almost perfect agreement.

APPENDIX VI: KNH-UoN ERC APPROVAL



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Ref: KNH-ERC/A/14

20th January 2020

APPROVED
20 JAN 2020
KNH-UoN-ERC

Dr. Irungu Anne Nyambura
Reg. No. H58/80808/2015
Dept. of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

Dear Dr. Irungu

RESEARCH PROPOSAL: QUALITY OF SLEEP IN PATIENTS WITH CHRONIC RHINOSINUSITIS AT KENYATTA NATIONAL HOSPITAL (P853/10/2019)

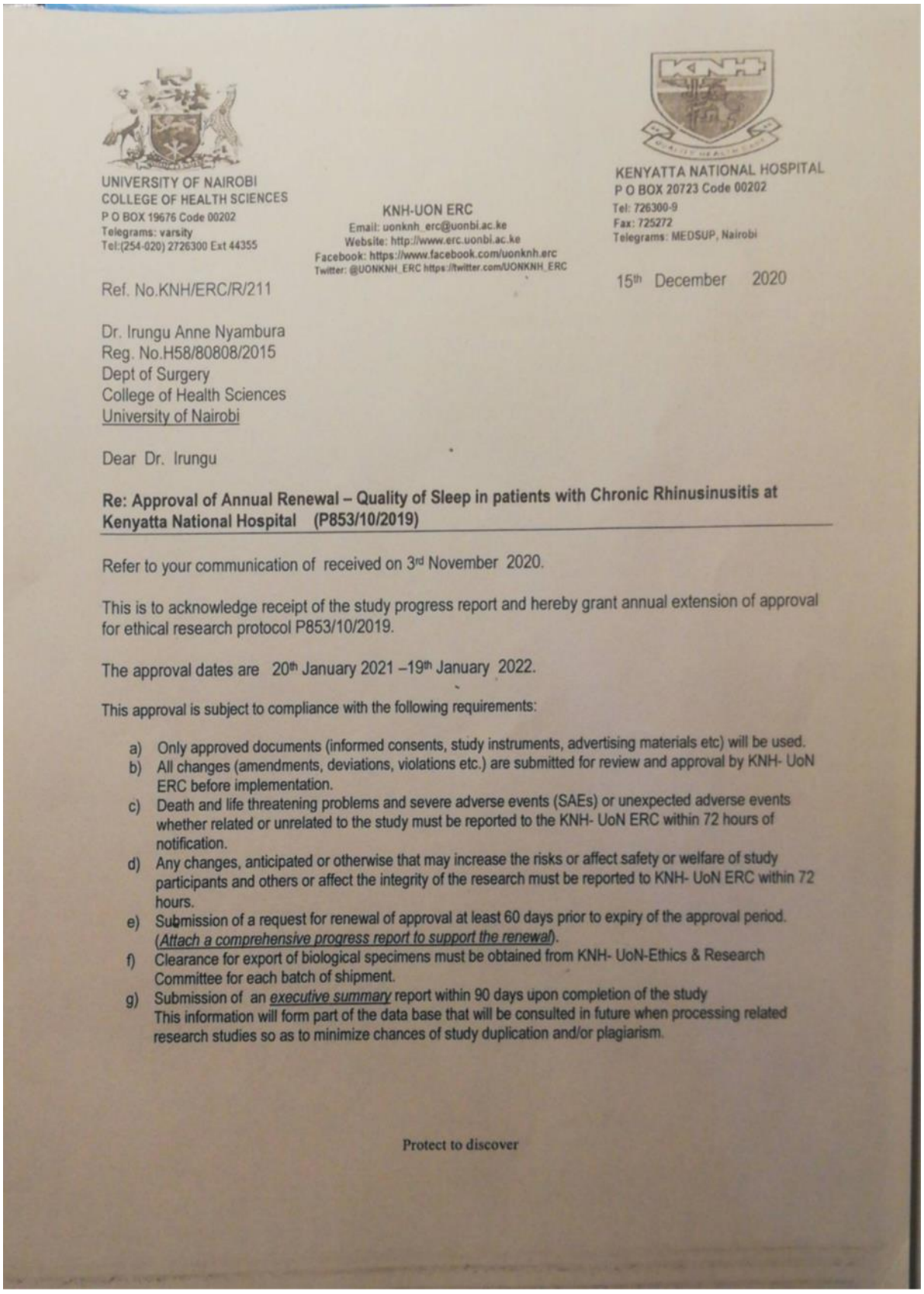
This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and approved your above research proposal. The approval period is 20th January 2020 – 19th January 2021.

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. 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*).
f. 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.

Protect to discover

APPENDIX VII: KNH-UoN ERC STUDY EXTENSION



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Ref. No.KNH/ERC/R/211

15th December 2020

Dr. Irungu Anne Nyambura
Reg. No.H58/80808/2015
Dept of Surgery
College of Health Sciences
University of Nairobi

Dear Dr. Irungu

Re: Approval of Annual Renewal – Quality of Sleep in patients with Chronic Rhinusinusitis at Kenyatta National Hospital (P853/10/2019)

Refer to your communication of received on 3rd November 2020.

This is to acknowledge receipt of the study progress report and hereby grant annual extension of approval for ethical research protocol P853/10/2019.

The approval dates are 20th January 2021 –19th January 2022.

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 severe 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) 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*).
f) Clearance for export of biological specimens must be obtained from KNH- UoN-Ethics & Research Committee for each batch of shipment.
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.

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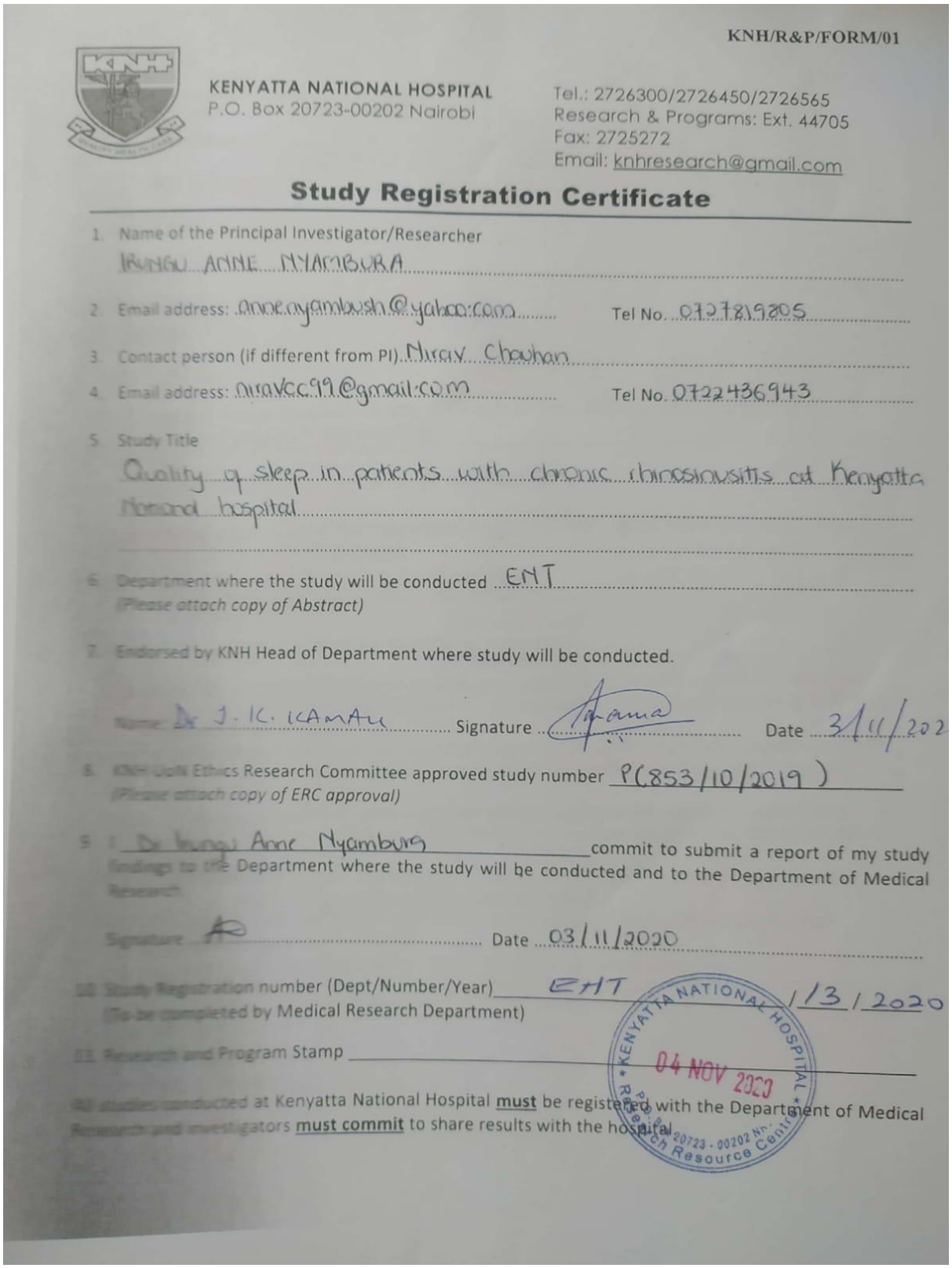
APPENDIX VIII: STUDY REGISTRATION



KNH/R&P/FORM/01

KENYATTA NATIONAL HOSPITAL
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Research & Programs: Ext. 44705
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Email: knhresearch@gmail.com

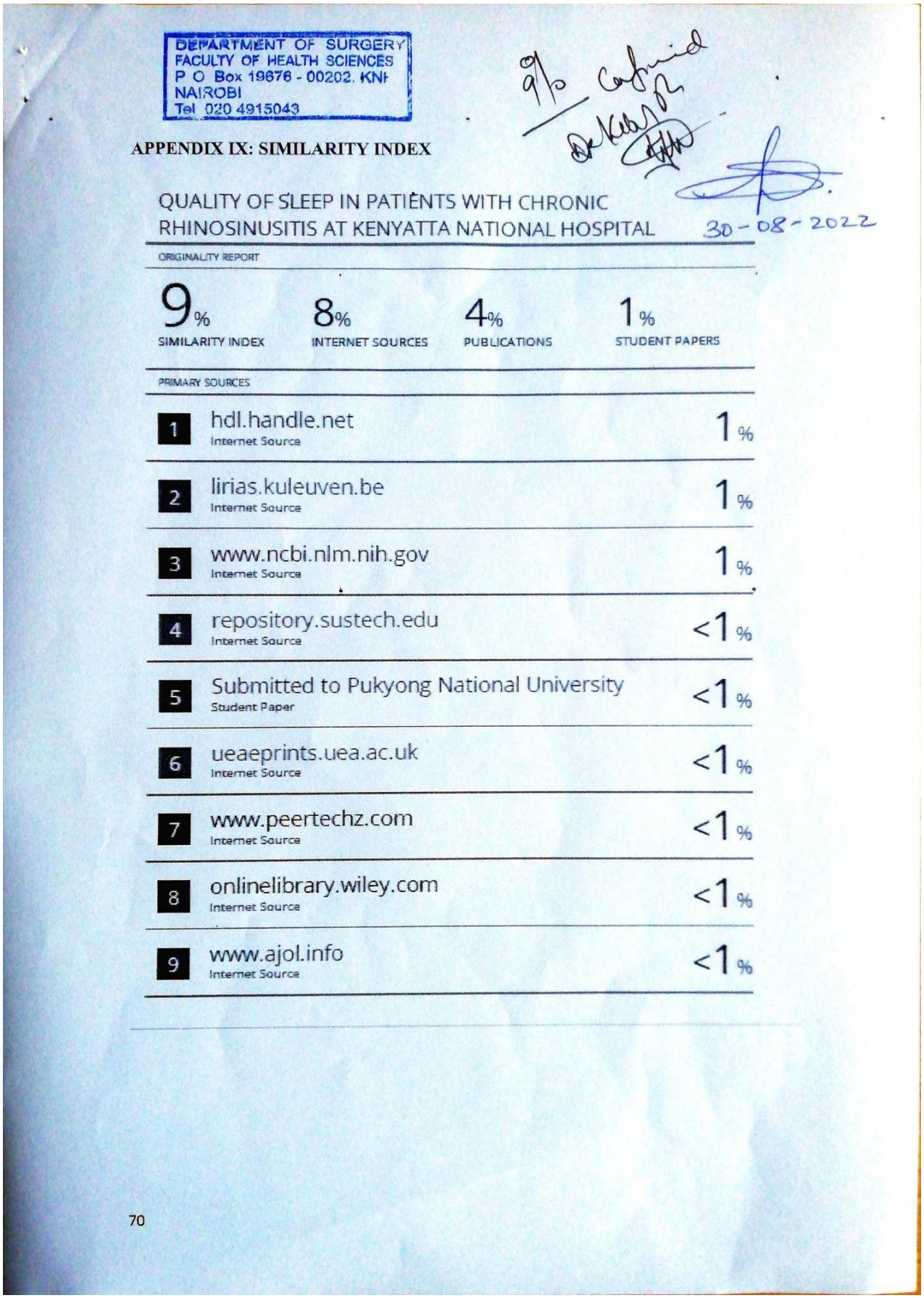
Study Registration Certificate

1. Name of the Principal Investigator/Researcher
IRUNGU ANNE NYAMBURA
2. Email address: anneayambush@yahoo.com Tel No. 0727819205
3. Contact person (if different from PI). Nirav Chauhan
4. Email address: niravcc99@gmail.com Tel No. 0722436943
5. Study Title
Quality of sleep in patients with chronic rhinosinusitis at Kenyatta National hospital
6. Department where the study will be conducted ENT
(Please attach copy of Abstract)
7. Endorsed by KNH Head of Department where study will be conducted.
Name Dr J. K. KAMAU Signature Date 3/11/202
8. KNH-UoN Ethics Research Committee approved study number P(853/10/2019)
(Please attach copy of ERC approval)
9. I Dr Irungu Anne Nyambura commit to submit a report of my study findings to the Department where the study will be conducted and to the Department of Medical Research
Signature Date 03/11/2020
10. Study Registration number (Dept/Number/Year) EMT /13/2020
(To be completed by Medical Research Department)
11. Research and Program Stamp

KENYATTA NATIONAL HOSPITAL
04 NOV 2020
P.O. Box 20723 - 00202 Nairobi
Research Resource Centre

All studies conducted at Kenyatta National Hospital **must** be registered with the Department of Medical Research and investigators **must commit** to share results with the hospital.

APPENDIX IX: SIMILARITY INDEX



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9% Cofirmed

APPENDIX IX: SIMILARITY INDEX

QUALITY OF SLEEP IN PATIENTS WITH CHRONIC RHINOSINUSITIS AT KENYATTA NATIONAL HOSPITAL

30-08-2022

ORIGINALITY REPORT

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SIMILARITY INDEX	INTERNET SOURCES	PUBLICATIONS	STUDENT PAPERS

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