

**OUTCOMES OF SELF INSTRUCTED HOME-BASED VERSUS
HOSPITAL SUPERVISED REHABILITATION FOLLOWING
ARTHROSCOPIC ANTERIOR CRUCIATE LIGAMENT
RECONSTRUCTION AT MUHIMBILI ORTHOPEDIC INSTITUTE**

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ORTHOPEDIC INSTITUTE**

By

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**A dissertation submitted in (partial) fulfillment of the Requirements for the Degree
of Masters of Medicine in Orthopaedics and Traumatology of Muhimbili University
of Health and Allied Sciences**

October 2021

CERTIFICATION

The undersigned certifies that the supervisor has read and hereby recommends the acceptance by MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES a dissertation entitled “OUTCOMES OF SELF INSTRUCTED HOME BASED VERSUS HOSPITAL SUPERVISED REHABILITATION FOLLOWING ARTHROSCOPIC ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION AT MUHIMBILI ORTHOPEDIC INSTITUTE” submitted in partial fulfillment of the requirement for the award of the degree of Master of Medicine in Orthopaedic and Traumatology.

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DECLARATION AND COPYRIGHT

I, **Kudisala Kulwa Shija**, declare that this dissertation is my original work and that it has not been presented to any other University for a similar or any other degree award

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DEDICATIONS

I dedicate this dissertation to my patients (research participants) for placing their deepest trust in me and making this work completed without difficulty.

This dissertation is dedicated to my beloved wife Alice James Emory and our son Avidan for their love, courage and prayers.

TABLE OF CONTENTS

CERTIFICATION	i
DECLARATION AND COPYRIGHT.....	ii
ACKNOWLEDGEMENT	iii
DEDICATIONS.....	iv
TABLE OF CONTENTS.....	v
LIST OF TABLES	viii
LIST OF FIGURES	ix
LIST OF ABBREVIATIONS.....	x
DEFINITION OF TERMS	xi
ABSTRACT.....	xiii
CHAPTER ONE.....	1
1.1 INTRODUCTION AND BACKGROUND INFORMATION	1
1.2 PROBLEM STATEMENT.....	4
1.3 RATIONALE AND STUDY JUSTIFICATION.....	5
1.4 NULL HYPOTHESIS	5
1.5 OBJECTIVES OF THE STUDY	5
1.5.1 BROAD OBJECTIVE.....	5
1.5.2 SPECIFIC OBJECTIVES.....	6
1.6 CONCEPTUAL FRAMEWORK.....	7
CHAPTER TWO	8
2.0 LITERATURE REVIEW	8
CHAPTER THREE	12
3.0 METHODOLOGY	12
3.1 STUDY DESIGN.....	12
3.2 STUDY AREA	12
3.3 STUDY PERIOD.....	12
3.4 STUDY POPULATION	12
3.5 INCLUSION CRITERIA.....	13

3.6 EXCLUSION CRITERIA	13
3.7 SAMPLE SIZE ESTIMATION	13
3.8 SAMPLING TECHNIQUE	14
3.9 RECRUITMENT OF PARTICIPANTS	14
3.10 DATA COLLECTION TOOLS, VALIDITY AND RELIABILITY	14
3.11 DATA COLLECTION AND ENROLLMENT	15
3.12 STUDY VARIABLES	18
3.13 DATA MANAGEMENT AND ANALYSIS	18
3.14 ETHICAL CONSIDERATION AND CONSENT	19
CHAPTER FOUR	20
4.0 RESULTS	20
4.1 BASELINE SOCIO-DEMOGRAPHIC CHARACTERISTICS	20
4.2 COMPARISON OF KNEE RANGE OF MOTION BETWEEN THE TWO REHABILITATION GROUPS	23
4.3 COMPARISON OF THE ANTERIOR KNEE LAXITY BETWEEN THE TWO REHABILITATION GROUPS DURING THE THIRD MONTH AFTER ACL RECONSTRUCTION	24
4.4 QUADRICEPS MUSCLE STRENGTH, THIGH MUSCLE ATROPHY, SURGICAL SITE INFECTION AND NUMBER OF SESSIONS	25
4.5 COMPARISON OF THE LYSHOLM KNEE SCALE SCORE BETWEEN THE TWO GROUPS PRE ACL RECONSTRUCTION, SECOND WEEK, FIRST MONTH AND THIRD MONTH	26
CHAPTER FIVE	27
5.0 DISCUSSION	27
5.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS	27
5.2 KNEE RANGE OF MOTION	28
5.3 ANTERIOR KNEE LAXITY	28
CHAPTER SIX	31
6.0 CONCLUSION AND RECOMMENDATION	31
6.1 CONCLUSION	31
6.2 STUDY LIMITATION	31

6.3 RECOMMENDATION	31
REFERENCES	32
APPENDICES	35
Appendix I: Consent form: English version	35
Appendix II: Fomu ya Makubaliano ya kushiriki Utafiti: Kiswahili.....	37
Appendix IV: questionnaire	39
Appendix V: Ethical clearance	46
Appendix VI: Introduction letter	48

LIST OF TABLES

Table 1 shows the Muscle power scale.....	17
Table 2: Socio-demographic characteristics of participants in the hospital supervised and home-based rehabilitation groups	22
Table 3: Showing anterior knee laxity of home-based and hospital supervised rehabilitation third-month after ACL reconstruction	24
Table 4: Showing quadriceps muscle strength, thigh muscle atrophy, surgical site infection and number of sessions between home-based and hospital supervised rehabilitation after ACL reconstruction	25
Table 5: Showing Lysholm knee score scale (LKSS) between home-based and hospital supervised rehabilitation pre ACL reconstruction, the second week, first month and third month after ACL reconstruction	26

LIST OF FIGURES

Figure 1: Conceptual framework 7
Figure 2: Consort Flow chart 21
Figure 3: Grouped bar graph showing knee range of motion between home-based and hospital supervised rehabilitation during the first month and third month after ACL reconstruction..... 23

LIST OF ABBREVIATIONS

ACL	Anterior cruciate ligament
ACL R	Anterior cruciate ligament reconstruction
AO	Arbeitsgemeinschaft für Osteosynthesefragen
AR	Attributable Risk
CI	Confidence Interval
CKC	Closed Kinetic Chain
HBR	Home-based rehabilitation
HSR	Hospital supervised rehabilitation
MOI	Muhimbili Orthopaedic Institute
MRI	Magnetic Resonance Imaging
MUHAS	Muhimbili University of Health and Allied Sciences
NW	Non-weight Bearing
OKC	Open Kinetic Chain
OTA	Orthopedics and Trauma Association
SPSS	Statistical Package for Social Science
Tsh	Tanzanian shillings
WB	Weight Bearing

DEFINITION OF TERMS

Open Kinetic Chain: According to Steindler defined an open kinetic chain is “a combination of successively arranged joints in which the terminal segments can move freely”. The distal segment of the extremity is free to move in space, for example: waving a hand, moving the foot during the swing phase of gait, or doing a seated knee extension (15)

Closed Kinetic Chain:

Steindler’s definition of a closed kinetic chain exercise is when the distal segment meets “considerable” external resistance that prohibits free movement.

In clinical practice, the definition of a closed kinetic chain is when “resistance is placed through the distal aspect of the extremity and remains fixed to the extremity”. For example, standing squat in which the feet remain fixed to the ground and the surface produces considerable resistance in response to the athlete’s bodyweight or added weight (15)

Physical therapy: is defined as the ability to evaluate, diagnose and treat impairment, functional limitations and disability in patients (15)

Home-based Physiotherapy: is when the patient performs exercise at home or to nearby gymnasium (a gym can be required if particular gears and instruments are required) unsupervised by the physiotherapist after being given education on how to perform alone and with the occasional presence of a physiotherapist to instruct the patient on how to execute exercises correctly (15)

Hospital Supervised physiotherapy: is when the patient proceeds to perform exercise under the supervision of a physiotherapist even after being instructed on how to do it even alone.

Arthroscopy: This is an examination of the interior of a joint using an endoscope that is inserted into the joint through small incisions

Functional outcome: Is measured by the recovery from pain, early return to regular activities and sports, knee stability and range of knee motion of greater than 135⁰ flexion following surgery

ABSTRACT

Background

Rehabilitation after arthroscopically reconstructed Anterior cruciate ligament is recommended for a better outcome and return to patients' daily and sports activities within a short period. The surgical reconstruction aims to restore the anatomy and normal functioning of the knee joint. Rehabilitation improves knee range of motion, muscular strength and gait to the optimum.

Objective

The purpose of this study was to compare the outcomes between patients receiving initial self-instructed home-based rehabilitation versus hospital-supervised rehabilitation following arthroscopic ACL reconstruction at MOI

The null hypothesis formulated that "There is no difference in functional outcomes between initial self-instructed home-based and Hospital supervised rehabilitation programs after arthroscopic ACL reconstruction at MOI".

Materials and Methodology

The study design was a prospective observational cohort study involving participants with anterior cruciate ligament tear treated by arthroscopic ACL reconstruction using hamstring tendon autografts. The study was conducted at MOI for the period of six months from July 2020 to December 2020.

A total of 50 participants were obtained through convenient sampling. They were assigned to either Hospital supervised rehabilitation or self-instructed home-based rehabilitation as preferred by their surgeon.

Participant's age, sex, site of the affected knee, knee range of motion, thigh muscle atrophy, quadriceps muscle strength grading. The patient's performance of the activity of daily living was assessed using the Lysholm knee score scale pre-operatively, and at the second, fourth and twelfth week. The angle of knee flexion was assessed before ACL reconstruction and at the fourth and twelfth week by using a goniometer.

Immediately after ACL, reconstruction patients in both groups started on supervised physiotherapy protocol until the day of discharge. The Hospital Supervised rehabilitation

group proceeded at the hospital under the supervision and self-instructed home-based group instructed to continue with self-exercise program at home. One month later both groups came to the outpatient clinics for the quadriceps muscle strengthening and knee range of motion program.

Data was collected, analyzed and reported by the principal investigator

Results

Out of 50 participants, three were lost to follow-up and analysis was done for 47 patients. The Hospital Supervised rehabilitation group had 23(49%) participants and the self-instructed home-based group was 24 (51%).

The number of the male was 36 (76.6%) and female 11 (23.4%) with the male to female ratio 3.3:1.

The majority of the Participants were below 40 years 40 (85.1%) with a total mean age of 32.15 ± 8.71 SD.

The study found 42 (89.4%) participants had their ACL reconstruction done more than three months post-injury and below three months 5.

The main cause of ACL tear was sports-related activities 40 and road traffic crush 7.

Two participants (4.3%) were observed to have grade one knee laxity from the hospital-supervised group. However, there was no significant statistical association of knee laxity between groups (P-value 0.234).

All participants had normal muscle strength in both rehabilitation groups.

Muscle atrophy was observed in two participants in home-based rehabilitation and one in the hospital-supervised group (P-value 1).

Two participants got superficial surgical site infection in the home-based rehabilitation group. There was an association of surgical site infection but not significant (P-value 0.489).

A consecutive assessment revealed a significant improvement in knee flexion over time in both groups however hospital supervised rehabilitation group had more compared to home-based rehabilitation at the first and third-month post ACL reconstruction. The hospital-supervised group demonstrated mean knee flexion at one month and three months after

ACL reconstruction $103.04^0 \pm 5.79^0$ and $125.2^0 \pm 5.14^0$ compared to the Home-based group $95.8^0 \pm 5.74^0$ and $115.3^0 \pm 5.74^0$ respectively.

The performance of daily life activity revealed a significant improvement in mean Lysholm score over time in both groups but no significant statistical difference between the rehabilitation groups regardless of initial disparity. The mean Lysholm score for the Home-based rehabilitation (before ACL reconstruction 52 ± 5.6 , second week 66 ± 4.9 , fourth week 78.5 ± 4.2 , twelfth week 88.3 ± 3.4) and the hospital-supervised rehabilitation (before ACL reconstruction 49.4 ± 7.4 , second week 64.3 ± 8.2 , fourth week 79.9 ± 7.4 , twelfth-week 92.9 ± 2.9).

Conclusion

The finding was that the hospital supervised rehabilitation group revealed a greater knee range of flexion during the first and third months compared to self-instructed home-based rehabilitation.

There were no significant statistical differences between the two rehabilitation groups in the anterior knee laxity, quadriceps muscle strength grading and thigh muscle atrophy and post-reconstruction superficial surgical site infection.

A consecutive assessment of the performance of daily life activity revealed a significant improvement in mean Lysholm score over time in both groups but no significant difference between groups at a given period of assessment

Recommendations

Hospital supervised and home-based rehabilitation programs can be used in rehabilitating patients after Anterior cruciate ligament arthroscopic reconstruction as both lead to an equally better outcome and return to patients' daily and sports activities within a short period.

Further prospective studies which involve randomization with large sample size, longer follow-up period are recommended.

CHAPTER ONE

1.1 INTRODUCTION AND BACKGROUND INFORMATION

1.1.1. ANATOMY OF THE LIGAMENTOUS KNEE INJURIES

The knee joint is the largest articulation in the body. It is a modified hinge with an extensive range of motion. The stability of the joint is provided by the soft tissue structures: the anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), the medial collateral ligament (MCL) and lateral collateral ligament, the menisci, the capsule and the muscles. The ACL and PCL add stability to the joint and aid in proprioception. The ACL and PCL limit the anterior and posterior displacement of the tibia on the femur respectively. Since the intact ACL prevents anterior motion of the tibia on the femur, an ACL injury leads to the abnormal forward movement of the tibial plateau. This abnormal motion leads to relative internal rotation of the tibia during the terminal part of an extension. The absence of a functioning ACL and the related anterolateral rotatory instability can result in the sensation that the knee is “buckling or giving out”. These symptoms occur with normal walking but maybe most prominent during pivoting movement such as those that occur with quick changes in direction. In the absence of knee, buckling patients with ACL disruption may express a loss of confidence in the stability of their knee possibly because of the ACL’s role in proprioception. (1)

ACL injuries caused by contact require a fixed lower leg (i.e., when planted) and torque with enough force to cause a tear. Contact injuries account for only about 30 percent of ACL injuries. The remaining 70 percent of ACL tears are non-contact injuries occurring primarily during deceleration of the lower extremity, with the quadriceps maximally contracted and the knee at or near full extension. In non-contact scenarios, the stress on the ACL resembles that of a collision of the knee. When the knee is at or near full extension, quadriceps contraction increases ACL tensile force. The hamstrings, which stabilize the ACL posteriorly, are often minimally contracted during these injuries, particularly if the hip is extended and the bodyweight is on the heel, allowing for excessive forward shifting of the femur on the tibia. (23)

The Anterior cruciate ligament reconstruction is often recommended after an ACL tear and followed by proper postoperative rehabilitation to help patients improve and return to their daily and sports activities within a short period. (3)

The standard rehabilitation protocol after ACL reconstruction is based on a model presented by Shelbourne & Wilckens (4). In this program, training starts before surgery to obtain the best mental and physical conditions for the patient. The program allows early postoperative weight-bearing; extension exercises are emphasized during the first weeks after surgery and strengthening exercises are performed mainly according to the closed kinetic chain (CKC) technique. This program also comprises exercises for proprioception and co-ordination (4).

Clinical experience and research on rehabilitation after ACLR have shown that limited physiotherapy visits, comprising patient education, information and guidance, along with a home exercise program, enable the patients to achieve their goals (5 -10). The accelerated rehabilitation after ACLR, which includes a pre-operative training phase (11, 12), may contribute to the patient being well prepared, physically and mentally, before surgery. This arrangement might lead to fewer post-operative physiotherapy visits and also minimize loss of knee function (11, 12).

Most patients with ACL injuries are young, physically active people; who have the knowledge and ability to take responsibility for the rehabilitation. The idea of transferring the responsibility from the physiotherapist to the patient is challenging (13).

1.1.1 DIAGNOSIS OF THE ANTERIOR CRUCIATE LIGAMENT TEAR

Patients who sustain ACL injuries classically describe a popping sound, followed by immediate pain and swelling of the knee. The feeling of instability or giving-way episodes typically limits the ability to participate in activities. Patients might describe the feeling of instability with the “double fist sign” (i.e., fists facing each other, rotating in a grinding motion) (23)

The Lachman test, anterior drawer test, pivot shift test are the physical examination maneuvers commonly used to assess the integrity of ACL injuries. In addition, confirmation of the ACL injuries maybe by the MRI and diagnostic arthroscopy of the knee joint. (1)

The Lachman test is performed while the patient lies supine with the knee flexed to 20⁰ to 30⁰. The examiner stands to the side of the patient’s leg with the patient’s heel on the examination table. The femur is grasped with one hand just above the knee, while the examiner grasps the femur firmly to prohibit motion of the upper leg and to relax the hamstrings, the other hand grasps the proximal tibia. The lower leg is then given a brisk forward tug and a discrete endpoint should be felt. The positive test is the one in which the endpoint is not discrete or there is increased anterior translation of the tibia. The test is more difficult to perform when the examiner has small hands or the patient has large legs, both situations making it more difficult to completely grasp the legs. In this situation, the patient may lie prone with the knee at the same degree of flexion while the examiner attempts the same motion of the tibia. (1)

The anterior drawer test is also typically performed with the patient supine and the knee in 90⁰ of flexion. The examiner quickly pulls the upper portion of the calf forward using both hands. The tibia must not be rotated and hamstrings must be relaxed to properly assess the ACL. An intact ACL abruptly stops the tibia’s forward motion as the ACL reaches its maximum length. If the tibia can be moved anteriorly without an abrupt stop referred to as a discrete end pull, this is considered a positive anterior drawer sign. It is often useful to

perform this test on the uninjured knee to determine whether the amount of anterior translation differs between knees. (1)

The lateral pivot shift test combines valgus stress (pushing the outside of the knee medially) with a twisting force while the knee is being flexed. The patient rests on his/her back with the knee at 45° flexions. The examiner places a hand on the lateral aspect of the knee and pushes medially creating a valgus strain. At the same time, the examiner's other hand supports and pulls the foot laterally. As the examiner slowly extends the knee, the tibia and the foot begin to twist internally. A positive test consists of an obvious "thud" or "jerk" at 10° to 20° flexion in the ACL-deficient knee representing anterior subluxation of the tibia on the femur. (1)

1.2 PROBLEM STATEMENT

At MOI, the patients undergo ACL reconstruction start immediately with physiotherapist supervised rehabilitation in the ward until the day of discharge. The patients are trained on how to proceed with daily home programs before the next visit one month later while some proceed with daily hospital supervised rehabilitation

According to Grant et al (8), Home-based rehabilitation has shown success in return of knee range of motion and strength in the first 3 months after ACL reconstruction. Some research studies have reported factors for successful Home-based rehabilitation to be that of preoperative education and postoperative rehabilitation goal setting, motivation and monitoring (8, 10, 11).

After ACL reconstruction, the required number of Hospital supervised rehabilitation sessions add costs, both directly as cost per session attended, and indirectly as the time taken away from work and school (8)

In addition, the undesired tendency of knee laxity has been observed in the patients who are undergoing Hospital supervised rehabilitation compared to the self-instructed Home Based rehabilitation group at the MOI OPD clinic

It is currently unknown as to whether patients can achieve a satisfactory level of postoperative function without direct supervision of a physiotherapist or not after ACL reconstruction at MOI

1.3 RATIONALE AND STUDY JUSTIFICATION

In preparation for this research study, a comprehensive review of the published research studies demonstrates scarcity of research studies comparing outcomes between a group of patients receiving self-instructed Home-Based rehabilitation and Hospital Supervised Rehabilitation program following ACL reconstruction in Tanzania and other Low and Middle-Income Countries.

Understanding that self-instructed Home-Based rehabilitation can achieve a satisfactory level of postoperative function and knee laxity will help us recommend the possible physiotherapy modality at MOI and other similar centers in Tanzania.

1.4 NULL HYPOTHESIS

There is no difference in outcome between self-instructed home-based exercise and Hospital supervised rehabilitation programs after arthroscopic ACL reconstruction at MOI

1.5 OBJECTIVES OF THE STUDY

1.5.1 BROAD OBJECTIVE

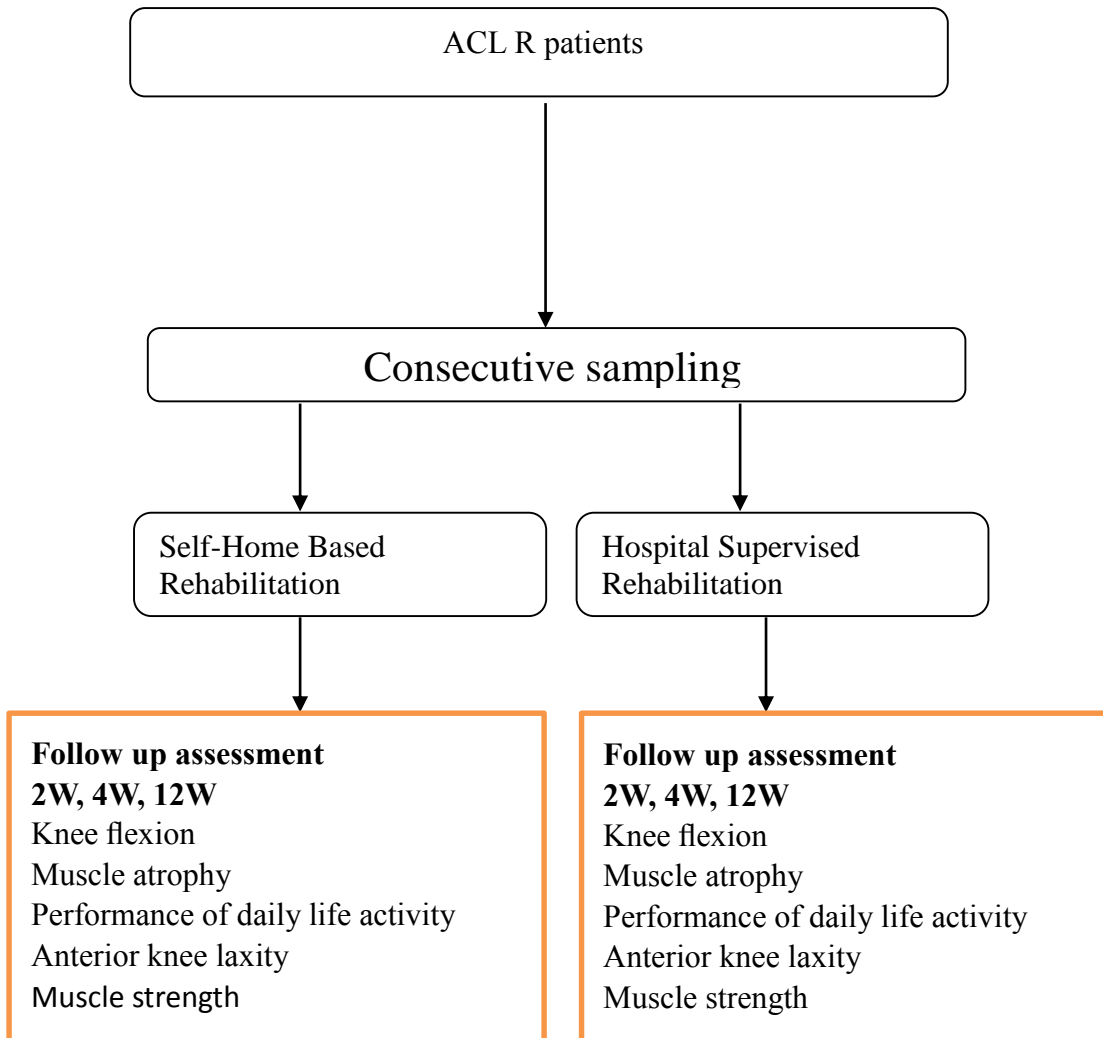
To compare the outcome between patients receiving self-instructed Home-based rehabilitation versus Hospital supervised rehabilitation following anterior cruciate ligament reconstruction at Muhimbili Orthopaedics Institute

1.5.2 SPECIFIC OBJECTIVES

1. To determine the socio-demographic distribution among patients receiving self-instructed HBR versus HSR after arthroscopic ACL R at MOI, from July 2020 to December 2020
2. To determine knee range of motion among patients receiving self-instructed HBR versus HSR after arthroscopic ACL R at MOI, from July 2020 to December 2020
3. To determine anterior knee laxity among patients receiving self-instructed HBR versus HSR after arthroscopic ACL R at MOI, from July 2020 to December 2020
4. To determine thigh muscle strength among patients receiving self-instructed HBR versus HSR after arthroscopic ACL R at MOI, from July 2020 to December 2020
5. To determine the performance of daily life activity among patients receiving self-instructed HBR versus HSR after arthroscopic ACL R at MOI, from July 2020 to December 2020

1.6 CONCEPTUAL FRAMEWORK

Figure 1: Conceptual framework



Source: adopted and modified from Beynon et al (3)

CHAPTER TWO

2.0 LITERATURE REVIEW

In this chapter, the socio-demographic characteristics, knee range of motion, anterior knee laxity, quadriceps muscle strength, the performance of daily life activity and postoperative infection after ACL reconstruction of the study are presented.

1.2.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS

According to the study done by Beard et al (5) showed the median age of the patients who participated was 28 years (20-46) and the median time since injury was 50 months (12-132 months). Also over 86% of patients sustained their injury during sporting and all had been diagnosed ACL deficient by arthroscopy or MRI scan.

Fischer et al study compared a postoperative home-based rehabilitation program with a clinic-based program of fifty-four patients who underwent arthroscopically assisted anterior cruciate ligament reconstruction with bone-patellar tendon-bone autograft or allograft. The fifty-four patients (mean age, 30 years) were assigned randomly to the home-based program (27 patients) or the clinic-based program (27 patients). The home-based schedule featured six physical therapy visits during a 6-month postoperative study period, whereas the clinic-based schedule specified 24 physical therapy visits during those 6 months. (7)

1.2.2 ANTERIOR KNEE LAXITY

The study by Beard et al. (5) found a remarkable improvement in function activity level, muscle strength and anterior knee translation but no difference between the two groups.

The Zulfikar et al study found better outcomes in the supervised group quadriceps girth, Tegner-Lysholm knee scale score, knee instability and knee range of motion compared to the unsupervised group. (16)

In addition, the study by Fischer et al found no significant statistical differences between the home-based and hospital supervised rehabilitation groups. (7)

Grant et al study found no significant differences between the rehabilitation groups in range of motion during walking, ligament laxity, and strength even though the home-based group had a significantly higher percentage of patients with acceptable flexion and extension range of motion compared to the standard physical therapy group (flexion, 67% vs 47%; extension, 97% vs 83%) (8)

1.2.3 QUADRICEPS MUSCLE STRENGTH AND THIGH MUSCLE ATROPHY

Beard et al. (5) assessed function activity level, muscle strength and anterior tibia translation preoperatively and at three and 6 months after ACL reconstruction between the homes-based group and a supervised rehabilitation group. Beard et al. (5) could not demonstrate a difference between the two groups.

The quadriceps muscle weakness is sequelae of an ACL tear that can persist even after reconstruction (28). The persistence of this weakness can be hazardous to the patient as it could alter the movement strategies, decrease functional activity and thus increase the chances of ACL re-injury (28).

Shubhan et al study noted quadriceps wasting even after ACL reconstruction hence recommended periodic evaluation during rehabilitation as this can help us modify or restructure existing protocols for early return of the patient to routine activity (28).

Early detection of quadriceps muscle atrophy can help in starting early rehabilitation protocols by using various newer modalities like Blood Flow Restriction (BFR) therapy and drug therapy (28).

1.2.4 KNEE RANGE OF MOTION

Grant et al in a single-blinded prospective study assessed range of motion up to 3 months post ACL surgery. Grant et al. (8) noted a better return to knee range of motion in the home-based rehabilitation group hospital supervised rehabilitation (97% vs 83% for extension; 67% vs 47% for flexion). Grant et al reported bilateral median differences between the two groups ((-2° vs -3° for extension; 3° vs 6° for flexion) (8).

Fischer *et al* study at 6-month follow-up, no significant statistical differences were found between the two groups in the range of motion, thigh atrophy, anterior drawer compliance, hopping tests, Lysholm scores, or subjective health status. (7)

1.2.5 PERFORMANCE OF DAILY LIFE ACTIVITY

Beard *et al* evaluated postoperative outcomes in a group of patients who attended regular supervised sessions of physical therapy supplemental to basic individual training, compared with those of patients fully exercising at home on their own. Lysholm scores, modified Tegner Scores and IKDC scale score recorded equivalent values for both approaches. (5)

Fischer *et al.* compared in a prospective study a home-based program that included six visits to the physiotherapist to a clinic-based program for 6 months. At the 6-month endpoint, no significant differences saw in range of motion, thigh atrophy, hopping tests and Lysholm scores. (7)

Hohmann *et al* reported a lack of significant differences for the main outcome variables between a supervised physiotherapy rehabilitation program and the home-based exercise program 12 months post-surgery (13)

Zulfikar *et al* reported no difference in functional scores until after one month of injury in both groups but as time progressed the Fear of their knee giving way when exercising and pain persisted significantly in the unsupervised group as compared to the supervised group. This correlated with the persistence of muscle weakness and instability in the unsupervised group after one month of rehabilitation as compared to the supervised group (16)

However, currently, there are no research studies published in Africa and Tanzania comparing patients receiving self-instructed home-based rehabilitation versus hospital supervised rehabilitation after ACL reconstruction in Tanzania and Africa.

1.2.6 POSTOPERATIVE INFECTION IN ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION

Postoperative infection is a relatively rare event after anterior cruciate ligament reconstruction but is considered a devastating complication of the knee joint when occurs. A study done on the effect of graft selection on the Incidence of postoperative infection after Anterior Cruciate Ligament reconstruction revealed that hamstring tendon autografts have a higher incidence of infection (1.44%) than bone-patellar tendon-bone autografts (0.45%) or allografts (0.44%) (25)

Another study on a large sample size (10,626) found an overall surgical site infection of 0.48% (n = 51), with 17 (0.16%) superficial infections and 34 (0.32%) deep infections. The Hamstring tendon autografts (n = 20; 0.61%) had the highest incidence of deep SSIs of the graft types with 8.2 times risk compared with BPTB autografts. (26)

CHAPTER THREE

3.0 METHODOLOGY

3.1 STUDY DESIGN

The study was a prospective observational cohort study.

3.2 STUDY AREA

The study was conducted at Muhimbili Orthopaedic Institute located in Dar Es Salam, Tanzania from July 2020 to December 2020. MOI is the only tertiary institute providing specialized Orthopedic, Trauma and Neurosurgical Care in the country-receiving patients from all over the country and from neighboring countries. Being a Tertiary National Referral Hospital specialized in trauma with well-trained specialists. MOI has a bed capacity of 272 in public and private wards. Averages of 410 patients attend all outpatients' clinics every day at the hospital premises. The hospital theatre has 9 operating tables with an average of 20 planned and emergency operations performed daily. Four Orthopedic and Trauma surgeons are doing arthroscopic ACL reconstruction and 8 physiotherapists are involved in rehabilitating ACL reconstructed patients at MOI. At MOI at least five arthroscopic assisted ACL reconstructions are done per week and then initiated on rehabilitation Isometric exercise, alphabetical exercise and closed kinetic chain exercise. Then discharged with either physiotherapist supervised rehabilitation or self-instructed home-based programs

3.3 STUDY PERIOD

This study is from November 2019 to June 2021. Data collection was done from July 2020 to December 2020

3.4 STUDY POPULATION

All patients were treated by arthroscopic anterior cruciate ligament reconstruction at MOI from July 2020 to December 2020.

3.5 INCLUSION CRITERIA

1. Age between 18 and 50 years
2. Patients with a unilateral ACL tear
3. Reconstruction with hamstring autograft

3.6 EXCLUSION CRITERIA

1. Previous knee surgery (Revision)
2. Patients with inflammatory disorders
3. Patients with contralateral contracture limb or fracture

3.7 SAMPLE SIZE ESTIMATION

The sample size estimation was calculated based on the change of anterior laxity between the injured limb and the contralateral limb. A 2.0-mm difference in anterior knee laxity between limbs the two limbs (q) and corresponding standard deviation (E) of 2.0 mm considered clinically relevant. (21)

The sample size of this study calculated from the formula

$$2N = 4(Z_1 + Z_2)^2 q^2 / E^2$$

Where:

2N = Total sample size

Z₁ = 1.96 Statistic for the level of confidence of 95%

Z₂ = 1.282 at power 90%

q = 2 mm (difference in anterior knee laxity)

E = 2 (standard deviation)

Substituting into the formula

$$2N = 4(1.96 + 1.282)^2 (2)^2 / 2^2$$

N =22

Therefore, each arm of the treatment was supposed to have at least 22 patients. A total of 44 patients were estimated to be involved in the study. Due to a 10% loss to follow-up, the adjusted sample size was 49.

However, using convenient sampling 50 patients enrolled in the study and all patients met the inclusion criteria and followed-up. In the end, 47 participants' data were analyzed and three patients were lost to follow up

3.8 SAMPLING TECHNIQUE

The convenient sampling technique is used in obtaining the required sample. All patients with eligible criteria were recruited in the study to attain the required sample size.

3.9 RECRUITMENT OF PARTICIPANTS

Participants were recruited from the MOI outpatient clinics and wards by the investigator. Patients with ACL reconstruction were recruited to participate in the study after being given all the information concerning the study and willingly signing the consent.

It was the surgeon's preference to assign patients to the rehabilitation program.

Participants were assigned by their surgeons in firm A or firm B to undergo either Hospital supervised rehabilitation program or self-instructed home-based rehabilitation respectively.

Then follow up made at the second weeks, fourth weeks and third months and progress recorded on questionnaires for each visit.

3.10 DATA COLLECTION TOOLS, VALIDITY AND RELIABILITY

A pre-tested questionnaire was used by the researcher to record participants' information. Questionnaire and were used as data collection tools. The assessment tools were the Lysholm knee score scale, tape measure and clinical goniometer.

The Lysholm knee score scale evaluates patients' function with an ACL injury and is proven valid and reliable (16). The score has eight domains with marks to score function

of the activity of daily living namely instability (25), pain (25), locking (15), swelling (10), stair climbing (10), limping (5), squatting (5) and support using cane or crutches (5) (16).

3.11 DATA COLLECTION AND ENROLLMENT

The patients who met inclusion criteria were enrolled in the study after a signed consent

The data was collected by the principal investigator.

Patient's age, sex, side of the affected knee, knee range of motion, muscle atrophy, muscle strength grading, the performance of daily life activity Lysholm knee score were obtained (both affected and unaffected knee).

Participants were enrolled in the study before ACL reconstruction then assigned to undergo either Hospital supervised rehabilitation program or self-instructed home-based rehabilitation.

The rehabilitation program was initiated on the first day after surgery in both groups. In the first phase of the recovery, the focus was controlling pain and inflammation, protecting the constructed graft, improving joint mobility, restoring full-extension, preventing muscle atrophy and improving muscle tone and strength. In the second recuperative phase, the main objective was gradual improvement in joint mobility by restoring the complete motion amplitude, resuming normal gait, improving the muscular strength and endurance, improving joint stability, proprioception and motor control and progressively resuming daily activities. The ultimate objective of complete recovery was restoring muscle-tone,-strength and endurance, fully restoring joint stability, proprioception and motor control with a gradual resumption of sports activities.

Patients were assessed preoperatively and postoperatively at the second weeks, fourth weeks and third months.

Measurement of Range of knee motion

Knee extension and flexion were measured with a standard clinical goniometer (14).

The knee flexion was measured while the participant was kept in the supine position on the examination table. A strap is placed around the ankle in a figure-of-8 fashion and the patient holds one end of the strap in each hand. While keeping the foot on the plinth, the patient was pulled on the strap and used his or her hamstrings to flex the knee as far as comfortably possible and hold it in that position while taking measurement. The knee popliteal angle was measured. The knee extension was measured with participants positioned prone with the knee joint positioned slightly beyond the end of the plinth. The knee flexion before ACL reconstruction has to be at least more than 100° for better rehabilitation outcomes.

Knee Ligament Laxity Testing

To assess the integrity of the ACL graft, anterior displacement at the tibiofemoral joint was done using a Lachman test. The results were considered positive if there was perceivable anterior subluxation of the tibia (grade 1, grade 2 or grade 3) or normal, (0) if there is no positive end-point to the subluxation with the knee in 10° to 20° of flexion Lee et al (17)

Assessment of the thigh muscle circumference (Thigh atrophy)

Thigh muscle circumference was measured with the patient in the supine position and the knee in 10° flexions. The circumference was measured with a tape 5 cm and 15 cm proximal to the superior patella. This procedure was repeated for the contralateral limb and measurements were compared. Then deference in circumference at points 5 cm and 15 cm were compared and recorded no atrophy or presence. To maintain uniformity the evaluation was done by a single examiner for all the cases. (18)

Assessment of quadriceps muscle strength

The quadriceps muscle strength was assessed by using the muscle power scale

Table 1 shows the Muscle power scale

Score	Description
0	No contraction
1	Flicker or trace of contraction
2	Active movement with gravity eliminated
3	The active movement against gravity
4	The active movement against gravity and resistance
5	Normal power

Adopted from Medical research council united kingdom

SECOND WEEK FOLLOW UP

The patients were assessed on the wound status, knee swelling, and performance of the activity of daily living and removing stitches. Then patients were instructed to continue walking with crutches, knee brace and active knee flexion and extension

SIXTH WEEK FOLLOW UP

During this visit the patients were assessed on a range of motion, performance of the activity of daily living using the Lysholm knee scoring scale and knee muscle power

TWELVETH WEEK FOLLOW UP

The patients were assessed on a range of motion, performance of the activity of daily living using Lysholm knee scoring scale, knee laxity, muscle atrophy and knee muscle power. Then grading of the outcome were done as excellent (100 - 95), good (94 - 84), fair (83 - 65) and poor (<64)

3.12 STUDY VARIABLES

The independent variables were age, sex, educational level, Bodyweight, socio-economic status. Dependent variables were knee range of motion, thigh muscle strength and anterior knee laxity

3.13 DATA MANAGEMENT AND ANALYSIS

Data entry, cleaning, coding and analysis were done using SPSS version 20 software. Frequency distribution was used to describe categorical variables such as age, sex and body mass index. The data is categorized as nominal or quantitative variables. The nominal variables were characterized using frequencies. The chi-square test was used to compare the frequencies of nominal variables. The quantitative variables comparison was done by either the T-test or the ANOVA test. The level of statistical significance was set at $p < 0.05$. Statistical analysis was performed using Graph Pad Software.

3.14 ETHICAL CONSIDERATION AND CONSENT

The ethical clearance to conduct this study was sought from the MUHAS Research and Publications Committee while permission to conduct the study was sought from the MOI administration. The Participants were informed about their autonomy to participate and assured confidentiality of their information.

The procedures in this study observed the guideline principles according to MUHAS Research and Publication Board requirements. These include informing the patients of the right and freedom whether to participate or not and, the protection of the patient's data and privacy. The information obtained from the participants will not be shared with another third party apart from the research and publication purposes.

Explanations were given to participants that the final report obtained may be used to develop future postoperatively ACL reconstruction rehabilitation protocols. Participants were asked to give signed consent. In addition, the MUHAS Research and Publications Committee Chairperson's mobile phone number was given to the participants in case of inquiries on their right to participate in the study.

CHAPTER FOUR

4.0 RESULTS

4.1 BASELINE SOCIO-DEMOGRAPHIC CHARACTERISTICS

The study period was done from July 2020 and December 2020, 50 patients with anterior cruciate ligament tear treated with arthroscopic ACL reconstruction using the hamstring tendon autograft were recruited and followed up for three months. However, three (3) patients were lost to follow-up (Home-based 2 and hospital supervised 1). The data analyzed at the end were of the remaining 47 patients. The number of participants in the Hospital Supervised rehabilitation and the self-instructed home-based group was 23(49%) and 24 (51%) respectively.

The number of male was 36 (76.6%) (Home-based 19 and hospital supervised 17) and the female 11 (23.4%) (Home-based 5 and hospital supervised 6) with the male to female ratio 3.3:1.

The majority of the Participants were below 40 years of age 40 (85.1%) (Home-based 19 and Hospital-supervised 21) with a mean age of 32.15 ± 8.71 SD.

Many participants had their ACL reconstruction above three months 42 (Home-based 22 and Hospital-supervised 20) and below three months 5 (Home-based 2 and Hospital-supervised 3)

The main cause of ACL tear was sports-related activities 40 (Home-based 20 and Hospital-supervised 20) and road traffic crush 7 (Home-based 4 and Hospital-supervised 3).

There were no significant differences found in age, occupation, educational level, body mass index (BMI), causes of the ACL tear, site of injured knee and period from injury to ACL reconstruction between the two groups. The detailed socio-demographic distribution characteristics as shown in table two (2).

CONSORT FLOW CHART

The Source of the chart was from Beynnon et al (3) and modified with own data

Figure 2: Consort Flow chart

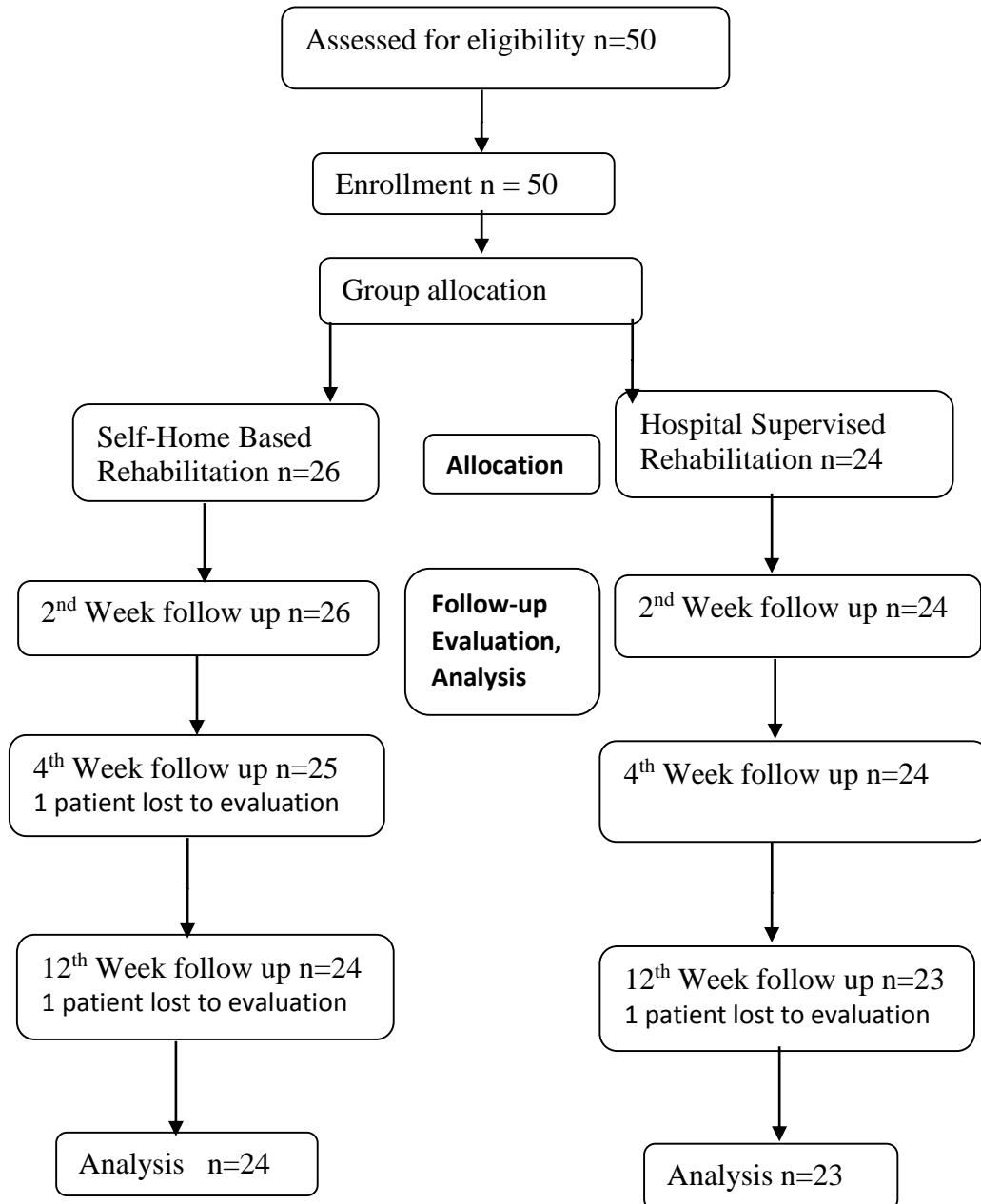


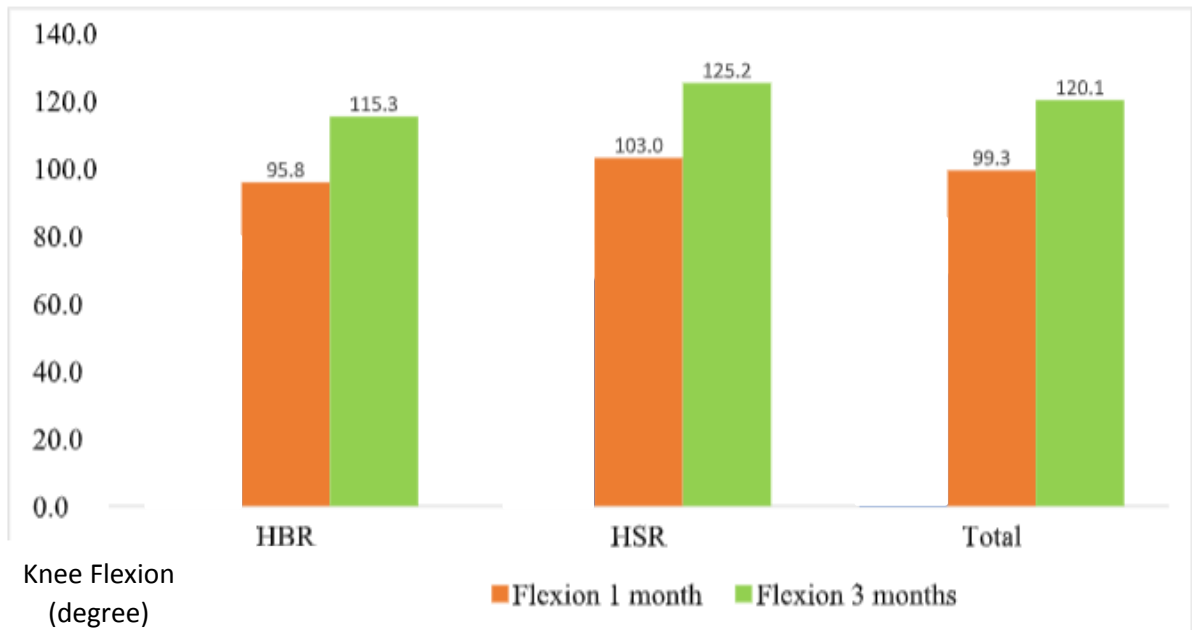
Table 2: Socio-demographic characteristics of participants in the hospital supervised and home-based rehabilitation groups.

Variable	HBR	HSR	Total
Sex	N (%)	N (%)	N
Male	19(52.78)	17(47.22)	36(76.6%)
Female	5(45.45)	6(54.55)	11(23.4%)
Age Group			
>40	5(71.43)	2(28.57)	7(14.9%)
≤ 40	19(47.50)	21(52.50)	40(85.1%)
BMI Group			
Normal	11(52.38)	10(47.62)	21(44.7%)
Overweight	13(50.00)	13(50.00)	26(55.3%)
Cause			
Sports-Related Injury	20(50)	20(50)	40(85.1%)
Road Traffic Crush	4(57.14)	3(42.86)	7(14.9%)
Date of injury			
Reconstructed within 3 months	2(40)	3(60)	5(10.6%)
Reconstructed more than 3 months	22(52.38)	20	42(89.4%)
Knee			
Right	19(54.29)	16(45.71)	35(74.5%)
Left	5(41.67)	7(58.33)	12(25.5%)

4.2 COMPARISON OF KNEE RANGE OF MOTION BETWEEN THE TWO REHABILITATION GROUPS

A consecutive assessment revealed a significant improvement in knee flexion over time in both groups however, the hospital supervised rehabilitation group had more knee flexion compared to home-based rehabilitation during the first and the third-month post ACL reconstruction as shown in the grouped bar graph below. The hospital-supervised group demonstrated mean knee flexion at one month and three months after ACL reconstruction $103.04^0 \pm 5.79^0$ and $125.2^0 \pm 5.14^0$ compared to the Home-based group $95.8^0 \pm 5.74^0$ and $115.3^0 \pm 5.74^0$ respectively.

Figure 3: Grouped bar graph showing knee range of motion between home-based and hospital supervised rehabilitation during the first month and third month after ACL reconstruction



4.3 COMPARISON OF THE ANTERIOR KNEE LAXITY BETWEEN THE TWO REHABILITATION GROUPS DURING THE THIRD MONTH AFTER ACL RECONSTRUCTION

The majority of the participants had no anterior knee laxity in both groups 45 (95.7%). The remaining two participants (4.3%) were observed to have a grade one-knee anterior knee laxity from the hospital-supervised rehabilitation group. However, there was no statistical significant difference between the two rehabilitation groups with a P-value 0.234 as shown in the table thee below:-

Table 3: Showing anterior knee laxity of home-based and hospital supervised rehabilitation third-month after ACL reconstruction

Grade	HBR	HSR	Total	P-value
Normal	24(100%)	21(91.3%)	45(95.7%)	0.234*
Grade I	0(0.0)	2(8.7%)	2(4.3%)	
Grade II	0(0.0)	0(0.0)	0(0.0)	
Grade III	0(0.0)	0(0.0)	0(0.0)	
Total	24(51.1%)	23(48.9%)	47(100%)	

4.4 QUADRICEPS MUSCLE STRENGTH, THIGH MUSCLE ATROPHY, SURGICAL SITE INFECTION AND NUMBER OF SESSIONS

The study found all participants had a normal grade of the quadriceps muscle strength in both rehabilitation groups as shown below in table four:-

Muscle atrophy was observed in three (6.4%) participants from both rehabilitation groups namely two (9.1%) in the home-based rehabilitation and one (4.5%) in the hospital-supervised rehabilitation group. However, the number of participants with muscle atrophy had no statistical significant between the two rehabilitation groups (P-value 1.0).

In addition, two participants (4.3%) got superficial surgical site infection in the home-based rehabilitation group. There was an association of surgical site infection in the home-based rehabilitation group however not statistically significant (P-value 0.489).

The participants in the hospital-supervised group had an average number of sessions 14 ± 2.15 for physical therapy and evaluation and home-based rehabilitation 6 ± 1.12 .

Table 4: Showing quadriceps muscle strength, thigh muscle atrophy, surgical site infection and number of sessions between home-based and hospital supervised rehabilitation after ACL reconstruction

Variable	HBR	HSR	Total	P-value
Strength				
Normal	24(100.0)	23(100.0)	47(100%)	
Decreased	0(0.0)	0(0.0)	0(0.0)	
Atrophy				
Yes	2(9.1%)	1(4.5%)	3(6.4%)	1.0*
No	22(90.9%)	22(95.5%)	44(93.6%)	
Infection				
No	22(90.9%)	23(100%)	45(95.7%)	0.489
Yes	2(9.1%)	0(0.00)	2(4.3%)	
Number of sessions	6.0(± 1.12)	14(± 2.15)		

4.5 COMPARISON OF THE LYSHOLM KNEE SCALE SCORE BETWEEN THE TWO GROUPS PRE ACL RECONSTRUCTION, SECOND WEEK, FIRST MONTH AND THIRD MONTH

The mean score of the Lysholm knee scale score progressively improved with time among patients in both rehabilitation groups after arthroscopic ACL reconstruction. However, there was no significant difference in the mean score at a particular period of assessment between the rehabilitation groups as shown below in the table five:-

Table 5: Showing Lysholm knee score scale (LKSS) between home-based and hospital supervised rehabilitation pre ACL reconstruction, the second week, first month and third month after ACL reconstruction

LKSS				
Mean (\pm SD)	LKSS Pre OP	2ndweek	LKSS 4thweek	LKSS 12thweek
HBR	52.0(\pm 5.6)	66.0(\pm 4.9)	78.5(\pm 4.2)	88.3(\pm 3.4)
HSR	49.4(\pm 7.4)	64.3(\pm 8.2)	79.9(\pm 7.4)	92.9(\pm 2.9)
Total	50.7(\pm 6.6)	65.1(\pm 6.7)	79.2(\pm 6.0)	90.6(\pm 3.9)

CHAPTER FIVE

5.0 DISCUSSION

The purpose of this study was to compare the outcome between patients receiving self-instructed home-based rehabilitation versus hospital-supervised rehabilitation following arthroscopic ACL reconstruction at MOI.

The finding in this study was that the hospital supervised rehabilitation group revealed greater knee range of flexion at one month and three months and higher patient-reported performance of daily life activity compared to self-instructed home-based rehabilitation.

There were no significant differences between the groups for the secondary outcomes of anterior knee laxity, thigh muscle strength, and thigh muscle atrophy and post-reconstruction superficial surgical site infection.

A consecutive assessment of the performance of daily life activity revealed a significant improvement in mean Lysholm score over time in both groups but no significant difference between groups at a given period of assessment

Previous studies have reported no significant difference in muscle strength, muscle atrophy (13, 16)

Fischer found home-based rehabilitation program was feasible, safe and effective (7)

5.1 SOCIO-DEMOGRAPHIC CHARACTERISTICS

There were no significant differences found in age, occupation, educational level, body mass index (BMI), causes of the ACL tear, site of injured knee and period from injury to ACL reconstruction between the self-instructed home-based rehabilitation and hospital supervised rehabilitation groups. They did not affect the functional outcome of participants at the twelfth week in both groups. This finding was similar to the previous studies (5, 13, 16, 17)

Beard et al (5) showed the median age of the patients who participated was 28 years (20-46) and the median time since injury was 50 months (12-132 months). Also Over 86% of

patients sustained their injury during sporting and all had been diagnosed ACL deficient by arthroscopy or MRI scan.

5.2 KNEE RANGE OF MOTION

A consecutive assessment revealed a significant improvement in knee flexion over time in both groups however hospital supervised rehabilitation group had more compared to home-based rehabilitation at the first month and third-month post ACL reconstruction.

The Zulfikar et al study found similar results of a better outcome in the supervised group quadriceps girth, Tegner-Lysholm knee scale score, knee instability and knee range of motion compared to the unsupervised group (16).

Contrary to the results found by Fischer et al study of no significant statistical differences in the range of motion between the home-based and hospital supervised rehabilitation groups (7).

Grant et al study found no significant differences between the rehabilitation groups in the range of motion during walking, ligament laxity, and strength even though the home-based group had a significantly higher percentage of patients with acceptable flexion and extension range of motion compared to the standard physical therapy group (flexion, 67% vs 47%; extension, 97% vs 83%) (8).

This difference could be due to ethnicity or participants' motivation during rehabilitation.

5.3 ANTERIOR KNEE LAXITY

A higher number of the participants had good anterior knee laxity in both home-based rehabilitation and hospital supervised rehabilitation groups except two participants in the hospital supervised group had grade one knee laxity. However, there was no significant statistical association of knee laxity between the two rehabilitation groups (P-value 0.234). Similar results were reported by Beard et al. which assessed function activity level, muscle strength and anterior tibia translation preoperatively, at the third and sixth month after ACL reconstruction between groups receiving home program plus supervised rehabilitation and another home program alone. Both groups showed remarkable improvement in function activity level, muscle strength and anterior knee translation but no difference between the two groups. (5)

Also, Fischer et al study found no significant statistical differences between the two groups in anterior drawer compliance. (7)

Contrary to the study done by Zulfikar et al which showed a better outcome in the supervised group in anterior knee instability compared to the unsupervised group (16).

This difference could be due to the choice of the graft type, ethnicity or participants' motivation during rehabilitation.

5.4 THE QUADRICEPS MUSCLE STRENGTH AND THIGH MUSCLE ATROPHY

The study found that all participants had normal quadriceps muscle grading in both rehabilitation groups.

A large number of participants in both rehabilitation groups had good thigh muscle bulkiness except two (9.1%) who had thigh muscle atrophy in the home-based rehabilitation and one (4.5%) in the hospital-supervised group.

Fischer et al found similar results of no significant statistical differences between the two groups in the range of motion, thigh atrophy, anterior drawer compliance and the Lysholm scores (7). Contrary to the study done by Zulfikar et al which showed a better outcome in the supervised group quadriceps girth, Tegner-Lysholm knee scale score and knee instability compared to the unsupervised group (16)

This difference could be due to participants' time intervals between trauma and reconstruction.

5.5 THE LYSHOLM KNEE SCORE SCALE

The mean Lysholm knee scale score progressively improved with time among participants in both rehabilitation groups after arthroscopic ACL reconstruction. However, in this study, there was no significant statistical difference in the mean score during a particular period of assessment between the two rehabilitation groups.

Beard *et al* evaluated postoperative outcomes in a group of patients who attended regular supervised sessions of physical therapy supplemental to basic individual training, compared with those of patients fully exercising at home on their own. The Lysholm scale

scores, modified Tegner Scores and IKDC scale score recorded equivalent values for both approaches. (5)

Fischer et al study found no significant statistical differences between the two groups in the range of motion, thigh atrophy, anterior drawer compliance and the Lysholm scores (7)

Hohmann et al. found similar results of no difference in home-based and supervised programs of physiotherapy on basis of Lyholm and Tegner score (13)

The Zulfikar et al study showed a better outcome in the supervised group quadriceps girth, Tegner-Lysholm knee scale score and knee instability compared to the unsupervised group (16).

This difference could be influenced by graft type, the time interval between trauma geographical location, ethnicity or participants' motivation during rehabilitation.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATION

6.1 CONCLUSION

The finding in this study was that the hospital supervised rehabilitation group revealed a greater knee range of flexion at one month and three months compared to self-instructed home-based rehabilitation.

There were no significant differences between the groups for the secondary outcomes of anterior knee laxity, thigh muscle strength and atrophy and post-reconstruction superficial surgical site infection.

A consecutive assessment of the performance of daily life activity revealed a significant improvement in mean Lysholm score over time in both groups but no significant difference between groups at a given period of assessment

6.2 STUDY LIMITATION

The follow-up period was limited to 12 weeks, which was inadequate to fully assess the outcomes of the participants.

The sample size was not large enough to make a strong argument.

Assessment of anterior knee laxity was done using the Lachman test which could have influenced the outcome instead of KT 1000 arthrometer which is not available in our setting

6.3 RECOMMENDATION

Hospital supervised and home-based rehabilitation programs can be used in rehabilitating patients after arthroscopic reconstructed Anterior cruciate ligament as both lead to a better outcome and return to patients' daily and sports activities within a short period.

Further prospective studies which involve randomization, a large sample size, longer follow up period is needed to distinguish the findings of this study

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APPENDICES

Appendix I: Consent form: English version

Consent to participate in the study titled “OUTCOMES OF SELF INSTRUCTED HOME BASED VERSUS HOSPITAL SUPERVISED REHABILITATION FOLLOWING ARTHROSCOPIC ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION AT MUHIMBILI ORTHOPEDIC INSTITUTE” JULY 2020 TO DECEMBER 2020

GREETING: I am DR. Kudisala K. Shija, a resident in Orthopedics and Traumatology at MUHAS expecting to do a study on “Outcome of self-instructed home-based versus hospital supervised rehabilitation following arthroscopic anterior cruciate ligament reconstruction at MOI" JULY 2020 TO DECEMBER 2020

PURPOSE OF THE STUDY: To compare the outcomes between patients receiving self-instructed home-based rehabilitation versus hospital-supervised rehabilitation following arthroscopic ACL reconstruction at MOI, From JULY 2020 TO DECEMBER 2020

PATIENT’S PARTICIPATION: If you agree to participate in this study, you will be asked questions and examined.

CONFIDENTIALITY: All information obtained will be kept confidential and it will be entered into a computer with only an identification number; your name will not be included

RISKS: We ensure there will be no harm if you participate in the study

RIGHT TO WITHDRAW: Taking part in this study is voluntary and refusal to participate or withdrawal will not involve penalty or loss of any benefits to which you are entitled. You will be treated and followed up as per the usual institute treatment protocol for all patients with ACL tear treated by arthroscopic ACL reconstruction.

BENEFITS: If you agree to participate in the study, you will be assessed on the progress of your condition by the investigating doctor. We hope the obtained information from this study will benefit others at large

WHOM TO CONTACT:

If you have other questions regarding this study, feel free to contact me, the investigator, Dr Kudisala K Shija, MUHAS, P.O. Box 65001, Dar es Salaam, Mobile number 0754978851

My Supervisors Dr. Samwel Nungu (0754313274) Dr. Felix Mrita (0713439493) and Mr. Lucas Machage (0712620474)

If you have any questions concerning your rights as a participant, you may contact the Chairman of the Senate Research and Publication Committee, Dr. Bruno Sunguya, P.O. Box 65001, Dares Salaam. Telephone: +255222152489.

Signature

Do you agree to participate? Yes No.....

I, have read and understood the consent form and my questions have been answered and I agree to participate in this study.

Signature of participant

Signature of Investigator.....

Date of signed consent

Appendix II: Fomu ya Makubaliano ya kushiriki Utafiti: Kiswahili

Ruhusa ya kushiriki Utafiti wa kulinganisha matokeo ya wagonjwa walioelekezwa kufanyia mazoezi nyumbani na wanaoendelea kusimamiwa na wataalamu wa mazoezi hospitalini baada ya matibabu ya kukatika ACL kwa kutumia video maalumu katika Taasisi ya Mifupa Muhimbili, Kuanzia Julai 2020 hadi Disemba 2020

SALAMU: Mimi naitwa Dr. Kudisala K. Shija ni mwanafunzi wa uzamili chuo kikuu cha tiba Muhimbili, nalinganisha matokeo ya wagonjwa walioelekezwa kufanyia mazoezi nyumbani na wanaoendelea kusimamiwa na wataalamu wa mazoezi hospitalini baada ya matibabu ya kukatika ACL kwa kutumia video maalumu katika Taasisi ya Mifupa Muhimbili, Kuanzia Julai 2020 hadi Disemba 2020

DHUMUNI LA UTAFITI HUU: kulinganisha matokeo ya wagonjwa walioelekezwa kufanyia mazoezi nyumbani na wanaoendelea kusimamiwa na wataalamu wa mazoezi hospitalini baada ya matibabu ya kukatika ACL kwa kutumia video maalumu katika Taasisi ya Mifupa Muhimbili, Kuanzia Julai 2020 hadi Disemba 2020

USHIRIKI WA MGONJWA: Kama unakubali kushiriki kwenye utafiti huu utaulizwa maswali, utachunguzwa kwa kina na utafuatiliwa hata baada ya upasuaji katika kliniki yetu.

USIRI: Taarifa zote za uchunguzi zitaingizwa kwenye kompyuta na nambari ya utambulisho; jina halitatumika.

MADHARA: Tunategemea kwamba hakuna madhara yoyote yatoakanayo na utafiti huu.

HAKI YA KUJITOA KWENYE UTAFITI: Kushiriki katika utafiti huu ni hiari na kutokubali kushiriki au kujitoahautaadhibiwa au kupoteza haki yako ya matibabu.

Utatibiwa kama taratibu za hospitali zinavyoelekeza kwa mtu aliye na matatizo ya kukatika ACL.

KUTOKEA KWA MADHARA: Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu. Hata hivyo kama madhara ya mwili yatatokea kutokana na utafiti huu, utatibiwa kulingana na kanuni na taratibu za matibabu ya Tanzania.

FAIDA YA KUSHIRIKI KWENYE UTAFITI:

Kama utakubali kushiriki kwenye utafiti huu, faida utakazopata ni pamoja na kuonwa kwa karibu na daktari anayefanya utafiti. Tunatumaini kwamba taarifa zitakazopatikana zitawanufaisha wengine pia. Kwa mawasiliano zaidi: Kama una maswali au maelezo kuhusu utafiti huu, uwe tayari kuwasiliana na mtafiti, Dr. Kudisala K. Shija, Taasisi ya upasuaji mifupa na ubongo Hospitali ya Taifa ya Muhimbili S.L.P 65474, DSM. Simu 0754978851

Wasimamizi wangu Dr Samwel Nungu simu 0754313274, Dr Felix Mrita simu 0713439493 na Mr Lucas Machage simu 0712620474

Kama una maswali kuhusu haki yako kama mshiriki.

Kwa maswali yoyote yahasuyo haki zako mshiriki unaweza kuwasiliana na Mwenyekiti wa Kamati ya Tafiti na Machapisho, Dr. Bruno Sunguya, S.L.P 65001, Dar es Salaam. Simu +255222152489.

Saini.....

Je, umekubalikushirikiNdio Hapana

Mimi.....Nimesoma maelezo na kuyaelewa vizuri na nimekubali kushiriki kwenye utafiti huu.

Sahihi ya Mshiriki

Sahihi ya Mtafiti

Tarehe

Appendix IV: questionnaire**TITLE**

OUTCOME OF SELF INSTRUCTED HOME-BASED VERSUS HOSPITAL SUPERVISED REHABILITATION FOLLOWING ARTHROSCOPIC ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION AT MUHIMBILI ORTHOPEDIC INSTITUTE FROM JULY 2020 TO DECEMBER 2020

1. Form number _____
2. Registration number _____
3. Place of residency _____
4. Age _____
5. Sex
 - i. Male _____ ii. Female _____ -
6. Place of domicile after hospital discharge and during clinic follow up
 - i. Dar es Salam
 - ii. Other Regions. Mention
7. Educational level
 - i. No formal education
 - ii. STD 7 up to form 4
 - iii. Form six
 - iv. College and above
8. Occupation
 - a) Government employee / Civil servant
 - b) Self-employed. Specify
 - c) Unemployed
 - d) Others. Specify
9. Injured leg
 - i. Right ____ ii. Left ____
10. Cause of injury

- i. Sports-related injury Soccer ___ ii. Road traffic injury _____
 iii. Falling from height ___ iv. Activity of daily living
 v. Others (specify) _____
11. Date of injury _____ 13. Date of ACL reconstruction _____
14. Weight _____ (Kg) Height _____ (M)
15. Body mass index _____ (Kg/m²)
16. Evaluation of muscle atrophy (Right) _____ (Left) _____
17. Muscle strength grade (Right) _____ (Left) _____
18. Knee flexion _____ % knee extension _____ %

LYSHOLM KNEE SCORING SCALE

19. Limping

- a) I have no limp when I walk. (5)
 b) I have a slight or periodical limp when I walk. (3)
 c) I have a severe and constant limp when I walk. (0)

20. Using cane or crutches

- a) I do not use a cane or crutches. (5)
 b) I use a cane or crutches with some weight-bearing. (2)
 c) Putting weight on my hurt leg is impossible. (0)

21. Locking sensation in the knee

- a) I have no locking and no catching sensation in my knee. (15)
 b) I have a catching sensation but no locking sensation in my knee. (10)
 c) My knee locks occasionally. (6)
 d) My knee locks frequently. (2)
 e) My knee feels locked at this moment.. (0)

22. Giving way sensation from the knee

- a) My knee gives way. (25)
 b) My knee rarely gives way, only during athletics or vigorous activity. (20)

- c) My knee frequently gives way during athletics or other vigorous activities.
In turn, I am unable to participate in these activities. (15)
 - d) My knee frequently gives way during daily activities. (10)
 - e) My knee often gives way during daily activities. (5)
 - f) My knee gives way to every step I take. (0)
23. **Pain**
- a) I have no pain in my knee. (25)
 - b) I have intermittent or slight pain in my knee during vigorous activities.
(20)
 - c) I have marked pain in my knee during vigorous activities. (15)
 - d) I have marked pain in my knee during or after walking more than 1 mile
(10)
 - e) I have marked pain in my knee during or after walking less than 1 mile.
(5)
 - f) I have constant pain in my knee. (0)
24. **SWELLING**
- a) I have swelling in my knee. (10)
 - b) I have swelling in my knee only after vigorous activities. (6)
 - c) I have swelling in my knee after ordinary activities. (2)
 - d) I have swelling constantly in my knee. (0)
25. **CLIMBING STAIRS**
- a) I have no problems climbing stairs. (10)
 - b) I have slight problems climbing stairs. (6)
 - c) I can climb stairs only one at a time. (2)
 - d) Climbing stairs is impossible for me. (0)
26. **SQUATTING**
- a) I have no problems squatting. (5)
 - b) I have slight problems squatting. (4)
 - c) I cannot squat beyond a 90deg. Bend in my knee. (1)
 - d) Squatting is impossible because of my knee. (0)

DODOSO

Utafiti wa kulinganisha matokeo ya wagonjwa walioelekezwa kufanyia mazoezi nyumbani na wanaoendelea kusimamiwa na wataalamu wa mazoezi hospitalini baada ya matibabu ya kukatika ACL kwa kutumia video maalumu katika Taasisi ya Mifupa Muhimbili, Kuanzia Julai 2020 hadi Disemba 2020

1. Namba ya Fomu _____
2. Namba ya faili _____
3. Eneo la makaazi _____
4. Umri _____
5. Jinsia
 - i. Me _____ ii. Ke _____ -
6. Mahali ulipokuwa unaishi baada ya kuruhusiwa na wakati wa mahudhurio ya kliniki
 - i. Dar es Salam
 - ii. Mkoa mwingine. Taja _____
7. Kiwango cha elimu
 - i. Sijasoma
 - ii. Darasa la saba
 - iii. kidato cha nne
 - iv. Kidato cha siti
 - v. Chuo na kuendelea
8. Kazi unayojishughulisha nayo
 - i. Mwajiliwa wa serikali
 - ii. Amejijili, changanua _____
 - iii. Sina ajira _____
 - iv. Shughuri zingenezo, changanua _____
9. Upande wa mguu uliouiia
 - i. Kulia _____ ii. Kushoto _____

10. Sababu iliyopelekea kuumia
- i. Nimeumia nikicheza mpira _____
 - ii. Ajar barabarani _____
 - ii. Kuanguka kutokea juu _____
 - iv. Shughuri zingine _____
11. Tarehe ya kuumia _____
12. Tarehe ya kufanyiwa operesheni _____
13. Uzito _____ (Kg)
14. Urefu _____ (M)
15. Body mass index _____ (Kg/m²)
16. Hali ya paja kusinyaa (cm) Kulia _____ Kushoto _____
17. Uwezo wa mguu kunyanyuka (grade) kulia _____ kushoto _____
18. Uwezo wa goti kujikunja Kulia _____ (%) Kushoto _____ (%)
19. Uwezo wa goti kujikunjua Kulia _____ (%) Kushoto _____ (%)

LYSHOLM KIPIMO CHA GOTI

20. Mguu kuchechemea
- i. Nikitembea sichechemei (5)
 - ii. Nikitembea nachechemea kiasi (3)
 - iii. Nikitembea nachechemea sana (0)
21. Matumizi ya fimbo au magongo
- i. Situmii fimbo au magongo (5)
 - ii. Natumia magongo wakati nikikanyagia kiasi (2)
 - iii. Siwezi kukanyagia hata kidogo mguuu utaumia (0)
22. Kuhisi kujifunga kwa goti
- i. Sihisi kujifunga na kukakamaa kwa goti (15)
 - ii. Nahisi kukakamaa lakini sio kujifunga goti (10)
 - iii. Goti langu huwa linajifunga mara chachechache (6)
 - iv. Goti langu huwa linajifunga mara kwa mara (2)
 - v. Goti langu nahisi limejifunga kwa sasa (0)

23. Kuhisi goti linaachia

- i. Goti langu huwa sihisi kuachia hata kidogo (25)
- ii. Goti langu huwa sihisi kuachia isipokuwa wakati wa mazoezi makali (20)
- iii. Goti langu huwa nahisi kuachia wakati wa mazoezi makali hadi ina sababisha kutoshiriki michezo (15)
- iv. Goti langu huwa linaachia mara kwa mara wakati wa kazi za kila siku (10)
- v. Goti langu huwa linaachia siku zote wakati wa shughuri za kila siku (5)
- vi. Goti langu huwa linaachia kila hatua ninayochukua(0)

24. Maumivu

- i. Sina maumivu ya goti (25)
- ii. Nina maumivu kiasi ya goti nikifanya mazoezi mazito (20)
- iii. Nina maumivu ya goti nikifanya mazoezi mazito (15)
- iv. Nina maumivu kiasi ya goti wakati wa mazoezi au hata nikimaliza kutembea zaidi ya maili moja (10)
- v. Nina maumivu ya goti wakati wa mazoezi au hata nikimaliza kutembea chini ya maili moja (5)
- vi. Nina maumivu makali ya goti muda wote (0)

25. Uvimbe

- i. Sina uvimbe kwenye goti (10)
- ii. Nina uvimbe kwenye goti wakati nikimaliza mazoezi mazito (6)
- iii. Nina uvimbe kwenye goti wakati nikimaliza mazoezi ya kawaida (2)
- iv. Nina uvimbe kwenye goti wakati wote (0)

26. Kupandangazi

- i. Sina tatizo wakati wa kupanda ngazi (10)
- ii. Nina tatizo kiasi wakati wa kupanda ngazi (6)
- iii. Nina tatizo kiasi wakati wa kupanda ngazi (5)
- iv. Nina weza kupanda ngazi moja moja tu (2)
- v. Siwezi kupanda ngazi hata kidogo (0)

27. Kuchuchumaa

- i. Sina shida wakati wa kuchuchumaa(5)
- ii. Nina shida kidogo wakati wa kuchuchumaa(4)
- iii. Siwezi kuchuchumaa zaidi ya 90^0 (1)
- iv. Siwezi kuchuchumaa sababu ya goti langu(0)

Appendix V: Ethical clearance

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF RESEARCH AND PUBLICATIONS

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Ref. No.DA.282/298/01.C/

Date: 29/07/2020

MUHAS-REC-07-2020-307
 KUDISALA KULWA SHIJA
 School of Medicine
 MUHAS

**RE: APPROVAL FOR ETHICAL CLEARANCE FOR A STUDY TITLED:
 OUTCOME OF SELF INSTRUCTED HOME BASED VERSUS HOSPITAL
 SUPERVISED REHABILITATION FOLLOWING ARTHROSCOPIC
 ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION - MOI**

Reference is made to the above heading.

I am pleased to inform you that the Chairman has on behalf of the University Senate, approved ethical clearance of the above-mentioned study, on recommendations of the Senate Research and Publications Committee meeting accordance with MUHAS research policy and Tanzania regulations governing human and animal subjects research.

APPROVAL DATE: 29/07/2020

EXPIRATION DATE OF APPROVAL: 28/07/2021

STUDY DESCRIPTION:

Purpose:

The purpose of this prospective observational cohort study is to compare the outcome between patients receiving self-instructed home based rehabilitation versus hospital supervised rehabilitation following arthroscopic Anterior Cruciate Ligament reconstruction at Muhimbili Orthopedic Institute

The approved protocol and procedures for this study is attached and stamped with this letter, and can be found in the link provided:

<https://irb.muhas.ac.tz/storage/Certificates/Certificate%20-%2054.pdf> and in the MUHAS archives.

The PI is required to:

1. Submit bi-annual progress reports and final report upon completion of the study.
2. Report to the IRB any unanticipated problem involving risks to subjects or others including adverse events where applicable.
3. Apply for renewal of approval of ethical clearance one (1) month prior its expiration if the study is not completed at the end of this ethical approval. You may not continue with any research activity beyond the expiration date without the approval of the IRB. Failure to receive approval for continuation before the expiration date will result in automatic termination of the approval for this study on the expiration date.
4. Obtain IRB amendment (s) approval for any changes to any aspect of this study before they can be implemented.
5. Data security is ultimately the responsibility of the investigator.
6. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
7. Apply for and obtain data transfer agreement (DTA) from NIMR if data will be transferred to a foreign country.
8. Apply for and obtain material transfer agreement (MTA) from NIMR, if research materials (samples) will be shipped to a foreign country,
9. Any researcher, who contravenes or fail to comply with these conditions, shall be guilty of an offence and shall be liable on conviction to a fine as per NIMR Act No. 23 of 1979, PART III section 10 (2)
10. The PI is required to ensure that the findings of the study are disseminated to relevant stake holders.
11. PI is required to be versed with necessary laws and regulatory policies that govern research in Tanzania. Some guidance is available on our website <https://drp.muhas.ac.tz/>.


 Dr. Bruno Sunguwa
 Chairman, MUHAS Research and Ethics Committee



Appendix VI: Introduction letter

**MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
OFFICE OF THE DIRECTOR OF POSTGRADUATE STUDIES**

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Ref. No. HD/MUH/T.173/2018

03rd August, 2020

The Executive Director,
Muhimbili Orthopaedics Institutes,
P.O. Box 6714,
DAR ES SALAAM

Re: INTRODUCTION LETTER

The bearer of this letter is Kudisila Kulwa Shija, a student at Muhimbili University of Health and Allied Sciences (MUHAS) pursuing MMed. Orthopaedics and Traumatology.

As part of his studies he intends to do a study titled: **“OUTCOME OF SELF INSTRUCTED HOME BASED VERSUS HOSPITAL SUPERVISED REHABILITATION FOLLOWING ARTHROSCOPIC ANTERIOR CRUCIATE LIGAMENT RECONSTRUCTION -MOI.”**

The research has been approved by the Chairman of University Senate.

Kindly provide him the necessary assistance to facilitate the conduct of his research.

We thank you for your cooperation.

Ms. Victoria Mwanilwa

For: DIRECTOR, POSTGRADUATE STUDIES

cc: Dean, School of Medicine, MUHAS
cc: Kudisila Kulwa Shija