UNIVERSITY OF NAIROBI

COLLEGE OF HEALTH SCIENCES

DEPARTMENT OF CLINICAL MEDICINE AND THERAPEUTICS

QUALITY OF SLEEP AND EXCESSIVE DAYTIME SLEEPINESS AMONG PATIENTS WITH EPILEPSY AT KENYATTA NATIONAL HOSPITAL.

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A DISSERTATION SUBMITTED IN PARTIAL FULFILLMENT OF THE DEGREE OF MASTER OF MEDICINE IN INTERNAL MEDICINE.

STUDENT DECLARATION

I ,Atieno Hariet Barbara ,do declare that this dissertation is my original work and has not been presented for a degree in any other institution.

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Thank you to the Almighty, all honor and glory belong to him.

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LIST OF ACRONYMS AND ABBREVIATIONS

ASM   Antiseizure medication

CBT-I   Cognitive Behavioral Therapy for Insomnia

ECG   Electrocardiogram

EDS   Excessive Daytime Sleepiness

EEG   Electroencephalogram

EMG   Electromyogram

ESS   Epworth Sleepiness Scale

FLE   Frontal Lobe Epilepsy

GABA   Gamma Aminobutyric Acid

IGE   Idiopathic Generalized Epilepsy

ICSD   International Classification of Sleep Disorders

KNH   Kenyatta National Hospital

LMIC   Low middle and income countries

MWT   Maintenance of wakefulness Test

MSLT   Multiple Sleep latency Test

NREM   Non-Rapid Eye Movement

PLWE   People living with epilepsy.

PSG   Polysomnography

PSQI   Pittsburgh Sleep Quality Index

QOLIE-10 Quality of Life in Epilepsy

QOL   Quality of Life

REM   Random Eye Movement

TLE   Temporal Lobe Epilepsy

UON   University of Nairobi

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ABSTRACT

Background

Patients living with epilepsy frequently report poor sleep quality and excessive daytime sleepiness which have been linked to seizure occurrence, seizure frequency and poor quality of life

Objective
To determine burden of Poor quality of sleep, excessive daytime sleepiness, and impact on quality of life in ambulatory patients with epilepsy.

Methods
The study was a descriptive cross sectional study carried out at Kenyatta National Hospital Neurology Outpatient clinic among ambulatory patients with epilepsy aged 13 years and above. Relevant sociodemographic and clinical data were collected with consent. Demographic characteristics, clinical characteristics, and epilepsy-related variables were summarized using frequency distributions and percentages. Global quality of sleep scores was summarized using frequency distributions either as good sleep (<5) and poor sleep (>5).The Prevalence of excessive daytime sleepiness and poor quality of life were determined. Associations between poor quality of sleep, excessive daytime sleepiness, epilepsy related variables and quality of life were assessed using Chi-square test at 95% confidence level. Probability values <0.05 showed statistical significance.

Results

The study, conducted between November and December 2022, involved screening 177 epilepsy patients, with 169 eventually being recruited. Out of these 56.2% were male and 43.8% were female with a mean age of 30.7±14.2 years. The duration of epilepsy for most of the participants was > 10 years (42.0%).Majority experienced generalised tonic seizures (72.8%) and 50.3 % had poor seizure control (≥ 1 seizure in last 4 weeks).One hundred and fifteen (68.0%, 95% CI=60.5-75.0%.) had poor sleep quality, and 60 (35.5%, 95% CI= 28.3-43.2%.) had excessive daytime sleepiness. The prevalence of poor quality of life was 41.4% (95% CI=33.9-49.2). No significant differences in seizure-related factors were found between participants reporting poor sleep quality or excessive daytime sleepiness, but those experiencing both had poorer quality of life.

Conclusion

There is a high prevalence of poor sleep quality and excessive daytime sleepiness among PLWE in Kenya and this negatively affects quality of life.

CHAPTER ONE: INTRODUCTION

Epilepsy is a neurological disorder affecting approximately 50 million people worldwide, with 80 percent of those affected living in Low middle-income countries (LMIC) (1) .The relationship between sleep and epilepsy is bidirectional as seizures can be triggered by poor sleep and seizure activity may affect sleep quality (2). Good-quality sleep is an essential and often overlooked component of overall health, but it is especially important for patients with epilepsy. Daytime sleepiness and poor quality of sleep are commonly reported among people living with epilepsy (PLWE) with incidences twice as common as in the general population (3,4).While sleepiness among patients with epilepsy is often blamed on antiseizure medication, it is crucial to consider factors beyond anti-seizure medication (ASM), such as evaluating the quality of sleep or for an underlying sleep disorder (5). Poor sleep quality and excessive daytime sleepiness are associated with severe quality of life impairment in epileptic patients (6). Direct impacts of seizures, side effects of ASM, psychiatric comorbidities, and underlying sleep disorders can all affect sleep architecture and subjective sleep quality (7).

A 2020 cross-sectional survey found that 53% of 123 adults with epilepsy had poor sleep quality, 50% had insomnia symptoms, and 32% had severe daytime sleepiness (8). A study in India found 24.6 % of people with epilepsy to have sleep disorders in comparison to controls 10.6 % (9). Research in Ethiopia found that 65.5 percent of people have poor sleep quality (10).

Studies on epilepsy in our setting have generated insights into quality of life and adherence to ASM, with sleepiness being the most common side effect (11). Despite the poor quality of life have persons with epilepsy and the link between poor sleep quality and epilepsy, the importance

of sleep-in patients with epilepsy has not been described in our environment ,a description of this relationship is thus necessary.

CHAPTER TWO: LITERATURE REVIEW

2.1 Epilepsy

The task group of the International League Against Epilepsy defines epilepsy as "at least two unprovoked (or reflex) seizures occurring within 24 hours of each other or One unprovoked (or reflex) seizure and a recurrence risk of at least 60% following two unprovoked seizures during the next ten years or an epilepsy syndrome has been diagnosed (12).

Epilepsy can occur due to altered extracellular ion balance, energy metabolism, receptor function, or transmitter uptake (13).

A seizure is an abnormal brain activity characterized by an imbalance between excitatory and inhibitory signals. It can be caused by various factors affecting different levels of brain function(14). During a seizure, there is an influx of calcium which leads to sodium ion influx and action potential generation. GABA receptors and chloride or potassium ion movement contribute to subsequent hyperpolarization. Seizure propagation occurs when neighboring neurons are recruited due to sufficient stimulation, spreading seizure activity through local cortical connections and long association pathways like the corpus callosum. The synchronized neuronal activity and high-frequency action potentials result in a spike-like pattern on EEG (13,14).

2.2 Sleep architecture

Sleep is a cyclic, active biological activity essential for survival accounting for a third of human life. It is characterised by alternation of two phases, non-rapid eye movement (NREM) and rapid eye movement (REM) sleep which occur in a certain order throughout sleep occurrence to complete 4-5 cycles (15).

Seventy-five to eighty percent of total sleep time is NREM and is further divided into three stages: N1, N2, and N3. These stages last anywhere from 5 -15 minutes or longer and repeat until REM sleep is reached. N1 serves as the transitional phase from wakefulness to sleep and lasts around 5 to 10 minutes (15).It can also occur during the transition from deep sleep to REM sleep. During this stage, muscle activity is still present, and individuals can be easily awakened. N2 is the transition from tiredness through light sleep to deep slow wave sleep characterized by slow brain waves and muscle relaxation. Adults spend approximately half of their night in stage 2.Towards the end of stage 2, the heart rate is slowed, and body temperature drops as the body prepares to enter stage.N3 is crucial for body repair and tissue restoration, lasting approximately 20 to 40 minutes (15,16).

REM sleep constitutes around 20 to 25% of total sleep time. It typically occurs every 90 minutes, and during this stage, brain activity is believed to be highly active. Not getting a full night's sleep can result in a shortened duration of REM sleep (17,18).

Factors that influence sleep in patients with epilepsy include the effect of antiseizure medication, seizures effect on sleep architecture, presence of undiagnosed sleep disorders, and inadequate sleep hygiene (7).

2.3 Link between Epilepsy and sleep

Sleep affects epilepsy in various ways. Sleep deprivation, interrupted sleep and the NREM stage of sleep have all been shown to influence seizure activity. Possible mechanisms include the shared thalamocortical networks leading to increased seizure frequency. In contrast, rapid eye movement (REM) sleep appears to have a mitigating effect on epileptic activity. REM sleep has been found to reduce the occurrence of abnormal brain waves and decrease the spike in EEG (15,16)

Effect of Seizures on Sleep.

Different types of seizures have varying impacts on sleep. Focal epilepsies cause more disruption compared to idiopathic generalized epilepsy (IGE).Temporal lobe epilepsy (TLE) is associated with reduced sleep efficiency, increased stage shifts, and more awakenings. Even in seizure-free conditions, interictal temporal lobe epileptic discharges have been found to disturb sleep more than frontal lobe epilepsy (FLE) and IGE. Objective assessments using polysomnography (PSG) indicate that interictal epileptiform discharges (IEDs) tend to increase during N3 non-rapid eye movement (NREM) sleep, while seizures are more common in lighter NREM sleep (7).

The shift from one sleep stage to another in patients with epilepsy is also altered leading to frequent awakenings which alter the sleep architecture. Furthermore, uncontrolled seizures during sleep can result in memory impairments and excessive daytime sleepiness (18)

Effect of antiseizure medication on sleep.

Antiseizure medication (ASM) has varying effects on sleep, having both beneficial and detrimental effects. Beneficial effects are thought to be a direct effect of the drugs on suppressing neuronal excitability, stabilizing seizures, and hence improving sleep. On the downside, ASM is commonly known to produce daytime fatigue and sleepiness, more so with first -generation ASM.A study by Mativo et al recognized sedation as the most common side effect of ASM with a prevalence of 73% (11). The use of 1st generation ASM i.e., barbiturates and benzodiazepines decrease REM and slow- wave sleep. They also fragment nocturnal sleep by increasing nighttime arousals and stage transitions, leading to sleepiness during the day. Patients receiving polytherapy often have poor sleep quality and excessive daytime sleepiness than patients receiving monotherapy (16).

Clinicians should therefore recognize how an ASM affects sleep quality to create a regimen that does not disrupt a patient's nocturnal sleep (19).

2.4 Sleep quality and excessive daytime sleepiness

The revised International Classification of Sleep Disorders (ICSD-3) was published by The American Academy of sleep medicine in 2014. This classification comprises seven major categories, which include Insomnia, sleep-related breathing disorders, central hypersomnolence disorders, circadian rhythm, sleep-wake disorders, sleep-related movement disorders, parasomnias, and other sleep disorders

The most prevalent sleep complaints among epileptic patients are poor sleep quality, insomnia, and excessive daytime sleepiness (EDS) (20).

Prevalence of Poor Quality of Sleep in Epilepsy

Sleep quality is a person's satisfaction with the sleep experience, taking into account factors such as sleep initiation, sleep maintenance, sleep quantity, and wakefulness (21). In a cross- sectional study in Spain among 123 patients, 53.6% had poor sleep quality. Poor seizure control is seen in these patients more than in those with good sleep quality (78.1% vs. 42%) (8).

Çilliler AE et al described a prevalence of 42.7% of poor sleep quality in 75 PLWE. Poor sleep quality was linked to fatigue and daytime sleepiness (22). In 2011 Nai-Ching Chen et al in Taiwan found an overall poor sleep quality of 50% in PLWE than in controls matched for age and sex. Key factors contributing to poor quality of sleep included polytherapy, poor seizure control, and partial seizure type (16).

A systematic review and meta-analysis of 25 studies where 2964 patients and 5232 controls were included. When compared to controls, epilepsy patients scored higher on the Pittsburgh sleep quality index (PSQI) (pooled mean difference: 1.27 [95 percent CI: 0.76, 1.78; P0.001]). The study's participants were on average 40 years old, with 50.4 percent of them being female. Mean differences in sleep quality between patients and controls were not influenced by age or sex (23). In an institutional based cross-sectional study done in Addis Ababa, Ethiopia in 2019 among 423 patients with epilepsy a prevalence of 65.4 % of poor sleep quality using the PSQI with an average age of 27 years and 55.7% being males was found (10).

Prevalence of Excessive daytime sleepiness.

EDS is characterized by daily episodes of uncontrollable desire to sleep, or daytime sleep lapses (24). Diagnosing EDS can prove to be difficult since it is easily misinterpreted as fatigue /exhaustion however teasing out the two can be made possible with adequate history i.e., fatigue improves with rest without necessarily having the desire to fall asleep, whereas EDS occurs during moments of rest.

EDS has been documented in PLWE in studies with mixed outcomes. In a 2006 study, Khatami et al discovered that the frequency of EDS was not higher in PWE than in controls (25). In a case-control research in 2016, Gammino et al assessed EDS in patients with epilepsy and found daytime drowsiness was higher in comparison to controls, however ,this was not statistically significant (26). Piperidou C et al assessed 124 patients in a cross sectional multicentre study in Greece and demonstrated a prevalence of 16.9% in PLWE (6). Similarly in Taiwan Chen et al found a prevalence of 20% of EDS in PLWE against 7% in controls matched for age and sex (27).In a systematic review by Giorelli AS of 34 studies conducted between 2002 and 2012, the majority of

which were Questionnaire based and cross sectional , EDS prevalence varied from 10% to 47.5% and was higher in developing countries (28). It is probable that discrepancies in EDS in epilepsy patients are due in part to biases in patient selection, as well as the use of different tests, sample sizes, and treatment types (mono-poly-therapy).

Risk factors of poor sleep quality and excessive daytime sleepiness.

1)Clinical factors

    a) Anti-seizure medication

The type, number, and timing of ASM have been shown to influence the quality of sleep among PLWE.1st generation ASM i.e., barbiturates, phenytoin ,and phenobarbital are associated with poor sleep quality. Additionally, patients on polytherapy often have poor sleep quality than patients on monotherapy (7,16).

    b) Seizure frequency

Poor seizure control/increased seizure frequency is associated with poorer sleep quality than good seizure control (6,27).

    c) Presence of comorbidities

The presence of a co-existing comorbidity other than epilepsy i.e., psychiatric, or medical conditions increases the odds of having poor sleep quality by 2-fold (10,23).

d) Seizure type

Poor sleep quality is more likely to occur in focal and temporal lobe epilepsy than in generalized epilepsy (7). This has been linked to an increase in inter epileptiform discharges among patients with focal epilepsy.

2) Behavioral factors and Environmental factors

Behavioral factors including Alcohol, cigarette, and sleep hygiene practices i.e., bedtime, watching tv and ,use of smartphone before bed have been known to influence the quality of sleep and are dependent on the patient. Environmental factors that include light, noise level, and temperature also influence sleep.

3) Demographic

In a 2016 meta-analysis by Melanie B et al Age did not influence sleep disturbance, this was also seen in the case -control study by Gutter T. This could be explained by the lack of epilepsy studies on age -dependent influence on sleep (23,29).

The influence of sex and employment on sleep has yielded conflicting results. Chen et al found no influence of gender on sleep, as did a study by Maka et al (27,30).

2.5 Sleep and epilepsy related Quality of Life

Health-related quality of life (HRQOL) encompasses physical health, psychological well-being, and social relationships. Epilepsy is a chronic illness that has a substantial detrimental influence on people's daily lives (31).

The main goal of epilepsy management is reducing seizure burden and improving quality of life. The frequency of seizures plays a significant role in determining the quality of life. When individuals with epilepsy are free from seizures, their health-related quality of life (HRQL) is comparable to that of the general population (32).

Kinyanjui et al demonstrated a significantly lower mean QOL among PLWE attending Kenyatta National Hospital (KNH) Neurology outpatient clinic at 49.90% (p<0.01) vs normal controls at 77.60%.

In comparison to epileptic patients who do not have sleep disturbances, epileptic patients with sleep disturbances have a lower quality of life (33).Patients living with epilepsy and EDS have been shown to have lower and total scores across all domains of epilepsy specific quality of life assessments (6).

For the measurement of HRQOL, epilepsy-specific tools are available. These instruments include the Quality of life in epilepsy (QOLIE-89), QOLIE-31 ,and QOLIE-10. By utilizing quality of life measurements, patients and healthcare providers can identify specific areas of concern and make necessary adjustments to treatment plans accordingly (34).

The Quality of Life in Epilepsy (QOLIE)-10 was derived from the QOLIE-30. The QOLIE-10 comprises seven components: seizure worry, overall QOL, emotional well-being, energy-fatigue, cognitive functioning, medication effects (physical effects and mental effects) ,and social function (work, driving, social function). The QOLIE-10 has been validated for epilepsy patients and measures the quality of life directly from the patient's perspective. The QOLIE-10 is a "concise questionnaire that lowers respondent fatigue and may be administered in an ambulatory neurology clinic" (34,35).

Implications of Poor sleep quality

In many epilepsies, seizures have sleep–wake and circadian patterns, disrupting sleep and circadian rhythms. Sleep deprivation is an aggravating factor for seizures, setting up a vicious cycle that can lead to disease progression and possibly death from epilepsy. The most common seizure triggers are emotional stress, sleep deprivation, and exhaustion. Breakthrough seizures are frequently triggered by a lack of sleep. Patients who have generalized seizures are more vulnerable to sleep deprivation, fatigue, and flickering light than those who have partial seizures (36).

Possible interventions to improve sleep in epilepsy.

a) Sleep hygiene

Sleep hygiene is the habits/behaviors and environment that influence the duration and quality of sleep. Poor sleep hygiene is associated with poor QoL independent of sleep quality (37). Sleep hygiene measures have the potential to significantly improve sleep quantity and quality. These measures are especially effective for sleep deprivation and may be somewhat effective for chronic insomnia (38). All patients who have sleep problems should be counseled on proper sleeping habits.

c) Cognitive Behavioral therapy

CBT-I (Cognitive Behavioral Therapy for Insomnia) is a type of cognitive behavioral therapy that was created primarily to help people with sleep problems-I may be suitable for patients with epilepsy. Sleep disturbances have been connected to habits such as a preference for nocturnal activities, sleep timing delays, and sleep anxiety. CBT-I leads to better sleep hygiene, sleep quality and ultimately quality of life (36).

c) ASM Prescribing

This includes avoiding polytherapy by streamlining the ASM regimen, prescribing ASM with the highest dose administered at night, and employing extended-release formulations.

Identifying causal factors, treating underlying sleep disturbances, and adjusting sedating ASM are the mainstays of EDS treatment in epilepsy patients. Removing sedating ASM from a patient's regimen may be helpful when ASM is suspected of causing daytime sleepiness

2.6 Sleep Quality Measures

Valid subjective and objective measures should be used to investigate sleep habits. Polysomnography (PSG) is the gold standard for objectively assessing sleep A PSG uses an Electroencephalogram(EEG),electrooculogram(EGO),electromyogram(EMG), electrocardiogram(ECG), pulse oximetry, as well as airflow and respiratory effort. However, it is expensive, labor intensive, and not readily available.

Measuring Quality of Sleep Using the PSQI.

The Pittsburgh sleep quality Inventory is a tool used to evaluate subjective sleep quality over the preceding month. It is quick, simple to administer and score, making it an excellent tool for assessing sleep quality. It consists of 24 questions, out of which 19 are self-reported and 5 require feedback from a room or bed partner. Answers are graded from 0 (worst) to 3 (best) on a Likert scale. Poor sleepers are given a score of equal to or more than five while good sleepers score less than five. It has a sensitivity and specificity of 89.6% and 86.5% respectively for detecting cases of Poor sleep (21).

The PSQI is a validated tool for measuring the quality of sleep-in chronic illness. Kotronoulas et al in Greece studied 209 patients with cancer receiving chemotherapy using the Greek version (GR-PSQI), an internal consistency of 0.76 and a test-retest reliability of 0.82 was reported (39). A study by Hita-Contreras et al in Spain in a population of 138 women with fibromyalgia demonstrated an internal consistency of 0.805 and test retest probability of 0.806 (40). Salahuddin et al in Ethiopia utilized the PSQI in screening a population of 311 adults, they found a moderate internal consistency of 0.59 with a sensitivity of 82%, and a specificity of 56.2% (41).In our setting PSQI has been utilized in various studies. Sokwalla et al found a prevalence of 53 % using the PSQI to evaluate sleep quality among patients with diabetes (42).

Jivanji et al evaluated sleep quality in patients with kidney disease on maintenance hemodialysis demonstrating a prevalence of 69.6% using the PSQI (43).

The University of Pittsburgh owns the copyright of the PSQI and allows its use without charge only for non-commercial research and educational purposes.

Measuring EDS using the Epworth Sleepiness Scale.

EDS can be studied subjectively or objectively. The Epworth Sleepiness Scale (ESS), a self-administered tool, is used to assess subjective sleepiness. It consists of eight sleeping scenarios scored from zero to three for every question. Higher ESS scores indicate the tendency to fall asleep in everyday life. It takes no more than 2 or 3 minutes to complete the questionnaire. Scores over 10 are regarded as abnormal, with a maximum of 24 points. It has a sensitivity of 94% and specificity of 100%, with strong internal consistency and construct validity by Cronbach's alpha (0.73– 0.86) enabling it to discriminate excessive daytime sleepiness from normal (44). Its

effectiveness has been demonstrated in Africans, as well as in studies with epilepsy patients (45,46).

The Multiple Sleep Latency Test (MSLT) and Maintenance of Wakefulness Test (MWT) measure sleepiness objectively. Despite having a high-test retest reliability, the MLST is a difficult, time-consuming test that usually requires the use of polysomnography. MWT on the other hand is costly.

2.7 Study Justification

Patients with Epilepsy seen at the KNH neurology clinic account for 16.6% of all patients seen, making it the most common neurological condition encountered (11).

Seizure management is only one facet of epilepsy treatment. Sleep as part of epilepsy patients' overall care should be assessed. Recognizing and treating comorbid sleep disorders improves seizure control and ultimately, quality of life.

Despite the high prevalence and negative consequences of poor sleep quality and daytime sleepiness in epilepsy patients, no local studies have been published.

This study will form a baseline strategy for management.

2.8 Research question

What is the burden of poor quality of sleep and excessive daytime sleepiness among persons living with epilepsy at the KNH neurology outpatient clinic?

General objective

To assess the prevalence of Poor quality of sleep and excessive daytime sleepiness and impact on quality of life among persons with epilepsy at The Kenyatta National Hospital, Neurology outpatient clinic.

Primary Objectives.

- To determine the prevalence of poor quality of sleep-in persons with epilepsy using the Pittsburgh sleep quality index (PSQI).
- To determine the prevalence of excessive daytime sleepiness using the Epworth sleepiness scale (ESS).

Secondary objectives

- To determine the quality of life in persons with epilepsy using the Quality of life in epilepsy inventory-10 (QOLIE-10).
- To determine the association between poor quality of sleep, excessive daytime sleepiness, and epilepsy related variables (Type of antiseizure medication, duration of treatment, seizure frequency, seizure type)
- To determine the association between poor quality of sleep, excessive daytime sleepiness, and quality of life in persons with epilepsy.

CHAPTER THREE: METHODOLOGY

3.1 Study design

Cross sectional, Hospital based descriptive study.

3.2 Study site

This study was conducted at The Kenyatta National Hospital neurology outpatient clinic. KNH is the largest national referral hospital in Kenya located in Nairobi, the capital city. The neurology clinic runs every Monday and Thursday from 8am-2pm.Patients have various neurological conditions including epilepsy, stroke, and Multiple sclerosis, among others. About ten patients with epilepsy are seen per visit. Consultant neurologists and Internal medicine residents run the clinic.

3.3 Study population

Persons with epilepsy on follow up at KNH neurology outpatient clinic.

Inclusion criteria

- Persons > 13 years of age

- Persons with epilepsy for at least 1 year

- Persons on ASM to control their seizures for 6 months

Exclusion criteria

- Patient on shift work

Sample size estimation

Using the prevalence of poor quality of sleep and of excessive daytime sleep in Africa and substituting it in Fisher's formula (Rosner Bernard, 2010) at a margin of error of 7.5% and a confidence interval of 95% .The margin of error acceptable can range between 4-8 %.The epilepsy population is highly heterogenous and so the higher margin of error was chosen to accommodate the inherent variability and ensure that the sample size is manageable and attainable. The higher of the two sample sizes was selected as shown:

$n = Z^2 * P (1 - P) / d^2$

Where.

n- Sample size

z- Standard normal deviation for α corresponding to 95% CI.

p- Estimated Prevalence (65.4 %)

d- Degree of Precision set at 0.075 (7.5%)

In Ethiopia, the prevalence of poor quality of sleep among patients with epilepsy was reported at 65.4% in 2019 (Adem K et al., 2019). Substituting this in the formula we get a sample size of:

$n = (1.96)^2 (0.654) (1-0.654) / (0.075)2$

$= 0.824622 \backslash 0.005625 = 154$

The required sample size is 154 participants.

In Nigeria, the prevalence of EDS among epileptic patients was reported to be 17% in 2015 (Komolafe et al., 2015). Substituting this in the formula we get a sample size of:

$n = (1.96)^2 (0.17) (1-0.17) / (0.075)2$

$= 0.542049 \backslash 0.005625 = 97$

The required sample size is 97 participants.

Overall, the minimum sample size was 154 participants. After a 10% markup to cover missing data and non respondence, 169 participants were required.

Participant recruitment process

Consecutive sampling was used to recruit participants.

Patient selection

- The primary investigator perused all the files of patients presenting to the neurology clinic.

- Those with epilepsy were identified and a rapport was formed. Those who agreed to take part in the study were asked to provide informed consent.

- We retrieved information such as demographics, current therapy, type of seizure and length of illness from the file. To ensure completeness of data ,unavailable information was obtained directly from the patient.

- Each patient enrolled completed the self-administered questionnaires ,the PSQI,ESS and QOLIE-10 questionnaires. Those unable were assisted by the PI and research assistants.

3.4 Data collection methods

Data on social, demographic, epilepsy- related variables, Quality of sleep and excessive daytime sleepiness was collected using questionnaires .The duration of epilepsy, current antiseizure drugs, and comorbid medical conditions were obtained either from the patient directly or from their clinical records.

This was followed by anthropometric measurements which include height, weight, and neck circumference.

The patient's height was measured using a tape measure while the patient looked straight ahead. The head plate was adjusted until it made contact with the patient's head, and the value obtained was recorded to the nearest centimeter. Weight was measured using a well-calibrated scale, with the patient wearing light clothing and no shoes. The BMI was calculated by dividing the weight in kilograms by the height in meters squared.

The neck circumference was measured using a tape measure placed below Adam's apple.

Quality of sleep was estimated using The Pittsburgh Sleep Quality Index

Excessive Daytime Sleepiness was estimated using The Epworth Sleepiness Scale.

Quality of life evaluated using quality of life in epilepsy inventory (QOLIE-10)

Definition of Study variables

- Age- Number of years documented or reported from date of birth.

- Sex- Male or female

- Marital status- Single, Married, Separated, Divorced, widowed.

- Education-Recorded as highest level attained.

- Current treatment-Defined as ASM used in last six months.

- Duration of Epilepsy-Time interval from Epilepsy diagnosis to current clinic follow up.

- Seizure type-As documented in the file Focal, Generalised tonic clonic, Absence and Unclassified

- Seizure control-Poor control ≥ 1 seizure in last 4 weeks

  Good control < 1 seizure in last 4 weeks

- Quality of sleep- Good or Poor-quality sleep based on the PSQI global score as follows :

  <5 related to good sleep quality and >5 related with poor sleep quality.

- Excessive daytime sleepiness-Risk of dosing off as assessed by the ESS.A score >10 is considered abnormal.

- Quality of life in epilepsy – Defined using QOLIE-10 where lower scores indicate better quality of life.

- Neck circumference –Abnormal neck circumference recorded as

  - >39.5 cm in men

  - >36.5 cm in women.

- BMI- Recorded as

  Underweight -<18.5 kg/m2

  Normal ->18.5-24.9 kg/m2

  Overweight ->25-29.9 kg/m2

  Obesity- > 30 kg/m2

3.5 Quality assurance

The use of validated questionnaires that were translated to Swahili.

Training of research assistants prior to onset of study on patient safety and taking required anthropometric measurements.

Use of well calibrated scales and tape measures that were assessed as necessary.

Data management

Data collection and validation

The principal investigator collected data relevant to the study while adhering to the research protocol. The PI reviewed all completed forms to ensure accuracy and completeness.

Data entry

Data was entered in a password protected Microsoft Excel 2013. Various categories were defined in the template i.e., name (field name), type (character or numeric).

Data cleaning

Questionnaires were filed and preserved in secure cabinets. Microsoft Excel was used to tidy up the data. Data was cleaned and validated. A dataset free of errors was saved on a hard drive and analyzed in STATA.

Data analysis

The Socio-demographics such as Gender, age was summarized using descriptive statistics and results presented in frequency distribution tables and charts using proportion for categorical variables and mean, standard deviation, interquartile range for continuous variables. Global quality

of sleep scores was computed and summarized using frequency distributions as good sleep (<5) and poor sleep (>5).

The prevalence of excessive daytime sleepiness and poor quality of life were determined by calculating the percentage of cases with excessive daytime sleepiness and poor quality of life.

The median QOLIE-10 score for the population was calculated and used as cut-off for quality of life. Patients with a median score less than the median for the population were considered to have good quality of life. Scores equal to or higher than the median indicated poor quality of life. The same analytic approach was used to evaluate specific quality of life domains (i.e., effects of epilepsy, mental health).

Associations between poor quality of sleep, EDS, and epilepsy related variables and poor quality of sleep and quality of life was determined using Chi-square test at 95% confidence level. Probability values <0.05 showed statistical significance
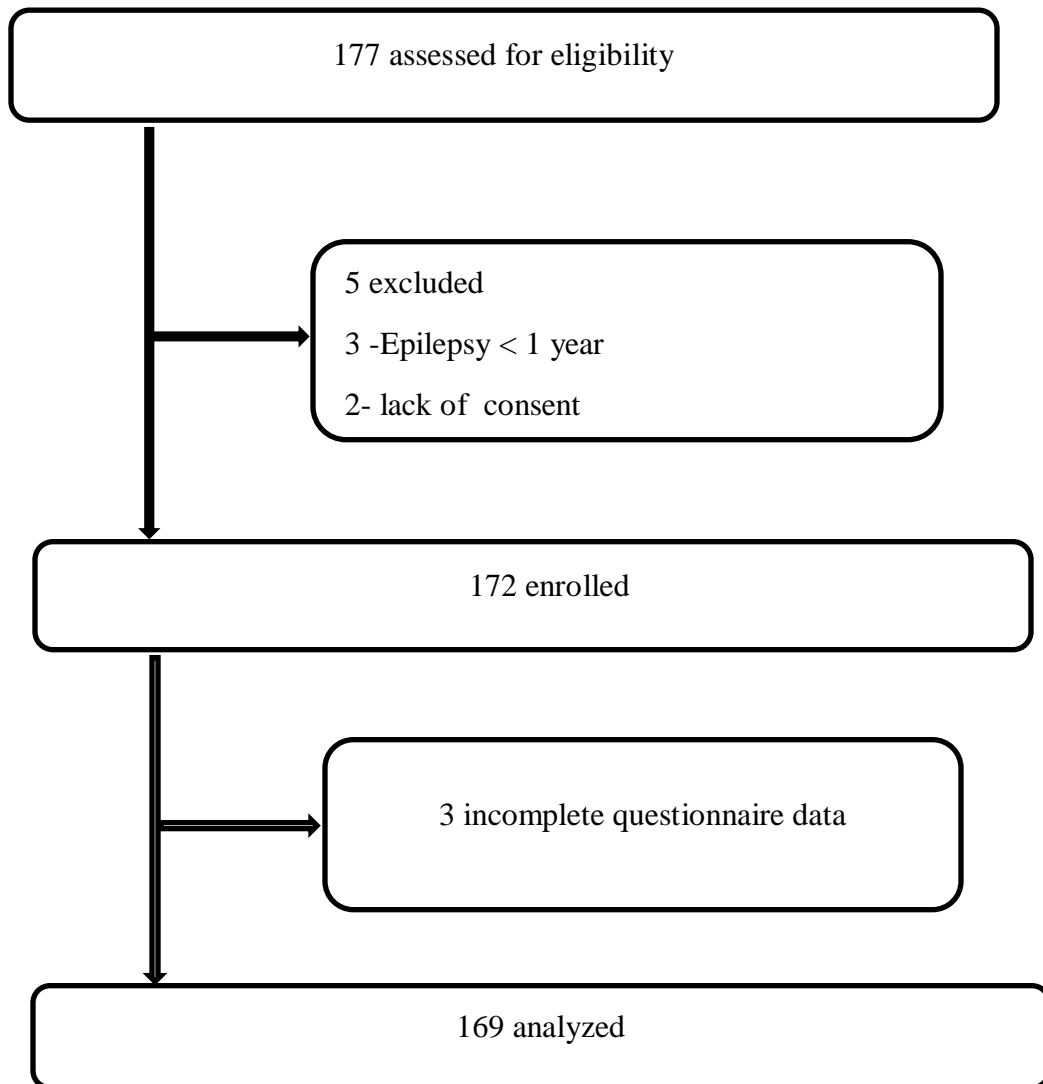
3.6 Ethical considerations

This study was conducted with the approval of the Department of Clinical Medicine and Therapeutics and the UON/KNH Ethics and Review Committee. Prior to participation, potential participants were verbally briefed on the study and given all necessary information. Additionally, written study information and consent forms were provided in both English and Swahili. Participants were given sufficient time to review the information and were encouraged to ask questions or express any concerns. For participants under the age of 18, a consent form for their parents or guardians was also provided. Participation was completely voluntary, and patients who declined to participate did not face any discrimination. Patient care remained uninterrupted

throughout the study, and participants were free to withdraw from the study without any prejudice. All patient data was treated with strict confidentiality.

CHAPTER FOUR: RESULTS

This was a questionnaire based, cross sectional study carried out at Kenyatta National Hospital Neurology outpatient clinic from November 2022-December 2022.Out of the 177 participants assessed for eligibility,5 did not meet the inclusion criteria. The remaining 172 were enrolled into the study. Three submitted incomplete forms leaving 169 who were included in the analysis.

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│            177 assessed for eligibility              │
└─────────────────────────────────────────────────────┘
        │
        │              ┌──────────────────────────────┐
        │              │  5 excluded                  │
        ├─────────────▶│  3 -Epilepsy < 1 year        │
        │              │  2- lack of  consent         │
        │              └──────────────────────────────┘
        │
        ▼
┌─────────────────────────────────────────────────────┐
│                  172 enrolled                        │
└─────────────────────────────────────────────────────┘
        │
        │              ┌──────────────────────────────┐
        ├─────────────▶│  3 incomplete questionnaire  │
        │              │            data              │
        │              └──────────────────────────────┘
        ▼
┌─────────────────────────────────────────────────────┐
│                  169 analyzed                        │
└─────────────────────────────────────────────────────┘
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Demographic data and clinical characteristics

One hundred and sixty-one (169) patients with a mean age of 30.7±14.2 years, age range of 13-85 years were evaluated. The majority were males (56.2%), single (68.0%), urban residents (76.9%). Most had primary education (39.6%), were employed (36.1%), had normal neck circumference (78.1%) and had normal body mass index (BMI) (54.4%). The most common comorbidities were hypertension (11.2%), cerebral palsy (3.0%), asthma (2.4%) and diabetes (1.8%,) (Table 1).

Table 1. Demographic and clinical characteristics of persons living with epilepsy.

Demographic characteristics	Categories	Frequency (%)
Gender	Female	74 (43.8)
	Male	95 (56.2)
Marital status	Married	50 (29.6)
	Single	115 (68.0)
	Separated/divorced/widowed	4 (2.4)
Residence	Urban	130 (76.9)
	Rural	39 (23.1)
Education level	No formal education	7 (4.1)
	Primary	67 (39.6)
	Secondary	55 (32.5)
	College/University	38 (22.5)
	Special school	2 (1.2)
Employment status	Employed	61 (36.1)
	Unemployed	59 (34.9)
	Student	49 (29.0)
Neck circumference	Normal	132 (78.1)
	Increased	37 (21.9)
Body Mass Index	Underweight	18 (10.7)
	Normal	92 (54.4)
	Overweight	33 (19.5)
	Obese	26 (15.4)
Comorbidities	Hypertension	19 (11.2)
	Cerebral palsy	5 (3.0)

Asthma		4 (2.4)
Diabetes		3 (1.8)
Mood disorder		3 (1.8)
Others*		4 (2.4)

*** Attention-deficit/hyperactivity disorder, autism, myelodysplastic syndrome, and rheumatoid arthritis***

Epilepsy related characteristics

The duration of epilepsy for most of the participants was > 10 years (42.0%). Around 30.8% had epilepsy for 5-10 years, while 27.2% had epilepsy for < 5 years. The majority were experiencing Generalized Tonic-Clonic (GTC) seizures (72.8%) and 50.3 % had poor control with ≥ 1 seizure in the last 4 weeks .The most common ASM medication that was being prescribed were carbamazepine (65.1%), sodium valproate (40.2%), and Levetiracetam (22.5%) (*Table 2*)

Table 2. Seizure characteristics of persons living with epilepsy

Seizure characteristic	Categories	Frequency (%)
Duration of epilepsy, years	< 5 years	46 (27.2)
	5-10 years	52 (30.8)
	>10 years	71 (42.0)
Seizure type	Generalized Tonic-Clonic	123 (72.8)
	Unclassified	36 (21.3)
	Focal	7 (4.1)
	Absence	3 (1.8)
Seizure control	Good-<1 in last 4 weeks	84 (49.7)
	Poor- ≥1 in the last 4 weeks	85 (50.3)
Type of ASM medication	Carbamazepine	110 (65.1)
	Sodium valproate	68 (40.2)
	Levetiracetam	38 (22.5)
	Phenytoin	16 (9.5)
	Phenobarbital	14 (8.3)
	Clonazepam	10 (5.9)
	Lamotrigine	8(4.7)
Monotherapy		88(52.1)
Combination therapy		81(47.9)

Other medications*	43(25.4)

Ace/Arb (11),CCB (9)),Thiazide diuretics (10),antipsychotics (7), B blockers (2) Diabetes drugs (2),statin

(1)bronchodilator(1)

Table 3.Combination therapy ASM

Carbamazepine, sodium valproate (33)
Carbamazepine, levetiracetam (11)
Carbamazepine, phenytoin (5)
Carbamazepine, phenobarbital (4)
Carbamazepine ,clonazepam (1)
Carbamazepine ,lamotrigine (1)
Sodium valproate, levetiracetam (4)
Sodium valproate, clonazepam (2)
Sodium valproate, phenytoin (2)
Levetiracetam, lamotrigine (1)
Levetiracetam, clonazepam (1)
Levetiracetam, Phenobarbital (1)
Phenytoin, Phenobarbital (2)
Sodium valproate, carbamazepine, clonazepam (3)
Sodium valproate ,carbamazepine, phenobarbital (2)
Sodium valproate, Carbamazepine, levetiracetam (1)
Sodium valproate, Phenobarbital, clonazepam (1)
Sodium valproate, phenobarbital, lamotrigine (1)
Sodium valproate, Levetiracetam, clonazepam (1)
Sodium valproate, levetiracetam, phenytoin (1)
Carbamazepine ,levetiracetam, clonazepam (1)
Carbamazepine, levetiracetam ,lamotrigine (1)
Levetiracetam ,lamotrigine, phenobarbital (1)

Sleep Quality and Excessive daytime sleepiness.

Primary Objective 1

Prevalence of poor quality of sleep-in persons with epilepsy using PSQI

Using a cut-off score of 5, the prevalence of poor sleep quality was 68.0%, 95% CI=60.5-75.0%.
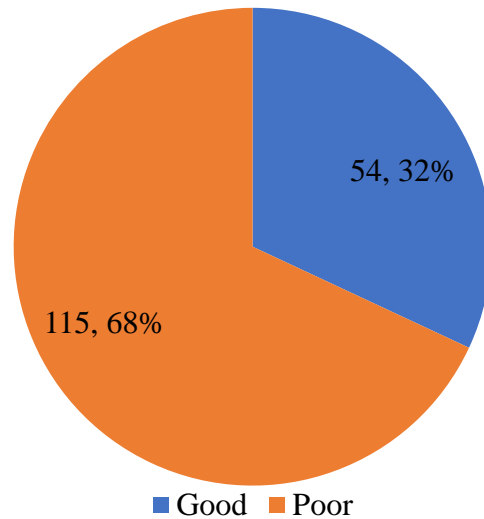

Figure 1. Prevalence of poor quality of sleep-in persons with epilepsy using PSQI

Overall, 72.2%, 62.7%, 50.3%, 57.4%, 87.0%, and 72.8% reported somewhat to high dysfunction in subjective sleep quality, sleep latency, sleep duration, habitual sleep efficiency, sleep disturbances, and daytime dysfunction. Only 11.2% reported somewhat to high dysfunction in the use of sleep medication. *(Table 4)*

Table 4. Pittsburgh Sleep Quality Index (PSQI) component scores

PSQI domains	Level of dysfunction			
	None 0 (n %)	Somewhat 1 (n%)	Moderate 2 (n%)	High 3 (n %)
Subjective sleep quality	47(27.8)	98 (58.0)	16 (9.5)	8 (4.7)
Sleep latency	63(37.3)	48 (28.4)	26 (15.4)	32 (18.9)
Sleep duration	84(49.7)	46 (27.2)	33 (19.5)	6 (3.6)
Habitual sleep efficiency	72(42.6)	39 (23.1)	27 (16.0)	31 (18.3)
Sleep disturbances	22(13.0)	116 (68.6)	31 (18.3)	0 (0.0)
Use of sleep medication	150(88.8)	12 (7.1)	3 (1.8)	4 (2.4)
Daytime dysfunction	46 (27.2)	76 (45.0)	33 (19.5)	14 (8.3)

Primary Objective 2

Prevalence of excessive daytime sleepiness using the ESS

Prevalence of excessive daytime sleepiness was 35.5%, 95% CI= 28.3-43.2%. Prevalence of mild, moderate, or severe daytime sleepiness was 20.7%, 6.5%, and 8.3% respectively (*Figure 2*).
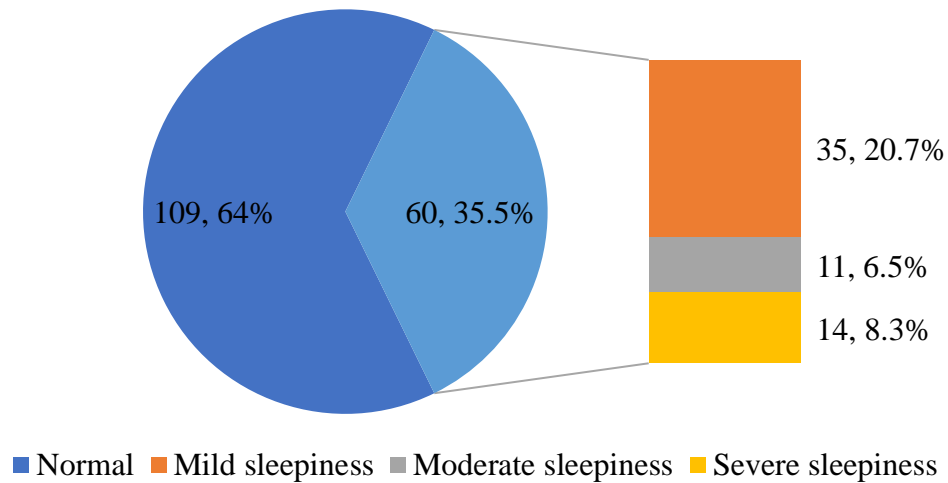

Figure 2. Prevalence of excessive daytime sleepiness in persons with epilepsy using ESS

Secondary Objective 1

Quality of life in persons with epilepsy using the QOLIE-10

Using the median of 22 as the cutoff (range 10-43), the prevalence of poor quality was 41.4% (95% CI 33.9-49.2%).The majority of the participants (52.7%) reported poor mental health. Approximately 46.7% and 44.4% reported having poor epilepsy effects and poor role functioning, respectively (*Table 5*).

Table 5. Quality of life of persons with epilepsy using the QOLIE-10

QOLIE scales	Poor n(%)	Good n (%)
Overall quality of life	70 (41.4)	99 (58.9)
Epilepsy effects	79 (46.7)	90(53.3)
Mental health	89 (52.7)	80(47.3)

Role functioning	75 (44.4)	94 (55.6)

Most felt they had a lot of energy most of the time (39.7%) and low or downhearted sometime (24.9%). About 65.1%, 59.8%, and 70.4% were bothered by work limitations, social limitations, and memory difficulties, while 49.1% and 47.1% were bothered by the physical and psychological effects of anti-seizure drugs (ASM) respectively. Approximately 81.1% were afraid of having a fit. The majority (59.2%) felt their quality of life was good/bad about equal. Only 4.1% felt that their quality of life was very bad (*Table 6*).

Table 6. QOLIE-10 domain scores

QOLIE-10	All the time	Most of the time	A good bit	Some time	A little of the time	None of time
Have a lot of energy	24 (14.2%)	64 (37.9%)	18 (10.7%)	42 (24.9%)	13 (7.7%)	8 (4.7%)
Felt low/downhearted	8 (4.7%)	21 (12.4%)	36 (21.3%)	42 (24.9%)	37 (21.9%)	25 (14.8%)
	Not at all bothersome	Only a little bothersome	Somewhat bothersome	A lot bothersome	Extremely bothersome	
Work limitations	59 (34.9%)	36 (21.3%)	28 (16.6%)	21 (12.4%)	25 (14.8%)	
Social limitations	68 (40.2%)	32 (18.9%)	25 (14.8%)	22 (13.0%)	22 (13.0%)	
Memory difficulties	50 (29.6%)	22 (13.0%)	37 (21.9%)	23 (13.6%)	37 (21.9%)	
Physical effects AED	86 (50.9%)	32 (18.9%)	23 (13.6%)	11 (6.5%)	17 (10.1%)	
Psychological. effects AED	89 (52.7%)	41 (24.3%)	16 (9.5%)	9 (5.3%)	14 (8.3%)	
	Not afraid	Not very afraid	Somewhat	Very afraid		
Afraid of having a fit	32 (18.9%)	37 (21.9%)	42 (24.9%)	58 (34.3%)		
	Very good	Pretty good	Good/ bad about equal	Pretty bad	Very bad	
Quality of life	6 (3.6%)	38 (22.5%)	100 (59.2%)	18 (10.7%)	7 (4.1%)	

Secondary Objective 2

Association between poor quality of sleep ,EDS and epilepsy characteristics.

Participants who had epilepsy for 5-10 years were 2.55 times (95% CI=0.94-6.15) more likely to report poor compared to good sleep quality, p=0.048. Those who reported EDS were 2.90 times (95% CI=1.38-6.45) more likely to report poor compared to good sleep quality, p=0.005.No significant differences in seizure type and seizure control of participants who reported poor compared to good sleep quality *(Table 7)*.

Table 7. Association between sleep quality and epilepsy characteristics, EDS, and quality of life

| | | Sleep quality | | | |
		Poor (N=115)	Good (N=54)	OR (95% CI)	p-Value
Duration of epilepsy	< 5 years	30 (65.2%)	16 (34.8%)	reference	
	5-10 years	43 (82.7%)	9 (17.3%)	2.55 (0.94-6.15)	**0.048**
	>10 years	42 (59.2%)	29 (40.8%)	0.77 (0.37-1.64)	0.510
Seizure type	Absence	2(66.7%)	1 (33.3%)	0.94 (0.11-13.8)	0.959
	Focal	5(71.4%)	2 (28.6%)	1.18 (0.24-6.09)	0.845
	GTC	82 (66.7%)	41 (33.3%)	0.79 (0.39-1.65)	0.529
	Unclassified	26 (72.2%)	10 (27.8%)	1.29 (0.58-2.85)	0.545
Seizure control	<1 in last 4 weeks	55 (65.5%)	29 (34.5%)	reference	
	≥1 in last 4 weeks	60 (70.6%)	25 (29.4%)	1.27 (0.66-2.48)	0.476
Excessive daytime sleep	Present	49 (81.7%)	11 (18.3%)	2.90 (1.38-6.45)	**0.005**
	Absent	66 (60.6%)	43 (39.4%)	reference	

No significant difference in the sleep quality of respondents who were prescribed Carbamazepine, Lamotrigine, Sodium valproate, Phenytoin, Phenobarbital, Levetiracetam, Clonazepam

AED prescribed		Sleep quality		OR (95% CI)	p-Value
		Poor n (%)	Good n (%)		
Carbamazepine	Yes	77 (70.0%)	33 (30.0%)	1.29 (0.66-2.58)	0.743
	No	38 (64.0%)	21 (35.6%)	reference	
Lamotrigine	Yes	5 (62.5%)	3 (37.5%)	0.77 (0.19-3.01)	0.730
	No	110 (68.3%)	51 (31.7%)	reference	
Sodium valproate	Yes	51 (75.0%)	17 (25.0%)	1.73 (0.87-3.31)	0.112
	No	64 (63.4%)	37 (36.6%)	reference	
Phenytoin	Yes	13 (81.3%)	3 (18.8%)	2.17 (0.66-7.38)	0.234
	No	102 (66.7%)	51 (33.3%)	reference	
Phenobarbital	Yes	8 (57.1%)	6 (42.9%)	0.59 (0.19-1.87)	0.361
	No	107 (69.0%)	48 (31.0%)	reference	
Levetiracetam	Yes	27 (71.1%)	11 (28.9%)	1.19 (0.56-2.58)	0.652
	No	88 (67.2%)	43 (32.8%)	reference	
Clonazepam	Yes	8 (80.0%)	2 (20.0%)	1.94 (0.45-9.33)	0.403
	No	107 (67.3%)	52 (32.7%)	reference	

There was no significant difference in the quality of sleep of patients who were on combination therapy compared to monotherapy.

	Quality of life		OR (95% CI)	p-Value
	Poor N=70	Good N=99		
Monotherapy	32 (36.4%)	56 (63.6%)	reference	
Combined	38 (46.9%)	43 (53.1%)	1.55 (0.82-2.82)	0.164

Excessive daytime sleepiness and epilepsy characteristics

Participants who had epilepsy for >10 years were 0.40 times (95% CI=0.19-0.90) less likely to report EDS compared to those who had epilepsy for <5 years, p=0.023. No significant differences seizure types, and seizure control of participants who reported EDS compared to those who did not (*Table 8*)

Table 8. Association between excessive daytime sleepiness and epilepsy characteristics

		Excessive Sleepiness			
		Present N=60	Absent N=109	OR (95% CI)	p-Value
Epilepsy duration	< 5 years	21 (45.7%)	25 (54.3%)	reference	
	5-10 years	21 (40.4%)	31 (59.6%)	0.81 (0.38-1.87)	0.599
	>10 years	18 (25.4%)	53 (74.6%)	0.40 (0.19-0.90)	**0.023**
Seizure type	Absence	2 (66.7%)	1 (33.3%)	3.72 (0.42-54.4)	0.259
	Focal	3 (42.9%)	4 (57.1%)	1.38 (0.34-5.28)	0.678
	GTC	47 (38.2%)	76 (61.8%)	1.57 (0.76-3.18)	0.229
	Unclassified	8 (22.2%)	28 (77.8%)	0.45 (0.19-1.03)	0.061
Seizure control	<1 last 4 weeks	26 (31.0%)	58 (69.0%)	reference	
	≥1 last 4 weeks	34 (40.0%)	51 (60.0%)	1.49 (0.79-2.84)	0.219

No significant difference in excessive daytime sleepiness of respondents who were prescribed Carbamazepine, Lamotrigine, Sodium valproate, Phenytoin, Phenobarbital, Levetiracetam, Clonazepam.

		Excessive daytime sleepiness			
		Yes	No	OR (95% CI)	p-Value
Carbamazepine	Yes	42 (38.2%)	68 (61.8%)	1.41 (0.71-2.83)	0.320
	No	18 (30.5%)	41 (69.5%)	reference	
Lamotrigine	Yes	2 (25.0%)	6 (75.0%)	0.59 (0.12-2.46)	0.525
	No	58 (36.0%)	103 (64.0%)	reference	
Sodium valproate	Yes	26 (38.2%)	42 (61.8%)	1.22 (0.64-2.31)	0.543
	No	34 (33.7%)	67 (66.3%)	reference	
Phenytoin	Yes	6 (37.5%)	10 (62.5%)	1.10 (0.38-2.96)	0.861
	No	54 (35.3%)	99 (64.7%)	reference	
Phenobarbital	Yes	3 (21.4%)	11 (78.6%)	0.47 (0.14-1.64)	0.251

	No	57 (36.8%)	98 (63.2%)	reference	
Levetiracetam	Yes	13 (34.2%)	25 (65.8%)	0.93 (0.44-2.04)	0.850
	No	47 (35.9%)	84 (64.1%)	reference	
Clonazepam	Yes	4 (40.0%)	6 (60.0%)	1.23 (0.38-4.86)	0.759
	No	56 (35.2%)	103 (64.8%)	reference	

There was no significant difference in the prevalence of EDS among patient who were on combination therapy compared to monotherapy.

	Excessive daytime sleepiness			
	Present N=60	Absent N=109	OR (95% CI)	p-Value
Monotherapy	28 (31.8%)	60 (68.2%)	reference	
Combined	32 (39.5%)	49 (60.5%)	1.39 (0.75-2.64)	0.297

Secondary objective 3

Association between poor quality of sleep ,EDS and quality of life in persons with epilepsy

Participants who had poor quality of life were 3.56 times *(95% CI=1.75-7.39)* more likely to have poor sleep quality compared to those who had good quality of life *p = 0.001*. Participants who were sleeping excessively during the day were 2.38 times *(95% CI = 1.25-4.46)* more likely to have poor quality of life compared to those who did not *(p = 0.008)*. (*Table 9*).

Table 9. Association between poor quality of sleep, EDS, and quality of life in persons with epilepsy

		Quality of life			
		Poor (n=70)	Good (n=99)	OR (95% CI)	p-Value
Sleep quality	Poor	58 (82.9%)	57 (57.6%)	3.56 (1.75-7.39)	**0.001**
	Good	12 (17.1%)	42 (42.4%)		
Daytime sleepiness	Excessive	33 (55.0%)	27 (45.0%)	2.38 (1.25-4.46)	**0.008**
	Normal	37 (33.9%)	72 (66.1%)	reference	

CHAPTER FIVE: DISCUSSION

The aim of this study was to analyze the prevalence of poor sleep quality and excessive daytime sleepiness in patients with epilepsy and impact on Quality of life. To the best of our knowledge, this is the first study in Kenya to do so. This study represents an important contribution to the literature on epilepsy and sleep disorders, particularly in the context of a Kenyan population.

The findings of the current study indicate a high prevalence of poor sleep quality among patients with epilepsy, with 68.0% of the study participants reporting poor sleep quality. This result is in line with previous studies conducted in other developing countries, such as Ethiopia and Brazil, which reported a prevalence of poor sleep quality among epilepsy patients of 65.5% and 67.3%, respectively (10,47).All of the studies, including the current one, were conducted in tertiary hospital settings and used the Pittsburgh Sleep Quality Index (PSQI) questionnaire as the primary tool for assessing sleep quality. The similarities in the prevalence of poor sleep quality across these studies could be attributed to a variety of factors. Patients with epilepsy in developing countries may have limited access to effective treatment and care, which can contribute to the development of sleep disorders. Cultural and socioeconomic factors may also influence the occurrence of poor sleep quality among PLWE.

In this study the prevalence of poor sleep quality was lower compared to a study in Pakistan 71% and USA 72% (48,49).This difference could be due to the study setting, demographic, and clinical characteristics of the Participants. When compared to the Pakistan study, our study was conducted in one tertiary center ,majority of participants were male and generalised epilepsy was the dominant type of epilepsy. Poor sleep quality is likely to occur in focal epilepsy and in women (7,50).The USA study reported a higher comorbidity rate of 48% compared to 22% in our study,

and medical comorbidities are known to contribute to poor sleep quality (10,12).On the other hand, our findings were higher than a study conducted in India 48%. The difference in prevalence is likely due to the smaller sample size used in the India study (51).

The current study found 35.5% of PWE had EDS which is similar to the reported prevalence of EDS ranging from 10%–47.5 % (28).Our findings are higher than those reported by piperidou et al 16.9% and Komolafe et al 17 % which may be because of exclusion patients with comorbidities in these studies such as depression or anxiety disorders, which are known to be associated with EDS in PLWE (6,52).As a result, the exclusion of patients with these comorbidities may have resulted in an underestimation of prevalence rates in these studies.

In our study 41.4% participants reported having a poor quality of life based on QOLIE-10 scores. A Kenyan study reported poor QOL among PLWE attending Kenyatta National Hospital Neurology outpatient clinic at 49.90% (53).The findings in our study is lower than the Kenyan study possibly due to use of the World Health Organization Quality of Life (WHOQOL-BREF).We acknowledge that the WHOQOL-BREF is a more comprehensive tool that addresses various aspects of quality of life than the QOLIE-10 and this could account for the differences observed. Despite the differences in findings, both studies emphasize the negative impact of epilepsy on the quality of life of PLWE.

The finding in our study is comparable to an Ethiopian study where poor quality of life was at 45.2% ,where a similar tool ,the QOLIE-10 was used (54).

Among the QOLIE10 domains, 65.1%, 59.8%, and 70.4% were bothered by work limitations, social limitations, and memory difficulties respectively ,while 49.1% and 47.1% were bothered by the physical and psychological effects of ASM respectively. Approximately 81.1% were afraid

of having a fit. We postulate that the perceived stigma in epilepsy accounts for the high numbers reporting social limitations. Fear of having a seizure is associated with stress, anxiety, and limits active participation in society. Psychological factors ,especially depression, has been shown to be a strong predictor of quality of life in PLWE compared to epilepsy characteristics (55)

In this study there were no significant differences in seizure type, type of ASM and seizure control of participants who reported poor compared to good sleep quality. This is in contrast to studies in Pakistan, Greece and Taiwan which found that poor sleep quality was associated with certain types of seizures and poorer seizure control (6,27,49).The discrepancy could be due to the study definitions of seizure control and differences in prevalent seizure type. The high prevalence of poor sleep quality in our study could be due to other social and environmental factors affecting sleep, rather than just seizure-related variables. Additionally, those who reported EDS were more likely to report poor compared to good sleep quality. Previous studies have linked poor sleep quality to daytime sleepiness (22).

In this study type of ASM, type of seizure and seizure control was not associated with the presence of EDS which is consistent with study findings in Greece and Nigeria (6,52). Participants who had epilepsy for >10 year were less likely to report EDS compared to those who had epilepsy for <5 years. It has been demonstrated that PLWE experience more sleepiness at the beginning of treatment, and this reduces as time goes by (56).

There was a significant negative association between poor sleep quality and Excessive daytime sleepiness and Quality of life in PLWE. Participants who had poor quality of life were 3.56 and 2.38 times more likely to have poor sleep quality and excessive daytime sleepiness respectively

compared to those who had good quality of life. This finding is supported by earlier studies (6,33,48)

This study highlights that poor sleep quality and excessive daytime sleepiness are prevalent among PLWE ,can occur independently of the type of antiseizure medication and seizure control and have a notable impact on their overall quality of life. A more comprehensive and personalized care that goes beyond just focusing on achieving seizure control should be provided. Therefore, Healthcare providers should incorporate routine sleep assessments during patient visits, address, psychosocial, and lifestyle factors to optimize treatment and improve patient outcomes.

Strength and limitations

Strengths.

1) One of the first studies in Kenya to formally assess sleep quality and EDS in a patient population with a lot of subjective sleep complaints (People living with Epilepsy)
2) Use of validated tools with excellent response rates of > 90%

Limitations

- Lack of a control group with which to compare the prevalence of sleep quality and excessive daytime sleepiness in PLWE.
- We obtained information regarding sleep and epilepsy variables i.e., seizure frequency from participants. This is subject to recall bias in a patient population with already subjectively reported memory problems.
- Quality of sleep can be influenced by multiple variables, some of which were not addressed in our study i.e., depression, anxiety.

- The participants were recruited from one medical center .Therefore, the findings may not be generalizable to all PLWE in Kenya.

Conclusions

This study revealed that the majority of PLWE have poor sleep quality and excessive daytime sleepiness which had an impact on their quality of life. The study did not find any significant association between the type of ASM, seizure frequency and seizure control with the presence of EDS and poor sleep quality. This study emphasizes the importance of addressing sleep quality as part of the overall care in PLWE to improve their quality of life.

Recommendations

- Prospective studies to assess sleep quality in PLWE starting from diagnosis and following up for years, and to compare the findings in other populations.

- These findings highlight the need to obtain a detailed history of sleep habits and sleep hygiene in PLWE attending our clinics.

- Effective strategies to be put in place to achieve good sleep quality in PLWE. This includes but is not limited to, developing stress management techniques, limiting screen time and the creation of a sleep-conducive environment.

- A study to look into the effects of psychosocial factors on quality of life in PLWE

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APPENDIX I: STUDY PROFORMA

Study date ——————————— Study Number————————————

Consent given YES   NO

SOCIO-DEMOGRAPHICS

1. Age (yrs.)

2. Sex
   - ☐ Male
   - ☐ Female

3. Marital status
   - ☐ Single
   - ☐ Married
   - ☐ Widowed
   - ☐ Divorced

4. Employment status
   - ☐ Employed
   - ☐ Unemployed
   - ☐ Others (please specify)

5. Education (Record highest level)

6. Residence
   - ☐ Urban
   - ☐ Rural

CLINICAL STATUS

1. Duration of Epilepsy ———————————

2. Seizure control

    ☐ Poor control ≥ 1 seizure in last 4 weeks
    ☐ Good control < 1 seizure in last 4 weeks

3. Anti-seizure medication _____

4. Height (meters)

5. Weight (Kilograms)

6. BMI (kg/m2)
    ☐ Underweight
    ☐ Normal
    ☐ Overweight
    ☐ Obese

7. Neck circumference (cm)

8. Comorbid condition (s)

SLEEP SCORE

Quality of sleep score

    ☐ > 5 (Poor sleep)
    ☐ < 5 (Good sleep)

Excessive daytime sleepiness

    ☐ <10 (normal)
    ☐ 11-14 (mild)
    ☐ 15-17 (moderate)
    ☐ 18-24 (severe)

APPENDIX II: PITTSBURGH SLEP QUALITY INDEX (PSQI)

Subject's initials _____   ID#_____   Date_____   Time
P.M.

PITTSBURGH SLEEP QUALITY INDEX

(Canadian English version of the Pittsburgh Sleep Quality Index - PSQI)

INSTRUCTIONS:

The following questions relate to your usual sleep habits during the past month (past 30 days) 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?

    BEDTIME _____

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 to the number of hours you spent in bed.)

    HOURS OF SLEEP PER NIGHT _____

For each of the remaining questions, checkmark the one best response. Please answer <u>all</u> questions.

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

a)   Could not get to sleep within 30 minutes

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

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

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

c)   Had to get up to use the bathroom

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

d)   Could not breathe comfortably

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

e)   Were coughing or snoring loudly

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

f)   Felt too cold

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

g) Felt 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) Had 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   Less than   Once or twice   Three or more times
    past month_____   once a week_____   a week_____   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   Less than   Once or twice   Three or more times
    past month_____   once a week_____   a week_____   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 partner or roommate?

No partner or roommate   _____

Partner/roommate in other room   _____

Partner in same room, but not same bed   _____

Partner in same bed   _____

If you have a roommate or 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 asleep

| 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 while asleep

| 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   asleep;   please describe_____

_____

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

*Buysse DJ, Reynolds CF, Monk TH, Berman SR, Kupfer DJ: Psychiatry Research, 28:193-213, 1989.*lmw:F5.PSQ (4/2002)

SCORING INSTRUCTIONS FOR THE PITTSBURGH SLEEP QUALITY INDEX:

The Pittsburgh Sleep Quality Index (PSQI) contains 19 self-rated questions and 5 questions rated by the bed partner or roommate (if one is available). Only self-rated questions are included in the scoring. The 19 self-rated items are combined to form seven "component" scores, each of which has a range of 0-3 points. In all cases, a score of "0" indicates no difficulty, while a score of "3" indicates severe difficulty. The seven component scores are then added to yield one "global" score, with a range of 0-21 points, "0" indicating no difficulty and "21" indicating severe difficulties in all areas.

Scoring proceeds as follows:

Component 1: Subjective sleep quality

Examine question #6, and assign scores as follows:

Response	Component 1 score
"Very good"	0
"Fairly good"	1
"Fairly bad"	2
"Very bad"	3

Component 1 score:_____

Component 2: Sleep latency

1. Examine question #2, and assign scores as follows:

Response	Score
≤15 minutes	0
16-30 minutes	1
31-60 minutes	2
> 60 minutes	3

Question #2 score: _____

2. Examine question #5a, and assign scores as follows:

Response	Score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Question #5a score: _____

3. Add #2 score and #5a score

Sum of #2 and #5a: _____

4. Assign component 2 score as follows:

Sum of #2 and #5a	Component 2 score
0	0
1-2	1
3-4	2
5-6	3

PSQI Page 3

Component 2 score:_____

55

Component 3: Sleep duration

Examine question #4, and assign scores as follows:

Response	Component 3 score
> 7 hours	0
6-7 hours	1
5-6 hours	2
< 5 hours	3

Component 3 score: _____

Component 4: Habitual sleep efficiency

1. Write the number of hours slept (question #4) here: _____

2. Calculate the number of hours spent in bed:

Getting up time (question #3): _____ _____

Bedtime (question #1): _____

Number of hours spent in bed: _____

3. Calculate habitual sleep efficiency as follows:

(Number of hours slept/Number of hours spent in bed) X 100 = Habitual sleep efficiency (%)

(_____ / _____) X 100 = %

4. Assign component 4 score as follows:

Habitual sleep efficiency %	Component 4 score
> 85%	0
75-84%	1
65-74%	2
< 65%	3

Component 4 score: _____

Component 5: Step disturbances

1. Examine questions #5b-5j, and assign scores for each question as follows:

Response	Score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

5b score: _____

5c score: _____

5d score: _____

5e score: _____

5f score: _____

5g score: _____

5h score: _____

5i score: _____

5j score: _____

2. Add the scores for questions #5b-5j:

Sum of #5b-5j: _____

3. Assign component 5 score as follows:

Sum of #5b-5j	Component 5 score
0	0
1-9	1
10-18-4	2
19-27	3

*Component 5 score:*_____

Component 6: Use of sleeping medication

Examine question #7 and assign scores as follows:

Response	Component 6 score
Not during the past month	0
Less than once a week	1
Once or twice a week	2
Three or more times a week	3

Component 6 score:

57

Component 7: Daytime dysfunction

1. Examine question #8, and assign scores as follows:

Response	Score
Never	0
Once or twice	1
Once or twice each week	2
Three or more times each week	3

Question #8 score: _____

2. Examine question #9, and assign scores as follows:

Response	Score
No problem at all	0
Only a very slight problem	1
Somewhat of a problem	2
A very big problem	3

Question #9 score: _____

3. Add the scores for question #8 and #9:

Sum of #8 and #9: _____

4. Assign component 7 score as follows:

Sum of #8 and #9	Component 7 score
0	0
1-2	1
3-4	2
5-6	3

Component 7 score: _____

Global PSQI Score

Add the seven component scores together:

Global PSQI Score: _____

APPENDIX III: EPWORTH SLEEPINESS SCALE (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

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Quality Of Life In Epilepsy: QOLIE-10 (US
English, V.1)

Today's Date:	Visit Number:
⎣⏟⎦ ⎣⏟⎦ ⎣⏟⎦ 　D　　M　　Y	⎣⏟⎦
Patient's Name (Patient's Initials): _____	**Sex:** ☐　Male ☐　Female
Patient's ID Number: _____	**Date of birth:** ⎣⏟⎦ ⎣⏟⎦ ⎣⏟⎦ 　D　　M　　Y

> **NOTE**: *If you experienced a simple or complex partial seizure within the previous four hours, or a generalized tonic-clonic seizure within the previous 24 hours, please delay completing this questionnaire*

INSTRUCTIONS:

This questionnaire asks about your health and daily activities. **Answer each question** by circling the appropriate number (1, 2, 3...).

If you are unsure about how to answer a question, please give the best answer you can and write a comment or explanation in the margin. Please feel free to ask someone to help you if you have difficulty reading or completing

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

How much of the time during the past 4 weeks…
(Circle one number on each line)

	All of the time	Most of the time	A good bit of the time	Some of the time	A little of the time	None of the time

1. Did you have a lot of energy?	**1**	**2**	**3**	**4**	**5**	**6**
2. Have you felt downhearted and low?	**1**	**2**	**3**	**4**	**5**	**6**

The following questions ask about problems you may have with certain ACTIVITIES.

How much of the time during the past 4 weeks your epilepsy or antiepileptic drugs have caused trouble with…

(Circle one number)

	A great deal	A lot	Somewhat	Only a little	Not at all
3. Driving (or other transport)	**1**	**2**	**3**	**4**	**5**

During the past 4 weeks…

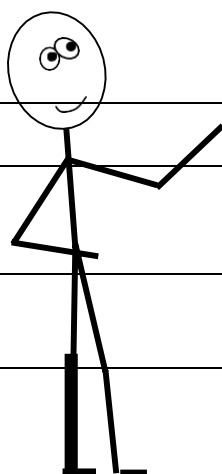|	Not at all bothersome				Extremely bothersome
4. How much do your work limitations bother you?	**1**	**2**	**3**	**4**	**5**
5. How much do your social limitations bother you?	**1**	**2**	**3**	**4**	**5**
6. How much do your memory difficulties bother you?	**1**	**2**	**3**	**4**	**5**
7. How much do physical effects of antiepileptic drugs bother you?	**1**	**2**	**3**	**4**	**5**
8. How much do psychological effects of antiepileptic drugs bother you?	**1**	**2**	**3**	**4**	**5**

	Very afraid	Somewhat	Not very afraid	Not afraid

	afraid			at all
9. How afraid are you of having a fit during the next 4 weeks?	**1**	**2**	**3**	**4**

10. How has your **QUALITY OF LIFE** been during the **past 4 weeks**
(that is, how have things been going for you)?

Very good: could hardly have been better	**1**
Pretty good	**2**
Good & bad about equal	**3**
Pretty bad	**4**
Very bad: could hardly have been worse	**5**

Please check to be sure you have answered every question on every page.

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE ABOUT LIVING

WITH EPILEPSY.

Quality Of Life In Epilepsy: QOLIE-10
SCORING INSTRUCTIONS

The QOLIE-10 screening questionnaire includes 10 questions. Three questions have opposite response sets, requiring reverse-scoring. The scoring should be calculated so that all positive responses are lower numbers, and all negative responses are higher numbers.
[The QOLIE-10-P includes 11 questions, with items 1-10 identical to the QOLIE-10.]

Items scored with "1" as best should be scored as indicated: items 1, 4, 5, 6, 7, 8, 10
Items scored with "1" as worst should be scored in "reverse": items 2, 3, 9

The conversion for item 2 is:
1=6
2=5
3=4
4=3
5=2
6=1

The conversion for item 3 is:
1=5
2=4
3=3
4=2
5=1

The conversion for item 9 is:

1=4
2=3
3=2
4=1

The total score is the sum of scores for all questions divided by the number of items answered. Thus, if a patient skipped an item, it is not reflected in the total score. Patients with lowest scores have the least problems.

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7. The user agrees to notify the QOLIE Development Group of any publications in which QOLIE-10 data are presented.

Joyce A. Cramer
joyce.cramer@gmail.com
For the QOLIE Development Group

APPENDIX V: PARTICIPANT INFORMATION AND CONSENT FORM

My name is Dr Atieno Barbara, a postgraduate student of internal medicine at the university of Nairobi. I am conducting a study on Sleep disturbance in patients with epilepsy. This document will give you information you need to help you decide whether you want to be in the study or not.

What is the study about?

The purpose of the study is to determine how many patients with epilepsy have sleep disturbances and how this impacts their quality of life.

Participation

Participation in this study is voluntary. If you decide to participate, you may discontinue participation at any time and for any reason without negative consequences by letting the researcher know.

What will happen when you agree to take part in the study?

The following is what will be done

1)We will Obtain personal information such as your age, marital status, level of education and information regarding your epilepsy treatment.

2)Filling in questionnaires that will ask about your sleep quality, daytime sleepiness, and quality of life.

3)Taking your height, weight, and neck circumference.

This will be done in a private room and will take 20 mins of your time.

Risk and cost

We shall be asking for information about yourself and medication use, this may be uncomfortable for you.

No costs will be incurred.

Benefits

This study will provide information on your sleep, the medications you are taking for your epilepsy treatment and how this impacts your quality of life.

You will not receive any monetary compensation to participate in this study

Confidentiality

The information you give will be private and confidential. Information collected will be kept in a secure place and only people involved with the study will have access to it. Your name will not appear in any of the documents**.**

You may refuse to participate at any time during the study. In case you refuse; you will not be denied services and you will continue to receive care.

You will receive a copy of this consent form.

Participant's statement.

I have been informed about the study's purpose. I willingly consent to participate in this study, and I understand that I can withdraw my consent at any time, and this will in no way alter the care being given to me. I give the researchers permission to use my medical records for the purposes specified in the consent form.

Participant name…………………………………….

Participant signature/ left thumb print……………………………….

Date……………………………….

Researcher's statement.

I have accurately and to the best of my ability made sure that the participant understands that the study is voluntary, and they can withdraw from the study, all information will be treated with confidentiality.

I can confirm that the participant was given the opportunity to ask questions about the study conducted and the questions answered appropriately.

I can confirm that the participant has not been coerced into signing the consent form.

Researcher taking consent……………………………….

Signature of researcher taking consent……………………………….

Date……………………………….

Contacts

If you have any questions about your rights as a research subject, you can call:

1)The principal investigator

Dr Atieno Barbara 0722492780

2)The secretary

UON/KNH Ethics and Review Committee Tel: 2726300

APPENDIX VI:INFORMED CONSENT FOR PARENTS/GUARDIANS OF PARTICIPANTS

My name is Dr Atieno Barbara, a postgraduate student of internal medicine at the university of Nairobi. I am conducting a study on Sleep disturbance in patients with epilepsy This consent form is a request for your child's participation in a research study

What is the study about?

The purpose of the study is to determine how many patients with epilepsy have sleep disturbances and how this impacts their quality of life

Participation

Participation in this study is voluntary. If your child does participate, he/she may discontinue participation at any time and for any reason without negative consequences by letting the researcher know .

What will happen when you agree to take part in the study?

The following is what will be done

1) Obtaining personal information and information regarding your child's epilepsy treatment.

2)Filling in questionnaires that will ask about your child's sleep quality, daytime sleepiness, and quality of life.

3)Taking your child's height, weight, and neck circumference

This will be done in a private room and will take 20 mins of your time.

Risk and cost

We shall be asking for information about yourself like age and medication use, this may be uncomfortable for you.

No costs will be incurred.

Benefits

This study will provide information on your child's sleep, the medications your child is taking for their epilepsy treatment and how this impacts their quality of life.

You will not receive any monetary compensation to participate in this study

Confidentiality:

You will be asked to provide a signature at the bottom of the next page signifying that you understand the information contained in this consent form.

The information given will be private and confidential. Information collected will be kept in a secure place and only people involved with the study will have access to it. Your child's name will not appear in any of the documents.

You will receive a copy of this consent form

Parent/Guardian statement

I have been informed about the study's purpose. I give my consent for my child to participate in this research study and I understand that I can withdraw my consent at any time, and this will in no way alter the care being given to my child. I give the researchers permission to use my child's medical records for the purposes specified in the consent form.

Child's Name:

Name of Parent/Guardian

Signature of Parent/Guardian

Date:

Researcher's statement.

I have accurately and to the best of my ability made sure that the participant understands that the study is voluntary, and they can withdraw from the study, all information will be treated with confidentiality.

I can confirm that the participant was given the opportunity to ask questions about the study conducted and the questions answered appropriately.

I can confirm that the participant has not been coerced into signing the consent form.

Researcher taking consent………………………………….

Signature of researcher taking consent……………………………….

Date…………………………….

Contact

If you have any questions about your rights as a research subject, you can call:

1)The principal investigator

Dr Atieno Barbara,0722492780

2)The secretary

UON/KNH Ethics and Review Committee Tel: 2726300

APPENDIX VII: ASSENT FORM FOR MINORS (13-17 YEARS)

My name is Dr Atieno Barbara, a postgraduate student of internal medicine at the university of Nairobi. I am inviting you to take part in research about sleep disturbances in patients with epilepsy and how this affects your quality of life.

If you decide you want to be part of this study, you will be asked about your personal details such as your name, age, education, residence etc. We will collect information regarding your sleep and how it affects your quality of life. We will also take your height, weight, and neck circumference measurements. This will be done in a private area and will take 20 mins of your time. If you do not want to take part in this study, this decision will not affect your treatment in any way.

The information collected will be treated with confidentiality and only available to the study team. You will not be harmed in any way by participating in this study. You will not pay any amount of money to participate in this study.

When we are finished with the study, a report will be written about what was learned. This report will not include your name or that you were in the study.

You do not have to be in the study if you do not want to. If you decide to stop after we begin that is okay too.

If you decide you want to be in this study, please sign your name

I …………………………………. want to be in this research study.

Signature/left thumb print………………………. Date………………………

KIAMBATISHO V: FOMU YA TAARIFA NA RIDHAA YA MSHIRIKI

Jina langu ni Dkt Atieno Barbara, mwanafunzi wa shahada ya uzamili ya udaktari wa ndani katika chuo kikuu cha Nairobi. Ninafanya utafiti juu ya usumbufu wa Usingizi kwa wagonjwa wenye kifafa. Hati hii itakupa taarifa uliyohitaji ili kukusaidia kuamua kama ungependa kuwa katika utafiti au la.

Utafiti unahusu nini?

Madhumuni ya utafiti ni kubainisha ni wagonjwa wangapi walio na kifafa wana matatizo ya usingizi na jinsi hii inavyoathiri ubora wa maisha yao.

Kushiriki

Kushiriki katika utafiti huu ni kwa hiari. Ukiamua kushiriki, unaweza kuacha kushiriki wakati wowote na kwa sababu yoyote bila matokeo mabaya kwa kumfahamisha mtafiti.

Je, nini kitatokea ukikubali kushiriki katika utafiti?

Yafuatayo ndiyo yatakayofanyika

1) Tutapata taarifa za kibinafsi kama vile umri wako, hali ya ndoa, kiwango cha elimu na taarifa kuhusu matibabu yako ya kifafa.

2)Kujaza dodoso ambazo zitakuuliza kuhusu ubora wako wa kulala, usingizi wa mchana, na ubora wa maisha.

3) Kuchukua urefu wako, uzito, na mduara wa shingo.

Hii itafanywa katika chumba cha faragha na itachukua dakika 20 za wakati wako.

Hatari na gharama

Tutakuwa tukiuliza habari kuhusu wewe mwenyewe na matumizi ya dawa, hii inaweza kuwa mbaya kwako.

Hakuna gharama zitakazotumika.

Faida

Utafiti huu utatoa taarifa kuhusu usingizi wako, dawa unazotumia kwa matibabu yako ya kifafa na jinsi hii inavyoathiri ubora wa maisha yako.

Hutapokea fidia yoyote ya fedha ili kushiriki katika utafiti huu

Usiri

Taarifa utakazotoa zitakuwa za faragha na za siri. Taarifa zitakazokusanywa zitawekwa mahali salama na watu wanaohusika na utafiti pekee ndio wanaoweza kuzifikia. Jina lako halitaonekana katika hati zozote.

Unaweza kukataa kushiriki wakati wowote wakati wa utafiti. Ikiwa unakataa; hutanyimwa huduma na utaendelea kupata huduma.

Utapokea nakala ya fomu hii ya idhini.

Kauli ya mshiriki.

Nimefahamishwa kuhusu madhumuni ya utafiti. Ninakubali kwa hiari kushiriki katika utafiti huu, na ninaelewa kuwa ninaweza kuondoa idhini yangu wakati wowote, na hii haitabadilisha kwa njia yoyote utunzaji ninaopewa. Ninawapa watafiti ruhusa ya kutumia rekodi zangu za matibabu kwa madhumuni yaliyobainishwa katika fomu ya idhini.

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Jina la mshiriki ……………………………………….

Sahihi ya mshiriki/ alama ya kidole gumba cha kushoto……………………………….

Tarehe………………………….

Kauli ya mtafiti.

Nimehakikisha kwa usahihi na kwa kadiri ya uwezo wangu kwamba mshiriki anaelewa kuwa utafiti ni wa hiari, na anaweza kujiondoa kwenye utafiti, taarifa zote zitashughulikiwa kwa usiri.

Ninaweza kuthibitisha kwamba mshiriki alipewa nafasi ya kuuliza maswali kuhusu utafiti uliofanywa na maswali yakajibiwa ipasavyo.

Ninaweza kuthibitisha kuwa mshiriki hajalazimishwa kusaini fomu ya idhini.

Mtafiti akipokea kibali ………………………………………….

Saini ya mtafiti anayekubali idhini ……………………………………….

Tarehe………………………….

Wasiliana

Ikiwa una maswali yoyote kuhusu haki zako kama somo la utafiti, unaweza kupiga simu:

1) Mchunguzi mkuu

Dk Atieno Barbara 0722492780

2) Katibu

Kamati ya Maadili na Mapitio ya UON/KNH

Simu: 272630

NYONGEZA VI:RIDHAA ILIYO HARIRI KWA WAZAZI/WALEZI

Jina langu ni Dkt Atieno Barbara, mwanafunzi wa shahada ya uzamili ya udaktari wa ndani katika chuo kikuu cha Nairobi. Ninafanya utafiti kuhusu usumbufu wa Usingizi kwa wagonjwa walio na kifafa Fomu hii ya idhini ni ombi la ushiriki wa mtoto wako katika utafiti wa utafiti.

Utafiti unahusu nini?

Madhumuni ya utafiti ni kubaini ni wagonjwa wangapi walio na kifafa wana shida ya kulala na jinsi hii inavyoathiri ubora wa maisha yao.

Kushiriki

Kushiriki katika utafiti huu ni kwa hiari. Ikiwa mtoto wako atashiriki, anaweza kuacha kushiriki wakati wowote na kwa sababu yoyote bila matokeo mabaya kwa kumfahamisha mtafiti .

Je, nini kitatokea ukikubali kushiriki katika utafiti?

Yafuatayo ndiyo yatakayofanyika

1) Kupata taarifa za kibinafsi na taarifa kuhusu matibabu ya kifafa ya mtoto wako.

2)Kujaza dodoso ambazo zitauliza kuhusu ubora wa usingizi wa mtoto wako, usingizi wa mchana, na ubora wa maisha.

3) Kuchukua urefu, uzito, na mzunguko wa shingo ya mtoto wako

Hii itafanywa katika chumba cha faragha na itachukua dakika 20 za wakati wako.

Hatari na gharama

Tutakuwa tukiuliza habari kukuhusu kama umri na matumizi ya dawa, hii inaweza kuwa mbaya kwako.

Hakuna gharama zitakazotumika.

Faida

Utafiti huu utatoa taarifa kuhusu usingizi wa mtoto wako, dawa anazotumia mtoto wako kwa matibabu yake ya kifafa na jinsi hii inavyoathiri ubora wa maisha yake.

Hutapokea fidia yoyote ya fedha ili kushiriki katika utafiti huu

Usiri:

Utaombwa kutoa saini chini ya ukurasa unaofuata ikiashiria kwamba unaelewa maelezo yaliyo katika fomu hii ya idhini.

Taarifa zitakazotolewa zitakuwa za faragha na za siri. Taarifa zitakazokusanywa zitawekwa mahali salama na watu wanaohusika na utafiti pekee ndio wanaoweza kuzifikia. Jina la mtoto wako halitaonekana katika hati zozote.

Utapokea nakala ya fomu hii ya idhini

Taarifa ya Mzazi/Mlezi

Nimefahamishwa kuhusu madhumuni ya utafiti. Ninatoa idhini yangu kwa mtoto wangu kushiriki katika utafiti huu na ninaelewa kuwa ninaweza kuondoa idhini yangu wakati wowote, na hii haitabadilisha kwa njia yoyote malezi anayopewa mtoto wangu. Ninawapa watafiti ruhusa ya

kutumia rekodi za matibabu za mtoto wangu kwa madhumuni yaliyobainishwa katika fomu ya idhini.

Jina la Mtoto:

Jina la Mzazi/Mlezi

Sahihi ya Mzazi/Mlezi

Tarehe:

Kauli ya mtafiti.

Nimehakikisha kwa usahihi na kwa kadiri ya uwezo wangu kwamba mshiriki anaelewa kuwa utafiti ni wa hiari, na anaweza kujiondoa kwenye utafiti, taarifa zote zitashughulikiwa kwa usiri.

Ninaweza kuthibitisha kwamba mshiriki alipewa nafasi ya kuuliza maswali kuhusu utafiti uliofanywa na maswali yakajibiwa ipasavyo.

Ninaweza kuthibitisha kuwa mshiriki hajalazimishwa kusaini fomu ya idhini.

Mtafiti akipokea kibali ………………………………….

Saini ya mtafiti anayekubali idhini …………………………………….

Tarehe………………………….

Wasiliana

Ikiwa una maswali yoyote kuhusu haki zako kama somo la utafiti, unaweza kupiga simu:

1) Mchunguzi mkuu

Dk Atieno Barbara

0722492780

2) Katibu

Kamati ya Maadili na Mapitio ya UON/KNH

Simu: 2726300

KIAMBATISHO VII: FOMU YA KURIDHIA KWA WATOTO (MIAKA 13-17)

Jina langu ni Dkt Atieno Barbara, mwanafunzi wa shahada ya uzamili ya udaktari wa ndani katika chuo kikuu cha Nairobi. Ninakualika ushiriki katika utafiti kuhusu usumbufu wa usingizi kwa wagonjwa wa kifafa na jinsi hii inavyoathiri ubora wa maisha yako.

Ukiamua ungependa kuwa sehemu ya utafiti huu, utaulizwa kuhusu maelezo yako ya kibinafsi kama vile jina lako, umri, elimu, makazi n.k. Tutakusanya taarifa kuhusu usingizi wako na jinsi unavyoathiri ubora wa maisha yako. Pia tutachukua urefu wako, uzito, na vipimo vya mduara wa shingo. Hii itafanywa katika eneo la kibinafsi na itachukua dakika 20 za wakati wako.

Ikiwa hutaki kushiriki katika utafiti huu, uamuzi huu hautaathiri matibabu yako kwa njia yoyote ile.

Taarifa iliyokusanywa itashughulikiwa kwa usiri na kupatikana kwa timu ya utafiti pekee. Hutadhurika kwa njia yoyote ile kwa kushiriki katika utafiti huu. Hutalipa kiasi chochote cha pesa kushiriki katika utafiti huu.

Tukimaliza na utafiti, ripoti itaandikwa kuhusu yale tuliyojifunza. Ripoti hii haitajumuisha jina lako au kwamba ulikuwa kwenye utafiti.

Si lazima uwe katika utafiti kama hutaki. Ukiamua kuacha baada ya sisi kuanza ni sawa pia.

Ukiamua ungependa kuwa katika utafiti huu, tafadhali saini jina lako

Mimi ……………………………………. wanataka kuwa katika utafiti huu.

Sahihi/alama ya kidole gumba cha kushoto…………………………………….

QUALITY OF SLEEPAND EXCESSIVE DAYTIME SLEEPINESS IN PATIENTS WITH EPILEPSY AT THE KENYATTANATIONAL HOSPITAL.

APPROVAL OF LEAD SUPERVISOR AND CHAIRMAN OF DEPARTMENT

This Dissertation has been submitted for the Award of Master of Medicine in Internal Medicine with the approval of my Lead Supervisor and Chairman of Department.

Dr Judith K Kwasa

Consultant Physician and Neurologist

Lecturer, Department of Clinical Medicine, and Therapeutics

The University of Nairobi

Signed.. Date...... 15/11/2023

Professor E.O Amayo

Chairman

Department of Clinical Medicine and Therapeutics

University Of Nairobi.

Signed.. Date...... 17/11/2022

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