Assessing the impact of the Heart and Sole Africa (HASA) prevention education program using clinical staging and quality of life measures of podoconiosis patients.

By

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DECLARATION

We, Ahamed Kallon, George Mkondo and Natnael Shimelash hereby declare that the practicum capstone thesis has been written by us without any external unauthorized help, that it has been neither presented to any institution for evaluation nor previously published in its entirety or in parts. Any parts, words, or ideas, of the thesis, however limited, which are quoted from or based on other sources, have been acknowledged as such without exception.

Ahamed Kallon	
Name	Signature
George Mkondo	
Name	Signature
Natnael Shimelash	
Name	Signature

DEDICATION

This one’s for me.
George Tavonga Mkondo

I dedicate this to my parents Tequam Woldehawariat and Zemedkun Tessema. Cheers!
Natnael Zemedkun Shimelash

I dedicate this piece of work to these wonderful women, Mariama Bawoh (Mother) and Aminata Kallon (Stepmother) who were taken away from me by cervical cancer and Ebola virus disease, respectively. May your souls rest in perfect peace my mamas. Also going out to the Ngombuklah Kallon family of Jawie, Sierra Leone.
Ahamed Flagbata Kallon

The PODO Squad dedicates this paper to Barnie and Fiona.

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ABSTRACT

Background: Podoconiosis is a non-infectious chronic lymphedema that occurs in genetically susceptible individuals, upon long-term feet exposure to irritant volcanic soil. It is a debilitating disease with profound psychological, social, and economic consequences. Nearly 4 million subsistence farmers and impoverished populations are affected worldwide, with more than 6,000 podoconiosis patients residing in Rwanda. Established cases of podoconiosis are often irreversible. Community-based lymphedema management is currently recommended for the management of the morbidity caused by podoconiosis. Only one organization (HASA) currently provides lymphedema management services in Rwanda. This study evaluated the adherence characteristics, the changes in clinical condition and quality of life of podoconiosis patients enrolled in HASA's community-based lymphedema management program.

Methods: A cross-sectional study was conducted using in-person surveys and physical examinations between May and June 2021. We included all HASA participants who joined the program within the past 5 years, residing in Musanze and Burera Districts. Data was collected at the two HASA clinics in Musanze City and Kinoni Village. The survey measured quality of life, adherence to podoconiosis management guidelines, patients' perceptions of the HASA PEP, and clinical staging. Quantitative analysis was conducted using SPSS (IBM, V.26). Pearson's Chi-square, Mann Whitney U, Kruskal Wallis, and Wilcoxon's signed-rank tests were used to test for association between variables and statistical significance was considered at $p < 0.05$. Qualitative thematic analysis was used to assess the open-ended questions.

Results: A total of 127 participants (18 male, 109 female) were enrolled in the study. Twenty-five participants had pre-HASA photographs for clinical staging. The mean age of our participants was 56.8 years (SD=17.9). Half (50.4%) of participants belonged to the lowest Ubudehe (category 1). Nearly half (44.1%) of the participants were farmers. More than two-thirds (69.3%) of participants washed their feet at least twice a day, while 45.7% raised their legs overnight. The majority (78.7%) of participants regularly wore shoes. Few (6.3%) participants experienced frequent ADLA episodes post-HASA when compared to pre-HASA intervention (89.8%). Almost all (98.4%) participants experienced an improvement in their QoL. The median QoL score decreased from 14 to 7 ($p<0.01$). There was no significant change in the clinical stage of participants ($p>0.99$). Participants reported improvements in mobility, self-esteem, and productivity. The disruption caused by Covid-19 and financial constraints were cited as major drivers for reduced adherence to the HASA PEP guidelines.

Conclusion: Community-based lymphedema management is an important tool for the reduction of morbidity caused by podoconiosis. Its benefits are not only limited to improvements in clinical condition but also the overall psychosocial wellbeing of patients. Programs should follow a holistic approach to improve adherence to programs and ensure optimal benefits.

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CHAPTER ONE: INTRODUCTION

1.1 Background

Podoconiosis is a non-infectious, tropical lymphedema that occurs in genetically susceptible individuals upon chronic foot exposure to irritant soils (Deribe et al., 2015). Typically, the disease presents with bilateral and uneven swelling of the lower limbs below the knees (WHO, 2015). The disease often presents in the third decade of life, with a high occurrence in subsistence farmers who do not wear shoes (Price, 1976).

More than four million people are affected by podoconiosis worldwide, with the majority being in Africa. In Rwanda, podoconiosis is found in all districts, mostly affecting poor populations in rural areas (Deribe et al., 2019). The chronic lower limb swelling, and related complications often lead to disability. Due to the condition of their feet, podoconiosis patients suffer from various forms of internalized, enacted, and perceived stigma (Deribe et al., 2013). As a result, patients are 11.4 times more likely to develop mental disorders than people who do not have the disease (Bartlett et al., 2015). Podoconiosis patients also suffer from adenolymphangioadenitis (ADLA) episodes, which are painful bouts of swelling, inflammation, weakness, and fever which affects their productivity (Molla et al., 2012a). Stigma and disability make it difficult for podoconiosis patients to obtain gainful employment, plunging them deeper into poverty (Yakob et al., 2010). Disability, pain, stigma and decreased productivity are associated with an overall poor quality of life (QoL) of podoconiosis patients (Chandler et al., 2020; Deribe et al., 2013; Phillips et al., 2019).

Currently, there is no diagnostic test for podoconiosis, and diagnosis relies on physical examination, comprehensive family history, and elimination of other diseases characterized by lymphedema (Sime et al., 2014). The early clinical stages of podoconiosis are treatable but later stages are often irreversible (Deribe et al., 2018). Management of podoconiosis involves community-based health education, daily foot hygiene and skincare practices, overnight leg raising, and consistent wearing of shoes (Davey, 2009; Deribe et al., 2017). Despite the simplicity of these intervention components, many patients face various barriers to fully adhere to the prevention and management guidelines. Lack of hygiene supplies, poor awareness, and limited access to reliable water facilities result in low adherence to community-based interventions (Getie et al., 2020). Stigma faced by the patients has also been implicated as a deterrent to healthcare-seeking behavior and participation in community-based lymphedema management programs (Davey, 2009; Tsegay et al., 2015).

In 2011, the World Health Organization (WHO) recognized podoconiosis as a neglected tropical disease (NTD). Currently, podoconiosis is managed under the WHO's Global Program for the Elimination of Lymphatic Filariasis (GPELF) (Deribe et al., 2015). However, in countries with low lymphatic filariasis prevalence such as Rwanda, podoconiosis elimination is not prioritized by the program (Ruberanziza et al., 2009; Tora et al., 2018). An international non-governmental organization (INGO), Heart and Sole Africa (HASA) is the only organization providing lymphedema management services in Rwanda. The purpose of the study was to ascertain the impact of this community-based lymphedema management program in Rwanda and possibly inform future interventions.

1.2 Problem statement

The impact of the HASA prevention education program (PEP) on the clinical staging and QoL of podoconiosis patients and their adherence level to program guidelines has never been studied in Rwanda.

1.3 Broad objective

To assess the impact of the HASA PEP on the clinical staging and QoL of podoconiosis patients, and their adherence to podoconiosis management instructions by July 2021.

1.4 Specific objectives

1. To assess changes in clinical staging of podoconiosis patients before and after participating in the HASA PEP within the past 5 years, by July 2021.

2. To ascertain the degree of adherence of HASA patients to the treatment guideline of the PEP, by July 2021.

3. To assess changes in the QoL of podoconiosis patients who participated in the HASA PEP within the past 5 years, by July 2021.

1.5 Organization of the report

This report consists of six chapters. Chapter one introduces the background of the study, the problem statement, study objectives, and the overall organization of the study. Chapter two reviews currently known information on podoconiosis as well as the gap our study intends to fill. Chapter three explains the study methods, including the setting, design, sampling and data collection procedures, and analysis. Chapter four reveals the study results while chapter five presents the discussion and study limitations. Chapter six presents the conclusion and recommendations.

CHAPTER TWO: LITERATURE REVIEW

2.1 Overview of Podoconiosis

Clinical Definition and Pathogenesis

Podoconiosis is a non-infectious, tropical lymphedema that is caused by long-term foot exposure to volcanic, red irritant soils and occurs only in genetically susceptible individuals. Although the pathogenesis of podoconiosis is not yet fully understood, mineral particles and genetic predisposition have been indicated as triggers (Davey et al., 2007; Price, 1990). Persistent exposure of the feet to volcanic soil leads to the entry of mineral particles through the skin. These particles are engulfed by macrophages of the skin which initiate an inflammatory process. This leads to endolymphangitis and fibrosis of the lymphatic vessels, obstructing the drainage of lymph. As a result, the lower limbs become swollen, eventually progressing to skin changes and elephantiasis (Chandler et al., 2020; Price, 1990).

Clinical Features

Podoconiosis typically presents with bilateral and asymmetrical lower limb swelling that is limited to below the knee. The progression of the disease occurs over a long period of time and goes through different phases. The prodromal phase, usually during adolescence, includes a transient mild fever, burning sensations in the foot, as well as itching of the skin of the forefoot (WHO, 2015). In the early disease stage, the toes become rigid, the forefoot splays, and leg swelling sets in with hyperkeratosis and mossy skin lesions. With continued exposure to irritant soil, podoconiosis may progress to elephantiasis. This encompasses two variants of irreversible swellings and skin change, ranging from a soft lymphedematous change to a fibrotic swelling with hard skin nodules (Chandler et al., 2020; Tekola et al., 2012). Furthermore, podoconiosis patients suffer from acute dermatolymphangioadenitis (ADLA) otherwise known as “acute attacks”. These are agonizing, recurring bouts of inflammation of the lymphedematous legs; characterized by malaise, fever, increased swelling of the affected limb, severe burning sensation, and inability to move the limb (Deribe et al., 2017).

Figure 1: Mossy foot, multiple nodules
Photo: Natnael Shimelash, with permission.

Figure 2: Lymphedema, nodules, and skin bands
Photo: Natnael Shimelash, with permission.

Diagnosis and Clinical Staging

At present, there is no diagnostic test for podoconiosis. Diagnosis is based on patient history, physical assessment, and exclusion of other lymphedema causing diseases such as lymphatic filariasis (LF), via blood smears or immunological tests (Sime et al., 2014). Physical assessment of podoconiosis entails clinical staging of the affected limbs; this is done according to the severity of the swelling, and skin changes. Staging is essential for diagnosis, planning management, monitoring of disease progression, and evaluation of interventions. The Lymphedema and Tekola staging systems are two of the few methods used to stage podoconiosis. However, neither has been universally accepted (Tekola et al., 2008).

The Lymphedema staging system is a three-stage system designed for any disease causing lymphedema (Greene & Goss, 2018). In this system, Stage 0 represents an asymptomatic lymphatic system abnormality. Stage 1 describes edema that subsides with the elevation of the limbs. Stage 2 describes edema that does not subside with limb elevation. In stage 3, patients present with fibro-adipose accumulation and dermatologic changes (ISL, 2013).

The Tekola staging system has five stages according to the degree of swelling, and skin changes. In stage 1, the lower limb swelling subsides overnight. Stage 2 describes below-knee edema that does not resolve overnight; with skin nodules present only below the ankles. Stage 3 describes below-knee edema that does not resolve overnight, with skin nodules present above the ankles. Stage 4 represents an above-knee swelling that does not resolve overnight and with skin nodules present at any location. Stage 5 represents fixated joints with swelling at any part of the leg that does not subside overnight. Although both systems are applicable for podoconiosis, the Tekola staging system was specifically devised and validated for podoconiosis (Tekola et al., 2008).

Risk Factors

Risk factors of podoconiosis are age, socioeconomic status, occupation, genetics, and the environment. As a result of slow progression and long-term exposure to irritant soil, podoconiosis is rarely seen in children under 10 but normally presents before the age of 30 (Alemu et al., 2011). It commonly affects poor communities in rural settings, with limited access to water and sanitation facilities. Subsistence farmers who do not wear shoes and live in uncovered floor houses are at high risk of developing podoconiosis (Price, 1976). Family-based genetic mapping of podoconiosis patients has revealed consistent variations of Human Leukocyte Antigen (HLA) class II locus, suggesting podoconiosis to be a T-cell mediated disease. Given exposure to volcanic, red irritant soil, relatives of an affected person are five times more likely to develop podoconiosis (Tekola et al., 2012). Podoconiosis is normally prevalent in populations that live in high-altitude regions more than 1000m above sea level and receive annual precipitation of more than 1000mm. These climatic conditions are conducive for the disintegration of lava and reconstitution of minerals into irritant silicate clays (Kihembo et al., 2017; Price & Henderson, 1978; WHO, 2015).

2.2 Distribution and Burden

2.2.1 Epidemiology

Podoconiosis is established or suspected to be endemic in 32 countries in Africa, Asia, and Latin America. It affects an estimated 4 million people worldwide, with men and women believed to be equally susceptible (Caprioli et al., 2020; WHO, 2015). Podoconiosis has been reported in highland areas of 19 Sub-Saharan countries (Figure 2) (Deribe et al., 2018). National prevalence studies have been carried out in 11 countries, of which 10 were in Africa. Uganda had the lowest prevalence (0.1%) recorded while Cameroon had the highest (8.08%) (Kihembo et al., 2017; Wanji et al., 2008). However, podoconiosis has only been nationally mapped in Ethiopia, Cameroon, and Rwanda. Cameroon and Ethiopia bear the highest known prevalence, with an estimated 160.6 cases per 100,000 and 1363.6 cases per 100,000 population affected, respectively (Deribe et al., 2015; Deribe et al., 2018).

Podoconiosis is distributed in all 30 districts of Rwanda, albeit with a relatively low prevalence of 68.5 cases per 100,000 population and a median age of 53 years. Northern and Western Provinces have the highest prevalence with approximately 70 cases per 100,000 population. At the district level, Nyarugenge District, in Kigali Province, recorded the lowest prevalence (28.3 cases per 100,000 population) while Nyamasheke District, in the Western Province, recorded the highest (119.2 cases per 100,000 population) (Deribe et al., 2019).

Created with mapchart.net

Figure 3: Distribution of podoconiosis in Africa (created with mapchart.net)

2.2.2 The Burden of Podoconiosis

Physical Disability

Physical disability is a major contributor to the burden of podoconiosis. In 2017, podoconiosis accounted for 172,073 Disability Adjusted Life Years (DALYs) in Ethiopia alone (Deribe et al., 2020). Physical disability results from progressive lower limb lymphedema and its complications. The enlargement and heaviness of the legs often make standing or movement hard and sometimes impossible (Chandler et al., 2020). Patients experience at least five episodes of ADLA annually, each lasting an average of four days (Molla et al., 2012b; Shenoy, 2008). As a result, ADLA contributes to 2.78 million DALYs globally (Murray et al., 2012). Despite the heavy burden of disability caused by podoconiosis, there are currently no studies that illustrate early mortality due to the disease (Deribe et al., 2020).

Stigma and Mental Health

Disease-related stigma is a social occurrence or related personal experience marked by experiencing or anticipating adverse social judgments such as exclusion, blame, or devaluation due to a particular disease (Weiss & Ramakrishna, 2006). Stigma is a major driver of poor QoL among podoconiosis patients (Bartlett et al., 2015; Mousley et al., 2013).

Podoconiosis patients suffer from internalized, perceived, and enacted stigma (Deribe, Tomczyk, Mousley, et al., 2013). Patients are often verbally abused by their peers and society at large. They are barred from attending religious and societal activities (Deribe et al., 2013; Tora et al., 2011). Abuse experienced by podoconiosis patients results in loss of confidence and has been associated with increased numbers of school dropouts (Alemu et al., 2011). In addition, patients are often prohibited from marrying unaffected persons (Shahvisi et al., 2018). However, those who are married are frequently subjected to verbal and physical abuse from their intimate partners (Tora et al., 2014; Tsegay et al., 2018; Yakob et al., 2008). Stigma towards podoconiosis is not limited to the patients only. Beliefs that podoconiosis is hereditary have resulted in stigmatization of podoconiosis patients' family members (Ayode et al., 2012).

Stigma has considerable mental health implications, which contribute to the overall disease burden of podoconiosis (Chandler et al., 2020). The mental health consequences of podoconiosis include depression, and mental distress, which are not only limited to the patients but family members as well (Phillips et al., 2019).

Podoconiosis patients are 11.4 times more likely to have depressive symptoms in comparison to people without the disease (Bartlett et al., 2015). Studies in Ethiopia and Cameroon reported depressive symptoms in 12.6% and 38.5% of podoconiosis patients respectively (Bartlett et al., 2015; Semrau et al., 2020). In Rwanda, a recent study reported a 68.5% prevalence of depressive symptoms in lymphedema patients that highlighted a high burden of depression due to podoconiosis (Semrau et al., 2020). Furthermore, studies in Rwanda and Ethiopia illustrated females with podoconiosis were more likely to have depressive symptoms compared to their male counterparts. This is attributed to violence at the hands of their partners, the stress of being primary caregivers, and other socioeconomic factors (Mousley et al., 2013; Semrau et al., 2020; van't Noordende et al., 2020).

Economic Impact

Podoconiosis has a significant economic impact, both on affected families and the wider economy (Chandler et al., 2020). A study in Ethiopia estimated that 9 out of 10 patients affected by podoconiosis are of working age (Alemu et al., 2011). ADLA contributes largely to the socioeconomic consequences; its frequency and severity inflict a total individual loss of 90 work days yearly (Molla et al., 2012b). Generally, podoconiosis related reduction of productivity and healthcare expenditure results in an estimated loss of about 200 million USD per year (Tekola et al., 2006). On average, Cameroonian podoconiosis patients spend about 142 USD per year on medical and non-medical costs. This expenditure accounts for more than a third of the average Cameroonian household income (Tembei et al., 2018).

2.3 Interventions

2.3.1 Overview of Prevention and Management Efforts

Podoconiosis is preventable, its early stages treatable, its progression deterrable, and has the potential to be eliminated within the century (Deribe et al., 2018). Primary prevention is achievable by avoiding prolonged contact with volcanic soil through regularly washing feet, wearing shoes, and covering soil floors (Chandler et al., 2020). For secondary and tertiary prevention, simple community-based self-management intervention is recommended to abate disease progress and decrease disability (Negussie et al., 2018). This scheme was adapted from the GPELF and contains five components including community teaching on cause and prevention, patient education on daily foot hygiene with soap and water, consistent use of emollient, overnight limb elevation, and consistent use of shoes and socks (Davey, 2009; Deribe et al., 2017; Sikorski et al., 2010).

Podoconiosis was successfully eradicated from Europe and North Africa as a result of urbanization and socio-economic development. This entailed increment in paved roads, shoe-wearing habits, and access to water facilities (Price, 1990). However, prevention and control in Sub-Saharan Africa, Asia, and South America has been difficult (Davey et al., 2007; Deribe et al., 2013). Various factors hinder the elimination of podoconiosis in these regions. In most endemic areas, poverty drives the prioritization of other needs such as nutrition over buying shoes (Shahvisi et al., 2018). Additionally, lack of awareness as well as limited access to water facilities, and poor foot-washing habits have been found to perpetuate exposure (Getie et al., 2020).

Afflicted patients are deterred by stigma, physical disability, fatalistic mentation, and a predilection to traditional medicine from seeking medical care. As a result, podoconiosis patients delay seeking medical care which leads to disease progression and worsened prognosis (Getie et al., 2020; Negussie et al., 2018; Shahvisi et al., 2018; Yakob et al., 2010).

Studies on the knowledge, attitudes, and practices of healthcare professionals on podoconiosis revealed deficits in medical practice. In Rwanda, a study showed that more than 90% of healthcare professionals harbor misconceptions and had inadequate knowledge of podoconiosis (Bayisenge et al., 2020). Similarly, a study in Ethiopia discovered that more than 50% of healthcare professionals in affected areas believed podoconiosis to be communicable and feared contracting it (Yakob et al., 2010). This contributes to frequent misdiagnosis of podoconiosis in medical centers (Chandler et al., 2020). In addition, long distances from health facilities and lack of transportation deter healthcare-seeking efforts (Getie et al., 2020; Tsegay et al., 2015).

Despite the social, economic, mental, and overall health impacts of podoconiosis, grand scale interventions are uncommon (Tomczyk et al., 2012). Although the WHO added podoconiosis to its list of NTDs in 2011, there is yet to be a global strategy for intervention; instead, podoconiosis is managed under the GPELF (Deribe et al., 2015). In the recently developed 2021-2030 road map for NTDs, podoconiosis remained integrated with the GPELF, hence, continues to be unattended in countries where LF is not prevalent such as Rwanda (Ruberanziza et al., 2009; Tora et al., 2018).

Despite the lack of global attention, some endemic countries have made strides to address it. Ethiopia has recognized podoconiosis as a public health concern and incorporated it in the 2013-2015 National Integrated Master Plan for NTDs (EMoH, 2013). The Government of Ethiopia has integrated podoconiosis in its primary health care by formulating diagnostic guidelines, training healthcare providers, and arranging household visits for severe conditions which have been cost-effective in scaling up interventions (Deribe et al., 2017; EMoH, 2013). Similarly, the Government of Rwanda has recognized the burden of podoconiosis and included it in its routine health management information system (Deribe et al., 2017). Furthermore, the Government of Rwanda carried out a national training of community health workers (CHW) on podoconiosis and other NTDs in 2018 (Bayisenge et al., 2020).

2.3.2 Intervention efforts

Podoconiosis is easy to control through simple cost-effective behavioral modifications (Davey & Burridge, 2009). Community-based lymphedema -management practice has proven vital in the treatment of lymphedema and ADLA of LF and podoconiosis in low resource settings. Patients are taught to wash their feet daily, use emollients, raise legs overnight, apply bandages and wear shoes. In addition, supplies necessary for foot care such as soap, bleach, files, emollients, and basins are provided (Akogun & Badaki, 2011; Dreyer et al., 2009; Negussie et al., 2018). When adhered to, it averts debilitating episodes of ADLA and promotes tissue recovery which decreases the level of severity and improves the QoL in advanced cases. In mild and asymptomatic cases, it can reverse or prevent edema from occurring (Akogun & Badaki, 2011; Tora et al., 2011).

Although a limited number of studies have evaluated the effectiveness of community-based self-management in podoconiosis, those done have demonstrated its effectiveness. Community education in Ethiopia has demonstrated a decrease in both perceived and enacted stigma associated with podoconiosis, protecting patients against mental illness (Mcbride et al., 2015). A follow-up study of podoconiosis patients at the Mossy Foot Treatment and Prevention Association (MFTPA) revealed clinical-stage improvements in 52% of participants while there were no deteriorations in the remaining patients. In the same study, 96% of participants reported significant improvements in their QoL, which assessed the level of pain, stigma, and social relationships, after enrollment (Sikorski et al., 2010). A community-based self-management package in Northern Ethiopia was affirmed to lower the frequency and duration of ADLA in podoconiosis cases (Negussie et al., 2018).

2.3.3 Study Justification

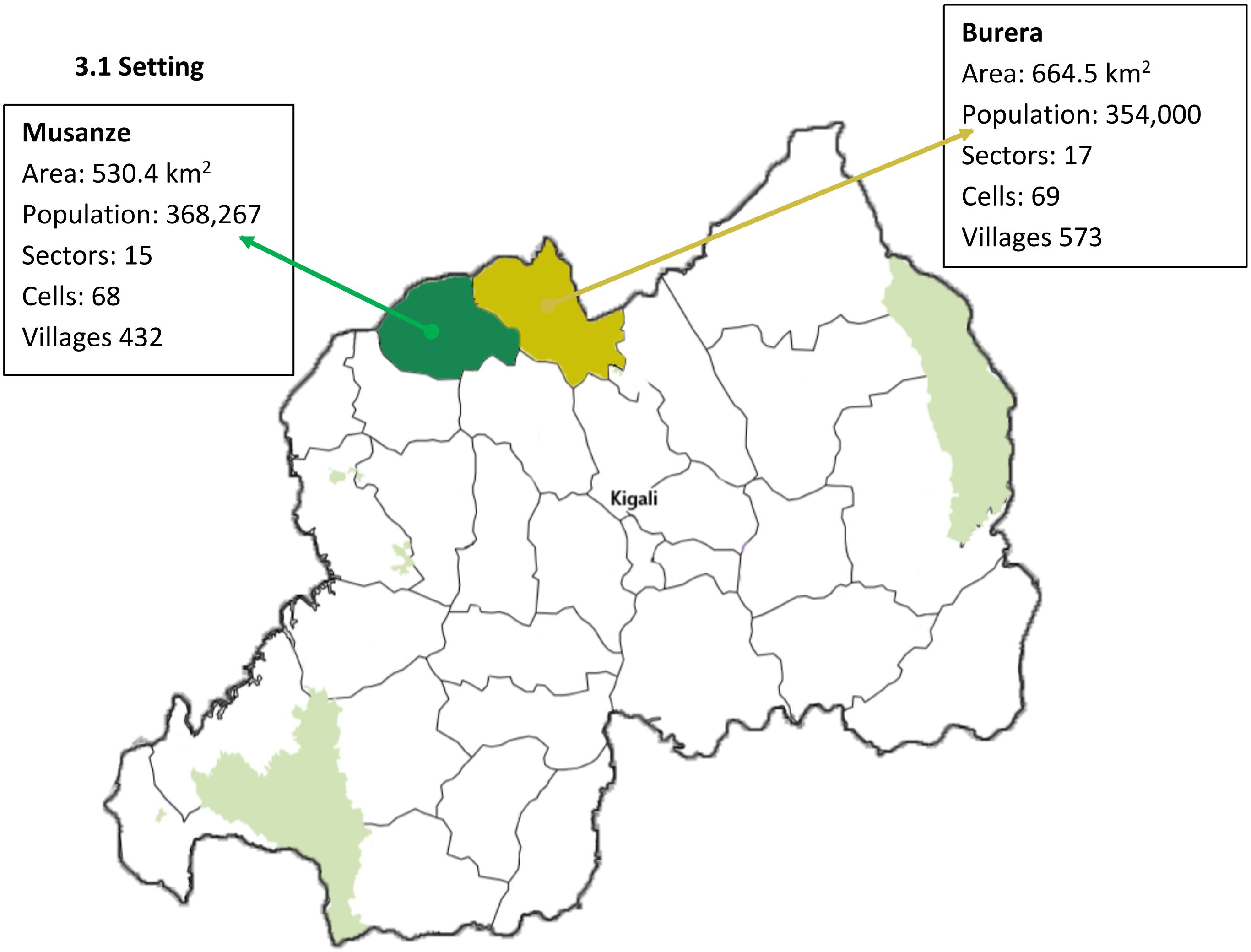
The WHO considers community-based lymphedema management as an essential tool for morbidity management and disability prevention of lymphedema patients. As such, it recommends the integration of such programs in the national health policies of affected countries (WHO, 2013). Even though the Government of Rwanda recognizes the burden of podoconiosis, to our knowledge, only one organization currently works on community-based self-management of podoconiosis in Rwanda and no impact assessment studies have been done.

HASA is an INGO seeking to eliminate podoconiosis in Rwanda. Situated in Northern Province with a clinic in Musanze District and a satellite station in Burera district, it serves 531 registered patients across Rwanda. Patients receive bi-weekly prevention education, including simple community-based lymphedema management protocols and monthly neighborhood education. HASA has a vision to expand its services to other affected districts across Rwanda, but they have never previously evaluated the effectiveness of the program on patient podoconiosis status. Before the expansion of its services, it is important to study the program's effectiveness.

Thus, we sought to ascertain the impact of the HASA PEP on the clinical staging, and QoL of podoconiosis patients, and characterize their adherence levels to the program guidelines. This information will be helpful to inform future interventions and efforts to implement community-based lymphedema management for podoconiosis.

CHAPTER THREE: METHODS

3.1 Setting



Burera
Area: 664.5 km^2
Population: 354,000
Sectors: 17
Cells: 69
Villages 573

Musanze
Area: 530.4 km^2
Population: 368,267
Sectors: 15
Cells: 68
Villages 432

Figure 4: Map of Rwanda (adopted from Deribe et., al 2019)

The study was conducted in Musanze and Burera Districts in the Northern Province of Rwanda. These two districts are where the podoconiosis management units of HASA operate and constitute the majority of PEP patients. The main HASA clinic in Musanze City mainly gives service to patients from Musanze and surrounding districts. The HASA satellite clinic in Kinoni provides service for podoconiosis patients in Burera District.

The Musanze district is the most mountainous area in the country with multiple dormant volcanoes gracing its landscape. Musanze has 15 sectors which are further divided into 68 cells. The district has a total population of 368,267, of which more than 50% live below the poverty line (less than 1.9 USD per day). Agriculture is the main source of household income in Musanze with 60.4% of the population relying on farming for income. Approximately 51.4% of the population lives within a 15-minute walking distance to an improved clean water source. The district has 18 healthcare facilities and the mean walking distance to reach health services is 1 hour (NISR, 2018; World Bank, 2019). Musanze has the third-highest prevalence of podoconiosis in Rwanda with 86.1 cases per 100,000 of its adult population affected by the disease (Deribe et al., 2018).

Burera is a mountainous district with a volcanic landscape ranging between 1728 m to 4098 m altitude above sea level and covers an area of 646 km^2 (NISR, 2012). This district is divided into 17 sectors, with 69 cells and 573 villages, with every cell having between five and 16 villages (Munyaneza et al., 2014). The district has a total population of 354,000, of which, 45.2% live below the poverty line. The main economic activity in the district is subsistence farming (80%). Just 36% of the population in Burera lives within a 15-minute walking distance to an improved clean water source. The district has 19 healthcare facilities and the mean walking distance to reach health services is 54.4 minutes. Also, 93.8% of flooring in Burera households is of beaten soil (NISR, 2012). Burera has the 6th highest prevalence of podoconiosis in Rwanda (Deribe et al., 2019).

3.2 Design

A survey-based cross-sectional quantitative study was used to determine the adherence to podoconiosis management guidelines and QoL, while physical examination and photograph assessments were used to determine the clinical stage of patients enrolled in the HASA PEP.

3.3 Sample

The target population of the study was all podoconiosis patients enrolled in the HASA PEP within the past 5 years and residing in Musanze and Burera districts.

Sampling Procedure

Pre-HASA photographs were used to determine the clinical stage at enrollment. Thus, only participants with good-quality photographs were eligible for the clinical staging section of the study. Photograph quality was determined according to the following criteria:

Photograph inclusion criteria:

- Identification: Photographs should be identified with the patient’s full name, contact information, and date.
- Resolution: The photographs should be at least 96dpi.

- Aspects: The photograph should include one or both legs with the toes and at least 2/3 of the shin included.
- Lighting: The photograph should be adequately lit; meaning every part of the legs in the frame should be visible.
- Rendering: Photographs should be signed off by HASA as not being altered in any way.

Any photograph missing any one of the above-mentioned criteria was excluded from the clinical staging section of the study.

All patients within the sample population, including those without pre-HASA photographs, were considered for the QoL and adherence survey.

Inclusion Criteria

- HASA patients currently residing in Musanze and Burera Districts.

Exclusion Criteria

- Those who joined the program after February 2021 (because less than 3 months of intervention is not enough to have clinical stage and QoL changes).
- Those who are under 18 years of age.

After filtering participants using the inclusion and exclusion criteria, we included all patients who fulfilled the selection criteria for the study.

3.4 Data collection tools

Questionnaire

Based on information gathered from literature, a questionnaire was developed (Appendix 4) by the primary research team. The tool had five sections:

Section 1 included eight questions on demographic information.

Section 2 comprised 13 before and after themed, Likert scale questions with the response options “Not at all”, “Seldom” and “Often”. Of these, seven assessed stigma, two assessed pain, two assessed swelling characteristics, and two assessed productivity.

Section 3 comprised four Likert scale questions with the response options “Not at all”, “Seldom” and “Often” assessing the participants' adherence to daily foot washing, emollient use, leg raising, and shoe wearing.

Section 4 comprised four open-ended questions with probing prompts to allow participants to provide any additional information regarding their experience with the program. The first open-ended question assessed the reasons for non-adherence if any. The second and third questions explored the participants' perception of the program and how it can be improved. The fourth and final question evaluated the overall wellness of participants since joining the program.

Section 5 served to record clinical staging. The clinical staging used was adopted from the Tekola staging system to assess the participants' clinical staging (Tekola et al., 2008). This system categorized clinical condition according to swelling characteristics, joint movement, and skin changes. A patient was staged as stage 1, when the lower limb swelling subsided overnight; stage 2 when there was below-knee edema that did not resolve overnight; with skin nodules present only below the ankles; stage 3 when there was below-knee edema that did not resolve overnight, with skin nodules present above the ankles; stage 4 when there was an above-knee swelling that did not resolve overnight and with skin nodules present at any location; and stage 5 when there was a fixation of the ankle joints with swelling at any part of the leg (Tekola et al., 2008).

The initial draft of the questionnaire was written in English, and it was translated into Kinyarwanda by a fluent Kinyarwanda speaker and then revised by two other Kinyarwanda speakers for quality assurance. A pretest was conducted using nine Kinyarwanda-speaking kitchen staff and MBBS students at the University of Global Health Equity (UGHE). The questionnaire was revised based on the feedback received.

3.5 Data collector(s)

The data collection team comprised three primary researchers and two local data collectors from the UGHE data collector pool. The data collectors were university graduates and were fluent in both English and Kinyarwanda. Primary researchers communicated in English.

A two-day training was provided to both data collectors three days before data collection. The training entailed the following: (a) short introduction to podoconiosis (b) research aims (c) methodology and data collection tools (d) procedures of acquiring consent and handling of sensitive information (e) basic training on recognizing and referring psychological distress. Each data collector conducted two practice surveys on HASA PEP patients who were not eligible for the study, one day before data collection. Practice runs were conducted under the supervision of the primary researchers and feedback was given accordingly.

Primary data collectors, who are certified medical doctors, also practiced real-time clinical staging and photography staging on non-eligible podoconiosis patients, under the lead of the HASA clinical staff.

3.6 Data collection procedures

Staging pre-HASA photographs

The pre-HASA photographs were de-identified using participant identification numbers (PINs) before being independently staged by two members of the primary research team. The results were compared, and staging discrepancies were presented to the third independent primary researcher, who independently staged patients before proceeding to tie-breaking discussions. For staging components that could not be evaluated with photographs, the staging was aided by survey questions pertaining to joint fixation and overnight edema reduction.

Surveying and Clinical Staging

Initial contact with eligible participants was made by the HASA staff to remind and invite them to their routine PEP. Patients were also informed about the study that was being undertaken at the HASA clinics. Contacted patients were asked to inform other eligible patients that could not be reached by phone. At the clinic, Kinyarwanda-speaking data collectors approached the patients and asked their willingness to participate in the study. A detailed explanation of the study was provided in predesignated private rooms at the HASA Clinic in Musanze and Kinoni Clinic in Burera before written consent was acquired. Their consent to record the entire survey was also sought. The survey was administered by data collectors. Data was entered directly on data collectors' laptops fitted with a data collection tool called Kobo toolbox. Entire surveys were recorded using voice recorders. After surveys, two of the primary researchers independently staged each patient. This was done by visualization and physical examination of the lower limbs to determine the current clinical stage of the patients using the Tekola staging system. After staging, photographs were taken by the researchers and compared with pre-HASA photographs, where possible. Staging discrepancies were presented to the third independent primary researcher, who independently staged patients before proceeding to tie-breaking discussions.

The study was approved by the University of Global Health Equity IRB (Appendix 7). For detailed ethical considerations see Appendix 1.

3.7 Measure(s)

The study assessed 6 key measures.

1. The pre-and post-HASA clinical-stage scores of participants were treated as ordinal categorical data, with absolute values ranging from 1 (mild disease) to 5 (severe disease).

2. The proportion of participants that experienced change in their clinical stage scores, were categorized into "positive change", "negative change" and "no change" for descriptive analysis.

3. Likert scale variables of each adherence component (washing, emollient use, leg raising, and shoe wearing) were treated as ordinal categorical data.

4. Likert scale variables of each adherence component were summed and transformed into percentages of adherence level. Percentages were categorized into low and high adherence levels.

5. The change in QoL score was treated as continuous variables ranging from -26 to +26.

6. The change in QoL score was categorized as “positive change”, “negative change” and “no change” for descriptive analysis.

3.8 Data management

Data was deleted from Kobo toolbox after downloading onto the researchers’ password-protected computers. It was then entered into a password-protected excel spreadsheet (v16.0) for cleaning by the primary researchers. Aberrant and missing data was cross-checked with data collectors and corrections were made when necessary.

At the end of each survey, the recordings were uploaded onto the primary researchers’ computers and deleted from the voice recorders. Afterward, the data collectors transcribed and translated the recordings. All digital files were stored on the primary researchers’ password-protected computer(s). All hardcopy files used during the study were stored in a locked cabinet that was only accessible to the primary researchers, at the HASA clinic. After completion of data collection, all files used for the study were uploaded onto encrypted computers at UGHE. All data collected during the study will be discarded after 10 years.

3.9 Data analysis

3.9.1 Quantitative analysis

Data was imported from the excel spreadsheet to SPSS (IBM v26.0) and a codebook was formulated to guide analysis.

Descriptive statistical analysis was performed for each variable. The age of participants was categorized into above and below the mean age. Demographics, clinical stages, QoL variables, and adherence components were summarized using frequencies. Shapiro-Wilk test was used to test for normality of distribution.

For bivariate analysis, the overall adherence level, and the change in QoL score served as dependent variables, while separate adherence components (washing, emollients, raising feet, and wearing shoes) were the independent variables. Primary source of income was collapsed into "employed" and "unemployed" to minimize empty cells.

Pre- and post-HASA enrollment clinical staging was scored from 1 to 5, 1 being mild disease and 5 being severe disease. Median and interquartile ranges (IQR) were used to describe clinical-stage scores. Wilcoxon signed-rank test was used to analyze the change between pre-and post-HASA enrollment clinical staging scores.

For descriptive purposes, clinical staging was categorized as "positive change" if it changed from a higher score in pre to a lower score in post, "negative change" if clinical-stage changed from a lower score in pre to a higher score in post, and "no change" if there was no change in score.

Pre- and post-HASA enrollment QoL were scored according to responses on a Likert scale as follows: 0- "not at all", 1- "seldom", 2- "often". The overall QoL scores were determined, and their minimum and maximum scores were 0 and 26, respectively. Median and IQR were used to describe QoL scores. Wilcoxon signed-rank test was used to analyze the change between pre-and post-HASA enrollment QoL scores.

The change in QoL score was determined by subtracting the post-HASA QoL score from the pre-HASA QoL score. Association between demographic variables and change in QoL scores was determined by using Mann-Whitney U test when demographics were binary and the Kruskal-Wallis test when demographics had more than two levels.

For descriptive purposes, the changes in QoL were categorized as "positive change" if QoL changed from a higher score in pre to a lower score in post, "negative change" if QoL changed from a lower score in pre to a higher score in post, and "no change" if there was no change in score.

The association between separate adherence components (washing, emollients, raising feet, and wearing shoes) and the change in QoL scores was determined using a Kruskal-Wallis test.

An overall adherence score was calculated by adding the separate adherence component scores. The overall adherence scores were then transformed into percentages and a cut-off of 80% was used to categorize high (≥80%) and low (<80%) overall adherence levels. This cut-off was informed by literature on optimal treatment adherence cut-offs for chronic diseases (Gellad et al., 2017; Lam & Fresco, 2015). Pearson's Chi-square test was used to determine the association between demographic variables (sex, age, employment status, Ubudehe category, duration of enrollment, and family history of podoconiosis) and overall adherence level.

All statistical tests used a confidence interval of 95% and a p-value of <0.05 to determine significance.

3.9.2 Qualitative analysis

Thematic analysis was used to analyze the qualitative aspect of the study. The translated transcripts were openly read independently by the three primary researchers. After multiple meetings and rigorous discussions, the researchers created a codebook manually. Conflicting codes and codes that did not align with the study objectives were removed. In this process, each primary researcher read a transcript at least twice and one joint reading was conducted to facilitate coding agreement. The codes and excerpts identified by the inductive coding process were then collapsed to create three main themes.

CHAPTER FOUR: Results

4.1 Quantitative results

We surveyed a total of 127 HASA PEP participants in Musanze (n=47, 38.1%) and Burera (n=80, 62.9%) Districts of Northern Rwanda. This was 84.6% of the expected number of participants (150), as most eligible participants, especially those in Musanze, did not have phones and were unreachable for invitations. The mean year of enrollment in the program was 3.4 years (SD=1.3). Our participants were predominantly female (85.8%). The age range of our participants was 18 – 87 years with a mean age of 56.8 years (SD=17.9). More than half (57.5%) of participants reported having no immediate family members with podoconiosis.

Three-quarters of our participants (74.8%) had no formal education. Nearly half (44.1%) relied on farming as a primary source of income, while a third (33.9%) were unemployed. Most of the participants (81.6%) belonged to Ubudehe categories 1 and 2, and 90.6% lived in households with earthen flooring. Nearly all (96.9%) participants were covered by the national health insurance during the time of the study.

Table 1: Demographics of HASA prevention education program participants in Musanze and Burera Districts, Northern Province, Rwanda 2021

Variable	Musanze (n=47)	Burera (n=80) n (%)	Total (N=127)
Sex			
Female	44 (93.6)	65 (81.3)	109 (85.8)
Male	3 (6.4)	15 (18.8)	18 (14.2)
Age (years)			
< 57	28 (59.6)	26 (32.5)	54 (42.5)
≥ 57	19 (40.4)	54 (67.5)	73 (57.5)
Marital status			
Single	13 (27.7)	9 (11.3)	22 (17.3)
Married	17 (36.2)	47 (58.8)	64 (50.4)
Divorced	1 (2.1)	2 (2.5)	3 (2.4)
Widowed	16 (34.0)	22 (27.5)	38 (29.9)
Family history of podoconiosis[1]			
Yes	21 (44.7)	33 (41.3)	54 (42.5)
No	26 (55.3)	47 (58.8)	73 (57.5)
Educational status			
No education	30 (63.8)	65 (81.3)	95 (74.8)
Primary	14 (29.8)	12 (15.0)	26 (20.5)
Secondary	3 (6.4)	3 (3.8)	6 (4.7)

Primary source of income			
Unemployed	18 (38.3)	25 (31.3)	43 (33.9)
Farmer	18 (38.3)	38 (47.5)	56 (44.1)
Day laborer	10 (21.3)	14 (17.5)	24 (18.9)
Business owner	1 (2.1)	2 (2.5)	3 (2.4)
Teacher	0 (0)	1 (1.3)	1 (0.8)
Health insurance[2]			
Yes	47 (100)	76 (95.0)	123 (96.9)
No	0 (0)	4 (5.0)	4 (3.1)
Ubudehe category[3]			
1	24 (51.1)	39 (48.8)	63 (50.4)
2	18 (38.3)	21 (26.3)	39 (31.2)
3	5 (10.6)	18 (22.5)	23 (18.4)
Flooring			
Soil	38 (80.9)	77 (96.3)	115 (90.6)
Concrete	8 (17.0)	3 (3.8)	11 (8.7)
Tiles	1 (2.1)	0 (0)	1 (0.8)
Years of enrollment			
1 or less	5 (10.6)	5 (6.3)	10 (7.9)
2	5 (10.6)	23 (28.8)	28 (22.0)
3	10 (21.3)	10 (12.5)	20 (15.7)
4	13 (27.7)	23 (28.8)	36 (28.3)
5	14 (29.8)	19 (23.8)	33 (26.0)

[1] Self-reported podoconiosis history in immediate family members (parents and siblings)

[2] Participants' health insurance status during the study period

[3] Government of Rwanda system of social categorization according to economic status (1 lowest – 4 highest)

The levels of adherence to the different podoconiosis management protocols varied among participants. Most participants often applied emollients after washing their feet (94.5%; Table 2). Nearly half (43.3%) of the participants reported never raising their legs overnight. Most participants washed their feet daily (98.4%). Of these, 29.1% washed their feet once per day and 69.3% washed twice or more per day. The majority of our participants (78.7%) wore closed shoes most of the time they were on their feet (standing, walking, or working) while 21.3% of them seldomly wore closed shoes.

Table 2: HASA patient adherence to podoconiosis management guidelines in Musanze and Burera Districts, Northern Province, Rwanda 2021

Variable	Musanze (n=47)	Burera (n=80) n (%)	Total (N=127)
Washing frequency			
Twice or more per day	31 (66.0)	57 (71.3)	88 (69.3)
Once per day	16 (34.0)	21 (26.3)	37 (29.1)
Less than once per day	0 (0)	2 (2.5)	2 (1.6)
Emollient use after washing			
Often	44 (93.6)	76 (95.0)	120 (94.5)
Seldom	2 (4.3)	4 (5.0)	6 (4.7)
Never	1 (2.1)	0 (0)	1 (0.8)
Leg raising behavior			
Often	22 (46.8)	36 (45.0)	58 (45.7)
Seldom	2 (6.4)	11 (13.8)	14 (11.0)
Never	22 (46.8)	33 (41.3)	55 (43.3)
Shoe wearing behavior			
Often	37 (78.7)	63 (78.8)	100 (78.7)
Seldom	10 (21.3)	17 (21.3)	27 (21.3)
Never	0 (0)	0 (0)	0 (0)

All of the QoL assessment variables improved when comparing pre-and post-HASA statuses (Table 3). The number of respondents who frequently suffered from shame due to foot appearance and odor reduced by 74% and 48.4%, respectively. The prevalence of frequent leg pain associated with podoconiosis decreased by 80.3%. Those who answered "often" to podoconiosis associated reduced earnings decreased by more than half when comparing pre and post-HASA responses. The number of participants who did not feel any exclusion from family members increased from 79.5% to 86.8%. Likewise, there was an 8.7% decrease in the number of participants who often experienced verbal abuse by partners. Participants who responded "not at all" to exclusion from religious gatherings and social activities increased from 90.5% to 94.4% and 78.7% to 85%, respectively. The percentage of participants who frequently suffered from ADLA reduced by 83.5%. There was a 74.8% reduction in those who often experienced difficulty moving their ankles, while frequent reduction of leg swelling overnight increased by 24.4%.

Table 3: HASA patient QoL indicators pre- and post-HASA (prevention education program) in Musanze and Burera Districts, Northern Province, Rwanda 2021

	Musanze (n=47)		Burera (n=80)		Total (N=127)	
	Pre-HASA	Post-HASA	Pre-HASA	Post-HASA	Pre-HASA	Post-HASA
Variable			n (%)			
Ashamed of foot appearance						
Not at all	7 (14.9)	19 (40.4)	21 (26.3)	36 (45.6)	28 (22.0)	55 (43.7)
Seldom	2 (4.3)	27 (57.4)	2 (2.5)	43 (54.4)	4 (3.1)	70 (55.6)
Often	38 (80.9)	1 (2.1)	57 (71.3)	0 (0)	95 (74.8)	1 (0.8)
Missing	0 (0)	0 (0)	0 (0)	1 (1.3)	0 (0)	1 (0.8)
Ashamed of foot odor						
Not at all	17 (37.0)	32 (68.1)	43 (53.8)	57 (71.3)	60 (47.6)	89 (70.1)
Seldom	2 (4.3)	14 (29.8)	1 (1.3)	22 (27.5)	3 (2.4)	36 (28.3)
Often	27 (58.7)	1 (2.1)	36 (45.0)	1 (1.3)	63 (50.0)	2 (1.6)
Missing	1 (2.1)	0 (0)	0 (0)	0 (0)	1 (0.8)	0 (0)
Leg pain						
Not at all	1 (2.1)	3 (6.4)	2 (2.5)	3 (3.8)	3 (2.4)	6 (4.7)
Seldom	3 (6.4)	38 (80.9)	3 (3.8)	67 (83.8)	6 (4.8)	105 (82.7)
Often	43 (91.5)	6 (12.8)	74 (93.7)	10 (12.5)	117 (92.9)	16 (12.6)
Missing	0 (0)	0 (0)	1 (1.3)	0 (0)	1 (0.8)	0 (0)
Decreased earnings[1]						
Not at all	7 (14.8)	8 (17.0)	10 (12.5)	16 (20)	17 (13.4)	24 (18.9)
Seldom	6 (12.8)	33 (70.2)	13 (16.3)	53 (66.3)	19 (15.0)	96 (67.7)
Often	34 (72.3)	6 (12.8)	57 (71.3)	11 (13.8)	91 (71.7)	17 (13.4)
Hindered daily chores[2]						
Not at all	14 (29.8)	18 (38.3)	17 (21.3)	26 (32.5)	31 (24.4)	44 (34.6)
Seldom	13 (27.7)	26 (55.3)	23 (28.7)	48 (60.0)	36 (28.3)	74 (58.3)
Often	20 (42.6)	3 (6.4)	40 (50.0)	6 (7.5)	60 (47.2)	9 (7.1)
Exclusion by family members						
Not at all	31 (66.0)	37 (78.7)	70 (87.5)	73 (91.3)	101(79.5)	110 (86.6)
Seldom	2 (4.3)	5 (10.6)	1 (1.3)	4 (5.0)	3 (2.4)	9 (7.1)
Often	14 (29.8)	5 (10.6)	9 (11.3)	3 (3.8)	23 (18.1)	8 (6.3)
Exclusion from religious gatherings						
Not at all	40 (85.1)	44 (93.6)	74 (93.7)	75 (94.9)	114 (90.5)	119 (94.4)
Seldom	2 (4.3)	1 (2.1)	1 (1.3)	4 (5.1)	3 (2.4)	5 (4.0)

Often	5 (10.6)	2 (4.3)	4 (5.1)	0 (0)	9 (7.1)	2 (1.6)
Missing	0 (0)	0 (0)	1 (1.3)	1 (1.3)	1 (0.8)	1 (0.8)
Exclusion from social activities						
Not at all	31 (66.0)	36 (76.6)	69 (86.3)	72 (90.0)	100 (78.7)	108 (85.0)
Seldom	6 (12.8)	9 (19.1)	1 (1.3)	6 (7.5)	7 (5.5)	15 (11.8)
Often	10 (21.3)	2 (4.3)	10 (12.5)	2 (2.5)	20 (15.7)	4 (3.1)
Verbal abuse from a partner						
Not at all	38 (80.9)	43 (91.5)	67 (83.8)	71 (88.8)	105 (82.7)	114 (89.8)
Seldom	2 (4.3)	3 (6.4)	3 (3.8)	4 (5.0)	5 (3.9)	7 (5.5)
Often	7 (14.9)	1 (2.1)	10 (12.5)	5 (6.3)	17 (13.4)	6 (4.7)
Physical abuse from a partner						
Not at all	39 (83)	43 (91.5)	75 (93.8)	77 (96.3)	114 (89.8)	120 (94.5)
Seldom	3 (6.4)	3 (6.4)	2 (2.5)	0 (0)	5 (3.9)	3 (2.4)
Often	5 (10.6)	1 (2.1)	3 (3.8)	3 (3.8)	8 (6.3)	4 (3.1)
Adenolymphangioadenitis episodes[3]						
Not at all	0 (0)	4 (8.5)	0 (0)	6 (7.5)	0 (0)	10 (7.9)
Seldom	6 (12.8)	41 (87.2)	7 (8.8)	68 (85.0)	13 (10.2)	109 (85.8)
Often	41 (87.2)	2 (4.3)	73 (91.3)	6 (7.5)	114 (89.8)	8 (6.3)
Restricted ankle movement						
Not at all	1 (2.1)	4 (8.5)	3 (3.8)	9 (11.3)	4 (3.1)	13 (10.2)
Seldom	5 (10.6)	39 (83.0)	10 (12.5)	62 (77.5)	15 (11.8)	101 (79.5)
Often	41 (87.2)	4 (8.5)	67 (83.3)	9 (11.3)	108 (85.0)	13 (10.2)
Overnight swelling reduction						
Not at all	9 (19.1)	15 (31.9)	63 (78.8)	19 (23.8)	101 (79.5)	24 (18.9)
Seldom	38 (80.9)	27 (57.4)	17 (21.3)	45 (56.3)	26 (20.5)	72 (56.7)
Often	0 (0)	5 (10.6)	0 (0)	16 (20.0)	0 (0)	31 (24.4)

[1] The condition of the patient’s foot disrupting his/her participation in income-generating activities

[2] The condition of the patient’s foot hindering him/her from performing daily chores e.g., cooking, cleaning, or fetching water

[3] A frequent podoconiosis complication characterized by increased swelling, pain, and burning sensation.

All participants had experienced change in QoL. The majority (98.4%; Table 4) had a positive change.

Table 4: Pre- and post-HASA (prevention education program) change in QoL categories in Musanze and Burera Districts, Northern Province, Rwanda 2021

Change in QoL[1]	Musanze (n= 47)	Burera (n=80) n (%)	Total (N = 127)
Positive change	45 (97.8)	75 (98.7)	120 (98.4)
Negative Change	1 (2.2)	1 (1.3)	2 (1.6)
No Change	0 (0)	0 (0)	0 (0)
Incomplete[2]	1 (2.1)	4 (5.0)	5 (3.9)

[1] Change is calculated as the difference between pre HASA prevention education program and post-HASA prevention education program quality of life scores of participants.

[2] Incomplete entries include participants who had missing responses to the quality of life inquiries

Median QoL scores decreased by almost half in both Musanze (46.7%) and Burera (53.6%; Table 5) Districts. There was a significant change between the pre (M= 14, IQR=4) and post (M=7, IQR =3) intervention QoL scores (p <0.01).

Table 5: Pre- and post-HASA QoL scores of HASA prevention education program participants in Musanze and Burera Districts, Northern Province, Rwanda 2021

QoL score	Musanze (n= 47) Pre-HASA	Musanze (n= 47) Post-HASA	Burera (n=80) Pre-HASA	Burera (n=80) Post-HASA	Total (N = 127) Pre-HASA	Total (N = 127) Post-HASA	Wilcoxon's sign test p-Value
Median	15	7	14	7.5	14	7	<0.01*
IQR	5	4	3	3	4	3	

*Significance at p <0.05

Twenty-five candidates were eligible for pre-and post-HASA clinical staging (Table 6). The clinical stages observed ranged from Stages 1 to 3. The majority of the participants had Stage 2 disease in both pre- (84%) and post- (76%) HASA clinical staging.

Table 6: Pre- and post-HASA (prevention education program) clinical staging indicators in Musanze and Burera Districts, Northern Province, Rwanda 2021

	Musanze (n= 5)		Burera (n=20)		Total (N= 25)	
	Pre-HASA	Post-HASA	Pre-HASA	Post-HASA	Pre-HASA	Post-HASA
Clinical stage[1]	n (%)					
Stage 1	0 (0)	1 (20.0)	2 (10.0)	2 (10.0)	2 (8.0)	3 (12.0)
Stage 2	3 (60.0)	1 (20.0)	18 (90.0)	18 (90.0)	21 (84.0)	19 (76.0)
Stage 3	2 (40.0)	3 (60.0)	0 (0)	0 (0)	2 (8.0)	3 (12.0)

[1] Clinical staging based on the Tekola staging system (Tekola et al., 2008).

Out of the 25 participants evaluated for change in clinical staging, the majority (84%; Table 7) remained unchanged when comparing their pre-and post-status. Of the remaining 16%, half had improvement in clinical staging.

Table 7: Pre- and post-HASA (prevention education program) change in clinical stage categories in Musanze and Burera Districts, Northern Province, Rwanda 2021

	Musanze (n= 5)	Burera (n=20)	Total (N = 25)
Change in clinical staging[1]	n (%)		
Positive change	1 (20.0)	1 (5.0)	2 (8.0)
Negative Change	1 (20.0)	1 (5.0)	2 (8.0)
No Change	3 (60.0)	18 (90.0)	21 (84.0)

[1] Change is calculated as the difference between the pre-HASA prevention education program and post-HASA prevention education program clinical stages of participants.

No significant change was observed between the clinical stages before and after the HASA intervention (p > 0.99; Table 8).

Table 8: Pre- and post-HASA (prevention education program) clinical stage scores in Musanze and Burera Districts, Northern Province, Rwanda 2021

Clinical staging score	Musanze (n= 5)		Burera (n=20)		Total (N = 25)		
	Pre-HASA	Post-HASA	Pre-HASA	Post-HASA	Pre-HASA	Post-HASA	Wilcoxon's sign test p-Value
Median	2	3	2	2	2	2	> 0.99
IQR	1	1.5	0	0	0	0	

There was no significant association between adherence characteristics and change in QoL (Table 9).

Table 9: Association between adherence components and change in QoL score of HASA (prevention education program) participants in Musanze and Burera Districts, Northern Province, Rwanda 2021

	Change in QoL score (N = 122)		
Adherence components	**N**	**Median**	**Kruskal-Wallis p-Value**
Washing frequency			
Twice per day	85	7.0	0.88
Once per day	35	7.0	
Does not wash daily	2	6.0	
Emollient use after washing			
Often	115	7.0	0.42
Seldom	6	7.0	
Not at all	1	-	
Shoe wearing behavior			
Often	97	7.0	0.94
Seldom	25	7.0	
Not at all	0	0	
Leg raising behavior			
Often	57	7.0	0.51
Seldom	13	7.0	
Not at all	52	7.0	

There was no significant association between demographics (sex, age, family history of podoconiosis, source of income, and Ubudehe category) and overall adherence levels to the HASA PEP (Table 10).

Table 10: Association between adherence levels and demographics of HASA (prevention education program) participants in Musanze and Burera Districts, Northern Province, Rwanda 2021

	Overall adherence level[2]		
Demographics	**Low (<80%)**	**High (≥80%)**	**Pearson Chi Square p-value**
Age(years)[1]			
≤57	28	26	0.56
>57	34	39	
Sex			
Female	53	56	>0.99
Male	9	9	
Family history of podoconiosis			
Yes	29	25	0.34
No	33	40	
Employment status			
Unemployed	18	25	0.26
Employed	44	40	
Ubudehe category			
1	30	33	0.71
2	21	18	
3	10	13	
Duration of enrollment (years)			
1 year or less	6	4	0.84
2	14	14	
3	9	11	
4	19	17	
5	14	19	

[1] The average age (57 years) of the sample population was used as a cut-off for comparison.

[2] Previous literature informed the use of 80% as a cutoff for high and low adherence levels (Gellad et al., 2017).

Bivariate analysis demonstrated a significant association between participant age and change in QoL (p = 0.02; Table 11). The median QoL change was higher in participants aged 57 and below (7.0) when compared to those above 57 years (6.0). Other demographics characteristics such as sex, family history of podoconiosis, employment status, and Ubudehe category showed no association with change in QoL.

Table 11: Association between change in QoL and demographic factors of HASA (prevention education program) participants in Musanze and Burera Districts, Northern Province, Rwanda 2021

		Change in QoL score	
Demographics	**Count (N=122)**	**Median**	**Mann-Whitney U test p-Value**
Age[1]			
≤57	51	7.0	0.02*
>57	71	6.0	
Sex			
Female	104	7.0	0.39
Male	18	6.0	
Family history of Podoconiosis			
Yes	53	7.0	0.97
No	69	7.0	
Employment status			
Unemployed	42	6.0	0.25
Employed	80	7.0	

Demographics	**N**	**Median**	**Kruskal-Wallis p-value**
Ubudehe category			
1	61	7.0	0.14
2	37	7.0	
3	22	6.0	
Duration of enrollment (years)			
1 or less	10	6.5	0.49
2	28	7.0	
3	19	8.0	
4	32	6.0	
5	33	7.0	

*Significance at $p < 0.05$

[1] The average age (57 years) of the sample population was used as a cut-off for comparison.

4.2 Qualitative results

Quality of Life

Theme 1: Physical and psychosocial changes

Participants’ responses revealed considerable physical improvements. Most participants mentioned improvements in the severity and frequency of pain. This has allowed participants to enjoy a greater degree of mobility.

“My life has changed. I was out of my mind due to pain but because of HASA, today I feel better. In ordinary life, I can work and do different jobs whether it is cultivation or any other job.” P 121, Female

“We no longer experience the same pain we felt before coming here. Before I could feel pain to the extent that I could not be able to put on my shoes.” P 57 Female

Most participants highlighted that they felt ashamed and excluded from society before joining HASA and reported decreased internalized stigma after joining the program. In addition, a sense of social cohesion was observed. Meeting participants with similar conditions made them feel part of a community that appreciated and supported them.

“…they taught us to be clean and stop undermining ourselves or be ashamed of how our feet look like because for me before I even used to hide from people.” P 22, Female

“Before joining the program, I was feeling lonely but after joining the program I met other patients, we have the same problem and now I feel good and hopeful.” P 05, Female

Improvements in the appearance and odor of participants’ feet have resulted in decreased stigma from their communities. This has increased participants’ self-esteem and involvement in social activities.

“Before joining HASA I had difficulties… people could run away from me saying that I have a bad smell [caused by the disease], today I no longer experience that because of the program.” P 104, Female

“…I had to wear long dresses to avoid people making fun of me, today there is a change and people no longer laugh at me.” P 121, Female

Despite the improvements, participants reiterated their desire for more advanced medications to hasten their recovery and cure them.

"I think what should be improved is to provide us with advanced medicine that can help us much better than the one we use." P 43, Female

"Normally, they give us medicine to mix with water for soaking our feet, it would be much better if there was some other type of advanced medicine that could help to improve our health situation." P 35, Female

"They should bring doctors and treat us so we can be completely healed from this disease." P 16, Female

Theme 2: Financial expectations versus reality

Most participants highlighted the improvement in their productivity. However, they also revealed that despite this improvement, it was not enough to change their overall economic status. Participants stated that even though they had improved physically, they still faced difficulty in finding gainful employment to support themselves.

"Yes, it has changed, before I was not able to walk, people would call me to go to work, but I was not capable. But ever since I joined HASA people call me to do some simple jobs that do not require so much energy and able to go and work." P 08, Female

"The pain in my legs reduced compared to how it was before joining HASA, I can even do household chores. In ordinary life nothing changed, I have no job and that is why it is difficult to earn a living." P 117, Female

Many expressed desires for a livelihood package from HASA to help them sustain themselves, as was done previously. They believed that this would significantly improve their financial status and ultimately, living standards.

"The person's life needs are many. They [HASA] give me body lotion and soap, but I have no domestic animal to help me in finding means [of livelihood]. If HASA gave me an animal such as chicken or goat, I would sell the eggs and earn money and get fertilizer". P 51, Female

Adherence

Theme 3: Determinants of adherence

Various reasons for poor adherence to the HASA teachings were documented. Participants were often not aware of the need to raise their legs overnight, with most stating that they were not instructed to do so. Some of those who were aware did not prioritize raising their leg. Others mentioned uncomfortable sleeping environments and financial constraints to attain comfortable beddings as barriers to raise their legs overnight.

"I do not sleep with my legs raised above my head; I do not do that because they have not told us yet." P 63, Female

"They educated us about it that you put a pillow or something else below the mattress to raise the legs above the head, but I do not do it." P 33, Female

"I don't [sleep with my legs raised above my head] at home we are not capable of affording proper beddings so we sleep wherever we can." P 08, Female

The Covid-19 pandemic was frequently cited as one of the major drivers of poor adherence to the HASA PEP. It led to the decrease of the clinic visits from twice a week to once a month and this subsequently affected the provision of supplies to the participants. Longer intervals between appointments and inadequate supplies to last the duration of each interval hindered participants from washing their feet and applying emollients.

"Before the pandemic, we used to come for soaking every week but today, we come once in a month… there are times we run out of medicine in the middle of the month when the time of coming for another medical appointment has not reached yet, and you find that it's a problem." P 88 Female

"…we do not use the medicine as recommended; we skip days so that we do not run out of it before the following monthly appointment comes. We use the prescribed medicine with reserve as if it is not for treatment." P 53, Female

Shortages in the monthly hygiene supplies that are provided by HASA and difficulties in accessing clean water, coupled with the financial deficits of participants, exacerbated non-adherence to PEP components.

"What should be improved is to provide us with a sufficient package and not let us run out of medicine and soap…sometimes we run out of body lotion. It would be better if we had a

sufficient package [medicine, soap, and body lotion] …. the problem is that the body lotion they provide at HASA is very expensive, we cannot afford it." P 108, Female

"Another challenge [to washing feet daily] we face is lack of enough water in our area, we buy a jerrycan of water FRW 20." P 98, Female

Despite the difficulties faced to comply with the program directives, participants emphasized the importance of adherence to the program and its benefits.

"When you participate and respect the guidelines they give you, you start noticing changes in your legs and feet." P 41, Female

"There is no patient who cannot participate in the program due to the good impact it makes. My health is gradually improving because of joining the program. I cannot miss [the instructions]." P 07, Female

CHAPTER FIVE: Discussion

To the best of our knowledge, this is the first study to assess the impact of community-based lymphedema management in Rwanda. Lymphedema caused by podoconiosis does not subside without intervention (Sikorski et al., 2010). Studies evaluating lymphedema management programs such as HASA's PEP have demonstrated improvements in the clinical condition and QoL of patients (Mues et al., 2014). This study discovered a significant improvement in the QoL of patients enrolled in HASA's community-based intervention. The GPELF and WHO's NTD roadmap of 2030 endorse the implementation of community lymphedema management and education in their efforts to reduce the morbidity caused by podoconiosis (WHO, 2020). However, poor attention by governments to morbidity management has perpetuated the neglect of podoconiosis (Gail Davey & Burridge, 2009). In Rwanda, podoconiosis has been left unattended by GPELF due to the low prevalence of LF (Deribe et al., 2015; Tora et al., 2018).

5.1 Clinical Stages

Staging is vital for monitoring disease progression and evaluating morbidity management and disability prevention programs (Tekola et al., 2008). In our study, participants had mostly mild disease, stages 1 and 2, in both pre-and post-HASA clinical staging. The severity of disability caused by podoconiosis increases with the advancement of the disease (Chandrasena et al., 2004; Mousley et al., 2013). This may have led to decreased involvement of advanced cases in the program. Difficulty in mobility and frequent pain in advanced stage podoconiosis prevent patients from accessing and adhering to lymphedema management services (Semrau et al., 2020; Tora et al., 2012). Willingness to participate in in-clinic podoconiosis studies increases with higher levels of commitment to program guidelines, and lower clinical stages (Sikorski et al., 2010). Studies have shown that both perceived and enacted stigma increase with advanced lymphedema (Deribe et al., 2013; Person et al., 2007). Additionally, stigma has been implicated in deterring lymphedema patients from attending in-clinic lymphedema management and related activities (Tsegay et al., 2015). This could also contribute to the low number of advanced cases in HASA's database and thus the study.

Previous studies have illustrated physical improvements in leg condition following simple lymphedema management practice (Mousley et al., 2013; Mues et al., 2014). Most of our participants reported improved physical conditions. Similarly, the primary researchers involved in staging observed improvements in the lymphedema and dermatologic changes of the participants' limbs. However, no significant post-HASA clinical-stage changes were observed. The wide range of intra-stage measures within the Tekola staging system does not account for the different reversible and irreversible components of a single stage. For instance, in stage 2 podoconiosis, below ankle nodules are irreversible while the mossy foot and intertriginous ulcers are reversible with lymphedema management (Tekola et al., 2008). This means significant improvements in the reversible components of stage 2 may not affect the overall stage as long as the irreversible component persists. Similar difficulties with intra-stage variations have been reported in cancer and other lymphedema staging systems, such as the Dreyer system (Douglass & Kelly-Hope, 2019; Ilhan et al., 2016).

Although there were no significant improvements in the clinical staging, only 8% of participants deteriorated. While the absence of deterioration cannot be fully attributed to the HASA PEP, participants' accounts of better foot condition and decreased morbidity indicate the importance of the program.

5.2 Adherence characteristics

Compliance and a positive attitude towards community-based lymphedema management protocols are essential predictors for improvements in the clinical condition and QoL of podoconiosis patients (Alemayehu, 2017; Sikorski et al., 2010). In this regard, our study observed the adherence of participants to the components of HASA's PEP through self-reports.

In Southern Ethiopia, low adherence to washing feet was attributed to the unavailability of water and lack of hygiene supplies (Churko et al., 2020; Sikorski et al., 2010). According to the WHO, access to safe water should not exceed a 15-minute walking distance (WHO, 2011). Approximately 64% of residents in Burera and 48.6% in Musanze Districts live farther than the recommended 15-minute walking distance from a protected water source (NISR, 2012, 2018). HASA participants reported low adherence to washing their feet daily due to inadequacies in hygiene supplies such as bleach, soap, and emollients. Limited access to water might also explain the low adherence because lymphedema patients usually require assistance to fetch water and perform foot hygiene. Podoconiosis patients capable of fetching more than 50 liters of water per day have higher foot hygiene practices (Chandrasena et al., 2004; Churko et al., 2020).

Historically, the widespread adoption of wearing shoes played a decisive role in the elimination of podoconiosis in Northern Africa and Europe (Price, 1990). As such, shoe-wearing is integral to the primary prevention of podoconiosis, halting the progression of lymphedema, and avoiding related complications such as foot ulcers and ADLA (Shahvisi et al., 2018). Despite shoe-wearing being one of the components of HASA's PEP, we discovered 78.7% of participants adhered to shoe-wearing, which was lower than the 80% cut-off used in the study. This might be due to the low Ubudehe status of most of our participants to buy shoes and the unavailability of fitting shoes due to the swelling. Poverty has been shown to be a major barrier to shoe-wearing (Ayode et al., 2012; Shahvisi et al., 2018). Another possible reason for the observed low adherence to wearing shoes could be the predominantly female study population. Studies among lymphedema patients in Ethiopia propose that men have greater access to footwear than women due to cultural practices that encourage social and economic gender inequalities (Fafchamps & Quisumbing, 2010; Kelemework et al., 2016; Molla et al., 2012a).

Another component of lymphedema management is leg raising. Leg raising overnight aids lymphatic circulation through the passive movement of lymph from damaged lower limb lymphatic vessels (Watu et al., 2020). Despite its proven benefits, less than half of our participants practiced it. Participants mentioned lack of awareness, low prioritization, and lack of suitable bedding materials to elevate legs were major barriers to adherence. The simplicity of the leg raising may have contributed to its low prioritization. Our participants reiterated their desire for more advanced interventions or medications to accelerate their recovery. A study of lymphedema management in Kenya demonstrated that preferences for more radical interventions over simple ones resulted in decreased motivation to adhere to existing interventions (Akogun & Badaki, 2011). Additionally, other studies where particularly low adherence to leg raising was observed revealed that participants felt leg raising was inconvenient and only provided temporary relief (Chandrasena et al., 2004; Nanda & Ramaiah, 2003).

5.3 Quality of Life (QoL)

ADLA is strongly linked with poor QoL and management of these painful bouts is possibly the most vital aspect of lymphedema management in limited-resource settings (McPherson, 2003; Ramaiah & Kumar, 2000). Before the HASA PEP, many participants experienced frequent attacks of ADLA and therefore could not undertake income-generating activities. This finding was in line with a study in Ethiopia that revealed podoconiosis patients lose up to 90 working days per year due to ADLA (Deribe et al., 2017). As a result, patients plunge further into poverty (Tekola et al., 2006). Considerable decrease in ADLA frequency and intensity has been noted following community-based lymphedema interventions (Negussie et al., 2018; Phillips et al., 2019). Our study observed a lower frequency of ADLA after enrollment in the HASA community-based PEP. Similar results were seen in studies in Haiti, and Ethiopia (Addiss et al., 2010; Negussie et al., 2018).

Stigmatization of podoconiosis patients is one of the major drivers of low productivity and poor QoL (Deribe et al., 2013; Tora et al., 2011). From our assessment, the majority of participants were stigmatized and had an overall lower QoL before enrolling in the HASA PEP. This was possibly a culmination of internalized stigma as well as exclusion from family, social and religious gatherings. Studies in Ethiopia have linked low QoL with internalized stigma and social exclusion (Mousley et al., 2013; Yakob et al., 2008). Participants reported less internalized and perceived stigma due to the HASA PEP. These changes were attributed to improved physical appearance and a sense of community that was developed among fellow participants. Social support among groups of people with similar diseases or challenges has been found to be beneficial in improving QoL (McPherson, 2003; Munikanan et al., 2017). Podoconiosis patients often experience physical and verbal intimate partner abuse (Tsegay et al., 2015). Our assessment of the frequency of verbal abuse by partners showed a significant decrease after enrollment in the HASA PEP. In line with this, participants mentioned improvements in their productivity, self-esteem, and involvement in society.

There were no significant associations between adherence to PEP components and change in QoL. However, participants emphasized the need for adherence to the program components for improved QoL outcomes. The reason for the lack of association could be the unmeasured benefits of the program such as social cohesion, community education, and individual psychosocial support. This has been noted in a study where the social interactions and support from lymphedema management groups had a profound impact on the QoL of participants (Hounsome et al., 2019).

5.4 Challenges and Limitations

The first challenge we faced was the lack of information on the pre-HASA clinical history and podoconiosis staging of participants. Nevertheless, we overcame this challenge by staging photographs of participants' affected limbs taken during enrollment into the program. Secondly, not all eligible participants had access to mobile phones which made it difficult to invite them for the survey. To mitigate this, we relied on those who were reachable to extend our invitations to those without phones. In addition, we arranged our data collection to coincide with the monthly PEP dates, when most HASA participants attend the clinics.

The lack of baseline medical information makes it difficult to assess and determine the impact of interventions (Khader et al., 2019). The majority of participants had no pre-HASA clinical staging at enrollment. As a result, we opted to use photographs taken at enrollment for pre-HASA clinical staging.

Photograph staging was used to aid the validation of the Tekola staging system (Tekola et al., 2008). However, to the best of our knowledge, photographs have never been used to assess change in the clinical staging of podoconiosis patients. Photographic staging is not the preferred method of evaluation as it misses findings that would otherwise be identified with physical examination, thereby potentially compromising the quality of our clinical staging. To account for information missing in photographic staging, we incorporated questions regarding ankle movement and swelling reduction to help minimize the limitation.

The limited sample size did not allow us to perform a direct statistical comparison of clinical staging versus changes in QoL and adherence characteristics. To maximize our sample size, we extended our study timeline to include participants enrolled within the past five years. However, this extension may have increased the risk of recall bias. To minimize this bias, we incorporated prompts and probes in our survey to triangulate accurate responses as much as possible.

CHAPTER 6: Conclusion and Recommendations

6.1 Conclusion

This study highlighted the adherence characteristics and changes in QoL of podoconiosis patients enrolled in HASA's PEP in Burera and Musanze Districts. The improvement in QoL scores was supported by a qualitative affirmation of positive changes in QoL. This was evident in the reported decreases in pain, and stigma as well as increased productivity, indicating the benefits of the HASA PEP. We discovered a gap in adherence to the program guidelines, signifying the need for adequate access to water, hygiene supplies, and health education. As podoconiosis is a disease of poverty, emphasis must be given to the capability of patients to sufficiently follow guidelines.

On a larger scale, the study underlines the importance of community-based lymphedema management in low-resource settings. It reiterates the complex interaction among physical wellbeing, financial capability, and social relations, in affecting the QoL of people with podoconiosis. This affirms the value of programs such as HASA in achieving the 2021-2030 NTD road map and GPELF targets to reduce the morbidity of NTDs. Our findings will inform future programs to incorporate a holistic approach when dealing with podoconiosis and possibly other skin NTDs.

6.2 Recommendations

The results of the study informed the following recommendations:

1. **Increase the quantity of monthly hygiene supplies**

   HASA hygiene supply provision should be revised to last in between each scheduled interval. This can help improve adherence to the washing and possibly ensure the improvement of clinical conditions.

2. **Improve record-keeping practices**

   Baseline clinical information is essential to monitor the effects of interventions and monitor the progression of disease (Khader et al., 2019). This can be achieved by clinical staging and photographing affected limbs at enrollment. For already enrolled patients, data generated during this study (post-HASA staging, and photographs) can be used as baseline clinical information for future evaluation of the clinical condition of participants. See appendix 6 for the proposed patient intake form.

3. **Quarterly staging of patients**

Podoconiosis has been shown to improve within three months of lymphedema management (Henok & Davey, 2008; Hounsome et al., 2020). As podoconiosis is a progressive disease, it is vital to continuously assess the condition of patients. A quarterly assessment would be essential for the early identification of management failure. This would enable timely identification of clinical deterioration, and exploration of possible reasons to offer timely interventions.

4. **Arrange psychological assistance for patients**

Our study did not explore the psychological effects of stigma; however, it did demonstrate widespread stigma among podoconiosis patients. Previous studies have shown that podoconiosis patients are likely to suffer from depression and/or mental distress which subsequently affects their QoL (Bartlett et al., 2015). In light of this, a recent study reported the importance of a holistic approach that incorporates both physical and mental healthcare in podoconiosis management programs (Ali et al., 2021). We, therefore, recommend HASA to include psychological evaluation and counseling of patients in its routine care. Additionally, HASA should expand and intensify its community education program to increase societal awareness and reduce stigma against podoconiosis patients. This can be accomplished by collaborating with the provincial health offices to incorporate podoconiosis in the local CHW health education curriculum.

REFERENCES

Addiss, D. G., Louis-Charles, J., Roberts, J., LeConte, F., Wendt, J. M., Milord, M. D., Lammie, P. J., & Dreyer, G. (2010). Feasibility and Effectiveness of Basic Lymphedema Management in Leogane, Haiti, an Area Endemic for Bancroftian Filariasis. *PLoS Neglected Tropical Diseases*, *4*(4), e668. https://doi.org/10.1371/journal.pntd.0000668

Akogun, O. B., & Badaki, J. A. (2011). Management of adenolymphangitis and lymphoedema due to lymphatic filariasis in resource-limited North-eastern Nigeria. *Acta Tropica*, *120*(SUPPL. 1). https://doi.org/10.1016/j.actatropica.2010.10.006

Alemayehu, B. (2017). Factors Associated with Lymphoedema Management Success Among Podoconiosis Patients in Wolaita Zone, Southern Ethiopia. *Science Journal of Public Health*, *5*(5), 392. https://doi.org/10.11648/j.sjph.20170505.16

Alemu, G., Tekola Ayele, F., Daniel, T., Ahrens, C., & Davey, G. (2011). Burden of Podoconiosis in Poor Rural Communities in Gulliso woreda, West Ethiopia. *PLoS Neglected Tropical Diseases*, *5*(6), e1184. https://doi.org/10.1371/journal.pntd.0001184

Ali, O., Mengiste, A., Semrau, M., Tesfaye, A., Fekadu, A., & Davey, G. (2021). The impact of podoconiosis, lymphatic filariasis, and leprosy on disability and mental well-being: A systematic review. *PLOS Neglected Tropical Diseases*, *15*(7), e0009492. https://doi.org/10.1371/JOURNAL.PNTD.0009492

Ayode, D., McBride, C. M., De Heer, H., Watanabe, E., Gebreyesus, T., Tadele, G., Tora, A., & Davey, G. (2012). The association of beliefs about heredity with preventive and interpersonal behaviors in communities affected by podoconiosis in rural Ethiopia. *American Journal of Tropical Medicine and Hygiene*, *87*(4), 623–630. https://doi.org/10.4269/ajtmh.2012.12-0204

Bartlett, J., Deribe, K., Tamiru, A., Amberbir, T., Medhin, G., Malik, M., Hanlon, C., & Davey, G. (2015). Depression and disability in people with podoconiosis: A comparative cross-sectional study in rural Northern Ethiopia. *International Health*, *8*(2), 124–131. https://doi.org/10.1093/inthealth/ihv037

Bayisenge, U., Schurer, J., Wong, R., Amuguni, H., & Davey, G. (2020). Podoconiosis in Rwanda: Knowledge, attitudes and practices among health professionals and environmental officers. *PLoS Neglected Tropical Diseases*, *14*(10), 1–14. https://doi.org/10.1371/journal.pntd.0008740

Caprioli, T., Martindale, S., Mengiste, A., Assefa, D., H/Kiros, F., Tamiru, M., Negussu, N., Taylor, M., Betts, H., & Kelly-Hope, L. A. (2020). Quantifying the socio-economic impact of leg lymphoedema on patient caregivers in a lymphatic filariasis and podoconiosis co-endemic district of Ethiopia. *PLOS Neglected Tropical Diseases*, *14*(3), e0008058. https://doi.org/10.1371/journal.pntd.0008058

Chandler, D. J., Grijsen, M. L., & Fuller, L. C. (2020). With Bare Feet in the Soil: Podoconiosis, a Neglected Cause of Tropical Lymphoedema. *Dermatology*, 1–12. https://doi.org/10.1159/000506045

Chandrasena, T. G. A. N., Premaratna, R., & de Silva, N. R. (2004). Lymphoedema management knowledge and practices among patients attending filariasis morbidity control clinics in Gampaha District, Sri Lanka. *Filaria Journal*, *3*(1), 1–6. https://doi.org/10.1186/1475-2883-3-6

Churko, C., Yohanes, T., Kassahun, A. B., Desalign, N., Endashaw, G., & Asfaw, M. A. (2020). *Foot Care Practice and Associated Factors among Patients with Lymphoedema in Boreda District, Gamo Zone, SNNPR, Ethiopia, 2020. Implications for Elimination of Podoconiosis and Lymphatic Filariasis*. https://doi.org/10.21203/rs.3.rs-572573/v1

Davey, G. (2009). Recent advances in podoconiosis. *Annals of Tropical Medicine and Parasitology*, *103*(5), 377–382. https://doi.org/10.1179/136485909X451762

Davey, Gail, & Burridge, E. (2009). Community-based control of a neglected tropical disease: the mossy foot treatment and prevention association. *PLoS Neglected Tropical Diseases*, *3*(5). https://doi.org/10.1371/journal.pntd.0000424

Davey, Gail, Tekola, F., & Newport, M. J. (2007). Podoconiosis: non-infectious geochemical elephantiasis. In *Transactions of the Royal Society of Tropical Medicine and Hygiene* (Vol. 101, Issue 12, pp. 1175–1180). https://doi.org/10.1016/j.trstmh.2007.08.013

Deribe, K., Cano, J., Newport, M. J., Golding, N., Pullan, R. L., Sime, H., Gebretsadik, A., Assefa, A., Kebede, A., Hailu, A., Rebollo, M. P., Shafi, O., Bockarie, M. J., Aseffa, A., Hay, S. I., Reithinger, R., Enquselassie, F., Davey, G., & Brooker, S. J. (2015). Mapping and modelling the geographical distribution and environmental limits of podoconiosis in Ethiopia. *PLoS Neglected Tropical Diseases*, *9*(7), 1–18. https://doi.org/10.1371/journal.pntd.0003946

Deribe, K., Cano, J., Njouendou, A. J., Eyong, M. E., Beng, A. A., Giorgi, E., Pigott, D. M., Pullan, R. L., Noor, A. M., Enquselassie, F., Murray, C. J. L., Hay, S. I., Newport, M. J., Davey, G., & Wanji, S. (2018). Predicted distribution and burden of podoconiosis in Cameroon. *BMJ Global Health*, *3*(3). https://doi.org/10.1136/bmjgh-2018-000730

Deribe, K., Cano, J., Trueba, M. L., Newport, M. J., & Davey, G. (2018). Global epidemiology of podoconiosis: A systematic review. *PLoS Neglected Tropical Diseases*, *12*(3). https://doi.org/10.1371/journal.pntd.0006324

Deribe, K., Kebede, B., Mengistu, B., Negussie, H., Sileshi, M., Tamiru, M., Tomczyk, S., Tekola-Ayele, F., Davey, G., & Fentaye, A. (2017). Podoconiosis in Ethiopia: From neglect to priority public health problem. *Ethiopian Medical Journal*, *55*(1), 65–74. /pmc/articles/PMC5582632/

Deribe, K., Kebede, B., Tamiru, M., Mengistu, B., Kebede, F., Martindale, S., Sime, H., Mulugeta, A., Kebede, B., Sileshi, M., Mengiste, A., McPherson, S., & Fentaye, A. (2017). Integrated morbidity management for lymphatic filariasis and podoconiosis, ethiopia. *Bulletin of the World Health Organization*, *95*(9), 652–656. https://doi.org/10.2471/BLT.16.189399

Deribe, K., Mbituyumuremyi, A., Cano, J., Jean Bosco, M., Giorgi, E., Ruberanziza, E., Bayisenge, U., Leonard, U., Bikorimana, J. P., Rucogoza, A., Turate, I., Rusanganwa, A., Pigott, D. M., Pullan, R. L., Noor, A. M., Enquselassie, F., Condo, J. U., Murray, C. J. L., Brooker, S. J., … Davey, G. (2019). Geographical distribution and prevalence of podoconiosis in Rwanda: a cross-sectional country-wide survey. *The Lancet Global Health*, *7*(5), e671–e680. https://doi.org/10.1016/S2214-109X(19)30072-5

Deribe, K., Mbituyumuremyi, A., Cano, J., Mbonigaba, J. B., Giorgi, E., Ruberanziza, E., Bayisenge, U., Uwayezu, L., Bikorimana, J. P., Rucogoza, A., Turate, I., Russanganwa, A., Pigott, D. M., Pullan, R. L., Noor, A. M., Enquselassie, F., Condo, J., Murray, C. J. L., Brooker, S. J., … Davey, G. (2018). Geographical Distribution and Prevalence of Podoconiosis in Rwanda: A Cluster Cross-Sectional Country-wide Survey. *The Lancet Global Health*.

Deribe, K., Negussu, N., Newport, M. J., Davey, G., & Turner, H. C. (2020). The health and economic burden of podoconiosis in Ethiopia. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, *114*(4), 284–292. https://doi.org/10.1093/trstmh/traa003

Deribe, K., Tomczyk, S., Mousley, E., Tamiru, A., & Davey, G. (2013). Stigma towards a Neglected Tropical Disease: Felt and enacted Stigma Scores among Podoconiosis Patients in Northern Ethiopia. *BMC Public Health*, *13*(1). https://doi.org/10.1186/1471-2458-13-1178

Deribe, K., Tomczyk, S., & Tekola-Ayele, F. (2013). Ten Years of Podoconiosis Research in Ethiopia. *PLoS Neglected Tropical Diseases*, *7*(10), e2301. https://doi.org/10.1371/journal.pntd.0002301

Deribe, K., Wanji, S., Shafi, O., M Tukahebwa, E., Umulisa, I., Molyneux, D. H., & Davey, G. (2015). The feasibility of eliminating podoconiosis. *Bulletin of the World Health Organization*, *93*(10), 712–718. https://doi.org/10.2471/BLT.14.150276

Douglass, J., & Kelly-Hope, L. (2019). Comparison of Staging Systems to Assess Lymphedema Caused by Cancer Therapies, Lymphatic Filariasis, and Podoconiosis. *Lymphatic Research and Biology*, *17*(5), 550. https://doi.org/10.1089/LRB.2018.0063

Dreyer, G., Mattos, D., Figueredo-Silva, J., & Norões, J. (2009). Paradigm shift in bancroftian filariasis. *Revista Da Associacao Medica Brasileira*, *55*(3), 355–362. https://doi.org/10.1590/s0104-42302009000300032

EMoH. (2013). *NatioNal Master PlaN for Neglected troPical diseases (Ntds) (2013-2015) addis ababa, ethiopia*.

Fafchamps, M., & Quisumbing, A. R. (2010). Control and Ownership of Assets Within Rural Ethiopian Households. *Http://Dx.Doi.Org/10.1080/00220380412331322581*, *38*(6), 47–82.

https://doi.org/10.1080/00220380412331322581

Gellad, W. F., Thorpe, C. T., Steiner, J. F., & Voils, C. I. (2017). The myths of medication adherence. *Pharmacoepidemiology and Drug Safety*, *26*(12), 1437–1441. https://doi.org/10.1002/PDS.4334

Getie, A., Atamenta, T., Nigatu, R., Abera, A., & Girma, M. (2020). Magnitude of Podoconiosis and Its Associated Factors among an Adult Population in Waghmra Zone, Ethiopia: A Cross-Sectional Study. *BioMed Research International*, *2020*. https://doi.org/10.1155/2020/9107562

Greene, A. K., & Goss, J. A. (2018). Diagnosis and Staging of Lymphedema. *Seminars in Plastic Surgery*, *32*(1), 12–16. https://doi.org/10.1055/s-0038-1635117

Henok, L., & Davey, G. (2008). Validation of the Dermatology Life Quality Index among patients with podoconiosis in southern Ethiopia. *British Journal of Dermatology*, *159*(4), 903–906. https://doi.org/10.1111/j.1365-2133.2008.08773.x

Hounsome, N., Kassahun, M. M., Ngari, M., Berkley, J. A., Kivaya, E., Njuguna, P., Fegan, G., Tamiru, A., Kelemework, A., Amberbir, T., Clarke, A., Lang, T., Newport, M. J., McKay, A., Enquoselassie, F., & Davey, G. (2019). Cost-effectiveness and social outcomes of a community-based treatment for podoconiosis lymphoedema in the East Gojjam zone, Ethiopia. *PLOS Neglected Tropical Diseases*, *13*(10), e0007780. https://doi.org/10.1371/journal.pntd.0007780

Hounsome, N., Kinfe, M., Semrau, M., Ali, O., Tesfaye, A., Mengiste, A., Bremner, S., Ahmed, A., Fekadu, A., & Davey, G. (2020). Economic assessment of a community-based care package for people with lower limb disorder caused by lymphatic filariasis, podoconiosis and leprosy in Ethiopia. *Transactions of The Royal Society of Tropical Medicine and Hygiene*, *114*(12), 1021–1034. https://doi.org/10.1093/trstmh/traa111

Ilhan, E., Ureyen, O., & Meral, U. M. (2016). Ongoing problems concerning 7th TNM Staging System and Proposals for 8th TNM Staging System of Gastric Cancer. *Przegląd Gastroenterologiczny*, *11*(4), 223. https://doi.org/10.5114/PG.2016.64069

ISL, I. (2013). THE DIAGNOSIS AND TREATMENT OF PERIPHERAL LYMPHEDEMA: 2013 CONSENSUS DOCUMENT OF THE INTERNATIONAL SOCIETY OF LYMPHOLOGY. In *Lymphology* (Vol. 46, Issue 1). https://journals.uair.arizona.edu/index.php/lymph/article/view/16991

Kelemework, A., Tora, A., Amberbir, T., Agedew, G., Asmamaw, A., Deribe, K., & Davey, G. (2016). “Why should I worry, since I have healthy feet?” A qualitative study exploring barriers to use of footwear among rural community members in northern Ethiopia. *BMJ Open*, *6*(3). https://doi.org/10.1136/bmjopen-2015-010354

Khader, Y. S., Khatatbeh, M., & Aouididi, O. M.-S. (2019). Baseline Health-Related Data for

Monitoring Sustainable Development Goals in Jordan. *Handbook of Healthcare in the Arab World*, 1–24. https://doi.org/10.1007/978-3-319-74365-3_163-1

Kihembo, C., Masiira, B., Lali, W. Z., Matwale, G. K., Matovu, J. K. B., Kaharuza, F., Ario, A. R., Nabukenya, I., Makumbi, I., Musenero, M., Zhu, B.-P., & Nanyunja, M. (2017). Risk Factors for Podoconiosis: Kamwenge District, Western Uganda, September 2015. *The American Journal of Tropical Medicine and Hygiene*, *96*(6), 1490–1496. https://doi.org/10.4269/AJTMH.16-0932

Lam, W. Y., & Fresco, P. (2015). Medication Adherence Measures: An Overview. *BioMed Research International*, *2015*. https://doi.org/10.1155/2015/217047

Mcbride, C. M., Price, C. S., Ayode, D., Tora, A., Farrell, D., & Davey, G. (2015). Issue: 6. *International Journal of Health Sciences & Research (Www.Ijhsr.Org)*, *5*, 518. www.ijhsr.org

McPherson, T. (2003). Impact on the quality of life of lymphoedema patients following introduction of a hygiene and skin care regimen in a Guyanese community endemic for lymphatic filariasis: A preliminary clinical intervention study. *Filaria Journal*, *2*(1). https://doi.org/10.1186/1475-2883-2-1

Molla, Y. B., Tomczyk, S., Amberbir, T., Tamiru, A., & Davey, G. (2012a). Podoconiosis in East and West Gojam Zones, Northern Ethiopia. *PLOS Neglected Tropical Diseases*, *6*(7), e1744. https://doi.org/10.1371/JOURNAL.PNTD.0001744

Molla, Y. B., Tomczyk, S., Amberbir, T., Tamiru, A., & Davey, G. (2012b). Podoconiosis in East and West Gojam Zones, Northern Ethiopia. *PLoS Neglected Tropical Diseases*, *6*(7), e1744. https://doi.org/10.1371/journal.pntd.0001744

Mousley, E., Deribe, K., Tamiru, A., & Davey, G. (2013). The impact of podoconiosis on quality of life in Northern Ethiopia. *Health and Quality of Life Outcomes*, *11*(1). https://doi.org/10.1186/1477-7525-11-122

Mues, K. E., Deming, M., Kleinbaum, D. G., Budge, P. J., Klein, M., Leon, J. S., Prakash, A., Rout, J., & Fox, L. M. (2014). *Impact of a Community-Based Lymphedema Management Program on Episodes of Adenolymphangitis (ADLA) and Lymphedema Progression-Odisha State, India*. https://doi.org/10.1371/journal.pntd.0003140

Munikanan, T., Midin, M., Daud, T. I. M., Rahim, R. A., Bakar, A. K. A., Jaafar, N. R. N., Sidi, H., & Baharuddin, N. (2017). Association of social support and quality of life among people with schizophrenia receiving community psychiatric service: A cross-sectional study. *Comprehensive Psychiatry*, *75*, 94–102. https://doi.org/10.1016/j.comppsych.2017.02.009

Munyaneza, F., Hirschhorn, L. R., Amoroso, C. L., Nyirazinyoye, L., Birru, E., Mugunga, J. C., Murekatete, R. M., & Ntaganira, J. (2014). *Leveraging community health worker system to map a mountainous rural district in low resource setting: a low-cost approach to expand use of geographic information systems for public health*.

https://doi.org/10.1186/1476-072X-13-49

Murray, C. J. L., Vos, T., Lozano, R., Naghavi, M., Flaxman, A. D., Michaud, C., Ezzati, M., Shibuya, K., Salomon, J. A., Abdalla, S., Aboyans, V., Abraham, J., Ackerman, I., Aggarwal, R., Ahn, S. Y., Ali, M. K., AlMazroa, M. A., Alvarado, M., Anderson, H. R., … Lopez, A. D. (2012). Disability-adjusted life years (DALYs) for 291 diseases and injuries in 21 regions, 1990-2010: A systematic analysis for the Global Burden of Disease Study 2010. *The Lancet*, *380*(9859), 2197–2223. https://doi.org/10.1016/S0140-6736(12)61689-4

Nanda, B., & Ramaiah, K. D. (2003). Lymphoedema-management measures practised by cases of chronic lymphatic filariasis. *Annals of Tropical Medicine and Parasitology*, *97*(4), 427–431. https://doi.org/10.1179/000349803235002308

Negussie, H., Molla, M., Ngari, M., Berkley, J. A., Kivaya, E., Njuguna, P., Fegan, G., Tamiru, A., Kelemework, A., Lang, T., Newport, M. J., McKay, A., Enquoselassie, F., & Davey, G. (2018). Lymphoedema management to prevent acute dermatolymphangioadenitis in podoconiosis in northern Ethiopia (GoLBeT): a pragmatic randomised controlled trial. *The Lancet Global Health*, *6*(7), e795–e803. https://doi.org/10.1016/S2214-109X(18)30124-4

NISR. (2012). *EICV 3 - Burera District profile | National Institute of Statistics Rwanda*. https://www.statistics.gov.rw/publication/eicv-3-burera-district-profile

NISR. (2018). *EICV4 DISTRICT PROFILE Musanze GOVERNMENT OF RWANDA REPUBLIC OF RWANDA NATIONAL INSTITUTE OF STATISTICS OF RWANDA*. https://musanze.gov.rw/fileadmin/templates/raports/Musanze_DDS_Final_Version__November._2018-1.doc

Person, B., Bartholomew, L. K., Addiss, D., & van den Borne, B. (2007). Disrupted social connectedness among Dominican women with chronic filarial lymphedema. *Patient Education and Counseling*, *68*(3), 279–286. https://doi.org/10.1016/J.PEC.2007.06.015

Phillips, C., Samuel, A., Tiruneh, G., Deribe, K., & Davey, G. (2019). The impact of acute adenolymphangitis in podoconiosis on caregivers: A case study in Wayu Tuka woreda, Oromia, Western Ethiopia. 'If she was healthy, I would be free.' *PLOS Neglected Tropical Diseases*, *13*(7), e0007487. https://doi.org/10.1371/journal.pntd.0007487

Price, E., & Henderson, W. (1978). The elemental content of lymphatic tissues of barefooted people in Ethiopia, with reference to endemic elephantiasis of the lower legs. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, *72*(2), 132–136. https://doi.org/10.1016/0035-9203(78)90048-2

Price, E. W. (1976). The Association of Endemic Elephantiasis of the Lower Legs in East Africa with Soil Derived from Volcanic Rocks. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, *70*(4), 288–295. https://doi.org/10.1016/0035-9203(76)90078-X

Price, E. W. (1990). Podoconiosis: non-filarial elephantiasis. *Podoconiosis: Non-Filarial*

Elephantiasis.

Ramaiah, K. D., & Vijay Kumar, K. N. (2000). Effect of lymphatic filariasis on school children. *Acta Tropica*, *76*(2), 197–199. https://doi.org/10.1016/S0001-706X(00)00102-9

Ruberanziza, E., Mupfasoni, D., Karibushi, B., Rujeni, N., Kabanda, G., Kabera, M., Kaberuka, T., Nizeyimana, V., Kramer, M. H., Mukabayire, O., Fenwick, A., & Ruxin, J. (2009). Mapping of lymphatic filariasis in Rwanda. *Journal of Lymphoedema*, *4*(1), 20–23.

Semrau, M., Davey, G., Bayisenge, U., & Deribe, K. (2020). High levels of depressive symptoms among people with lower limb lymphoedema in Rwanda: a cross-sectional study. *Transactions of The Royal Society of Tropical Medicine and Hygiene*, *114*(12), 974–982. https://doi.org/10.1093/trstmh/traa139

Shahvisi, A., Meskele, E., & Davey, G. (2018). A human right to shoes? Establishing rights and duties in the prevention and treatment of podoconiosis. *Health and Human Rights*, *20*(1), 53–65. /pmc/articles/PMC6039730/?report=abstract

Shenoy, R. K. (2008). Clinical and pathological aspects of filarial lymphedema and its management. In *Korean Journal of Parasitology* (Vol. 46, Issue 3, pp. 119–125). Korean Society for Parasitology. https://doi.org/10.3347/kjp.2008.46.3.119

Sikorski, C., Ashine, M., Zeleke, Z., & Davey, G. (2010). Effectiveness of a Simple Lymphoedema Treatment Regimen in Podoconiosis Management in Southern Ethiopia: One Year Follow-Up. *PLoS Neglected Tropical Diseases*, *4*(11), e902. https://doi.org/10.1371/journal.pntd.0000902

Sime, H., Deribe, K., Assefa, A., Newport, M. J., Enquselassie, F., Gebretsadik, A., Kebede, A., Hailu, A., Shafi, O., Aseffa, A., Reithinger, R., Brooker, S. J., Pullan, R. L., Cano, J., Meribo, K., Pavluck, A., Bockarie, M. J., Rebollo, M. P., & Davey, G. (2014). Integrated mapping of lymphatic filariasis and podoconiosis: Lessons learnt from Ethiopia. *Parasites and Vectors*, *7*(1), 397. https://doi.org/10.1186/1756-3305-7-397

Tekola Ayele, F., Adeyemo, A., Finan, C., Hailu, E., Sinnott, P., Burlinson, N. D., Aseffa, A., Rotimi, C. N., Newport, M. J., & Davey, G. (2012). HLA Class II Locus and Susceptibility to Podoconiosis. *New England Journal of Medicine*, *366*(13), 1200–1208. https://doi.org/10.1056/nejmoa1108448

Tekola, F., Ayele, Z., Mariam, D. H., Fuller, C., & Davey, G. (2008). Development and testing of a *de novo* clinical staging system for podoconiosis (endemic non-filarial elephantiasis). *Tropical Medicine & International Health*, *13*(10), 1277–1283. https://doi.org/10.1111/j.1365-3156.2008.02133.x

Tekola, F., Mariam, D. H., & Davey, G. (2006). Economic costs of endemic non-filarial elephantiasis in Wolaita Zone, Ethiopia. *Tropical Medicine and International Health*, *11*(7), 1136–1144. https://doi.org/10.1111/j.1365-3156.2006.01658.x

Tembei, A. M., Kengne-Ouaffo, J. A., Ngoh, E. A., John, B., Nji, T. M., Deribe, K., Enyong, P., Nkuo-Akenji, T., Davey, G., & Wanji, S. (2018). A comparative analysis of economic cost of podoconiosis and leprosy on affected households in the Northwest Region of Cameroon. *American Journal of Tropical Medicine and Hygiene*, *98*(4), 1075–1081. https://doi.org/10.4269/ajtmh.17-0931

Tomczyk, S., Tamiru, A., & Davey, G. (2012). Addressing the Neglected Tropical Disease Podoconiosis in Northern Ethiopia: Lessons Learned from a New Community Podoconiosis Program. *PLoS Neglected Tropical Diseases*, *6*(3), e1560. https://doi.org/10.1371/journal.pntd.0001560

Tora, A., Davey, G., & Tadele, G. (2011). A qualitative study on stigma and coping strategies of patients with podoconiosis in Wolaita zone, Southern Ethiopia. *International Health*, *3*(3), 176–181. https://doi.org/10.1016/j.inhe.2011.06.006

Tora, A., Davey, G., & Tadele, G. (2012). Factors related to discontinued clinic attendance by patients with podoconiosis in southern Ethiopia: A qualitative study. *BMC Public Health*, *12*(1), 1–7. https://doi.org/10.1186/1471-2458-12-902

Tora, A., Franklin, H., Deribe, K., Reda, A. A., & Davey, G. (2014). Extent of podoconiosis-related stigma in Wolaita Zone, Southern Ethiopia: a cross-sectional study. *SpringerPlus*, *3*(1), 1–7. https://doi.org/10.1186/2193-1801-3-647

Tora, A., Mengiste, A., Davey, G., & Semrau, M. (2018). Community Involvement in the Care of Persons Affected by Podoconiosis—A Lesson for Other Skin NTDs. *Tropical Medicine and Infectious Disease*, *3*(3), 87. https://doi.org/10.3390/tropicalmed3030087

Tsegay, G., Deribe, K., Deyessa, N., Addissie, A., Davey, G., Cooper, M., & Trueba, M. L. (2018). “I should not feed such a weak woman”. Intimate partner violence among women living with podoconiosis: A qualitative study in northern Ethiopia. *PLOS ONE*, *13*(12), e0207571. https://doi.org/10.1371/JOURNAL.PONE.0207571

Tsegay, G., Wubie, M., Degu, G., Tamiru, A., Cooper, M., & Davey, G. (2015). Barriers to access and re-attendance for treatment of podoconiosis: A qualitative study in northern Ethiopia. *International Health*, *7*(4), 285–292. https://doi.org/10.1093/inthealth/ihu085

van’t Noordende, A. T., Aycheh, M. W., & Schippers, A. P. (2020). An exploration of family quality of life in persons with leprosy-, lymphatic filariasis– and podoconiosis-related disabilities and their family members in Ethiopia. *Transactions of The Royal Society of Tropical Medicine and Hygiene*, *114*(12), 1003–1012. https://doi.org/10.1093/trstmh/traa090

Wanji, S., Tendongfor, N., Esum, M., Che, J. N., Mand, S., Mbi, C. T., Enyong *, P., & Hoerauf, A. (2008). *Elephantiasis of non-filarial origin (podoconiosis) in the highlands of north-western Cameroon*. https://doi.org/10.1179/136485908X311849

Watu, E., Supargiyono, & Haryani. (2020). The Effect of Lymphoedema Exercises and Foot Elevation on the Quality of Life of Patients with Elephantiasis. *Journal of Tropical Medicine*, *2020*. https://doi.org/10.1155/2020/6309630

Weiss, M. G., & Ramakrishna, J. (2006). Stigma interventions and research for international health. *The Lancet*, *367*(9509), 536–538. https://doi.org/10.1016/S0140-6736(06)68189-0

WHO. (2011). The Human Right to Water and Sanitation Media brief. *UN-Water Decade Programme on Advocacy and Communication and Water Supply and Sanitation Collaborative Council*, *April 2011*, 1–8. http://www.un.org/waterforlifedecade/pdf/human_right_to_water_and_sanitation_media_brief.pdf

WHO. (2013). *F I L A R I A S I S L Y M M P H A T I C Y M T I C LYMPHATIC FILARIASIS: MANAGING MORBIDITY AND PREVENTING DISABILITY GLOBAL PROGRAMME TO ELIMINATE LYMPHATIC FILARIASIS WORLD HEALTH ORGANIZATION AN AIDE-MÉMOIRE FOR NATIONAL PROGRAMME MANAGERS*.

WHO. (2015). WHO | Podoconiosis: endemic non-filarial elephantiasis. *WHO*. http://www.who.int/lymphatic_filariasis/epidemiology/podoconiosis/en/

WHO. (2020). *A road map for neglected tropical diseases 2021–2030*. https://www.who.int/neglected_diseases/Ending-the-neglect-to-attain-the-SDGs--NTD-Roadmap.pdf

World Bank. (2019). *Number of Poor Rate (million) (%)*. www.worldbank.org/poverty

Yakob, B., Deribe, K., & Davey, G. (2008). High levels of misconceptions and stigma in a community highly endemic for podoconiosis in southern Ethiopia. *Transactions of The Royal Society of Tropical Medicine and Hygiene*, *102*(5), 439–444. https://doi.org/10.1016/J.TRSTMH.2008.01.023

Yakob, B., Deribe, K., & Davey, G. (2010). Health professionals' attitudes and misconceptions regarding podoconiosis: potential impact on integration of care in southern Ethiopia. *Transactions of the Royal Society of Tropical Medicine and Hygiene*, *104*(1), 42–47. https://doi.org/10.1016/j.trstmh.2009.07.021

APPENDICES

Appendix 1: Ethical Considerations

Vulnerable populations

Podoconiosis patients are a vulnerable population. Many of them have suffered from stigma and lack of employment opportunities due to their condition. Vulnerabilities that may arise with the condition were considered in the approach and questionnaire administration manner. Medical and psychosocial support referral systems were set up to refer participants to nearby care providers if the need arose. Minors (those under 18) were excluded from the study.

Assessment of risks to participants

We expected certain participants to have minimal discomfort/uneasiness during surveys as the questions could invoke unpleasant memories. When participants showed discomfort during the interview, data collectors paused to remind them that they could withdraw consent at any time.

We anticipated that participants may fear refusal of participation and/or fear to give honest responses because they might think it could impact their access to HASA services. To prevent this, assurances were given to all participants that participation was entirely voluntary and would not affect access to HASA services in any way.

Risks of privacy breaches with participant responses were mitigated by data collector training on ethics and handling of sensitive information.

Considering the current Covid-19 pandemic, primary investigators, data collectors, and participants were required to wear masks and maintain a social distance of at least two meters. Participants who arrived without masks were provided surgical masks by the research team. In addition, there were washing stations at the clinic, and participants were asked to wash their hands with soap up on arrival. In case of water supply interruption, hand sanitizers were availed at the entrance and exit of the study area.

Medical or psychosocial support

The study involved physical examinations of participants’ joint movement by the primary researchers. We did not expect the participants to require any medical support during the data collection. However, if any medical or psychosocial support was required, they were linked to HASA staff for appropriate referral procedures. Participants only answered the questions they were comfortable with and could stop at any moment.

Participants were provided refresher lessons on foot care and undertook routine PEP sessions at the clinics.

Information and consent process

For participants accessed by phone an information and consent form (Appendix 1) was translated from English to Kinyarwanda and discussed with participants via phone to obtain verbal consent. Before data collection, participants were presented with the information and consent form. Those who could read were given time to read and for those who could not, data collectors read out the form. The form contained information regarding the study, including research aim and guidelines on participation and withdrawal, the confidentiality of data collected, and privacy. Participants were assured that none of their answers would subject them to harm or loss of benefits and they were given enough time to ask any questions they may have about the study. In addition, they were reassured that they could skip any questions they did not want to answer, withdraw consent from the study at any time, and that withdrawal would not affect their relationship with HASA. The information and consent form was required to be signed or confirmed with a fingerprint stamp before data collection proceeded.

Protection of privacy and confidentiality

Data was collected from participants only after signing the informed consent form by using a questionnaire on QoL and a clinical staging tool to assess the lymphedema. Any information shared by participants was not available to those outside the research team. All consented participants were assigned unique participant identification numbers (PINs) for the protection of their identity. Photographs taken for staging purposes only included the lower limbs (below the knee) and were tagged with the respective PINs for identification. Data collected with the Kobo toolbox and audio recorders was stored on password-protected computers that were kept in a safety cabinet.

De-identification of data

Participants' identities were made anonymous by using PINs. Any identifiable data was not used for data analysis or submitted in the report. Reported results were given in an aggregated form to avoid the identification of participants.

Safekeeping of data

All raw data on Kobo toolbox was deleted after uploading data to a password-protected excel database. Similarly, all recordings on the audio recorders were permanently deleted from devices after copying to the primary researcher's computers. All anonymized data was stored in password-protected computers that were only accessible to the three primary researchers during the study. After the study, the data was stored in the UGHE archive, where it will be kept for ten years and destroyed thereafter.

Appendix 2: Practicum project Information and Consent Form – English

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INFORMATION AND CONSENT FORM

Participant ID: ______________________

Project title: Assessing the impact of the HASA prevention education program (PEP) on the clinical staging and quality of life of podoconiosis patients.

Study population: The target population of the study is all podoconiosis patients enrolled in the HASA podoconiosis prevention education program, within the past 5 years.
Version date: March April 2, 2021

Principal Investigators:
Ahamed Kallon, Natnael Shimelash MD., George Mkondo MD.

About this consent form

Dear participant,
Before joining this study {Assessing the impact of the HASA prevention education program (PEP) on the clinical staging and quality of life of podoconiosis patients}, you must comprehend and take note of the contents of this form, since it covers vital information to guide you in making decision on participating or not in the study. Please take as much time as possible in deciding to take part in this research, and you might even involve your family, friends, and doctor if necessary, in this process. Please do not hesitate to ask questions pertaining to this research or about this form. If you agree to partake, you will sign this form and be given a duplicate for your records.

Participation is voluntary.
It is your choice whether to take part in this study or not. Should you decide to take part, you have the right to change your mind and leave the study at any time. Declining to participate or halting your participation will not condemn you to any penalty or affect your relationship with HASA.

What should you know about this research study?
This study is part of the University of Global Health Equity's master's program. It aims to assess the impact of the HASA prevention education program on the clinical condition and lives of patients enrolled in the program. Details of this study will be explained to you by employees of HASA clinic. We invited you to participate in the study to gather information on how the program has impacted the condition of your feet and your quality of life. This will be done via a survey, voice recording, taking photographs and physical examination of your feet and legs.

What is the purpose of this project?
The purpose of this study is to assess the impact of the HASA prevention education program (PEP) on the clinical staging, adherence to the program recommendations and quality of life of podoconiosis patients. The outcome of this study is to build knowledge on the effect of HASA PEP on the clinical condition and the quality of life of podoconiosis patients. This information will be used to inform HASA about the strength and weakness of the program, and recommended areas of improvement for future interventions.

How many people will take part in this research?
Approximately, 150 participants from the HASA Podoconiosis patient's database will take part in this research.

What is the procedure for participation in this project?
To participate in this study, you need to read (or be read) all the information on this form. If you understand and agree with all the information, you will be required to give consent either by signature, or thumb print. Once consent is affirmed a survey will be administered to you by one of our data collectors. Your answers for the last four questions of the survey will be voice recorded in order to make sure they are thoroughly analyzed. At the end of the survey two primary researchers will assess the condition of your feet and take photographs of your feet for analysis. The process of responding to survey questions and clinical staging will last a maximum of 30 minutes.

What are the possible risks or discomforts related to taking part in this project?
Participating in this study may cause minimal discomfort as we will address sensitive topics. If you feel discomfort during the interview, data collectors will pause to ascertain your wellbeing and confirm willingness to continue. If you need seek emotional support, we will provide you with referrals for support and psychological care.

As you are being called to travel for this study, we will consider your transport expenditure and financial reimbursements will be provided at the end of the survey. Please note that deciding to opt out of the study will not compromise you from getting your transport fee reimbursement.

What are the possible benefits of taking part in this project?
If you choose to participate, you will be helping to develop context detailed recommendations to improve the service delivery of prevention education program on podoconiosis and similar lymphedemas. This may potentially lead to improved and better health for your community and the world at large.

What are my alternatives to participating in this study?
The only alternative to participating in this research study is not to take part.

Will I be compensated for participating in this research?
Besides your transport reimbursement, there is no compensation for participating in this research study.

What will I have to pay for if I participate in this research?
Participation in this study is completely free.

What happens if I am injured as a result of participating in this research study?
If physical injury ensuing from participation in this research should happen, although UGHE's policy is not to offer compensation, medical treatment will be accessible including first aid, emergency treatment and follow-up care as needed, and your insurance carrier may be

billed for the cost of such treatment. In making such medical treatment available, or providing it, the persons conducting this research project are not acknowledging that your injury was their fault.

Can my taking part in the research end early?

You may choose not to remain in the study at any point in time without it being held against you. The researchers in charge of this study can also remove you from the research at any time without your consent for any reason. If necessary, the researcher(s) might provide Possible reasons for your withdrawal from the study.

If I take part in this project, how will my privacy be protected? What happens to the information you collect?

The data collected will not contain your full name, but a unique participant identity number (PIN) will be used to identify you. Any information that you share will not be available to those outside the research team. Data collected will be stored on password-protected computers that will be kept in a safety cabinet. After the study, the data will be stored in the UGHE archive for ten years and destroyed thereafter. Results of the study will be shared with HASA to inform the effectiveness of their program and to help make recommendations for areas of improvement. In addition, data may be published in scientific journals. Should you require results of the study, these will be communicated to you via mobile phone by July 2021.

If I have any questions, concerns, or complaints about this project, who can I talk to?

The primary researchers for this study are Ahamed Kallon, George Mkondo, and Natnael Shimelash who can be reached on george.mkondo@student.ughe.org, and on mobile 0730180434 or 0786547276. These researchers are students of the Master of Global Health Equity (MGHD) class at the University of Global Health Equity (UGHE), from the One Health department. This study is supervised by senior faculty Janna Schurer (jschurer@ughe.org) and junior faculty, Gebreselassie Agazi Fitsum (gagazi@ughe.org).

- If you have questions, concerns, or complaints;
- If you would like to talk to the project team;
- If you wish to withdraw from the study;
- If you want to get information or provide input about this research.

This research study has been reviewed by University of Global Health Equity Institutional Review Board. For more information from the IRB, please contact the IRB at irb@ughe.org, telephone: 0788316894 or Office of Human Research Administration (OHRA) at Kigali Heights Building, 5th floor, Kacyiru, Kigali, P.O. Box 6955, Rwanda, for any of the following:

- If you have any ethical concerns regarding the research or research team;
- If your questions, concerns, or complaints are not being answered by the research team;
- If you cannot reach the research team;
- If you want to speak withs someone besides the research team;
- If you have questions about your rights as a research participant, or;
- If you think the project has harmed you.

Statement of consent

Your fingerprint below acknowledges that:

- You have understood the content of this form;
- You have had the opportunity to ask questions and received answers that were satisfactory;
- If needed, you took time to discuss this information with others to help you decide whether to participate;
- You will receive a dated and signed copy of the form;
- You agree to participate in this research project.

☐ I consent to have the interview audio-recorded

☐ I consent to have the photographs of my feet to be used for educational & publication purposes

___________________________________ ____________________

Full name and signature of the witness Date and location

______________________________________ ____________________

Full name and signature of the person requesting consent Date and location

I have read the information in this consent form including risks and possible benefits. All my questions about the research have been answered to my satisfaction. I understand that I am free to withdraw at any time without penalty or loss of benefits to which I am otherwise entitled.

I consent to participate in the study.

SIGNATURE

Your signature below indicates your permission to take part in this research

Name of participant

Signature of participant — Date

Signature of person obtaining consent — Date

Your signature below indicates you acknowledge that:

- You have understood the content of this form;
- You have had the opportunity to ask questions and received answers that were satisfactory;
- If needed, you took time to discuss this information with others to help you decide whether to participate;
- You will receive a dated and signed copy of the form;
- You agree to participate in this project.

________________________________ ________________________

Full name and signature of the participant Date and location

___________________________________ _________________________

Full name and signature of a parent or Date and location
legal guardian if respondent is a minor (>21)

________________________________ ________________________

Co-signature by child if they are older than 9 Date and location
years and of appropriate maturity, psychological

and physical condition

_________________________________ __________________________

Full name and signature of the person requesting consent

Date and location

Appendix 3: Practicum project Information and Consent Form – Kinyarwanda

UNIVERSITY OF
Global Health
EQUITY

IFISHI YO KUMENYEKANISHA UBUSHAKE MU KUGIRA URUHARE MU BUSHAKASHATSI NYUMA YO GUSOBANURIRWA NEZA IBIBWEREKEYE

Ibiranga Uwitabiriye Ubushakashatsi: ______________________

Umutwe w' Ubushakashatsi: Gusuzuma ingaruka za gahunda ya HASA yo kwigisha no gukumira (PEP) indwara y'imidido [indwara yo kubyimba amaguru] **mu nzego z' ayo** n' ubuzima bw' abarwayi.

Abazitabira ubushakashatsi: Abitezweho kwitabira ubu bushakashatsi ni abarwayi bose b' imidido [indwara yo kubyimba amaguru] bari muri gahunda ya HASA yigisha kwirinda imidido [indwara yo kubyimba amaguru], mugihe cy' imyaka 4 ishize.
Version date: March 24, 2021

Abakora Ubushakashatsi:
Ahamed Kallon, Natnael Shimelash MD, George Mkondo MD.

Ibijyanye n' ifishi y' abashaka kugira uruhare mu bushakashatsi

Mutumirwa wacu,
Mbere yuko ugira uruhare muri ubu bushakashatsi {Gusuzuma ingaruka za gahunda yo kwigisha gukumira HASA (PEP) ku nzego z' indwara n' ubuzima bwiza bw' abarwayi barwaye imidido [indwara yo kubyimba amaguru, ugomba kubanza kumva no kwandika ingingo z' ingenzi muri iyi fishi/nyandiko, kuberako harimo amakuru y' ibanze akuyobora mu gufata umwanzuro wo kugira uruhare muri ubu bushakashati cyangwa kutagiramo uruhare. Turagusaba ngo ufate umwanya ushoboka kandi uhagije mbere yuko ufata umwanzuro wo kugira uruhare muri ubu

bushakashatsi, ushobora no kwifashisha umuryango wawe, inshuti na muganga aho bikenewe, muri iyi nzira yo guhitamo kugira uruhare muri ubu bushakashati. Turabasaba ngo ntimushidikanye kubaza ikibazo icyo ari cyo cyose kubijyanye n' ubu bushakashatsi cyangwa ku nyandiko y'iyi fishi. Niba mutwemereye kugira uruhare muri ubu bushakashatsi, murashyira umukono kuri iyi fishi kandi murahabwa urupapuro ruriho umukono wanyu.

Kwitabira iki kiganiro ni ubushake

Ni uburenganzira bwawe gufata umwanzuro wo kwitabira iki kiganiro cyangwa kutakitabira. Nuhitamo kwitabira, ushobora no kugera hagati ugahindura umwanzuro ukakivamo igihe icyo ari cyose. Kutitabira iki kiganiro cyangwa kutakirangiza ku mpamvu iyo ari yo yose nta ngaruka bizakugiraho cyangwa ngo bibe hari ingaruka byagira hagati yawe na porogaramu ya HASA.

Ibyo ugomba kumenya kuri ubu bushakashatsi?

Ubu ubushakashatsi buri gukorwa nka kimwe mu bisabwa kugira ngo duhabwe impamyabumenyi y'icyiciro cya gatatu cya kaminuza mu bijyanye n'ubuzima rusange (Master of Science in Global Health Delivery) muri kaminuza ya Global Health Equity. Igamije gusuzuma ingaruka za gahunda HASA yo kwigisha gukumira (PEP) iyi indwara mu nzego zayo zitandukanye n' ubuzima bwiza bw' abarwayi binjijwe muri porogaramu. Amakuru menshi kuri ubu bushakashatsi muzayahabwa n' abakozi bo kw' ivuriro rya HASA. Twabatumiye ngo mugire uruhare muri ubu bushakashatsi muburyo bwo gukusanya amakuru yuko iyi porogaramu yabafashije mu gukumira indwara y'imidido nuko ifasha mu kongera ubuzima bwiza. Ibi birakorwa hifashishijwe urutonde rw' ibibazo byo gusuzuma ingingo zibasiwe n'ubu burwayi (amaguru n' ibirenge). Ubu bushakashatsi buzakorwa mu buryo bwo gufata amajwi, amafoto, n'isuzuma ry'ingingo zibasiwe n'ubu burwayi (ibirenge n'amaguru).

Intego y' ubu bushakashatsi?

Intego y' ubu bushakashati ni gusuzuma ingaruka za gahunda ya HASA yo kwigisha no gukumira (PEP) indwara y'imidido **mu nzego z'ayo**, n' ikurikizwa ry' inama zitangwa muri porogaramu ndetse n' ubuzima bwiza bw' abarwayi [indwara yo kubyimba amaguru]. Ibizava muri ubu bushakashatsi bizongera ubumenyi kujyanye n' uruhare rwa porogaramu ya HASA PEP ku nzego z'indwara n' ubuzima bwiza bw' abarwayi b' imidido [indwara yo kubyimba amaguru]. Amakuru yo muri ubu bushakashatsi azakoreshwa mukumenyesha HASA ibijyanye n' ibikorwa neza hamwe n' imbogambizi z' iyi porogaramu, ndetse kandi n' ahakenewe gushyirwamo imbaraga ugendeye kuzindi gahunda zizakorwa mu bihe bizaza.

Ni bangahe bazagira uruhare muri ubu bushakshatsi?

Abasaga 150 bo muri porogaramu ibika amakuru y' abarwayi muri HASA nibo bazagira uruhare muri ubu bushakashatsi.

Inzira/uburyo bwo kugira uruhare muri ubu bushakashatsi?
Kwitabira ubu bushakashatsi, ugomba gusoma (cyangwa ugasomerwa) amakuru yose ari kuri iyi fishi. Niwumva kandi ukemeranya n' amakuru yose, urasabwa kwemeza ushyiraho mumukono cyangwa n' igikumwe. Nyuma yo gutanga ubwemere bwawe uzahabwa urutonde rw' ibibazo n' umwe mubashinzwe gukusanya amakuru. Ibisubizo byawe ku bibazo bine byanyuma by'ubushakashatsi hazafatwa amajwi kugirango abashakashatsi babyumve neza. Nyuma yo gusubiza ibibazo byose, abashakashatsi bibanze barasuzuma uko ibirenge bimerewe ubu kandi bafate amafoto azifashishwa mubusesenguzi bwimbitse. Igikorwa byo gusubiza ibibazo no kureba urugero rw' uburwayi ntibirenga iminota 30.

Ni izihe mbogamizi (cg kubangamirwa) ushobora guhura na zo witabiriye ubu bushakashatsi?
Kwitabira ubu bushakashatsi bishobora kuguteza ukubangamirwa koroheje bitewe nuko turi kwiga ku ngingo ikomeye. Uramutse ubangamiwe mugihe ki kiganiro, abashinzwe gukusanya amakuru bazafata ikiruhuko kugirango ubone umwanya wo kwiyitaho kandi bagusabe uburenganzira bwo gukomeza kubushake bwawe. Nukenera ubufasha bujyanye n' amarangamutima, turagufasha kububona ahabugenewe kandi hizewe.

Kuberako bizasaba gutega ngo mwitabire ubu bushakashatsi, tuzita ku mafaranga muzakoresha y' urugendo kuko muzayasubizwa ku musozo w' isubiza ry' ibibazo. Nuramuka wifuje guhagarika kwitabira/kugira uruhare mu bushakashatsi, ntakizabuza kuba wasubizwa amafaranga y' urugendo wakoresheje. Kuva mu bushakashatsi butarangiye ntago bizababuza kwishyurwa amafaranga yanyu y'urugendo muzaba mwakoresheje.

Ni izihe nyungu zishoboka zo kwitabira ubu bushakashatsi?
Nuhitamo kwitabira/kugira uruhare muri ubu bushakashatsi, uzaba uri gufasha kugirango havugururwe uburyo serivisi zitangwa muri porogaramu ya HASA ku ndwara y' imidido [indwara yo kubyimba amaguru]. Ibi kandi birashobora kuganisha ku kuzamuka k' ubuzima bwiza bw' abaturage baho utuye.

Ni ubuhe buryo bundi bwanjye bwo kwitabira ubu bushakashatsi?
Ubundi buryo bwonyine bujyanye no kwitabira ubu bushakashatsi n' ukutabugiramo uruhare.

Nzabahwa ingurane zo kwitabira ubu bushakashatsi?
Usibye gusubizwa amafaranga y' urugendo, nta ndishyi zo kugira uruhare muri ubu bushakashatsi.

Nzagomba kwishyura iki nidamuka nitabiriye ubu bushakashatsi?
Kwitabira ubu bushakashati ni ubuntu.

Bigenda bite igihe nkomerekejwe bitewe no kwitabira ubu bushakashatsi?
Gukomereka ku mubiri bitewe n' ubu bushakashatsi ntibishoboka cyane kandi imirongo ngenderwaho ya UGHE ntabwo itanga indishyi. Uburyo bw' ubuvuzi buzaba bugerwaho harimo ubuvuzi bw' ibanze, ubuvuzi bwihutirwa no gukurikiranwa aho bikenewe. Ubwishingizi bwawe bushobora kwishyura ikiguzi cyo kwivuza. Mukwita kugirango ubuvuzi buboneke, cyangwa butangwe, abari gukora ubu bushakashatsi ntibemera ko gukomereka kwawe ari amakosa yabo*.*

Uruhare rwanjye muri ubu bushakashatsi rushobora kurangira hakiri kare?
Ushobora guhitamo kutaguma muri ubu bushakashatsi umwanya uwariwo wose utarinze kubyingingira.

Ni nitabira ubu bushakashatsi, nigute muzabungabunga amakuru bwite natanze, Bigenda gute iyo amakuru akusanijwe?
Amakuru yafashwe muri ubu bushakashatsi ntabwo azagaragaza amazina yombi, ariko hatangwa umubare w' ibanga kuri buri wese witabiriye ubushakahshatsi [PIN] kugirango bibe byamenyekana ko ariwose. Amakuru yose muzatanga ntabwo azagaragarizwa abari hanze y' itsinda ry' ubushakashatsi. Amakuru yafashwe azabikwa muri mudasobwa ifite umubare w' ibanga kandi nayo izabikwa ahantu hari umutekano. Nyuma y' ubushakashatsi, amakuru azabikwa mu bubiko bwa UGHE kandi azasibwa nyuma y' imyaka 10. Ibivuye mu bushakashatsi bizasangirwa na HASA kugirango bimenyeshe imikorere ya porogaramu yabo kandi bifashe kuba hashyirwaho ibyifuzo byo kuvugurura. Ikindi nuko, amakuru ashobora gutangazwa mu binyamakuru by' ubumenyi. Ukeneye amakuru kuti ububushakashatsi twazayaguha kuri terefone muri Nyakanga 2021.

Niba mfite ibibazo, impungenge, cyangwa ibyo ntumva kuri ubu bushakashatsi, ninde nshobora kuvugisha?
Abashakashatsi bambere kuri ubu bushakashatsi ni Ahamed Kallon, George Mkondo, and Natnael Shimelash bashobora kuboneka kuri george.mkondo@student.ughe.org no kuri mobile 0730180434 cyangwa 0786547276. Aba bashakashatsi ni abanyeshuri b' icyiciro cya gatatu cya kaminuza mu bijyanye n'ubuzima rusange (Master of Science in Global Health Delivery), muri Kaminuza ya Global Health Equity (University of Global Health Equity), bo mw' ishami ry' ibinyabuzima [One Health Department]. Ubu bushakashatsi bugenzurwa n'umwarimu mukuru Jannah Schurer (jschurer@ughe.org) hamwe n' umwarimu umwungirije, Gebreselassie Agazi Fitsum (gagazi@ughe.org).

- Niba ufite ibibazo, impungenge, cyangwa ibyo utumva;
- Niba ushaka kuvugana n'itsinda ry' abashakashatsi;
- Niba wifuza kuva mu bushakashatsi;

- Niba ushaka kubona amakuru cyangwa gutanga ibitekerezo kubyerekeye ubu bushakashatsi.

Ubu bushakashatsi bwakorewe igenzura n’ itsinda rishinzwe kugenzura ubushakashatsi muri Kaminuza ya Global Health Equity. Ukeneye ubusobanuro bwimbitse butangwa n’ itsinda rishinzwe kugenzura ubushakashatsi [IRB], Mushobora kuvugisha iryo tsinda kuri irb@ughe.org, telefone: 0788316894 cyangwa Ibiro bishinzwe ubushakashatsi bw’ abantu (OHRA) ku nyubako ya Kigali Heights, igorofa ya 5, Kacyiru, Kigali, P.O. Agasanduku 6955, u Rwanda, kuri kimwe muri ibi bikurikira:

- Niba mufite ikibazo kerecyeranye n’ubushakashatsi cyangwa itsinda rikora ubushakashatsi;
- Niba ibibazo byawe, impungenge, cyangwa ibyo utumva bitashubijwe n’itsinda ry’ ubushakashatsi;
- Niba udashobora kugera kw’ itsinda ry’ ubushakashatsi;
- Niba ushaka kuvugana n’ umuntu utari mw’ itsinda ry’ ubushakashatsi;
- Niba ufite ibibazo bijyanye n'uburenganzira bwawe nk’uwitabira ubushakashatsi, cyangwa;
- Niba utekereza ko umushinga wakugiriye nabi, cyangwa.

Inyandiko y’ ubwemere

Igikumwe cyawe hepfo cyemeza ko:

- Wumvise ibikubiye muri iyi fishi;
- Wagize amahirwe yo kubaza ibibazo no kwakira ibisubizo byakunyuze;
- Niba bikenewe, wafashe umwanya wo kungurana ibitekerezo n' abandi kugirango bagufashe guhitamo niba witabira;
- Uzakira ifishi iriho itariki kandi yashyizweho umukono;
- Uremera kwitabira uyu mushinga w' ubushakashatsi.

☐ Nemeye kugira ikiganiro kiribufatwe amajwi

☐ Nemeye ko amafoto y’ibirenge byange afatwa agakoreshwa mu mpamvu z’uburezi

____________________________________ ____________________

Izina ryuzuye n’ umukono by’ umutangabuhamya Itariki n’ ahantu

_______________________________________ ____________________

Izina ryuzuye n’ umukono w’ umuntu usaba uruhushya Itariki n’ ahantu

Nasomye amakuru muriyi ifishi y' ubwemere harimo ingaruka n' inyungu zishoboka. Ibibazo byanjye byose bijyanye n'ubushakashatsi byashubijwe ndanyurwa. Ndumva ko mfite uburenganzira bwo kuvamo igihe icyo ari cyo cyose nta gihano cyangwa gutakaza inyungu nemerewe mu nyandiko.

Nemeye kwitabira muri ubu bushakashatsi.

UMUKONO

Umukono wawe hepfo werekana uruhushya rwawe rwo kugira uruhare muri ubu bushakashatsi

Izina ry' uwibitabiriye	
Umukono w’ uwitabiriye	Itariki
Umukono w'umuntu usaba ubwemere	Itariki

Umukono wawe hepfo uremeza ko:

- Wumvise ibikubiye muri iyi fishi;
- Wagize amahirwe yo kubaza ibibazo no kwakira ibisubizo byakunyuze;
- Niba bikenewe, wafashe umwanya wo kuganira aya makuru n' abandi kugirango bagufashe guhitamo niba witabira;
- Uzakira ifishi iriho itariki kandi yashyizweho umukono;
- Uremera kwitabira uyu mushinga w' ubushakashatsi.

________________________________	________________________
Izina ryuzuye n’ umukono by’ uwitabira	Itariki n’ ahantu byakorewe
____________________________________	_________________________
Izina ryuzuye n'umukono w'ababyeyi cyangwa umurera wemewe n'amategeko niba uwabajijwe ari muto (> 21)	Itariki n'ahantu byakorewe
________________________________	________________________
Ufasha umwana gusinya niba afite imyaka 9 y’ubukure, imitekerereze n'imiterere y'umubiri	Itariki n' ahantu byakorewe
________________________________	_________________________
Izina ryuzuye n'umukono w' umuntu usaba ubwemere	Itariki n' ahantu byakorewe

Appendix 4: Questionnaire – English Version

Questionnaire

Interview date	
Interviewer Code	
Participant ID Number (PIN)	
What year did you enroll in the HASA program?	

Section 1 - Demographics

No	Questions	Response
1.	How old are you?	___________Years
2.	What is your sex?	Male Female Other
3.	What is your marital status?	Single Married Divorced Widowed
4.	Do you have immediate family members who have podoconiosis?	Yes No I do not know
5.	What is your highest education level?	No education Primary School Secondary School Tertiary School
6.	What is your primary source of income?	Unemployed Farmer Day Laborer Student Business owner Other *(Please specify)* ___________________________________
7.	What is your 'Ubuduhe' category?	1 2 3 4 5 6
8.	Do you have health insurance?	Yes No

Section 2 - Quality of Life

We now want to ask you a series of questions about your condition before joining HASA. We will then ask you questions about your current state. Please feel free to take as much time as you need to recall and answer these questions.

No	Questions	Before HASA	Currently
9.	How often have you felt shame because of the appearance of your feet?	Not at all Seldom Often	Not at all Seldom Often
10.	How often have you felt ashamed that your feet smell badly?	Not at all Seldom Often	Not at all Seldom Often
11.	How often did/do you experience pain related to podoconiosis?	Not at all Seldom Often	Not at all Seldom Often
12.	How often has the condition of your feet stopped you from earning income?	Not at all Seldom Often	Not at all Seldom Often
13.	Did/do you earn enough money to support your basic needs? (food, housing, personal care items, medical bills)	Yes No	Yes No
14.	How often has the condition of your feet stopped you from carrying out your day-to-day household duties? *(e.g., cooking, cleaning, fetching water)*	Not at all Seldom Often	Not at all Seldom Often
15.	How often did/do you feel excluded by your family members because of the condition of your feet?	Not at all Seldom Often	Not at all Seldom Often
16.	How often have you **felt** excluded from religious gatherings because of the condition of your feet?	Not at all Seldom Often	Not at all Seldom Often
17.	How often have you **felt** excluded from social activities such as festivals markets, or other community gatherings because of the condition of your feet?	Not at all Seldom Often	Not at all Seldom Often
18.	How often has podoconiosis led to verbal abuse from your intimate partner? (spouse, boyfriend/girlfriend)	Not at all Seldom Often	Not at all Seldom Often
19.	How often has podoconiosis led to physical abuse from your intimate partner? (spouse, boyfriend/girlfriend)	Not at all Seldom Often	Not at all Seldom Often

20.	How often did/do you experience Adenolymphangioadenitis (Guhindurwa)?	Not at all Seldom Often	Not at all Seldom Often
21.	Did/do you have difficulty moving/bending your ankles?	Not at all Seldom Often	Not at all Seldom Often
22.	Did/does the swelling of your feet or legs reduce overnight?	Not at all Seldom Often	Not at all Seldom Often
23.	Have you noticed any difference in the condition of your feet and leg since joining HASA?	Not at all It has gotten better It has gotten worse	

Section 3 - Adherence

No	Questions	Response
24.	How often do you wash your feet with soap and water?	I do not wash everyday Once Twice or more
25.	What type of floor-covering does the inside of your house have?	Soil Mat/carpet Tiles Concrete Other (*Please specify)* ________________________
26.	Do you wear shoes every time your feet have contact with soil? *(E.g., Moving inside the house, outside working, going to the market)*	Not at all Seldom Often
27.	Do you sleep with your legs raised above your head?	Not at all Seldom Often
28.	Do you apply Vaseline or body lotion every time after you wash your feet?	Not at all Seldom Often
29.	Attendance	Once a month Three times a month Twice a month More than 4 times

Section 4 -Open ended Questions

30.	If you answered “Not at all” or “I do not” for questions 23 – 27, please explain why.

31.	What was good about participating in the HASA program?
32.	What do you think can be improved in the HASA program?
33.	Has your overall wellness changed since participating in the HASA program? Why or why not? *(Probe various reasons other than HASA)*

Now we will have two researchers come separately, to evaluate the condition of your feet and take photographs of your feet.

Section 5 - Staging

		Pre-HASA		
Stage 1	Stage 2	Stage 3	Stage 4	Stage 5

		Post-HASA		
Stage 1	Stage 2	Stage 3	Stage 4	Stage 5

Thank you for your time, do you have any questions for the research team?

____

____

____

Appendix 5: Questionnaire – Kinyarwanda

Urutonde Rw’ Ibibazo

Itariki y’ ikiganiro	
Kode y’ ubaza	
Ibiranga Uwitabiriye Ubushakashatsi (PIN)	
N' uwuhe mwaka wiyandikishije muri gahunda ya HASA?	

Igice cya Mbere - Irangamimerere

No	**Ibibazo**	**Ibisubizo**
1.	Ufite imyaka ingahe	Imyaka ___________
2.	Igitsina	Gabo Gore Ikindi
3.	indangamimerere	Ingaragu Ndubatse Naratandukanye Umupfakazi/Umupfakare
4.	Ufite abo mu muryango wawe barwaye imidido [uburwayi bwo kubyimba amaguru]?	Yego Oya Ntabwo mbizi
5.	Ni uruhe rwego rwo hejuru rw' amashuri ufite?	Ntabwo nize Amashuri abanza Amashuri yisumbuye Kaminuza
6.	N’ubuhe buryo winjirizamo amafaranga?	Umushomeri Umuhinzi Umukozi w’umubyizi Umunyeshuri Nyir'ubucuruzi/Ndikorera Ikindi *(sobanura)* _____________________________________
7.	Icyiciro cyawe cy’ 'Ubuduhe ni ikihe?	1 2 3 4
8.	Ufite ubwishingizi bw'ubuzima?	Yego Oya

Igice cya Kabiri - Ubuzima Bwiza

Muri iki cyiciro turakubaza urutonde rw' ibibazo bijyanye n' ubuzima bwawe mbere yo kwinjira muri HASA. Hanyuma tukubaze ibibazo bijyanye n' uko umerewe ubu. Mushobora kwisanzura ugafata umwanya uhagije wo kwibuka mbere yuko usubiza ibi bibazo.

No	Questions	Mbere ya HASA	None
9.	Ni kangahe wigeze wumva ufite ipfunwe kubera uko ibirenge byawe bigaragara?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
10.	Ni kangahe wigeze wumva ufite isoni zo kuba ibirenge byawe binuka?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
11.	Ni kangahe wigeze/ujya ugira ububabare buterwa n' imidido [indwara yo kubyimba ibirenge]?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
12.	Ni kangahe imiterere y'ibirenge byawe biterwa n’uburwayi yakubujije gukora mu kazi?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
13.	Wabonye /ubona amafaranga ahagije kugirango ubone ibyo ukenera by'ibanze? (ibiryo, aho kuba, ibikoresho byo kwita ku muntu, fagitire yo kwivuza)	Yego Oya	Yego Oya
14.	Ni kangahe imiterere y'ibirenge byawe yakubujije gukora imirimo yawe ya buri munsi? (urugero: guteka, gusukura, kuzana amazi, n’ibindi)	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
15.	Ni kangahe wigeze/ujya wumva ko uhejwe n'abagize umuryango wawe kubera ibirenge byawe?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
16.	Ni kangahe wigeze wumva ko uhejwe mu materaniro y'idini kubera ibirenge byawe?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
17.	Ni kangahe wigeze wumva ko uhejwe mu bikorwa bihuza abantu nk'amasoko, iminsi mikuru, cyangwa andi materaniro y' abaturage kubera uko ibirenge byawe bimeze?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
18.	Ni kangahe uburwayi bw’imidido [indwara yo kubyima ibirenge] yatumye ubwirwa amagambo mabi n' uwo mukundana? (uwo mwashakanye, umukunzi w' umuhungu/ umukobwa)	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
19.	Ni kangahe uburwayi bw’imidido bwatumye ugira ihohoterwa ry' umubiri rikozwe n' uwo mukundana ? (uwo mwashakanye, umukunzi w' umuhungu/umukobwa)	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi

20.	Ni kangahe wigeze uhura na Guhindurwa?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
21.	Wagize/ugira ikibazo cyo kunanirwa kugenda /guhina ikirenge?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
22.	Ese kubyimba ibirenge cyangwa amaguru biragabanuka mw' ijoro?	Nta na rimwe Gake Kenshi	Nta na rimwe Gake Kenshi
23.	Wigeze ubona itandukaniro mu miterere y'ibirenge byawe n'amaguru kuva winjira muri HASA?	Ntaryo/Ntabwo Byarushijeho kuba byiza Byarushijeho kuba bibi	

Igice cya 3 Kubahiriza

No	Ibibazo	Ibisubizo
24.	Ni kangahe woza ibirenge ukoresheje isabune n'amazi ku munsi?	Ntabwo noza buri munsi Rimwe ku munsi Kabiri cyangwa inshuro zirenze kabiri
25.	Mu nzu yawe hasi hubakishije iki?	Igitaka Umusambi/Umucyeka Amakaro Sima Ikindi (*sobanura)* _______________________
26.	Wambara inkweto igihe cyose ibirenge byawe bihuye n' ubutaka? (Urugero: Kugenda imbere mu nzu, hanze ukora, kujya ku isoko)	Nta na rimwe Gake Kenshi
27.	Uryama amaguru yawe aseguye ku buryo aba ari hejuru gato?	Nta na rimwe Gake Kenshi
28.	Ukoresha Vaseline cyangwa amavuta yo kwisiga buri munsi nyuma yo koza ibirenge?	Nta na rimwe Gake Kenshi
29.	Ni kangahe witabira kujya kw' ivuriro rya HASA?	1/Ku kwezi 2/Ku kwezi 3/Ku kwezi Cyangwa birenze 4/ ku kwezi

Igice cya 4 Ibibazo Bifunguye

30.	Niba wasubije "Nta na rimwe" cyangwa "Ntabwo" kubibazo 23 - 27, sobanura impamvu.

31.	Niki cyiza cyo kwitabira gahunda ya HASA?
32.	Niki cyanozwa muri gahunda ya HASA?
33.	Ubuzima bwawe muri rusange bwaba bwarahindutse kuva witabira gahunda ya HASA? Kuki bwahindutse cyangwa butahindutse? (Shakisha impamvu zitandukanye usibye HASA)

Muri iki cyiciro abashakashatsi babiri barasuzuma uko ibirenge byawe bimeze, bafate n'amafoto y'ibirenge byawe.

Igice cya 5 - Ikigero cy' indwara

Mbere ya HASA				
Urwego rwa 1	Urwego rwa 2	Urwego rwa 3	Urwego rwa 4	Urwego rwa 5

Nyuma ya HASA				
Urwego rwa 1	Urwego rwa 2	Urwego rwa 3	Urwego rwa 4	Urwego rwa 5

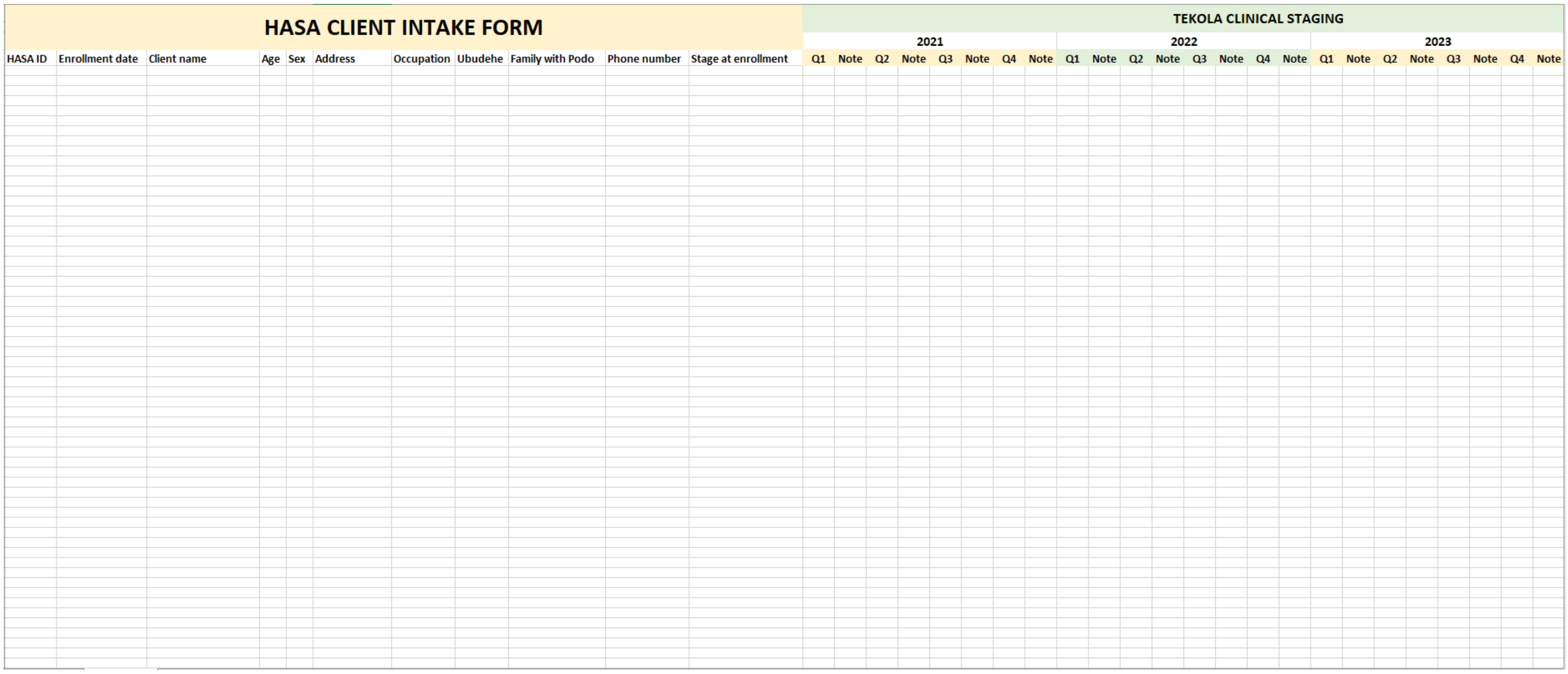
Urakoze ku mwanya wawe, ufite ikibazo kw' itsinda ry' ubushakashatsi?

____

____

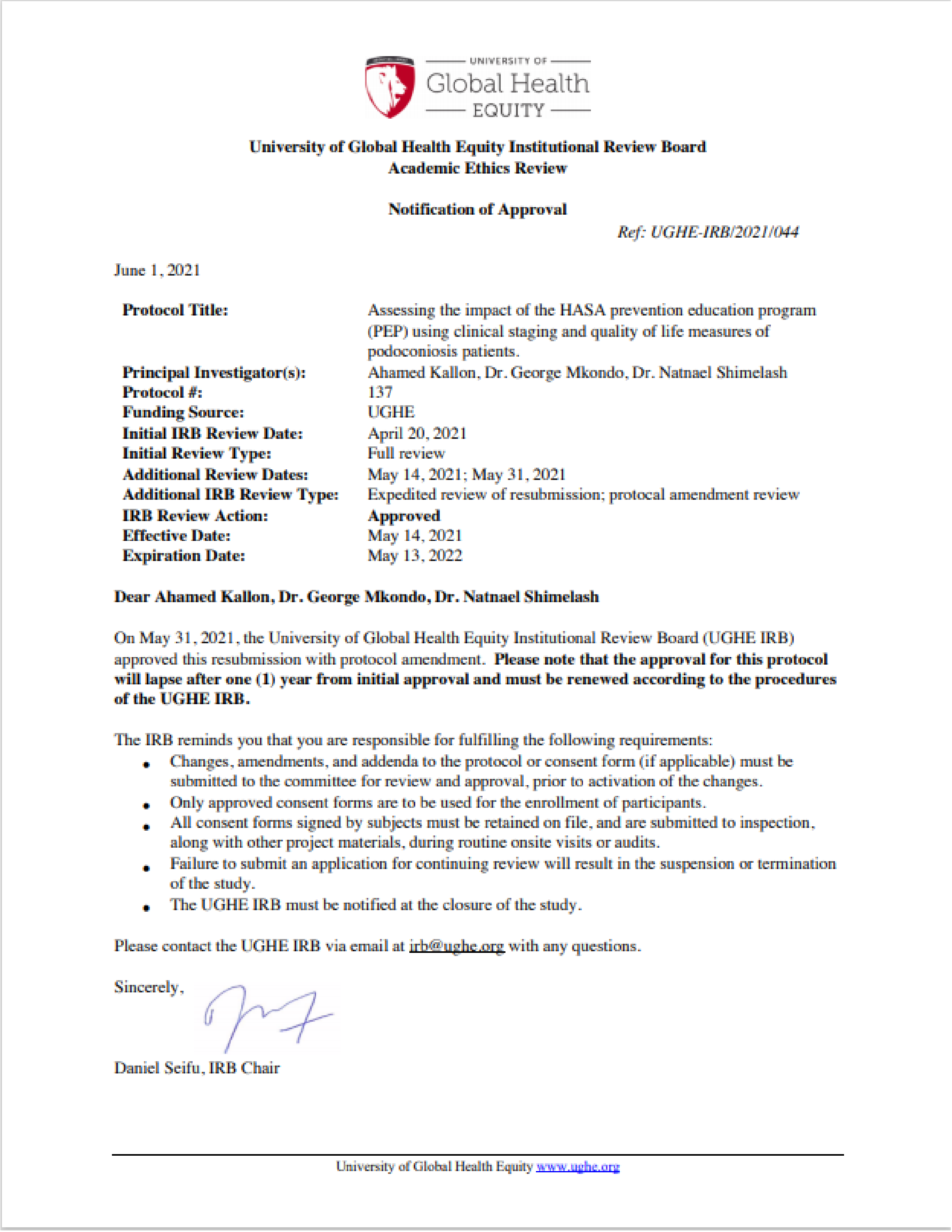
____

Appendix 6: Proposed podoconiosis Excel intake form



HASA CLIENT INTAKE FORM											TEKOLA CLINICAL STAGING																							
											2021								2022								2023							
HASA ID	Enrollment date	Client name	Age	Sex	Address	Occupation	Ubudehe	Family with Podo	Phone number	Stage at enrollment	Q1	Note	Q2	Note	Q3	Note	Q4	Note	Q1	Note	Q2	Note	Q3	Note	Q4	Note	Q1	Note	Q2	Note	Q3	Note	Q4	Note

Appendix 7: IRB Approval



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University of Global Health Equity Institutional Review Board
Academic Ethics Review

Notification of Approval

Ref: UGHE-IRB/2021/044

June 1, 2021

Protocol Title:	Assessing the impact of the HASA prevention education program (PEP) using clinical staging and quality of life measures of podoconiosis patients.
Principal Investigator(s):	Ahamed Kallon, Dr. George Mkondo, Dr. Natnael Shimelash
Protocol #:	137
Funding Source:	UGHE
Initial IRB Review Date:	April 20, 2021
Initial Review Type:	Full review
Additional Review Dates:	May 14, 2021; May 31, 2021
Additional IRB Review Type:	Expedited review of resubmission; protocal amendment review
IRB Review Action:	**Approved**
Effective Date:	May 14, 2021
Expiration Date:	May 13, 2022

Dear Ahamed Kallon, Dr. George Mkondo, Dr. Natnael Shimelash

On May 31, 2021, the University of Global Health Equity Institutional Review Board (UGHE IRB) approved this resubmission with protocol amendment. **Please note that the approval for this protocol will lapse after one (1) year from initial approval and must be renewed according to the procedures of the UGHE IRB.**

The IRB reminds you that you are responsible for fulfilling the following requirements:

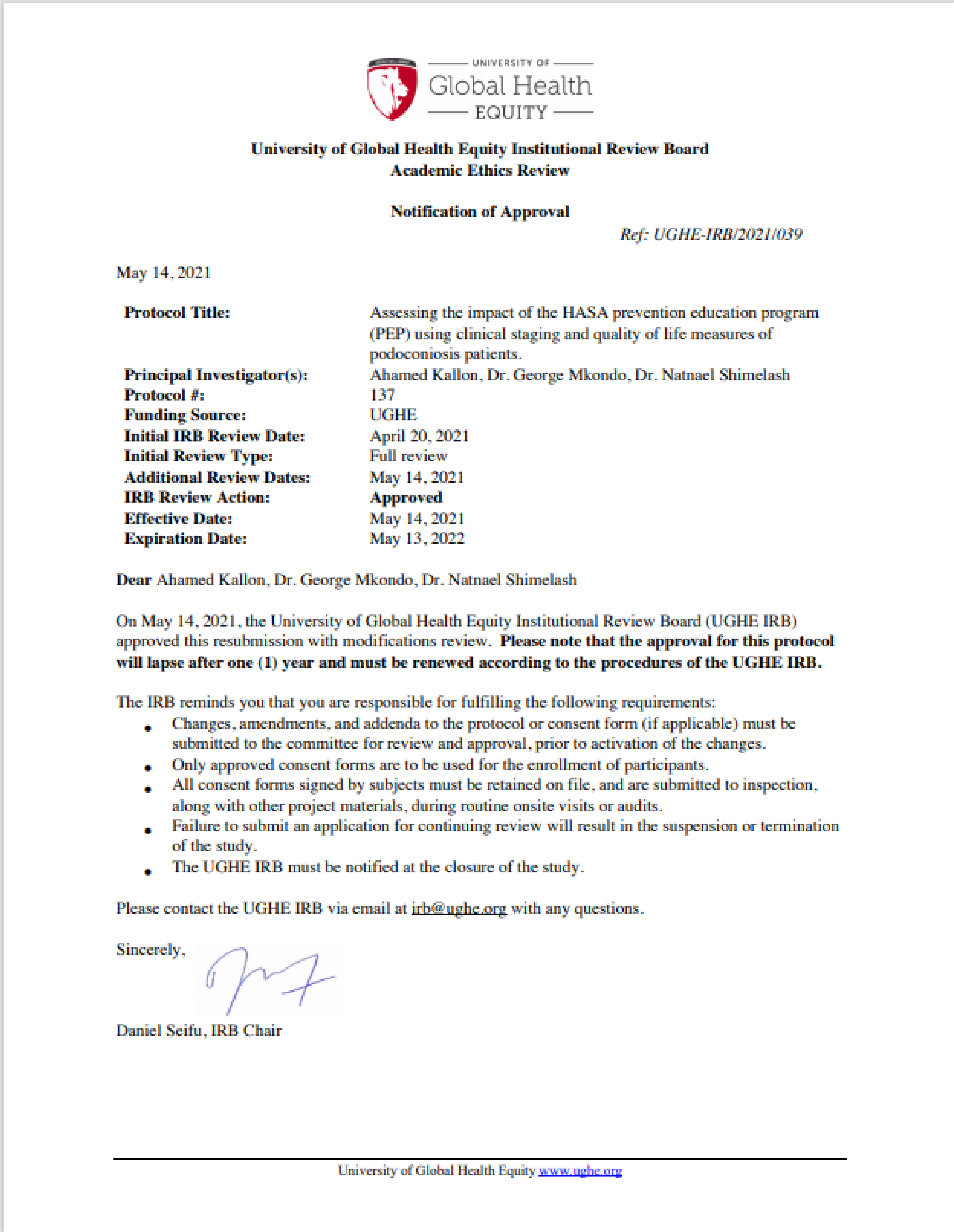
- Changes, amendments, and addenda to the protocol or consent form (if applicable) must be submitted to the committee for review and approval, prior to activation of the changes.
- Only approved consent forms are to be used for the enrollment of participants.
- All consent forms signed by subjects must be retained on file, and are submitted to inspection, along with other project materials, during routine onsite visits or audits.
- Failure to submit an application for continuing review will result in the suspension or termination of the study.
- The UGHE IRB must be notified at the closure of the study.

Please contact the UGHE IRB via email at irb@ughe.org with any questions.

Sincerely,

Daniel Seifu, IRB Chair

University of Global Health Equity www.ughe.org



UNIVERSITY OF
Global Health
EQUITY

University of Global Health Equity Institutional Review Board
Academic Ethics Review

Notification of Approval

Ref: UGHE-IRB/2021/039

May 14, 2021

Protocol Title:	Assessing the impact of the HASA prevention education program (PEP) using clinical staging and quality of life measures of podoconiosis patients.
Principal Investigator(s):	Ahamed Kallon, Dr. George Mkondo, Dr. Natnael Shimelash
Protocol #:	137
Funding Source:	UGHE
Initial IRB Review Date:	April 20, 2021
Initial Review Type:	Full review
Additional Review Dates:	May 14, 2021
IRB Review Action:	**Approved**
Effective Date:	May 14, 2021
Expiration Date:	May 13, 2022

Dear Ahamed Kallon, Dr. George Mkondo, Dr. Natnael Shimelash

On May 14, 2021, the University of Global Health Equity Institutional Review Board (UGHE IRB) approved this resubmission with modifications review. **Please note that the approval for this protocol will lapse after one (1) year and must be renewed according to the procedures of the UGHE IRB.**

The IRB reminds you that you are responsible for fulfilling the following requirements:

- Changes, amendments, and addenda to the protocol or consent form (if applicable) must be submitted to the committee for review and approval, prior to activation of the changes.
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Please contact the UGHE IRB via email at irb@ughe.org with any questions.

Sincerely,

Daniel Seifu, IRB Chair

University of Global Health Equity www.ughe.org