UNIVERSITY of RWANDA

COLLEGE OF MEDICINE & HEALTH SCIENCES
SCHOOL OF MEDICINE & PHARMACY
DEPARTMENT OF SURGERY

THE EFFECT OF HIGH ENERGY NUTRITION SUPPLEMENTATION ON SEVERE BURNS OUTCOME AT KIGALI UNIVERSITY TEACHING HOSPITAL (CHUK)

Dissertation submitted in partial fulfillment of the requirements for the award of the degree of Master of Medicine in General surgery, University of RWANDA

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Kigali, May 30, 2019

DECLARATION

THE RESEARCHER:

I hereby declare that this dissertation **"THE EFFECT OF HIGH ENERGY NUTRITION SUPPLEMENTATION ON SEVERE BURNS OUTCOME AT KIGALI UNIVERSITY TEACHING HOSPITAL (CHUK)."** Is my own work and it has not been submitted by anyone to any other University for the award.

Signed ....

Date: May 30, 2019

Dr Eugene MUNEZA

SUPERVISOR:

I hereby declare that this dissertation:" **THE EFFECT OF HIGH ENERGY NUTRITION SUPPLEMENTATION ON SEVERE BURNS OUTCOME AT KIGALI UNIVERSITY TEACHING HOSPITAL (CHUK)."** Was submitted by Dr Eugene MUNEZA with my approval.

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DEDICATION

To my beloved wife and best friend, INGABIRE Marie Pacifique,

Our Daughter INEZA KAZE Ella Livia,

Our sons MUNEZA Eloi and MUNEZA Elyon

My parents

My brother and sisters,

For your invaluable support.

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LIST OF ABBREVIATIONS

CHUK: Centre Hospitalier Universitaire de Kigali (University Teaching Hospital of Kigali)

LOHS: Length of Hospital Stay

REE: Resting Energy Expenditure

MNA: Mini Nutritional Assessment

TBSA: Total Body Surface Area

UR: University of Rwanda

ICU: Intensive Care Unity

HDU: High Dependent Unit

DALYs: Disability- adjusted life years

LMICs: Low- and middle-income countries

NIs: Nosocomial Infections

WHO: World Health Organization

WFP: World Food Program

UNICEF: United Nations Children's Funds

UN: United Nations

RFW: Rwandan Francs

ABSTRACT

Back ground: Burns are one of the most common forms of trauma, with devastating consequences, prolonged length of hospital stay, increased morbidity and mortality worldwide.
This study aims at identifying the impact of high energy nutrition supplementation on the outcome of severe burn patients.

Methods: This is a before and after intervention study, conducted in 2 phases.
Phase I, was a retrospective assessment of 30 patients with severe burn admitted and followed at CHUK burn unit for the year 2017. During that period, no specific nutrition supplementation was offered in CHUK burn unit.
Phase II, was a post-intervention prospective analysis of 27 patients with severe burn, where, on top of food brought by families, high energy nutrition (plumpy' nut) was supplemented on daily basis by burn Unit. From March 2018 up to January 2019.
The data was collected using a pre- established questionnaire. Analysis done using SPSS version 16.0. Descriptive statistics, student t-test and chi-square test were used where applicable.

Results: The male were predominant in both groups with 56.7% and 55.6% respectively. The majority of patients were children in the age group of 1 to 10 years with 63.4% before intervention and 88.9% after intervention. Scald was the predominant cause of burn in both groups with 53.3% and 77.8% respectively. Partial thickness burn was predominant in both groups with 70% and 74.1% respectively.TBSA between 21% and 30% was predominant for both groups, with 56.6% and 62.9% respectively. Diarrhea was a predominant early side effect on high energy nutrition with 14.8%.Bacilles gram negative (23.3%), klebsiella sp (16.7%), staphylococcus coagulase negative (13.3%) were the predominant isolated pathogens before intervention.Whereas,klebsiella sp(11.1%),pseudomonas aeriginosa(7.4%), staphylococcus aureus(7.4%) were predominant after intervention. The in hospital mortality was predominant in patients with TBSA ranging between 31 and 40% for pre-intervention group (37.5%) and was predominant in patients with TBSA >50% for post-intervention group (66.6%).
The overall in hospital mortality was 26.7% for the pre-intervention group and 11.1% for the post-intervention group, with a significant association (P=0.000).
The mean length of hospital stay was 35.2 days for the pre-intervention group with Std.Dev of 18.3 and was 22 days for the post-intervention group with Std.Dev of 10, with a significant association(P=0.006).

Conclusion: A wide variety of factors may be linked with overall outcome in severe burns. However, early nutrition supplementation with plumpy 'nut has contributed significantly to the reduction in length of hospital stay, morbidity and mortality at CHUK burn unit.
Key words
Nutrition; severe; burn; energy, plumpy'nut

CHAPTER I: INTRODUCTION

1.1 Background

Burn injuries are a global public health problem, accounting for an estimated 200000-300000 deaths annually worldwide[1][2][3]. There are more deaths from scalds, electricity, chemical burns and other forms of burns. Furthermore, death from burn injury in low- and middle-income countries (LMICs) is estimated to be eleven times higher than in high-income countries. Over 95% of fire related burns occur in LMICs and are among the leading causes of disability-adjusted life years(DALYs) lost in LMICs[4][5]**.**

The costs associated with burn injury are higher than those of some other well known health related problems such as stroke and AIDS in industrial countries[6].There is a dearth of literature on the costs associated with burn in LMICs.

The rate of child deaths from burns is currently over 7 times higher in LMICs than in high-income countries.

Seventy five percent of all deaths are currently related to sepsis from burn wound infections or other infection complications in patients with severe burns over more than 40% of total body surface area (TBSA) [7].Seriously burnt patients have an increased risk for nosocomial infections (NIs) due to the nature of burn injury itself and nosocomial infection is the most common cause of death following burns[8].

Burns are one of the most common forms of trauma, with devastating consequences and prolonged length of hospital stay. Moreover, burns are among the traumatic lesions with the highest costs for care due to the their hospitalization time, treatment required and the need for rehabilitation therapy[9].

Burns patients with >20% body surface area injury suffer a long and severe response to injury, including a hyperdynamic and hypermetabolic response with lipolysis,proteolysis and glycolysis.This catabolic state ultimately results in a profound reduction of lean body mass. Poor wound healing, immune dysfunction, multiorgan failure, and even death can ensure[10].

Improved outcomes of severely burnt patients have been attributed to medical advances in fluid resuscitation, nutritional support, pulmonary care, burn wound care and infection control practices [2][11].

In Rwanda, Petroze et al found that among 3599 patients in a trauma registry over a period of 17 months, burns ranked 4th with about 5% of all cases after road traffic crashes, falls and blunt forces[12].

1.2 Problem statement

The survival rates for burn patients have improved substantially in the past few decades due to advances in resuscitations, nutritional support, pulmonary care, wound care, and infection control practices in specialized burn units.

Severe burn is a life-threatening surgical emergency at CHUK, bearing a significant morbidity and mortality. Data got from patients records in burn unit CHUK for the year 2016 revealed in hospital mortality of 28.8% and a mean length of hospital stay of 37.8days.
The burden of burns disproportionately falls to the world's poor residing in low and middle income countries.

Like many other hospitals operating in low- and middle-income countries, most of patients with severe burn who present to CHUK are of poor socio-economic status may even not manage to get adequate nutritional daily calorie requirement for severe burn survival.

1.3 Study justification

Although nutrition therapy was found to be a cornerstone of burn care from early resuscitation phase until the end of rehabilitation[13],meeting daily nutrition requirement is a big challenge for severe burn patients at CHUK burn unit, due to the fact that hospital doesn't provide food for patients, every patient struggle to get food depending on patient or family means .
Data got from patients records in burn unit CHUK, for the year 2016 revealed a high mortality and increased length of hospital stay compared to other specialized burn units for such category of patients.

Furthermore, adequate management of severe burn patients with only 10 beds is a big challenge for the CHUK burn unit, that require tight measures in optimizing nutrition, control infection, early surgical management with a target to decrease the length of hospital stay, morbidity and in hospital mortality in those patients.

By doing this study we aim to establish a nutrition protocol which can help in improving outcome in patients with severe burn.

1.4 Research question

What is the effect on outcomes to supplement severely burn patients with high energy nutrition (plumpy'nut)?

1.5 Objectives of the study

1.5.1 General objective

To improve outcomes of burn patients at CHUK.

1.5.2 Specific objectives

1. To describe epidemiological profile of severe burn patients at CHUK.
2. To determine the impact of high energy nutrition supplementation on the length of hospital stay, morbidity and in hospital mortality in severe burn patients.
3. To determine the microbial profile isolated from severe burn patients.

CHAPTER II. LITERATURE REVIEW

1. Introduction

Worldwide, burn injury is a problem. Annually more than 310000 people die as a result of fire-related burns. Furthermore, death from burn injury in low- and middle-income countries (LMICs) is estimated to be eleven times higher than in high-income countries. Over 95% of fire related burns occur in LMICs and are among the leading causes of disability-adjusted life years(DALYs) lost in LMICs[4][5].

Severely burned patients have active catabolism and high levels of energy consumption that may result in progressive weight loss, immune dysfunction, visceral organ dysfunction, delayed wound healing, or death[14].

The goals of nutritional support include[15]:

Optimal wound healing and rapid recovery from burn injuries, restore visceral and somatic protein losses, minimize complications including infection and to attain and maintain normal nutritional status.

2. Pathophysiology of burn

2.1. Fluid loss

In the early phase of burns >20% of body surface, there is a transient massive increase in capillary permeability, which result in plasma loss from the intravascular space into the extra vascular compartment, which causes the generalized edema in major burns. The loss is proportional to the extent of injury. The permeability changes last for about 24h, being maximal during the first 12h and this results in extensive fluid requirements [16].

2.2. Metabolic response

Immediately after injury, there is a period of hemodynamic instability with reduced tissue perfusion, and release of high levels of catecholamine. This initial phase is known as “ebb phase “It is mainly characterized by a lowered total oxygen consumption and low metabolic rate.

The initial phase is progressively replaced by the "flow phase "characterized by high oxygen consumption, elevated resting energy expenditure (REE), elevated substrate flows and accelerated potassium and nitrogen losses. Visceral blood flow ,total cardiac output and splanchnic oxygen consumption increase[16][17].

It was reported that patients with severe burns are characterized by [3].

- Metabolic rate is elevated to 118% to 210% in adults
- Resting metabolic rate elevated to approximately 180%

The recovery phase starts when the acute phase declines and the burned surface are covered. In this phase, high levels of energy are required to cope with physical rehabilitation, and completion of wound healing. For severe burn this phase may last up to 2 years[16].

2.3. Proteins metabolism in burn patients

Post-burn, muscle protein is degraded much faster than it is synthesized[18].

Persistent muscle protein catabolism is a major problem in severely injured patients.

Over the first 21 days after injury, critically ill trauma patients lose up to 16% of their total body protein content despite full nutritional support [16][19].

Mortality and morbidity in relation to loss of lean body mass post-burn[3] [17][18]:

Percent loss of Lean mass	complications	Mortality
10%	Impaired immunity Increased infection	10%
20%	Decreased wound healing, weakness, infection	30%
30%	Pressure ulcer, Pneumonia	50%
40%	Death commonly due to pneumonia	100%

An accurate knowledge of energy consumption is necessary for development of adequate targeted nutritional intervention[18][20] [21].

2.4. Glucose metabolism in burn patients

During the early post burn phase, hyperglycemia occurs as a result of increased rate of glucose appearance, along with an impaired tissue extraction of glucose, this result in an overall increase of glucose and lactate[3].

The resultant hyperglycemia is associated with increased infections, increased risk of sepsis and increased incidence of pneumonia, increased catabolism and hyper metabolism; as a result there is increased post burn mortality[3][17].

2.5. Energy requirements

There is an important and prolonged hyper metabolic response in patients with severe burn injuries which is grossly proportional to the severity of the injury. This response is due to the endocrine stress response, the classical factors age and sex,the inflammatory response, and the extent and timing of wound healing[13][17][21].

After major burn, the energy requirements are significantly increased above basal resting energy expenditure (REE) and it is grossly proportional to the burned body surface area (TBSA).

The concept of hyper alimentation was developed for burn patients in the 1970s, and many formulae were devised to assess the energy requirements.

As both under feeding and overfeeding have deleterious consequences, accurate assessment of REE is desirable to adjust the individual caloric intake,particulary in patients the access to indirect calorimetric determination of REE is recommended[16].

Daily caloric requirements are frequently estimated using the CURRERI formula in patients with severe burn[2]:

The adult daily caloric requirement is: 25Kcal/Kg+40Kcal/% burn.

The children daily caloric requirement is: 60kcal/kg+35 kcal/% burn.

2.6. Plasma albumin in burn patients

During the acute-phase response, the plasma albumin levels decrease and the fractional synthesis increase. After injury, during the early phase serum concentrations are frequently below 20g/l due to increased capillary permeability and fluid dilution, as well as increased catabolism.

For many weeks, serum albumin remains between 25 and 30 g/l and, this is well tolerated. There is no data supporting providing albumin to burn patients on a systematic basis[16].

3. Nutrition

Aggressive, early enteral feeding improves outcomes in burn patient, by mitigating the degree and extent of catabolism. Enteral nutrition reduces translocation of bacteremia and sepsis[22][23].

3.1. Enteral nutrition in burn patient

Enteral nutritional support should be initiated as early as possible to optimize total burn care and decrease long-term morbidity. Early enteral feeding within the first 12 hours after injury is an integral part of initial resuscitation of burn management [3].

Late introduction of enteral feeding in severely burned patients, leads to increased mortality. Absence of food in the intestinal lumen leads to impaired function of the immune system and the development of the inflammatory response[24][25][10].

3.2. Micronutrient requirements

There are increased micronutrient requirements in patients with major burns; this is due to the hyper metabolic response, to wound healing requirements and to the significant cutaneous exudative losses which characterize burns with open wounds.[13][16].

3.3. Antioxidants supplementation

Severely burned patients incur significant oxidative stress due to both the injury and fluid resuscitation early in the treatment process. In order to protect organs against this oxidative stress, antioxidants that scavenge free radicals or inhibit their formation need to be provided to the burn patients. Antioxidant therapies such as, ascorbic acid; glutathione; N-acetyl-L-cysteine; vitamins A, C and E; alone or in combination have been proven to protect microvascular circulation, mitigate changes in cellular energetic ,decrease tissue lipid peroxidation and decrease the volume of fluid required for resuscitation[26].

3.4. Trace Elements

Copper, iron, selenium and zinc are trace elements that play on important role in the recovery of burn patients. In burns, early copper, selenium and zinc supplementation for 8-14 days has been associated with a reduction of lung infections complications, and antioxidant supplementation has also been linked to shorter duration of mechanical ventilation and ICU stay [27].

3.5. Carbohydrate

The provision of adequate amounts of carbohydrates is important for the preservation of lean body mass in the burn population as it spares protein from being used as an energy source [28].

3.6. Nutrition in children with burn.

Children's high metabolic rate and growth needs result in less tolerance to nutritional deprivation. Therefore, enteral feeding on day 1 decreases stress hormone release, improves nitrogen balance, maintains gut mucosal integrity, lowers the incidence of diarrhea and decreases hospital stay[29].

4. Nutrition assessment tools

4.1. MNA (Mini Nutritional Assessment tool) in adults

It is a convenient tool, not only assessing but also screening for the nutritional status. It is commonly used to measure the risk of malnutrition in older- adults[30](see Appendix I).

4.2. Z SCORE in children

The WHO 2005, define weight for height as accurate tool to assess nutritional status in children[31].

5. Plumpy'Nut composition and Price

Plumpy'Nut is a lipid based ready to use therapeutic food, specifically formulated for nutritional rehabilitation of children from six months of age and adults suffering from severe acute malnutrition[32].

Composition of plumpy 'nut (WHO, WFP, UNICEF, UN standing commit on nutrition, joint declaration may, 2007):

Moisture content	2.5% maximum	Vitamin D	15–20 µg/100 g
Energy	520–550 Kcal/100 g	Vitamin E	20 mg/100 g minimum
Proteins	10%–12% total energy	Vitamin K	15–30 µg/100 g
Lipids	45%–60% total energy	Vitamin B1	0.5 mg/100 g minimum
Sodium	290 mg/100 g maximum	Vitamin B2	1.6 mg/100 g minimum
Potassium	1,110–1,400 mg/100 g	Vitamin C	50 mg/100 g minimum
Calcium	300–600 mg/100 g	Vitamin B6	0.6 mg/100 g minimum
Phosphorus (excluding phytate)	300–600 mg/100 g	Vitamin B12	1.6 µg/100 g minimum
Magnesium	80–140 mg/100 g	Folic acid	200 µg/100 g minimum
Iron	10–14 mg/100 g	Niacin	5 mg/100 g minimum
Zinc	11–14 mg/100 g	Pantothenic acid	3 mg/100 g minimum
Copper	1.4–1.8 mg/100 g	Biotin	60 µg/100 g minimum
Selenium	20–40 µg	n-6 fatty acids	3%–10% of total energy
Iodine	70–140 µg/100 g	n-3 fatty acids	0.3%–2.5% of total energy
Vitamin A	0.8–1.1 mg/100 g	Vitamin D	15–20 µg/100 g

With reference to **WFP and UNICEF** report, the price of plumpy 'nut is **50$ for 150 packets/box** (which is around 0.30$ or 265 RWF per one packet).

CHAPTER III.METHODS

3.1. Study Design

This is a before and after study, conducted in 2 phases:

- Phase I**,** was a pre-intervention (retrospective) study where we assessed the outcome of severe burn patients for the year 2017, with the purpose to get the baseline data on the outcome of severe burn patients without any specific intervention.
- Phase II, was a post-intervention study, where we assessed severe burn patients after the intervention period. In that phase, severe burn patients fed as usual depending on patient or family means (normally 3 food per day) plus total daily calories of high energy nutrition based on calculated daily energy requirement by CURRERI formula by the burn unit team with the support of nutritionist.
- Thereafter, we compared the outcomes of study participants investigated before the intervention with those measured afterwards.
- The primary outcome of interest was length of hospital stay; morbidity and mortality were evaluated as secondary outcomes.

3.2. Study setting

The study was conducted in the department of surgery at University Teaching Hospital of Kigali (CHUK), a national referral hospital. The hospital has a capacity of 513 beds and the department of surgery accounts 170 beds. The burn unit accounts 10 beds and accommodates burn patients who are not requiring critical care services admission.

3.3. Study Population

All patients ≥1 year with severe burn injuries admitted to the burn unit of University Teaching Hospital Kigali who met the inclusion criteria during the time period of the study.

3.4. Selection of the study population

3.4.1. Inclusion criteria

Any adult or pediatric patient ≥ 1 year of age admitted to CHUK burn unit with a severe burn.

Severe burn was defined as a patient with TBSA>20%.To determine the size of burned area, we used the WALLACE's "rule of nines"(adult) and modified WALLACE's(children) (see appendix III).

For the retrospective part, we included all patients with acute severe burn treated at CHUK burn unit for the year 2017.

For the post-intervention group, we included patients with acute severe burn admitted at CHUK burn unit from March 2018.

Patients meeting the inclusion criteria were consecutively enrolled in the study until the sample size was achieved.

3.4.2. Exclusion Criteria

Children less than 1 year of age (as they are mostly still dependent to breast feeding only).

Patients already admitted in burn unit when the study is approved were also excluded.

Patients with electrical burn (as most injuries are internal, estimation of Total burn surface area is not accurate, and associated complications which may impair the outcome lead us to exclude this category of burn).

3.5. Sample Size calculation

Assuming a baseline mean length of hospital stay of 35 days with a standard deviation of 18 days .Assuming alpha of 0.05, power 80%, two-sided test.

We need a sample size of 18 patients for the post-intervention group to detect a decrease of 15 days in LOHS.

Sample size calculation:

		Intervention LOHS			
		20days	25days	30days	35days
Baseline LOHS	30days	37	141	-------	-------
	35days	18	37	141	-------
	40days	11	18	37	141
	45days	-------	11	18	37

For our study as the sample size of 18 patients gave a power of 80%, by using two-sided test, in order to get a power of 95% we calculated the sample size of 27 patients for the post intervention group.

3.6. Data collection and management

A. Pre-intervention group

Data were collected through data collection form using hospital patients' records. Data administered in the questionnaire included variables (appendix IV).

B. Post-intervention group

Data were collected using a structured questionnaire by the investigator. Data administered in the questionnaire included variables (appendix V).

A thorough physical examination was performed. Attention was directed toward MNA for adults (appendix II) and Z-scores (weight for height) for children (appendix I).

Upon admission, each patient's nutritional status was assessed and patients were categorized as malnourished, at risk for malnutrition or good nutritional status in accordance with the Mini Nutritional Assessment (Long form) score and Z score (Weight for Height).

On day one of admission every patient who met the inclusion criteria received plump 'nut enteraly on daily basis up to discharge, for those who were not able to fed themselves a nasogastric tube was inserted and feeding was started .

Either the attendant or patient answered all the questions depending on the age and the condition of the patient.

The same assessment was done prior to discharge to assess the impact of burn on change in nutritional status during the hospitalization.

Sample for cultures were taken at discretion of the treating physician based on clinical presentation of the patient and weekly albumin was taken.

The outcome was documented and compared with burn severity and clinical status.

3.7. Statistical analysis

Analysis was done using SPSS version 16.0.Descriptive statistics were used for prevalence, description of demographic and other baseline characteristics of the population under trial.

Student t-tests were used for continuous variables and Chi-square tests was used for categorical variables to test for associations between groups. A p-value below 0.05 was considered significant for any association.

3.8. Recruitment and data collection tools

Patients enrolled upon presentation to the CHUK Burn Unit and upon completion of informed consent document. A Mini Nutritional Assessment (Long form) for adult, Z score for children and data collection sheet were used to gather required information.

3.9. Ethical considerations

For the intervention part, Informed consent was obtained from the patients (or next of kin) before enrollment into the study.

Ethical approval for this study was sought from the Ethics & research committee, Department of Surgery, and University of Rwanda institutional review board (IRB).

We expect no harm to patients in the study because the high energy nutrition (plump ‘nut) we used is known as good nutritional supplement and well tolerated by children aged >6 months and adults based on World Food Program(WFP) and World Health Organization(WHO) report 2007.

All patients who met the inclusion criteria received high energy nutrition freely, because we got a support from CHUK nutritional service.

The information obtained was confidential, and only used for the purpose of this study.

3.10. Limitations of the study

For the pre-intervention group, the fact of being a retrospective study some data may be missing in patients records.

Delays in the referral system and poor initial management at district hospitals may affect the morbidity and mortality, and may influence patient outcomes.

3.11. Benefits

There were some benefits for individual patients involved in the research because they received nutritional supplement in terms of plump ‘nut. There was no financial compensation for patients or families to be enrolled in the study. There was no cost to the patient to receive the nutrition supplementation.

3.12. Conflict of interests

The principle investigator and co-investigators of this study declare to have no conflict of interests and no proprietary interests.

3.13. Dissemination of Research Findings

All research results were shared with study collaborators and the institution.

The collaborators strived to produce quality publications in regional or international journals.

CHAPTER IV: RESULTS

Figure 1: Distribution according to Sex

Male were predominant in both groups with 56.7% and 55.6% respectively.

Table 1: Distribution according to Age

Age group	**Pre-intervention Group**		**Post-intervention Group**	
	Frequency	**Percentage**	**Frequency**	**Percentage**
1-10	19	63.4	24	88.9
11-20	3	10	0	0
21-30	4	13.3	0	0
Above 30	4	13.3	3	11.1
Total	30	100	27	100

The majority of patients were in the age group of 1 to 10 years with 63.4% and 88.9% for both groups respectively.

Table 2: Cause of Burn

Cause of Burn	Pre-intervention Group		Post-intervention Group	
	Frequency	Percentage	Frequency	Percentage
Scald	16	53.3	21	77.8
Flame	14	46.7	6	22.2
Total	30	100	27	100

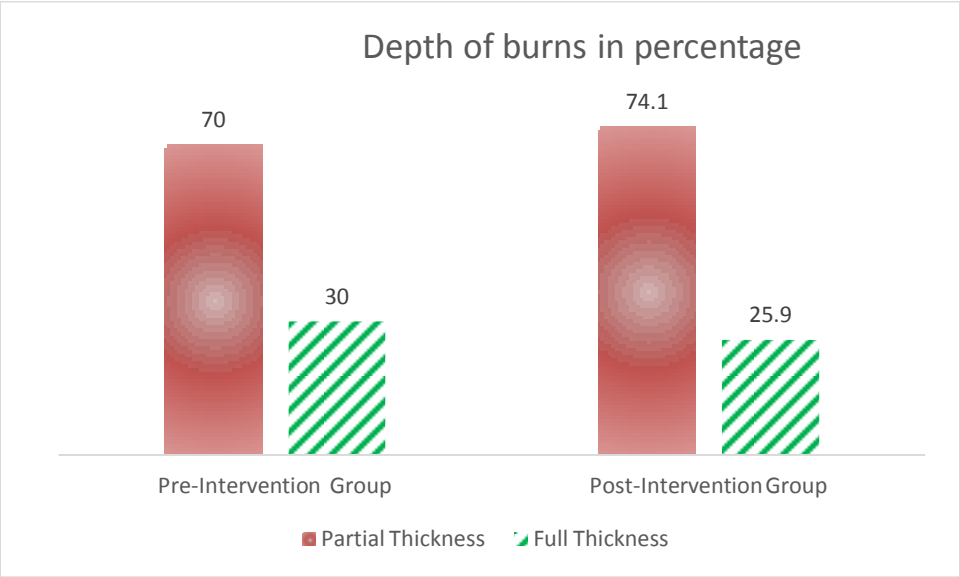
Scald was the predominant cause of burn in both groups with 53.3% and 77.8% respectively.

Table 3: Extent of Burn surface area

Extent of burn surface area (%)	Pre-intervention Group		Post-intervention Group	
	Frequency	Percentage	Frequency	Percentage
21-30	17	56.6	17	62.9
31-40	9	30	7	25.9
41-50	2	6.7	1	3.7
Above 50	2	6.7	2	7.5
Total	30	100	27	100

TBSA between 21 % and 30 % was predominant for both groups, with 56.6% and 62.9% respectively.

Figure 2: Depth of Burn



Partial Thickness was predominant in both groups, with 70% and 74.1% respectively.

Table 4: Modality of treatment

Modality of treatment	Pre-intervention Group		Post-intervention Group		Chi-square
	Frequency	Percentage	Frequency	Percentage	p-value
Skin graft	12	54.5	11	45.8	
Secondary intention	10	45.5	13	54.2	
Total	22	100	24	100	0.000

In survivors, skin graft was the predominantly used modality of treatment in pre-intervention group with 54.5%, whereas healing by secondary intention was predominant in post-intervention group with 54.2%. There was a significant association with P-value of 0.000

Table 5: Nutritional assessment for children at admission and discharge (Post-intervention group)

Weight for Height Z Score(children)	Nutritional assessment at admission		Nutritional assessment at discharge		Chi-square
	Frequency	Percentage	Frequency	Percentage	p-value
-1<WHZ<0(normal, well nourished)	21	87.5	16	72.8	
-2<WHZ<-1(Mildly Malnourished)	2	8.3	5	22.7	
-3<WHZ<-2(Moderately Malnourished)	1	4.2	1	4.5	0.000
WHZ<-3(Severely wasted /malnourished)	0	-	0	-	
Total	24	100	22	100	

The nutritional assessment in children at admission and discharge for the post-intervention group revealed that the majority of children were well nourished at admission compared to discharge nutrition status with 87.5% and 72.8% respectively. We noted also that more children were mildly malnourished at discharge compared to the admission status with 22.7% and 8.3% respectively. There was a significant association with P-value of 0.000

Table 6: Nutritional assessment for adult at admission and discharge (post-intervention group)

MNA Score(adults)	Nutritional assessment on admission		Nutritional assessment on discharge	
	Frequency	**Percentage**	**Frequency**	**Percentage**
Less than 17 points	0	0	0	-
17 to 23.5 points	1	33.3	1	50
24 to 30 points	2	66.7	1	50
Total	3	100	2	100

For post-intervention group, nutrition assessment in adult using MNA score revealed that at admission 66.7% were with normal nutritional status and 50% were with normal nutrition status at discharge.

Table 7: Albumin (g/l) variability (post-intervention group)

	Obs	**Mean**	**Std. Dev.**	**Min**	**Max**
Week1	27	17.9	4.5	8.8	30
Week2	26	23.8	6.5	12.2	39.8
Week3	24	29.3	6.1	14.5	36
Week4	15	32.1	5.4	22.1	39
Week5	1	35.7	.	35.7	35.7
Week6	1	37.0	.	37	37

We noted that albumin increased as number of weeks increase from 17.9 g/l first week of admission to 37.0 g/l last week.

Table 8: Early side effect on high energy nutrition supplementation (post-intervention group)

	Frequency	**Percentage**
Diarrhea	4	14.8
Vomiting	3	11.1
None	20	74.1
Total	27	100

Diarrhea was a predominant early complication on high energy milk with 14.8%.

Table 9: Estimate of daily energy requirement-Kcal/day (post-intervention group)

Kcal/day	Frequency	Percentage
1000-1450	9	33.3
1500-2000	11	40.8
Above 2000	7	25.9
Total	27	100

The predominant estimated daily energy requirement ranged between 1500 to 2000 Kcal/day with 40.8%.

Table 10: Estimate of daily plumpy 'nut cost (post-intervention group)

Rfw	Frequency	Percentage
100-450	6	22.2
500-1000	19	70.4
Above 1000	2	7.4
Total	27	100

The estimated daily cost of plump 'nut was predominantly ranging between 500 to 1000Rfw with 70.4%

Table 11: Estimate of total plumpy' nut cost (post –intervention group)

Rfw	Frequency	Percentage
1000-4900	1	3.7
5000-9900	6	22.2
10000-14900	11	40.8
15000-20000	6	22.2
Above 20000	3	11.1
Total	27	100

The total cost of plump 'nut during hospital stay was predominantly ranging between 10000 and 14900Rfw, with 40.8%.

Table 12 : Difference in complications between 2 groups

Complications	Yes/No	Pre-intervention Group		Post-intervention Group		Chi-square
		Frequency	Percentage	Frequency	Percentage	p-value
Sepsis	Yes	10	33.3	5	18.5	0.001
	No	20	66.7	22	81.5	
	Total	30	100	27	100	
Pneumonia	Yes	8	26.7	4	14.8	0.001
	No	22	73.3	23	85.2	
	Total	30	100	27	100	
Wound infection	Yes	8	26.7	5	18.5	0.000
	No	22	73.3	22	81.5	
	Total	30	100	27	100	
Acute renal failure	Yes	5	16.7	2	7.4	0.002
	No	25	83.3	25	92.6	
	Total	30	100	27	100	
Burn eschar	Yes	6	20.0	3	11.1	0.001
	No	24	80.0	24	88.9	
	Total	30	100	27	100	
Multiorgan failure	Yes	4	13.3	1	3.7	0.015
	No	26	86.7	26	96.3	
	Total	30	100	27	100	

For the pre-intervention group, sepsis, pneumonia, wound infection were the predominant complications with 33.3%, 26.7%, 26.7% respectively.

Whereas, for the post-intervention group, sepsis, wound infection, pneumonia were the predominant complications with 18.5%, 18.5%, 14.8% respectively.

There was a significant association with P-value <0.05 for all components.

Table 13: Isolated pathogens in wound swab, urine, blood cultures comparison between 2 groups

		Pre-intervention Group		Post-intervention Group		Chi-square
	Yes/No	Frequency	Percentage	Frequency	Percentage	p-value
	Yes	5	16.7	3	11.1	
	No	25	83.3	24	88.9	
Klebsiella Sp	Total	30	100.0	27	100.0	0.000
	Yes	3	10.0	1	3.7	
Candidans	No	27	90.0	26	96.3	
albicans	Total	30	100.0	27	100	0.004
	Yes	1	3.3	3	11.1	
Pseudomonas	No	29	96.7	24	88.9	
aeriginosa	Total	30	100.0	27	100	0.004
	Yes	3	10.0	1	3.7	
	No	27	90.0	26	96.3	
E. coli	Total	30	100.0	27	100	0.004
	Yes	3	10.0	1	3.7	
Acinetobacte	No	27	90.0	26	96.3	
r Sp	Total	30	100.0	27	100	0.004
Bacilles	Yes	7	23.3	2	7.4	
Gram	No	23	76.7	25	92.6	
negative	Total	30	100.0	27	100	0.013
Staphylococc	Yes	4	13.3	1	3.7	
us coagulase	No	26	86.7	26	96.3	
negative	Total	30	100.0	27	100	0.015
	Yes	3	10.0	1	3.7	
	No	27	90.0	26	96.3	
Proteus Sp	Total	30	100.0	27	100	0.004
	Yes	3	10.0	2	7.4	
Staphylococc	No	27	90.0	25	92.6	
us aureus	Total	30	100.0	27	100	0.000

For the pre-intervention group, bacilles gram negative, klebsiella sp, staphylococcus coagulase negative were the predominant isolated pathogens with 23.3%, 16.7%, 13.3% respectively.
Whereas, for the post-intervention group, klebsiella sp, pseudomonas aeriginosa, staphylococcus coagulase negative, staphylococcus aureus were the predominant isolated pathogens with 11.1%,7.4%,7.4%,7.4% respectively.
There was a significant association with P-value <0.05 for all components.

Table 14: ICU/HDU admission

	Pre-intervention Group		**Post-intervention Group**		**Chi-square**
	Frequency	**Percentage**	**Frequency**	**Percentage**	**p-value**
Yes	11	36.7	5	18.5	0.003
No	19	63.3	22	81.5	
Total	30	100	27	100	

The ICU/HDU admission was more noted in the pre-intervention group with 36.7%, whereas, for the post-intervention group was 18.5%. There was a significant association with P-value of 0.003.

Table 15: outcome

	Pre-intervention Group		**Post-intervention Group**		**Chi-square**
	Frequency	**Percentage**	**Frequency**	**Percentage**	**p-value**
Discharge	22	73.3	24	88.9	0.000
Dead	8	26.7	3	11.1	
Total	30	100	27	100	

For the pre-intervention group the mortality was 26.7%, whereas for the post-intervention group the mortality was 11.1%. There was a significant association with P-value of 0.000.

Table 16: Correlation TBSA-in hospital mortality

Extent of burn surface area (%)	**Pre-intervention Group**		**Post-intervention Group**	
	Frequency/Dead	**Percentage**	**Frequency/Dead**	**Percentage**
21-30	2	25	0	0
31-40	3	37.5	1	33.4
41-50	1	12.5	0	0
Above 50	2	25	2	66.6
Total	8	100	3	100

The in hospital mortality was predominant in patients with TBSA ranging between 31 and 40%, for pre-intervention group (37.5%) and was predominant in patients with TBSA >50% for post-intervention group (66.6%).

Table 17: Length of hospital stay

Table 17.1

Length of stay	**Obs**	**Mean**	**Std. Dev.**	**Min**	**Max**
Pre-Intervention Group	30	35.2	18.3	2	84
Post-Intervention Group	27	22.0	10.0	4	53

The mean length of hospital stay was 35.2 for the pre-intervention group with Std.Dev of 18.3 and the mean length of hospital stay was 22 for the pre-intervention group with Std.Dev of 10.

Table 17.2

	Paired Differences							
Length of hospital stay	Mean	Std. Deviation	Std. Error Mean	95% Confidence Interval of the Difference		t	df	Sig. (2-tailed)
				Lower	Upper			
Pre-Intervention Group*Post-Intervention Group	13.852	24.121	4.642	4.310	23.394	2.984	26	.006

The mean length of hospital stay for the pre-intervention group was 35.2, whereas for the post-intervention group was 22.0, there is a statistical difference in length of hospital stay for the 2 groups as shown by a P-value of 0.006.

CHAPTER V: DISCUSSION

Burns are among the most serious and significant health problems worldwide and cause considerable physical, psychological and economical losses.

In our study, Children between 1 to 10 years account for a large proportion of the populations with severe burn injury, with 63.4% and 88.9% respectively for the pre- and post-intervention study. These data were similar to data from other studies[33].

Males were predominant in both pre- and post-interventions group with 56.7% and 55.6% respectively, these data were similar to data from other studies[33][34][35].

In our study, TBSA between 21 % and 30 % was predominant for both groups, with 56.6% before intervention and 62.9 % after intervention. The in hospital mortality was predominant in patients with TBSA ranging between 31 and 40% for pre-intervention group (37.5%) and was predominant in patients with TBSA >50% for post-intervention group (66.6%).There is a similarities to the results of a study done in North Carolina/US where they report that increases in TBSA increased inpatient mortality, they found that a 20% TBSA increased mortality almost 3 times, a 40% TBSA increased mortality almost 9 times and a 60% TBSA increased mortality almost 20 times[36].A study done in Israel also report a strong correlation between the TBSA and mortality[37].

Scalding followed by flame were the most common cause of burn injuries in different studies, in Palestine scalding was 66.2% and flame was 23.8 %[33], In China scalds 42.27% and flame 40.59 %[38].These are similar to our results where scalds (53.3%, 77.8%) and flame (46.7%, 22.2%) respectively for both phases.

For the post-intervention group, the nutritional assessment in children at admission and on discharge using the weight for height z score, revealed that the majority of children were well(normal) nourished at admission compared to discharge nutrition status with 87.5% well nourished at admission and 72.8% well nourished on discharge. We noted also that more children were mildly malnourished at discharge with 22.7% and 8.3% were mildly malnourished on admission. There was a significant association with P=0.000.

For post-intervention group, nutrition assessment in adult using MNA score revealed that at admission 66.7% were with normal nutritional status and 50% were with normal nutrition status at discharge. We noted that despite intervention, severe burn still affects the nutrition status of children and adults during the course of hospital stay. There is a dearth of literature in this regard in LMICs to compare with our results.

For the post-intervention group, we noted that serum albumin increased as number of weeks increase from 17.9 g/l first week of admission to 37.0 g/l last week(6^{th} week), these results have similarities to the results of a study done in Switzerland[16] where they reported that, after injury, during the early phase serum concentrations are frequently below 20g/l due to increased capillary permeability and fluid dilution, as well as increased catabolism. For many weeks, serum albumin remains between 25 and 30 g/l and, this is well tolerated.

For the pre-intervention group, the predominant organisms isolated were bacillus gram negative (23.3%), klebsiella(16.7%),staphylococcus coagulase negative(13.3%).For the post-intervention group, the predominant organisms isolated were pseudomonas aeriginosa (11.1%),klebsiella Sp(11.1%) and bacillus gram negative(7.4%) .We found a statistically significant association in all elements for both group with $P<0.05$.A study done in Ghana[39]the predominant organisms isolated were pseudomonas sp(30.2%),Acinetobacter sp(20.9%) . A study done in Nepal[40], staphylococcus aureus (28.0%),klebsiella (16.0%),pseudomonas(13.0),these results have similarities with our study.

For the pre-intervention group, sepsis, pneumonia, wound infection were the predominant complications with 33.3%, 26.7%, 26.7% respectively.

Whereas, for the post-intervention group, sepsis, wound infection, pneumonia were the predominant complications with 18.5%, 18.5%, 14.8% respectively. We found a statistically significant association in all elements for both group with $p<0.05$.We found similarities with a study done in German where pneumonia was most common followed by sepsis[41].

In our study, for the pre-intervention group the overall in hospital mortality was 26.7%, whereas for the post-intervention group the overall in hospital mortality was 11.1%.There was a significant association with P-value of 0.000.The results in post-intervention were similar to the results of a study in Nepal where in hospital mortality was 14.0%[40].

The mortality was low in a study done in Egypt at 9.8 %[9]and the results in pre-intervention were high to the results of a study done in Washington where in hospital mortality was 18.5%[42].

In our study, the mean length of hospital stay was 35.2 days and 22.0 days respectively for the pre-and post-intervention group. We found a decrease in length of hospital stay for the post-intervention group, with a statistically significant association (P=0.006).
A study done in Palestine[33] revealed a length of hospital stay of 11.45 (SD±12.60)days, another study done in Egypt revealed a mean length of hospital stay of 24.23 days in patients with severe burn[9]with similarity to the results in post-intervention group . The overall length of hospital stay was 16.3 days in a study done in Washington and was 16 days in a study done in Jordan[34]which is low compared to our study. A study done in Nepal revealed a mean length of hospital stay of 73±33days[6],this results were high compared to the results of our study.

CHAPTER VI: CONCLUSION AND RECOMMENDATION

A wide variety of factors are linked significantly with overall outcome in severe burns.
However, early nutrition supplementation with plumpy ‘nut have contributed significantly to the reduction in length of hospital stay, morbidity and mortality at CHUK burn unit.

We recommend that plumpy’nut should be supplemented on daily basis in severe burn patients on top of food brought by families, with the purpose to reduce the length of hospital stay, morbidity and mortality associated with those injuries.

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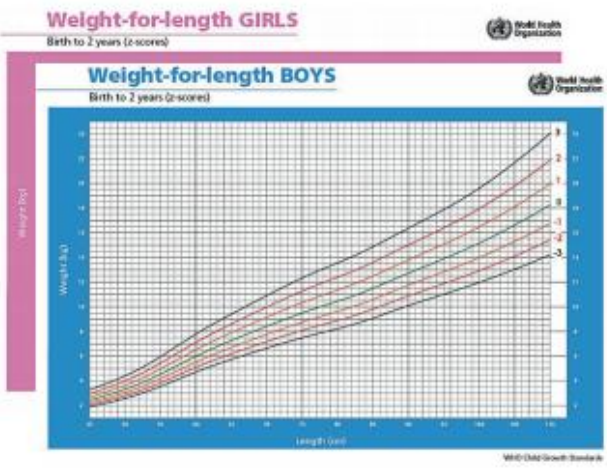
APPENDIX I


Weight-for-length GIRLS
Birth to 2 years (z-scores)
Weight-for-length BOYS
Birth to 2 years (z-scores)


Weight-for-Height GIRLS
2 to 5 years (z-scores)
Weight-for-height BOYS
2 to 5 years (z-scores)

APPENDIX II

Mini Nutritional Assessment
MNA®

Nestlé Nutrition Institute

Last name: First name:

Sex: Age: Weight, kg: Height, cm: Date:

Complete the screen by filling in the boxes with the appropriate numbers.
Add the numbers for the screen. If score is 11 or less, continue with the assessment to gain a Malnutrition Indicator Score.

Screening

A Has food intake declined over the past 3 months due to loss of appetite, digestive problems, chewing or swallowing difficulties?
0 = severe decrease in food intake
1 = moderate decrease in food intake
2 = no decrease in food intake ☐

B Weight loss during the last 3 months
0 = weight loss greater than 3kg (6.6lbs)
1 = does not know
2 = weight loss between 1 and 3kg (2.2 and 6.6 lbs)
3 = no weight loss ☐

C Mobility
0 = bed or chair bound
1 = able to get out of bed / chair but does not go out
2 = goes out ☐

D Has suffered psychological stress or acute disease in the past 3 months?
0 = yes 2 = no ☐

E Neuropsychological problems
0 = severe dementia or depression
1 = mild dementia
2 = no psychological problems ☐

F Body Mass Index (BMI) (weight in kg) / (height in m²)
0 = BMI less than 19
1 = BMI 19 to less than 21
2 = BMI 21 to less than 23
3 = BMI 23 or greater ☐

Screening score (subtotal max. 14 points) ☐☐
12-14 points: Normal nutritional status
8-11 points: At risk of malnutrition
0-7 points: Malnourished
For a more in-depth assessment, continue with questions G-R

Assessment

G Lives independently (not in nursing home or hospital)
1 = yes 0 = no ☐

H Takes more than 3 prescription drugs per day
0 = yes 1 = no ☐

I Pressure sores or skin ulcers
0 = yes 1 = no ☐

J How many full meals does the patient eat daily?
0 = 1 meal
1 = 2 meals
2 = 3 meals ☐

K Selected consumption markers for protein intake
- At least one serving of dairy products (milk, cheese, yoghurt) per day yes ☐ no ☐
- Two or more servings of legumes or eggs per week yes ☐ no ☐
- Meat, fish or poultry every day yes ☐ no ☐

0.0 = if 0 or 1 yes
0.5 = if 2 yes
1.0 = if 3 yes ☐.☐

L Consumes two or more servings of fruit or vegetables per day?
0 = no 1 = yes ☐

M How much fluid (water, juice, coffee, tea, milk...) is consumed per day?
0.0 = less than 3 cups
0.5 = 3 to 5 cups
1.0 = more than 5 cups ☐.☐

N Mode of feeding
0 = unable to eat without assistance
1 = self-fed with some difficulty
2 = self-fed without any problem ☐

O Self view of nutritional status
0 = views self as being malnourished
1 = is uncertain of nutritional state
2 = views self as having no nutritional problem ☐

P In comparison with other people of the same age, how does the patient consider his / her health status?
0.0 = not as good
0.5 = does not know
1.0 = as good
2.0 = better ☐.☐

Q Mid-arm circumference (MAC) in cm
0.0 = MAC less than 21
0.5 = MAC 21 to 22
1.0 = MAC 22 or greater ☐.☐

R Calf circumference (CC) in cm
0 = CC less than 31
1 = CC 31 or greater ☐

Assessment (max. 16 points) ☐☐.☐
Screening score ☐☐.☐
Total Assessment (max. 30 points) ☐☐.☐

Malnutrition Indicator Score

24 to 30 points	☐	Normal nutritional status
17 to 23.5 points	☐	At risk of malnutrition
Less than 17 points	☐	Malnourished

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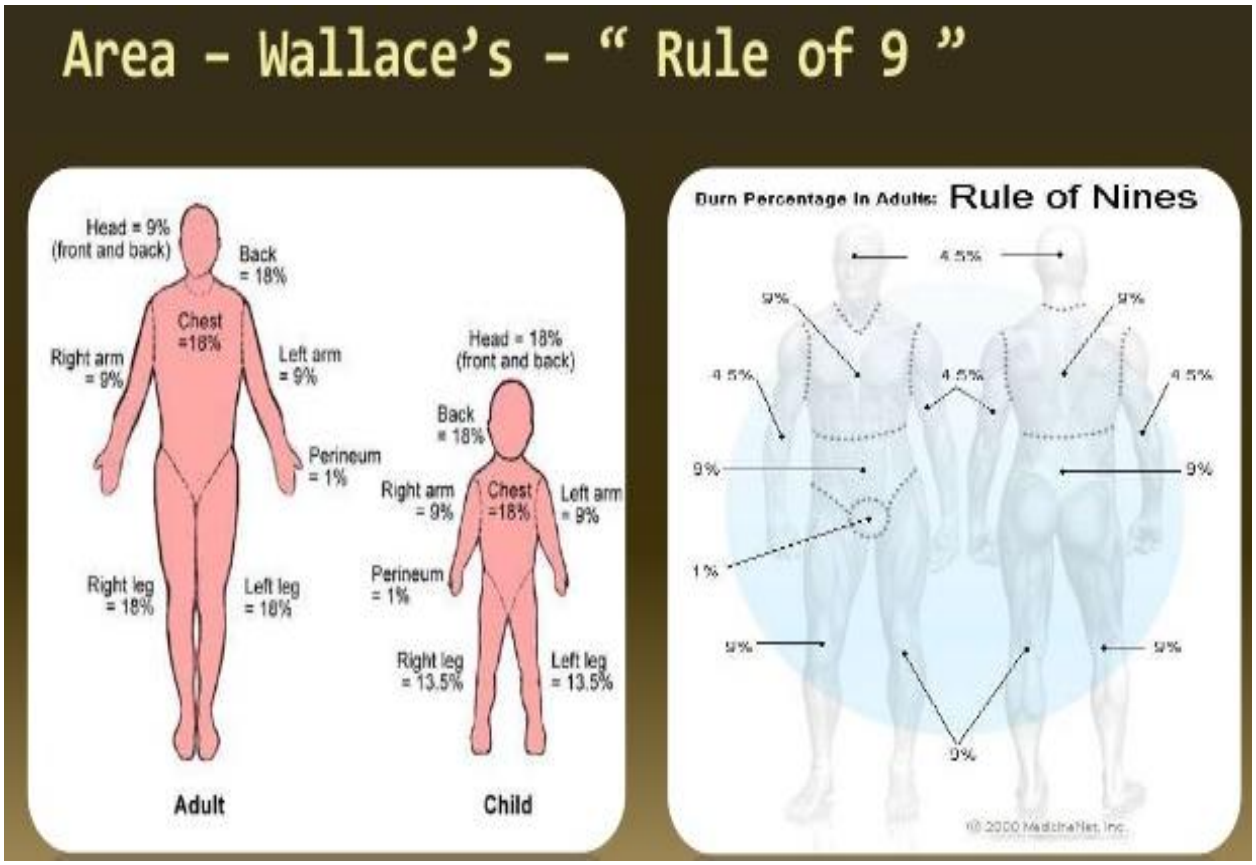
For more information: www.mna-elderly.com

APPENDIX III



APPENDIX IV

I. Data collection form (Retrospective part)

Informed consent form was signed before collecting data

Code……../……/…….

1. ID No: …….
2. Medical insurance: yes/no
3. Age on admission: ……
4. Sex: …..
5. Weight ….
6. Height
7. Vital signs at admission: BP(mmHg):……PR:……RR:……T:……SPO2:..…….
8. past medical history (recent medication):
   Past surgical history (recent operation):
9. Hydration status:

……

10. TBSA%: ……

1st degree burn…..

2nd degree burn :a) Partial thickness

b) Full thickness

11. Heal by: Skin graft

Second intension

12. Early Complications (<5 days): ……..
    Mid-Late complications (5-15days): ……..
    Far-late complications (15-30 days)……
13. Isolated pathogens (where necessary):

A) Urine culture

b) Wound swab

c) Hemoculture

14. Length of stay (in days): ……..

15. Outcome:

A) Dead

B) Discharge

16. ICU/HDU admission

APPENDIX V

I. Data collection form (Prospective part)

Informed consent form was signed before collecting data

Code……../……/…….

1. ID No: ……..

2. Medical insurance: yes/no

2. Age on admission: ……

3. Sex: …..

4. Weight ….

5. Height

6. Vital signs at admission: BP (mmHg)…PR…RR…T…SPO2…

7. past medical history (recent medication):

   Past surgical history (recent operation):

   Allergies:

   Food intolerance:

   High energy nutrition intolerance:

8. Hydration status:

……

9. TBSA%: ……

1st degree burn…..

2nd degree burn :a) Partial thickness

b) Full thickness

10. Heal by: Skin graft

Second intension

11. Early Complications (<5 days): ……..

Mid-Late complications (5-15days): ……..

Far-late complications (15-30 days)……

12. Isolated pathogens (where necessary):

A) Urine culture

b) Wound swab

c) Hemoculture

13. Length of stay (in days): ……..

14. Outcome:

A) Dead

B) Discharge

15. Z score (weight for height) in children

16. Daily energy requirement in Kcal/day by Curreri formula:

For adult: 25Kcal/Kg+40Kcal/% burn.

For children: 60kcal/kg+35 kcal/% burn.

17. Daily cost of plumpy'nut (Rfw)

18. Total cost of plumpy'nut (Rfw)

19. ICU/HDU admission

20. MNA score for adults (classify): a) at admission: …… b) at discharge…

APPENDIX VI: CONSENT FORM

ASSSENT FORM (children)

We are doing a research study on nutrition in burn patients, where patients will be supplemented with high energy nutrition (plump 'nut). If you decide that you want to be part of this study, you will be asked by a clinician to answer questions related to the study.

The purpose of this study is to assess the outcome of high energy nutrition supplementation on burn patients at CHUK, in order to make recommendations after the study. It will help in making guidelines for the management of severe burn patients.

I am aware that the result of this study may be published but I will not be identified as an individual. I reserve the right to withdraw from the study at any time; without any consequence to the care provided to me.

We will also ask your parents if they would like you to be in the study. Even if you say yes now, you can change your mind later.

ASSENT

I want to take part in this study. I know I can change my mind at any time.

Name of the child: …….

Verbal assent given: yes **Date**: …/…/……

I confirm that I have explained the study to the participant to the extent compatible with the participant understands, and that the participant has agreed to be in the study.

Name of person obtaining the assent and signature: …… Date: …/…/……

CONSENT FORM (adult)

We are doing a research study on nutrition in burn patients, where patients will be supplemented with high energy nutrition (plump ‘nut). If you decide that you want to be part of this study, you will be asked by a clinician to answer questions related to the study.

The purpose of this study is to assess the outcome of high energy nutrition supplementation on burn patients at CHUK, in order to make recommendations after the study. It will help in making guidelines for the management of severe burn patients.

I am aware that the result of this study may be published but I will not be identified as an individual. I reserve the right to withdraw from the study at any time if i so wish; without any consequence to the care provided to me.

CONSENT

I want to take part in this study. I know I can change my mind at any time.

Name of the person giving consent: …… **Date**: …/…/……

I confirm that I have explained the study to the participant to the extent compatible with the participant understands, and that the participant has agreed to be in the study.

Name of person obtaining the consent and signature: …… Date: …/…/……

ICYEMEZO CYUBURENGANZIRA BWO KWINJIRA MUBUSHAKASHATSI (munsi y'imyaka 18)

UMUTWE WI BYIGWA: "Kureba icyo kongera ibiryo bikungahaye kubitera imbaraga kubiryo bisanzwe, byakongera kumikirire yabarwayi bafite ubushye bukomeye".

Turakora ubushakashatsi kubijyanye n' imirire mubarwayi bahiye". Niwemera kwitabira ubu bushakashatsi,umuganga azagira ibibazo akubaza bijyanye n'indwara ufite anagusuzume,uzemera ko igipimo cyagenwe kibiryo bikungahaye kubitera imbaraga cyongerwa kumirire yawe yaburimunsi kuva winjiye ibitaro kugera utashye,ntakiguzi usabwe.Ushobora kubaza abaganga cyangwa umuryango wawe, cyangwa undi muntu uwo ariwe wese, igihe icyo aricyo cyose .

Ntabwo ari itegeko kwitabira ubu bushakashatsi. Ntawe uzakurakarira nuba utabyitabiriye. Tuzabaza n'ababyeyi bawe niba bemera ko witabira ubu bushakashatsi. Nubwo wakwemera ubu, wemerewe kuva muri ubu bushakashatsi igihe cyose ushakiye.

Niturangiza ubu bushakashatsi, tuzandika amakuru y' ibyo twabonye ariko izina ryawe ntaho rizagaragara.

Icyemezo: Nemeye kwitabira ubu bushakashatsi

Izinary'umwana……..

Itariki …… / ……. /……

Ndemeza ko nsobanuriye uwitabiriye ubu bushakashatsi ku rwego abisobanukirwa bituma yemera kwitabira.

Amazina n'umukono by' uwasobanuriye umwana:

……

Itariki: ……/…..../……

INFORMATION SHEET & CONSENT (Above 18 years)

Amasezerano yo kwemera kujya mu bushakashatsi (abarengeje imyaka 18)

Please read this consent agreement carefully before you decide to participate in the trial

Musome ibikubiye muri aya masezerano mbere yo kwemera kujya muri ubu bushakashatsi

Purpose of the trial: The purpose of the trial is to assess the impact **OF HIGH ENERGY NUTRITION SUPPLEMENTATION ON SEVERE BURNS OUTCOME.**

Ibigamijwe mu bushakashatsi: kureba icyo kongera ibiryo bikungahaye kubitera imbaraga byamarira abarwayi bahiye cyane igihe byongewe kumirire yabo isanzwe.

What will be done in the trial: For this trial, the patient will be enrolled after fully and clear informed consent to participate in the trial. First, the patient will be explained the trial in all its aspects, and the possibility to withdrawal at any time. Second, all patients' great than one year with severe burn admitted in burn unit will be enrolled in the study after obtaining an informed consent. The study will be conducted in 2 phases, where phase one will be a pre-intervention study, aiming to get the baseline data in terms of length of hospital stay and mortality then phase 2 (a post-intervention study) where we will supplement high energy nutrition then assess the outcome.

Hazakorwa iki muri ubu bushakashatsi: Mbere y'uko ubu bushakashatsi butangira, umurwayi azajya abanza amenyeshwe neza ibigamijwe gukorwa mu bushakashatsi bwose, anemere kubujyamo ku bushake. Umurwayi azasobanurirwa ko ashobora kwikura mu bushakashatsi igihe cyose abishakiye.

Ubushakashatsi buzakorwa mubice bibiri,igice cyambere aho tuzasubirinyuma tukareba ishusho rusange yigihe abarwayi bahiye cyane bamara mubitaro nimikirire cy' imipfire yabo muri 2017 icyogihe nta bufasha budasanzwe abarwayi baba barahawe mubijyanye nimirire,noneho hakaba ikiciro cyakabiri aho tuzunganira abarwayi tubongerera kumirire yabo isanzwe ibiryo bikungahaye kubitera imbaraga tukareba niba harimbinduka kubijyanye nigihe bamara mubitaro ndetse tureba nimpinduka mugukira cy gupfa.

Time required/*Igihe usabwa*: The study will initially require about approximately 30 minutes of your time. Subsequent visits may require you 10 minutes each and their number will depend on your length of stay/ Ubushakashatsi buzagwusaba iminota nka 30 kw' ikubitiro, ariko

muganga azajya agusura na nyuma amara nk' iminota icumi inshuro azaza zikazaterwa n' igihe uzamara mubitaro.

Risks/ *ingaruka mbi* : we don't expect risks of being involved in the research, because that high energy nutrition is commonly used as a nutrition support, and safety was approved by WHO and WFP, may be poor tolerance to high energy nutrition as it may happen to other nutrient in some patients, the treating team will be around to assess the risk ,to adjust the dose and discuss with the patient further plan/ntangaruka mbi zigaragara kujya mubushakashatsi bizakugiraho kuko ibyo biribwa bikungahaye kubitera imbaraga bituwe bikoreshwa mukunganira imirire bikaba bifite ubuziranenge bwizewe nkuko byemejwe na WHO ,ndetse na WFP,uretse nko kuba umubiri utakwakira neza ibiryo bikungahaye kubitera imbaraga muntangiriro; kimwe nibindi biribwa kubantu bamwe nabamwe ,ariko ikipe ivura izaba irihafi mugukurikirana umurwayi no kuganira nawe kukibazo cyavuka,no kugifatira umwanzuro.

Benefits/ *Ingaruka nziza*: You will not be compensated for your participation. The study may help us understand if and at which extent nutrition affects outcomes in burn patients. Results provided by this study will allow us to propose a nutrition care plan in burn patients taking into consideration burn severity but also keeping in mind the current setting which has limited resources. This study will serve as a benchmark and tool that can be used to advocate for improved nutritional support in burn patients who cannot afford appropriate nutritional supplementation at CHUK and in LMICs in general. Ntabihembo bigenewe uzitabira ubu bushakashatsi, ahubwo buzadufasha kumva akamaro k' imirire mu gukira kw'abahiye bidufashe no gushyiraho gahunda ignore y' imirire mubarwayi bahiye cyane hitawe kubushobozi buke bw'abatugana. Ibivuye muri ubu bushakashatsi kandi bizadufasha kuvuganira abarwayi bahiye twakira n' abandi bose batabona ibyo kurya bikwiye byabafasha gukira neza.

Confidentiality/*Kugirirwa ibanga:* The information that you give in the study will be handled confidentially. Your information will be assigned a code number. The list connecting your name to this code will be kept in a locked file. When the study is completed and the data have been analyzed, this list will be destroyed. Your name will not be used in any report/Amakuru uzaduha azakoreshwa muburyo bw' ibanga. Uzahabwa code kandi impapuro zihuza amazina na code zizabikwa mukabati gafungwa, zizanatwikwe ubushakashatsi burangiye. Ntahantu nahamwe havugwa ubu bushakashatsi hazagaragara amazina yawe.

Voluntary participation: The participation in the trial is completely voluntary

Ubushake bwo kujya mu bushakashatsi: Kujya mu bushakashatsi ni ubushake.

Right to withdraw from the study/*Uburenganzira bwo kwikura mubushakashatsi*: You have the right to withdraw from the study at any time without penalty/ wemerewe kwivana mubushakashatsi igihe cyose wabishakira ntazindi nkurikizi cg ingaruka mu kuvurwa kwawe.

How to withdraw from the trial: If the patient wants to withdraw from the trial, he/she should contact Dr Eugene Muneza or Dr Faustin Ntirenganya at the information provided below at any time. There is no penalty or reprisal for withdrawing.

Payment: There is no compensation or payment for participating in the trial, and no benefit to the investigators.

Ikiguzi: Nta kiguzi cyangwa kwishyurwa biri mu kujya muri ubu bushakashatsi, kandi nta nyungu ihari no ku itsinda rikora ubu bushakashatsi.

If you have questions about the trial, contact:

Ufite ikibazo kuri ubu bushakashatsi, wabaza:

Eugene Muneza, MD (Trial Coordinator)
Department of Surgery
University of Rwanda
Telephone: + (250) 788698605
Email address: eugoes@gmail.com
And
Faustin Ntirenganya, MD, Mmed (PI)
Onco-plastic surgeon
Program Director/Department of Surgery
University of Rwanda
Telephone: + (250) 788732667
Email address: fostino21@yahoo.fr

If you have questions about your rights in the trial, contact:

Ufite ikibazo ku burenganzira bwawe muri ubu bushakashatsi, wabaza:

esearchcenter@ur.ac.rw

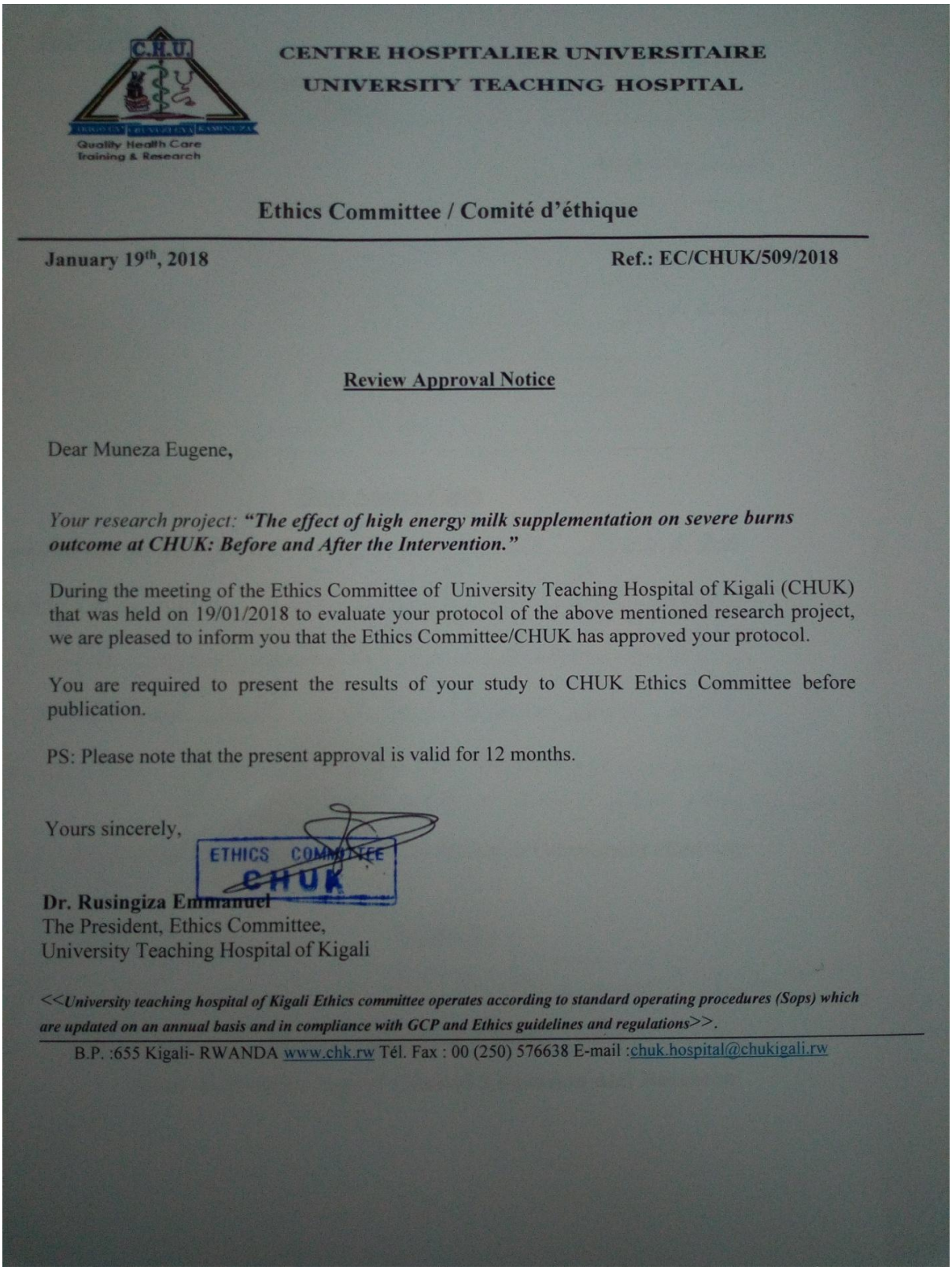
UNIVERSITY OF RWANDA, Kigali Campus
College of Medicine and Health Sciences
Directorate of Research, Technology Transfer and Consultancy
PO Box 3286 Kigali
Tel: + (250) 788563312
Chairperson
Institutional Review Board
CMHS / University of Rwanda
Prof Kato J. NJUNWA Tel 0788490522

Agreement:

I agree to participate in the research study described above/*Nemeye kujya mubushakashatsi nasobanuriwe haruguru.*

Signature: _____ Date: _____

APPENDIX VII: ETHICAL APPROVAL



CENTRE HOSPITALIER UNIVERSITAIRE
UNIVERSITY TEACHING HOSPITAL

Quality Health Care
Training & Research

Ethics Committee / Comité d'éthique

January 19th, 2018 **Ref.: EC/CHUK/509/2018**

Review Approval Notice

Dear Muneza Eugene,

Your research project: ***"The effect of high energy milk supplementation on severe burns outcome at CHUK: Before and After the Intervention."***

During the meeting of the Ethics Committee of University Teaching Hospital of Kigali (CHUK) that was held on 19/01/2018 to evaluate your protocol of the above mentioned research project, we are pleased to inform you that the Ethics Committee/CHUK has approved your protocol.

You are required to present the results of your study to CHUK Ethics Committee before publication.

PS: Please note that the present approval is valid for 12 months.

Yours sincerely,

ETHICS COMMITTEE
CHUK

Dr. Rusingiza Emmanuel
The President, Ethics Committee,
University Teaching Hospital of Kigali

<<University teaching hospital of Kigali Ethics committee operates according to standard operating procedures (Sops) which are updated on an annual basis and in compliance with GCP and Ethics guidelines and regulations>>.

B.P. :655 Kigali- RWANDA www.chk.rw Tél. Fax : 00 (250) 576638 E-mail :chuk.hospital@chukigali.rw

UNIVERSITY OF RWANDA

COLLEGE OF MEDICINE AND HEALTH SCIENCES

CMHS INSTITUTIONAL REVIEW BOARD (IRB)

Kigali, 6th /12/2017

Dr MUNEZA Eugene
School of Medicine and Pharmacy, CMHS, UR

Approval Notice: No 415 /CMHS IRB/2017

Your Project Title ***"The Effect of High Energy Milk supplementation on Severe Burns Outcome at Kigali University Teaching Hospital(CHUK), Before and after the Intervention"*** has been evaluated by CMHS Institutional Review Board.

Name of Members	Institute	Involved in the decision		
		Yes	No (Reason)	
			Absent	Withdrawn from the proceeding
Prof Kato J. Njunwa	UR-CMHS		X	
Prof Jean Bosco Gahutu	UR-CMHS	X		
Dr Brenda Asiimwe-Kateera	UR-CMHS	X		
Prof Ntaganira Joseph	UR-CMHS	X		
Dr Tumusiime K. David	UR-CMHS	X		
Dr Kayonga N. Egide	UR-CMHS	X		
Mr Kanyoni Maurice	UR-CMHS	X		
Prof Munyanshongore Cyprien	UR-CMHS		X	
Mrs Ruzindana Landrine	Kicukiro district		X	
Dr Gishoma Darius	UR-CMHS	X		
Dr Donatilla Mukamana	UR-CMHS	X		
Prof Kyamanywa Patrick	UR-CMHS		X	
Prof Condo Umutesi Jeannine	UR-CMHS		X	
Dr Nyirazinyoye Laetitia	UR-CMHS	X		
Dr Nkeramihigo Emmanuel	UR-CMHS		X	
Sr Maliboli Marie Josee	CHUK	X		
Dr Mudenge Charles	Centre Psycho-Social	X		

After reviewing your protocol during the IRB meeting of where quorum was met and revisions made on the advice of the CMHS IRB submitted on 22nd November 2017, **Approval has been granted to your study.**

Please note that approval of the protocol and consent form is valid for **12 months**.

You are responsible for fulfilling the following requirements:

1. Changes, amendments, and addenda to the protocol or consent form must be submitted to the committee for review and approval, prior to activation of the changes.
2. Only approved consent forms are to be used in the enrolment of participants.
3. All consent forms signed by subjects should be retained on file. The IRB may conduct audits of all study records, and consent documentation may be part of such audits.
4. A continuing review application must be submitted to the IRB in a timely fashion and before expiry of this approval
5. Failure to submit a continuing review application will result in termination of the study
6. Notify the IRB committee once the study is finished

Sincerely,

Date of Approval: The 6th December 2017

Expiration date: The 6th December 2018

FOT

Professor Kato J. NJUNWA
Chairperson Institutional Review Board,
College of Medicine and Health Sciences, UR

Cc:

- Principal College of Medicine and Health Sciences, UR
- University Director of Research and Postgraduate Studies, UR