TRANSLATION AND VALIDATION OF A SWAHILI VERSION OF THE TINNITUS HANDICAP INVENTORY

DR. OYWER AUSTINE H58/87786/2016

A dissertation submitted in partial fulfillment of the requirements of the award of Degree of Master of Medicine in Otorhinolaryngology, Head and Neck Surgery, University of Nairobi

STUDENT'S DECLARATION

I hereby certify that this thesis is my original work and has not been submitted for a degree award at any other university or publication in any journal.

Dr. Oywer Austine
MBChB
H58/87786/2016
Postgraduate student,
M. Med Otorhinolaryngology, Head and Neck Surgery,
University of Nairobi

Signature ..... Date 31-03-2022

SUPERVISORS' APPROVAL

This dissertation has been submitted with our approval as supervisors.

Dr. Joyce Aswani

MBChB, M.Med (ORL-HNS),

Consultant Otorhinolaryngologist, Head and Neck Surgeon,

Senior Lecturer,

Department of Surgery,

University of Nairobi

Signature ..... Date 31-03-2022

Dr. Sophie Gitonga

MBChB, M.Med (ORL-HNS)

Consultant Otorhinolaryngologist, Head and Neck Surgeon,

ENT department,

Kenyatta National Hospital

Signature ..... Date 31/3/2022

Ms. Serah Ndegwa,

Dipl, Clinical Medicine, HDipl ENT, Msc Audiology

Consultant Audiologist and Lecturer,

Department of Surgery,

University of Nairobi

Signature ..... Date 31/3/2022

DEPARTMENTAL APPROVAL

This dissertation was presented at the thematic unit of Otorhinolaryngology-Head and Neck Surgery meeting at the University of Nairobi on 24th March 2022 and is hereby approved.

Dr. Joyce Aswani,
Thematic Head, Otorhinolaryngology-Head and Neck Surgery,
Department of Surgery,
Faculty of Health Sciences,
The University of Nairobi

Signature…… Date 31-03-2022

Dr. Julius G. Kiboi,
Chairman, Department of Surgery,
Faculty of Health Sciences,
University of Nairobi.

Signature…… Date 4/4/2022

DEPARTMENT OF SURGERY
COLLEGE OF HEALTH SCIENCES
P. O. Box 19676 - 00202 KNH
NAIROBI
TEL: 2722890 / 2726300, Ext. 43773

DECLARATION OF ORIGINALITY

Name of Student:	**Dr. Oywer Austine Registration Number:** H58/87786/2016
Faculty/School/Institute:	Faculty of Health Sciences
Department:	Department of Surgery
Course Name:	Otorhinolaryngology, Head and Neck Surgery
Study Title:	**"Translation and Validation of a Swahili Version of the Tinnitus Handicap Inventory"**

DECLARATION

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2. I declare that this dissertation is my original work and has not been submitted elsewhere for examination, award of a degree or publication. Where other people's work, or my own work has been used, this has properly been acknowledged and referenced in accordance with the University of Nairobi's requirements.
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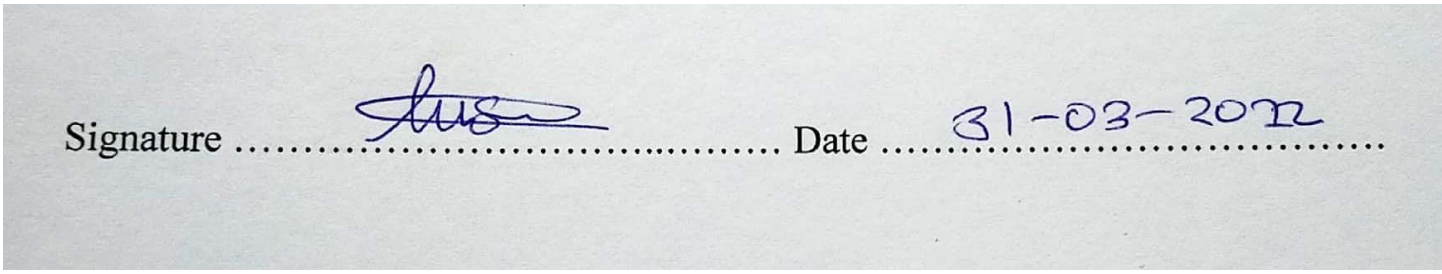

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LIST OF ABBREVIATIONS

dB - Decibel

ENT – Ear, Nose, and Throat

Hz - Hertz

KNH – Kenyatta National Hospital

KHz - Kilohertz

PTA – Pure Tone Audiometry

THI - Tinnitus Handicap Inventory

THI-S - Tinnitus Handicap Inventory Swahili

ABSTRACT

Background: The Tinnitus Handicap Inventory questionnaire addresses the functional, emotional and catastrophic aspects of tinnitus. Its questions are uncomplicated and the responses are most precise when administered in local languages. Thus, it has been translated into multiple languages.

Objective: To translate and validate a Swahili version of the Tinnitus Handicap Inventory.

Study Design: This was a cross-sectional study.

Study Setting and Duration: The study was conducted from March 2021 to January 2022 at the Kenyatta National Hospital Ear, Nose and Throat clinic.

Study Subjects: There were 50 patients with tinnitus attending the Kenyatta National Hospital Ear, Nose and Throat clinic.

Methodology: The Brislin model was used to translate the English Tinnitus Handicap Inventory into Swahili. Forward and back translation by blinded bilingual Otorhinolaryngologists was done. History, examination, pure tone audiometry and tinnitus loudness and pitch matching tests were done on patients. The Swahili questionnaire was administered to 50 patients with a re-test given two weeks later.

Data Analysis: The Cronbach's alpha and Pearson Product moment tests were calculated to determine the internal consistency, validity and reliability of the Swahili version. Correlations of hearing loss, tinnitus loudness and pitch matching tests and handicap were drawn.

Results: Fifty patients aged 21 to 61 years were recruited. The Cronbach’s alpha was 0.944 showing excellent internal consistency and validity. The Pearson Product moment was 0.969 confirming reliability. The Fisher’s Exact test confirmed an association between hearing loss and handicap levels and an association between tinnitus loudness and pitch matching test with P values of 0.025 and 0.003 respectively.

Conclusion: The Swahili Tinnitus Handicap Inventory demonstrated excellent internal consistency, reliability and validity. Hearing loss and tinnitus loudness and pitch have a negative impact on the handicap level a patient with tinnitus experiences.

Recommendations: The Swahili Tinnitus Handicap Inventory be used in assessing the handicap level in tinnitus patients and follow up for response to their management.

1.0 CHAPTER ONE

1.1 Introduction

Tinnitus is derived from a Latin word tinnire, which means to ring. Tinnitus may be described as hearing a ringing, thumping, buzzing, roaring or whistling sound in the absence of any external auditory stimuli. Such a phenomenon is extremely debilitating to a patient because it interferes with the ability to work and even socialize [1, 2].

Newman et al developed a self-report tinnitus handicap measure, the Tinnitus Handicap Inventory Questionnaire (THI) [2]. The THI was initially a 45 item questionnaire and was modified into a beta version 25 item questionnaire that had outstanding internal consistency and reliability after achieving a Cronbach's alpha = 0.93.[2] The THI was brief hence easy and quick to administer and later interpret the impact of tinnitus on functionality in a busy clinic. The THI addressed the psychological impact while retaining reliability and validity [2,3]. The THI has been a universally accepted tool, to assess the degree of handicap in an individual's personal lifestyle and has been the gold standard against which various translations have been measured for reliability and validity.

The Tinnitus Cognition Questionnaire (TCQ) and the Tinnitus Reaction Questionnaire (TRQ) were later developed by Wilson et al [3]. The TRQ had both reliable internal consistency and test-retest but it emphasized the psychological aspect of distress rather than the functional, emotional and catastrophic aspects [3]. Miekle et al. [4] published the Tinnitus Functional Index (TFI) that had excellent sensitivity to the treatment effects, addressed all aspects of the impact of tinnitus and had validity for estimating the bleak outcome of tinnitus [4].

Locally, there is no Swahili version of the THI questionnaire that can be used to evaluate the degree of handicap in patients with tinnitus in a language that they are conversant with. Internationally, various translations in Telugu, Urdu, Polish, Persian, Lithuanian and Gujarati have been instrumental in establishing a baseline for handicap assessment of the patients with tinnitus and initiating proper treatment of the causal factors.

2.0 CHAPTER TWO

2.1 Epidemiology of Tinnitus

Over 600 million adults suffer from tinnitus Worldwide and it is estimated that 21.4 million adult Americans had experienced tinnitus in 2016 [5]. Of these, 27% had experienced tinnitus for over 15 years with 36% of them having constant tinnitus [5]. In England, the prevalence among adults was found to be 10.1% [6]. In Egypt, tinnitus affects 5.17 cases per 100 inhabitants while the prevalence in Nigeria and Japan, is 14.1% and 18.6% respectively [7,8,9]. In Kenya, 39.2% of hypertensive patients have tinnitus, with females being more affected [10].

2.2 Pathophysiology of Tinnitus

Tinnitus is categorized into subjective and objective tinnitus [11, 12]. Subjective tinnitus is perceived by the patient in the absence of external stimuli and is caused by disruption or alteration of inputs to the auditory pathway. The disruption causes the creation of new neural connections and loss of suppression of the intrinsic cortical activity. [11-13] Objective tinnitus is noise caused by physiologic events occurring in proximity to the tympanic cavity. It may also be heard by the examiner. [11, 12]

The Jastreboff neurophysiological model postulates that tinnitus is caused by abnormalities in the cochlear function and the distress experienced is due to activation of the limbic system[14]. The discordant theory states that tinnitus is induced by aberrant function of the damaged outer hair cells with intact inner hair cells [15]. Low gamma-aminobutyric acid and increased serotonin levels have also been implicated in the onset of tinnitus or exacerbation [16].

2.3 Etiology of Tinnitus

Causes of subjective tinnitus are conditions associated with Sensorineural hearing loss (SNHL) like acoustic trauma, Presbycusis, ototoxic drugs, Meniere's disease, and central nervous system tumours. Cerumen impaction, otitis media and temporomandibular joint dysfunction are also implicated. [11-13]

Objective tinnitus is associated with tumultuous flow in the carotid artery or the internal jugular vein and middle ear tumors that are highly vascular. Other causes include myoclonus, palatal muscles spasms and spasms of stapedius or tensor tympani [11, 12].

2.4 Evaluation of Tinnitus

The evaluation of a patient with tinnitus begins with history taking i.e. duration of tinnitus, side affected, character, exacerbating or relieving factors and associated hearing loss. Vertigo, otalgia, otorrhea, symptoms of anxiety and depression, ear trauma and infections, radiation therapy to the head region and use of ototoxic drugs are also important [17].

Otologic examination is done for identification of ear discharge, cerumen impaction, tympanic membrane perforation or dimpling as tensor tympani contracts, cholesteatoma, and features of glomus tympanicum or jugulare [11-13, 17]. Weber and Rinne tuning fork tests for hearing loss should also be done. Auscultation for bruit over the carotid arteries and jugular veins and over the ear. Palatal myoclonus may be seen on oral examination with clicking sound heard in the ear using a stethoscope. A tympanometer is used to confirm changes in the tympanic membrane compliance [13,17]. Cranial nerve examination for associated neuropathies is also done. Some of the red flags from the examination will include unilateral tinnitus that may suggest an acoustic neuroma; bruit over the neck, skull or ear suggesting a vascular pathology and accompanying neurological symptoms that suggest tumours [17].

The THI is then administered to quantify tinnitus and the effect on daily living. It will determine the need for further management like counseling and masking devices. It is often used at diagnosis and during follow up to measure progress. The tool has 11 items in the functional subscale, 9 in the emotional subscale and 5 in the catastrophic subscale. The functional, emotional and catastrophic sub-scales of the THI are calculated to complete the assessment of the tinnitus severity and impact on the patient's life. The minimum score is 0 indicating no disability and maximum is 100 indicating severe disability. Question 24 in the THI that highlights the effect on tinnitus brought about by stress, has the greatest association with the total score. Stress fundamentally determines the degree of distress experienced.

Pure tone audiometry (PTA) determines presence, type and degree of hearing loss including tinnitus loudness and pitch matching tests to characterize the tinnitus. The threshold shift is recorded at the frequency level where the patient experiences hearing loss as seen on the pure tone audiogram. Imaging investigations such as Gadolinium-enhanced Magnetic Resonance Imaging (MRI), computed tomography (CT) scan and CT Angiogram are indicated where a space occupying lesion or tumour is suspected. [17]

2.5 Tinnitus Treatment

Treatment of the underlying disorder may ablate the tinnitus. The options available range from use of hearing aids embolization of vascular abnormalities to use of tinnitus masking devices. Tinnitus retraining programs (TRT) override the abnormal auditory cortex neural connections by generating low-level noise. Cognitive-behavioral therapy (CBT) promotes adaptive behaviors and habituation that may improve tinnitus tolerance, quality of life and sleep. Randomized clinical trials show alprazolam, clonazepam and amitriptyline are beneficial [17-21].

2.6 Cross-Cultural Translation and Adaptation of Survey Instruments

For instruments to be valid, they need to be appropriately translated and culturally acceptable. Cross-cultural translation of documents and tools helps in increasing the access to resources for knowledge, research, teaching and social purposes. Medically speaking, it enables the inclusion of more people in research and interventions not forgetting their socio-cultural backgrounds, hence eliminating the issue of selection bias in studies. Adaptation of translated tools is weighed heavily upon by the translation process itself and taking into account culture, idioms and lifestyle too. [22-23]

The THI has been of great use in setting up a start point and also keep track of efficacy of treatment. The THI has been translated into Telugu, Urdu, Polish, Gujarati, Persian and Brazilian-Portuguese among others. For a tool that has been translated to be culturally appropriate, it must be conceptually and technically equivalent to the original language, linguistically appropriate to the target population and also culturally competent. This means it must have the same meaning, content, grammar, and syntax. A direct translation is not required but content and meaning in the translated version has to be same as in the original version. Direct translation does not guarantee equivalent content of the translated tool. For validation and usefulness of a translated tool, back translation is essential. [22] Brislin's back translation model is popular for use in cross-cultural translation. Conceptually equivalent words are achieved by clear use of words in cross-cultural research. Avoidance of colloquialisms, vague terms and use of short and simple sentences are some of the simple rules suggested by Brislin et al. [24]

In order to maintain equivalence in cross-cultural translation and adaptation, decentering is applied. Decentering implies that a direct translation is not required if the newly translated version keeps the original meaning and content. It is recommended that the bilingual translators

have similar qualifications to ensure content equivalence in the translated tool. Problems commonly encountered in maintaining content equivalence may be in the vocabulary, idiom use, grammar and conceptual equivalences that are tackled during decentering. In pusuit of maintaining content equivalence, the Brislin model advocates for use of back translation, bilingual technique, committee approach and pretest procedure. Repeated translation and back translation by blinded bilingual translators ensures the comparison for conceptual equivalence is done. An error in the back translated version is re-translated by a different translator until the translators agree that the two versions are identical. The committee approach uses bilingual experts in the translation and any error made by a member is quickly identified and corrected during the meeting. Pretest involves carrying out a pilot study with the translated version to identify potential problems that may be encountered in the larger study. [23-24]

Following the translation, pertinent measures of reliability and validity will be done. **Reliability** refers to the extent to which a tool is able to consistently produce the same results. It has two main components, i.e. internal consistency and test-retest reliability. Internal consistency means the tool is free from errors, items in the scale correlate and are homogeneous. Internal consistency is measured using the Cronbach's alpha that is reported as 0 - 69% is poor, 70 - 79% is fair, 80 - 89% is good and 90 - 99% is excellent.

Test-retest reliability confirms that the tool can be administered repeatedly at different times and be able to reproduce the same results over and over. [25]

Validity refers to the tool's ability to actually measure what it is intended to measure. The two main aspects are criterion validity and construct validity. Criterion validity will compare the new tool to an existent tool that is the gold standard.

Construct validity refers to the new tool's ability to measure the theoretical construct for which it was made to measure. Construct validity is further subdivided into convergent and divergent validity.

Convergent validity refers to how two tools are able to measure the same subject matter and shows that they are truly related like the THI and TRQ.

Divergent validity on the contrary confirms that unrelated subject matters are indeed not related. [26]

2.7 Literature Review

Several translations of the THI have been developed. In these studies, a linguist proficient in both the local language and English was used. The linguists would rate the translated items on

a scale from excellently translated to inadequately translated. Items that were inadequately translated were changed and the final documents had items that had been rated highly.

Porika et al.[27] conducted a case-control study on "Translation of the Tinnitus Handicap Inventory into the Telugu Language and Standardization". The translated version was piloted on 10 Telugu speakers and well understood. Pure tone audiometry was done in the cases and controls groups then tinnitus loudness and pitch matching in the cases. The 60 cases and 60 controls then filled out the questionnaire. The correlation between the total score of each item scale showed statistical significance of $P<0.001$ confirming validity. Internal consistency was confirmed by a Cronbach's $\alpha = 0.981$. Test-retest using the Pearson two tailed correlation gave a score of 0.99 which showed a high reliability. They were able to classify patients into clusters of mild, moderate and severe handicap at 10, 35 and 30 percent respectively. The Telugu version was adopted and is in use in assessing tinnitus patients in their native Telugu language.

In a prospective cross-sectional study by Skarzynski et al. [28] titled "Adaptation of the Tinnitus Handicap Inventory into Polish and Its Testing on a Clinical Population", (THI-POL) 167 tinnitus patients filled the questionnaire. They found it easy to comprehend, addressed their tinnitus experiences and took 10 minutes to complete. The Cronbach's alpha coefficient was very high $\alpha=0.95$ that confirmed reliability. The test-retest reliability was significant $P<0.001$ and $r=0.91$. Convergent validity with the Tinnitus Subscale showed strong correlation while divergent validity showed a moderate correlation. The participants reported no difficulty in understanding the presented statements. The time needed to fill in the questionnaire was on average 10 minutes and the overall impression given by the questionnaire was very good. The patients said that the questionnaire addressed important issues connected to their tinnitus experience and that the way of answering the questions was uncomplicated.

In the "Persian language version of the Tinnitus Handicap Inventory: translation, standardization, validity, and reliability" study by Mahmoudian et al. [29], up to six translations were done of the THI-P to come up with the final version. In this Prospective cross-sectional study, the final version was administered to 112 tinnitus patients. They were able to demonstrate the reliability and validity of the Persian version of the THI to measure the consequences of tinnitus. They were hence able to show the relationship between tinnitus and the psychological distress experienced by adult patients suffering from tinnitus after grading them according to the functional, emotional and catastrophic subscales. The Pearson product

moment correlates showed test-retest reliability r=0.96 and the Cronbach's α = 0.939-0.944 showed the tool had internal consistency and hence reproducible.

A cross-sectional Psychometric validation on "Reliability and Validity of the Lithuanian Tinnitus Handicap Inventory" by Uloziene et al, [30] was piloted on 20 patients with tinnitus. 248 subjects with tinnitus completed the Lithuanian version and retest was done after 2-4 weeks. 55 of the subjects also filled the Hospital Anxiety and Depression scale to evaluate their anxiety and depression levels. Twenty-nine of the participants were found to have slight handicap, 81 had mild, 60 were moderate, 43 with severe and 35 had catastrophic handicap. Interventions were tailored to the degree of handicap. The final version showed robust internal consistency with a Cronbach's α = 0.93. Test-retest using the split half reliability was 0.99 that showed it was reliable. Significant correlations were observed between the Lithuanian THI and measures of self-perceived levels of anxiety and depression.

"Translation, Adaptation and Cross Language Validation of Tinnitus Handicap Inventory in Urdu" by Muhammad et al. [31] in a cross-sectional study came up with the Pakistan version (THI-U). The THI-U was piloted among 30 students at a foundation school and later filled by 110 tinnitus patients with a retest in 15 days. Construct validity correlation with the Pearson product moment was significant for all subscales P<0.001. Internal consistency and reliability were confirmed by Cronbach's α = 0.93 and thus found to be reliable. The test-retest Pearson correlation for the total score was 0.99 indicating good test retest reliability. They were able to conclude that the responses to the self-rating questionnaires are the most precise when administered in the native or local language of the individual.

Ajeet et al. [32] in a Prospective Observational study on "Translation and Validation of the Tinnitus Handicap Inventory into Gujarati Language", piloted the THI-Guj in 20 Gujarati speakers for validity. 68 patients with tinnitus were then administered the THI-Guj. THI-Guj was able to measure the degree of handicap and classify patients into slight to catastrophic tinnitus. About 30.9% of the patients were classified as moderate tinnitus. Patients with severe were 26.4% and 19.1% were catastrophic. This enabled the patients with moderate to catastrophic to undergo more aggressive tinnitus rehabilitation methods as compared to the mild group. A Cronbach's α = 0.980 was obtained that confirmed internal consistency. Construct validity was significant across all subscales P<0.000 confirming validity of the tool. A fair deal of challenges was also faced by researchers. Uloziene[30] et al found that question 6,

"Do you complain a great deal about your tinnitus?" and questions 19, "Do you feel that you have no control over your tinnitus?" had weak correlations with the item total score i.e. 0.332 and 0.389. They noted that question 19 was the most problematic and its removal resulted in the Cronbach's alpha would reach 0.703 which meant the Lithuanian version would have low internal consistency and reliability. They decided to retain it in their translated version. Mahmoudian[29] et al expressed concern over item 17 that had a relatively desirable score but included it in their final document to maintain the high internal consistency. Muhammad[31] et al noted item number two did not demonstrate satisfying reliability because of the overlap with other items namely, 8, 9 and 19. They thus recommended that future research eliminate or add on or modify this item and increase reliability.

Locally, Sitima et al [33] in a prospective cohort study on "Translation and Validation of a Swahili Version of the Sinonasal Outcome Test Snot-22" were able to achieve good internal consistency, validity and reliability of the Swahili version of the Snot-22 quality of life questionnaire. A total of 69 patients were tested on day 1 and day 14 with the questionnaire.

Of these, 35 were rested after undergoing endoscopic sinus surgery. The Cronbach's alpha was 0.799 while the interclass correlation coefficient was 0.799. They were able to demonstrate that the tool was valid in assessing the quality of life of Swahili speaking patients suffering from sinus disease. The Swahili version was found to be applicable in patient care and clinical research.

2.8 Study Rationale

Tinnitus has been found to affect over 600 million people Worldwide who need to be evaluated for their degree of handicap using the THI. Despite the existence of the English THI, some may not be adequately evaluated due to the unavailability of the THI in a language they are conversant with. Various researchers have been able to show that patients felt their tinnitus was better evaluated in a language they were more comfortable with. The patients reported that the questionnaire addressed important issues connected to their tinnitus experience and that the way of answering the questions was uncomplicated. This has led to the THI being translated into several languages including, Telugu, Urdu, Polish, Gujarati and Persian. Worldwide, the THI has been of great use in setting a starting point and keeping track of treatment. This study aimed to translate and validate the THI into Swahili which is the national language in Kenya. Swahili is widely spoken and read by patients who present at the Kenyatta National Hospital (KNH).

2.9 Research Question

How reliable and valid will a Swahili version of the THI be in assessing the degree of handicap in patients suffering from tinnitus?

2.10 Study Objectives

2.10.1 Primary objective

a) To translate the Newman English THI into Swahili and to validate the Swahili version.

2.10.2 Secondary objectives

a) To correlate the level of hearing loss with the tinnitus handicap.
b) To correlate the level of tinnitus handicap with the tinnitus loudness and pitch matching test.

2.10.3 Specific Objectives

a) To translate the English THI into Swahili.

b) To test the translated Swahili THI for consistency, reliability and validity against the English THI in patients with tinnitus.

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a cross-sectional study.

3.2 Study Setting

The setting was the KNH Ear, Nose and Throat (ENT) clinic.

3.3 Study Subjects

The study patients were 50 adult patients with tinnitus who presented at the KNH ENT Clinic. They were recruited into the study and followed up in two weeks for re-assessment for the degree of handicap using the Swahili THI (THI-S).

Inclusion criteria

- **a)** Patients 18 years and above presenting to the KNH ENT clinic suffering from tinnitus.
- **b)** Patients who understood Swahili.
- **c)** Patients who gave consent to take part in the study.

Exclusion criteria

- **a)** Patients with cognitive impairment who could not give consent.
- **b)** Patients with altered ear anatomy impairing examination and audiometry.

3.4 Sample Size

Sample size (n) needed for testing and estimating coefficient alpha was determined by the Cochran's formula [34]

$$n = \frac{Z^2 x\ P(1-P)}{d^2}$$

Where,

n = Desired sample size

Z = value from standard normal distribution corresponding to desired confidence level (Z=1.96 for 95% CI)

P = expected true proportion (estimated at 58.6%, from a study conducted by Macharia et al [35] in 2019, found 95 of them had temporary tinnitus.)

d = desired precision (0.05)

$$n_0 = \frac{1.96^2 x\ 0.586(1-0.586)}{0.05^2} = 372$$

Currently in Kenyatta National Hospital approximately 70 patients are seen per year with tinnitus as the primary diagnosis. Adjusting the sample size for finite populations less than 10,000

$$nf = \frac{n_0}{1 + \frac{n_0 - 1}{N}} = \frac{372}{1 + \frac{372 - 1}{48}} = 42$$

An additional 20% were recruited to account for drop outs and incomplete data. Hence a sample size of 50 patients was required for the study.

3.5 Sampling Method

In this study, convenience consecutive sampling was used. Patients suffering from tinnitus presented to the KNH ENT clinic. The patients who met the inclusion criteria were recruited. The study was explained to them and consent obtained. History, examination, pure tone audiometry and tinnitus loudness and pitch matching tests done. Following the tests, the patients then had the Swahili THI administered to them by the principal researcher. Two weeks after each patient filled the questionnaire, the patients were contacted to return for readministration of the questionnaire. Only 36 patients were recruited in the retest phase as 6 patients had resolution of their tinnitus while 8 did not show up when contacted. The figure below illustrates the sampling method that was used.

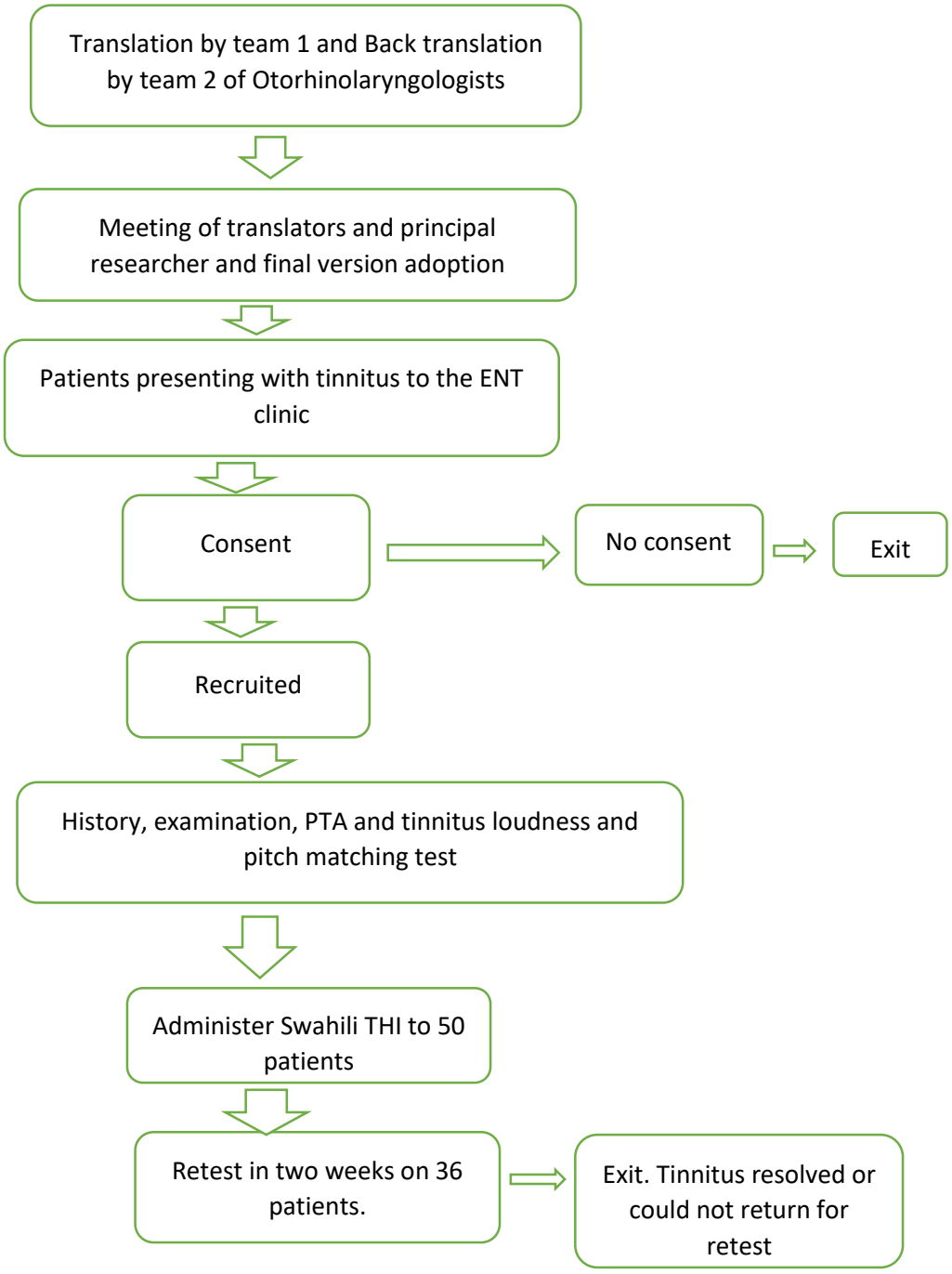

Figure 1: Sampling and procedure flow chart

3.6 Procedure

The procedure of the study involved the translation of the THI using the revised Brislin model for cross-cultural adaptation. Translation from English to Swahili was done by two Otorhinolaryngologists proficient in Swahili. To ensure that we achieved conceptual equivalence, we used short and simple sentences, avoided colloquialisms and vague terms.

Decentering was also used to cater for words and phrases that could not be directly translated into Swahili. The Otorhinolaryngologists compared the versions and a consensus was reached on the translated version. Back-translation was done by a second group of two blinded Otorhinolaryngologists well versed in Swahili and English to test for any material that may be lost in the translation process. The versions that the second group developed were compared and a final version was then derived. A committee meeting involving all translators and the principal researcher was then held to confirm the translated version was free of errors and agreed on the final version of the Swahili THI. The Swahili translated version was then piloted as a pretest technique prescribed by Brislin model, among twenty patients who presented with complaints of tinnitus at the KNH ENT clinic, for refining purposes. The patients from the piloting were included in the study. Piloting helped us know whether the Swahili THI was understandable in preparation to administer it to the 30 study patients.

History, otologic examination and Pure Tone Audiometry (PTA) for the study participants was carried out. PTAs were performed using the modified Hughson-Westlake method as recommended by the American Association on Hearing [36]. Testing begun with the ear that had better hearing as reported by the patient. The audiologist first determined the threshold in the better ear at 1000Hz by presenting a pure tone at 60 dB sound level. If the tone was not heard, the audiologist increased the intensity by increments of 10 dB until a response was obtained. If a response was given by the patient at the 60 dB level, the audiologist decreased the intensity of the tone by 10 decibels (dB) and presented the same tone once more. If the patient responded to this tone, a trend of decreasing the tone by 10 was used. The audiologist continued to decrease the intensity of the tone presented by 10 dB and presented the same tone until the patient did not respond anymore. The audiologist then performed 5 dB increments of the same tone until the point was reached where the patient responded. This was performed at the 250Hz, 500Hz, 1000Hz, 2000Hz, 4000Hz and 8000Hz frequencies for air conduction. For bone conduction testing, the same method was used but at 500Hz, 1000Hz, 2000Hz and 4000Hz frequencies. The results were then plotted on an audiogram.

The patients also had tinnitus loudness and pitch matching tests done[37]. This begun with quality judgement of the tinnitus. The patients were presented with both broad band and narrow band noises and pure tones. This was done in the opposite ear if the patient had tinnitus in one ear. The patient was required to identify which tone is closest to the tinnitus he/she experienced. A loudness match was then performed. This begun with the patient being presented with a pure tone at a frequency of 1 kHz in the opposite ear. The next step was to perform a loudness

balance that was compared to the tinnitus being experienced and the value was recorded as the sensation level and decibel hearing level. An attempt was then made to find the central tinnitus pitch. If the tinnitus experienced was more than one, the patient was asked to focus on which tinnitus disturbed them the most. Following this, the tones were presented in the opposite ear at 1 KHz and in octave steps higher than the obtained level up to the point the tinnitus pitch was matched as closely as possible. In a case where the tinnitus matching frequency was not above 1KHz, the tones were presented at levels below 1KHz.

The patients then filled in the self-administered Swahili THI questionnaire in the presence of the lead researcher in case any of the patients needed help. In two weeks, after the first completion of the form, the questionnaire was re-administered to 36 patients for test-retest purposes.

3.7 Study Duration

The study was conducted between March 2021 to January 2022.

3.8 Quality control

Quality control was a continuous process to ensure results were reliable and could be replicated. A standard data collection tool was used by the principal researcher to perform the history taking and examination portion of data collection. The same 512Hz Heine tuning fork was used by the principal researcher and the same Heine otoscope for examination. The Swahili THI was administered by the principal researcher. The PTA was administered in the same ENT department Audiology room using the same PTA machine for all recruited study patients. The PTA was carried out by an audiologist on a calibrated PTA machine. The PTA machine to be used was a yearly calibrated Interacoustic AC33 clinical audiometer.

3.9 Data Management and Analysis

All the data collected was entered into an excel sheet. Data was cleaned for incomplete results. The final excel sheet was exported to SPSS version 21 for analysis. Descriptive statistics were represented as percentages, frequencies, mean scores and standard deviation for the continuous variables such as age. The categorical variables were also presented as percentages. During analysis, the external reliability of the Swahili THI was measured using the test retest reliability. Internal consistency of the questionnaire was done by calculating the Cronbach's alpha coefficient. The Pearson product moment was calculated between the total score of the Swahili THI and the scores of its subscales, age and pure tone averages to assess for correlations. Statistical significance was set at $P<0.005$ in all the analysis. Patients were

classified into the functional, emotional and functional subscales depending on their degree of handicap. Correlations comparing the level of discomfort with the tinnitus loudness and pitch matching tests were also made.

3.10 Ethical Considerations

This study was carried out after approval by the UON ENT department, KNH administration and the KNH/UON Ethics and Research Committee Reference number KNH-ERC/A/108. Each patient underwent relevant education and counseling before giving Informed written consent. Patients in the study did not incur any extra costs. For purposes of maintaining confidentiality, the patients were identified by study numbers. Any patient who failed to give consent was not be victimized and continued to be managed for the condition they were suffering from. All data collected was safely stored by the principal researcher and was not accessible to unauthorized persons. Upon presentation of the study results, all data collection materials will be destroyed and discarded. The results derived from the study will be submitted in the form of a thesis. The results will be shared during scientific forums, in journals and at meetings and seminars. A soft copy version of the study will be made available on the UON online portal for dissemination and reference. The hard copy forms of the study will be availed to the ENT Department library, UON department of Surgery library and the College of Health Sciences Library. A manuscript will be availed for publication in a journal as part of partial fulfillment of the Master of Medicine in Ear, Nose and Throat Surgery.

4.0 CHAPTER FOUR: RESULTS

4.1 Initial Translation

The translation team translated the THI English version into the commonly spoken Swahili language.

The translation done by the first team of Otorhinolaryngologists is as shown in Table 1 below.

Table 1: Forward Translation of The THI into Swahili

NUMBER	ENGLISH	TRANSLATOR 1	TRANSLATOR 2
1	Because of your tinnitus, is it difficult for you to concentrate?	Unapata tabu kumakinika juu ya kele sikioni?	Kwa sababu ya kelele sikioni , unapata shida kumakinika?
2	Does the loudness of your tinnitus make it difficult for you to hear people?	Idadi ya kelele sikioni huwa inakuzuia kusikiliza watu wengine?	Unapata taabu kusikiliza watu kwa sababu ya wingi wa kelele sikioni?
3	Does your tinnitus make you angry?	Kuwa na kelele sikioni huwa kunakukasirisha?	Unakasirishwa na kelele sikioni?
4	Does your tinnitus make you feel confused?	Kelele sikioni hufanya kuhisis kuchanganyikiwa?	Unahisi kuchanganikiwa kwa sababu ya kelele sikioni?
5	Because of your tinnitus, do you feel desperate?	Unahisi kunyangalika juu ya kelele sikioni?	Unahisi hauna namna nyingine kwa sababu ya kelele sikioni?
6	Do you complain a great deal about your tinnitus?	Huwa unalalamika kwa sababu ya kelele sikioni?	Unapata huwa unalalamika kusudi ya kelele sikioni?
7	Because of your tinnitus, do you have trouble falling to sleep at night?	Kelele sikioni huwa inachangia kukosa usingizi usiku?	Unapata shida kulala usiku kwa sababu ya kelele sikioni?
8	Do you feel as though you cannot escape your tinnitus?	Huwa unahisi kushikwa mateka na hali ya kelele sikioni?	Unahisi kana kwamba huwezi kuepuka kelele sikioni?
9	Does your tinnitus interfere with your ability to enjoy your social activities (such as going out to dinner, to the movies)?	Je, kelele sikioni hufanya ushindwe kuburudika na familia na marafiki kama chakula cha jioni au sinema?	Unapata ugumu wa kujumuika kwa sababu ya kelele sikioni?
10	Because of your tinnitus, do you feel frustrated?	Unahisi kupingwa kwa sababu ya kelele sikioni?	Kwa sababu ya kelele sikioni, unahisi hauna amani?
11	Because of your tinnitus, do you feel that you have a terrible disease?	Unahisi kuwa kelele sikioni ni ugonjwa mbaya zaidi?	Kelele sikioni hufanya unahisi kama uko na ugonjwa mbaya zaidi?
12	Does your tinnitus make it difficult to enjoy life?	Kelele sikioni hufanya uwe na ugumu wa kufurahia maisha?	Unahisi kutofurahia maisha juu ya kelele sikioni?

13	Does your tinnitus interfere with your job or household responsibilities?	Unapata shida kufanya kazi ofisini au kazi za nyumbani	Huwa unapata ugumu wa kufanya kazi yako au kazi
		kwa sababu ya kelele sikioni?	za nyumbani kwa sababu ya kelele sikioni?
14	Because of your tinnitus, do you find that you are often irritable?	Huwa unacheneteshwa na kelele sikioni?	Kwa sabau ya kelele sikioni, huwa unapata kuchokozwa kwa urahisi?
15	Because of your tinnitus, is it difficult for you to read?	Kwa sababu ya kelele sikioni, unapata shida kusoma?	Unapata ugumu wa kusoma kwa sababu ya kelele sikioni?
16	Does your tinnitus make you upset?	Unakereka kwa sababu ya kelele sikioni?	Kelele sikioni hukufanya kuhisi kukasirishwa?
17	Do you feel that your tinnitus problem has placed stress on your relationships with members of your family and friends?	Unahisi kwamba kelele sikioni imeleta changamoto katika uhusiano wako na familia na marafiki?	Unahisi kama kelele sikioni inaleta ugumu kuhusiana na jamaa na marafiki?
18	Do you find it difficult to focus your attention away from your tinnitus and on other things?	Unapata ugumu wa kukusanya fikra zako kwa mambo mengine bali na kelele sikioni?	Unapata shida kufikiria mambo mengine bila kufikiria kelele sikioni?
19	Do you feel that you have no control over your tinnitus?	Je, unahisi kama hauna uwezo wa kudhibiti kelele sikioni?	Unahisi hauna uwezo kudhibiti kelele sikioni?
20	Because of your tinnitus, do you often feel tired?	Unahisi uchovu kwa sababu ya kelele sikioni?	Kwa sababu ya kelele sikioni, unahisi kuchoka?
21	Because of your tinnitus, do you feel depressed?	Unahisi huna hamu maishani kwa sababu ya kelele sikioni?	Kwa sababu ya kelele sikioni, unahisi hauna furaha maishani?
22	Does your tinnitus make you feel anxious?	Unahisi ukadirifu kwa sababu ya kelele sikioni?	Kelele sikioni unafanya unahisi uwoga?
23	Do you feel that you can no longer cope with your tinnitus?	Unahisi huwezi kuendelea kukabiliana na kelele sikioni?	Kelele sikioni inafanya uhisi ni kama hauwezi kuendeleza maisha yako?
24	Does your tinnitus get worse when you are under stress?	Unahisi kelele sikioni huongezeka ukiwa na kikazo?	Kelele sikioni huwa inaongezeka wakati unapata changamoto mingi?
25	Does your tinnitus make you feel insecure?	Unahisi hauna usalama kwa sababu ya kelele sikioni?	Kelele sikioni inafanya unahisi hauna usalama?

4.2 Verification of the Translation

Table 2: Consensus forward translation of the THI into Swahili

NUMBER	ENGLISH	Consensus
1	Because of your tinnitus, is it difficult for you to concentrate?	Unapata tabu kumakinika kwa sababu ya kelele sikioni?
2	Does the loudness of your tinnitus make it difficult for you to hear people?	Unapata taabu kusikiliza watu kwa sababu ya wingi wa kelele sikioni?
3	Does your tinnitus make you angry?	Unakasirishwa na kelele sikioni?
4	Does your tinnitus make you feel confused?	Unahisi kuchanganyikiwa kwa sababu ya kelele sikioni?
5	Because of your tinnitus, do you feel desperate?	Unahisi kunyangalika juu ya kelele sikioni?
6	Do you complain a great deal about your tinnitus?	Huwa unalalamika kwa sababu ya kelele sikioni?
7	Because of your tinnitus, do you have trouble falling to sleep at night?	Unapata shida kulala usiku kwa sababu ya kelele sikioni?
8	Do you feel as though you cannot escape your tinnitus?	Huwa unahisi kushikwa mateka na hali ya kelele sikioni?
9	Does your tinnitus interfere with your ability to enjoy your social activities (such as going out to dinner, to the movies)?	Unapata ugumu wa kujumuika kwa sababu ya kelele sikioni?
10	Because of your tinnitus, do you feel frustrated?	Unahisi kupingwa kwa sababu ya kelele sikioni?
11	Because of your tinnitus, do you feel that you have a terrible disease?	Unahisi kuwa kelele sikioni ni ugonjwa mbaya zaidi?
12	Does your tinnitus make it difficult to enjoy life?	Unahisi kutofurahia maisha juu ya kelele sikioni?
13	Does your tinnitus interfere with your job or household responsibilities?	Huwa unapata ugumu wa kufanya kazi yako au kazi za nyumbani kwa sababu ya kelele sikioni?
14	Because of your tinnitus, do you find that you are often irritable?	Huwa unacheneteshwa na kelele sikioni?
15	Because of your tinnitus, is it difficult for you to read?	Kwa sababu ya kelele sikioni, unapata shida kusoma?
16	Does your tinnitus make you upset?	Unakereka kwa sababu ya kelele sikioni?
17	Do you feel that your tinnitus problem has placed stress on your relationships with members of your family and friends?	Unahisi kwamba kelele sikioni imeleta changamoto katika uhusiano wako na familia na marafiki?
18	Do you find it difficult to focus your attention away from your tinnitus and on other things?	Unapata ugumu wa kukusanya fikra zako kwa mambo mengine bali na kelele sikioni?
19	Do you feel that you have no control over your tinnitus?	Je, unahisi kama hauna uwezo wa kudhibiti kelele sikioni?
20	Because of your tinnitus, do you often feel tired?	Unahisi uchovu kwa sababu ya kelele sikioni?
21	Because of your tinnitus, do you feel depressed?	Kwa sababu ya kelele sikioni, unahisi hauna furaha maishani?

22	Does your tinnitus make you feel anxious?	Unahisi ukadirifu kwa sababu ya kelele sikioni?
23	Do you feel that you can no longer cope with your tinnitus?	Unahisi huwezi kuendelea kukabiliana na kelele sikioni?
24	Does your tinnitus get worse when you are under stress?	Unahisi kelele sikioni huongezeka ukiwa na kikazo?
25	Does your tinnitus make you feel insecure?	Unahisi hauna usalama kwa sababu ya kelele sikioni?

4.3 Back Translation

Table 3: Back translation of the Swahili THI into English

NUMBER	Consensus	TRANSLATOR 1	TRANSLATOR 2
1	Unapata tabu kumakinika kwa sababu ya kelele sikioni?	Do you get difficulty concentration because of tinnitus?	Do you get difficulty concentration because of tinnitus?
2	Unapata taabu kusikiliza watu kwa sababu ya wingi wa kelele sikioni?	Do you get difficulty listening to people because of tinnitus?	Do you have difficulty hearing people because of tinnitus?
3	Unakasirishwa na kelele sikioni?	Are you angered by tinnitus?	Do you get angry because of tinnitus?
4	Unahisi kuchanganyikiwa kwa sababu ya kelele sikioni?	Do you feel confused because of tinnitus?	Do you feel confused by the tinnitus?
5	Unahisi kunyangalika juu ya kelele sikioni?	Do you feel hopeless because of tinnitus?	Does tinnitus make you feel ?confused?
6	Huwa unalalamika kwa sababu ya kelele sikioni?	Do you complain because of tinnitus?	Does the tinnitus make you complain?
7	Unapata shida kulala usiku kwa sababu ya kelele sikioni?	Do you get insomnia due to tinnitus?	Do you have difficulty sleeping because of tinnitus?
8	Huwa unahisi kushikwa mateka na hali ya kelele sikioni?	Do you feel you are trapped by tinnitus?	Do you feel you cannot escape from tinnitus?
9	Unapata ugumu wa kujumuika kwa sababu ya kelele sikioni?	Do you have difficulty socializing because of tinnitus?	Do you have a hard time socializing because of tinnitus?
10	Unahisi kupingwa kwa sababu ya kelele sikioni?	Do you feel opposed because of tinnitus?	Does tinnitus make you feel opposed?
11	Unahisi kuwa kelele sikioni ni ugonjwa mbaya zaidi?	Do you feel tinnitus is a very bad disease?	Does tinnitus make you feel like you have a very bad disease?
12	Unahisi kutofurahia maisha juu ya kelele sikioni?	Do you feel you cannot enjoy life because of tinnitus?	Does tinnitus make you feel you are depressed or cannot enjoy life?

13	Huwa unapata ugumu wa kufanya kazi yako au kazi za nyumbani kwa sababu ya kelele sikioni?	Do you find it difficult working or doing house chores because of tinnitus?	Does tinnitus make it hard to work or do house chores?
14	Huwa unacheneteshwa na kelele sikioni?	Does tinnitus make you irritable?	Do you feel moody because of tinnitus?
15	Kwa sababu ya kelele sikioni, unapata shida kusoma?	Do you have difficulty reading due to tinnitus?	Does tinnitus make it hard for you to read?
16	Unakereka kwa sababu ya kelele sikioni?	Do you get angered by tinnitus?	Does tinnitus make you angry?
17	Unahisi kwamba kelele sikioni imeleta changamoto katika uhusiano wako na familia na marafiki?	Do you feel tinnitus has brought issues when relating with family and friends?	Does tinnitus affect your relationship with friends and family?
18	Unapata ugumu wa kukusanya fikra zako kwa mambo mengine bali na kelele sikioni?	Do you experience difficulty concentrating your thoughts on other things because of tinnitus?	Does tinnitus make it hard to be attentive on other things?
19	Je, unahisi kama hauna uwezo wa kudhibiti kelele sikioni?	Do you feel you cannot control the tinnitus?	Does tinnitus make you feel you cannot control it?
20	Unahisi uchovu kwa sababu ya kelele sikioni?	Do you feel fatigued by tinnitus?	Does tinnitus make you feel tired?
21	Kwa sababu ya kelele sikioni, unahisi hauna furaha maishani?	Do you feel you are unhappy because of tinnitus?	Does tinnitus make you feel sad?
22	Unahisi ukadirifu kwa sababu ya kelele sikioni?	Do you have feelings of fear or anxiety because of tinnitus?	Does your tinnitus make you feel fearful?
23	Unahisi huwezi kuendelea kukabiliana na kelele sikioni?	Do you feel you cannot continue to cope with tinnitus?	Does tinnitus make you feel hopeless?
24	Unahisi kelele sikioni huongezeka ukiwa na kikazo?	Do you feel the tinnitus is aggravated by limitations in life?	Does your tinnitus worsen when you face difficulties?
25	Unahisi hauna usalama kwa sababu ya kelele sikioni?	Do you feel you are insecure?	Does tinnitus make you feel insecure?

The back translation was read by the first team of forward translators and it was noticed that some questions were not easily understood. Refinements were then made to the translated version.

In question number 5, the word “nyangalika” was taken to mean hopeless which is a synonym for desperate. It was felt that this would rather be changed to “hauna namna” for better understanding by the study patients.

Question 14 also posed a challenge. The word moody is a synonym for irritable but it was agreed to change the word “kucheneteshwa” to “kuchokozwa kwa urahisi” for better understanding. For question 21, sad/ unhappy describes depression and was left as it was. A similar challenge was encountered in question 22 where it was felt that anxious also implies fear and was left as was.

This final Swahili version of the THI was agreeable to the four translators and was named, THI-S

4: The Final Swahili version of the THI, (THI-S)

	SWALI	NDIO	WAKATI MWINGINE	LA
1	Unapata tabu kumakinika kwa sababu ya kelele sikioni?			
2	Unapata taabu kusikiliza watu kwa sababu ya wingi wa kelele sikioni?			
3	Unakasirishwa na kelele sikioni?			
4	Unahisi kuchanganyikiwa kwa sababu ya kelele sikioni?			
5	Unahisi hauna namna juu ya kelele sikioni?			
6	Huwa unalalamika kwa sababu ya kelele sikioni?			
7	Unapata shida kulala usiku kwa sababu ya kelele sikioni?			
8	Huwa unahisi kushikwa mateka na hali ya kelele sikioni?			
9	Unapata ugumu wa kujumuika kwa sababu ya kelele sikioni?			
10	Unahisi kupingwa kwa sababu ya kelele sikioni?			
11	Unahisi kuwa kelele sikioni ni ugonjwa mbaya zaidi?			
12	Unahisi kutofurahia maisha juu ya kelele sikioni?			
13	Huwa unapata ugumu wa kufanya kazi yako au kazi za nyumbani kwa sababu ya kelele sikioni?			
14	Huwa unachokozwa kwa urahisi na kelele sikioni?			
15	Kwa sababu ya kelele sikioni, unapata shida kusoma?			
16	Unakereka kwa sababu ya kelele sikioni?			
17	Unahisi kwamba kelele sikioni imeleta changamoto katika uhusiano wako na familia na marafiki?			
18	Unapata ugumu wa kukusanya fikra zako kwa mambo mengine bali na kelele sikioni?			
19	Je, unahisi kama hauna uwezo wa kudhibiti kelele sikioni?			
20	Unahisi uchovu kwa sababu ya kelele sikioni?			
21	Kwa sababu ya kelele sikioni, unahisi hauna furaha maishani?			
22	Unahisi ukadirifu kwa sababu ya kelele sikioni?			
23	Unahisi huwezi kuendelea kukabiliana na kelele sikioni?			
24	Unahisi kelele sikioni huongezeka ukiwa na kikazo?			
25	Unahisi hauna usalama kwa sababu ya kelele sikioni?			

Table

4.4 Age and Sex Characteristics of the Patients

The THI-S was administered to a total of 50 patients in the test group. The mean age of the patients was 35.2 (SD 8.9) years. The median age was 33.0 (IQR 29.0 – 41.0) years. Males were majority at 64%. The male to female ratio was 1.7:1. Their age and gender profile is given in Table 5 below.

Table 5: Age and Sex characteristics of the patients

		Frequency *(n=50)*	**Percent**
Sex	Male	32	64.0
	Female	18	36.0
Age	21 – 30	17	34.0
	31 – 40	20	40.0
	41 – 50	9	18.0
	>50	4	8.0

4.5 Degree of Handicap

A majority of the patients, 78% (n=39), had a slight or no handicap. This was followed by mild handicap in 14% (n=7) of the participants as shown in tables 6 and 7 below.

Table 6: Tinnitus Handicap

Score	**Frequency *(n=50)***	**Percent**	**Category**
0	27	54.0	Slight or No Handicap (Grade 1)
2	1	2.0	Slight or No Handicap (Grade 1)
4	3	6.0	Slight or No Handicap (Grade 1)
6	1	2.0	Slight or No Handicap (Grade 1)
8	2	4.0	Slight or No Handicap (Grade 1)
10	1	2.0	Slight or No Handicap (Grade 1)
12	3	6.0	Slight or No Handicap (Grade 1)
16	1	2.0	Slight or No Handicap (Grade 1)
20	1	2.0	Mild Handicap (Grade 2)
22	2	4.0	Mild Handicap (Grade 2)
24	1	2.0	Mild Handicap (Grade 2)
26	1	2.0	Mild Handicap (Grade 2)
30	1	2.0	Mild Handicap (Grade 2)
34	1	2.0	Mild Handicap (Grade 2)
42	1	2.0	Moderate Handicap (Grade 3)
48	2	4.0	Moderate Handicap (Grade 3)
58	1	2.0	Severe Handicap (Grade 4)

Table 7: Tinnitus Handicap

	Frequency *(n=50)*	**Percent**
Slight or No Handicap (Grade 1)	39	78.0
Mild Handicap (Grade 2)	7	14.0
Moderate Handicap (Grade 3)	3	6.0
Severe Handicap (Grade 4)	1	2.0

4.6 Item-Total correlations for Swahili THI

In the calculation of the item-total correlation score, the lowest score was question 8 at 0.383 (good correlation). The internal consistency of the THI-S questionnaire yielded a very high internal consistency with a total Cronbach's α=0.944 as in Table 8 below.

Table 8: Descriptive statistics for THI

Item	**Yes, n (%)**	**Sometimes, n (%)**	**No, n (%)**	**Item-total correlation**	**Cronbach's alpha is item deleted**
THI 1	1 (2.0)	13 (26.0)	36 (72.0)	0.829	0.939
THI 2		10 (20.0)	40 (80.0)	0.442	0.945
THI 3	5 (10.0)	8 (16.0)	37 (74.0)	0.825	0.939
THI 4*			50 (100.0)		
THI 5	3 (6.0)	6 (12.0)	41 (82.0)	0.801	0.939
THI 6	2 (4.0)	6 (12.0)	42 (84.0)	0.742	0.941
THI 7	6 (12.0)	8 (16.0)	36 (72.0)	0.773	0.940
THI 8	4 (8.0)	4 (8.0)	42 (84.0)	0.383	0.947
THI 9		6 (12.0)	44 (88.0)	0.584	0.943
THI 10	2 (4.0)	11 (22.0)	37 (74.0)	0.736	0.940
THI 11	2 (4.0)	3 (6.0)	45 (90.0)	0.793	0.940
THI 12		6 (12.0)	44 (88.0)	0.805	0.941
THI 13		4 (8.0)	46 (92.0)	0.595	0.943
THI 14	1 (2.0)	6 (12.0)	43 (86.0)	0.600	0.943
THI 15		4 (8.0)	46 (92.0)	0.773	0.942
THI 16	3 (6.0)	9 (18.0)	38 (76.0)	0.888	0.938
THI 17*			50 (100.0)		
THI 18		8 (16.0)	42 (84.0)	0.835	0.940
THI 19	2 (4.0)	7 (14.0)	41 (82.0)	0.459	0.945
THI 20	3 (6.0)		47 (94.0)	0.644	0.942
THI 21		4 (8.0)	46 (92.0)	0.585	0.944
THI 22	6 (12.0)	1 (2.0)	43 (86.0)	0.514	0.945
THI 23*			50 (100.0)		
THI 24	15 (30.0)	2 (4.0)	33 (66.0)	0.738	0.943
THI 25*			50 (100.0)		

Total Cronbach's alpha 0.944

Table

*** = item with zero variance therefore not included in the Cronbach's alpha calculation**

4.7 Cronbach's Alpha for subscales

The Cronbach's α for the subscales was highest in the functional category at 0.875 while lowest in the catastrophic category at 0.663 in the test phase of the study as in table 9 below.

Table 9: Cronbach's Alpha for the subscales in the Test group

	Cronbach's Alpha
Functional	0.875
Emotional	0.834
Catastrophic	0.663

4.8 Retest

On retest of the complete tool, the Cronbach's α =0.934, was excellent. Question 4 had the lowest itemtotal correlation of 0.138 and removal of the question would raise the Cronbach's alpha to 0.93. Questions 17, 23 and 25 had zero variance as shown in table 9 below. The Pearson product moment two-tailed correlation showed a test-retest reliability of r=0.969, that was statistically significant ($p<0.001$). The functional, emotional and catastrophic subscales had Cronbach's α values of 0.857, 0.851 and 0.707 respectively as shown in table 10 below.

Table 10: Descriptive statistics for THI (Retest)

Item	Yes, n (%)	Sometimes, n (%)	No, n (%)	Item-total correlation	Cronbach's alpha is item deleted
THI 1	1 (2.8)	17 (47.2)	18 (50.0)	0.773	0.929
THI 2	1 (2.8)	13 (36.1)	22 (61.1)	0.450	0.933
THI 3	6 (16.7)	11 (30.6)	19 (52.8)	0.766	0.928
THI 4		1 (2.8)	35 (97.2)	0.138	0.935
THI 5	4 (11.1)	7 (19.4)	25 (69.4)	0.706	0.929
THI 6	2 (5.6)	7 (19.4)	27 (75.0)	0.721	0.929
THI 7	9 (25.0)	6 (16.7)	21 (58.3)	0.758	0.929
THI 8	6 (16.7)	5 (13.9)	25 (69.4)	0.444	0.935
THI 9		7 (19.4)	29 (80.6)	0.545	0.932
THI 10	2 (5.6)	12 (33.3)	22 (61.1)	0.804	0.928
THI 11	3 (8.3)	5 (13.9)	28 (77.8)	0.806	0.928
THI 12	2 (5.6)	7 (19.4)	27 (75.0)	0.696	0.930
THI 13		6 (16.7)	30 (83.3)	0.485	0.933
THI 14	2 (5.6)	6 (16.7)	28 (77.8)	0.649	0.930
THI 15		5 (13.9)	31 (86.1)	0.695	0.931
THI 16	3 (8.3)	10 (27.8)	23 (63.9)	0.844	0.927
THI 17*			36 (100.0)	-	
THI 18		9 (25.0)	27 (75.0)	0.775	0.929
THI 19	2 (5.6)	7 (19.4)	27 (75.0)	0.500	0.933
THI 20	3 (8.3)	1 (2.8)	32 (88.9)	0.597	0.931
THI 21		3 (8.3)	33 (91.7)	0.620	0.932
THI 22	4 (11.1)	2 (5.6)	30 (83.3)	0.601	0.931
THI 23*			36 (100.0)	-	
THI 24	18 (50.0)	4 (11.1)	14 (38.9)	0.615	0.933
THI 25*		1 (2.8)	35 (97.2)	-	

Total Cronbach's alpha 0.934

***= item had zero variance therefore not included in the Cronbach's alpha calculation**

Table 11: Test Retest Subscales

	Cronbach's Alpha
Functional	0.857
Emotional	0.851
Catastrophic	0.707

Table

4.9 Hearing Loss Type

The hearing loss types were as shown in the table 11 below

Table 12: Hearing loss type

Hearing loss Type	Number of patients (n=50)	Percent
Mild Hearing Loss	32	64
Moderate Hearing Loss	18	36
Severe Hearing Loss	0	0
Profound Hearing Loss	0	0

4.9.1 Correlation of Hearing Loss and Handicap Level

A Fisher's Exact test was used to test the association between hearing loss and the handicap level. The P value was <0.01 that indicates there is a statistical significant association between the two as shown in Table 13 below.

Table 13: Association between hearing loss and the handicap level

	Moderate HL	Slight/Mild HL	p-value
Slight or No Handicap (Grade 1)	11	28	**0.025**
Mild Handicap (Grade 2)	3	4	
Moderate Handicap (Grade 3)	3	0	
Severe Handicap (Grade 4)	1	0	

4.10 Tinnitus Loudness and Pitch Matching Test

The tinnitus loudness and pitch matching test scores for the frequencies tested were as shown in the table 14 below

Table 14: Tinnitus loudness and pitch matching test

Tinnitus Loudness Hz	Number of patients *(n=50)*	Percent
250	28	56
500	13	26
1000	8	16
2000	1	2

4.10.1 Correlation of Tinnitus Loudness and Pitch Matching Test with the Handicap Level

A Fisher's exact test was used to test the association between Tinnitus loudness and Pitch matching test with the handicap level. A P value of 0.003 was obtained indicating there is a statistical significant association between the two as represented in Table 15 below.

Table 15: Association between Tinnitus loudness and pitch matching test with handicap level

	250	**500**	**1000**	**2000**	**p-value**
Slight or No Handicap (Grade 1)	26	8	5	0	**0.003**
Mild Handicap (Grade 2)	2	1	3	1	
Moderate Handicap (Grade 3)	0	3	0	0	
Severe Handicap (Grade 4)	0	1	0	0	

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION AND RECOMMENDATIONS

5.1 Discussion

Tinnitus is of a significant burden on the lives of patients who suffer from it. In an attempt to address the level of handicap produced by tinnitus, the English THI was developed [2]. However, this English version could not be administered to a great number of patients who only spoke their native languages. This presented a need to translate and validate the tool among different languages. The tool has been translated into Telugu [27], Gujarati[32], Persian[29], Lithuanian [30], Polish [28] and Urdu [31] languages among others.

The THI was translated by following standard procedures of the Brislin model used in cross cultural translation and adaptation of research instruments. We then evaluated the THI-S tool for internal consistency, reliability and validity by calculating the Cronbach's alpha and Pearson product moment.

The internal consistency and reliability of the THI-S was calculated, with a Cronbach's alpha of 0.944. This value is close to 1 that indicates the questionnaire has a high internal consistency and thus a reliable tool for measuring the level of handicap in patients with tinnitus. Our results are similar to the Cronbach's alpha values of the Telugu [27] (α =0.981), Gujarati [32] (α=0.98), Lithuanian [30](α=0.93), Persian [29] (α=0.96), Polish [28] (α=0.95) and Urdu [31] (α=0.93) validated questionnaires.

Despite the high internal consistency and reliability, some questions posed a challenge during the study and thus had low item-total correlation scores. Questions 2, 8 and 19 had low itemtotal correlation scores of 0.442, 0.383 and 0.459 respectively. Question 2 asked, "Does the loudness of your tinnitus make it difficult for you to hear people?". This was translated to, "unapata taabu kuskiliza watu kwa sababu ya wingi wa kelele sikioni?" The term "wingi" may have been interpreted to mean many. Probably we should have used the phrase "sauti kubwa" that implies loud, the patients would have interpreted it as such. Question 8 asked, "do you feel as though you can't escape your tinnitus?". The translated version asked, "huwa unahisi kushikwa mateka na hali ya kelele sikioni?". This may have implied the patient was being held hostage by their tinnitus. Perhaps a more direct translation such as" kutoroka" would have been taken to mean escape better. Question 19 asked, "do you feel that you have no control over your tinnitus?" This translated to, "je, unahisi kama hauna uwezo wa kudhibiti kelele sikioni?" The word kudhibiti is understood as control but may have been a more complex word to some patients as

opposed to “kuzuia” that means prevent or overcome. Deletion of questions 2, 8 and 19 would have given Cronbach’s alpha values of 0.945, 0.947 and 0.945 respectively implying they might have slightly better assessed the aspects of tinnitus they were meant to. Since our Cronbach’s alpha was 0.944 which is excellent, and the values were above the accepted limit (>0.3), the questions were retained for completeness of the THI-S questionnaire.

The validity of the THI-S was tested using the Pearson Product Moment that had a score of r=0.969 and a P value<0.001. This shows that the tool is stable as there was no significant change in scores in the retest group when the THI-S was administered after two weeks. This is comparable to the Telugu [27], Lithuanian [30] and Polish [28] that had values of 0.99, 0.99 and 0.91 respectively.

The internal consistency of the functional, emotional and catastrophic subscales was tested and revealed Cronbach’s alpha values of 0.857, 0.851 and 0.707 respectively with a total Cronbach’s alpha score of 0.805. A value above 0.69 is acceptable and the catastrophic subscale is regarded to have scored fairly. The score implies the THI-S is able to measure the catastrophic aspects of tinnitus in the questions asked. The low score may be attributed to the subscale having only five questions out of the tool’s 25 questions. Questions 8 and 19 that had low item-total correlation scores, are also in the catastrophic subscale may have also contributed to the low scores. Similar low scores in the catastrophic scales were seen in the Lithuanian [30] and Polish [28] versions with scores of 0.70 and 0.76 respectively.

A Fisher’s Exact test was able to show there was a statistically significant association between hearing loss and the handicap level with a P value was <0.01. The Fisher’s Exact test was also able to show a statistically significant association between Tinnitus Loudness and Pitch matching test with the handicap level. A P value of 0.003 was obtained. These results imply that the level of hearing loss and the tinnitus loudness and pitch have an effect on the level of handicap that the patient was experiencing.

5.2 Study Limitation

An element of test retest bias might have impacted the study, especially for patients who improved after an intervention. This would mean the patients would give varied answers during the retest phase. Recall bias may also not be completely ruled out.

5.3 Conclusion

The Swahili version (THI-S) has demonstrated excellent internal consistency, reliability and validity by passing the statistical tests. THI-S is thus able to assess the degree of handicap in Swahili speaking patients with tinnitus. Hearing loss and tinnitus loudness and pitch have a negative impact on the handicap level a patient with tinnitus experiences.

5.4 Recommendations

The THI-S be used in clinically assessing the handicap level in tinnitus patients and follow up for response to their management. Assessment of the tinnitus loudness and pitch should be done to fully assess patients with tinnitus. Future studies to assess if the suggested changes to the troublesome questions 2, 8 and 19 will improve the Cronbach's alpha.

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APPENDICES

Appendix I: Participant Information and Consent Form (English)

Adult Consent for Enrollment in the Study Title of Study: Translation and validation of the Swahili version of the Tinnitus Handicap Inventory at The Kenyatta National Hospital
Principal Investigator\and institutional affiliation: Dr. Oywer Austine (Postgraduate student in Ear, Nose and Throat Surgery, The University of Nairobi).
Co-Investigators and institutional affiliation:

Dr. Joyce Aswani Dr. Sophie Gitonga

Ms. Serah Ndegwa Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not to be a participant in the study. Feel free to ask any questions about the purpose of the research, what happens if you participate in the study, the possible risks and benefits, your rights as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide to be in the study or not. This process is called 'informed consent'. Once you understand and agree to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in a medical research:

i) Your decision to participate is entirely voluntary
ii) You may withdraw from the study at any time without necessarily giving a reason for your withdrawal
iii) Refusal to participate in the research will not affect the services you are entitled to in this health facility or other facilities. We will give you a copy of this form for your records.

May I continue? YES / NO

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

What is this Study About?

The researchers listed above are interviewing individuals who are suffering from tinnitus and those who are not. The purpose of the interview is to translate The Tinnitus Handicap Inventory (THI) into Swahili and validate it for reliability. Participants in this research study will be asked questions about tinnitus and how it affects their lives. There will be approximately one hundred

and twenty-eight participants in this study randomly chosen. We are asking for your consent to consider participating in this study.

What will happen if you decide to participate This Research Study?

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

You will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately ten minutes. The interview will cover topics such as your biodata and inquiry on tinnitus symptoms. After the interview has finished, you will be allowed to go about your other activities of the day. We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include to get more information concerning the study.

Are There Any Risks, Harms Discomforts Associated With This Study?

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify you in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting your confidentiality can be absolutely secure, so it is still possible that someone could find out you were in this study and could find out information about you.

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

Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews. You may feel some discomfort when your ears are examined and tuning fork tests are done. In case of an injury, illness or complications related to this study, contact the study staff right away at the number provided at the end of this document. The study staff will treat you for minor conditions or refer you when necessary.

Are There Any Benefits Being In This Study?

You may benefit by receiving free ear examination and hearing testing i.e. otoscopy and tuning fork tests. We will refer you to the KNH ENT clinic for care and support where necessary. Also, the information you provide will help us better understand the debilitating effect of tinnitus. As is the norm in scientific research, we would like to share our findings with

colleagues doing similar studies. The findings will thus be presented at scientific conferences and shared in publications.

Will Being In This Study Cost You Anything?

You will neither incur any costs nor benefit financially when you participate in this study.

Will You Get Refund For Any Money Spent As Part Of This Study?

All costs incurred arising directly from taking part in the study will be refunded.

What If You Have Questions In Future?

If you have further questions or concerns about participating in this study, please call or send a text message to the study staff at the number provided below. The study staff will pay you back for your charges to these numbers if the call is for study-related communication.

Principal Investigator:

Dr. Oywer Austine,
E.N.T., Head and Neck Surgery,
Department of Surgery,
School of Medicine, University of Nairobi, P.O.
Box 701128-00400 Nairobi.
Email: aoywer@gmail.com
Mobile: 0725397717 **Supervisors:**

Dr. Joyce Aswani,
Consultant E.N.T., Head and Neck Surgeon,
Lecturer E.N.T.-Head and Neck Surgery,
UoN, Department of Surgery,
Email: joyceaswani@gmail.com

Dr. Sophie Gitonga,
Consultant E.N.T., Head and Neck Surgeon,
Kenyatta National Hospital,
P.O. Box 20723-00202 Nairobi.

Ms. Serah Ndegwa,
Consultant Audiologist and Lecturer,
Department of Surgery, University
of Nairobi.
Email: serahndegwa8@gmail.com

Secretary/Chairperson,

Kenyatta National Hospital-University of Nairobi Ethics and Research Committee,
Telephone No. 2726300 Ext. 44102
Email: uonknh_erc@uonbi.ac.ke

What Are Your Other Choices?

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

Consent Form (Statement of Consent) Participant's statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential. By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

I agree to participate in this research study: Yes No I agree to provide contact information for follow-up: Yes No

Participant printed name:

_____

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

Researcher's statement

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

Researcher's Name: _____ **Date**: _____

Signature _____

Role in the study: _____

For more information contact _____ at _____ from _____ to _____

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

Name _____ Contact information _____

Signature /Thumb stamp: _____ Date; _____

Appendix II: Participant Information and Consent Form (Swahili)

Fomu ya Makubaliano

Mada ya Utafiti: Kutafsiri na kuidhinisha fomu ya Kiswahili ya Tinnitus Handicap Inventory katika Hospitali Kuu ya Kenyatta.

Mtafiti Mkuu:

Dkt. Oywer Austine

Mwanafunzi wa Shahada ya uzamili ya Upasuaji wa Sikio, Pua na Koo, Chuo kikuu cha Nairobi **Watafiti Wasaidizi:**

Dkt. Joyce Aswani,

Dkt. Sophie Gitonga Bi

Serah Ndegwa.

Utangulizi:

Ningependa kukueleza kuhusu utafiti unaofanywa na watafiti walioorodheshwa hapo juu. Fomu hii itakuwezesha kufanya uamuzi wa kuhusishwa katika utafiti huu. Unakubaliwa kuuliza maswali kuhusu umuhimu wa utafiti huu, kitakacho fanyika ukujihusisha katika utafiti huu, faida au madhara ya utafiti huu, na mambo mengine yoyote kuhusiana na utafiti huu. Tutakapo jibu maswali yako yote kikamilifu, unaweza kukubali au kukataa kuhusishwa katika utafiti huu. Mpanilio huu unaitwa “idhini wa habai”. Baada ya kuelewa na kukubali kuhusishwa katika utafiti huu, nitakuomba utie sahihi katika fomu hii. Unapaswa kuelewa yafuatayo:

i) Uamuzi wako ni wa huru

ii) Unaweza kujiondoa katika utafiti huu wakati wowote bila maelezo

iii) Kukataa kuhusishwa katika utafiti huu hautaathiri matibabu yako katika hospitali hii au nyingine. Tutakupea nakala yako ya fomu hii.

Je ninaweza kuendelea? Ndio/ La

Utafiti huu umeidhinishwa na tume ya maadili na utafiti wa Hospitali Kuu ya Kenyatta nambari _____

Utafiti Huu Unahusu Nini?

Watafiti hawa watafanya mahojiano kwa wagonjwa wanaosikia kelele sikioni na wale wasiosikia kelele. Kusudi wa mahojiano ni kujua namna utafsiri wa fomu hii ya Tinnitus Handicap Inventory (THI) utaweza kubaini madhara ya kelele sikioni kwa wagonjwa.

Kutakuwa na wahusiwa mia moja, ishirini na nane watakao chaguliwa kwa nasibu. Tunaomba ruhusa kwako kuhusishwa katika utafiti huu. **Nini Kitafanyika Nikihusishwa Katika Utafiti Huu?**

Ukikubali kuhusishwa katika utafiti huu, yafuatayo yatafanyika. Utaweza kufanyiwa mahojiano kwa njia ya siri ili uweze kujibu maswali bila wasiwasi. Mahojiana yatachukua muda wa dakika yasiyozidi kumi. Mtafiti atazungumzia mada kama ilivyoelezwa hapo juu. Baada ya mahojiano utaruhusiwa kuendelea na mipango yako ya siku. Tutaomba uweze kutupatia nambari yako ya simu tuweze kuwasiliana nawe zaidi. Nambari yako itatumika na wahusika wa utafiti huu pekee bila kupewa mtu mwingine yeyote. Kuwasiliana na wewe itakuwa kupata ujumbe zaidi kuhusu utafiti huu.

Je, Kuna Madhara Yanayotokana Na Utafiti Huu?

Utafiti wa kisayansi, unaweza kukuadhiri kijinsia, kisaikolojia, kijamii, kiwiliwili na kihisia. Kuhusishwa katika utafiti unaweza kuadhiri faragha kwa nafsi yako. Maelezo yote utakayotupatia yatawekwa kwa njia ya siri. Utaweza kutambulika kwa nambari ya siri katika rekodi ya kompyuta itakayotumika na makatasi yote kuwekwa katika kabati itakayofungwa. Kuna uwezekano kuwa bila idhini yetu mtu kupata rekodi yako. Maswali mengine katika utafiti huu yanaweza kukuletea usumbufu na unaruhusiwa kukataa kuyajibu. Watafiti wote ni wataalamu katiak utafiti. Iwapo utahisi usumbufu wowote katika utafiti huu, wasiliana na watafiti wasaidizi au mkuu mara moja kwa nambari katika nakala hii.Utaweza kutibiwa kwa madhara madogo au kutumwa kwa mhudumu anayefaa.

Je, Kuna Faida Ya Utafiti Huu?

Utaweza kufaidika kwa kuangalilliwa masikio bila malipo na pia kupimwa kusikia kwako. Utaweza pia kupata matibabu katika kliniki ya masikio hapa Kenyatta iwapo utahitaji matibabu zaidi. Majibu utakayo tuambia yatatuwezesha kujua madhara ya kelele sikioni mwa wagonjwa. Utafiti huu pia utachangia katika mikutano ya kisayansi.

Je, Kuhusishwa Utanigarimu Pesa Ngapi?

Hakuna malipo yoyote utahitajika kufanya katika utafiti huu.

Je, Utapata Kurudishiwa Pesa Utakayotumia Katika Utafiti Huu?

Hakuna gharama ya ziada itakayo kupata katika utafiti huu.

Iwapo Una Maswali Baadaye?

Unaweza kuwasiliana na watafiti kwa nambari za rununu zilizowekwa katika nakala hii. Unaweza kupiga simu au kutuma ujumbe mfupi kwa mtafiti yeyote. Watafiti watagharamia malipo ya kupiga simu kuhusiana na utafiti huu.

Mtafiti mkuu:

Dkt. Oywer Austine,
E.N.T., Upasuaji wa Kichwa na Shingo,
Idara ya Upasuaji,
Shule ya Masomo ya Matibabu, UoN, Sanduku
La Posta 701128-00400 Nairobi.
Barua Pepe: aoywer@gmail.com
Rununu: 0725397717 **Wasimamizi:**
Dkt. Joyce Aswani,
Mshauri wa upasuaji wa masikio, mapua na koo,
Idara ya Upasuaji,
Chuo Kikuu cha Nairobi,
Sanduku la Posta 20723-00202, Nairobi.
Barua pepe: joyceaswani@gmail.com

Dkt. Sophie Gitonga,
Mshauri wa upasuaji wa masikio, mapua na koo,
Hospitali Kuu ya Kenyatta,
Sanduku la Posta 20723-00202, Nairobi.
Barua pepe: sophiegitanga@gmail.com

Bi. Serah Ndegwa,
Mshauri wa kusikia,
Chuo kikuu cha Nairobi,
Barua pepe: serandegwa@gmail.com

Katibu,
Tume ya maadili na utafiti, Hospitali kuu ya Kenyatta na Chuo Kikuu cha Nairobi, Sanduku La Posta 20723-00202, Nairobi.
Nambari ay simu: 2726300 Ext 44102,
Barua pepe: uonknh-erc@uonbi.ac.ke

Je Uko na Uchaguzi?

Kuhusishwa katika utafiti huu ni kwa hiari yako. Unaruhusiwa kukataa kuhusishwa au kujiondoa katika utafiti huu kwa wakati wowote bila dhuluma.

Fomu ya Makubaliano Tamko la mshiriki

Mimi nimesoma au nimesomewa yaliyochapishwa katika fomu hii. Nimeweza kupata maelezo kutoka kwa mtaalamu wa utafiti. Maswali yangu yamejibiwa kwa lugha ninayoelewa. Ninaelewa ya kwamba, kushiriki kwa utafiti huu ni kwa hiari yangu na kwamba ninaweza

kujiondoa kwa utafiti huu kwa wakati wowote. Nimekubali kwa hiari yangu kuhusishwa katika utafiti huu. Kwa kutia sahihi, sitakuwa nimekata tamaa ya haki zangu kama mhusishwa katika utafiti huu.

Nimekubali kuhusishwa katika utafiti huu: Ndio/ La

Nimekubali kupeana njia za mawasiliano zangu kwa mazungumzo zaidi: Ndio/La

Jina la mhusiwa: _____

Sahihi la mhusiwa / kidole gumba _____ Tarehe _____

Tamko la Mtafiti

Mimi, niliyetia sahihi, nimeeleza kwa kina yanayohusiana na utafiti huu na ninatumai mhusiwa ameelewa vyema na kukubali kwa hiari yake kuhusishwa. **Mtafiti: _____**

Tarehe: _____

Sahihi _____

Uhusiano katika utafiti: _____

Kwa mawasiliano zaidi, wasiliana na _____ kwa nambari

_____ saa _____ hadi _____

Jina la mshuhudia

Jina _____ Simu ya Rununu _____

Sahihi/Kidole gumba: _____ Tarehe; _____

Appendix III: Data Collection Sheet

Study number: …….. **Date:** ……..

Biodata

Age: ……. **Sex:** ……..

History

a) Duration of tinnitus ☐ acute tinnitus (≤1 year) ☐ chronic tinnitus (>1 year)

b) Tinnitus is ☐ right ☐ left ☐ bilateral

c) Tinnitus is ☐ constant ☐ intermittent

d) Tinnitus pitch ☐ high ☐ low ☐ varying

e) Exacerbating factors ☐ head position ☐ swallowing ☐stress ☐ none ☐ others…..

f) Effect of tinnitus ☐ anxiety ☐ depression ☐ none ☐ others ……..

g) Insomnia due to the tinnitus ☐ yes ☐ no

h) History of ear trauma ☐ yes ☐ no

i) History of ear infection ☐ yes ☐ no

j) History of radiation to the head ☐ yes ☐ no

k) History of chronic illness ☐Diabetes ☐Hypertension ☐ End stage Renal disease ☐none ☐others…….

l) Hearing loss ☐ yes ☐ no

m) Ototoxic drugs if known ……..

Examination

a) Ear discharge right ☐ yes ☐ no left ☐ yes ☐ no

b) Cerumen impaction right ☐ yes ☐ no left ☐ yes ☐ no

c) Tympanic Membrane

Right ☐ normal ☐ bulging ☐ inflamed ☐perforation ☐retracted

Left ☐ normal ☐ bulging ☐ inflamed ☐perforation ☐retracted

d) Tuning fork tests

1. Weber ☐ central ☐ left lateralizing ☐ right lateralizing
2. Rinne Left ☐ positive ☐ negative Right ☐ positive ☐ negative

e) Pure Tone Audiometry (Audiogram attached)

Degree	Normal	Conductive Hearing Loss	Sensorineural Hearing loss	Mixed Hearing Loss
Normal				
Mild (25-40 dB)				
Moderate (41-55dB)				
Moderately Severe (56-70dB)				
Severe (71-90 dB)				
Profound (>90 dB)				

f) Loudness and Pitch matching test

Pitch (Hz) Loudness (dB)	250	500	1000	2000	4000	8000
Right						
Left						

Appendix IV: Tinnitus Handicap Inventory

Tinnitus Handicap Inventory (T.H.I.) as Developed by Newman et al.

Instructions: The purpose of this questionnaire is to identify difficulties that you may be experiencing because of your tinnitus. Please answer every question. Please do not skip any questions.

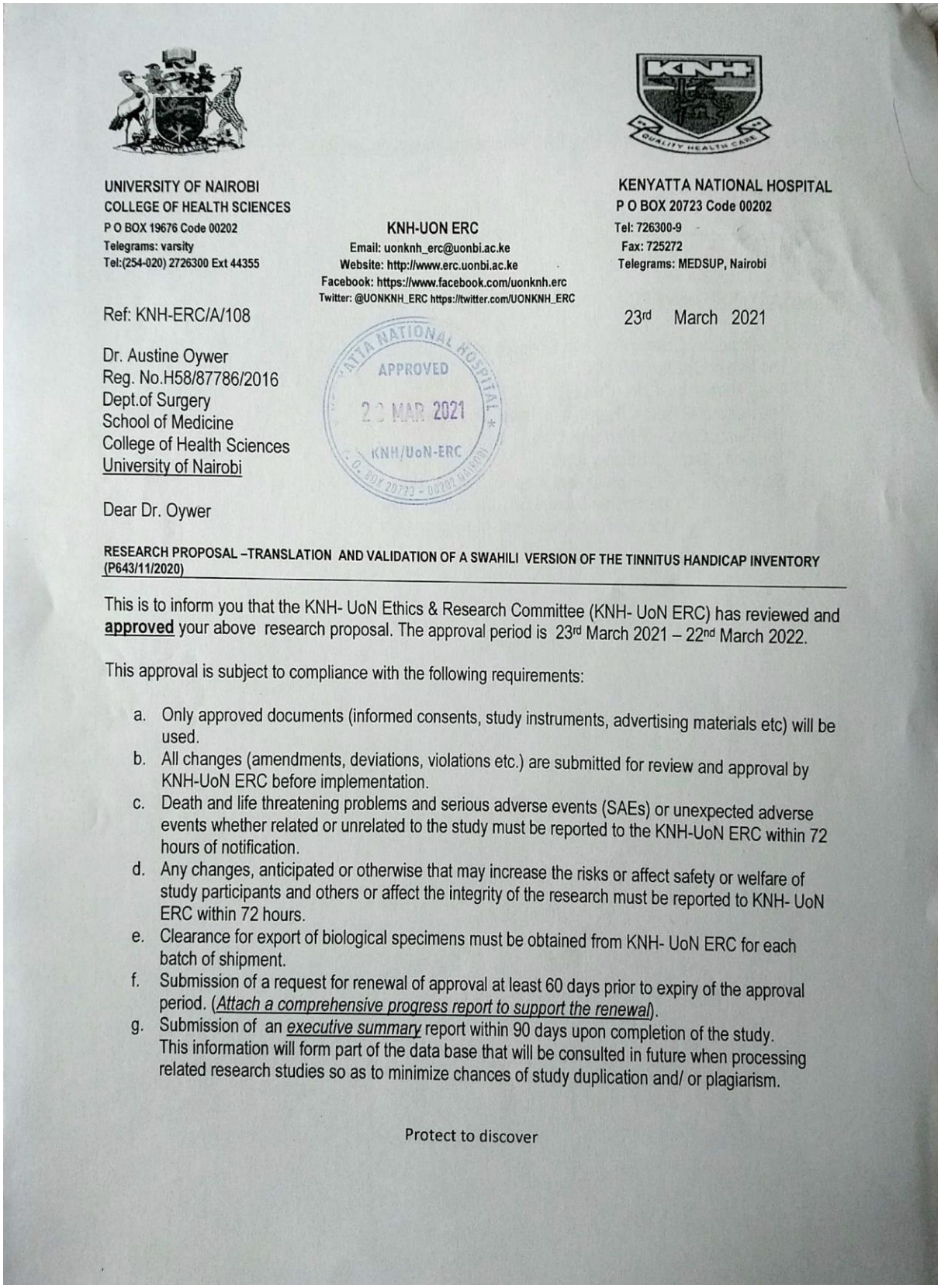
1. Because of your tinnitus, is it difficult for you to concentrate?	○ Yes	○ Sometimes	○ No
2. Does the loudness of your tinnitus make it difficult for you to hear people?	○ Yes	○ Sometimes	○ No
3. Does your tinnitus make you angry?	○ Yes	○ Sometimes	○ No
4. Does your tinnitus make you feel confused?	○ Yes	○ Sometimes	○ No
5. Because of your tinnitus, do you feel desperate?	○ Yes	○ Sometimes	○ No
6. Do you complain a great deal about your tinnitus?	○ Yes	○ Sometimes	○ No
7. Because of your tinnitus, do you have trouble falling to sleep at night?	○ Yes	○ Sometimes	○ No
8. Do you feel as though you cannot escape your tinnitus?	○ Yes	○ Sometimes	○ No
9. Does your tinnitus interfere with your ability to enjoy your social activities (such as going out to dinner, to the movies)?	○ Yes	○ Sometimes	○ No
10. Because of your tinnitus, do you feel frustrated?	○ Yes	○ Sometimes	○ No
11. Because of your tinnitus, do you feel that you have a terrible disease?	○ Yes	○ Sometimes	○ No
12. Does your tinnitus make it difficult to enjoy life?	○ Yes	○ Sometimes	○ No
13. Does your tinnitus interfere with your job or household responsibilities?	○ Yes	○ Sometimes	○ No
14. Because of your tinnitus, do you find that you are often irritable?	○ Yes	○ Sometimes	○ No
15. Because of your tinnitus, is it difficult for you to read?	○ Yes	○ Sometimes	○ No
16.			○ No

Does your tinnitus make you upset?	○ Yes	○ Sometimes	
17. Do you feel that your tinnitus problem has placed stress on your relationships with members of your family and friends?	○ Yes	○ Sometimes	○ No
18. Do you find it difficult to focus your attention away from your tinnitus and on other things?	○ Yes	○ Sometimes	○ No
19. Do you feel that you have no control over your tinnitus?	○ Yes	○ Sometimes	○ No
20. Because of your tinnitus, do you often feel tired?	○ Yes	○ Sometimes	○ No
21. Because of your tinnitus, do you feel depressed?	○ Yes	○ Sometimes	○ No
22. Does your tinnitus make you feel anxious?	○ Yes	○ Sometimes	○ No
23. Do you feel that you can no longer cope with your tinnitus?			
24. Does your tinnitus get worse when you are under stress?	○ Yes	○ Sometimes	○ No
25. Does your tinnitus make you feel insecure?	○ Yes	○ Sometimes	○ No

For clinician use only:

Total THI Score: (number of 'Yes' responses x 4) + (number of 'Sometimes' responses x 2) = _____	Determine the presence of perceived tinnitus handicap based on total THI score. 0-16: Slight or No Handicap (Grade 1) 18-36: Mild Handicap (Grade 2) 38-56: Moderate Handicap (Grade 3) 58-76: Severe Handicap (Grade 4) 78-100: Catastrophic Handicap (Grade 5)

Appendix V: KNH/UoN-ERC Letter of Approval



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

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
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KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/108

23rd March 2021

Dr. Austine Oywer
Reg. No.H58/87786/2016
Dept.of Surgery
School of Medicine
College of Health Sciences
University of Nairobi

KENYATTA NATIONAL HOSPITAL
APPROVED
23 MAR 2021
KNH/UoN-ERC
P.O. BOX 20723 - 00202 NAIROBI

Dear Dr. Oywer

RESEARCH PROPOSAL –TRANSLATION AND VALIDATION OF A SWAHILI VERSION OF THE TINNITUS HANDICAP INVENTORY (P643/11/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 23rd March 2021 – 22nd March 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 serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

Protect to discover

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

Yours sincerely,

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

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information Dept, KNH
The Dean, School of Medicine, UoN
The Chair, Dept. of Surgery, UoN
Supervisors: Dr. Joyce Aswani, Dept. of Surgery, UoN
Dr. Sophie Gitonga,ENT Department, KNH
Ms.Serah Ndegwa, Dept. of Surgery, UoN

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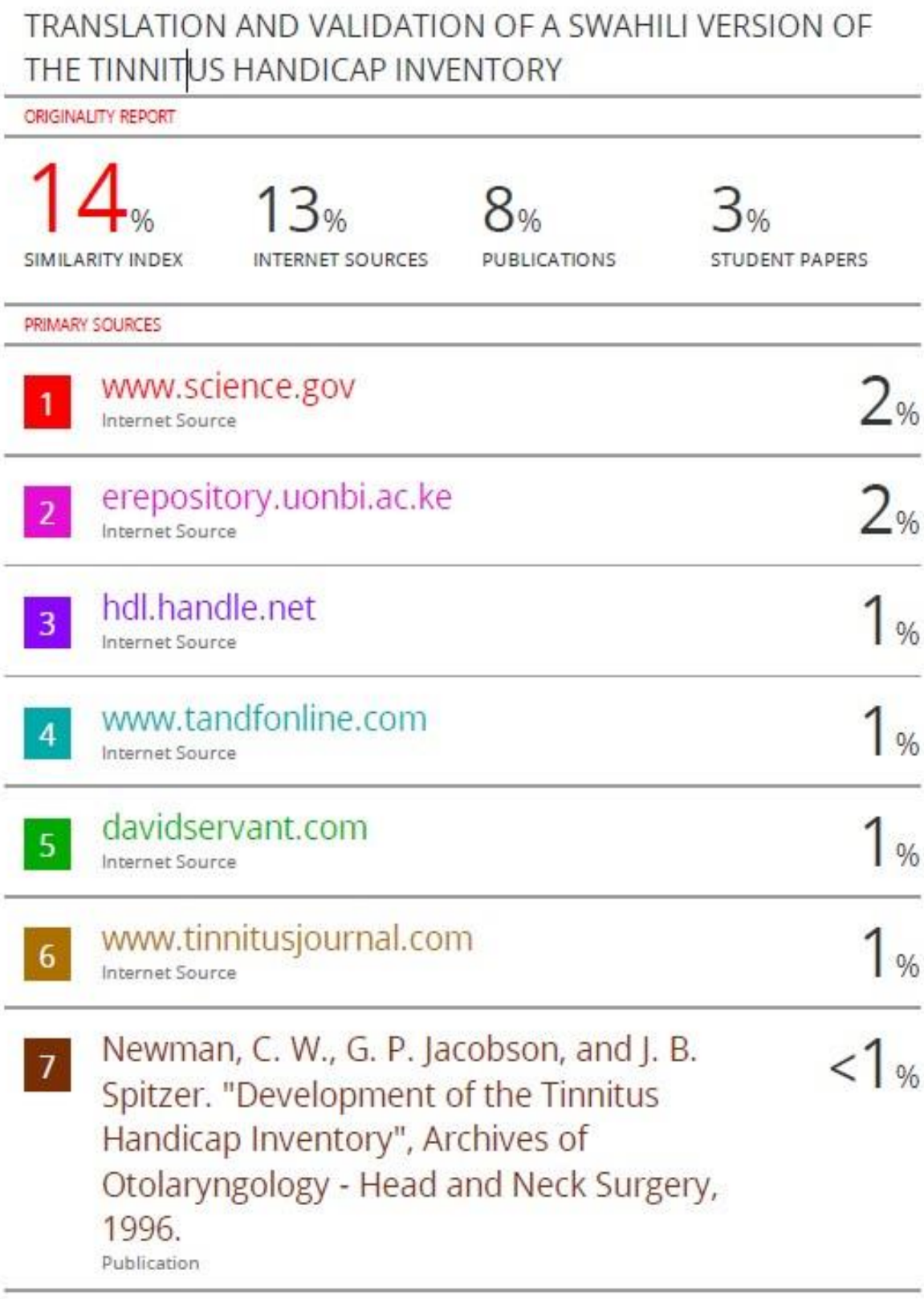
Appendix VI: Certificate of Plagiarism



TRANSLATION AND VALIDATION OF A SWAHILI VERSION OF THE TINNITUS HANDICAP INVENTORY

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7	Newman, C. W., G. P. Jacobson, and J. B. Spitzer. "Development of the Tinnitus Handicap Inventory", Archives of Otolaryngology - Head and Neck Surgery, 1996. Publication	<1%