

EFFICACY OF COCONUT OIL IN THE CONTROL OF TUNGIASIS

By

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DECLARATION

This thesis is my original work and has not been, presented for a degree in any other university to the best of my knowledge.

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We confirm that the student, under our supervision, carried out the research work reported in this thesis and it has been, submitted with our approval

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Signature.....Date.....

DEDICATION

I dedicate this work to my two sons, Francis and Festus for bearing with me as i channeled all my energy to my studies. I surely did not manage to offer them the right fatherly attention all this time I engaged in research. I hope this work will inspire them to study hard when they grow up.

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LIST OF ABBREVIATIONS

KNH: Kenyatta National Hospital

KEMRI: Kenya Medical Research Institute

PHO: Public Health Officer

SSAT: Severity score for acute tungiasis

SSCT: Severity score for chronic tungiasis

***r* :** Correlations coefficient

WHO: World Health Organization

AHADI: Africa Health and Development International

ABSTRACT

Tungiasis is a disease caused by a jigger flea (*Tunga penetrans*). The flea turns into an ectoparasite once embedded on the host. It is a public health problem in Kenya, particularly in poor rural communities, which has not, been given the due attention it deserves. The World Health Organization has categorized tungiasis among the neglected diseases. Tungiasis control has been, left in the hands of non-governmental organizations and has had no scientific or serious research inputs. There is therefore a need to explore the possibilities of developing innovative local solutions to this problem based on scientific data.

This study aimed at evaluating the efficacy of coconut oil in the control of tungiasis in a rural setting. A baseline survey was, carried out to assess infestation and severity of the disease. Two severity scores, one for acute disease and the other for chronic disease were, used in the study. A cohort of 39 individuals, with varying degrees of infestation was, recruited for treatment and follow up. The recruited study participants were first examined for a period of 30 days followed by an intervention treatment with coconut oil applied twice daily for a period of ten weeks to prevent re-infestation. The severity scores for both acute and chronic status of the disease were, expected to reduce to zero after the intervention.

The spearman rank correlation coefficient was, calculated to assess the significance of the association between the severity scores and infestation rate. The correlation coefficient was strong in both acute and chronic conditions ($r = 0.6$ and $r = 0.8$ respectively). To compare findings before and after the intervention, the mean of each variable was determined for each patient during baseline assessment and during the intervention. Significance of differences was assessed using Wilcoxon matched pairs signed rank test. The difference was, found to be significant leading to rejection of the null hypothesis. These results proved that coconut oil is

efficacious in controlling tungiasis. The findings of this study indicate that coconut oil can provide a reliable, simple and inexpensive means of controlling the disease.

CHAPTER 1: Introduction and Literature Review

1.1: Introduction

Tungiasis is a disease caused by the penetration of the female sand flea, *Tunga penetrans*, into the epidermis and the subsequent hypertrophy of the parasite (Gordon, 1941; Hoeppli, 1963). The flea originally occurred in South America and Caribbean islands but was inadvertently, introduced into sub-Saharan Africa in late 19th century (Hoeppli, 1963). This ectoparasitosis is today endemic in sub-Saharan African countries, Caribbean and Latin America. Tungiasis is associated with high morbidity (Gordon, 1941). Some diseases especially those afflicting the resource poor communities in Africa have gone on without much recognition. These diseases are termed neglected because they have had less attention from medical authorities and researchers. According to a study conducted in Brazil, the medical profession wholly neglects this ectoparasitosis, and physicians do not diagnose tungiasis during consultation, unless the patient mentions the disease. Most poor communities live hidden away from the limelight with no access to urbanized services. These communities are, stigmatized due to their disadvantaged social status. The diseases associated with people like these can thus go unattended for a long time. Tungiasis is among such diseases (Arene, 1984).

In Kenya, tungiasis is endemic in Central, Western, Nyanza, Coastal and Western regions. It is also present in other regions in the country, but in low levels, which are likely to rise if not addressed. The prevalence in endemic areas ranges between 15 to 40% (Ministry of Health, 2014). A Kenyan news reporter once described jigger infestation in Muranga, a county in central Kenya, “as shocking and of unbelievable magnitude”. More attention and energy have, been given to diseases like malaria, HIV, and tuberculosis. Data relating to the effects of tungiasis is

very limited (Chadee, 1994). Tungiasis is highly prevalent in children between 5 and 14 years. Among the adults, the prevalence is low (Arene, 1984; Chadee, 1994). It however increases among the elderly. The ectoparasitosis has, also been reported in individuals with diseases like epilepsy and mental disabilities (Chadee, 1994). Tungiasis inhibit progress and development due to associated morbidity including difficulties in walking, persistent itching and insomnia (Chadee, 1994). A population highly infested with jiggers is not able to participate in the democratic processes of the country and general economic activities. African Health and Development International (AHADI) Kenya Trust, an organization that works in Kenya to eradicate the jigger flea, estimates that the flea may have infested over 2.6 million Kenyans (AHADI Kenya trust, 2011). Among these are children who are unable to walk to school, write properly or even participate in learning activities. This inability becomes a source of ridicule and scorn among their peers both in and out of school.

In most parts of the world, growing urbanization, improved housing and use of appropriate footwear have led to overall reduction of this ectoparasitosis (Eisele *et al.*, 2003). Tungiasis is a zoonosis and affects domestic and peridomestic animals such as dogs, cats, pigs, and rats. Where human live in close contact with these animals, and where environmental factors and human behavior favor exposure, the risk of getting the disease is high (Hoepli, 1963). *Tunga penetrans*, the causative agent for Tungiasis, thrives well in a habitat with warm, dry soil. Its multiplication is high in the sandy beaches, stables and stock farms. It invades the unprotected parts of the skin, mostly in the feet. The inter-digital skin and subungual region (area under the nail) are normally highly infested (Hoepli, 1963).

Both the male and female jigger fleas are hematophagous and can jump up to 20 cm vertically. They can crawl or run up to 1 cm per second (Arene, 1984). The male does not burrow into the

host and dies after copulation. The female sheds between 150 to 200 eggs over a period of 2 to 3 weeks and then dies. Most of the eggs fall to the ground where the larvae hatch within 3 to 4 days. The larvae develop into pupae 10 to 15 days later. The pupae reach adulthood after additional 5 to 14 days. Under optimal conditions, the transition from egg to adult can be as brief as 18 days (Cardoso, 1990).

1. 2: Background information of tungiasis

The first author to mention the ectoparasite was Gonzales Fernandez de Oviedo. In 1525, he noted that Spanish conquerors in Haiti frequently suffered from the disease (Gordon, 1941; Hoeppli, 1963). Some years later, Gonzalo Ximenes de Quesada, a Spanish conqueror on a military expedition in Columbia reported that an entire village had been abandoned because of tungiasis. His soldiers were, so infested with jiggers that they could hardly walk (Hoeppli, 1963; Reiss, 1966).

The first scientific description of tungiasis came from Aleixo de Abreu, a Portuguese physician in the service of governor in Brazil in early 17th century (Hesse, 1899). The flea originally occurred in Caribbean and Latin America. It was, inadvertently introduced in Africa in 1872 by a load of infested ballast sand on board a ship travelling from Brazil to Angola (Hesse, 1899; Henning, 1904; Gordon, 1941). From there, *Tunga penetrans* spread throughout Africa (Hesse, 1899; Hicks, 1930; Henning, 1904; Jeffreys, 1952). The spread of tungiasis followed trade routes. It was also highly propagated by military expedition (Jeffreys, 1952). Within 20 years, it had reached East Africa and Madagascar (Blanchard, 1899; Hesse, 1899; Jeffreys, 1952; Hoeppli, 1963).

Indian soldiers, without appropriate footwear became jigger infested in Africa and took the ectoparasite to Bombay and Karachi in 1869 (Gordon, 1941; Bruce *et al.*, 1942; Hoeppli, 1963).

Tungiasis did not become widely distributed in Indian subcontinent for unknown reasons (Sane & Satoskar, 1985; Turkhud, 1928). The common English name for *Tunga penetrans* is sand flea. Many local names like jigger, chique, chigoe, puce-chique, nigua and chica indicate that tungiasis has long been a common disease in tropics (Soria & Capri, 1953; Matias, 1989; Mashek, Licznarski & Pincus, 1997). Tungiasis is a health problem of underdeveloped areas where environmental conditions favor a high infestation rate, and social neglect is intricately linked to poverty and inadequate healthcare behavior (Heukelbach, *et al.*, 2003). Morse (1995) convincingly argued that tungiasis is not purely a microbiologic event, but has causative cofactors such as ecological changes, changes in human demography, international travel and breakdown of public health measures.

Tungiasis is associated with a wide range of both acute and chronic morbidity, as this study has demonstrated. In determining the status of tungiasis (whether acute or chronic), visual findings and history probing were used in this study, just like Feldmeier *et al.*, (2003) did in their research.

1. 3: Morphology of *Tunga penetrans*

In some cases, the female has a bigger epipharynx and maxillar palpus than the male. Due to its burrowing activities, *Tunga penetrans* has well developed lacinia and epipharynx (Nagy *et al.*, 2007). Its relatively flattened head aids in burrowing through epidermal and dermal layers. It is angular with no comb of spines (Nagy *et al.*, 2007). The thoracic segments are narrow at the top. The flea has a hypertrophic region between the 2nd and 3rd tergites. These tergites as well as abdominal sternites stretch considerably and are bent apart. Chitinous clasps that are, built for abdominal enlargement surround these regions and hold onto the hypertrophic zone (Eisele *et al.*, 2003). There are no significant morphological differences between male and female. The female

is, however, generally smaller than the male (Nagy *et al.*, 2007). Figure 1.1 below shows a generalized drawing of the female flea.

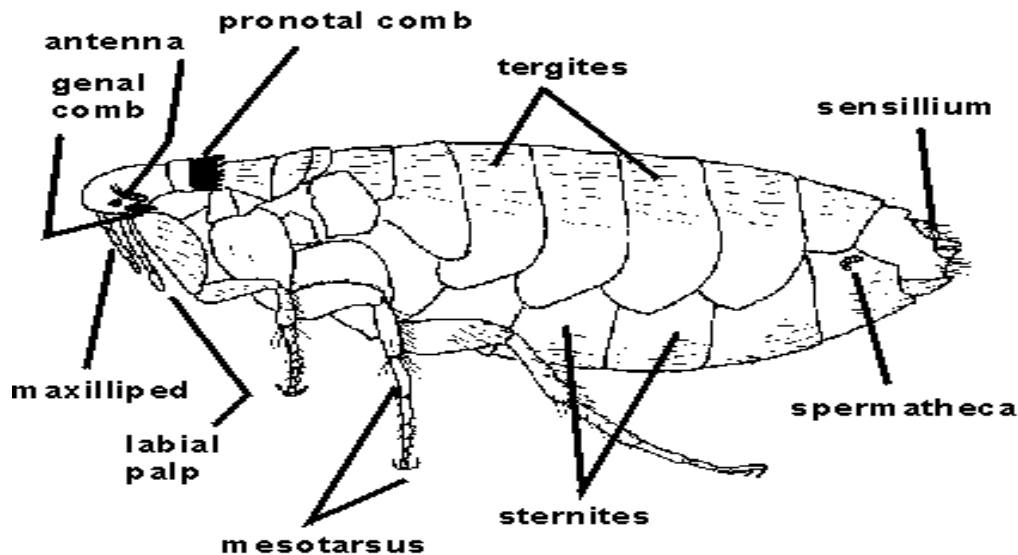


Figure 1.1: Generalized drawing of a female flea

1. 4: Life cycle and reservoir host of *Tunga penetrans*

Tunga penetrans can inhabit various types of soils but its development is mostly favored by dry and sandy grounds. Adult male flea sucks blood from the host but does not embed into its body (Cardoso, 1990). Hosts include man, dog, cat, and pig (Copper, 1967; Verhulst, 1976; Rietschel, 1989). Other animals found infested include sheep, goats, horses, rats, mice, chicken, birds, elephants, monkeys and other wild mammals (Cardoso, 1990; Ruthe, 1961). There is an assumption that infested domestic animals and rats contribute to high human infestation rates (Ruthe, 1961). Some authors assert that fertilization occurs after penetration of the female flea into the host (Geigy, 1953; Geigy and Suter, 1960). Some authors however describe penetration of gravid fleas (Bruce *et al.*, 1942; White, 1987).

Eggs are, shed by gravid female into the environment and hatch into larvae in about 3-4 days.

Tunga penetrans pass through two larval stages before forming pupae. Pupae are in cocoons that

are, covered with debris from environment. The larval and pupal stages take about 3-4 weeks to complete (Karsten, 1865; Guyon, 1870; Hesse, 1899). Both male and female feed intermittently on their host but only female burrows into the skin (epidermis) where it causes a nodular swelling (Rietschel, 1989). The female does not have any specialized burrowing organs, and simply claw into the epidermis after attaching with its mouthparts. After penetrating the stratum corneum, it burrows into the stratum granulosum, with only its posterior end exposed to the environment. The female flea continues to feed and its abdomen extends up to about 1 cm. The female sheds about 150 eggs over a two-week period, after which it dies, and is, sloughed away by the host's skin. Figure 1.2 below shows the life cycle of *Tunga penetrans* as illustrated by United States Centers for Disease Control and prevention (CDC).

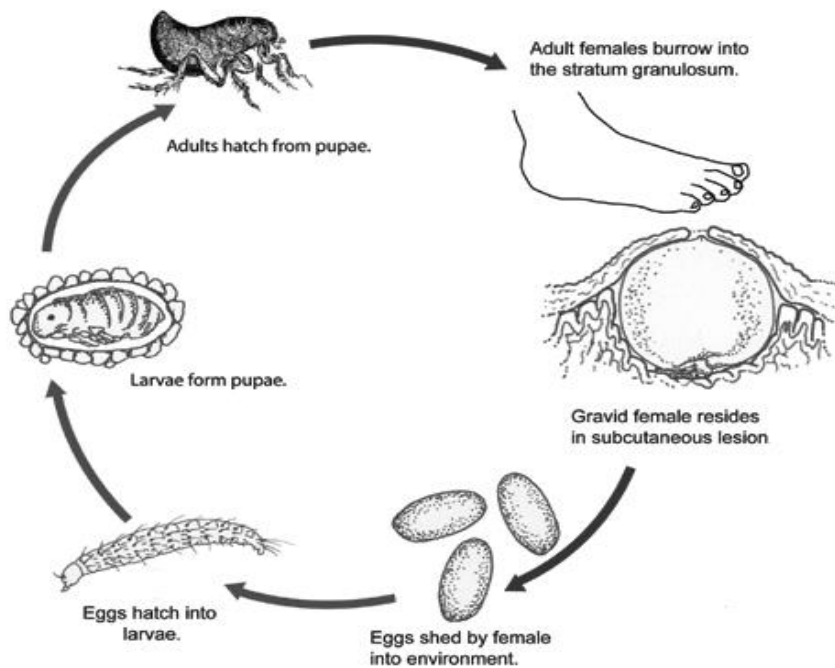


Figure 1.2: Life cycle of *Tunga penetrans*

1. 5: Epidemiology of tungiasis

1.5.1: *Tungiasis and age*

Though very few studies on tungiasis have been, conducted worldwide, the available data show the prevalence in children to be significantly higher than in adults, with a peak of 5-10 years old age group (Chadee, 1994). In a survey in Fortaleza in northeast Brazil, infestation and severe pathology were more common in children than in adults (Arene, 1984). It has, however, not been conclusively established why the prevalence is higher in children than in adults. Some authors assume that the age related decline of prevalence is due to increasing keratinization of the skin in adults (Chadee, 1994). Elderly adults are, infested if their eyes are too weak to see the embedded flea and are neglected (Arene, 1984; Chadee, 1994). Ugbomoiko *et al.*, (2007), found an S-shaped prevalence pattern, with the highest prevalence in the age of 5-14 years and 60 years and above age groups. The same pattern has, been reported in a study conducted in a rural community in Brazil (Muehlen *et al.*, 2003). Marked increase in infestation in the old people (60 years and above) is caused by factors other than the hosts immune system. It is, attributed to different exposure and behavior with age. For example, middle-aged groups are composed mainly of the working population who spend more time outside the endemic community and may have different disease related behavior; they remove embedded fleas more rigorously (Muehlen *et al.*, 2003).

In contrast, school going children and the elderly have longer duration of interaction with the endemic environment without adopting appropriate protective behavior; majority of them walk barefooted or, at best, wear slippers. High exposure correlates with parasite load (Fieldmeier *et al.*, 2006 a). High infestation in children is due to high exposure (they play bare footed), whereas older individuals may find it more difficult to remove the embedded fleas (Ugbomoiko *et al.*,

2007). Other studies have reported children to be highly infested, but have not confirmed the increase in prevalence in elderly populations (Carvalho *et al.*, 2003; Chadee, 1998; Wilcke *et al.*, 2002). Anecdotal observations have revealed that skillful older children carry out flea extraction for their friends and younger children at school (Ugboimoko *et al.*, 2007). Such assistance is rarely, rendered to less skillful, poor sighted and sometimes even helpless older individuals. According to Ugboimoko, *et al* (2007), most manipulated lesions are, found in children. In the elderly persons, they are able to complete their natural history embedded without interruption.

1.5.2: *Tungiasis and gender*

Preponderance of male over female in infestation has, been observed (Ade-serrano & Ejezie, 1981; Arene, 1984; Chadee, 1984; Chadee, 1998). Prevalence has, been shown to be higher in boys than in girls (Arene, 1984; Chadee, 1998). In Fortaleza, Brazil, a study indicated 28% of boys aged between 7 and 14 years, who did not attend school, spent the whole day playing in unpaved street, bare footed. Within the same age class, only 17% of the girls spent the whole day playing in unpaved street (Saboiamoura, personal communication, July 2000). A significant difference in prevalence between sexes has, also been observed in a study conducted in Trinidad (Chadee, 1998). Studies in Nigeria and Brazil have found no statistically significant difference between the sexes (Ugbomoiko *et al.*, 2007; Muehlen *et al.*, 2003; Ugbomoiko *et al.*, 2008). Carvalho *et al.*, (2003) observed more females than males infested in south Brazil, whereas other studies from Brazil, Trinidad, and Nigeria found more males infested or no significant difference between the sexes (Ade-selano & Ejezie, 1981; Arene, 1984; Chadee, 1998; Welcke *et al.*, 2002).

Data on tungiasis distribution along gender have not been consistent. They appear to vary from one population to another. The inconsistency could, be related to differences in exposure and disease-related behavior, as observed in Fortaleza above. Whereas in some study areas the males have been, found to be more vulnerable for tungiasis, in others, the females are more prone to infestation, or no gender differences have been, observed (Ejezie, 1981).

1.5.3: Seasonal variation of tungiasis

In northeast Brazil, where most studies on tungiasis have been, conducted, there is considerable seasonal fluctuation of the infestation rate (Matias, 1989). During rainy season, the incidence of new lesions decreases significantly. During the dry months, new cases of tungiasis show up every day. The cause of this seasonal fluctuation remains unknown (Matias, 1989). It has not been established whether the reproduction of fleas is impaired by low temperatures, or whether it is due to less exposure, because people spend more time indoors during the rainy season (Geigy, 1953). Several historical and anecdotal reports indicate a higher incidence of tungiasis in the dry season (Cotes, 1899; Atunrase *et al.*, 1952; Silvado, 1908). There is a clear seasonal variation of infestation with only few cases occurring during the rainy season and a high incidence and consequently prevalence during the dry season (Heukelbach *et al.*, 2005). The considerable seasonal variation in the intensity of infestation indicates that transmission varies during the year (Heukelbach *et al.*, 2005a). In the semi-arid Northeast Brazil, infestation rates decrease as soon as the rainy season begins and re-increase when the weather becomes dryer. Environmental determined patterns in off-host propagation and development of *Tunga penetrans* underlie the seasonal variation of infestation rates (Linardi *et al.*, 2010).

In a longitudinal study conducted from March 2001 to January 2002, incidence of tungiasis was, found to vary significantly with the local seasons of an endemic community in Brazil. In

particular, the study found that occurrence of tungiasis varied throughout the year and followed local precipitation patterns. It was suggested that the correlation was due to the high humidity in the soil, impairing larval development during the rainy season, as well as the more obvious reason that rain might simply wash away all stages of *T. penetrans* due its small size. The peculiar variation occurred irrespective of age (Heukelbauch *et al.*, 2005). The overlap of precipitation patterns and prevalence suggested that infestation rates started to increase sharply as soon as the rain stopped (July) and reached a peak when precipitation was zero (September). Infestation rate in the human population was, accompanied by similar changes of disease occurrence in dogs, cats, and experimentally exposed sentinel animals. Since the parasite load is directly responsible for the degree of tungiasis-associated morbidity, morbidity also varies during the year (Heukelbauch *et al.*, 2005).

1.5.4: Geographical distribution of tungiasis

Tungiasis is today endemic in Latin America, Caribbean and sub-Saharan Africa. It has, also been reported in Asia and Oceania (Goldsmith, 1981; Sane & Satoskar, 1985; Mazzini *et al.*, 1988; Ibanez-Bernal & Velasco-castrejon, 1996). In Latin America, it has been, found in regions spanning from Mexico to Northern Argentina and Chile (Faust & Maxwell, 1930; Soria & Capri, 1953; Chadee *et al.*, 1991a; Ibanez-Bernal & Velasco-Castrejon, 1996; Oliver, Alfonzo & Garco, 1997). In Africa, the ectoparasite is, found in all sub-Saharan regions, from Sierra Leone, Nigeria, Ivory Coast, and Ethiopia to South Africa (Obengui, 1989). It has, also been reported in Zanzibar and Madagascar (Fuga *et al.*, 1997; Arene, 1994; Obengui, 1989; Sanusi *et al.*, 1989; Tonge, 1989; Fimiani *et al.*, 1990; Nte & Eke, 1995; Douglas-Jones, Liewellyn & Mills, 1995). In Mexico and Colombia, tungiasis has been observed at altitudes above 2000 m (Karsten, 1865; Guyon, 1870; Hesse, 1899). Single cases have been, reported from India and southern Italy (Sane

& Satoskar, 1985; Veraldi *et al.*, 2000). In Brazil, tungiasis has been, reported throughout the country; from Yanomami populations in Roraima state in the far north to rural areas in Rio Grande do Sul State in the far South (Sane & Satoskar, 1985; Veraldi *et al.*, 2000). The physical factors limiting the geographical distribution of *Tunga penetrans* remain unknown (Karsten, 1865; Guyon, 1870; Hesse, 1899). Figure 1.3 below shows a map by Global Infectious Diseases and Epidemiology Networks (GEDION) depicting the worldwide distribution of tungiasis as of 2015. According to GEDIONS, the disease is endemic or potentially endemic, globally, in 89 countries.

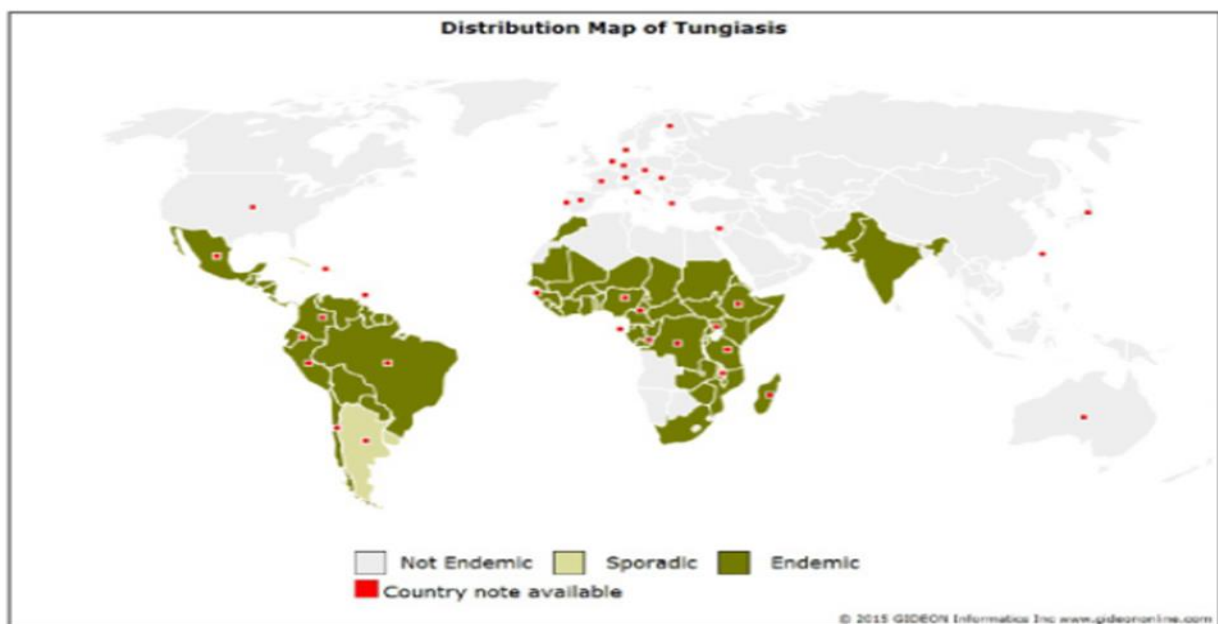


Figure 1.3: Global map, showing tungiasis distribution

1. 6: Clinical manifestation of tungiasis

As the flea cannot jump very high, infestation is usually limited to the feet. Penetration mostly occurs in the periungual region (area under the nail) but can also occur in any other part of the

body. This is because if undisturbed, fleas systematically explore various sites of the body surface before burrowing into the skin (Cardoso, 1990; Fimiani *et al.*, 1990; Bezzer, 1994). After 24 hours, the penetration site feels irritated and painful. The inevitable pruritus causes the host to scratch the lesion, something that in turn helps to expel the eggs. Without appropriate treatment, secondary infections are common (Goldman, 1976; Zalar & Walther, 1980; Cardoso, 1990). Pathogenic bacteria have been isolated from tungiasis lesions: *Clostridium tetani* (Tonge, 1989), *Streptococcus pyogenes*, pathogenic *staphylococcus aureus*, *Klebsiella aerogenes*, *Enterobacter agglomerans*, *Escherichia coli* and other enterobacteriaceae (Chadee *et al.*, 1991a; Litvoc, Leite & Katz, 1991; Chadee, 1998). Tungiasis is thus associated with lethal tetanus in non-vaccinated persons. In a study conducted in Sao Paulo state in Brazil, point of lesion has been associated with 10% tetanus entry (Tonge, 1989).

1. 7: Diagnosis of tungiasis

Diagnosis of tungiasis is by macroscopic inspection of the lesion. One day after penetration, a small red spot develops. In the subsequent days, the embedded gravid female is, seen as a white patch with a black dot in the center, which represents the posterior abdominal segments. After the death of the flea, the lesion is, covered by a black crust consisting of debris and coagulated blood (Reiss, 1966; Goldman, 1976; Zalar & Walther, 1980; Fimiani *et al.*, 1990; Douglas-Jones, Lliwellyn & Mills, 1995).

1. 8: Tungiasis treatment, prevention and control

For *Tunga penetrans* to complete its natural history, it has to pass through on- host and off- host stages of its life cycle. The total control and prevention must entail measures that would interrupt the development of egg, larvae, pupae and adult. These measures include environmental and

personal hygiene, traditional methods, biological control, mechanical and physical control, and chemical control (Heukelbauch, 2002).

1.8.1: *Environmental and personal hygiene*

Cleanliness is highly effective in controlling jiggers and their vectors and can lead to their elimination. *Tunga penetrans* develops best in dry dusty soil containing organic materials. Suppressing dust by wetting the house and compound floors after sweeping away food remains, litter and other debris is an effective environmental control measure. This helps to eliminate the breeding sites and hideouts for jiggers (Ministry of Health, 2002). Keeping the domestic jigger reservoir hosts including dogs, cats, pigs, sheep, and chicken away from dwelling houses is an important control measure. Prompt clean up after cooking and regular garbage disposal helps to keep rats and mice away (Heukelbauch, 2003). Rat-proofing of dwelling houses and granaries also help in the control. Environmental cleanliness should, be sustained through health education and community sensitization (Ministry of Health, 2002).

Daily feet washing and regular bathing with soap and water enhance personal hygiene, which in turn keep the fleas away. Constant wearing of closed shoes also helps to prevent jigger infestation. According to Simon *et al* (2010), both adults and children should keep nails short by clipping to prevent jiggers from infesting the subungual regions (area under the nails).

1.8.2: *Traditional (primordial) methods*

According to Feldmeier *et al* (2013 a), there are effective and time-tested cultural and traditional methods of household vector and vermin control. These include the use of materials like slime mixed with ash to smear floors and walls of dwelling houses built in temporally materials to remove breeding places or repel the jigger fleas. Traditional communities have also traditionally

used dust-suppressing method by regular wetting of floors with water as a hygiene practice, which helps eliminate breeding sites. Traditionally, people have surgically extracted jiggers using thorns and sharpened wooden sticks, unaware of possible infections. In communities where tungiasis is regarded a curse, people have visited witchdoctors for solutions. It has, however, not been documented if witch doctors have ever provided reliable solutions to jigger menace (Olukya, 2010).

1.8.3: Biological control

Biological methods of jigger control include topical application of extracts from plants like neem and *Aloe vera*. Zanzarin, a derivative of coconut oil, *Aloe vera* extracts and jojoba oil has been, used in tungiasis control with tremendous results in countries like Brazil (Schwalfenberg *et al.*, 2004). These topical applications are environmentally friendly and effective control measures, which also help in controlling the jigger, associated clinical pathologies. Neem solution is, applied on house floors and outdoor animal resting areas to kill jigger flea. It is environmentally friendly and non-toxic (Heukelbauch, 2003).

1.8.4: Chemical control

Chemicals kill, control and prevent jiggers from causing damage. Pesticides either kill or repel jiggers and provide the fastest control measure. The drawback is that chemicals are toxic, persistent and environmentally unfriendly. They should hence, be handled judiciously (World Health Organization, 2004). According to Ministry of Health (2002), jigger has no known resistance to pesticides. Fumigants, rodenticides, botanicals, carbamates, organophosphates and pyrethrins have all, been used with much success in jigger control. A carbamate called carbaryl is cheap and has a very strong knock down effect on jigger flea. Deet is a reliable topical

repellent in jigger control. Propoxur, as an insecticidal dust or spray is another effective chemical used in the control (Ministry of Health, 2002).

There are reports of successful treatment with a single dose of oral ivermectin at 0.2 mg/kg body weight (Saraceno *et al.*, 1999). Topical as well as oral ivermectin has been, proved an effective treatment for human ectoparasitosis such as pediculosis, scabies, and cutaneous larva migrans (Dunne, Malone & Whitworth, 1991; Caumes, Datry & Paris, 1992; Ottesen & Campbell, 1994; Youssef *et al.*, 1995). Oral thiabendazole at 25mg/kg body weight daily for 10 to 12 days has been, administered with success against generalized tungiasis (Cardoso, 1981; Cardoso, 1990). Imidazole has equally been, used with success but has since been withdrawn due to its many side effects (Heukelbach *et al.*, 2003). Though DDT is very highly effective in jigger control, it is not included in chemical interventions due to its high toxicity. DDT has been used in eliminating jiggers in some countries. In 1950's, tungiasis had gone down, globally, due to the heavy use of DDT in the control of mosquitoes. This intervention in malaria control led to elimination of *Tunga penetrans* in many areas. There is a documented fact in Mexico where by the whole country was without tungiasis for a record 40 years; it however recurred in 1989. This is according to Allison Anthony in his lecture on malaria and the sickle-cell connection, in Stanford University (2009).

1.8.5: Physical and mechanical control

The use of machines, barriers, devices and other mechanized methods to control jiggers or alter their environment help to reduce jigger flea infestations to negligible levels. Physical interventions include plastering of floors with cement mortar and regular cleaning of these floors with water to make them dust free (Ministry of Health, 2002). Original knapsack sprayer, mounted on human back, to manually spray floors, walls and compounds is a physical mean used

to enhance chemical control. Motorized or mechanical sprayers are also, used in big jigger control exercises to spray large compounds like school grounds, or where many households are to be attended (Ministry of Health, 2002). Swing fog machines are, used to spray exterior environment or compounds of fumigated buildings. Wearing of closed shoes, though a hygiene measure, is a potential physical barrier used in jigger control. Ready to use shaker canisters are other physical means used to enhance chemical control on pets and floors. Removal of jiggers using sharp instruments, like needles fall under physical control method (Simon *et al.*, 2010).

People have also used traditional remedies against tungiasis. Mixtures of candle wax and kerosene, volatile medicinal oils and extracts of various plants have been, applied on the lesion (Schwalfenberg *et al.*, 2004). The later has been, largely used in Brazil at a place called Fortaleza. Coconut oil has been, used more than any other oil. It contains a triglyceride called lauric acid, which is a powerful anti-microbial agent (Schwalfenberg *et al.*, 2004). Feet bathing of dogs with 0.2% metrifonate and subcutaneous injection of ivermectin (0.2mg/kg body weight) have been, reported to be effective against tungiasis in veterinary medicine (Rietschell, 1989). Pouring water on dusty floor has also worked in discouraging the multiplication of the flea (Schwalfenberg *et al.*, 2004).

Prevention consists of using closed shoes. However, shoes may not be affordable or available in tungiasis prone communities. Daily inspection of feet with immediate extraction of embedded fleas, together with subsequent disinfection of lesion helps to avoid complications. Treatment of infested areas (off-host treatment) such as mixing insecticidal dusts with infested soil or spraying its surface with liquid insecticides can be useful prevention means (Matias, 1989). Treatment of domestic animals with anti-flea compounds (on host treatment) is another intervention. This

limits available reservoirs and helps in reducing *Tunga penetrans* population (Cardoso, 1981; Cardoso, 1990).

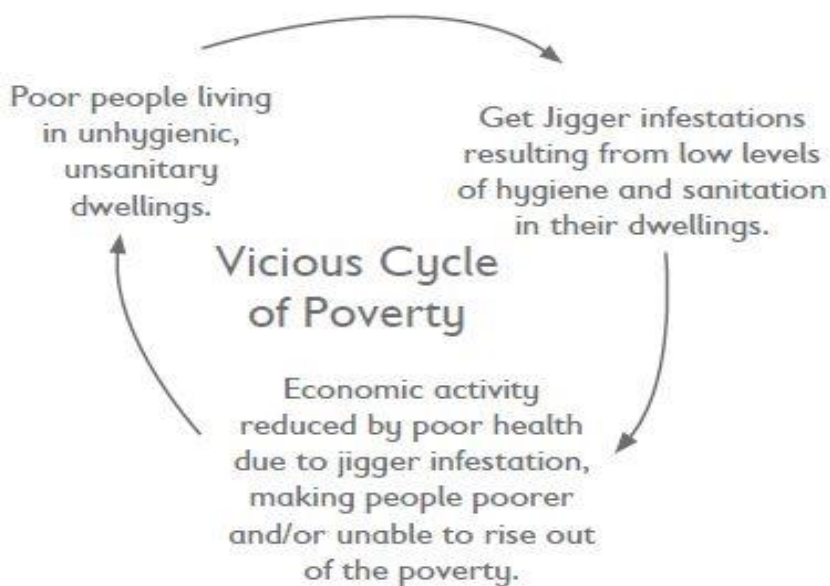
1. 9: Statement of the problem

In Kenya, like elsewhere in the world, tungiasis has remained a neglected parasitic skin disease of the impoverished populations. The scientists and the victims themselves associate the disease with some stigma (Heukelbach *et al.*, 2001). Victims of tungiasis have not, in most cases, taken tungiasis as a major health threat. Parents do not present their children to the health centers even when the ectoparasitosis is severe, due to stigma. Stigma leads to low esteem in the victims. It appears like negligence on their part. In some communities, tungiasis has been looked at as a curse and thus inherent in some families. It has thus been, taken as part of life for those infested. Due attention has thus not been accorded to the menace (AHADI Kenya trust, 2011).

Entomologists, parasitologists and health workers have intensified their researches on other health problems; tungiasis has not attracted much interest. Most effort and funds have been, directed to diseases like malaria and its vector. The disease has thus continued to pervade almost all geographic regions unchecked. The intervention has only been, done by a few non-governmental organizations, like AHADI Kenya, which may not have the real scientific background of the causative agent. Tungiasis is associated with debilitating problems like ulcers, gangrene, loss of entire limbs and auto amputation of digits (Decle, 1900). From a tungiasis outbreak in Haiti, three cases of death were, reported to have been, caused by tetanus and severe super-infection (Cardoso, 1990; Feldmeier *et al.*, 2002; Joseph *et al.*, 2006; Linardi, 1995). Infectious diseases like HIV/ Aids can be, transmitted from one person to the other as they share needles and pins while removing jiggers (Cardoso, 1990). The debilitating problems associated

with tungiasis have continued to increase rapidly and will continue in the same tread if no permanent solution is, found.

Victims of tungiasis do not perform their daily duties appropriately and thus poor economic performance of the geographic regions affected. They are also not able to exercise their democratic rights like voting when they are jigger infested to a level of not being able to walk or use their hands. Children affected are not able to go to school regularly and thus illiteracy eventually goes high. Chemotherapy, besides being expensive, has proved not to be very effective (Heukelbach *et al.*, 2003). Some chemicals like hydrogen peroxide and potassium permanganate are corrosive especially when they get into wounds and fissures. Some chemical compounds like niridazole have been, withdrawn from the intervention due to their considerable side effects (Heukelbach *et al.*, 2003). The menace is spreading fast in Kenya with the prevalence in endemic counties ranging between 15 and 40 %. Today there is no single county in Kenya, where tungiasis has not been, reported. Variation has only been in prevalence levels (AHADI Kenya trust, 2011). The following is a poverty vicious cycle associated with tungiasis according AHADI Kenya trust (2011).



1. 10: Justification for the study

Chemotherapy used in Muruka ward is expensive for the victims who happen to be poor. Hydrogen peroxide, a chemical used conventionally in combating tungiasis in the area costs 4.5 dollars per liter and is, used for between one and three treatments per patient according to the rate of infestation. It is, mixed with water at a ratio of 1:1. More of this chemical must be bought repeatedly in case of re-infestation. Around 11.3 dollars are, spent on one patient per month on chemical expenses. The same applies to potassium permanganate, another chemical in use conventionally. It also causes staining on the patient after treatment, restricting his movement there after due to stigma. There is also a drawback in that chemicals are poisonous if ingested accidentally, especially by children. These two chemicals are corrosive and may cause harm to tungiasis victims if not used with expertise. This necessitates their application only by public health experts.

Zanzarin, which has been, used in tungiasis control in Brazil with tremendous results is not locally available for Muruka jigger victims to access. Even if it was locally available, it is expensive for the poor Muruka tungiasis victims to afford. Zanzarin is a derivative of Coconut oil and extracts of neem and *Aloe vera*. This study aimed at determining whether coconut oil alone is efficacious in tungiasis control. Coconut oil is not expensive and has no side effects. The oil used in this study did not have any preservatives or additives. During this study, half a liter bottle costed 2.27 dollars and it served one patient for two and half months while applying twice per day. Coconut oil also repels the flea about to attach. It has been, used in repelling other ectoparasites like ticks from domestic animals (Wall and Shearer, 2001). It does not need special expertise to apply and thus victims can apply by themselves regardless of age or education levels. Tungiasis by itself is a threat to realization of vision 2030 and the national goals of

accessible education and health for all citizens. The oil, thus, can serve as a reliable and alternative means of controlling tungiasis by the ministry of health. Coconut oil provides a more reliable, less sophisticated and inexpensive means of controlling tungiasis

1. 11: Objectives

General objective

-To evaluate the efficacy of coconut oil in the control of tungiasis

Specific objectives

-To determine efficacy of coconut oil in the control of chronic tungiasis

-To determine efficacy of coconut oil in the control of acute tungiasis

1. 12: Hypothesis

Null: Coconut oil is not efficacious in control of tungiasis.

Alternative: Coconut oil is efficacious in control of tungiasis.

CHAPTER 2: Materials and Methods

2.1: Study area and settings

Muranga County where Muruka ward is located is about 60 km driving from Nairobi city. The County has two rainy seasons. The rain is between 1200 and 1600 mm. The county has temperature ranging between 21 and 35 °c .The variation in temperature is due to the differences in altitude as the area is hilly. The area has a volcanic loam soil. The large Muranga County is among those leading in tungiasis. This study was, conducted in Muruka ward in Kandara constituency to serve as a typical representation of all the wards in the county. Kandara is located at latitude 0 ° 54' 0 S and longitude 37° 0'0 E. It is at altitude 5308 feet above the sea level. Muruka ward has an area of approximately 38.50 sq km and a population of about 23,535 people. The local community is, characterized by poor housing mostly of mud walls. Overcrowding, poor hygienic conditions, illiteracy and unemployment are rampant. Only few houses have concrete floor. The following is a map of Muranga County showing Kandara sub-county where Muruka ward is situated. The arrow in the map is pointing the ward.

MURANG'A COUNTY CONSTITUENCIES BOUNDARY WITH CURRENT EXISTING WARDS

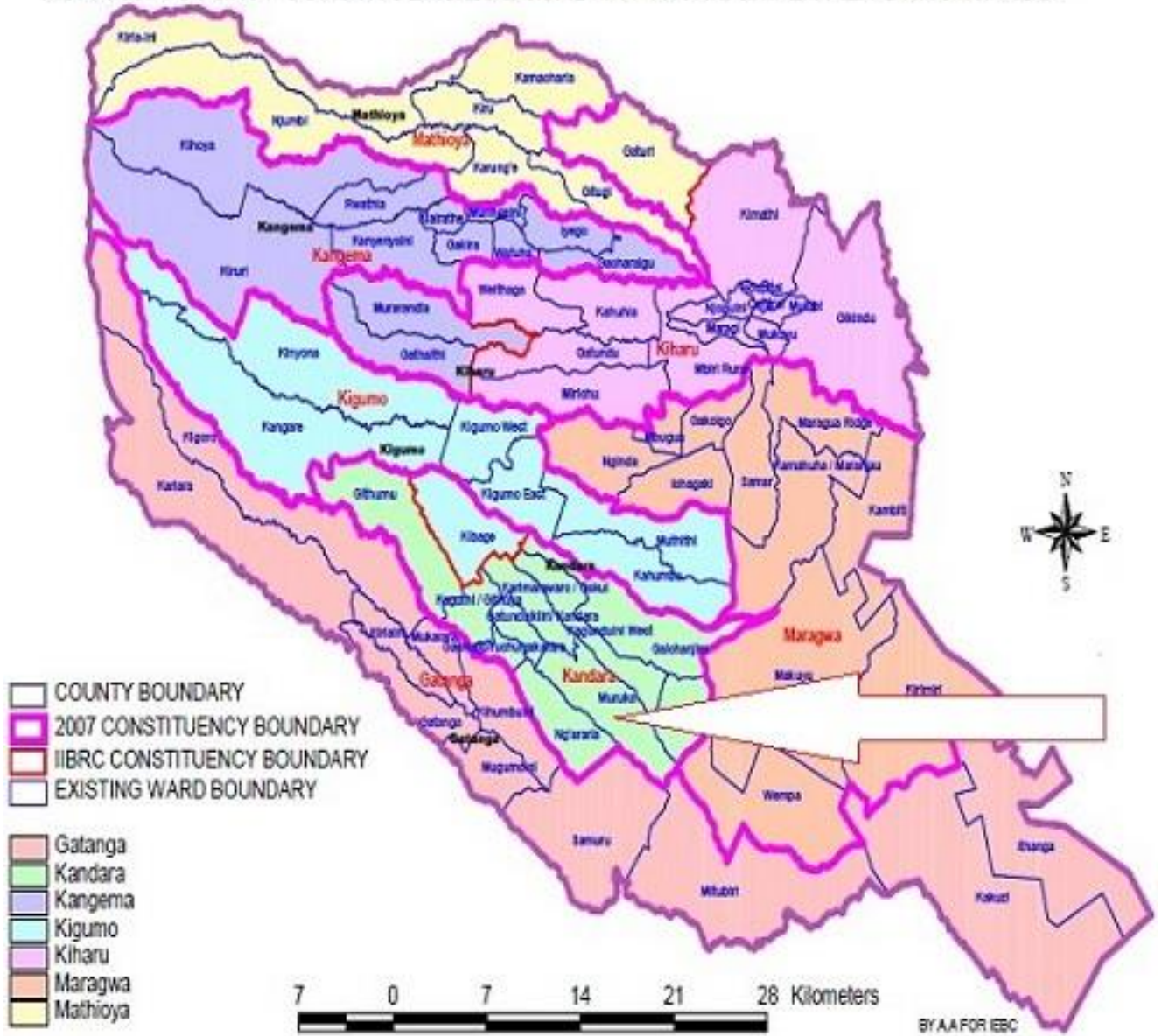
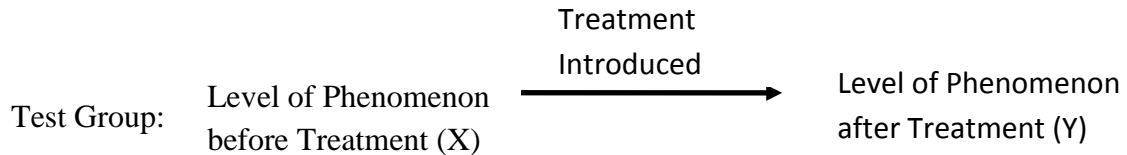


Figure 2.1: Map of Murang'a County showing Muruka ward where the study was, carried out

2. 2: Research design

This study entailed comparing the tungiasis phenomenon before intervention to the same after treatment with coconut oil. A control group was not included in the study due to ethical considerations. An informal experimental design adopted from Kothari (2004) was thus appropriate for the study. The design is as outlined below:



$$\text{Treatment Effect} = (Y) - (X)$$

2. 3: Sampling design

In this study, snowball-sampling technique, a non-probability sampling design was, used. The concept “snowball” is following the way a snowball picks on more snow and enlarges as it rolls down the hill (Biernacki & Waldorf, 1991). It involved identifying a few participants with tungiasis who in turn assisted in bringing the others with the same disease on, board. This design was appropriate as tungiasis is associated with some stigma and thus not everyone infested was willing to participate. The participants joined the study on their own volition after explaining to them the benefits they were to get from the study. Sample size in this study was not important, as any size would yield the desired results. Using this sampling design, a cohort group of 39 individuals, who included both gender was, formed.

2. 4: Ethical clearance and consideration

Permission to conduct this study was, granted by KNH/UON ethics committee. The ministry of health also cleared the study through Public Health Officer Kandara sub-county. Permission was, obtained from relevant local leaders before meeting their subjects. Written consent (for adults) and assent (for children) were, obtained from participants before recruiting them. This was, done after explaining to them the objectives of the study and the benefits they were likely to get during and after the study. The obvious benefit was to become jigger free.

2. 5: Clinical examination of the flea stage

The whole body was, examined as the flea can attack any topographic site. Lesions were, classified according to the Fortaleza classification (Eisele *et al.*, 2003), a recently elaborated staging system outlined as follows;

Stage I: a dark and itching spot in the epidermis with a diameter of 1-2 mm with or without local pain. It is an adult flea in the process of penetration (*status penetradi*).

Stage II: called early lesion or a lesion, which is whitish with a central black dot, and having a diameter of between 3 and 10 mm.

Stage III: a mature lesion, which is a brown-blackish circular crust with or without necrosis of the surrounding epidermis.

Stage IV: a dead lesion defined as a dark central crust surrounded by necrotic tissues.

Stage V: a lesion altered through manipulation by patient. This stage also includes suppurated lesions mainly caused by using non-sterile perforating instruments such as needles or thorns.

2. 6: Signs and symptoms observed

Signs and symptoms observed included erythema, edema, itching, pain upon pressure, hyperkeratosis, fissures, pustules, suppurations and ulcers. Others included deformation of toes defined as deviation from the normal axis of the toe caused by intense swelling, deformation of nails, loss of nails and difficulty in walking. In this last problem, it was based on patients own statements that pain restricted their movements. Specific characteristics were, examined for acute and chronic tungiasis as shown in table 2.1 below.

Table2. 1: Signs and symptoms of Chronic and acute tungiasis

<p><u>Chronic tungiasis:</u> -Deformation of toes -loss of nails -Deformation of the nails -Hypertrophic nail rim -Hyperkeratosis</p>	<p><u>Acute tungiasis</u> -Edema, Erythema -Ulcer -Fissure -Pustule -Suppuration -Lesion in clusters -Itching -Sleeping disturbances due to itching -Pain upon pressure -Pain while walking -Persistent pain -Difficulty in walking</p>
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2.7: Determination of severity score

The scoring system for this study was adopted from Heukelbach and Feldmeier (2006), one for acute and the other for chronic disease manifestations. Symptoms and signs used to determine severity score for acute tungiasis (SSAT) were, divided into two categories as summarized in table 2.2 below. The first category comprised variables that could be associated with individual sand flea lesion or with a group of them in a defined topographical area. Since more than 90% of sand flea lesions were, found on feet, ectopic localizations were, not recorded. The surface of

each foot was, divided into nine topographic areas in which sand fleas mainly penetrate. The areas included toes one to five, sole, lateral and medial foot rim and heel, giving a total, of 18 topographic areas for both feet. According to topographic area affected, 0 to 3 points were, awarded to the above variables. The other category involved symptoms and signs which could not be, localized precisely or which affected the patient in general manner.

Table2. 2: SSAT (severity score for acute tungiasis)

Signs and Symptoms		Points Attributed
According to the number of topographic areas affected;		
-Edema, Erythema, warmth ^a	0	0
	1-6	0.5
	7-12	1
	13-18	2
-Ulcer	0	0
	1-6	1
	7-12	2
	13-18	3
-Fissure	0	0
	1-6	1
	7-12	2
	13-18	3
-Pustule, abscess ^a	0	0
	1-6	1
	7-12	2
	13-18	3
-Supuration	0	0
	1-6	1
	7-12	2
	13-18	3
-Lesions in clusters ^b	0	0
	1-6	1
	7-12	2
	13-18	3
-Above 18 for any of the above symptoms		4
Irrespective of the number of topographic areas affected;		
-if negative for any of		
	the symptoms below	0
	- itching	0.5
	-Sleeping disturbances due to itching	0.5
	-pain upon pressure	1
	-pain while walking	1
	-persistent pain	1
	-Difficulty walking ^c	3

^a Sign alone or in combination

^b Dense accumulation of embedded sand fleas, also described as “honeycomb-like lesion” (Valença *et al.*, 1972)

^c Difficulty walking was defined as an altered gait pattern, caused by the attempt to alleviate the pain while walking

For chronic scores (SSCT), the following signs were considered: nail deformation, loss of nail, hypertrophic nail rim, deformation of the toe, and hyperkeratosis. The scores were, awarded as, shown on the table below:

Table 2.3: SSCT (severity score for chronic tungiasis)

Signs and Symptoms	Points Attributed
According to the number of topographic areas affected;	
- Hyperkeratosis ^a : 0	0
1-5	1
6-10	2
11-16	3
16 and above	4
According to the number of toes affected;	
-If negative for any of the symptoms below	0
- Hypertrophic nail rim(0.5 points for each toe)	0.5-5
- Deformation of toe nail(0.5 points for each toe)	0.5-5
- Loss of toe nail (1 point for each toe)	1-10
- Deformation of toe ^b (1 point for each toe)	1-10

^a Because of the difficulty to differentiate between physiological and tungiasis-associated hyperkeratosis, it was not taken in account when present at the sole.

^b Deformation due to chronic edema

2. 8: Study cohort

A group of 39 individuals with varying degrees of tungiasis was, identified using the sampling design earlier stated and recruited for the study. On accepting to take part in the study, the participants were requested to sign a consent form, incase adult (Appendix IV) or assent form for the children (Appendix V). For very young children, the mentally hand caped, the illiterate and those unable to write, their consent forms were signed by their guardians. Selection of the participants was, based on inclusion and exclusion criteria. One had to be 2yrs and above to qualify for the study. The individual had also to have at least ten lesions and above to be

included in the cohort group. Children below two years with tungiasis were not included in the study, but were, referred to Kandara hospital for treatment. Persons with extreme tungiasis incidences like ulcerated lesions were not eligible for the study but were also, treated in the hospital. Those with tungiasis but with other diseases like elephantiasis were, equally referred to the hospital for treatment (appendix VI). Individuals were eligible for the study provided they resided in their present dwelling places for the whole study duration (14 weeks).

2. 9: Baseline survey

Cohort members were, visited twice a week for a period of 30 days during the baseline survey. During this period, the severity scores and infestation rate were, assessed and recorded. Demographic and parasitological information were, also recorded. Demographic information recorded included age and gender of the participant. The parasitological information included the number of the fleas embedded, their specific stages according to Fortaleza classification, the number viable, manipulated or dead, and the number of clusters. This was, done through macroscopic examination of the patient with the aid of magnifying glasses. Baseline survey was, followed by a 10 weeks period of intervention with coconut oil.

2. 10: Intervention

After 30 days of baseline observation, an intervention was, carried out using coconut oil. Pure coconut oil without a preservative or additives was, applied twice a day on the infested areas by, community health worker under the supervision of public health officer of Muruka ward. The mode of application was direct by simply smearing about 2mls of the oil on the palms and spreading it over the infested areas. Before applying the oil, the nails were, trimmed in order to enable the oil reach all the areas. Before application, washing was, done with water to remove

dirt. The community health workers had protective gloves on. Symptoms, signs and infestation rate were, monitored during the intervention to see how their scores changed. Through direct observation method of data collection, the findings of each visit were, recorded in data sheets (appendix I & II) until the end of the study. Assessment was, carried out immediately the intervention was over.

2. 11: Statistical analysis

On statistical analysis, the concept of spearman correlation coefficient was, applied. This correlation coefficient helped to determine whether the two variables (infestation rate and severity scores) correlated in a monotonic function, that is, when one variable increased, so did the other, or vice-versa. The strength of the correlation was determined using the following guideline adopted from Page (1963).

- 0- 0.19 {very weak}
- 0.20- 0.39 {weak}
- 0.40- 0.59 {moderate}
- 0.60- 0.79 {strong}
- 0.80-1.0 {very strong}.

The mean of each variable was determined for each patient during the baseline and intervention period. The Wilcoxon matched pairs signed rank test was, used to determine the significance of the difference between the two sets of scores that came from the same participants (in baseline and after intervention). The data was, presented using the column graphs. Statistical software, IBM 20 SPSS was, used in this analysis.

CHAPTER 3: Results

3. 1: Demographic and parasitological characteristic of the study cohort

The demographic and parasitological characteristics of the cohort group were as summarized in table 3.1 below.

Table 3.1: Demographic and parasitological characteristics of the study cohort

Variables	N	Median	Range
Age in years	39	48	94
Female/Male ratio	39		16/23
Total no of lesions per patient	39	56	41
Viable Lesions (stage i-iii)	39	41	63
Dead Lesions (Stage iv)	39	9	26
Manipulated Lesions	39	12	27
Lesions in Clusters	39	6	7

3. 2: Clinical pathologies in the cohort group

The clinical pathologies in the 39 individuals and the percentage of those possessing them were as recorded in table 3.2 (overleaf).

Table 3.2: Clinical pathology in the 39 individuals

Type of Clinical Pathology	N	%
Deformation of toe nail	19	49
Difficulty walking	39	100
Fissure	20	51
Loss of toe nail	19	49
Signs of acute inflammation ^b	20	51
Signs of chronic inflammation ^a	19	49
Signs of super infection ^c	30	77
Ulcer	20	51

^a Hyperkeratosis and/or hypertrophic nail rim of at least one toe with or without deformation of digit

^b Erythema, edema, warmth

^c Suppuration, pustule or abscess

3.3: General tungiasis

The various variables for the general disease were, examined before narrowing down to the specific disease statuses (acute and chronic). Signs and symptoms for acute and chronic diseases at baseline were as presented in figures 3.1 and 3.2 respectively. Both males and females findings were put together for comparison purposes. The p-values for the variables were as presented in table 3.3. The photographs for several acute and chronic cases were, taken to demonstrate how the signs and symptoms changed after applying coconut oil.

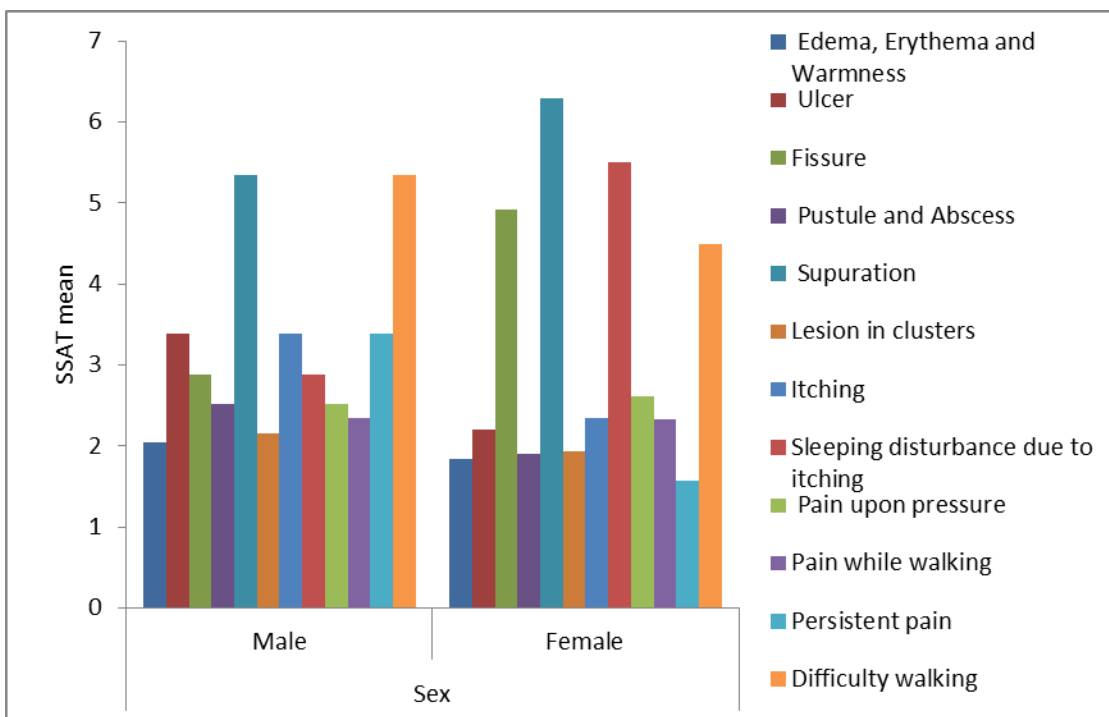


Figure 3.1: Severity scores in the acute tungiasis (SSAT) along gender at baseline

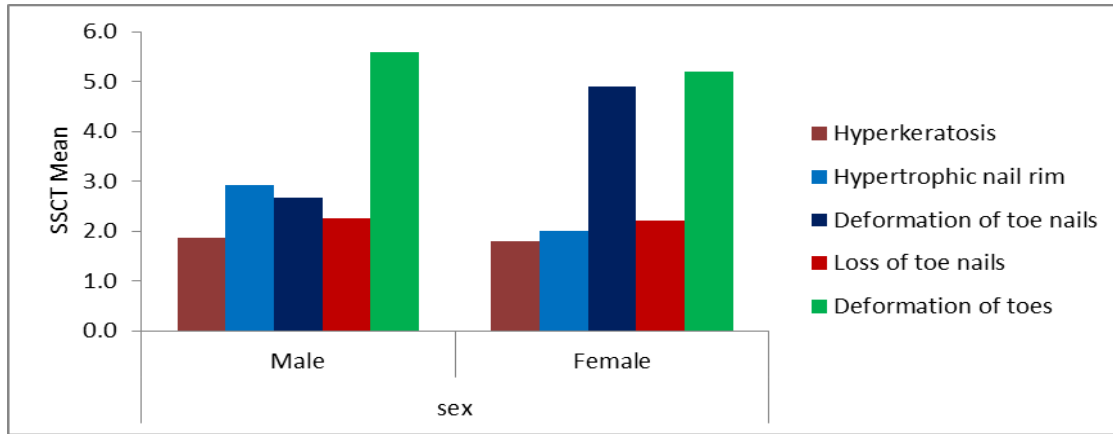


Figure 3.2: Severity scores in chronic tungiasis (SSCT) a long gender at baseline

Table 3.3: Various variables at baseline and after intervention

Variables	Mean at Baseline	Mean after Intervention	<i>p-value</i>
Number of embedded fleas	4	1	0.001
Infestation rate	2.1	0.02	0.001
SSAT	3.2	1.03	0.001
SSCT	4.9	4.7	0.076

3.3.1: Tungiasis cases

The figures below show photographs of a few chronic and acute cases at baseline and after treatment with coconut oil. Figures 3.8 and 3.9 show two unique cases encountered in the study.

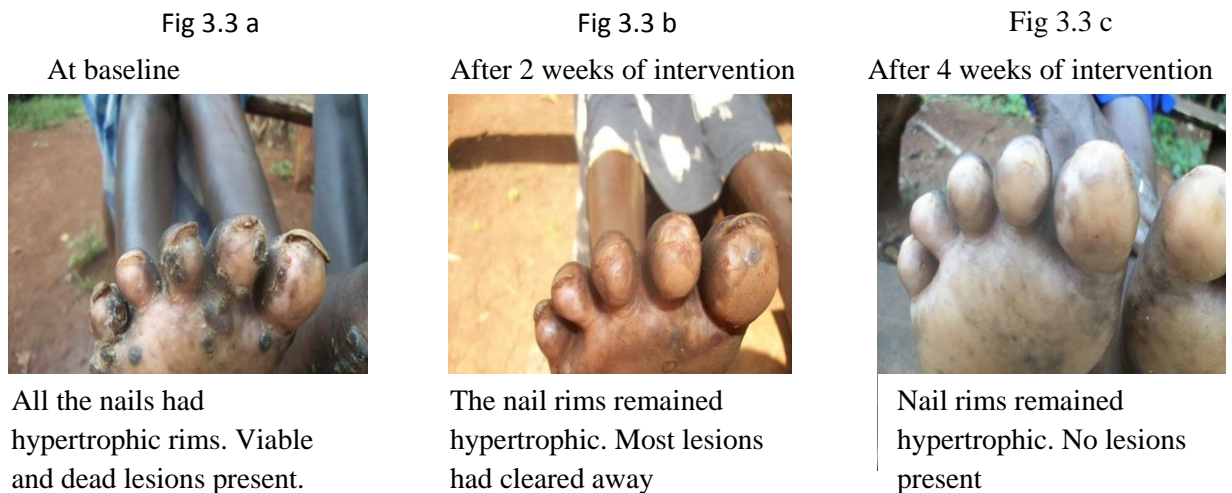


Figure 3.3: A chronic case of a 45-year-old mentally challenged woman

Fig 3.4 a

At baseline



The 1st and 3rd toes of the right foot had clusters of lesions. All the nails had some deformation.

Fig 3.4 b

After 2 weeks of intervention



Most lesions had died and sloughed away. The dead skin tissues on the feet had started to peel off. Nails remained deformed.

Fig 3.4 c

After 4 weeks of intervention



The feet were devoid of jiggers. The nails however remained deformed.

Figure 3.4: A chronic case of 18-year-old mentally challenged boy

Fig 3.5a

At baseline



A hyperkeratosis of 2.0 points was present

Fig 3.5b

After 2 weeks of intervention



There was a drastic reduction of hyperkeratosis

Fig 3.5c

After 4 weeks of intervention



Hyperkeratosis had disappeared paving way for a normal skin.

Figure 3.5: A chronic case of a 98-year-old man

Fig 3.6a

At baseline



1st, 4th and 5th toes had clusters of lesions. Ulceration and Suppuration were present on the 4th and 5th toes.

Fig 3.6b

After 2 weeks of intervention



Jiggers had died and sloughed away. Suppuration had stopped and ulcers had healed up.

Fig 3.6c

After 4 weeks of intervention



The dead skin tissues, at the areas, which were formally ulcerated and suppurative, had peeled off.

Figure 3.6: An acute case of 8-year-old boy

Fig 3.7a

At baseline



Each toe had developed edema to some degree. This made the skin around the nails shine.

Fig 3.7 b

After 2 weeks of intervention



After the death of jiggers, edema had greatly reduced.

Fig 3.7 c

After 4 weeks of intervention



No jiggers observed and edema had cleared away.

Figure 3.7: An acute case of 12 years old boy



A photo showing a left foot of a 50 year old man encountered during the study. He was having elephantiasis and tungiasis together, something that hampered proper intervention.

Figure 3.8: Tungiasis case compounded by elephantiasis



These children were at home during the study. They could not walk comfortably to school due to jigger infestation on their feet.

Figure 3.9: Children out of school due to tungiasis

3. 4: Acute tungiasis

In this study, acute cases occurred in individuals aged 60 years and below. Infestation rate along age classes and gender was as shown in figures 3.10 and 3.11 respectively.

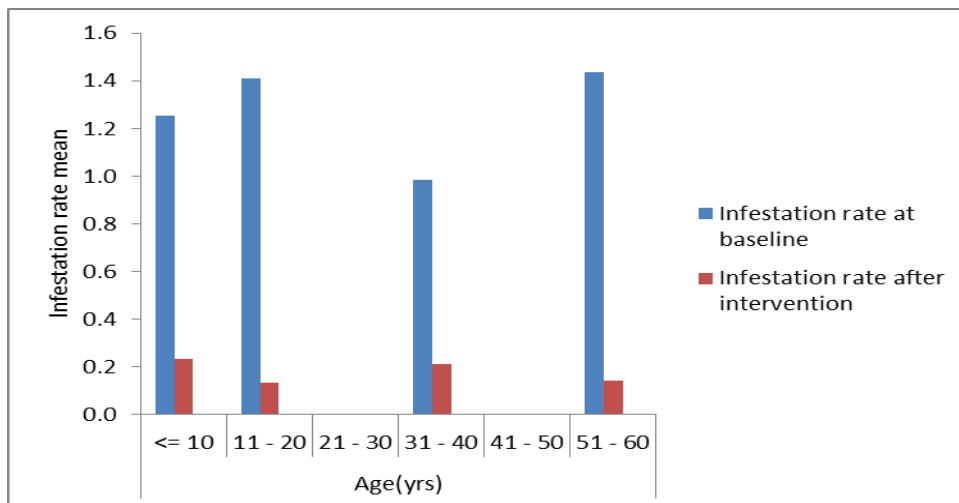


Figure 3.10: Infestation rate for acute tungiasis along age at baseline and after intervention.

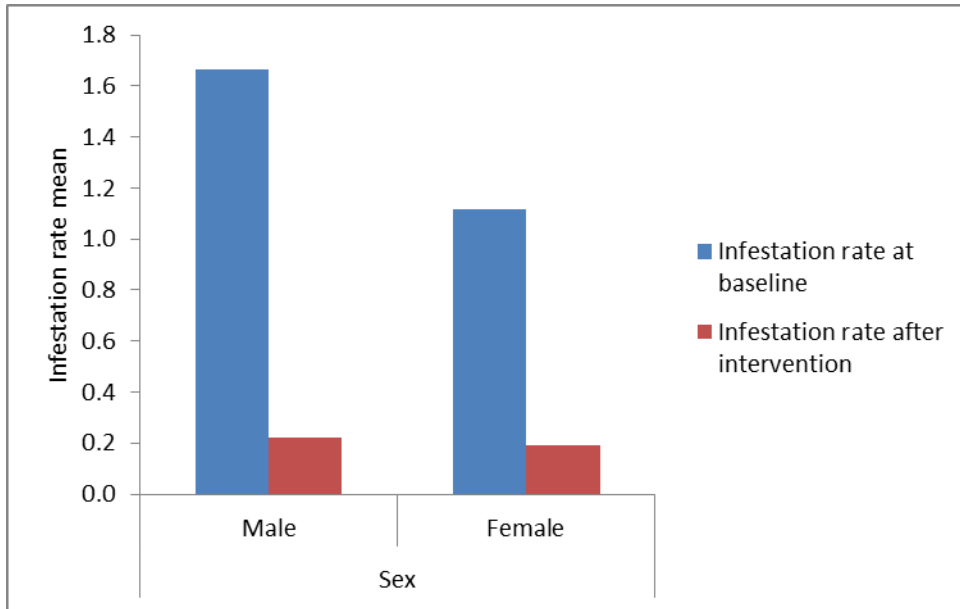


Figure 3.11: Infestation rate for acute tungiasis along gender at baseline and after intervention

The signs and symptoms of acute tungiasis were assessed along age classes and gender. The results were as presented in figures 3.12 and 3.13 respectively.

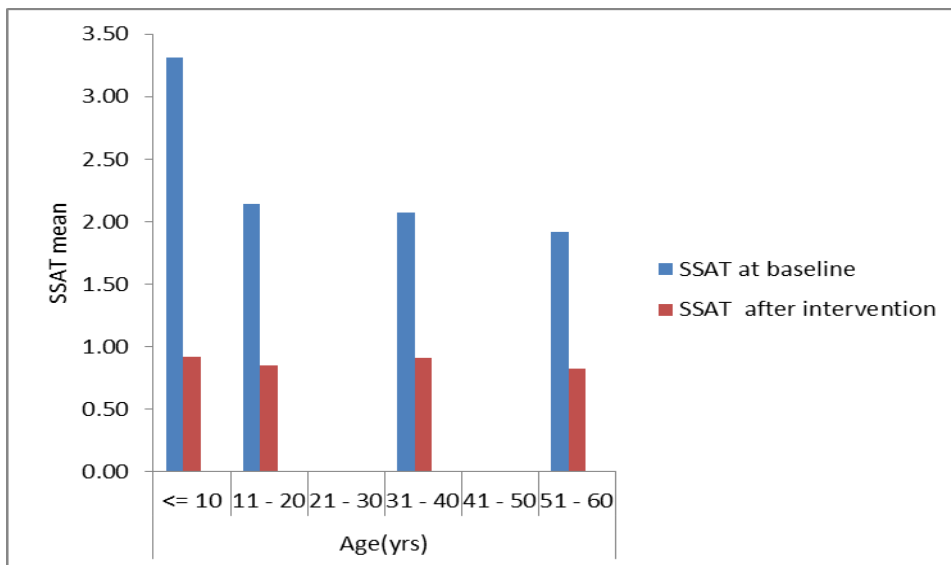


Figure 3.12: Severity scores for acute tungiasis (SSAT) along age at baseline and after intervention

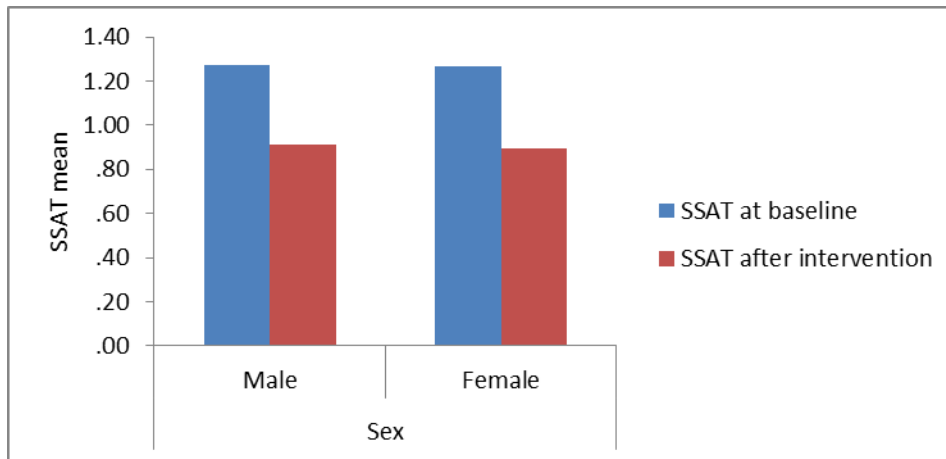


Figure 3.13: Severity scores for acute tungiasis (SSAT) along gender at baseline and after intervention

In fig 3.14 below, five acute parameters were, analyzed and their means at baseline compared to the same after intervention, to show how they changed. Their p- values were as shown in table 3.4

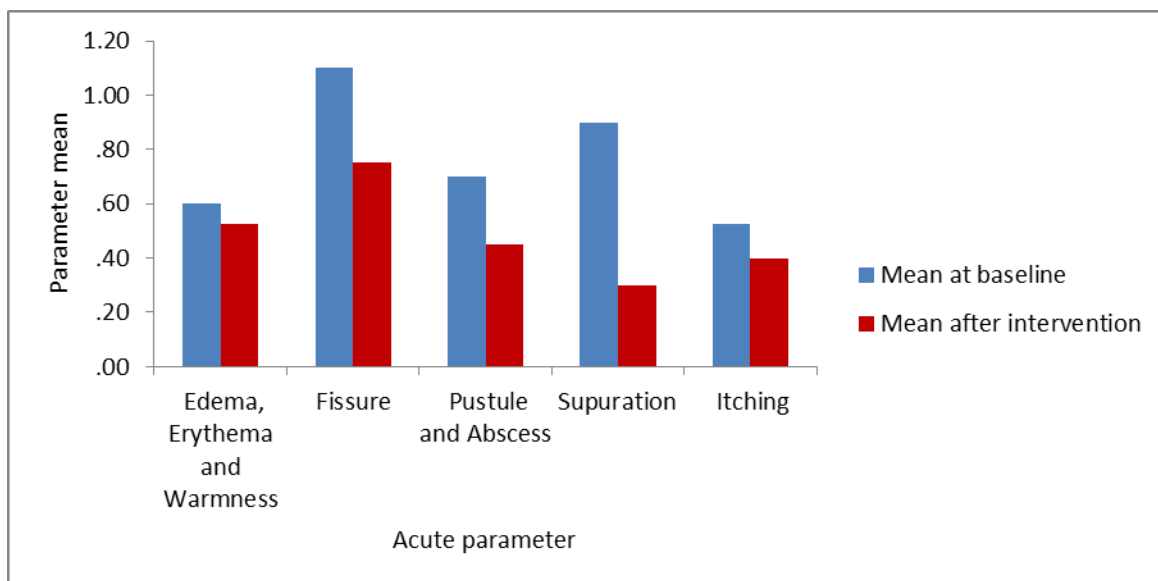
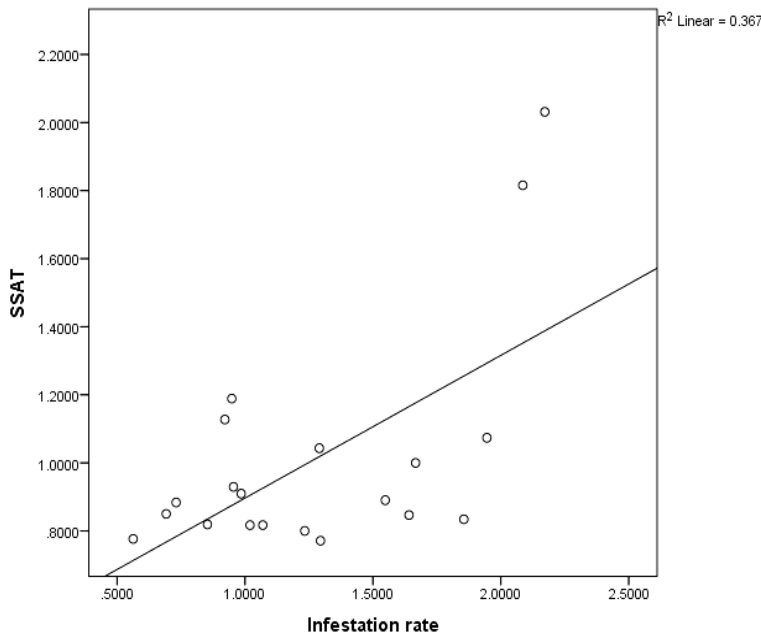


Figure 3.14: Various acute parameters at baseline and after intervention

Table 3.4: P- values of various acute parameters

Signs and symptoms	N	Mean at baseline	Mean after intervention	P-value
Edema, Erythema and Warmness	20	0.6	0.33	0.03
Fissure	20	1.10	0.75	0.02
Pustule and Abscess	20	0.70	0.35	0.02
Suppuration	20	0.90	0.30	0.01
Itching	20	0.53	0.24	0.02



Spearman correlation between severity score for acute tungiasis and infestation rate indicated a strong correlation coefficient (R) of 0.6. R is significant when it occurs below 1.0 i.e $R < 1.00$.

Figure 3.15: Correlation between SSAT and infestation rate

3.4.1: Wilcoxon matched pairs signed rank test

A Wilcoxon signed rank test showed that a four weeks, twice daily treatment course with coconut oil elicited a statistically significant change in lowering the acute severity scores ($Z=-3.946, p=0.001$). The test also showed that the same treatment elicited a significant change in lowering the infestation rate ($Z=-3.971, p=0.001$).

3. 5: Chronic tungiasis

Prolonged infestation, which leads to chronic tungiasis was analyzed along age classes and gender. Results were as shown in figures 3.16 and 3.17 respectively.

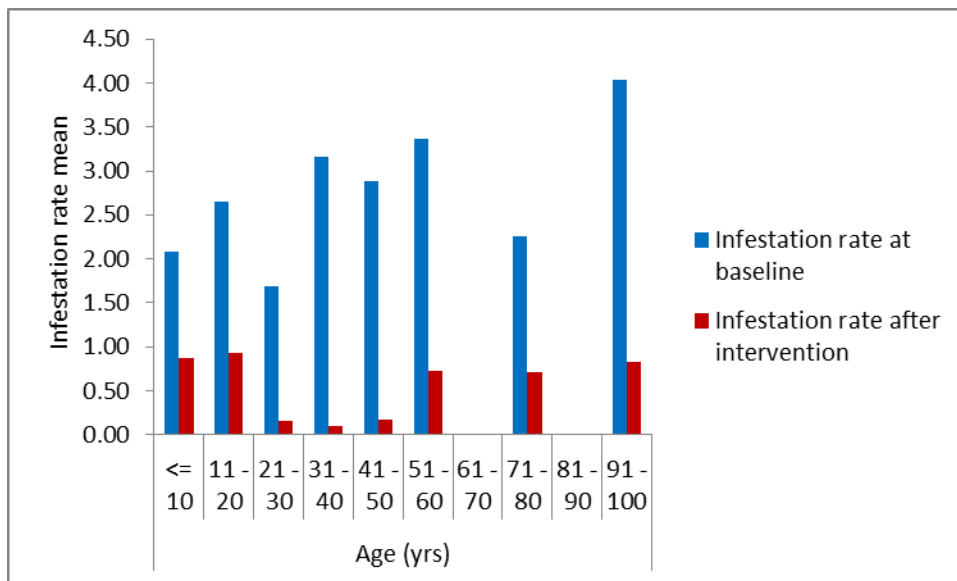


Figure 3.16: Infestation rate for chronic tungiasis along age at baseline and after intervention

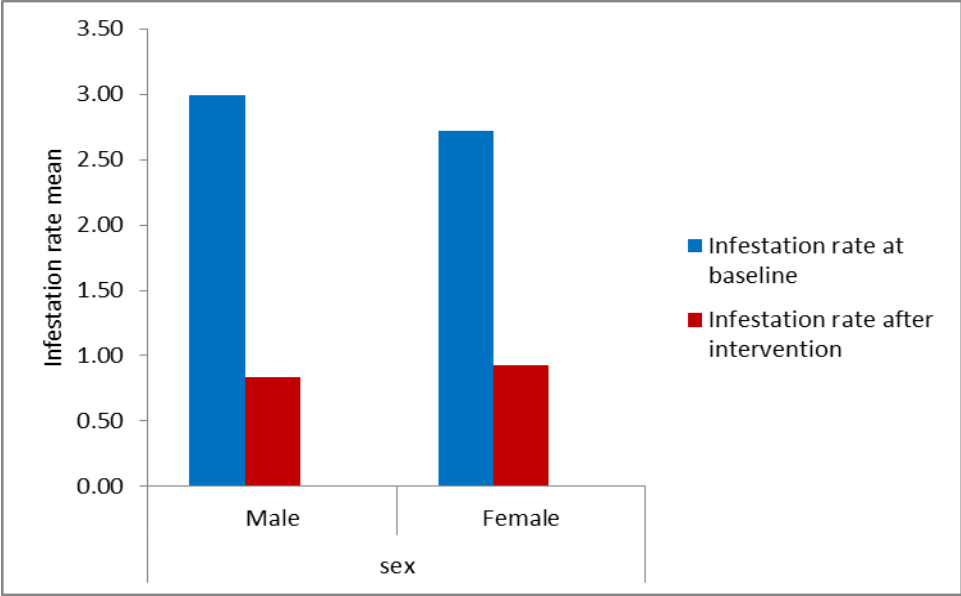


Figure 3.17: Infestation rate for chronic tungiasis along gender at baseline and after intervention

Chronic signs and symptoms were, analyzed along age classes and gender. The results were as shown in figures 3.18 and 3.19

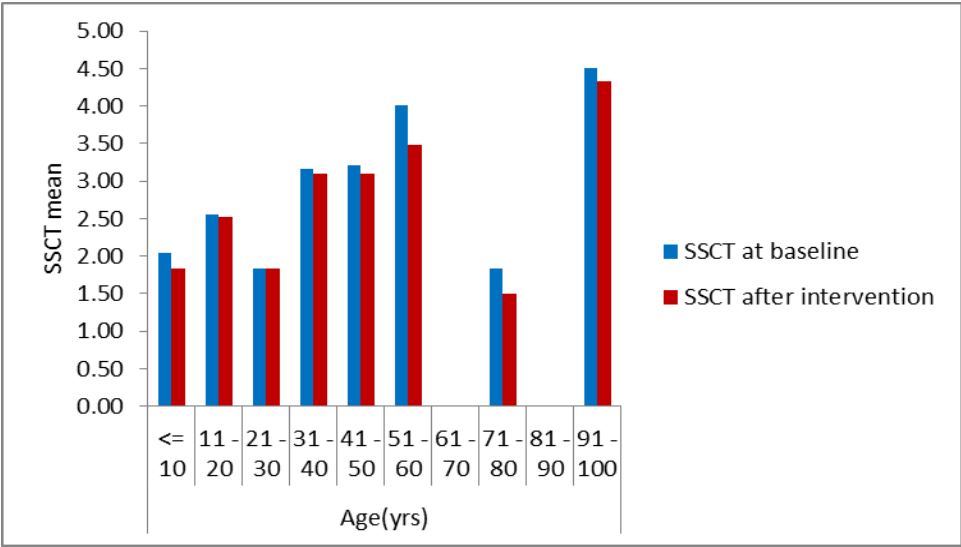


Figure 3.18: Severity scores for chronic tungiasis (SSCT) along age at baseline and after intervention

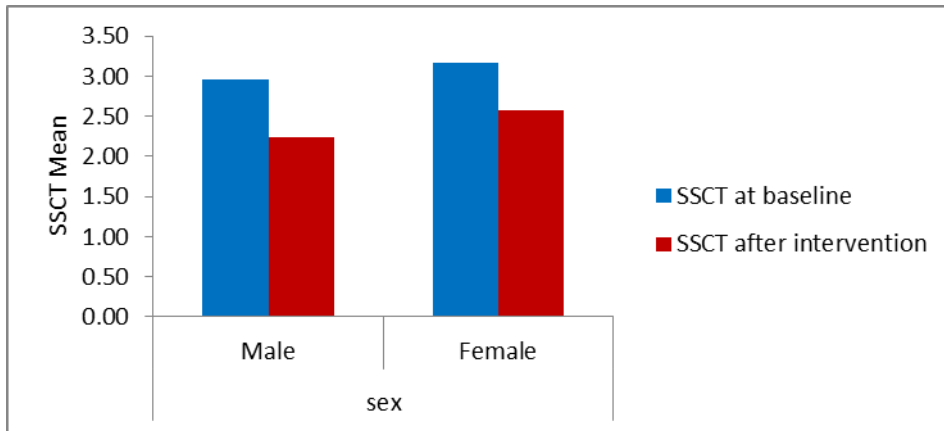


Figure 3.19: Severity scores for chronic tungiasis (SSCT) along gender at baseline and after intervention.

Chronic signs and symptoms at baseline and after intervention were analyzed to see how they changed. The findings were as shown in fig 3.20 below. Their p-values are as recorded in table 3.5

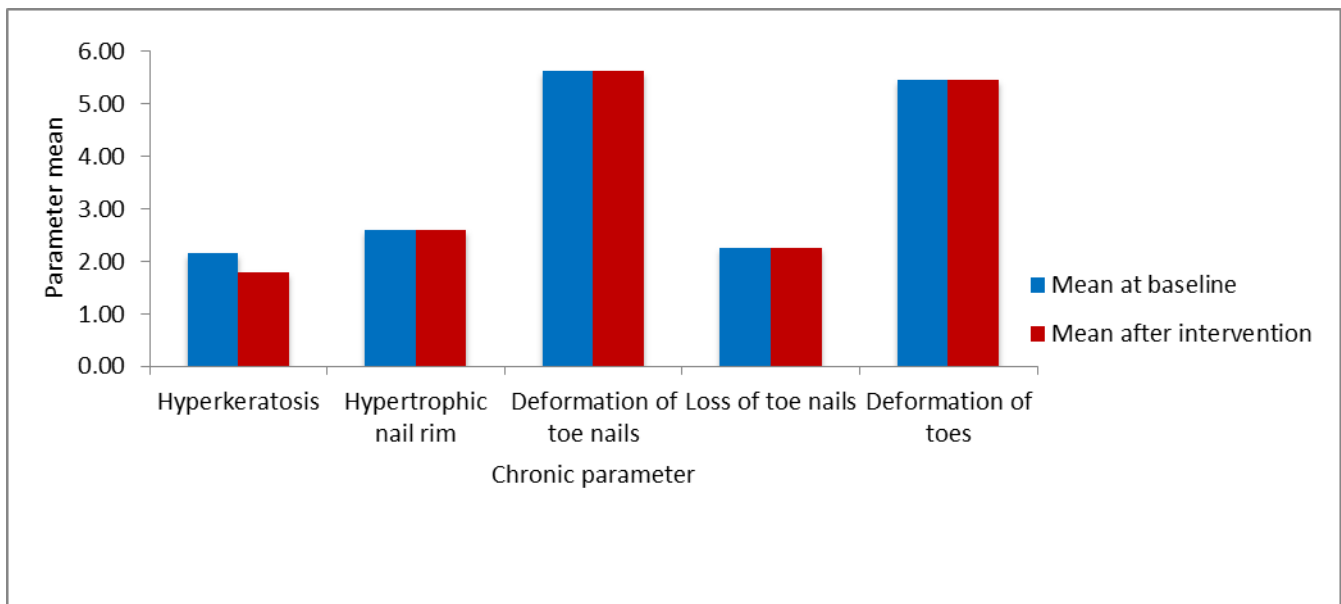
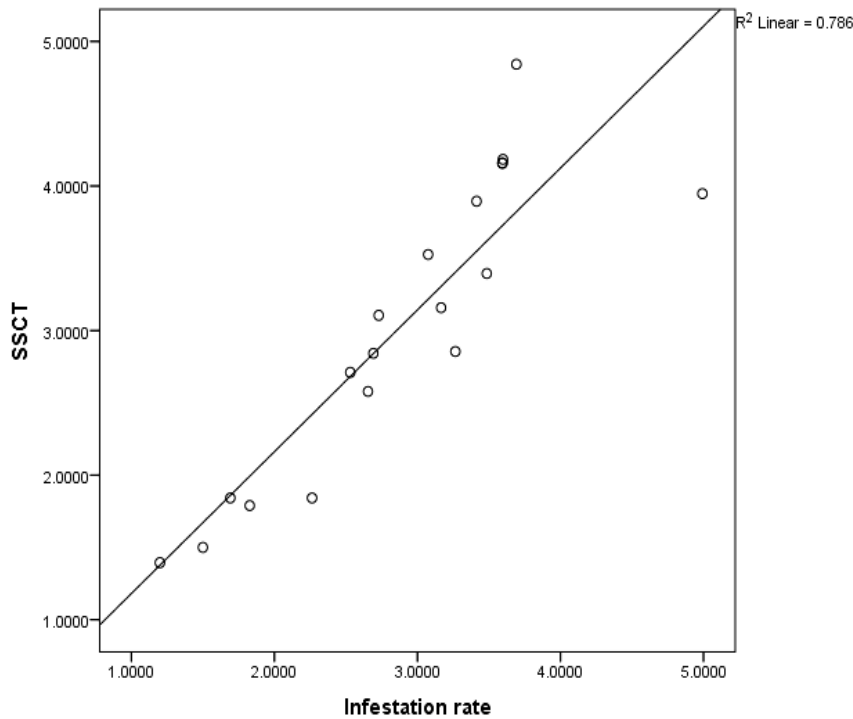


Figure 3.20: Chronic parameters at baseline and after intervention.

Table 3.5: P-values of chronic parameters

Signs and symptoms	N	Mean at baseline	Mean after intervention	P-value
Hyperkeratosis	19	2.16	1.789	0.08
Hypertrophic nail rim	19	2.605	2.605	0.090
Deformation of toe nails	19	5.632	5.632	0.090
Loss of toe nails	19	2.26	2.26	0.09
Deformation of toes	19	5.47	5.47	0.09



Spearman correlation between severity score for chronic tungiasis and infestation rate indicated a very strong correlation coefficient (R) of 0.88. R is significant when it occurs below 1.0 i.e $R < 1.00$.

Figure 3.21: Correlations between SSCT and infestation rate.

3.5.1: Wilcoxon matched pairs signed rank test

Wilcoxon signed rank test showed that a four weeks, twice daily treatment course with coconut oil elicited a statistically significant change in lowering the infestation rate ($Z=-3.871, p=0.001$). However, the test showed that the same treatment did not elicit a significant change in lowering the severity scores for chronic tungiasis ($Z=-1.811, p=0.07$).

CHAPTER 4: Discussion, Conclusion and Recommendations

4.1: Discussion

4.1.1: *Demographic and parasitological characteristics of the cohort group*

The demographic and parasitological characteristics of this study were as summarized in table 3.1. In the study, only the age and gender of the participants were important and thus reflected in the results. Among the 39 cohort members, 16 were females while 23 were males, including both children and adults. Their ages ranged from 3 to 97 years. There was an assumption that age and gender would not have any effect (negative or positive) on the performance of coconut oil. This assumption was, adopted from a study conducted in Fortaleza, a town in Northeast Brazil, by Feldmeier *et al* (2006b). In their study, they used zanzarin (a derivative of coconut oil, neem and jojoba oil) to control tungiasis with a lot of success.

The lesions were classified using Fortaleza classification adopted from Eisele *et al* (2003), as elaborated in section 2.5 of this thesis. In this study, manipulated lesions were more than, those encountered by Judith *et al* (2006). This is an indicator that there had been an attempt to extract the lesions but with no success. The lesions occurring in clusters were not as many as those encountered by, Judith *et al* (2006) in their study. Viable lesions (stages I-III) were many with a median of 41. Only a few lesions were found dead (Stage IV) with a median of 9. The median of the total number of lesions (dead or viable) in the cohort members was 56. The parasitological characteristics of this study were unique to itself. This is because, as observed by other researchers, there is no parasitological pattern in tungiasis. The parasitological characteristic of a cohort group depends on the risk factors surrounding it, and this varies from place to place and from season to season (Judith *et al.*, 2006; Feldmeier *et al.*, 2006a; Feldmeier *et al.*, 2003).

4.1.2: Clinical pathology in the cohort group

As this study depicted, tungiasis presents in various kinds of clinical pathologies. Each of the pathologies was, analyzed and the percentage of the individuals in the cohort afflicted by it calculated as shown in table 3.2. In this study, a number of clinical pathologies were present in the same person. Many of the participants were having both acute and chronic symptoms. Signs of acute inflammation included erythema, edema, and warmness. Chronic inflammation was exhibited by hyperkeratosis and hypertrophic nail rims. Suppuration, pustule and abscess were signs of super infection. Signs of super infection were present in 77% of the group. In this study, every member of the cohort had difficulties while walking. Deformation of toes was in 49% of the cohort. Acute inflammation, ulcers and fissures afflicted the group in equal proportions of 51% each. Only 49% of the cohort group had lost their nails due to tungiasis.

The clinical pathologies reported in this study were characteristic findings in different stages of the disease, just as confirmed by Eisele *et al.* (2003) and Feldmeier *et al.* (2003). According to this study, the ectoparasitosis presents with intense clinical pathology depending on the status (whether chronic or acute), and that the disease morbidity is directly proportional to infestation rate, confirming the findings of Judith *et al.*(2006) and Feldmeier *et al.*(2003). These results, on clinical pathologies, disputes the observation made by Sanushi (1989). Sanushi having studied 14 cases of tungiasis imported to United States reported that patients showed only one or two lesions and that except for itching and local pain, no clinical pathology was, observed (Sanushi, 1989).

4.1.3: Acute tungiasis

As observed in this study, acute tungiasis is characterized by symptoms and signs like pustules, abscess, suppuration, lesions in clusters, persistent pain and pain upon pressure, erythema, ulcers and edema among others. This is in line with the findings of Feldmeier *et al.* (2002). Acute inflammation in the victims was, characterized by erythema, edema, itching and pain. It resulted due to tissue damage induced by a metabolically highly active and continuously enlarging parasite, as Eisele *et al.*, (2003) observed. Suppuration observed among the acute victims was an indication of infection by bacteria, which may have been on the flea surface or within its body. The bacteria may also, have entered into the victims as they scratched themselves, as most of them complained of pruritus. Inflammatory response among the victims could also, have been caused by proteolytic enzymes released by the flea during penetration, or by the immune response of the individuals, as Feldmeier *et al.*, (2002) concluded in their findings.

As Geigy and Suter (1960) explained in their study, honey comb like lesions (clusters) encountered in this study were thought to be related to reproductive biology of *Tunga penetrans*, enabling a single male to fertilize several embedded females within a short period of time. Most acute victims confessed that often they attempted to extract the embedded fleas using thorns and unsterilized needles, which might create avenues for bacterial infections. As Feldmeier *et al.* (2002) observed in their study, the bacteria might have aggravated the case as the jigger decomposed. Every acute victim in this study had difficulty in walking due to persistent pain, which is a known fact among tungiasis victims since the first description of the ectoparasitosis (Cotes, 1899; Gordon, 1941; Jolly, 1926; Linardi, 1998).

In this study, there was a strong positive correlation between acute severity scores and infestation rate at baseline, with a correlation coefficient (r) of 0.6 (fig 3.15). Thus once the infestation is

eliminated, the disease severity comes under control. This confirms prior findings by Fildmeier *et al* (2006a) and Eisele *et al* (2003) that acute morbidity and infestation rate strongly correlates. This study also supports their diagnosis that the signs and symptoms highlighted in table 2.1 characterize acute tungiasis. After intervention with coconut oil, there was a big decline in the rate of acute infestation as depicted in figures 3.10 and 3.11. The acute severity scores also reduced tremendously (figures 3.12, 3.13 and 3.14). This was evident in the specific acute cases highlighted in figures 3.6 and 3.7. Both acute infestation rate and severity scores reduced to levels below the mean of 1.0. Statistically, the reduction in signs and symptoms in acute victims was very significant as epitomized by their p-values in table 3.4.

4.1.4: Chronic infestation

As seen in this study, chronic symptoms include hyperkeratosis, hypertrophic nail rims, deformation of toes and nails among others, just as observed by Eisele *et al.*, (2003). Real mechanisms of symptoms such as deformation of toes and nails, hyperkeratosis and hypertrophy of nail rims could, not be well understood as in the studies of Soria & Capri (1953) and Casala , Copello & Pensa (1954). Auto-amputation of digits, which results from necrosis of bones and ligaments occurred in some chronic cases as also encountered by Gordon (1941) and Linardi (1998) in their respective studies. This study confirmed the findings of Bezzera (1994) that chronic tungiasis is associated with persons with particular risk factors such as alcoholics and the mentally challenged, who have prolonged contact with the ground or are unable to care for themselves.

Chronic infestation was also, found in neglected elderly persons in the cohort group. As observed in this study, chronic infestation can cause permanent change in gait and even immobility, in agreement with the findings of Declé (1900).

As seen in figure 3.9, the ectoparasitosis has potential to negatively, affect many facets of life including children's education as Heukelbach *et al.*, 2003 explained. These accounts shows that chronic tungiasis is an important health problem. At baseline, chronic signs and symptoms strongly correlated with infestation rate with a strong correlation coefficient (r) of 0.8 (figure 3.21). After the application of coconut oil, the infestation rate in chronic cases lowered to levels below the mean of 1.0 as depicted in figures 3.16 and 3.17. Just like in a study conducted by Judith *et al* (2006), the chronic signs and symptoms did not change as shown in figure 3.20, except for hyperkeratosis, which registered minimal change. This minimal decline in hyperkeratosis is the one reflected by the slight changes observed in figures 3.18 and 3.19 along age classes and gender respectively.

The p-values for chronic signs and symptoms shown in table 3.5 are an indicator that the overall change observed was not significant, further confirming the findings of Judith *et al* (2006) above. In this study, chronic signs and symptoms remained as permanent features in the individuals even after jiggers cleared. Figure 3.3 shows how the nail rims in a chronic case remained hypertrophic even after applying coconut oil for four weeks. The nails in figure 3.4 also remained deformed even after the same treatment above. Figure 3.5, however, demonstrates the changes in hyperkeratosis as the case was treated.

4.1.5: *Tungiasis* along gender

In this study, both acute and chronic infestation rates were higher in males than in females at baseline (figures 3.11 and 3.17). There were no specific factors encountered in the study that could explain this finding. After intervention with coconut oil, infestation in both chronic and acute victims reduced to levels below the mean of 1.0. Acute and chronic morbidity occurred in almost equal proportions in males and females (figures 3.13 and 3.19). After intervention, acute morbidity declined below the mean of 1.0 (fig 3.13). The chronic morbidity did not change much as only hyperkeratosis responded to treatment (fig 3.19). This is similar to observations made by Ade-serrano and Eisele (1981), Arene (1984) and Chadee (1998). According to these authors, preponderance of males over females occurs in jigger infestation.

In Fortaleza, Brazil, Chadee (1998) observed that 28% of boys aged between 7 and 14 years were highly infested with jiggers. In the same age class, only 17 % of the girls were jigger infested. A significant difference in prevalence along gender was also, observed in a study conducted in Trinidad (Chadee, 1998). In other studies in south Brazil, higher prevalence was, observed in females than in males (Carvalho *et al.*, 2003). Studies in Trinidad, Brazil and Nigeria have found no significant differences along gender (Ade-serrano and Ejezie, 1981; Arene, 1984; Chadee, 1998; welcke *et al.*, 2002). Data on tungiasis distribution along gender has not been consistent. It appears to vary from one population to the other. As observed in Fortaleza, Brazil, the inconsistency is due to differences in exposure and disease related behavior like walking bare footed, as Ejezie (1981) observed.

4.1.6: *Tungiasis along age*

In this study, acute cases were present in participants of age 60 years and below. Among these cases, children were the most (fig 3.10). Infestation was very high in participants of age 20 years and below. For unknown reasons, the cohort did not have victims in age classes of 21-30 and 41-50 years. Infestation was not high in participants of middle ages (fig3.10). In this study, acute morbidity was highest in children. Participants of middle ages did not present with very severe morbidity among the acute cases (figure 3.12). In chronic tungiasis, almost every age class was jigger infested. The oldest participant in chronic category had 97 years (fig 3.16). The highest chronic morbidity and infestation were in age class of 91-100 years (figures 3.16 and 3.18).

Just like observed by Ugbomoiko *et al* (2007), an S-shaped prevalence pattern along age occurred in acute cases, with the highest prevalence in participants of age 20 years and below, and 51-60 years age class (fig 3.10). This S- shaped prevalence pattern in acute tungiasis also reflected in a study conducted in a rural community in Brazil (Muehlen *et al.*, 2007). According to this author, marked increase in infestation among the old people is due to different exposure. Middle-aged people spend most of the time working outside their respective endemic communities. They also remove the embedded flea more rigorously. In contrast, children and the old people, as confirmed in this study, spend most of the time in endemic areas, as they do not go out to work (Muehlen *et al.*, 2007).

4.1.7: *Efficacy of coconut oil*

The intervention results of this study showed that, coconut oil is highly efficacious in tungiasis control. According to other researchers like Schwalfenberg *et al.* (2004), coconut oil has been mostly, used than any other oil in controlling ectoparasites like ticks and mosquitoes. According

to these authors, the oil contains a triglyceride called lauric acid, which is a powerful anti-microbial agent. It also contains caproic, caprylic and capric acids, which have some anti-bacterial properties and work synergistically with lauric acid, making coconut oil so healing to the skin.

Wilcoxon signed rank test showed that, a four weeks, twice daily treatment course with coconut oil elicited a statistically significant change in lowering the acute severity scores ($Z=-3.946, p=0.001$). The test also showed that the same treatment elicited a significant change in lowering acute infestation rate ($Z=-3.971, p=0.001$). The same test showed that a four weeks, twice daily treatment course with coconut oil elicited a statistically significant change in lowering the chronic infestation rate ($Z=-3.871, p=0.001$). However, the test showed that the same treatment did not elicit a significant change in lowering the severity scores for chronic tungiasis, as most features had become permanent in the victim ($Z=-1.811, p=0.07$). According to these statistical results, coconut oil is highly efficacious in controlling tungiasis

4.1.8: *Tungiasis and other diseases*

As this study depicted, tungiasis can be confused with other diseases, which clinically manifest with more or less the same signs and symptoms. Examples of these diseases are scabies, cercarial dermatitis, and cutaneous larval migrans. Scabies (seven-year itch), is an infestation of the skin caused by a mite called *Sarcoptes scabiei* and is associated with poverty, unhygienic conditions and overcrowding, just like tungiasis according to Feldmeier and Heukelbach (2009). Like tungiasis, scaby is, propagated by rooming domestic and peridomestic animals, like those found in the study area. As this study revealed, tungiasis is a self-limiting disease like scuby. Hoeffler (1974) highlighted cercarial dermatitis as a self- limiting disease, which appears as a skin rash. It

causes severe itching like the one experienced by tungiasis victims in this study. Most victims in the cohort group complained of pruritus especially at night. Any other self-limiting parasitic disease manifesting with pruritus, like creeping eruption (cutaneous larval migrans) can be mistaken for tungiasis (Herbener and Borak, 1988).

As this study demonstrated, tungiasis can sometimes be confused with human myiasis due to the characteristic ulceration associated with the two diseases. Fissures and ulcers seen in the participants of this study could act as entry points for myiasis causing larvae as Diaz (2006) expressed. Most ulcerated victims in this study walked bare footed, thus risking getting infections like tetanus. Pathogenic bacteria like *Clostridium tetani* have been isolated from tungiasis lesions according to Tonge (1989). According to this author, a study conducted in Sao Paulo state, Brazil, associated point of lesion with 10% tetanus entry. Almost every individual in the cohort confessed to using and sharing unsterilized materials in jigger extraction. According to Feldmeier *et al* (2003), sharing of unsterilized materials like needles in removing jiggers can aid in HIV and hepatitis-B transmission. The cohort group was thus at a risk of contracting these infections.

Pediculosis, an ectoparasitosis caused by lice infestation and, which causes pruritus like tungiasis as the lice suck blood from the host was, encountered among some cohort members. It is a health problem associated with poverty, poor hygienic conditions and overcrowding, like tungiasis as Elston (2005) explains. As observed in this study, tungiasis is a disease that ranges from an asymptomatic status to very severe levels like malaria, in confirmation of Helbok (2005) observation. Other diseases, like elephantiasis, (fig 3.8) can compound tungiasis, marking it hard to bring it under control, as this study depicted.

4.1.9: Limitations

One limitation of this study is that individuals were only eligible if they had a minimum of ten embedded fleas at recruitment. It remains unknown if the correlation between infestation rates and severity scores would have changed if those with fleas below a total of ten had been included in the study. Another limitation is that the infestation rate was, assessed for a period of 30 days. It is not known what changes would occur if the individuals were followed for a longer period.

4.2: Conclusion

This study has clearly demonstrated that there is a strong relationship between infestation rate and the disease morbidity (figures 3.15 and 3.21). The higher the infestation rate, the higher the disease morbidity as depicted by both acute and chronic signs. After applying the coconut oil, the infestation rate reduced to insignificant levels (figures 3.10, 3.11, 3.16 and 3.17). The number of embedded fleas also drastically reduced after the intervention with coconut oil (table 3.3). The signs also disappeared except in chronic cases where they had assumed a permanent status. The Wilcoxon matched pairs signed rank test elicited significant difference between baseline findings and intervention results for acute tungiasis. The same test indicated a significant difference in infestation rate between baseline and intervention results for chronic case. However, the test did not show a significant change in symptoms and signs in chronic tungiasis between baseline and intervention results. Though jigger infestation cleared away in chronic cases, many signs and symptoms assumed permanent status in the individuals. They remained as future indicators that jigger infestation was once a problem with the victim. Since both acute and chronic individuals recuperated and infestation in both reduced to zero, the null hypothesis was, thus rejected in the

study leading to acceptance of alternative hypothesis. In this study it was, concluded that coconut oil is efficacious in treating tungiasis.

4.3: Recommendations

- Three means of intervention namely good sanitation, use of footwear and application of coconut oil would comfortably combat jigger menace at the convenience of the victims' homes.
- Early intervention in jigger control is also called for to avoid the irreversible damage caused by chronic tungiasis. Due to low efficacy of most treatment options in tungiasis control, efforts towards prevention and control of jigger flea transmission ought to be, enhanced. This should entail environmental and personal hygiene.
- Tungiasis prevention and control interventions should target the infested households, schools and communities for maximum impact. The government can achieve this through community health strategies. Jigger treatment camps should be regularly, organized as effective reach out mechanisms.
- To prevent secondary infections and associated morbidities, feet and other infested body parts should be, treated with antiseptic solutions. Tetanus Toxoids (TT) vaccine should be administered to jigger victims and those at risk in order to prevent infections with tetanus.
- National Environment Management Authority (NEMA) should monitor the impact of various chemicals used in jigger control, on the environment with the aim of recommending on the right insecticides to use.
- The ministry of health (2014) jigger prevention and control guidelines should be, enforced at county and sub-county levels with an aim of bringing tungiasis under full

control. The ministry of health should try the inexpensive, non-toxic and victim friendly coconut oil in curbing the ectoparasitosis. Application of coconut oil should go in hand with ecological measures aimed at interfering with the life cycle of sand flea. The Ministry of Health (MOH) should enhance cross-sectional surveys in all counties to determine the prevalence and social- economic impacts of tungiasis.

- The ministry of health ethics committee should ensure that all researches conducted on tungiasis in Kenya respect ethical values so as not to subject the victims to further stigma. This will in turn make them cooperate in jigger control programs.
- World Health Organization (WHO), through its regional office, should work to raise awareness on tungiasis and formulate appropriate strategies to address this debilitating parasitic skin disease.
- The fact that the standard correlation coefficient of $r = 1.0$ was not attained in both acute and chronic cases (when severity scores were compared with their respective infestation rates) is a revelation that other unknown factors could be exacerbating tungiasis menace. Thus, further studies are called for to unravel the unknown factors.

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APPENDIX-I: DEMOGRAPHIC AND PARASITOLOGICAL INFORMATION(ACUTE)

NAME:.....SEX:.....AGE.....

Total number of lesions.....

Viable lesions (stages i-iii).....

Dead lesions (stage iv).....

Manipulated lesions.....

Number of clusters of lesions.....

SSAT (SEVERITY SCORE FOR ACUTE TUNGIASIS)

SIGNS AND SYMPTOMS	BASELINE SURVEY POINTS				POINTS SCORED AFTER INTERVENTION WITH COCONUT OIL														
	wk1	wk2	wk3	Wk4	Wk1	Wk2	Wk3	Wk4	Wk5	Wk6	Wk7	Wk8	Wk9	Wk10					
<i>According to number of topographic areas affected:</i>																			
Edema,Erythema and Warmness																			
Ulcer																			
Fissure																			
Pustule and Abscess																			
Supuration																			
Lesion in clusters																			
<i>Irrespective of the topographic areas affected:</i>																			
Itching																			
Sleeping disturbances due to itching																			
Pain upon pressure																			
Pain while walking																			
Persistent pain																			
Difficulty walking																			

INFESTATION RATE

	BASELINE SURVEY				AFTER INTERVENTION WITH COCONUT OIL														
	wk1	wk2	wk3	Wk4	WK1	Wk2	Wk3	Wk4	Wk5	Wk6	Wk7	Wk8	Wk9	Wk10					
Number of embedded fleas since last examination																			
Number of days since last visit																			
Infestation rate																			

**APPENDIX-II: DEMOGRAPHIC AND PARASITOLOGICAL INFORMATION
(CHRONIC)**

NAME:SEX:AGE.....

Total number of lesions.....

Viable lesions (stages i-iii).....

Dead lesions (stage iv).....

Manipulated lesions.....

Number of clusters of lesions.....

SSCT (SEVERITY SCORE FOR CHRONIC TUNGIASIS)

SIGNS AND SYMPTOMS	BASELINE SURVEY POINTS				POINTS SCORED AFTER INTERVENTION WITH COCONUT OIL														
	wk 1	wk 2	wk 3	Wk 4	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10					
<i>According to number of topographic areas affected:</i>																			
Hyperkeratosis																			
<i>According to number of toes affected</i>																			
Hypertrophic nail rim																			
Deformation of toe nails																			
Loss of toe nails																			
Deformation of toes																			

INFESTATION RATE

	BASELINE SURVEY				AFTER INTERVENTION WITH COCONUT OIL														
	wk 1	wk 2	wk 3	Wk 4	Wk 1	Wk 2	Wk 3	Wk 4	Wk 5	Wk 6	Wk 7	Wk 8	Wk 9	Wk 10					
Number of embedded fleas since last examination																			
Number of days since last visit																			
Infestation rate																			

APPENDIX –III: DEFINATION OF TERMS

Tungiasis- disease caused by jigger flea

Chronic disease- one that has persisted for a long time

Acute disease-one that has only presented for a short time

Pediculosis-disease caused by lice

Status penetradi-adult flea in the process of penetration

Elephantiasis-lymphatic filariasis caused by a roundworm called *wuchereria bancrofti*.

Hyperkeratosis: thickening of the outer layer of the skin

Hypertrophic nail rim: overgrowth or thickening of nails

Super infection: is reinfection of an individual who is already infected

Suppuration: discharge of pus

Edema: swelling caused by fluid retention or excess fluid trapped in body tissues.

Abscess: is a tender, easily pressed mass, generally surrounded by a colored area from pink to deep red. The middle of the abscess is full of puss and debris.

Erythema: is reddening of skin due to inflammatory or immunological processes.

Fissures: is a groove, natural divisions, deep furrow, elongated cleft or tear in various parts of the body.

Ulcer: are open sores on the linings.

Pustule: small-circumscribed elevation of the skin, containing pus and having an inflamed base.

Itching: is a sensation that causes a desire or reflex to scratch

Pruritus: an urge to scratch

APPENDIX –IV: RESEARCH PARTICIPANT CONSENT FORM

TITLE OF THE RESEARCH: EFFICACY OF COCONUT OIL IN THE CONTROL OF TUNGIASIS

I am asking you to take part in a research study. The following is important information to know before participating;

1. Explanation of objectives and procedures;

- The purpose of the study is to evaluate the efficacy of coconut oil in the control of tungiasis.
- The study involves twice, daily treatments with the repellent for a period of 10 weeks in a cohort of 35 individuals.
- The procedures to be, followed will include counting the number of jigger lesions, determining infestation rate, and examining the various tungiasis associated symptoms.
- No specimen (e.g blood, tissue, body fluids) will be collected as part of the study.
- You are required to be residing in your present home during the study duration.

2. **Benefits:** You will benefit directly if the repellent proves efficacious. This study may however, yield a more reliable means of treating tungiasis in future. If you choose not to participate in the study, you may instead receive routine treatment from a health facility near your home. There will be no other benefits or compensation for taking part in the study.

3. **Confidentiality:** Information obtained about you for this study will be, kept confidential to the extent allowed by law.

4. Refusal or withdrawal without penalty:

Whether or not you take part in this study is your choice. There will be no penalty if you decide not to be in the study. You can withdraw from this research at any time. Your choice to leave the

study will not affect your relationship with the researcher. You are however, requested to cooperate freely so that the objectives of the study may be achieved.

5. Consent:

(A) I (candidate) freely agree to participate in the study

Signature.....code.....

(B)I (guardian) freely agree that the candidate participate in the study

Signature.....code.....

APPENDIX- V: CHILD ASSENT FORM

TITLE OF THE RESEARCH: EFFICACY OF COCONUT OIL IN THE CONTROL OF TUNGIASIS

I am asking you to take part in a research study. The following is important information to know before participating:

1. Explanation of objectives and procedures;

- The purpose of this study is to evaluate the efficacy of coconut oil in the control of tungiasis.
- The study involves twice daily, treatment with coconut oil for a period of 10 weeks in a cohort group of 39 individuals.
- Procedures to be, followed include counting the number of jigger lesions, determining infestation rates and examining the various tungiasis associated symptoms.
- No specimen e.g blood, tissue, body fluids etc will be, collected as part of the study.
- You are required to be residing in your present home during the study duration.

2. Benefits: You will benefit directly if the oil proves efficacious. The other children will equally benefit. The study may yield reliable means of controlling tungiasis in future.

3. Risks: There are no risks or discomfort associated with this study.

4. Refusal or withdrawal without penalty: You should know that:

- You do not have to be in this study if you do not want to. You are, however, encouraged to participate.
- You may stop being in the study at any time. There is no punishment or penalty associated with withdrawal.

- The consent of your parents or guardian will be, sought first for you to be in this study. Even if they grant permission to you, it is still your choice whether to participate or not.
- You are, allowed to ask any questions you may have to the researcher at any stage of the study.

4. Confidentiality: Information obtained about you in this study will be, kept confidential to the extent allowed by the law.

Sign this form only if you:

- have understood what you will be doing for the study.
- have had all your questions answered.
- have talked to your parents or guardian about this project and they have agreed.
- have agreed to take part in this study.

Your Signature..... Printed Name..... Date.....

Name of Parent(s) or Legal Guardian(s).....

Researcher explaining study

Signature.....Printed Name.....Date.....

APPENDIX –VI: PATIENT REFERRAL LETTER

GITAU ANTHONY KIRAGU

PO BOX 6113,

THIKA

Phone no.0722268555

Email: anthonygitau@yahoo.com

10-11-2014

PHO,

KANDARA HOSPITAL

PO BOX 98,

KANDARA.

Dear Sir/ Madam

RE: PATIENT REFERRAL

After treating (patient's name).....against tungiasis with coconut oil for a duration of 4 weeks, the desired cure was not realized. Kindly attend to this case so, as to restore the patient to good health. In case of any consultation, please contact me through the phone number above.

Thank you for your kind assistance.

Yours sincerely,

GITAU ANTHONY KIRAGU

Sign.....