THE EPIDEMIOLOGY AND FUNCTIONAL OUTCOMES AFTER A MAJOR LOWER LIMB AMPUTATION (LLA) IN JOHANNESBURG

Lonwabo L Godlwana

Student number: 9702688E

This thesis is being submitted in fulfilment of the requirements for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg.

DECLARATION

I, Lonwabo Lungile Godlwana, declare that this thesis is my own work. It is being submitted for the degree of Doctor of Philosophy at the University of the Witwatersrand, Johannesburg. Due acknowledgement has been made in the text, where material from other authors has been used. This thesis has not been submitted for any degree or examination at this or any other University before.

……………………………………….

Signature of Candidate

………27.. day of …July.., 2015

DEDICATION

I dedicate this work to:

my daughter (iNkosazana yam) uLiyabukwa Lelethu Godlwana,

my wife Akhona Andiswa Godlwana (Nee Stofile),

my late mother (iNkosazana yamaMpondo), Mrs. Claribel Nonkululeko Godlwana (Nee Mdlangaso), my late aunt (iNkosazana yamaMpondo), Mrs. Nomfundo Iris Euphemia Twabu (Nee Mdlangaso), and my mother in-law Mrs. Nambitha P Stofile (Nee Magwentshu).

PUBLICATIONS AND PRESENTATIONS IN SUPPORT OF THIS THESIS

1. Godlwana L., Stewart A 2013 The impact of lower limb amputation on community reintegration of a population in Johannesburg: a qualitative perspective, South African Journal of Physiotherapy-Special edition: 48-54

2. Godlwana L., Stewart A, Musenge E.2012 Quality of life following a major lower limb amputation in Johannesburg, South Africa. South African Journal of Physiotherapy; 68 (2); 17-22

3. Godlwana L., Stewart A., Musenge E 2011 Differences in characteristics between people with lower limb amputations who died before 12 weeks and those who survived, South African Journal of Physiotherapy; 67 (1); 44-47

4. Godlwana L, Nadasan T, Puckree T, 2008: Global trends in incidence of Lower limb amputation: A review of the literature. South African Journal of Physiotherapy; 64 (1); 8-11.

PRESENTATIONS RELATED TO THE DISSERTATION

Event	Topic	Mode of Delivery
9th World Congress of the International Society of Physical and Rehabilitation Medicine, 19-23 June 2015, Berlin, Germany	Functional independence during the intermediate stage of rehabilitation after lower limb amputation: A randomized controlled trial."	Oral
9th World Congress of the International Society of Physical and Rehabilitation Medicine, 19-23 June 2015, Berlin, Germany	Incidence and prevalence of disease related lower limb amputations in Johannesburg, South Africa.	E-Poster Oral
17th International WCPT Congress 01-04 May 2015, Singapore	Mobility during the intermediate stage of rehabilitation after lower limb amputation in an under resourced community: a randomized controlled trial	Oral
17th International WCPT Congress 01-04 May 2015, Singapore	Using premorbid patients' non-clinical characteristics to predict survival following a lower limb amputation	Oral
17th International WCPT Congress 01-04 May 2015, Singapore	Integrating Evidence Into Lower Limb Prosthetic Rehabilitation In Today's World	Focused Symposia
World Confederation of Physical Therapy-Africa- 10th Biennial congress-Lusaka, Zambia 19-24 May 2014	Were the premorbid profiles of patients who died different from those who survived three months after lower limb amputation?	Oral presentation
World Confederation of Physical Therapy-Africa- 9th Biennial congress-Nairobi-Kenya 6-9 June 2012	Measures for the outcome of rehabilitation after lower limb amputation: A pilot study	Oral presentation
SASP Congress, 21-23 March 2012 Bloemfontein	Measures for the outcome of rehabilitation after lower limb amputation: A pilot study	Oral presentation

ABSTRACT

Background:

The incidence and prevalence of disease related lower limb amputation (LLA) operation at the Johannesburg metropolitan hospitals is unknown.

Lower limb amputation (LLA) results in a marked decline in functional independence. In Johannesburg South Africa, the LLA population is generally underprivileged, and Chris Hani Baragwanath Hospital and Charlotte Maxeke Johannesburg Academic hospital are not in a position to offer long-term rehabilitation to them on an inpatient basis. Patients often get discharged early as these tertiary hospitals have a high turnover and the demand for hospital beds is high.

Aims:

To establish the cumulative incidence and prevalence of disease related LLA at Johannesburg Metropolitan Hospitals.

To establish whether a self-administered postoperative exercise programme (home programme) will improve function and other selected outcomes. Measures were taken at three months and six months after the LLA.

Methods:

A population sample of all theatre register records was used to review theatre registers for the epidemiological study. All records of general surgery and vascular operations were reviewed to count the number of LLA operations performed over a two year period from June 2011-June 2013.

A randomised controlled trial (RCT) (n=154, n=77 per group) was conducted on participants who met the inclusion criteria. Allocation into groups was concealed and the assessor was blinded**.** The Barthel index to measure function (BI), Modified Amputee Body Image Scale (MABIS), Participation Scale (P-Scale), Euroqol EQ-5D quality of life (EQ-5D), Modified Locomotor Capabilities Index (MLCI) and the Timed Up and Go test (TUG) were used to gather data from the participants. The control group received the standard rehabilitation from Chris Hani Baragwanath or Charlotte Maxeke Johannesburg Academic hospitals and the intervention group received an additional exercise programme and an exercise diary (ED) to keep a record of compliance. The intervention was a home exercise programme which was administered from discharge until three month post amputation. A research assistant (a physiotherapist) administered the intervention and did weekly reminding of the participants about the exercises and the researcher did all the testing (interviews and physical tests).

Data were analyzed using IBM SPSS version 22. Descriptive and ratio analysis was used for the prevalence study. All continuous data are presented as means, standard deviations and

medians and percentiles. The two groups were compared using Fisher's exact test for categorical data and the Mann Whitney U-test for continuous data. Bonferroni correction method was used when testing the tools item by item. Survival was established using the Kaplan-Meier test and the Log Rank (Mantel-Cox) test for comparison. Generalised Linear models (GLM) Generalised Estimating Equations (GEE), Repeated Measures Analysis of Covariance (RM-ANCOVA and Analysis of Variance (ANOVA) were used to exclude confounders. A multiple linear regression was used to establish associations between baseline characteristics and functional outcomes. An intention to treat analysis was used.

Results:

A total population of N=23617 people underwent general and vascular surgical procedures at the Johannesburg Metropolitan Hospitals during the study period. The majority of the amputations were BKA followed by AKA. The total number of amputations performed was 879. The cumulative prevalence of LLA operations is 0.037 (95% CI) (or 3722.0 per 100 000 persons seen at the Johannesburg Metropolitan hospitals).Total amputation number of new LLA performed was 743. The cumulative incidence of LLA is 0.031(95% CI) (or 3146 per 100 000 persons -2-years of study). The cumulative incidence of LLA in males is 0.038(95% CI) (or 3849.14 per 100 000 persons -2-years of study). The cumulative incidence of LLA in females is 0.023(95% CI) (or 2300 per 100 000 persons -2-years of study).

In the RCT, the median age was 58 per group (p=0.505), the control group had 66.2% males and the intervention group had 63.6% males (p=0.433). There were no significant (p>0.05) differences in demographic characteristics between the two groups at baseline but the intervention group had a significantly (p=0.005) more participants with a BKA than the control group.

The groups were comparable at baseline on all the outcome measures except participation with the intervention group demonstrating significantly more participation restriction (P-Scale) (p=0.038) (25th percentile 0;0, median 0;0, 75th percentile 0;5 for group 1 and 2 respectively). However, the intervetion group demonstrated significantly less (p=0.004) participation restriction at three months postoperatively compared to the control group (25th percentile 10;6, median 28;18, 75th percentile 41;27 for group 1 and 2 respectively).

The intervention group demonstrated significantly lower (p=0.039) activity limitation levels (BI) at three months postoperatively compared to the control group (25th percentile 16;18, median 18;18, 75th percentile 19;20 for the control group and the intervention group respectively) and significantly lower (p=0.005) activity limitation levels (MLCI) (25th percentile 13;20, median 21;24, 75th percentile 30;38 for the control and the intervention group respectively) at three months postoperatively compared to control group. The intervention group demonstrated significantly lower (p=0.040) activity limitation levels at three months postoperatively compared to control group in the MLCI Basic Subscale score(25th percentile

7;9, median 9;11, 75th percentile 17;21 for the control and the intervention group respectively). Group 2 demonstrated significantly lower (p=0.001) activity limitation levels at three months postoperatively compared to the control group in the MLCI Advanced score (25th percentile 6;10, median 11;15, 75th percentile 14;19 for the control and the intervention group respectively). Body image perception (MABIS) showed no significant (p=0.201) difference between the groups (25th percentile 20;25, median 28;35, 75th percentile 40;43 for the control and the intervention group respectively) at three months.

The intervention group demonstrated a significantly (p=0.001) better QOL VAS (25th percentile 30;50, median 60;80, 75th percentile 80;80 for the control and the intervention group respectively) and a significant (p=0.033) index scores(25th percentile 0.264;0.689, median 0.725;0.796, 75th percentile 0.796;0.796 for the control and the intervention group respectively) of QOL at three months postoperatively compared to control group. The intervention group demonstrated significantly less risk of falling (better ability to balance) (TUG) at three months(25th percentile 25;19, median 34;24, 75th percentile 45;36 for the control and the intervention group respectively) (p=0.036) and six months (25th percentile 19;13, median 25.5;21, 75th percentile 36;32 for the control and the intervention group respectively) (p=0.046) postoperatively compared to the control group. Only balance remained different at six months, the other outcomes were similar between the groups. Being in the intervention group was associated with higher functional outcomes (activity levels, higher participatation levels, higher QOL and lower risk of falling) postoperatively. Being old was associated with lower functional outcomes (lower activity levels and high risk of falling) postoperatively. Being female was associated with lower functional outcomes (lower activity levels), absence of diabetes was associated with high QOL and absence of other comorbidities was associated with lower risk of falling.

Thirty-three participants died during the study period. There were significantly more smokers (p=0.016) and drinkers (p=0.022) among the group that died compared to the survivors. In the regression analysis, death was predicted by cigarette smoking, alcohol drinking and reduced preoperative participation.

Conclusion:

The intervention ensured early functional independence of the intervention group compared to the control group. This study suggests that the intervention could be adopted as standard care for lower limb amputation patients especially those from situations with limited resources as they tend to be discharged early from the hospitals in order to accommodate other admissions.

ACKNOWLEDGEMENTS

I thank:

Professor Aimee Stewart, Dr. Eustasius Musenge, Mrs. Thembisa Mbatha, the Postgraduate hub staff, Mr. Bonginkosi P. Vilakazi, Mr. Senzo Nkala, Mr. Skhumbuzo A Mbona, Dr Veronica M Ntsiea, Mrs. Lebo Maseko, Mr. Papi Mthimkhulu, Yvonne Gxabeka, Janine Webber, Oratile Sephecholo, Mr. MN Thupana, Miss. N Thupana, Janine Van Der Linde, the Physiotherapy staff at Wits and Mrs Irene Janse Van Noordwyk for their assistance.

- Participants for taking part and their families.

- Chris Hani Baragwanath Hospital, Charlotte Maxeke Johannesburg Academic Hospital, Helen Joseph Hospital, Edenvale Hospital, South Rand Hospital staff (clinical staff, theatre staff and administrative staff) in Physiotherapy, Vascular, General Surgery and theatre units for their assistance.

- Carnegie large grant, the South African Medical Research Council grant and the Wits Health Sciences faculty grant.

- Both clinical and administrative at the various hospitals including Sebokeng hospitals, Tladi clinic, Selby, Tambo Memorial Hospital, Chiawelo clinic, Orange farm ext 2 clinic, Diepsloot ext 2 clinic, the prosthethic physiotherapist at Milpark Hospital for their cooperation.

- Prof J Geertzen (Head of the Department of Rehabilitation Medicine Center, for Rehabilitation, University Medical Center Groningen -Netherlands).

- Prof. F Franchignoni (Serv. Fisiatria Occupazionale e Ergonomia FONDAZIONE SALVATORE MAUGERI Istituto Scientifico di Riabilitazione - Italy).

- Prof. Wim van Brakel (Netherlands).

- Prof. Jennifer Jelsma (University of Cape Town).

- Mrs. Akhona Godlwana (wife) and Liyabukwa (daughter) for their support, inspiration and courage.

TABLE OF CONTENTS

		Page

		Page
4.10.3	Training of the Research Assistant…………………………....................................	66
4.10.4	The Exercise Diary…………………………..	66
4.11	Summary of Data Collection for the Randomised Controlled Trial............................	67
4.12	Data Management and Analysis of the Randomised Controlled Trial………………..	68
5.	**Chapter 5: Pilot Study of the Randomised Controlled Trial**................................	70
5.1	Introduction……………………………………………………………...........................	70
5.2	Aim………………………………………..	70
5.3	Objectives of the Pilot Study………………………...	70
5.4	Participants and Sampling………………………...	70
5.5	Inclusion Criteria………………………..	70
5.6	Exclusion Criteria………………..………………………..	70
5.7	Instruments…………………………………………………………................................	70
5.8	Ethical Considerations……………………..……………...	71
5.9	Procedure of the Pilot Study………………………………...	71
5.9.1	Data Collection of the Pilot………………………..……...	71
5.9.2	Analysis of the Pilot Study………………………………………….................................	71
5.10	Results of the Pilot Study………………………..	71
5.10.1	Demographic Characteristics…………………………..	71
5.11	Internal Consistency of the Instruments……………………………...............................	72
5.11.1	The Barthel Index……………………...	72
5.11.2	The Amputee Body Image Scale…………………………..	73
5.11.3	The P-Scale………………………..	74
5.11.4	The Locomotor Capabilities Index………………………………....................................	75
5.11.5	The EQ-5D………………………..	75
5.12	Correlation of the Instruments……………………………..	76
5.13	Discussion of the Pilot Study Results…………………………….....................................	76
5.14	Limitations Observed in the Pilot Study……………………………..................................	77
5.15	Conclusion…………………………..……………………………………………………	77
6.	**Chapter 6: Results of the Randomised Controlled Trial**……………………………	78
6.1	Introduction……………………………..…………………………………………………	78
6.2	Flow of Participants through the Study…………………………....................................	78
6.3	Demographic Characteristics of the Participants……………………………...................	80
6.4	Participation Restriction…………………………...	81
6.5	Activity Limitation…………………………...	86
6.6	Body Image…………………………...	95
6.7	Quality of Life…………………………..	99
6.8	Balance (Risk of Falling) ……………………………..	101
6.9	Association between Baseline, Demographic, Clinical Characteristics and Functional Outcomes…………………………………………………………………	101

LIST OF FIGURES

LIST OF TABLES

LIST OF ABBREVIATIONS

ABIS	- Amputee Body Image Scale
ABIS-R	- Revised Version Amputee Body Image Scale
ADL	- Activities of Daily Living
AKA	- Above Knee Amputation
ANCOVA	- Analysis of Covariance
ANOVA	- Analysis of Variance
AOFAS	- American Orthopaedic Foot and Ankle Society
BI	- Barthel Index
BKA	- Below Knee Amputation
CAD	- Coronary Artery Disease
CHBH	- Chris Hani Baragwanath Hospital
CHD	-Coronary heart disease
CI	- Confidence Interval
CLAD	- Censored Least Absolute Deviations
CMJAH	- Charlotte Maxeke Johannesburg Academic Hospital
COPD	- Chronic Obstructive Airway Disease
CVA	- Cerebrovascular Accident
Df	- Degrees of Freedom
DV	- Dependent Variable
ED	- Exercise Diary
EQ-5D	- EuroQol
ESRD	- End Stage Renal Disease
FGA	- Flexible Goal Adjustment
GEE	- Generalised Estimating Equations
GLEA	- Global Lower Extremity Amputation
GLM	- Generalised Linear Model
HESSI	- Household Economic and Social Status
HIV	- Human Immunodeficiency Virus
HPT	- Hypertension
HRQOL	- Health Related Quality of Life
IADL	- Instrumented Activities of Daily Living
ICC	- Intraclass Correlation
ICD-10	- AM (International Classification of Disease Version 10)
ICF	- International Classification of Functioning, Disability and Health
IHD	- ischaemic Heart Disease
ITT	- Intention to Treat Analysis

IV	- Independent Variable
LCI	- Locomotor Capabilities Index
LCI-5	- Five Level Locomotor Capabilities Index
LEA	- Lower Extremity Amputation
LLA	- Lower Limb Amputation
MABIS	- Modified Amputee Body Image Scale
MDC	- Minimal Detectable Change
MI	- Myocardial Infarction
MidT	- Mid-Tarsal
MLCI	- Modified Locomotor Capabilities Index
MOXFQ	- Manchester-Oxford Foot Questionnaire
MRSA	- Methicillin Resistant Staphylococcus Aureus
OMs	- Outcome measures
PAD	- Peripheral Arterial Disease
PPA	- Per Protocol Analysis
P-Scale	- Participation Scale
PVD	- Peripheral Vascular Disease
QOL	- Quality of Life
RA	- Research Assistant
RCT	- Randomised Controlled Trial
RM	- Repeated Measures
SD	- Standard Deviation
SF-36	- Short-Form-36
TBI	- Traumatic Brain Injury
TF	-Transfemoral
TGP	- tenacious Goal Pursuit
TKA	- Through Amputation
TMT	-Transmetatarsal
TT	- Transtibial
TUG	- Timed Up and Go test.
VAS	- visual Analogue Scale
WHO	- World Health Organisation

CHAPTER 1

1.1 INTRODUCTION

Recent local research has revealed that persons with lower limb amputation (LLA) end up with significant reductions in function (Godlwana et al., 2012). In addition there is a lack of clarity about the amount of rehabilitation people with LLA in the public hospital system in Johannesburg receive given the difficulties these patients have in accessing rehabilitation because of their poor socio-economic status. While age and one's physical condition before the operation may dictate their functional outcome following LLA (Godlwana et al., 2011, Burger and Marincek, 2007, Nehler et al., 2003), there appears to be a need to investigate the impact of an appropriately designed rehabilitation programme for these patients. This need is especially important because it seems that people with LLA in Johannesburg end up not being able to access rehabilitation once discharged, because of their poor socioeconomic status as they are unable to afford transport to attend rehabilitation as outpatients (Godlwana et al., 2012).

As a result of the impact of LLA on function, participation and activity levels may be reduced. Godlwana and Stewart (2013 reported that people with LLA withdraw from social activities owing to their physical limitations, perceived body image and lack of disability supported facilities. The ability to walk is reduced during the early stages of recovery after LLA (Czerniecki et al., 2012; Godlwana et al., 2012). Such challenges in mobility result in persons with LLA experiencing problems in activities of daily living like household chores, recreational activities and returning to work (Gallagher et al., 2011). The inability to be independent in daily activities like going to the toilet, dressing and washing may result in the person feeling so insufficient that they see the need to relearn these functions as soon as possible. People with a LLA often express inability to walk, inability to operate automobiles (Bosmans et al., 2007). These functional losses can again impact negatively on their social participation and activity levels. People with a lower limb amputation lose independence and participation in their hobbies due to the amputation and majority experiences difficulty spending the day in a productive way (Zidarov et al., 2009b; Bosmans et al., 2007). As a result of the above, the impact on participation and activity levels may influence the outcome of the operation in the long term.

Persons with LLA in the Johannesburg metropolitan area seem to have the highest mortality rates in the world (Godlwana et al., 2011). This is associated with characteristics such as poor preoperative function, smoking and drinking (Godlwana et al., 2011). People who stop smoking reduce their likelihood of undergoing a major amputation whereas those who continue with their smoking habits may have a greater chance of undergoing a major amputation (Ohtar et al., 2004). Thus, emphasis on lifestyle modification may be necessary in order to improve the outcome of LLA in Johannesburg.

Lower limb amputation outcomes are influenced by factors such as, functional and physical independence, social interaction and functioning, emotion, body image, general and mental health (Zidarov et al., 2009b, Bosmans et al., 2007). Therefore studies in Johannesburg need to consider the administration and impact of a rehabilitation programme following LLA in order to change these factors. The current rehabilitation set up seems not to be within reach of people with LLA due to not only their socioeconomic situation but also the distance from their homes from healthcare facilities and the centralisation of health care facilities (Godlwana and Stewart, 2013)

Quality of life (QOL) three months after a LLA also seems not to change in the Johannesburg LLA population as measured by the VAS in the EQ-5D, although a significant decline in functional levels is reported (Godlwana et al., 2012). However, recent international research has shown that QOL can improve if people with LLA receive proper rehabilitation after the amputation (Zidarov et al., 2009a).

The body image of people with LLA is associated with QOL (Zidarov et al., 2009a). A person may perceive their body image as distorted and some will never completely acknowledge and accept their new body image (Zidarov et al., 2009a).

Zidarov et al. (2009a, reported success with treatment interventions such as inpatient rehabilitation programmes. However in South Africa the dynamics of the socioeconomic, health economics, current policy and the current rehabilitation model are unable to cater (poorly resourced) for this. As a result people with LLA are discharged home and have to come as outpatients which on its own can depend on whether one has the resources to attend treatment. Thus, the outcome of an exercise programme (home programme) self-administered postoperatively after a LLA needs to be examined bearing in mind that in our setting we do not have the resources to keep LLA people as inpatients for rehabilitation.

On the other hand, there is a death of literature on the prevalence of LLA. International research reports amputation rates of 20 per 100 000 (Peacock et al., 2011). Lower limb amputation is common in males, people with diabetes and in rural (Peacock et al., 2011; Alvarsson et al., 2012). Alvarsson et al. (2012, reported amputation rates of 1.07 amputations per person in a study that found a reduced rate of major LLA rates over a seven year period in Sweden. In an Irish study, Buckley et al. (2012, reported that a person with diabetes is 22.3 times more likely to have a non-traumatic LLA than their non-diabetic counterpart. In their study, no significant difference was found in amputation rates from year 2005-2009. In South Africa we would not be able to comment on whether the rates of amputations are on the decline or rise as we lack recent research in this topic. In South Africa, Henry (1993) found that white females get amputated fifteen years later that coloured females, and that the leading causes of LLA are vascular (83% a combination of PVD and diabetic cases).

1.2 CONCEPTUAL FRAMEWORK OF THIS RESEARCH

This section outlines the concepts and ideas reviewedto inform the studies in order to support the rationale, answer the research questions, develop, implement, report and evaluate the research (Kitchel and Ball, 2014, Smyth, 2004). The section thus helps to guide the studies.

1.2.2 BELIEFS AND ASSUMPTIONS ON THE PART OF THE RESEARCHER

While doing his masters degree, the researcher noticed that the current rehabilitation available following LLA in Johannesburg's public tertiary hospitals was insufficient and this was shown in these publications (Godlwana et al 2012, Godlwana and Stewart 2013). This led to the postulation and expectation that an additional and more supportive intervention is needed if one is to improve patient outcomes in this population. A summary of the problems reported as experienced/encountered by persons with LLA is presented in Table 1.1 below.

Table 1.1: Anticipated Problems Following LLA

Functional Problem	**References**
Decreased muscle strength	(Livingstone et al., 2011)
Poor balance	(Godlwana and Stewart 2013, Livingstone et al 2011)
Decreased activity levels	(Glemne et al., 2012, Norvell et al., 2011)
Decreased participation levels	(Gallagher et al., 2011, Ephraim et al., 2006)
Decreased quality of life levels	(Godlwana et al., 2012, Norvell et al., 2011)
Poor psychological profile (e.g. depression, anxiety, poor body image, pain)	(Godlwana and Stewart 2013)
Additional or Circumstantial Problems	
Difficulty affording transport to get to outpatients rehabilitation	(Godlwana and Stewart 2013)
Poor levels of education	(Godlwana et al 2012)
Poor socioeconomic background	(Godlwana et al 2012)
No long term inpatient rehabilitation beds and treatment- hence the need to emphasize a home treatment programme	Anecdotal evidence from practice and current status quo at the tertiary hospitals that will be study sites
High mortality rate	See table 2.1

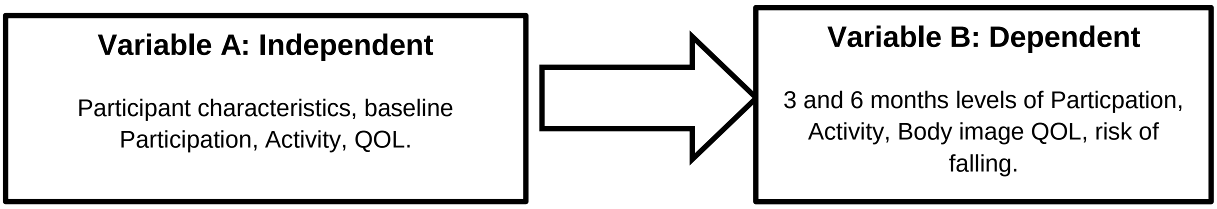


Figure 1.1: Fundamental Structure of a Conceptual Framework

Figure1.1 illustrates a fundamental structure of a conceptual framework taken from p190 (Kitchel and Ball, 2014). In the above, the researcher maps concepts that will be studied. A conceptual framework in its simplest form should have a flow of independent to dependent variables (Kitchel and Ball 2014). This best illustrates the relationship between the cause and the effect. In the planned study the researcher will conduct a study to address the problems identified and thus formulated as objectives of the study.

There is no available literature showing a trial on a sample of outpatient LLA persons. However, outcomes of studies like Zidarov el at (2009a) Czerniecki et al (2012) and Norvell et al (2011) are presented although they were on inpatients. Figure 1.2 illustrates a map of the steps taken in designing the RCT.

The primary aim of any intervention is to improve functional independence and this was the underlying principle of this thesis. The independent and dependent variables to be considered (Kitchel and Ball 2014) in this conceptual framework are outlined in Table 4.2.

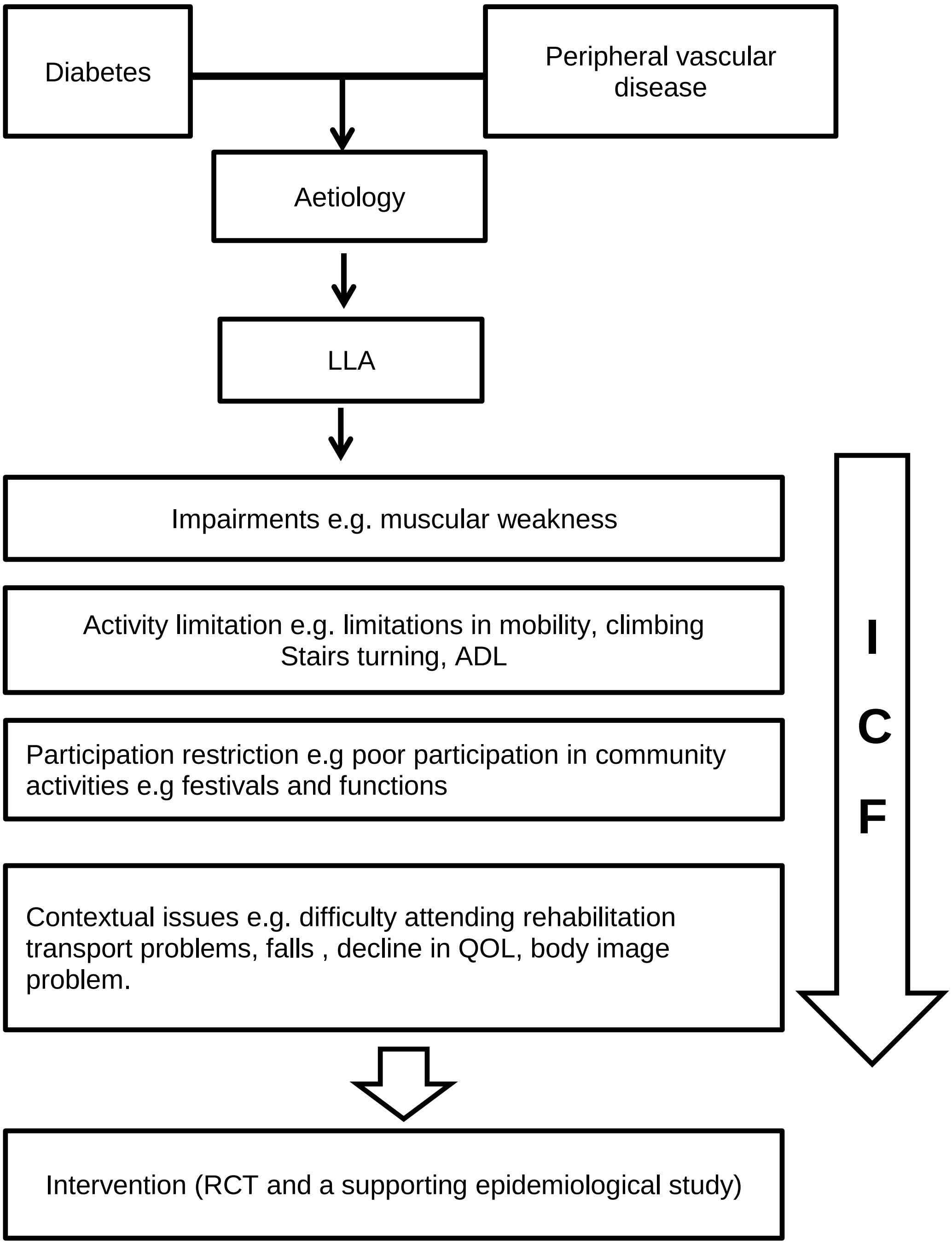


Figure 1.2: Illustrates a Map of the Steps Taken in Designing the RCT

Figure 1.3 illustrates a flowchart of the conceptual framework underpinning this thesis.

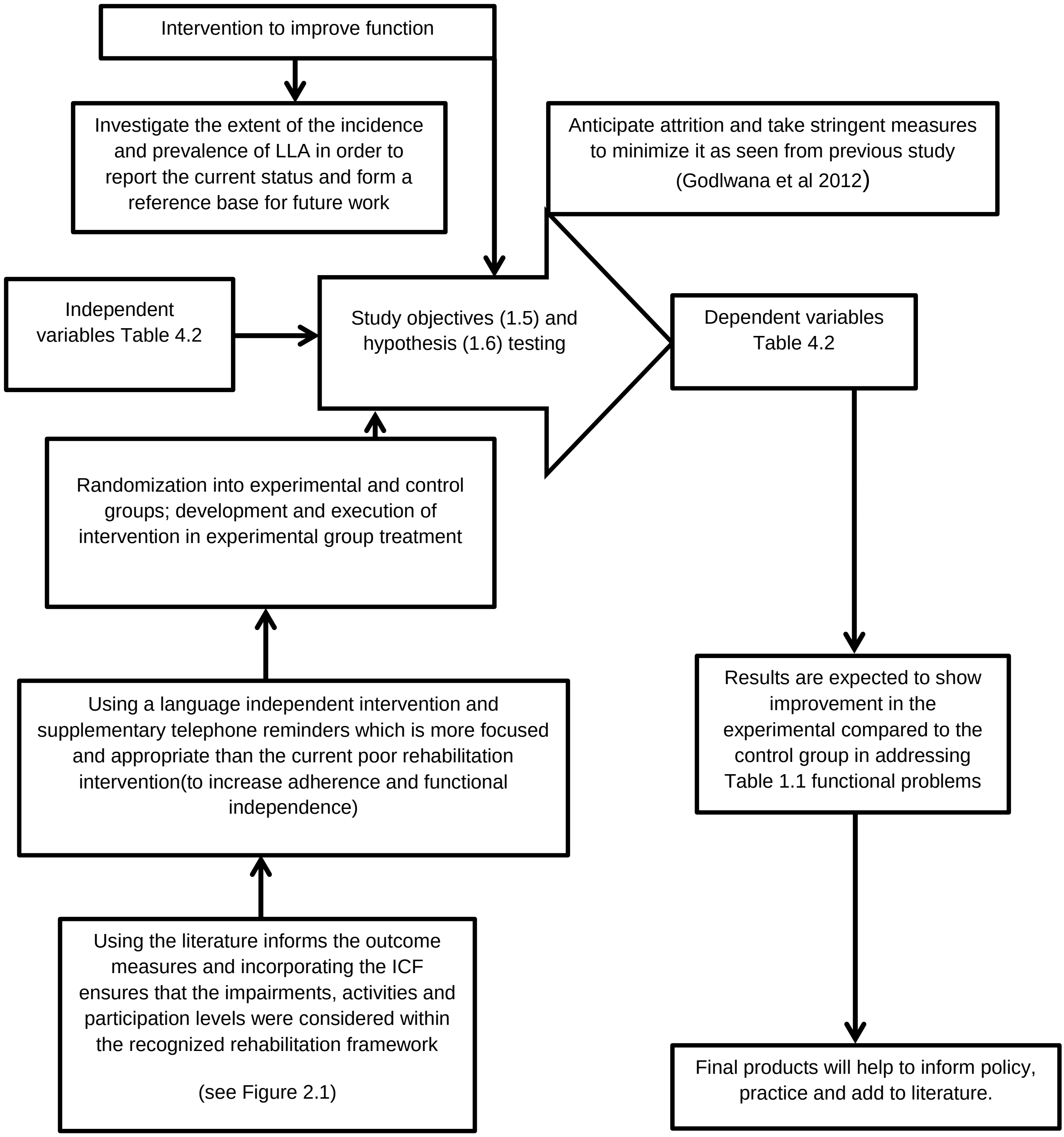


Figure 1.3: Flowchart of the Conceptual Framework Underpinning this Thesis

In the above framework the identified problems will be addressed in two forms namely, a randomised controlled trial and an epidemiological study. An intervention added to the current treatment will be tested against the current treatment alone. The researcher will control the environment of the study as regards randomization, concealed allocation to groups, use of a language independent tool and reminders and home visits to minimise attrition. The International Classification of Functioning, Disability and Health will be used to guide the outcome measure in order to get a clear perspective of the outcomes.

In the current situation it seems that patients with LLA need more than treatment as what is currently available is potentially not enough and this is supported by previous findings from research in this population (Godlwana et al 2012, Godlwana and Stewart 2013). This is especially so because of a range of challenges they face including difficulty getting to hospital, poor socioeconomic backgrounds, low levels of education and limited financial resources.

In addition to strengthening the results of the project, knowing the incidence and prevalence helps us to understand the extent of the problem and thus the need for an intervention especially if these are high. Most importantly, through publications out of this work, the findings will help to inform policy, practice and provide evidence.

1.3 PROBLEM STATEMENT

The lower limb amputation population is generally underprivileged and lacks the financial resource to diligently attend outpatients' rehabilitation service. Bearing in mind that tertiary hospitals such as Chris Hani Baragwanath Hospital and Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) are not in a position to offer long-term inpatient rehabilitation as they have a high patient turnover, there is a need to investigate alternative ways to assist persons with LLA with their rehabilitation in order to improve their functional independence. Furthermore, in Johannesburg, the incidence and prevalence of disease related LLA opertions at Chris Hani Baragwanath Hospital (CHBH), Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Helen Joseph Hospital, South Rand Hospital and Edenvale Hospital is unknown.

1.4 RESEARCH QUESTION

1.4.1 What is the impact of a self-administered postoperative exercise programme (home programme) on function and other selected outcomes three months and six months after a LLA?

1.4.2 What is the two year incidence and prevalence rate of disease related LLA operations at the five public hospitals servicing the Johannesburg metropolitan area?

1.5 AIMS OF THE STUDY

1.5.1 Aim of the Randomised Controlled Trial

To determine the impact of a self-administered exercise programme (home programme) administered postoperatively on function and other selected outcomes three months and six months after a LLA

1.5.1.1 Objectives of the Randomised Controlled Trial

- To compare pre and postoperative levels of participation restriction between the intervention and the control group.
- To compare pre and postoperative levels of activity limitation between the groups.
- To compare the perceived body image between the groups.
- To compare pre and postoperative quality of life (QOL) between the groups.
- To compare balance and falls prediction (risk of falling) between the groups.
- To compare survival rate between the groups including a comparison of their preoperative (baseline) characteristics.
- To establish the relationship between function, body image, participation and compliance with home exercises (using the Exercise diary (ED)) in these patients.
- To establish the association between functional outcomes of the exercise program intervention and the baseline characteristics (demographic and clinical characteristics).

1.5.2 Aim of the Epidemiological Study

To establish the two year incidence and prevalence of disease related LLA operations on people who underwent general or vascular surgery at the five public hospitals servicing the Johannesburg metropolitan area.

1.5.2.1 Objectives of the Epidemiological Study

- To establish the two-year prevalence of LLA operations.
- To establish the incidence of LLA operations in this population.

1.6 HYPOTHESIS

In this study, p≤0.05 at 95% CI is regarded as significant.

Ha1: The postoperative levels of participation restriction, activity limitation, QOL and risk of falling will be significantly improved in the intervention compared to the control group.

Ho1: The postoperative levels of participation restriction, activity limitation, QOL and risk of falling will not be significantly improved in the intervention compared to the control group.

Ha2: The intervention group will experience/report significantly less perceived body image disturbance than the control group.

Ho2: The intervention group will not experience/report significantly less perceived body image disturbance than the control group.

1.7 SIGNIFICANCE AND JUSTIFICATION FOR THE STUDY

Rehabilitation is a crucial part of improving the quality of life and outcomes of people with lower limb amputation (Kelly and Dowling, 2008). Recent local research has shown that an intervention such a single telephone call a month, together with a home exercise programme can help improve the condition of people with chronic disease (Stewart et al., 2005). Therefore this study tested a self-administered home programme and the use of an exercise diary to supplement current rehabilitation practice. The use of a home programme is a realistic method of rehabilitation given the difficulty these patients have in accessing existing rehabilitation services.

The nature of the exercises has also been informed by recent local research where significant reduction in function and reduction in activity was evident hence this study introduced a programme that would influence function (Godlwana et al., 2012). The exercises have also been informed by Robinson et al. (2010) and Broomhead et al. (2006) to target the area known in the literature to be vulnerable. Godlwana et al. (2012) and Godlwana and Stewart (2013) identified problems in the rehabilitation outcomes of people with LLA some of which included people's reported concerns of physical and social functioning while others were identified as characteristics/ predictors of poor outcome. These outcomes included poor physical function, poor social interactions, and poor coping mechanisms. This study may help shape evidence based practice in the current management of LLA survivors. The intervention has the potential to become the treatment protocol for these patients within the existing South African health care model as it improves physical function, social interactions, quality of life and coping mechanisms.

1.8 OUTLINE OF THE CHAPTERS

- Chapter 1 : Introduction
- Chapter 2 : Literature Review
- Chapter 3 : Epidemiological study
- Chapter 4 : Methodology of the randomised controlled trial
- Chapter 5 : Pilot study of the randomised controlled trial
- Chapter 6 : Results of the randomised controlled trial
- Chapter 7 : Discussion of the randomised controlled trial
- Chapter 8 : Conclusions

CHAPTER 2

2. LITERATURE REVIEW

2.1 INTRODUCTION

The review explores the literature on the functional, physical, psycho-social-economic, quality of life and survival outcomes of people with lower limb amputation (LLA). In this chapter, lower limb amputation (LLA) is described as we as the causes and risk factors. The review also return of people into their community of origin, return to work, the International Classification of Functioning (ICF) and its applicability to lower limb amputation (LLA), as well as outcome measures used in this thesis.

2.2 LITERATURE SEARCH STRATEGY

The literature used in this thesis was collected through the internet sources; Elsevier Science Direct, PubMed, PubMed central, EBSCO HOST electronic journal service, Sabinet and Google scholar. Various keywords were used to search and obtain literature for this review. The following keywords were used: amputation, amputee, preoperative status in lower limb amputation, lower limb amputation, lower extremity amputation, incidence, prevalence, epidemiology, quality of life, functional outcomes, physical impact, psychological impact, socio-economic impact, outcomes, prosthesis, ICF, outcome measures in rehabilitation, amputee outcome measures, Barthel Index, EQ-5D, Locomotor Capabilities Index, Amputee Body Image Scale, Participation Scale and Timed Up and Go.

The literature was examined to gain insight into international and local research on lower limb amputation outcomes as well as to provide the context for this study. The review was mostly limited to literature published in English in the past 10 years, but occasionally, literature older than 10 years appears in the review.

2.3 DEFINITION OF LOWER LIMB AMPUTATION

The Global Lower Extremity Amputation (GLEA) Study Group (2000) defined a lower extremity amputation as a complete loss or ablation of any part of the lower limb, regardless of the reason, in these anatomical planes: in the transverse plane proximal to, and including, the subtalar joint and in the frontal anatomical plane distal to the subtalar joint. An amputation can be “major” or “minor”. The Global Lower Extremity Amputation (GLEA) Study Group (2000, further states that a major amputation is that through, or proximal to the tarsometatarsal joint and a minor amputation is one distal to this joint.

It is however worth noting that there is neither consistency nor consensus in the literature on the definite classifications of lower limb amputation. Lazzarini et al. (2012) consider a minor lower limb amputation as an amputation from the level of the ankle through the malleoli of the tibia and fibula or levels distal to that. A major lower limb amputation is regarded as one below the knee (anywhere in the leg but above the ankle) and going all the way proximally to the level of the hindquarter and this classification is consistent with the ICF (ICD-10-AM) (Lazzarini et al., 2012).

Possible surgical anatomical levels of lower limb amputation include:

1. Toe-ectomy- amputation through the metatarsal phalangeal joint/s to remove the toe/s.
2. Transmetatarsal - amputation through the shafts of the metatarsals.
3. Mid-tarsal - amputation through the tarsals.
4. Symes - amputation through the ankle joint.
5. Transtibial - amputation below the knee.
6. Knee disarticulation - amputation through the knee joint.
7. Transfemoral - amputation above the knee.
8. Hip disarticulation - the femur is disarticulated from the acetabulum, often done in oncology.
9. Hindquarter - removing the lower limb from the ipsilateral half of the pelvis, again usually performed in malignancy to control the metastasis.

(Robinson et al., 2010, Marshall and Stansby, 2010, Kelly and Dowling, 2008, Lazzarini et al., 2012)

2.4 AETIOLOGY AND EPIDEMIOLOGY OF LOWER LIMB AMPUTATION

Lower limb amputation is done in order to salvage a limb in the event of tissue loss as a result of vascular occlusive disease, or to combat infection (Coffey et al., 2014, Henke, 2009, Nather et al., 2008, Engstrom and Van de Ven, 1999). Diabetes is the leading cause of LLA (Lazzarini et al., 2012, Moxey et al., 2010, Nather et al., 2008, Stineman et al., 2008, Godlwana et al., 2008) and traumatic amputations are performed in minority of the patients. In African regions where violence and wars are rife, trauma is the main cause of LLA (Godlwana et al., 2008, Amosun et al., 2005). It must be noted that this finding may have been a once off event particularly affecting a specific region of Africa during her regional conflicts.

Studies show that diabetic complications such as peripheral vascular disease (PVD), neuropathic foot, ischaemic foot, infection, as well as conditions like trauma, malignancy and congenital lower limb defects result in LLA, at varying rates (Lazzarini et al., 2012, Godlwana et al., 2012, Wong, 2005, Spichler et al., 2001, The Global Lower Extremity Amputation (GLEA) Study Group, 2000). Eskelinen et al. (2004, also identified that burns, rhabdomyolysis, sepsis and cellulitis may result in lower limb amputation. Risk factors for lower limb amputation include modifiable conditions of life style such as coronary arterial disease, hypertension, tobacco smoking and end stage renal disease (ESRD) (Abou-Zamzam et al., 2003).

People with hypertention (systolic range of 135-221), (diastolic range 86-117), higher pulse pressure (53-125), severe retinopathy, pack-years smoked greater or equaling 15 have a high incidence of LLA (Moss et al., 1999). In keeping with the smoking findings, Norvell et al. (2011) reported the proportion of smokers increases with the anatomical level of amputation, 19%, 42% and 71% of the sample had a transmetetartal, BKA and AKA respectively ($p<0.05$). This means that smoking is not only a risk for a lower limb amputation but also a risk for a higher amputation level.

A Singapore study however reported that sex, race, duration of diabetes, smoking, excessive alcohol use, obesity, hyperlipidaemia are not predictive factors for LLA while age, gangrene and infection, comorbidities (e.g. stroke and IHD), complications (e.g. PVD and nephropathy), sensory neuropathy, ischaemia, endocrine control and pathogens (e.g. MRSA and staphylococcus) were all identified as predictors for limb loss (Nather et al., 2008). This was a retrospective review of the patients' medical records, and accuracy of the records, data abstraction and even history taking cannot be ascertained.

Non-traumatic LLA rates increase with age with more than 80% occurring in those older than age of 65 who are retired (Wong, 2005, Calle-Pascual et al., 1997). Lazzarini et al. (2012) reported that diabetes type 2 amputees had a mean age of 67(SD10), type 1 had a mean age of 52 (SD12). In Johannesburg, a mean age of 53 was reported by Godlwana et al. (2012). The socioeconomic stati among the study settings potentially could be the reason for the Johannesburg participants being amputated at a younger age compared to those in the international literature.

Low income and being of single marital status (regardless of divorced, a widow, or never been married) as well as a history of foot ulcers are associated with a higher incidence rate of LLA in patients with diabetes and cardiovascular diseases

(Godlwana et al., 2012, Godlwana et al., 2008, Resnick et al., 2004, Hennis et al., 2004). However, these data are limited to Caribbean studies on and black South Africans in Johannesburg, South Africa. Calle-Pascual et al. (1997, reported a 5% unemployment in this population, again reiterating that persons with LLA are generally from a low socioeconomic background.

An association between rates of LLA and race has been reported (Godlwana et al., 2012, Feinglass et al., 2005, Dillingham et al., 2002). These studies showed that a black person is two times more likely to have a LLA due to PVD as other races. This could be due to their lifestyles and habits e.g. tobacco smoking, alcohol consumption, diet and their socioeconomic background. However, Godlwana et al. (2012) studied patients in public hospitals and it is not clear if the outcome would have been the same if private hospitals were included in their study as the demographic profile of the patients as well as the care they receive in public versus private hospitals may not be similar. Being from a minority race group (Native American or Black) is associated with undergoing a LLA compared to a limb salvage treatment such as revascularization (Henry et al., 2011). This may not necessarily be the the case in the South African context as the minority may be the ones mostly covered by medical insurance and thus having access to private health care. This study stated that being from a minority group often results in being vulnerable to less specialized care as these groups may not afford tertiary hospital care. In a South African study, Henry (1993) reported that coloures males get amputated ten years earlier than coloured males and females have a higher risk of undergoing early LLA, compared to whites. This is potentially because of their lifestyles as well social habits of these patients e.g. tobacco smoking, alcohol consumption, possible genetic predisposition and or differences in socio-economic stati. It is concerning that there are no recent studies on epidemiology of lower limb amputation in South Africa. A huge concern about this study is not only that it is 20 years old but also that it seems not to have included the black population. This study included only two racial groups probably because it was done in Cape Town and at that time the majority of the population there was coloured and white.

Similarities in incidence of LLA in both genders have been reported in various regions (different study sites) as well as lower rates in males compared to females in other regions (at isolated study sites) although generally, the incidence is higher in males than females (Moxey et al., 2010; The Global Lower Extremity Amputation Study, 2000). Moxey et al. (2010) reported that the above results are because of the impact of diabetes and that diabetes is consistently the primary cause of major LLA.

The GLEA Study however only included Japan, Taiwan, Spain, Italy, North America and England as their study sites, meaning that not all study sites reported higher incidence for males. In their study, North America reported the highest rates for both genders while Japan reported the lowest rates and had Spain much lower incidence rates than England (The Global Lower Extremity Study, 2000). The GLEA (2000) also states that the variations in the results were as a result of under-ascertainment (when using the capture-recapture estimation technique) during the medical records review. Lazzarini et al. (2012) reported an amputation rate in males (69%) significantly ($p<0.001$) higher than females (31%).

Fortington et al. (2013b, reported no change for all ages in incidence of LLA for the period 1991-1992 (8.9 per 100 000 person years (95%CI)) compared to the 2003-2004 (8.8 per 100 000 person years) ($p<0.05$) in the Dutch population. In this study, age at amputation and gender remained the same at amputation compared at both comparison periods (1991-992 compared to 2003-2004) and the incidence remained higher in older patients. In this study, females with diabetes were amputated at an age 3.1 years earlier than their non-diabetic counterparts ($p=0.0095$) and females were significantly older than males (76.4 years years compared to 71.4) regardless of diabetic status ($p\leq0.003$). Fortington et al. (2013b) excluded persons with LLA as a result of trauma, oncology, complex regional pain syndrome and congenital birth defects so as to look at vascular (diabetes and PVD) type only. This makes their study important as regards conclusions about persons who are amputated due to a vascular cause. Similarily, Buckley et al. (2012, found no significant decline ($p=0.11$) in the incidence of diabeties related LLA with an incidence of 144.2-175.7 per 100 000 from 2005-2009 in diabetic related amputations and a nonsignificant decline ($p=0.16$) of 12-9.2 per 100 000 for the same period in nondiabetes related LLA .

In South Africa, only Henry (1993) is an epidemiological study. The mean age at first amputation in her study was 60 years (Henry, 1993). The latest data are from Henry (1993, who reported that leading causes of LLA are congenital limb defects (0.2%),infection (2%), malignancy (3%), trauma (12%), and vascular (83% a combination of PVD and diabetic cases). In her study, there were more females regardless of the causes of LLA, coloured participants outnumbersed white participants, and apart from the fact that her study included only the public sector, no reasons given for this variation. When comparing the groups, a ratio of 1:5 was found for whites to colouredswith LLA as a result traumatic cause. This may have been partly as a result of the population demographics of race of the study setting, as the Western Cape Province was predominantly coloured, at the time of the study.

2.4.1 **Preoperative Characteristics of Persons with Lower Limb Amputation**

There is no preoperative differences in function among prosthetic users and non-prosthetic users with the Five Level Locomotor Capabilities Index (LCI-5) score all indicating high (median=42 and 41.5 respectively) functional independence ($p<0.05$) and this is the case for both the basic subscale and the advanced subscales categories of the index LCI-5 scores (medians of 24 and 27 as well as 18 and 14 for basic and advanced subscales respectively) (see Chapter 5 for interpretation of the LCI) (Glemne et al., 2012). Fleury et al. (2013) reported that preoperative ambulation status was associated with the level of amputation in their study. Patients who were not able to walk before the amputation were more likely to have an AKA than a BKA, and the reason for this may be that, those ending up with AKA may have had the worst medical condition at initial presentation. Claudication may have resulted in difficulty in walking preoperatively (Fleury et al., 2013). Thus patients were no longer walking because of the claudication pain and this led to general deconditioning, which can also be seen postoperatively as a result of slow stump healing and subsequent decline in mobility (Fleury et al., 2013).

Ambulation declines from the premorbid to the presurgical period. Ambulation declines from the premorbid state to about six weeks post amputation and then improves during the intermediate post amputation stage from six weeks to four months but does not reach premorbid ambulation states (Czerniecki et al., 2012) and the decline continues to a year after LLA (Norvell et al., 2011). Being 65 year or older, having an alcohol disorder, being hypertensive, having been treated for anxiety or depression are all associated with a lower success in regaining mobility postoperatively (Norvell et al., 2011).

There is a link between preoperative functional status and postoperative death within 30 days (Karam et al., 2013). In their study, twenty percent of patients who were functionally dependent died compared to 4.3% who were independent preoperatively ($p<0.001$). These findings are similar to those of Godlwana et al. (2011) who found that patients who died following an LLA had significantly poorer preoperative scores in mobility ($p=0.001$), ability to transfer ($p=0.03$) and total scores on the Barthel index ($p=0.01$). Preoperative factors positively influencing maintenance of preoperative ability to ambulate, maintaining independent living status, survival are: a younger age, lower levels of amputation, male gender, absence of coronary artery disease (CAD), absence of dementia, being ambulatory preoperatively, preoperative independent living status and failure of ambulation is predicted by; age≥70, age 60-69, bilateral amputation, End Stage Renal Disease (ESRD), and being homebound

(Taylor et al., 2005). Preoperative factors resulting in failure to maintain independent living and death are; age≥70, age 60-69, level of amputation, ambulatory status limited to home, presence of dementia, bilateral amputation, presence of PAD, nonambulatory preoperative status, and having CAD (Taylor et al. 2005). Their study showed that the older the person the worse the outcome and this was especially prominent in those over the age of 70 years.

2.5 SURVIVAL FOLLOWING LOWER LIMB AMPUTATION

Major LLA is known for its fatality (Fortington et al., 2013a, Karam et al., 2013, Papazafizopoulou et al., 2009, Basu et al., 2008). Mortality following lower limb amputation is shown in Table 2.1.

Table 2.1: Survival and Mortality Following Lower Limb Amputation

Mortality rate	Reported predictor/cause of death	Follow up period	Study
22%	Cardiac disease, Old age, CVA, Renal cause	30 days	(Fortington et al. 2013a)
13.5%	Old age, heart disease, renal cause, COPD	30 days	(Jones et al., 2013)
9.1%	Old age, white race, preoperative/ postoperative pneumonia, heart disease, renal failure, being on dialysis, COPD, dyspnea at rest, CVA, emergency amputation, preoperative blood transfusion	30 days	(Karam et al. 2013)
14.7% of participants with diabetes and 21.3% of participants without diabetes	Old age	Within 30-day to six months	(Papazafizopoulou et al. 2009)
10%		Operative	(Basu et al., 2008)
12%, and 29% respectively	Not stated	One week, 30-days	(Eskelinen et al., 2004)
15%	Heart disease, pneumonia, septicaemia, CVA, cancer, gastrointestinal bleeding	30 days	(Leung and Wong, 2004)
9.2%,	High anatomical level of amputation	30 days	(Wong, 2005)
10%.	Renal disease, cardiac disease, pulmonary, stroke, thromboembolism, sepsis	30 days	(Nehler et al., 2003)
10%	Renal, cardiac, pulmonary, CVA, thromboembolism, sepsis	30 days	(Pernot et al., 2000)
33%	Old age, smoking, alcohol consumption, poor preoperative functional status	3 months	(Godlwana et al., 2011)
7.7%	Unspecified	4 months	(Hershkovitz et al., 2012)
A third dies by six months irrespective of age and gender.	Old age		(Back-Pettersson and Bjorkelund, 2005)
13.6%			(Basu et al. 2008)
44%	Cardiac disease, Old age, CVA, Renal insufficiency	1 year	(Fortington et al., 2013a)
48%	Being discharged home	1 year	(Dillingham and Pezzin, 2008)
48.3%	Old age, heart disease, renal disease, COPD	1 year	(Jones et al., 2013)
22%	Discharge to an inpatient rehabilitation	1 year	(Dillingham and Pezzin, 2008)
39%	Discharge to a skilled nursing home	1 year	(Dillingham and Pezzin, 2008)
41%	Irrespective of discharge destination	1 year	(Dillingham and Pezzin, 2008)
36%, in diabetics and 28%, in non-diabetics	Unspecified	1-2year	(Papazafizopoulou et al., 2009)
52%	Not stated	1 year	(Eskelinen et al., 2004)
44%	Old age	1 year	(De Godoy et al., 2005)
20%	Old age, poor self-care	2years	(Otiniano et al., 2003)
50%	Old age	2years	(De Godoy et al., 2005)
37%		2 years	(Leung and Wong, (2004)
70.9%	Old age, heart disease, renal disease, COPD	3 years	(Jones et al. 2013)
45%	Renal, cardiac, pulmonary, stroke, thromboembolism, sepsis	3year	Nehler et al. (2003).
47% in diabetics and 44%, in non-diabetics		3-4year	(Papazafizopoulou et al. 2009).
60%	Old age	3year	(De Godoy et al., 2005)
64%	Old age	4years	(De Godoy et al., 2005)
55%			(Leung and Wong, 2004)
48% in diabetics and 46% in non-diabetics	Old age	5-6 year	(Papazafizopoulou et al. 2009).
68%	Old age	5 years	(De Godoy et al., 2005)
77%	Cardiac disease, Older age, CVA, Renal insufficiency	5 years	(Fortington et al. 2013a)
72%	Old age	6years	(De Godoy et al., 2005)

Footnote: The information in Table 2.1 on predictor/cause of death is the same cause of death at different follow up periods. Although some studies did not state the cause or predictor of death, all the studies in the table were done on persons who had an LLA due to a dysvascular cause.

Table 2.1 shows that LLA has a high mortality rate in people with dysvascular lower limb amputation. The table also shows that Johannesburg survival is substantially poorer compared to the international literature. This is undoubtedly because the patients are from a poor socioeconomic background (Godlwana et al., 2011; Godlwana et al., 2012), thus, facing more trying challenges as regards resources and health care accessibility. McIntyre et al. (2009, views access in three ways; availability (physical access and geographical), affordability (financial access) and acceptability (cultural access). In these, availability, affordability were expressed as prominent problems by Godlwana and Stewart (2013). Another factor to consider when viewing the Johannesburg population is that even when a health facility is geographically accessible (e.g. a local clinic) it may not have some of the services such as specialist clinics in which a patient can for instance be seen by a vascular specialist as well as the therapists instead of spending money and time to attend different facilities. In the access evaluation framework, a local clinical (in the example above) is an inappropriate facility to meet the needs of patients with amputation who require specialised care and care of chronic diseases(McIntyre et al., 2009).

None of the literature explored in Table 2.1 mentioned the effects of or type of anaesthesia on survival post LLA. In this regard, Khan et al. (2013, conducted a score-matched observational study on the effects of anaesthetic technique in LLA and found that the 30 day mortality was significantly higher ($p=0.04$) at 13.7% for the general anaesthetic group compared to the 9.3% for the regional anaesthetic group. They say this supports the evidence that avoiding general anaesthetic improves outcomes in patients undergoing LLA. Both values are comparable with those in Table 2.1 for the same period but in Khan et al. (2013) study, the differences in these values was accounted for by anaesthetic technique. This reiterates that general anaesthesia is associated with less favourable conditions in the acute care period. Khan et al. (2013) detected no significant difference in mortality at 90 days between the general and the regional anaesthetic group ($p<0.05$ for all sub-groups analysed). Also important to note is that there was no difference in postoperative hospital length of stay with anaesthetic type. In this regard, Karam et al. (2013) found that the type of anaesthesia did not affect outcome (death) post LLA in a study where they examined the effect on surgery outcome (30 day survival) in persons with LLA.

Table 2.1 attempts to show a variety of studies. The outcomes revealed in this table vary by country, population, aetiology and the methodologies used, as population structures are not homogenous among countries.

2.6 PSYCHOLOGICAL ASPECTS OF LOWER LIMB AMPUTATION

2.6.1 Overview of the General Psychological Impact

People with LLA report feelings of sadness, shock, insurgence, anger, non-acceptance and suicidal thoughts. Amputation is associated with pain relief from primary pathology e.g. tissue loss related pain, depression, sleep disorder, anxiety and irritability (Senra et al., 2011). In this regard, LLA is devastating. Psychological support is important for rehabilitation to e successful after LLA (Wegener et al., 2009, Bosmans et al., 2007, Desmond and MacLachlan, 2006). People amputated as a result of diabetes have poorer psychological adjustments to their situation (Couture et al., 2012, Coffey et al., 2009). Coffey et al. (2009) cite distancing strategy (patients detaching themselves from the situation) for this while Couture et al. (2012) attributes this to the impact of body image disturbances on the relationship between amputation due to diabetes and psychological adjustment. Coffey et al. (2013a, further found that being female, younger, having an acute cause of amputation and high pain levels negatively affect the person with LLA's emotional well-being. Family support as well as professional intervention plays a critical role in assisting the people with LLA to cope with life without the limb (Couture et al., 2012; Godlwana and Stewart, 2013). Thus, regular screening for adverse psychological implications of LLA is important (Coffey et al., 2009).

2.6.2 Body Image Following a Lower Limb Amputation

Body image is a broad concept, including a range of sociopsychologic components regarding both how people look and how they think they look (Flannery and Faria, 1999). The person's perception of how they look will influence their subjective well-being. Body image disturbance is evident when a patient cannot accept their current body image and clings to the old body image which is not the same as the current reality (Flannery and Faria 1999). Senra et al. (2011) found that people with LLA report changes in identity as well as affective and asexual life.

Lower limb amputation may often result in a person experiencing psychological difficulties accepting the stump. Among other problems is body image (Holzer et al., 2014, Couture et al., 2012). Evidence of body image disturbance surfaces early during hospitalization and while it varies across patients, it persists (Couture et al., 2012) and people with LLA report more body image disturbances compared to the general population without LLA (Holzer et al., 2014). At a later stage, patients perceive their body image derranged and often fail to acknowledge and accept their new image (Couture et al., 2012; Zidarov et al., 2009a). Changes in perception of one's body image following LLA are not new in the literature on people with LLA (Fisher and Hanspal, 1998a, Breakey, 1997). Body image disturbance may at times have negative implications on various other aspects of one's well-being, including high levels of anxiety, and depression and dissatisfaction with one's body image may result in emotional distress (Couture et al., 2012; Fisher and Hanspal, 1998a). Zidarov et al. (2009a) found that females experience higher body image disturbances compared to males ($p=0.007$) and people with AKA have poorer body image perception than those with a BKA ($p=0.017$). They find no other explanation for these results except that they may reflect that women have greater concerns about their body image. Coffey et al. (2009) reported significant correlations between body image and general adjustment ($\rho=-0.48$, $p<0.01$), social adjustment ($\rho=-0.51$, $p<0.01$), adjustment to limitations ($\rho=-0.45$, $p<0.05$), social restriction ($\rho=0.44$, $p<0.05$), weight satisfaction ($\rho=-0.36$, $p<0.05$) and functional satisfaction ($\rho=-0.46$, $p<0.01$).

Studies also show that psychological problems may lead to physical deterioration because a person may be demotivated and tend not to walk rather that actually not being able to walk. This is especially reported in persons who have a negative attitude towards rehabilitation after LLA, thus impacting on compliance with treatment (Desmond and MacLachlan, 2006; Fisher and Hanspal, 1998a).

2.6.3 Feeling of Worthlessness

People with an LLA may express that they fell worthless and undervalued in their society (Amosun et al., 2005). However, sometimes people with a lower limb amputation report higher subjective well-being during rehabilitation and that although their lives have changed, they are not less worth living. People with a lower limb amputation may report higher subjective well-being even when they experience severe phantom pain while those with barely any pain may report low subjective well-being (Bosmans et al., 2007). This shows that there are no clear cut outcomes and individual variations may be seen as evidenced by Bosmans' (2007) qualitative study. According to Bosmans et al. (2007), patients who were able to substitute their employment by other employment or activities seem to report better subjective well-being than those who are not able to have such substitutions/ alternatives and they conclude that phantom pain has a small impact on subjective well-being. This shows that people whose challenges are accommodated by the environment they interact with tend to have better wellness outcomes. The study by Amosun et al. (2005) however is different in that it was on young people who were amputated due to trauma (mean age 30.4 SD 13.4) from war injuries, from a developing country, Rwandans who possibly have different needs and expectations compared to vascular patients.

2.6.4 Depression in People with Lower Limb Amputation

Depression is a huge problem in people with LLA (Couture et al., 2012, Desmond and MacLachlan, 2006, Schoppen et al., 2003). About 19% and 11% of people with LLA report depression at two weeks and six weeks respectively after the operation (Schoppen et al., 2003) and 31% are depressed two to three months after discharge from rehabilitation as reported by Couture et al. (2012). The study by Schoppen et al. (2003) was strong in that their sample had controls.

People with a LLA have been reported to be depressed from as early as during hospitalization right through to the time they returned home (Couture et al., 2012). Their study was able to ascertain this using both qualitative and quantitative methods. It has been however found that greater use of problem solving (β=-0.211, t=24.25, p=0.003) and social support seeking (β=-0.184, t=3.43, p=0.001) strategies are associated with lower levels of depression and use of avoidance is associated (β=0.589, t=11.50, p<0.001) with higher levels of reported depression (Desmond and MacLachlan, 2006). In this study, Desmond and MacLachlan, (2006) concluded that avoidance was generally reported in patients with poor psychological adaptation to amputation. For instance, people who have poor or no social support and and those who tend to avoid facing their new circumstances are more likely to have depression (Desmond and MacLachlan, 2006). Couture et al. (2012) found that highly depressed people with LLA use a lot of escape- avoidance (r=0.747, p=0.001). In their study, patients with depressive symptoms used/ relied on escape- avoidance to cope with their amputation.

Sorrow and anger may also occur in the early stages (during hospitalization) following LLA (Couture et al., 2012). Patients may be bitter, destructive and even cry once they realize that have no leg (Couture et al., 2012). Efforts to cope with this may include looking on the bright side of things and realization that being negative with not yield a good result for them (Couture et al., 2012). Humour and smiling are used in order to remain positive (Couture et al., 2012). Godlwana and Stewart (2013) conducted a qualitative study in the Johannesburg metropolitan area of South Africa and found that patients were in shock, disbelief and some were copying poorly after losing a limb. The findings by Godlwana and Stewart (2013) further included suicidal thoughts. All these were because of maladaptive skills to deal with a lower limb amputation.

People with above knee amputation (AKA) have high depression scores, followed by those with a below knee amputation (BKA), then bilateral BKA (Coffey et al., 2009). They reported a significant correlation between depression and body image ($\rho=0.75$, $p<0.01$); and functional restriction ($\rho=0.39$, $p<0.05$); social restriction ($\rho=0.54$, $p<0.01$); weight satisfaction ($\rho=0.-43$, $p<0.05$); general adjustment ($\rho=-0.49$, $p<0.01$); social adjustment ($\rho=-0.49$, $p<0.01$) as well as adjustment to limitation ($\rho=-0.44$, $p<0.05$).

2.6.5 Anxiety in People with LLA

Desmond and MacLachlan (2006) report that time since amputation as well as the person's age are important predictors of anxiety in people with LLA, the more recent the operation the more severe is their level of anxiety ($\beta=-0.13$, $t=2.50$, $p=0.013$) and the younger the patient the more severe is their level of anxiety. This is because psychological adaptation happens over time (Desmond and MacLachlan, 2006), the more recent the amputation, the greater the post-trauma psychological problems like being distressed and anxious symptomatology and being young is associated with poor adjustment to LLA (Desmond and MacLachlan, 2006). Furthermore, higher levels of avoidance behaviour are associated with higher scores of anxiety ($\beta=0.52$, $t=10.46$, $p<0.001$); greater use of problem solving is associated with less anxiety ($\beta=-0.14$, $t=2.98$, $p=0.003$) (Desmond and MacLachlan, 2006), so high levels of acceptance result in less anxiety (Desmond and MacLachlan, 2006).

People with above knee amputation (AKA) have high anxiety scores, followed by those with a below knee amputation (BKA), then bilateral BKA (Coffey et al., 2009). Their study found a significant correlation between anxiety and depression ($\rho=0.62$, $p<0.01$); body image disturbance ($\rho=0.77$, $p<0.01$); social restriction ($\rho=0.41$, $p<0.01$); weight satisfaction ($\rho=-0.39$, $p<0.05$); functional satisfaction ($\rho=-0.36$, $p<0.05$); general adjustment ($\rho=-0.48$, $p<0.01$); and social adjustment ($\rho=-0.58$, $p<0.01$). Body image disturbance may be a possible risk factor for psychological distress in this population (Coffey et al., 2009).

There is no association between mortality and depression or anxiety (Singh et al., 2009). Anxiety and depression are high (23.5%) during hospitalisation for LLA and drop (2.9%) at discharge; anxiety and depression are often present at admission and then a recurrence of symptoms in these patients is seen post amputation. There is no association between gender, living alone, vascular cause and age with depression or anxiety (Singh et al., 2009).

2.6.6 Religious Beliefs

Praying to God assists people with LLA in releasing their negative emotions. At times they would rather pray than talk to other people about their amputation; as early as during hospitalization, they ask God what to do (Couture et al., 2012). The local literature has also reported strong religious ties with God following this devastating operation. Although unpublished (M Med thesis), Kamel (2000, reported on some of the reactions exhibited by people with LLA following this operation. "Why me, why now?", "God is not fair" (Kamel, 2000). LLA results in many concerns for the person (Kamel, 2000). Godlwana and Stewart (2013) found similar cases where people with LLA sought help from God and relied on prayer for comfort. However, in a three month follow up study by Zidarov et al. (2009a), spirituality was measured preoperatively, at discharge and three months later with LLA participants consistently reporting low scores of spirituality. The commonality with the study by Couture et al. (2012), Godlwana and Stewart (2013) and Kamel (2000) is that they used qualitative methods whereas Zidarov et al. (2009a) used quantitative means to examine this issue. This did not allow Zidarov et al. (2009a) to get the in-depth information which qualitative studies allow.

2.7 THE FUNCTIONAL IMPACT OF LOWER LIMB AMPUTATION

2.7.1 Overview of the International Classification of Functioning, Disability, and Health (ICF)

"Impairments are problems in the body function or structure as a significant deviation or loss" (World Health Organisation, 2001) short version, p16.

"Activity is the execution of a task or action by an individual" (World Health Organisation, 2001) short version, p12. "Activity limitations are difficulties an individual may have in executing activities" (World Health Organisation, 2001) short version, p121.

"Participation is the involvement in a life situation" (World Health Organisation, 2001) short version, p121 "Participation restrictions are problems an individual may experience in involvement in life situations" (World Health Organisation, 2001) short version, p121.

Lower limb amputation negatively impacts on all the above ICF components. Studies consistently show that people with LLA struggle with these issues postoperatively (Fortington et al., 2013b, Czerniecki et al., 2012; Glemne et al., 2012; Godlwana et al., 2012; Raya et al., 2010; Resnick et al., 2004). Figure 2.1 attempts to map the various aspect of how LLA impacts on the person.

Figure 2.1 illustrates the ICF in amputation.

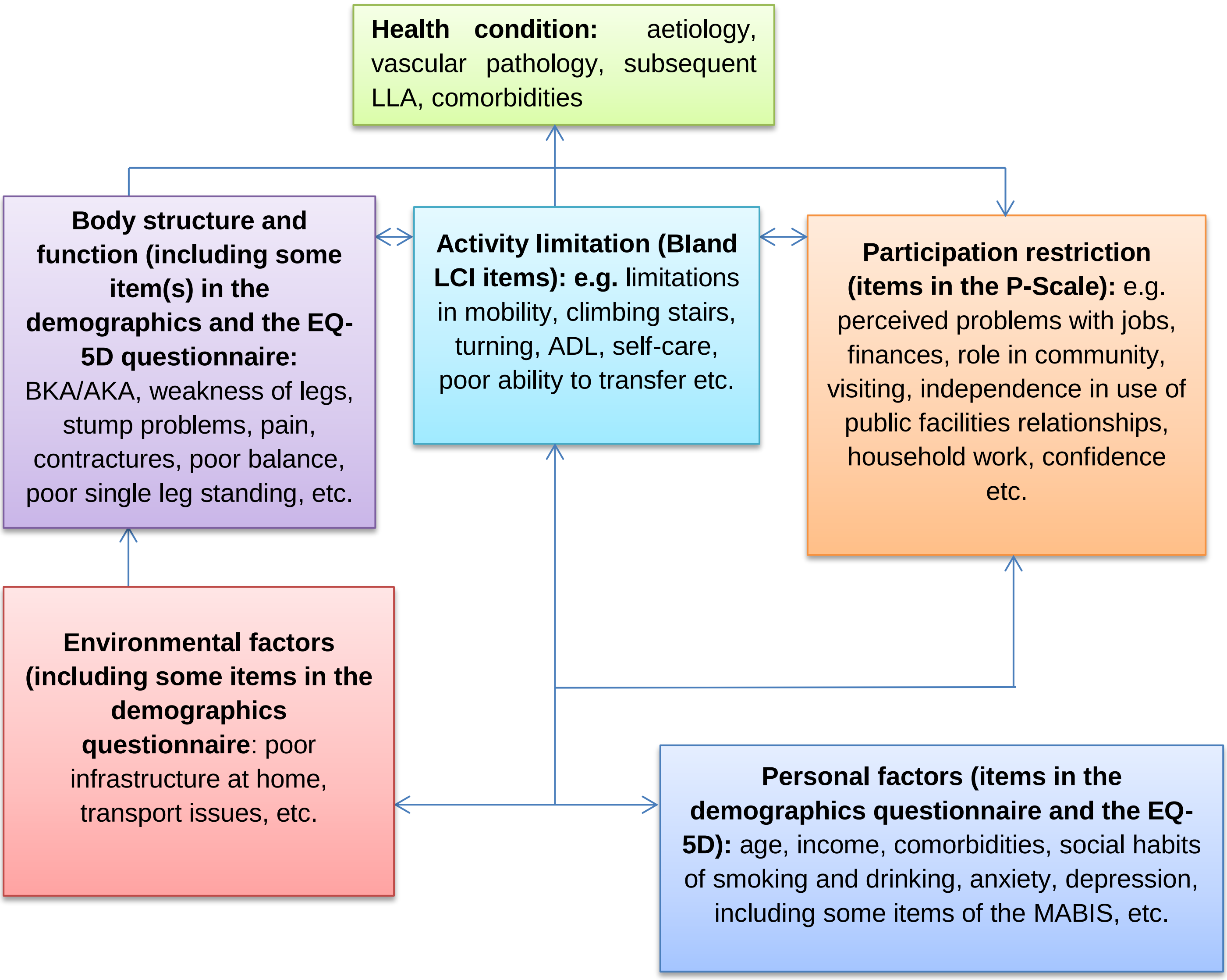


Figure 2.1: ICF in Amputation

(*The ICF flow chart was adapted from WHO, 2001 p26*)

2.7.2 **Mobility**

Ambulatory function has been reported to decline in the intermediate period following a LLA (Coffey et al., 2014, Fortington et al., 2013b, Czerniecki et al., 2012, Godlwana et al., 2012, Resnick et al., 2004). In a three months follow up observational study of forty participants, Godlwana et al. (2012) found a significant decline in mobility at three months postoperatively (p=0.04) while Czerniecki et al. (2012) also found a decline in mobility at both six weeks and four months in their follow up study of 87 participants. In the study by Godlwana et al. (2012), a lack of rehabilitation explained this outcome. The findings by Czerniecki et al. (2012) further stated that the decline in mobility was irrespective of the level of amputation (transmetatarsal (TMT), BKA or AKA) but this result was not a fair comparison as the study comprised of 31% (n=24/75) TM and 9% (n=7/75) AKA with the remaining participants BKA. If the distribution across the three levels of amputation was similar, this result would be more convincing. Basu et al. (2008) found no significant difference (p=0.44) in mobility between AKA and BKA patients in their retrospective survey of 75 vascular participants while Cox et al. (2011) reported higher quality of life and functional independence among BKAs compared to AKAs in their prospective survey of 87 participants. In their study, Basu et al. (2008) concluded that the level of amputation is thus not a predictor of walking even when they considered the participant's age while Cox et al. (2011, attributed their fingings to the more debilitation and frailty in AKAs compared to BKA patients. The anatomical level of amputation has also been found to predict the amount of mobility that will be possible with regard to safe function (Burger and Marincek, 2007, Taylor et al., 2005). The study by Taylor was a larger retrospective review of 553 participants. In these studies, it was found that a higher amputation level (anatomical) resulted in limited mobility compared to patients with a lower level of amputation. In general, the above studies show that there is no consensus about the role level of amputation plays in the prognosis and regaining functional independence following LLA.

Age at time one undergoes LLA is especially important for their general functioning, younger people generally become more functional compared to older people (Fortington et al., 2013b; Schoppen et al., 2003). The studies by Fortington et al (2013b) Schoppen et al (2003) were strong studies in that they were multicentre prospective follow up study of 18 months of 82 participants and 12 months or 46 participants respectively. Schoppen et al. (2003) further reported that the ability to balance in standing two weeks after the operation is a significant predictor of all functional outcomes, for instance, patients with poor balance have a reduced chance of ambulation. The role of the contralateral leg is very important in determining functioning especially in the intermediate period where there is no prosthesis. They found that patients who were able to stand on one leg had better functional outcomes including prosthetic use during the prosthetic phase of rehabilitation. The functional outcome is likely to be poor in people who are not able to stand on the contralateral leg unsupported.

Complications of the operation may also impact on the return to function; in diabetic patients, poor vision or even blindness may restrict functional outcome (Zidarov et al., 2009a). Norvell et al's (2011) multisite prospective follow up study that involved 87 participants found that age (65 and older), alcohol use, hypertension (HPT), history of having been treated for anxiety or depression are all factors negatively associated with mobility success,but that the level of amputation was not a predictor of mobility success. However, these findings were because their study included participants with TMT amputations and the sample had few AKA. Again this can be problematic when the inclusion criteria are not clear on what is considered a major or a minor amputation. Age and preoperative physical condition generally dictates the functional outcome following LLA (Norvell et al., 2011; Burger and Marincek, 2007; Nehler et al., 2003).

Many factors impact on postoperative mobility in LLA but balance and hip strength are the most significant as these are important in walking (Raya et al., 2010). Being older, having a vascular amputation, higher level of amputation, longer duration since amputation result in poor walking. Balance is poor following LLA, especially in those amputated due to vascular reasons (Miller et al., 2002). Balance may differ across various patient characteristics (age, gender, cause of amputation, mobility device used, comorbidities, problems of the contralateral leg, perceived health, (activities of daily living (ADL) limitations) except social support, level of amputation, joint pain and recent falls (last 12 months). Miller et al. (2002) also reported that people with vascular LLA have poorer balance compared to nonvascular related LLA especially in situations such as; walking in crowded areas, sweeping the floor, reaching while on their toes, walking around the house, getting in and out of the car and reaching at eye level. On the other hand, being a younger people with LLA, being male, ability to walk without having to concentrating on the actual walking, less activity limitations, less depression, and no fear of falling were all independently related to good balance. The study by Raya et al (2010) comprised of a sample of convenience (n=72) while that by Miller et al (2002) was a survey on 435 participants. The weakness of the latter study was that 47% of the sample comprised of nonvascular persons with LLA.

Using a walking device, fear of falling, having to concentrate while walking are all independently related to poor balance (Miller et al., 2002). Schoppen et al. (2003) reported that people with LLA perform poorly in ADLs (e.g. mobility) and instrumented activities of daily living (IADL) (e.g. TUG); with people with LLA obtaining a mean TUG of 23.9 seconds (SD 13.2) and median 21.3 seconds. Balance at two weeks is an important predictor of ADL during the intermediate stage of rehabilitation. People with LLA with good balance as early as two weeks post operatively are more independent in ADL later on during the intermediate stage of rehabilitation and vice versa. People with LLA with impaired mobility, have diminished activity levels, and tend to realise these limitations and use adaptation styles to improve their physical limitations. An inability to walk up or down inclines or rough terrains arises due to poor balance following LLA (Livingstone et al., 2011). The strength of the study by Livingstone et al (2011) was that it was a qualitative study to develop a grounded theory based on the experiences of people amputated due to diabetes.

Physical capacity (muscle strength and balance) as well as walking ability (walking velocity and symmetry) deteriorate considerably, following LLA (Livingstone et al., 2011) and the aerobic capacity is lower than that of able-bodied people. The number of people with LLA who are able to regain ambulatory status post LLA ranges from 56% to 97%. In summary, the literature shows that balance is a huge challenge following LLA (van Velzen et al., 2006).

Age and stump problems correlate negatively with mobility (as measured by the BI). Mobility (as measured by the LCI) levels are higher in patients with an ideal stump and lower in those with a combination of stump pain and flexion deformities (Traballesi et al., 2007). People with LLA report difficulties like loss of basic skills, loss of functional independence and ADL function (Senra et al., 2011). The strength of the study by Senra et al (2011) was that it was a cross-sectional thematic analysis on 42 participants. Age of a person with LLA influences gait re-education (activity levels). The presence of comorbidities, poor premorbid function, higher level of amputation, poor state of the contralateral leg and poor motivation have a negative influence on gait re-education (Fleury et al., 2013).

Gait re-education is not always possible in all vascular persons with LLA; some may only achieve independence in transfers and wheelchair dexterity (Fleury et al., 2013) with age being inversely correlated with the ability to climb stairs (Hobara et al., 2012). The strength of Hobara et al (2012)'s cross-sectional study was that it included AKA participants only and the strength of Fleury et al (2013)'s study was that is was a well designed systematic review with a clearly stated inclusion and exclusion criterion for the articles to be reviewed. The older the person with LLA the more difficult it is to negotiate stairs. People with LLA perceive themselves as impaired, as a result, they use assistive devices and adapt their lives to the new life (living with an amputation) while the majority often does not accept their new situation (Senra et al., 2011).

2.7.3 Activity in People with a Lower Limb Amputation

Hoshino et al. (2008) showed that only 39.5% of LLA patients walk independently at discharge, 29.6% walk independently with a stick, 9.9% are ambulant with a stick and assistance, while the rest are either wheelchair bound or bedridden. Fifty-nine percent (59%) of patients with a BKA were ambulant at discharge and none of the AKA patients were ambulant at discharge. They state that "Amputation at a higher level may increase the possibility of better wound healing and, thus, operative success. However, amputation at higher levels may reduce the patient's ADL". This may be the explanation for why BKA patients are more ambulatory than AKA patients. All the AKA patients and 41% of BKA patients are either wheelchair bound or bedridden respectively (Hoshino et al., 2008). However, it must be noted that their study included participants with minor amputation (e.g. toectomy amputations) in their 81 cases.

In both the BKA and the AKA patients, prolonged length of stay in hospital indicates a decrease in ADL. Persons with LLA experience their biggest hindrance in having their ADL running smoothly (Coffey et al., 2013b). The strength of their study was that it was large (n=98) but the weakness was that it did not have follow up. This may be attributed to the challenges LLA people face in aspects of functional independence. The authors went on to say that this was expected as patients were still undergoing rehabilitation and were yet to reach their full potential in ADL independence. Their study involved LLA participants who were undergoing inpatient rehabilitation and were then followed up six months post discharge from the rehabilitation facility; Ensuring safety (in physical function) was rated highly by people with LLA on admission to the rehabilitation centre and acquiring ADL such as going to the toilet, (un)dressing and washing may make patients so uncomfortable that they may feel the need/pressure to relearn these as soon as possible (Bosmans et al., 2007).

Glemne et al. (2012) also reported a decline in function from preoperative to six months post operatively. Using the LCI-5, a basic LCI-5 subscale score decline (p=0.039) was found but with no significant decline in the advanced LCI-5 subscale (Scoring of the LCI and the LCI-5 tool has been explained in the outcome measures (OMs) section and Chapter 4) and the total score in the group that used a prosthesis. In their study, participants using a prosthesis at a median Timed Up and Go (TUG) score of 39.2 seconds (SD=2.4), indicatating a very high risk of falling. Mostly activity limitation in persons with LLA includes difficulty standing for long periods, walking long distances as well as the emotional effects of disability (Gallagher et al., 2011). Although Glemne et al (2012) had a small sample (n=23), the participants were followed up to six months. The weakness of the Gallagher et al (2011)'s study was that it used secondary data from a national data base which may limit the nature of the data collected e.g. participants characteristics like social habits, althought they had a large sample (n=148).

2.7.4 **Participation in People with a Lower Limb Amputation**

People with amputation are often restricted in participation especially in aspects related to climate (wet weather conditions), physical environment (varying/uneven slopes), and income generation (Gallagher et al., 2011). Commonly, people with LLA also experience participation restrictions in sport or physical recreation, leisure/ cultural activities, employment seeking as well as community life (Gallagher et al., 2011). Involvement in walking a long distance and or standing for at least 30 minutes has also been reported as challenging affecting participation in LLA patients (Gallagher et al., 2011). About 43% of LLA patients report that these difficulties interfere severely or extremely with their lives (Gallagher et al., 2011). Similar to those of van der Sluis et al. (2009, who found that LLA patients experience more physical role limitations in their case control study 144 LLA persons.

Older age, smoking and vascular causes of LLA have a negative influence on participation (e.g. in sports) (Bragaru et al., 2013a). Their study looked at barriers and facilitators for participation in sport on a Dutch cohort of persons with LLA and found that sport was perceived as enjoyable, and it promotes health as well as improves social contacts. On the other hand, insufficient facilities, transport challenges, trivialisation from other people, poor state of health, poor motivation and lack of sporting partners were perceived as barriers. Poor sporting facilities and prostheses were also raised as technical issues. People with LLA complain that they are not able to walk more that 200-300m as the prosthesis starts to give them blisters (Bragaru et al., 2013b). Their study however included participants ranging from 2-35 years since amputation and it included trauma (n=7), as well as oncology (n=4) in their total sample of (n=26) in their thematic analysis while Bragaru et al (2013a) was a large cross-sectional survey (n=780).

Being a male and an older person with LLA is associated with being more socially adjusted (Sinha et al., 2013); being younger with being less restricted in function and social life; and being employed with being less restricted in function, less restricted in athletic performance and social life. Their cross-sections study had a large sample (n=368) but the weakness was that only 16% of the participants were amputated due to vascular reasons. Females with LLA are less likely to perceive persistent barriers (participation) in physical/structural (environment). This is because women have lower expectations in areas of being active than men have (Ephraim et al., 2006). People with LLA aged 55-64 are less likely to perceive persistent barriers (participation) in physical/structural (environment), attitudes/support as well as services/assistance compared to those between the ages of 18-44 and those aged 65 and older (Ephraim et al., 2006). In their study, it is noted that these outcomes may either be because older people handle or cope better with living with a LLA thus adapting better to disability or they are less involved in activities where they may experience barriers. In this regard, the findings by Sinha et al. (2013, Ephraim et al. (2006, that there is some concensus that younger people with LLA perceive less barriers in participation and that any findings to the contrary may potentially be as a results of not being able to determine the actual reasons why older persons perform better than younger ones in participation. The strength of Epraim et al (2006)'s cross-sectional survey was a large sample size (n=914).

People with LLA are more likely to perceive persistent barriers (participation) in policies, physical/structural (environment), attitudes/support as well as services/ assistance. Their perceived persistent barriers are greater than that of the general disabled population except in the areas of work/school and services/assistance (Ephraim et al., 2006). The reasons given in their study were that; the questions on work/school were not relevant for most people with LLA as some may not be in school or may not be currently working. Their tool was not able to measure barriers that may have prevented the participants from working or attending school. And thirdly, those paticipants who were able to work or attend school were the ones who were less likely to perceive barriers in this aspect of their life thus reporting less problems (Ephraim et al., 2006).

Having more comorbidities is associated with more functional restriction. As a result, people with LLA who report two or more co-morbidities are two to three times more likely to perceive barriers (policies, physical/structural (environment), attitudes/ support as well as services/assistance) than those who report no comorbidities (Ephraim et al., 2006). This is because most amputations are as a result of diabetes or PVD and people with diabetes often have multiple comorbidities including cardiovascular conditions, morbid obesity, peripheral neuropathy, and visual impairments thus increasing the likelihood of experiencing environmental barriers, functional limitations and disability (Ephraim et al., 2006).

Poverty is a predictor of increased perceived barriers in the environment in persons with LLA from a poor socioeconomic background. This makes persons with LLA two to three and a half (3.5) times more likely to perceive barriers in policies, attitudes/support and services/assistance (Ephraim et al., 2006). Limited resources in their community may be another reason for the perceived barriers in participation.

People with LLA with stump pain are twice as likely to perceive barriers in physical/structural environment as those who reported no pain and the same is true of persons with LLA with back pain (this may imply that any pain will result in perceived barriers). Back pain is a known sequale to LLA especially as a result of gait demands and walking (Ephraim et al., 2006).

Livingstone et al. (2011) found that persons with LLA have diminished capacity to actively participate in their routine functions (e.g. farming) due to role restrictions and restricted social contact is also reported. Social participation is poor due to impaired mobility, inability or reluctance to drive, and embarrassment in social situations due to poor balance. Persons with LLA encounter considerable restrictions in daily functioning (Schoppen et al., 2003) because environmental barriers to LLA include climate, physical environment and income (Gallagher et al., 2011).

In conclusion, participation restriction is most expressed in sports/physical recreation, leisure/ cultural activities, as well as employment and job seeking (Gallagher et al., 2011). As seen in the above studies, this may be attributed to the ability of the person with a LLA to navigate various infrastructural surfaces (environment). This may be during times of leisure, in the place of work as well as during cultural practices.

2.8 QUALITY OF LIFE IN PEOPLE WITH LOWER LIMB AMPUTATION

Predictors of quality of life following a LLA include symptoms of depression, social support, comorbidities, social participation, and age (Asano et al., 2008). A weak correlation between physical activity and quality of life (QOL) has also been reported (Deans et al., 2008). Their paper identified that the support from family, friends, and peers is vital and while physical activity should be encouraged, social interaction should not be compromised. People with LLA report feelings of inferiority and problems related to well-being (Senra et al., 2011). According to Asano et al. (2008, , depression and participation in ADL are modifiable characteristics influencing QOL and higher QOL is reported by those with lower depression scores, suggesting the Senra et al. (2011) findings are of modifiable aspects following a LLA. People with LLA who achieve mobility success are more likely to be satisfied with life than those who do not (Norvell et al., 2011) and this reiterates that although Deans et al. (2008) found a weak correlation with QOL, their study was not discouraging physical activity but stressing the importance of social support. The social aspect of these findings is similar to those of Asano et al. (2008) and Godlwana and Stewart (2013). Physical function, social function, pain, vitality and perceived change in health improve with time in people with LLA (Fortington et al., 2013b, Asano et al., 2008). Most of the improvement in these QOL domains is seen at six months post amputation (Fortington et al., 2013b). People with LLA over the age of 65 have a poorer outcome compared to those under 65 but all patients have reduced mobility during the first six months post amputation (Fortington et al., 2013b; Czerniecki et al., 2012) and physical function remains below that of population norms (Fortington et al., 2013b).

Flexible goal adjustment (FGA) (which is when the patient adjusts their goals to suit the constrains of the situation they find themselves in) and tenacious goal pursuit (TGP) (which is when a patient manages discrepancies between perceived and desired goal attainment through modification of their life situation or behaviour in order to suit their goals) have been reported to influence subjective well-being in various ways (Coffey et al., 2013b). They observed that FGA promotes positive affects and FGA buffers against negative affects especially in patients with high levels of pain in the LLA population, with a positive correlation between FGA and TGP. This study excluded patients with severe cognitive impairments and the participants were in-patients with a time elapse since amputation of 6-260 weeks with a mean of 30.32 (SD 36.97) and a median of 20 weeks. Coffey et al. (2013a, studied the importance of life goal characteristics and goal adjustment capabilities in psychological adjustment following LLA and found that being healthy was the most important goal identified by persons with LLA followed by keeping up their self-confidence.

People with LLA who have higher education levels, considerable time since amputation, and are employed post amputation have a significantly better health-related quality of life (HRQOL) than those who are less educated, have a recent LLA and are not employed (Dajpratham et al., 2011) and those who have no body anxiety also have a significantly better HRQOL compared to those who have anxiety. They state that this is because having a higher level of education increases the likelihood of finding employment and longer time since the amputation increases adaptation to the life with amputation. Gender, age, aetiology, level of amputation and stump pain show no significant differences between the groups with low or high HRQOL (Dajpratham et al., 2011).

People with LLA who report stump pain associate it with poor quality of life and poor adjustment to the new life (Van der Schans et al., 2002) and those with LLA who have phantom pain report a poorer QOL than those with no phantom pain. Walking distance and stump pain are important determinants of QOL following LLA. These findings mean that characteristics such as low anxiety/depression and no pain would be favourable to improve QOL and adjustment to living with an amputation (adjustment to new life).

2.9 RETURN TO WORK AFTER LLA

Men are more likely to return to driving and riding (in the case of a motorbike if that was their mode of transport) ($p<0.05$) compared to women following a LLA (Engkasan et al., 2012) and persons with a prosthesis are more likely to return to driving and riding. Age, side of amputation, level of amputation, aetiology and pre-amputation driving frequency are not associated with return to driving/riding. Engkasan et al. (2012) cited lack of confidence on the part of the patient, ill-health and a protective family as the reasons for not returning to driving and riding.

Being under the age of 45 with an amputation allows a better return to work compared to persons over 45 years of age. Males have a higher chance of being employed following a lower limb amputation than females (Burger and Marincek, 2007); but they did not state or discuss the reasons for this difference, for instance, they also did not mention whether there was a difference in levels of education or the nature of the employment that were available to both genders. However, they stated that, people with a lower level of education pre-amputation have a lower rate of return to work and some have to change their employment (Burger and Marincek, 2007). This may be especially true in the case where the person with LLA was a manual labourer. Bosmans et al. (2007) further report that some work at a slower pace while others have to have a change employment.

Characteristic features such as an AKA compared to a person with a BKA, presence of a history of multiple amputations compared to a single primary amputation, presence of co-morbidities, cause of amputation, persistent associated stump complications e.g. stump and phantom pain, period it takes to receive a permanent prosthesis, wearing comfort of the prosthesis, walking distance and restrictions in mobility, all have a negative impact on return to work and as a result, a person may not return to work (Burger and Marincek, 2007). Persons with AKA have more co-morbidities than those with BKA and this may further exacerbate the likelihood of poor functional outcome in this group as rehabilitation may be impacted negatively in such cases (Basu et al., 2008). In addition, people who have social benefits and a low pre-injury income return to work less often (Burger and Marincek, 2007).

A good salary, higher job involvement, good support from the employer, and a good social support network also influence return to work for people with a LLA. Patients with a high annual salary often return to work (Burger and Marincek, 2007) and this could be because they are in white collar employment, they still feel that they are valuable to the employer or that the place of employment is worth returning to, thus, these factors act as an incentive. Their study did not specify the nature of the occupation, the social support and employer support that the people with LLA had in order to achieve the high rate of return to work.

2.10 SOCIOECONOMIC PROFILE IN LOWER LIMB AMPUTATION

People with LLA as a result of dysvascular cause are generally from a lower socioeconomic level (Venermo et al., 2013, Liao et al., 2013, Godlwana et al., 2012, Henry et al., 2011, Ferguson et al., 2010). Venermo et al. (2013), Liao et al. (2013), Henry et al. (2011) and Ferguson et al. (2010) established socioeconomic status using databases while Godlwana et al. (2012) interviewed participants using the Household Economic and Social Status Index (HESSI) (Godlwana et al., 2012). Godlwana et al. (2012) reported on a metropolitan population while Venermo et al. (2013) presented country wide data from Finland in their observations. They showed that age, gender, type of diabetes, duration of diabetes and higher income are associated with a lower risk of first time amputation ($p<0.001$). The relative risk is highest in the lower income group and the incidence of first time major amputation decreases as income increases. However, the weakness in the studies by Venermo et al. (2013), Liao et al. (2013), Henry et al. (2011) and Ferguson et al. (2010) is that they used a population register data which meant that they were not able to consider other clinical factors as well as lifestyle factors like smoking, drinking and body mass index. Sinha et al. (2013) found that being employed is associated with being more socially adjusted and being adjusted to functional limitation (p<0.001), but this study had 76.1% persons amputated due to traumatic causes in their sample (n=368), with only 16% of their participants amputated due to dysvascular causes and the mean time since amputation was 12.9 (SD 10.1) years. In this study, it was found that being younger, and employed, were associated with less functional and social restriction.

Henry et al. (2011) found that being from a lower socioeconomic group often meant that patients will most likely undergo a LLA as opposed to revascularisation surgery and this was attributed to factors like old age, being male, and having no health insurance. These were found to be stronger predictors especially in African Americans or native Americans. In this study, those who were not admitted to a teaching hospital or did not have an angiogram were more likely to have an LLA compared to revascularisation, again exhibiting how affordability of tertiary care can deny choices in healthcare and potentially better care.

2.11 OUTCOME MEASURES

The aim of this section is to report on the basic characteristics, reliability, validity as well as the use of these OMs in persons with a lower limb amputation.

2.11.1 EuroQol 5 Domain Quality of Life Measure

The EuroQol 5 domain Quality of life measure (EQ-5D) is a generic measure of quality of life. It has two sections, the utility index and the visual analogue scale (VAS). The total index score ranges from -0.59 to 1.0 with lower scores indicating a poor state of health in the functional construct and the VAS ranges from 0-100 where zero indicates the worst imaginable state of health and 100 indicates the best in the quality of life construct (Lin et al., 2013); (Dawson et al., 2012).

The internal consistency is high (Cronbach α=0.743) (Kontodimopoulos et al., 2008). Pinto et al. (2011, also reported a good inter-observer agreement in all dimension of the EQ-5D, with k scores ranging from 0.621-0.754 (p<0.01 for mobility and p<0.001 for the other four dimensions). While Pinto et al. (2011) was a study done in a third world country, it is still difficult to generalise to other clinical conditions as it was done on stroke patients.

The EQ-5D also provides the ability to discriminate between health related quality of life (HRQOL) of people of different socioeconomic backgrounds as well as people with or without a clinical condition (Barton et al., 2008). Barton et al. (2008) had a huge sample (n=1865) and a variety of clinical conditions including heart disease, asthma, diabetes, and people with LLA.

While there is a high correlation between EQ-5D index or VAS and other frequently used outcomes measures in rehabilitation, however the EQ-5D index is potentially less sensitive to change especially because of its bimodal distribution of scores that transposes into a ceiling or floor effect (Finch et al., 2002). This results in scores that are on the extremes (top or bottom) of the scale, which is potentially misleading when one interpretes the data.

There is a death of literature on the minimal detectable changes of EQ-5D scores in amputations and those where it has been investigated vary widely. (Clark et al., 2002) using the Tobit model and the censored least absolute deviations (CLAD) regression analysis model to estimate EQ-5D utility index values for health states of type 2 diabetes patients, found a change of 0.28 and 0.266 (at 95% CI) from the two models respectively. This was the biggest change on EQ-5D index values compared to other complications of diabetes such as MI, IHD, stroke, heart failure and blindness although the sample of people with LLA was small (n=19). Lin et al. (2013, reported a change of 0.33 (SD±0.33) in the EQ-5D index. This was however a study on total knee replacements. Dawson et al. (2012, studied the responsiveness of the Manchester-Oxford foot questionnaire (MOXFQ) in comparison to American Orthopaedic Foot and Ankle Society (AOFAS) score, SF-36 and EQ-5D and recorded a change of 0.9 in the utility index on patients post foot surgery suggesting that it was more responsive than the SF-36 and as responsive as the tested MOXFQ. (Parker et al., 2012) investigated minimum clinical important difference (MCID) in pain, disability, and QOL post fusion for symptomatic pseudoarthrosis using various outcome measures including the EQ-5D and noted a MCID threshold ranging from 0.14-0.24. The mean change was 0.18 (SD±0.19) ($p<0.001$). However, none of the studies reported on the EQ-5D VAS minimum detectable change (MDC). Scoring of the EQ-5D utility index is attached as Appendix vii.

In a South African context, this tool is available in Afrikaans, English, Sesotho, Xhosa and Zulu. There are no publications on the validity and reliability of the EQ-5D in

Afrikaans, Sesotho and Zulu but there is a validated and reliable Xhosa version (Louwagie et al., 2007 , Wouters et al., 2009).

2.11.2 Amputee Body Image Scale

The Amputee Body Image Scale (ABIS) is a reliable 20-item tool designed to measure amputee body image (Breakey, 1997).This tool has a Cronbach's α of 0.88 (Breakey, 1997). Bumin et al. (2009) reported a Cronbach α of 0.834 for the test and 0.842 for the retest. In the study by (Bumin et al., 2009), the cross-cultural adaptation and the reliability of the Turkish version of the ABIS was established. Another Turkish study by (Safaz et al., 2010) revealed a Cronbach α of 0.882 again showing that the tool is reliable. In their study the item-test correlation coefficients ranged from 0.25 to 0.78 ($p=0.05$) and the test-retest Spearman rank correlation coefficient was 0.78 ($p \leq 0.01$). This study further looked at a revised version of the Turkish ABIS (ABIS-R) and found a Cronbach's α of 0.863. The item-test correlation coefficients ranged from 0.33 to 0.76 ($p \leq 0.01$). However, this study included patients ranging from transtarsal to above knee amputations. During the development and validation of the Chinese version, Lai et al. (2005, established linguistic validity in terms of clear presentation, understandability and relevancy to concepts. Lai et al. (2005) further established content validity and content relevancy with a percentage agreement ranging from 85.7%-100%. In the rest-retest, the reliability was 0.837. This study is similar in many respects to the Turkish study by Bumin et al. (2009), in that both studies has a sample of 50 patients (BKAs) and the main aim was to develop an ABIS from the English version to their home language. However the Chinese study had an older sample compared to the Turkish study with age ranges of 35-75 years and 18-60 years respectively. However, none of the studies reported on the minimum detectable change for the ABIS.

2.11.3 Participation Scale

The Participation Scale (P-scale) is an 18 item tool developed to measure client-perceived participation restriction among persons with a disability (Van Brakel et al., 2006). The tool measures social participation and can be used in rehabilitation, stigma reduction as well as social reintegration programmes (Van Brakel et al., 2006). The P-scale is a reliable and valid measure of participation in people affected by disability (Van Brakel et al., 2006) and is based on the ICF domains. Van Brakel et al. (2006) reported a Cronbach's α of 0.92 with an item to total correlation ranged from 0.32-0.73 and intratester reliability (stability) of 0.83 as well as an inter-tester reliability of 0.80. In the factor analysis, the first factor accounted for 90% of the variability.

Van Brakel et al. (2006) further found that the scale shows significant external validity ($p=0.005$). It is worth noting that van Brakel et al.'s (2006) work was carried out on patients with leprosy or other disabilities. Their study however failed to point out what clinical conditions comprised other disabilities in their sample. However, the other strength of the study is, not only was it a multicenter (multi country) study with a large sample (minimum $n=90$ per centre) but that they used controls with persons without any other clinical conditions. However, no studies have reported on the minimum detectable change for the P-scale.

2.11.4 Barthel Index

The Barthel Index (BI) has 10 items all covering various ADLs. These range from feeding, bathing, grooming, dressing, bowel and bladder control, toileting, ambulation, transfers and stair climbing. The total score ranges from 0-20 (fully dependent to independent) (Yang et al., 2008 , Houlden et al., 2006). The literature reports a student-therapist reliability or ICC of 0.85 with 95%CI. Item reliability of 0.52 to 1.00 has been reported using κ_w statistics, implying moderate to excellent agreement (Yang et al., 2008). In the study by Yang et al. (2008) bathing showed excellent agreement ($\kappa_w=1.00$), stair climbing ($\kappa_w=0.86$), feeding, bowel control, bladder control toileting, transfers and mobility showed good agreement ($\kappa_w=0.63$-0.82), with grooming and dressing demonstrating moderate results at $\kappa=0.57$ and 0.52 respectively. It must be acknowledged however that the study was on cerebrovascular accidents (CVA) and spical cord injuries (SCI) patients and the sample was small ($n=30$).

The BI has also been reported to have floor and ceiling effects (Houlden et al., 2006). While this may be the case, the BI correlates well ($r=0.733$) with measures such as the Functional Independence Measure (FIM) (Houlden et al., 2006). Both the BI and the FIM are appropriate measures when looking at ADL (Houlden et al., 2006). Again the study by Houlden et al. (2006) was on CVA patients and traumatic brain injury (TBI) patients. While the sample was large ($n=152$), they were not sampled randomly and there was no test-retest.

According to Finch (2002), the BI has been used to study people with LLA. Typical reliability estimated on this scale are a Cronbach α of 0.87- 0.92. A Pearson product-moment correlation of 0.99 ($p<0.001$) and Kappa scores of 0.70-0.88 have been found. On test-retest, Kappa scores of 0.98 has also been found (Finch et al., 2002).

There is a death of literature on the minimal detectable changes of the BI scores in amputations. Hsieh et al. (2007, reported a minimal detectable change of 1.85 in the index, in a study on stroke patients. In their study, the interval for rest-retest was 14 days. A MDC of 1.04 have being reported in people with LLA (Rushton and Miller, 2002). In their study, the authors acknowledge the limitation that their sample size was very small (n=10).

2.11.5 Locomotor Capabilities Index

The Locomotor capabilities Index (LCI) is a 14 item tool designed for people with LLA to measure locomotor activities in persons using a prosthesis. These are selected from the locomotor disabilities classification of the World Health Organization (Gauthier-Gagnon and Grise, 1998). Although this measure was originally developed for prosthetic users, it has been used successfully in the intermediate phase of rehabilitation on persons not using a prosthesis as it measures the generic aspects of mobility activities (Norvell et al., 2011; Czerniecki et al., 2012). The scale is subdivided into basic and advanced subscales (see Chapter 4). The LCI is a reliable and valid measure of locomotor activities in people with a LLA (Gauthier-Gagnon and Grise, 1998). In the literature, the original LCI is referred to as the Standard LCI and the revised version Five level Locomotor capabilities Index is the LCI-5 (Franchignoni et al., 2004). Franchignoni et al. (2004) found that both versions have a Cronbach's α of 0.95 and the item-to-total correlations ranges from 0.50-0.87 ($p<0.001$). Franchignoni et al. (2004) further found that the percentage agreement and the k values in the LCI item scores ranged from 78.4%-100% and 0.58-1.00 respectively while those on the LCI-5 ranges from 75.7%-97.3% with k values of 0.54-0.96 respectively. The intraclass correlation (ICC) for both versions is 0.98. Franchignoni et al. (2004) also concluded that both versions capture the global locomotor ability although the LCI-5 has a lower ceiling effect and better psychometric properties.

Larsson et al. (2009, found a Cronbach's α of 0.95 at 95% CI in their study looking at the cross-cultural adaptation of the LCI into Swedish. In this study, the item-total correlation ranged from 0.42 to 0.85. In the rest- retest, the ICC was 0.91 at 95% CI. A MDC of 3.7 have being reported in the LCI (Rushton and Miller, 2002) and a MDC of 5.5 for the LCI-5, MDC of 2.74 for the LCI-5 Basic subscale and 3.79 for the Advance subscale has been reported in the LCI-5 (Salavati et al., 2011).

2.11.6 The 'Timed Up and Go' Test

The 'Timed Up and Go' test (TUG) is a brief performance based measure of basic mobility that incorporates walking, turning while walking, balance and transfers

(Resnik and Borgia, 2011). This test has been reported to have an intrarater reliability of 0.93 ($p<0.001$) and an interrater reliability of 0.96 ($p<0.001$) (Schoppen et al., 1999) as well as an ICC of 0.88 and 0.96 at 95% CI and is valid for use in LLA (Resnik and Borgia, 2011). The TUG is a reliable and valid measure of functional mobility in LLA (Schoppen et al., 1999). The studies by Schoppen et al. (1999) and Resnik and Brogia (2011) were done on persons with LLA which makes them credible for this study. Resnik and Borgia (2011) studied the reliability of various outcome measures for persons with LLA in an effort to detect true change from statistical error. Their study found a MDC_{90} of 3.6 seconds for the TUG.

2.11.7 Relationship between the Outcomes Measures

The TUG and the LCI correlate strongly ($r=-0.75$, $p<0.001$ at 95% CI) (Larsson et al., 2009). There is a strong correlation between the TUG and the EQ-5D index ($r=0.84$, $p<0.001$ at 95% CI) (Larsson et al. 2009). Pinto et al. (2011) also reported a mild correlation between the Barthel index and the EQ=5D ($r=0.512$, $p<0.001$). Pinto et al. (2011) study was in patients with stroke and is not necessarily generalizable to other conditions.

2.12 CONCLUSION OF THE LITERATURE REVIEW

It appears that dysvascular conditions are still the major causes of LLA and this is the case with or without the presence of diabetes. Most populations with LLA seem to be of an older age, and often this population presents with multiple comorbidities including renal, endocrine, and cardiac among others. The incidence and prevalence of LLA is consistently biased towards males, and survival is poor following a LLA. About a tenth dies within a month and more than half of people with LLA die in five years. On this outcome, local literature show the poorest survival rates compared to international data.

Psychological adjustment, adaptation and coping vary among people with LLA. Generally these improve with time since amputation and they also impact on aspects such as return to work and participation. LLA generally results in activity limitation, a decline in physical function and poor quality of life and this is evident in both the local and international literature.

Unlike what is seen in the international literature, locally, there is no available literature on inpatient rehabilitation of LLA persons. This is because our hospitals are not able to admit and treat these patients due to resource contraints. For example tertiaty hospitals in Johannesburg have a high turnover and the priority is to save lives and discharge patients as soon as they are stable. This then leaves patient in a situation where they have to undergo rehabilitation from home and this comes with multiple challenges that broadly included access to care in terms of availability, affordability and acceptability (McIntyre et al., 2009) in addition to the findinds by Godlwana and Stewart (2013). These challenges then trigger ideas in exploring a process of supplementing persons with LLA with a home based exercise programme so as to meet them halfway with their problems. Local research reports a decline in function following LLA and this cannot be allowed to prevail (Godlwana et al 2012).

CHAPTER 3

3. EPIDEMIOLOGICAL STUDY

3.1 INTRODUCTION

This chapter describes how the prevalence and incidence study was conducted and outlines the pilot study undertaken prior to the epidemiological study. Theatre register records of all general and vascular surgery operations at the public hospitals in the Johannesburg metropolitan region were reviewed to study the incidence and prevalence of lower limb amputation operations at these hospitals (Chris Hani Baragwanath Hospital (CHBH), Charlotte Maxeke Johannesburg Academic Hospital (CMJAH), Helen Joseph Hospital, South Rand Hospital and Edenvale Hospital).

3.2 EPIDEMIOLOGICAL STUDY

3.2.1 Aim of the Epidemiological Study

To establish the two year incidence and prevalence of disease related LLA operations on people who underwent general or vascular surgery at the five five public hospitals servicing the Johannesburg metropolitan area.

3.2.2 Objectives of the Epidemiological Study

- To establish the two-year prevalence of LLA operations.
- To establish the incidence of LLA operations in this population.

3.3 METHODOLOGY

3.3.1 Design

A retrospective longitudinal observational study was conducted in the form of an operating theatre register records review. Theatre register records from June 2011-June 2013 were reviewed after June 2013.

3.3.2 Participants and Sampling

Participants were drawn from those who underwent a dysvascular lower limb amputation at the five hospitals in the Johannesburg Metropole during the study period. Using population sampling, participants were consecutively sampled during the study period.

3.3.3 Inclusion Criteria

For the purpose of this study, all adult persons who underwent a LLA of dysvascular cause were included. Only the theatre records for general and vascular surgery were reviewed.

3.3.4 Exclusion Criteria

Trauma and oncology related amputations were not included.

3.3.5 Instruments

A data abstraction sheet was developed (Appendix A2). This sheet collected data on the date of amputation, age of participant, gender and level/type of amputation/s.

3.3.6 Ethical Considerations and Confidentiality

Ethical approval was obtained from the University of The Witwatersrand Committee for Research on Human Subjects (ethical clearance no.M110124) (Appendix V1). Permission to conduct the study at each candidate hospitals was obtained (Appendix V2). The names of the patients were only recorded for the purpose of ensuring that the researcher was aware of subsequent operations (revisions/re-amputations). All data abstraction forms (as they had identifying information) were kept safely and locked in a cupboard in the researcher's office. Name, age, gender and hospital number of the patients were used to verify whether the patient had a subsequent operation or it was a different patient.

3.3.7 Piloting of the Prevalence Study

3.3.7.1 Aim

- To familiarize the researcher with the data abstraction sheet and how to use it to obtain data from the theatre register.
- To establish the intra-observer reliability of the researcher (test-retest)

3.3.7.2 Procedure of the pilot study

The theatre nurse in charge at each of the candidate hospitals was approached with proof of hospital permission (Appendix V2) to avail the register of surgery (dysvascular) cases. Six records were taken twice at a two week intervals (test-retest interval) using the data abstraction sheet. Spearman's rho test was used to assess the correlation between the initial and second test.

3.3.7.3 **Results of the pilot study**

The review ranged from about 10-30 minutes per hospital depending on the number of records requiring review. Results: The final analysis was done on n=6 x 5 hospitals (n=30). The Spearman's rho (ρ) values revealed a perfect correlation for all variables (see Table 4.1). No changes were necessary to prepare for the main study.

Table 3.1 illustrates the test-retest correlation of the pilot study.

Table 3.1: Test-Retest Correlation of the Pilot Study

<table>
<tr><td>Age</td><td colspan="2">Mean age time1</td><td colspan="2">Mean age time2</td><td></td></tr>
<tr><td rowspan="5"></td><td colspan="2">66.23(15.30SD)</td><td colspan="2">66.23(15.30SD)</td><td></td></tr>
<tr><td colspan="4">Spearman's rho (ρ)</td><td>p-value</td></tr>
<tr><td colspan="4">1</td><td>p<0.0001</td></tr>
<tr><td>Left leg time 1</td><td>Left leg time 2</td><td>Right leg time 1</td><td>Right leg time 2</td><td></td></tr>
<tr><td colspan="2">Spearman's rho</td><td colspan="2">Spearman's rho</td><td>p-value</td></tr>
<tr><td>Toe-ecomy</td><td colspan="2">1</td><td colspan="2">1</td><td>p<0.0001</td></tr>
<tr><td>TMT</td><td colspan="2">1</td><td colspan="2">1</td><td>p<0.0001</td></tr>
<tr><td>Midtarsal</td><td colspan="2">1</td><td colspan="2">1</td><td>p<0.0001</td></tr>
<tr><td>Symes</td><td colspan="2">1</td><td colspan="2">1</td><td>p<0.0001</td></tr>
<tr><td>BKA</td><td colspan="2">1</td><td colspan="2">1</td><td>p<0.0001</td></tr>
<tr><td>TKA</td><td colspan="2">1</td><td colspan="2">1</td><td>p<0.0001</td></tr>
<tr><td>AKA</td><td colspan="2">1</td><td colspan="2">1</td><td>p<0.0001</td></tr>
</table>

Table 3.1 shows that the pilot achieved excellent reliability when reviewing the operating theatre register records at the five hospitals. Following these results, the researcher was confident that he could go ahead and collect data for the main prevalence study.

3.4 PROCEDURE OF THE PREVALENCE STUDY

The nursing sister in-charge at the surgical theatres of the respective candidate hospitals were approached again for the main epidemiological so that they could assist in availing the theatre registration books of operations that could be reviewed for June 2011-June 2013. Data on the number of amputations, the type as well as the demographic details (age and gender,) were collected (Appendix A2). The review process ranged from about 10 minutes to 5 hours per theatre visit.

3.5 **DATA MANAGEMENT AND ANALYSIS**

An Excel spreadsheet was used to capture and store the data. The researcher used a computer with a password which only he knew. This maintained confidentially as well as protecting the autonomy of the participants. SPSS version 22 was used to test the data. Data are presented in tables. The cumulative prevalence was calculated to estimate the prevalence of LLA operations in the Johannesburg Metropolitan hospitals. Cumulative risk rates (cumulative incidence) were also established.

3.6 **RESULTS OF THE PREVALENCE STUDY**

3.6.1 **Introduction**

A total of N=23617 (accessible population) general and vascular operating threatre register records were reviewed at the five hospitals, n =743 patients underwent LLA.

3.6.2 **Demographic Information**

Table 3.2 illustrates the demographic information of the patients who were amputated.

Table 3.2: Demographic Information of the Patients who were Amputated

Age(n=743)	**Mean Age**	**60.72±13.31SD**
	25th percentile Median age 75th percentile	53 60 69
	Male n(%)	Female n(%)
People with LLA (n=743)	446(60)	297(40)
People without LLA (n=22874) (Patients who underwent procedures other than amputation)	11141(48.7)	11733(51.3)
Overall (N=23617)	11587(49.1)	12030(50.9)

Table 3.2 shows that the average age of patients with amputations was 60 years and the majority were male (60%).

3.6.3 **The Two-Year Prevalence (Cumulative Prevalence) of Lower Limb Amputation Operations at Johannesburg Metropolitan Hospitals**

Table 3.3 illustrates levels of amputation performed and side of amputation

Table 3.3: Amputation Performed (n=743)

		Left n(%)	Right n(%)
Toe-ecomy	Yes	73(9.8)	69(9.3)
	No	670(90.2)	674(90.7)
TMT	Yes	14(5.4)	30(4)
	No	703(94.6)	713(96)
Midtarsal	Yes	26(3.5)	22(3)
	No	717(96.5)	721(97)
BKA	Yes	199(26.3)	181(24.4)
	No	544(73.2)	562(75.6)
TKA	Yes	9(1.2)	9(1.2)
	No	734(98.8)	734(98.8)
AKA	Yes	128(17.2)	128(17.2)
	No	615(82.8)	615(82.8)
Total no. of operations per side		440	439
Total no. of operations		879	

Table 3.3 shows that the majority of the amputations were BKA followed by AKA. Total amputation performed 879. The cumulative prevalence is 879/23617 =0.037 (95% CI) (or 3722.0 per 100 000 persons seen at the Johannesburg Metropolitan hospitals).

Table 3.4 illustrates the revisions/re-amputations performed.

Table 3.4: Revisions/Re-Amputations Performed

	n(%)
Not revised/not re-amputated	642(86.4)
revised/re-amputated once	84(11.3)
revised/re-amputated twice	16(2.2)
Revised/re-amputated thrice	1(0.1)
Total n from which amputations were perfomed	743(100)

Footnote: A bilateral amputation in not a revision/re-amputation and thus is not in this statistic. A revision/re-amputation is the amputation at a higher anatomical level of the same leg, this is what is reflected in the table.

Table 3.4 shows that 13.6% of people with LLA had a revision/ re-amputation. This means that a revised/ re-amputated rate of more than 13.6% was attained considering that some people were revised more than once.

Table 3.5 illustrates the final amputation status/ level a patient ended up with (n=743).

Table 3.5: Final Amputation Status/ Levels of the Sample (n=743)

	n(%)
Toe-ecomy	93(12.5)
TMT	42(5.7)
Midtarsal	28(3.8)
BKA	325(43.7)
TKA	11(1.5)
AKA	230(31)
Bilateral major amputations	14(1.9)

Table 3.5 shows that the majority of the amputations were BKA (43.7%) followed by AKA (31%). Major bilateral amputation was done in less than 2% of the sample.

3.6.4 Cumulative Incidence of Amputation in this Population (N)

Table 3.6 illustrates first time amputations performed.

Table 3.6: First Time Amputations Performed

	n(%)
First time amputation	743(3.1)
People without LLA	22874(96.9)
Total number of theatre cases (N)	23617(100)

The cumulative incidence of LLA is 743/23617 =0.031(95% CI) (or 3146 per 100 000 persons -2-years of study). The cumulative incidence of LLA in males is 446/11587 =0.038(95% CI) (or 3849.14 per 100 000 persons -2-years of study). The cumulative incidence of LLA in females is 297/12030 =0.023(95% CI) (or 2300 per 100 000 persons -2-years of study).

3.7 DISCUSSION OF THE EPIDEMIOLOGICAL STUDY

The results suggest that the incidence of LLA is high in the Johannesburg Metropolitan area. The findings show that the incidence of LLA is higher in this population compared to studies done by Fortington et al. (2013c, Buckley et al. (2012, Peacock et al. (2011, Witsø et al. (2010, Johannesson et al. (2009, Leggetter et al. (2002, The Global Lower Extremity Amputation (GLEA) Study Group (2000, and Calle-Pascual et al. (1997, . This vast difference in incidence may be attributed to various differences between the different populations (local, being this study, and international). The socioeconomic differences, the burden of disease profile of different populations, the life expectancy as well as the health resource accessibility cannot be excluded as contributors to these differences.

These findings are because poor people with dysvascular conditions are more likely to undergo LLA than a revascularisation procedure (Henry et al., 2011, Ferguson et al., 2010). The catchment area of this study may be a similar situation as the findings in these studies as South Africa has wide disparities in health care and poverty is widespread (Mayosi and Benatar, 2014). In addition the changing burden of disease now shows that chronic diseases of lifestyle such as, diabetes, HPT, obesity have risen from 1990 to 2010 regardless of an urban or rural setting (Mayosi and Benatar, 2014).

Life expectancy has been reduced from 63 years to 60 years from the year 1995 to 2010 in South Africa (Mayosi and Benatar, 2014). Findings by Godlwana et al. (2011, and in this thesis (Chapter 6) show that the death incidence is high following LLA in the Johannesburg area and that the median age of those who died was 59 (Godlwana et al., 2011) and 58 in this thesis (Chapter 6) . Both figures are similar to the age reported by Mayosi and Benatar (2014).

Finally, the South African public health sector is poorly resourced (Mayosi and Benatar, 2014) which further means that the findings by Henry et al. (2011, that patients are more likely to undergo a LLA if they are cared for in a less specialised hospital are true especially in the case of public hospitals. In this study, three of the five hospitals do not have a vascular unit, hence patients cared for at those hospitals would not have revascularisation unless referred to the tertiary hospitals in the metropolitan area. Anecdotal evidence also shows that patients in Johannesburg tend to present late for treatment, leaving very little possibility of revascularisation, thus leading to more amputations being performed.

The following studies (Fortington et al., 2013c, Buckley et al., 2012, Peacock et al., 2011, Witsø et al., 2010, Johannesson et al., 2009, Leggetter et al., 2002, The Global Lower Extremity Amputation (GLEA) Study Group, 2000, Calle-Pascual et al., 1997) show a much lower incidence of LLA (ranging from 1.6-197 per 100 000) compared to the Johannesburg population. In this study, the incidence was higher in males and that finding is similar to Fortington et al. (2013c), Lazzarini et al. (2012), Henry et al. (2011) and Calle-Pascual et al. (1997). Males are more affected because they have a higher chance of presenting with conditions that are known to be independent predictors of LLA (Peek, 2011). These conditions are: diabetic foot ulcers, PAD, smoking and peripheral neuropathy (sensory neuropathy), with the latter being the most important because it is the most common neuropathy related to foot ulcers (Peek, 2011). Generally, males are taller than females making them more vulnerable to sensory neuropathy as it is partly determined by one's height (as regards the length of the peripheral nerve) (Peek, 2011). Lastly, hormonal factors have a protective effect on females of child bearing age. Female have better endothelial function in their macrovasculature and microvasculature because of their hormones, (Peek, 2011). Considering that males have a high prevalence of smoking compared to females (dos Santos et al., 2013) poor vascular health would be expected in them compared to their female counterparts.

About fourteen percent (13.6%) of patients had a revision/ re-amputation. These results are better than Johannesson et al. (2009) who found that the incidence of revision was 19 per 100 and 14 per 100 for diabetics and PVD respectively showing that in this study there were less/fewer revisions. In this study, the participants were not divided into diabetic and PVD for the epidemiological study, they were all classified as dysvascular participants. The first possible reason why this study had fewer revisions could be that the surgeons were able to choose the correct amputation level most of the time. Secondly, it could be that the rate of healing was generally good with fewer incidences of stump complications such as infection. The above reasons are similar to Taylor et al. (2005) in that a carefully selected LLA level with vigorous rehabilitation is preferable to a vascular procedure that may later fail and that requires a higher anatomical level of amputation. Thirdly, as the death rate is high in this population (study setting) as seen both in this study (Chapter 6) and the findings by Godlwana et al. (2011), it is possible that some people died before they were surgically/ anaesthetically fit for a revision and those cases would not reflect in the theatre register.

The results show that the prevalence of LLA operations is high in the Johannesburg metropolitan area, and that the prevalence of LLA is higher in this population compared to Tseng (2006). The findings by Tseng (2006) were in a Chinese population; potentially showing that the differences in genetic and dietary habits could be the reason. In their study, being tall was associated with high prevalence of LLA (Tseng, 2006); again although this study did not record the height of the participants, it is possible that the South African participants were taller than the Chinese. This again possibly explains the high prevalence in this study and that the findings are similar to the findings on tall peoples in the study by Tseng (2006).

The majority of the amputations were BKA. This finding is similar to the literature (Fortington et al., 2013c, Eskelinen et al., 2004) confirming that BKA is the most common level of amputation. Major bilateral amputation was done in less than 2% of the sample. Johannesson et al. (2009) found an incidence of contralateral amputation of 17 per 100 for diabetics and 13 per 100 for PVD patients while 10% of diabetics and 6% of PVD underwent a further contralateral amputation. This again shows that in this study, the rate of contralateral amputation was lower than that found by Johannesson et al. (2009) implying that although more persons are amputated, the majority undergo a unilateral amputation in Johannesburg. A possible explanation for these findings is that the surgeons in the Johannesburg metropolitan area got the operation right at first attempt, possibly because the vascular disease was clear not borderline in terms of decision making for the level of amputation; or there were no complications to warrant further interventions (Taylor et al., 2005).

3.8 LIMITATIONS OF THIS STUDY

Using the theatre records was a limitation in that some data on participant characteristics are not available in such records, e.g. clinical and some demographic data. This is a know limitation in this type of research (Venermo et al, 2013, Liao et al 2013, Henry et al 2011,Ferguson et al 2010) but it does show the extent of lower limb amputation in Johannesburg.

3.9 CONCLUSION

The most common LLA is a BKA followed by an AKA. The prevalence and incidence of LLA in high in this population and is higher than any other published rate worldwide. Males have a higher incidence of LLA than females and this is consistent with the literature.

CHAPTER 4

4. METHODOLOGY OF THE RANDOMISED CONTROLLED TRIAL

4.1 INTRODUCTION

This section outlines how data on demographic information, activity limitation, quality of life, participation restrictions, risk of falling and body image outcomes were collected, as well as how the exercise programme was administered. The chapter also outlines how data were analysed and reported. This study ran from June 2011 to February 2014 (follow up included). The chapter also gives a detailed account of the pilot study related to the randomised controlled trial (RCT). To avoid redundancy, the aim and objectitives of the RCT appear in Chapter 1 section 1.4 subsections 1.4.1 and 1.4.1.1 respectively.

4.2 STUDY DESIGN

An RCT was conducted. This was a prospective longitudinal pretest-posttest single blinded (assessor) RCT design. Eligible participants were divided into two groups, an intervention group and a control group.

4.3 PARTICIPANTS AND SAMPLING

Participants were drawn from the preoperative lists of people scheduled for first time major unilateral LLA at the Chris Hani Baragwanath Academic Hospital and Charlotte Maxeke Johannesburg Academic Hospital, South Africa from June 2011 to August 2013 (baseline data).

4.3.1 Inclusion Criteria

Participants were included:

- If they were due for a first time major unilateral lower limb amputation (LLA) during the study period (Godlwana et al., 2012).
- The amputation was because of dysvascular (diabetes or PVD) problems (Ferguson et al., 2010, Moxey et al., 2010, Johannesson et al., 2009).
- If they were of adult age (18+ years old) (Godlwana et al., 2012).

4.3.2 Exclusion Criteria

The following participants were excluded:

- Those who were due to have an amputation as a result of a carcinoma related or a traumatic amputation (Godlwana et al., 2012; Johannesson et al., 2009; Moxey et al., 2010).
- Those who had physical co-morbidities that interfered with function preoperatively, and that would potentially impact on their recovery/outcome e.g. participants with major physical co-morbidities e.g. stroke, paraplegia etc. (Godlwana et al., 2012).
- Those who were unable to understand the explanations of the study.
- If they were due for a bilateral major LLA during the study period.
- If they confirmed that they would be moving to another province within/during the study period (i.e. during the follow up period).

4.3.3 Sample Size Calculation

A Microsoft Excel sample size calculator was used to calculate the sample size. The effect change to be detected in the Barthel Index=2 (Hsieh et al., 2007), with a standard deviation (±SD) of ±3, alpha=5%, power of 90%, a drop out of 15% and non-compliance of 15% resulting in n=77 per group (see Appendix AC). This sample is an overestimate based on recommendations from previous research in order to protect the study from high mortality rates and difficulties with follow up as experienced in studies by Godlwana (2009, and Godlwana et al. (2012). A total sample of n=154 was considered sufficient for the study. Moreover, this sample is sufficient according to the central limit theorem (Polgar and Thomas, 2008). The literature discussing the MDCs of the OMs is available in Chapter 2 for the OMs where MDC have been published.

4.3.4 Assignment of Participants into Groups

Computer generated random sampling was employed using Microsoft Excel. The software generated 154 numbers and divided then into group one and two of equal size. These numbers showing a number from 1-154 corresponding to either Group 1 or 2 were then printed, separated and placed in opaque and sealed envelopes to ensure concealed allocation. The researcher did not keep a record of the Excel spreadsheet with the groups to ensure blinding. The researcher only kept a record of the spreadsheet with the numbers 1-154 without the groups corresponding to the numbers. All the envelopes were then handed over to the research assistant (RA) for group allocation. Allocation into groups was therefore concealed. The names of all the potential participants who meet the inclusion criteria scheduled for lower limb amputation at the study site were retrieved from the respective surgical/ vascular surgery department wards' operative lists at the candidate hospitals.

4.4 VARIABLES MEASURED

Table 4.1 illustrates variables measured in this study.

Table 4.1: Variables Measured

Variable	Independent variable (IV)	Dependent variable (DV)	ICF component addressed
Age, gender, race, income, smoking, drinking, cause of amputation, comorbidities	IV		Personal factors
Mode of transport	IV		Environmental factor
level of amputation	IV		Body structure and function
Pain		DV	Body structure and function
Anxiety, depression		DV	Personal factors
Body image disturbance		DV	Personal factors
Self- care, transfers, mobility including stairs, risk of falling		DV	Activity limitation
Social involvement in areas of occupation, role in community, visiting, household work, and confidence		DV	Participation restriction

Table 4.1 shows the independent and the dependent variables measured in this study.

4.5 INSTRUMENTS

4.5.1 Demographic Questionnaire

A demographic questionnaire (Appendix B-D) was used (Godlwana et al., 2012; Godlwana et al., 2011). **Section one** gathers demographic details. Information regarding the participant's date of birth, age, gender, race, marital status, geographical location, occupation, mode of transport used, social habits (drinking and smoking) and source of income is gathered in this section. **Section two** gathers medical history and co-morbidities including the aetiology of the amputation and level of amputation the participant is due to undergo.

4.5.2 The Barthel Index

The Barthel Index (BI) (Appendix H-J) is a 10 item functional scale used to measure functional independence and amount of nursing care needed. The participant is examined in the areas of bowel function, bladder function, personal hygiene, moving from wheelchair to bed and return, getting on and off the toilet, bathing self, walking on level surface/propelling a wheelchair, ascending and descending stairs, dressing and feeding (Finch 2002). The researcher has successfully used this OM in a previous study in the field of amputation (Godlwana et al., 2011; Godlwana et al., 2012). The instrument requires about five minutes if the interviewer is recording verbal information. The instrument was administered by the researcher (Godlwana et al., 2012) . In this scale the participant can score anything from zero to 20 points where 20 is the maximum full normal functional independence. The tool covers the ICF component of activity limitation.

4.5.3 The EQ-5D

The EQ-5D (Appendix E-G) is a generic measure of health related quality of life (Liles et al., 2006, Dhillon et al., 2005). This instrument was developed by the EuroQol Group in order to provide a simple, generic measurement of health for clinical and economic appraisal. The EQ-5D is a five item instrument used to measure the participant's quality of life (www.euroqol.org). It covers mobility, self-care, usual activities, pain/discomfort, anxiety /depression. A number line is used to rate the overall state of health on that day by making a mark indicating their state of health ranging from zero to one hundred where zero indicates the worst imaginable state of health. In South African this instrument is available in English, Zulu, and Sotho (Appendix E-G) and has been used in research on people with LLA (Godlwana et al., 2011; Godlwana et al., 2012). The tool covers the ICF component of activity limitation and personal factors.

4.5.4 The Amputee Body Image Scale

The original ABIS has been attached (Appendix K). The ABIS is a 20 item tool used to measure how a person with a leg amputation perceives their body and how they feel the amputation impacts on their life (Breakey, 1997). The instrument uses a Likert scale of 1-5 where 1= none of the time and 5=all of the time. The maximum score possible is 100 and the minimum is 20 with a higher scores implying high body image disturbance and lower scores indication low body disturbance. It must be noted that item 3, 12 and 16 are scored in reverse (Bumin et al., 2009). The ABIS was translated in to Zulu and Sotho. The method of translation of the outcome measures is described below.

4.5.5 The Participation-Scale

The (P-Scale) (Appendix O-Q) was developed by a group of researchers as a generic tool in order to assess the impact of rehabilitation interventions on social participation (Van Brakel et al., 2006, Magasi and Post, 2010). Among other purposes the scale was developed for use in stigma reduction and social integration programmes. This 18-item tool has a 0-5 point rating scale ranging from no restriction (0) ; some restriction, but no problem; small problem ; medium problem ; large problem(5). The total score ranges from 0-90. Further grading of the total score to determine participation restriction is such that a 0-12 means no significant restriction, 13-22 means a mild restriction, 23-32 means a moderate restriction, 33-52 means a severe restriction and a 53-90 means extreme restriction.

The tool addresses the ICF domains of community, major life domains, domestic life, self-care, mobility, social and civil life and social interactions. The P-Scale is a client report and is cross-culturally relevant in measuring participation and is easy to use even for non-professional interviewers (Van Brakel et al., 2006). It takes about 20 minutes to complete.

4.5.6 Locomotor Capabilities Index

The Locomotor Capabilities Index (LCI) (Appendix AM) is a 14 item tool used to measure the perceived degree of independence in locomotor capabilities on people with LLA. The tool covers different aspects of locomotion selected from the locomotor classification of the World Health Organization (WHO). It is a 4-level ordinal scale ranging from 0=not able to, to 3=able to do the activity independently. The total score is 42 where 0= the worst and 42 = the best (Franchignoni et al., 2004, Treweek and Condie, 1998). The scale can be further divided into two 7 item subscales, the basic subscale (items 1,4,5, 8-11) and advanced subscale (2,3,6,7,12-14) (Frachignoni et al., 2004; Treweek and Condie 1998). The basic and the advances subscales can be scored from 0-21 respectively (Larsson et al., 2009). The tool can be administered face-to-face, self reported, or telephonically. It takes about five minutes to administer (Larsson et al., 2009).

4.5.7 The Timed Up and Go Test

The Timed Up and Go test (TUG) (Appendix R-T) is used for people who are able to walk on their own. Walking aids are allowed during testing. The equipment needed: arm chair (40-50cm height) with armrests, tape measure (the STRAMM 5M X 19 mm was used in this study), tape (ordinary adhesive tape was used in this study), stop watch (the Monaco S-075 was used in this study), room (testing space), person wore their usual shoe (Schoppen et al., 1999; Schoppen et al., 2003).

- The participant was seated in a chair with their back against the back-rest and their arms resting on the arm rests.
- The participant was asked to stand and walk over a three meters (3m) distance measured with a tape and marked.
- The participant then turned around at the 3m spot and came back to sit in the chair again.

The assessor timed this activity from start to finish using a stop watch in seconds.The ranges are:<10 is considered freely mobile, <20 is considered mostly mobile, 20-29 seconds is considered variable mobility, >30 is considered impared mobility and ≥40 indicates a high risk of falls. A practice trial run was given to all the participants and then they were tested three times and the average time taken as their ability. There was no physical assistance given to participants apart from the instructions (See Appendix for full test description R, S, and T).

The English, Sotho and Zulu versions of the MABIS and the P-Scale were piloted for reliability after institutional ethical approval had been obtained (see pilot study below). The TUG was also piloted to check the practicality of using it and familiarising the researcher with the test and the intervention tested to ensure that it was easy to understand and that the exercise diary was easy to understand and use. The diary allowed participants to record each time they had done the exercises. See Appendix AG-AI for a copy of the diary.

4.6 TRANSLATION

4.6.1 Introduction

This section outlines how the OMs were translated as well as how data were collected. People in Johannesburg generally do not really speak their mother tongue in its pure form, they tend to mix vernacular words with English at times (Godlwana et al., 2012, Barbarin and Richter, 2001). In some situations they are multilingual.

4.6.2 Translation of the Outcome Measures

The ABIS, P-Scale, intervention programme and LCI were translated into Zulu and Sotho.Two translations from English to Zulu and Sotho were done by two independent translators whose mother tongue was Zulu and Sotho respectively (Bumin et al., 2009). This allowed the researchers to identify errors and differences in interpretation of the English version. One of the translators was aware of the purpose of the translation of this work in order to optimise the idiomatic and conceptual meaning rather than the literal meaning or the instrument and this promotes reliability (Bumin et al., 2009). The second translator was unaware of the reason for the translation so that the researcher could potentially discover the unexpected meanings derived from a person who is unaware of the reason to translate (Bumin et al., 2009). Following this, both translators reached consensus about the choice of words on the final documents.

List of what had to be agreed on:

In the Zulu LCI, item 1 'get up from the chair' the options were- ukusukuma esitulweni, ukusukuma, ukuphakama esitulweni. Consensus was reached to use ukusukuma esitulweni.

In the Zulu LCI, item 14 'walk while carrying an object' the options were- ukuhamba uphethe into ezandleni, ukuhamba uphethe into, ukuhamba unento oyiphethe. Consensus was reached to use ukuhamba uphethe into ezandleni.

Two back translations (Bumin et al., 2009) from Zulu and Sotho to English were done by two independent translators whose mother tongue was Zulu and Sotho respectively. Following this, both translators reported that their back translation was a good resemblance of the original tools. The researcher used the final Zulu and Sotho outcome measures.

4.6.3 Modifications of Instruments

4.6.3.1 Modifications on the original ABIS to form the Modified Amputee Body Image Scale (MABIS) in order to adapt it to the participants

These modifications were done in order to accommodate the reality that most of the participants would not have got their prostheses during the research period. All the modifications were about removing the statements that relate to the prosthesis. All attempts were made to ensure that this instrument still measured body image although in this case it excluded the role of the prosthesis. Items 2, 3, 5, 10, 12, 14, 17 were modified by either excluding or not referring to the prosthesis (Appendix L, M, N). This left the scale with 16 items.

4.6.3.2 The Modified Locomotor Capabilities Index

After email correspondence with F Frachignoni, the researcher was advised by this expert to try using the tool although the participants would not be using a prosthesis. This has been done previously (Norvell et al., 2011; Czerniecki et al., 2012). The standard LCI (Appendix AJ) has been modified to the Modified Locomotor Capabilities Index (MLCI) (Appendix AK, AL, AM). This was done by removing the two parts referring to the prosthesis and allowing them to refer to a walking aid as most participants were not expected to have, or did not have a prosthesis during the study period. This was done on the standard question and item no. 2. Furthermore, item no. 7 of the LCI referred to snow and ice in some of its examples and this was modified to wet surfaces because it was unlikely that the study setting was unlikely to have snow or icy conditions. These were minor modifications. The MLCI was translated into Zulu and Sotho (Appendix AL, AM).

4.7 THE EXERCISE DIARY

The exercise diary (ED) (Appendix AG, AH, AI) is a pamphlet that was used to record (Whyte and Niven, 2001) home exercises by participants in the intervention group. The tool allowed the participants to log a daily record for the home exercises for the three months period of the study. The user was required to place a tick or a cross on the day corresponding to the date they did the exercises. The diary included all the days of the week and the participants received a weekly telephone call from the research assistant reminding them about the recordings after each exercise session.

4.8 JUSTIFICATION OF THE INTERVENTION

4.8.1 The Issues that Informed the Approach

Rehabilitation is pivotal in order to improve outcomes of people with lower limb amputation (Kelly and Dowling, 2008) and this is generalisable to communities such as Johannesburg where it has been found that people with LLA are not able to afford transport to attend regular outpatient appointments for their physiotherapy treatments, if these are available and they often are not (Godlwana and Stewart, 2013; Godlwana, 2009). Following the findings of Godlwana (2009) which were subsequently published in Godlwana et al. (2012) and Godlwana and Stewart (2013), this study planned to address issues on poor functional indepedence in areas of balance, transfers, walking, poor physical and social functioning, falls as well as lifestyle modification while bypassing the difficulties associated with attendance and by using an inexpensive self-administered home based intervention. Self management is vital in improving function and is beneficial in persons with LLA (Wegener et al., 2009) and this was used to supplement any available rehabilitation.

To promote efficiency, the research assistant (RA) called (telephone) the paticipants in order to remind them about their exercises (Stewart et al., 2005). To assist with monitoring compliance, exercise diaries were administered and contained simple instructions on how to complete the diary and a sample page was issued as an example of how to do the daily recording (Whyte and Niven, 2001) (Appendix AG-AI). Participants were issued the contact telephone number of the research assistant in case they needed clarifications on how the exercises were to be performed or how to record them in the diary (Whyte and Niven, 2001). In this study, it was hoped that the participants would find the recording easy as they did not have to record hourly like in Whyte and Niven (2001).

4.8.2 Issues Informing the Exercises

Further to the findings by Godlwana (2009) which were subsequently published in Godlwana et al. (2012) and Godlwana and Stewart (2013) in this study setting; the researcher included exercises that could improve functional independence in persons with a LLA. Balance problems are a persistent concern in the LLA literature (Schoppen et al., 2003; Raya et al., 2010; Livingstone et al., 2011) and they reduce the chance of ambulation (Schoppen et al., 2003; Raya et al., 2010).

In addition to the above, the role of the unaffected leg is very important for functioning especially in the intermediate period without a prosthesis. The ability to stand on the unaffected limb without support yields better functional outcomes (Schoppen et al., 2003). This means that the intervention must pay special attention to the unaffected leg. Physical capacity, that is muscle strength and walking ability (walking velocity and symmetry) deteriorate considerable, following LLA (Livingstone et al., 2011). This further strengthens the importance of including exercises to address these areas, in the intervention.

The exercises have been informed by Robinson et al. (2010) and Broomhead et al. (2006) in an effort to target the areas known to be vulnerable during recovery following LLA. In this regard, the intervention included:

- Education, stump positioning to prevent contractures, safe transfer techniques, stretching exercises.
- Strengthening exercises for the controlling muscles, hip extensor and flexor exercises bilaterally, eccentric hip flexor exercises and ankle plantar flexor exercises
- Balance re-education, mobility, prevention of contractures, safe functional transfer re-education.

  (Broomhead et al., 2006 , Robinson et al., 2010, Biswas et al., 2010)

To accommodate the high probability of low levels of education in this poputation as reported in the literature (Coffey et al., 2014; Godlwana et al., 2012; Burger and Marincek, 2007) a language independent intervention was used (Haig et al., 2009). All the explanations of the exercises were supplemented by pictorial illustrations of the exercises or activity. This was done to assist those who could not read to combine the explanations of the RA with the pictorial illustration in order to perform the exercises correctly. The exercise intervention is found as Appendix AD-AF.

4.9 PROCEDURES OF THE RANDOMISED CONTROLLED TRIAL

4.9.1 Ethical Considerations and Confidentiality

Ethical approval was obtained from the University of The Witwatersrand Committee for Research on Human Subjects (ethical clearance no. M110124 (Appendix V1)). Permission to conduct the study at each candidate hospital was obtained (Appendix V2). The study was explained to each participant and an information leaflet was given out to potential participants (Appendix W-Y) and willing participants were given English, Zulu or Sotho consent forms to sign (Appendix Z-AB). All identifying information was kept separately from the study data. The researcher kept all questionnaires in a lock-up cupboard in his office. Participants were coded as number 1-154 in order to maintain confidentiality. Their names only appeared in the consent form and the contact details sheet and these were kept separate from the questionnaires.

4.9.2 Data Collection

Data collection commenced after the pilot study (June 2011-February 2014 - follow up included). All data were obtained in the form of interviews and the TUG test was perfomed. Each testing session lasted about 30-40 minutes. The interviews and assessments were carried out by the researcher who was blinded to group allocation. In an effort to minimise loss to follow up and difficulties getting hold of participants during follow up, the researcher also collected extra information about landmarks that could assist in finding the participant during follow up as the researcher may have needed to drive to the participant, particularly if they lost their cellphone or they were due for follow up but had no means to get to the hospital; these included schools, police station, churches, parks, clinics and shopping centres close by the participant's home. Participants were further asked to provide not only their telephone numbers but also those of relatives and friends in order to ensure they could be traced if they lost their cellphones. Participants were assured that the researcher would not divulge any medical information about the participant to any of the people whose numbers were provided except to say the researcher is a physiotherapist who met the participant at the candidate hospital and is now looking for them. All information on contact details of the participants was shared with the RA and the RA was not allowed to indicate which participants they needed contact details of, to ensure that the researcher remained blided to group allocation.

The participants were recruited preoperatively or shortly after the operation (within a week or two). This was done because it was not always possible to enter a participant into the study preoperatively (Norvell et al., 2011; Czerniecki et al., 2012) for various reasons, ranging from insufficient time from decision to amputation and day of amputation (Norvell et al., 2011; Czerniecki et al., 2012), uncertainty of the surgeons as to whether they would perform angioplasty or amputation, patient being undecided but not refusing outright yet, to being helped by the family on the decision as to whether they could participate or not. This was regarded as a reasonable procedure by the researcher as studies shows that interviews with retrospective recall of data on premorbid function, smoking and drinking are reliable (Norvell et al., 2011; Czerniecki et al., 2012).

In the studies by Norvell et al. (2011) and Czerniecki et al. (2012), only 33% (n=29) of the participants were enrolled preoperatively. The rest were enrolled at six weeks postoperatively. In this study, all the participants were enrolled preoperatively or within two weeks postoperatively. Norvell et al. (2011) and Czerniecki et al. (2012), found no difference in assessments between those who had to recall information at six weeks to those who had to recall the information preoperatively (mean difference=1.6, $p=0.52$). Czerniecki et al. (2012), reported good agreement on a recall of smoking status ($\kappa=0.53$, $p=0.03$) and a high interclass correlation (ICC) in recall for drinking (ICC=0.98, $p=0.001$) and a strong correlation in recall of mobility status in participants enrolled preoperatively and assessed again 6 weeks postoperatively ($\rho=0.83$, $p<0.01$). Norvell et al. (2011), found an ICC=0.87, $p=0.003$ for premorbid status assessed at six weeks postoperatively and that assessed preoperatively. Norvell et al. (2011) and Czerniecki et al. (2012) concluded that retrospective recall of premorbid information is a reliable way measuring premorbid status.

The structure of the whole initial interview assessing premorbid participant state (using the BI, EQ-5D and P-Scale), was such that it accommodated issues of participation as opposed to asking a participant whether they are currently able to attend social events like weddings while in reality they are in hospital and may have been in hospital for weeks. This was done by formulating the questions such that the participants gave the premorbid status of their life or well-being. For instance, the premorbid level of mobility meant that the participant reported about their state before the tissue loss, leg pain of the involved side or before onset of disability (Norvell et al., 2011; Czerniecki et al., 2012). In cases where there was never disability, the participant responded as per information on experiences preoperatively (Norvell et al., 2011; Czerniecki et al., 2012).

Participants were phoned weekly by the research assistant (RA) to remind then about the exercise programme and the exercise diary and to discuss any difficulties the participant may have had with the exercises. All testing (interviews and physical test as necessary) was conducted at the CHBH and CMJAH for all baseline data and CHBH and CMJAH, clinics or participants' homes during follow up.

4.10 THE EXPERIMENT

4.10.1 Control Group

The control group received the standard care currently offered at the study sites (Appendix vi). The standard care aims to increase participation and decrease activity limitation and the use of the caregiver as an active role player is advocated. The programme engages the patient in exercises including: those to prevent oedema, deformity, maintain strength and joint mobility, improve balance and gait as well as stump coning and phantom limb pain control.

The probems with the standard care programme are that:

- Lacks specificity of focus on the areas (at risk structures) to be treated. This may make it difficult for patients to perform exercises on their own, e.g balance exercises are stated but are unclear on the starting position. Saying lower limb strengthening does not give patients information on what aspects of strengthening to target especially considering their level of education is generally low.

- It has no pictorial illustration in order to remind patients without having to read the document.
- Its has no way of reminding patients of what to do.
- Compounding the above is that the participants cannot afford to diligently attend their treatment sessions due to both financial and geographical constraints and even those who can, the hospitals are not able to make the appointments (treatment session) as frequently as they wish due to staff shortages and having to prioritise acute patients as these are tertiary centres.

4.10.2 **Experimental Group**

The intervention handout was available in English, Zulu and Sotho to enable easy use by all participants (Appendix for details AD-AF). Pictorial images were included to allow the document to be language independent as it could not be assumed that participant were able to read the language they chose for the information sheet, consent and the intervention programme.

The experimental group received the standard care which was the same as the control group. They also were given the self-administered structured exercise programme (home programme). Participants were required to do the programme daily from discharge until three months postoperatively and were contacted regularly to check on their programmes and give help and advice as required.

The main distinct attributes of the intervetion programme are that:

- Telephonic reminders were used in order to improve compliance.
- Education on lifestyle modification was included.
- Pictorial illustrations were used in order to make the programme language independent. This allowed the patient to just look at the picture and perform the exercise without having to read the description of the exercise. In this way, even illiterate persons can still do their exercises.
- The exercise diary serves as a reminder to perform the exercises and keep a log (probably more efficient if the sample is literate).
- The exercises are specific in terms of targeting muscles at risk (Broomhead et al 2010, Robinson et al 2010, Biswas et al 2010). Examples included specification of plantarflexor strengthening exercises, eccentric muscle control of triceps surae, quadriceps and gluteal muscles.
- It emphasises safety by make intermittent use of the assistive devise during (within) the exercise being performed e.g. during standing, the patient is allowed to hold on to the frame or let go of it as he feels safe (Appendix AD figure 1).

- Exercises were done daily at home as opposed to hospital outpatient appointments that may in most cases be difficult to attend.

4.10.3 Training of the Research Assistant

The researcher trained the RA on:

- How to conduct the concealed and random sampling as well as how to blind the assessor. The research assistant was also instructed to inform the participant not to disclose to the researcher any aspect of the grouping and or whether participants had the intervention or needed help with it, to the researcher.
- How to standardise and implement the intervention for the experimental group. In this regard, the participants chose a copy of the programme in the language of their preference. The research assistant explained the programme in a similar manner for all the participants. Under no circumstances did any participant receive the intervention without the research assistant's explanation.
- How to promote contact with participants and minimise loss to follow up including phoning them to remind them about the study, the intervention and follow up.
- The RA was instructed to inform the participants of the intervention group not to share the intervention exercises with the control group in order to prevent cross over to the intervetion group.
- Ensuring that she educates the participants to perform the exercises twice per day as shown in the diary. Exercises had to be done in the morning and afternoon.
- Ensuring that she educates the participants to perform the exercise ten repetitions and progress to 30 repetition as seen in the explanation corresponding to the exercise pictures (Figure 1-3 and 7). For figure 4 the RA educated the particiants to practice these at every opportunity they get and record twice a day in the ED. For figure 5 the participants were educated to perform this over 10 minutes and progress to 30 minute as they could tolerate the exercise. For figure 6 participants were educated to perform this 20-30 times twice a day.

4.10.4 The Exercise Diary

The exercise diaries (Appendix AG-AI) were given by the research assistant to the participants in the experimental group at the same time as the intervention exercise sheets. They were then collected by the research assistant from the participants after the three months period and given to the researcher for analysis at the end of the study (after group comparisons were completed in 2014. No diaries were given to the researcher during data collection or before completion of analysis of the two groups in order to ensure continued blinding of the researcher (assessor).

4.11 SUMMARY OF DATA COLLECTION FOR THE RANDOMISED CONTROLLED TRIAL

i. The researcher explained the study to the patient (potential participant).
ii. The patient (potential participant) gave written consent.
iii. The researcher interviewed the participant. At baseline, the interview was in the past tense. At three and six months, the interview was in the present test.
iv. The researcher gave the research assistant the details of the participant (hospital, name of participant, gender of participant, ward number, bed number, telephone details and physical address of the participant).
v. The research assistant allocated the participants into groups and administered the intervention and educated the participant on how to utilise the ED if they were in the intervention group.
vi. The research assistant phoned the participants in the intervention group weekly and reminded them to do the exercises and to record what was done in the diary.
vii. At three months the research assistant collected the ED from the participants.
viii. At three and six months the researcher perfomed follow up interviews and the physical test.

Table 4.2 illustrates a summary of data collection timelines for the RCT.

Table 4.2: Summary of Data Collection Timelines for the RCT

	Preoperative	**Between discharge and three months**	**Three months postoperative (the RA collected ED)**	**Six months postoperative**
Demographics	√	intervention	-	-
BI	√	intervention	√	√
P-Scale	√	intervention	√	√
EQ-5D	√	intervention	√	√
MABIS	-	intervention	√	√
TUG	-	intervention	√	√
MLCI	-	intervention	√	√

Table 4.2 shows a summary of data collection timelines for the RCT.

4.12 DATA MANAGEMENT AND ANALYSIS OF THE RANDOMISED CONTROLLED TRIAL

An Excel spreadsheet was used to capture and store the data. The researcher used a computer with a password and only the researcher knew the password. This maintained confidentially as well as protecting the autonomy of the participants. The researcher conducted and completed data analysis without knowing which of the groups the control or intervention group was. Only on receipt of the EDs did the research assistant reveal participant allocation into groups.

Data were analysed using IBM SPSS version 22. Data were tested for statistical assumptions and they satisfied all but the Gaussian distribution (Appendix 1B) and baseline comparability if the P-scale and this led to median tests. Baseline comparability was established by comparing the central tendencies of the outcome measures on preoperative data and the outcomes of the demographic questionnaire. All continuous data are presented as medians and percentiles. All categorical data have been presented as frequencies. The two groups were compared using the Mann-Whitney U test for continuous data and Fisher's exact test for categorical data from baseline to six months. A Bonferroni corrected p-value was used to ensure a stringent level of significant when testing outcomes measures item by item. Wilcoxon signed rank test and Two-way Friedman's ANOVA were used to test the within group medians. Survival was established using the Kaplan-Meier test, Cox proportional hazard and the Log Rank (Mantel-Cox) test for comparison. Data are presented as statistical figures in tables and graphs. Generalised Estimating Equations (GEE) regression analysis (Ma et al., 2012) was used to determine/exclude confounders (adjusting for baseline differences) based on baseline differences in participant characteristics. Where GEE were not possible to model, Generalised Linear Model (GLM) Repeated Measures Analysis of Covariance (RM- ANCOVA) and Generalised Linear Model (GLM) univariate regression Analysis of Variance (ANOVA) was used used to determine/exclude confounders based (adjusting for baseline differences) on baseline differences in participant characteristics. Association between baseline characteristics and functional outcomes was tested using multiple linear regression.

To preserve randomisation, the large sample size and optimise the power of the study, Intention to treat analysis (ITT) was used (Ma et al., 2012, Wiens and Zhao, 2007, Montori and Guyatt, 2001). Using the ITT method of averages, data were imputed for participants lost during follow up. Participants with missing data were given a group average score (medians) of the group they belonged to. This was done at assessment points where there was missing data, i.e. at three and six month. Participants who died were only analysed to their last assessment and no scores were imputed after death was confirmed. To promote transparency, Per Protocol Analysis (PPA) was used and has been presented in Appendix iva.

CHAPTER 5

5. PILOT STUDY OF THE RANDOMISED CONTROLLED TRIAL

5.1 INTRODUCTION

This section outlines the pilot study of the RCT. Data on demographic information, activity limitation, quality of life, participation restrictions, risk of falling and body image outcomes were collected, analysed and reported. This study was conducted in April- May 2011.

5.2 AIM

To test the instruments to be used in the RCT.

5.3 OBJECTIVES OF THE PILOT STUDY

- To familiarize the researcher with how to use the OMs
- To test reliability (internal consistency) of the instruments
- To check the extent to which the instruments correlate with each other

5.4 PARTICIPANTS AND SAMPLING

Participants were recruited from the patients with LLA attending outpatient physiotherapy and or prosthetic fittings at CHBH. A sample size of n=15 was considered sufficient as it is 10% of the sample size for the main study.

5.5 INCLUSION

- Adults (18+ years old) with a major unilateral LLA.
- Any type of major LLA irrespective of the cause
- Ability to understand the study and give consent.

5.6 EXCLUSION

Patients who had physical co-morbidities other than LLA e.g. paraplegia, stroke etc were excluded.

5.7 INSTRUMENTS

The demographics question, BI and the EQ-5D were not the main focus of the pilot study as these have already been used by the researcher (Godlwana, 2009; Godlwana et al., 2011; Godlwana et al., 2012). Only the LCI, P-Scale, ABIS, the TUG were piloted. Demographic data collected included age, gender, level of amputation, time since amputation and reason for amputation.

5.8 ETHICAL CONSIDERATIONS

Ethical approval was obtained from the University of The Witwatersrand Committee for Research on Human Subjects (ethical clearance no.M110124 (Appendix V1)). Permission to conduct the study at each candidate hospital was obtained (Appendix V2). Participants gave informed consent (Appendix Z-AB). All data were treated with confidentiality.

5.9 PROCEDURE OF THE PILOT STUDY

5.9.1 Data Collection of the Pilot Study

After ethical clearance was obtained and the hospitals granted permission, a group of participants were interviewed to check reliability (internal consistency) and feasibility of using these instruments. Interviews were conducted using the BI, EQ-5D, P-Scale, ABIS and the TUG was used to test balance.

5.9.2 Analysis of the Pilot Study

STATA version 11.0 was used. Both descriptive (frequencies, means and medians) and inferential statistics were used to analyse the data. Due to the small sample for the pilot (10% of the main RCT) as well as the nature of the data, Spearman's correlation was used. The correlation between the OMs was tested (Larsson et al 2009). Internal consistency (reliability) was calculated using Cronbach's alpha.

5.10 RESULTS OF THE PILOT STUDY

5.10.1 Demgraphic Characteristics

Each test session took about 25-40 minutes.

Table 5.1 illustrates the demographic characteristics of the sample (n=15).

Table 5.1: Demgraphic Characteristics (n=15)

Age	**54.3 (SD±15.4)**
Gender	
- Male	13(86.7%)
- Female	2(13.3%)
Level of Amputation	
- BKA	4(26.7%)
- AKA	10(66.7%)
- HQ	1(6.6%)
Cause of amputation	
- Diabetes	7(46.7%)
- PVD	3(20%)
- Trauma	5(33.3%)

Table 5.1 shows that the majority (86.7%, n=13) of the participants were male. Most (46.7%, n=7) people were amputated as a result of diabetes.

Table 5.2 illustrates percentiles for the instruments as well as age and time since amputation

Table 5.2: Percentiles for the Instruments as well as Age and Time since Amputation

	25th	**50th**	**75th**
BI	19	20	20
ABIS	35	46	55
P-Scale	3	12	30
LCI	29	40	42
TUG	12	17	43
EQ-5D VAS	50	75	90
AGE	45	58	66
Years since amputation	0	1	20

Table 5.2 shows that the participants were highly functional as seen by the LCI, BI ,P-scale and TUG, BUT they still had major body image disturbances (median ABIS of 46).

5.11 INTERNAL CONSISTENCY OF THE INSTRUMENTS

5.11.1 The Barthel Index

Table 5.3 illustrates the internal consistency of the BI

Table 5.3: Internal Consistency of the BI

Item	**Observations**	**Sign**	**Item-test correlation**	**Item-rest correlation**	**Average inter Item correlation**	**Alpha**
BI Transfer	15	-	0.79	0.58	0.25	**0.49**
BI Mobility	15	+	0.59	0.27	0.44	0.70
BI Dressing	15	+	0.79	0.58	0.25	**0.49**
BI Stairs	15	+	0.65	0.36	0.38	0.65
TEST SCALE					0.33	**0.66**

Table 5.3 shows that the BI has good internal consistency with a Cronbach's alpha of 0.66. The internal consistency of the BI drops to mild (alpha=0.49) when the BI transfer or BI dressing item is omitted from the scale and it improves to good when the BI mobility or BI stairs is omitted. This indicates the role of the individual items in the overall scale.

5.11.2 The Amputee Body Image Scale

Table 5.4 illustrates the internal consistency of the ABIS

Table 5.4: Internal Consistency of the ABIS

Item	Observations	Sign	Item-test correlation	Item-rest correlation	Average inter Item correlation	Alpha
ABIS1	15	+	0.4441	0.3525	0.2694	0.8550
ABIS2	15	+	0.1673	0.0615	0.2910	0.8678
ABIS3	15	-	0.2239	0.1194	0.2866	0.8654
ABIS4	15	+	0.4859	0.3980	0.2661	0.8530
ABIS6	15	+	0.4549	0.3980	0.2685	0.8545
ABIS7	15	+	0.7589	0.7077	0.2447	0.8383
ABIS8	15	+	0.7497	0.6969	0.2455	0.8388
ABIS9	15	+	0.7497	0.6969	0.2455	0.8388
ABIS11	15	+	0.7172	0.6590	0.2480	0.8407
ABIS12	15	+	0.6129	0.5395	0.2562	0.8464
ABIS13	15	+	0.4909	0.4036	0.2657	0.8527
ABIS14	15	+	0.7076	0.6479	0.2488	0.8412
ABIS15	15	+	0.6878	0.6250	0.2503	0.8423
ABIS16	15	+	0.2664	0.1636	0.2832	0.8634
ABIS18	15	+	0.8631	0.8317	0.2366	0.8322
ABIS19	15	+	0.6223	0.5501	0.2554	0.8459
ABIS20	15	+	0.7799	0.7324	0.2431	0.8371
TEST SCALE					0.2609	**0.8572**

Table 5.4 shows that the ABIS has excellent internal consistency with a Cronbach's alpha of 0.86. The ABIS generally maintains excellent internal consistency (alpha=0.8) at any given time even when any item is dropped from this scale. This indicates that the items contribute equally to the scale. Item 5,10 and 17 were constant and therefore omitted from the analysis.

5.11.3 **The P-Scale**

Table 5.5 illustrates the internal consistency of the P-Scale.

Table 5.5: Internal Consistency of the P-Scale

Item	Observations	Sign	Item-test correlation	Item-rest correlation	Average inter Item correlation	Alpha
PSCALE1	15	+	0.6845	0.6273	0.2777	0.8673
PSCALE2	15	-	0.3110	0.2193	0.3060	0.8823
PSCALE3	15	+	0.1845	0.0883	0.3155	0.8868
PSCALE4	15	+	0.6833	0.6259	0.2778	0.8674
PSCALE5	15	+	0.4732	0.3924	0.2937	0.8761
PSCALE6	15	+	0.4941	0.4152	0.2921	0.8753
PSCALE7	15	+	0.8883	0.8648	0.2624	0.8581
PSCALE8	15	+	0.5829	0.5130	0.2854	0.8716
PSCALE9	15	+	0.7502	0.7026	0.2728	0.8644
PSCALE10	15	+	0.5148	0.4378	0.2906	0.8744
PSCALE11	15	+	0.8603	0.8315	0.2645	0.8594
PSCALE12	15	+	0.6275	0.5629	0.2821	0.8698
PSCALE13	15	+	0.9171	0.8993	0.2602	0.8567
PSCALE14	15	+	0.4319	0.3478	0.2968	0.8777
PSCALE15	15	-	0.2824	0.1895	0.3081	0.8833
PSCALE16	15	+	0.5615	0.4893	0.2870	0.8725
PSCALE17	15	+	0.5148	0.4378	0.2906	0.8744
PSCALE18	15	+	0.5148	0.4378	0.2906	0.8744
TEST SCALE					0.2863	**0.8784**

Table 5.5 shows that the P-scale has excellent internal consistency with a Cronbach's alpha of 0.88. The P-scale generally maintains excellent internal consistency (alpha=0.8) at any given time even when any item is dropped from this scale. This indicates that the items contribute equally to the scale.

5.11.4 **The Locomotor Capabilities Index**

Table 5.6 illustrates the internal consistency of the LCI.

Table 5.6: Internal Consistency of the LCI

Item	Observations	Sign	Item-test correlation	Item-rest correlation	Average inter- Item correlation	Alpha
LCI2	15	-	0.1163	0.0013	0.5298	0.9311
LCI3	15	+	0.1268	0.0130	0.5286	0.9308
LCI4	15	+	0.6803	0.6092	0.4509	0.9079
LCI5	15	+	0.8814	0.8525	0.4247	0.8986
LCI6	15	+	0.8814	0.8525	0.4247	0.8986
LCI7	15	+	0.7598	0.7030	0.4397	0.9040
LCI8	15	+	0.8430	0.8075	0.4251	0.8987
LCI9	15	+	0.8285	0.7882	0.4321	0.9013
LCI10	15	+	0.8814	0.8525	0.4247	0.8986
LCI11	15	+	0.8814	0.8525	0.4247	0.8986
LCI12	15	+	0.7789	0.7288	0.4389	0.9037
LCI13	15	+	0.8143	0.7711	0.4341	0.9020
LCI14	15	+	0.6061	0.5286	0.4628	0.9118
TEST SCALE					0.4493	**0.9138**

Table 5.6 shows that the LCI showed excellent internal consistency with a Cronbach's alpha of 0.91. The LCI generally maintains excellent internal consistency (alpha above 0.8) at any given time even when any item is dropped from this scale. This indicates that the items contribute equally to the scale.

5.11.5 **The EQ-5D**

Table 5.7 illustrates the internal consistency of the EQ-5D.

Table 5.7: Internal Consistency of the EQ-5D

Item	Sign	Item-test correlation	Item-rest correlation	Average inter-Item correlation	Alpha
Eq5d mob	+	0.79	0.44	-0.0000	.
eq5dpain	+	0.69	0.27	0.2004	0.33
eq5danxiety	-	0.58	0.12	0.4226	0.59
TEST SCALE				0.2077	**0.4402**

Table 5.7 shows that the EQ-5D usual activity and self-care were constant, thus omitted by the test. The EQ-5D showed mild internal consistency with a Cronbach's alpha of 0.44. The EQ-5D gained a moderately good internal consistency (alpha=0.59) when the item on anxiety/depression is dropped from the scale. The lower overall internal consistency in this scale may be as a result of the fact that it has few items (five).

5.12 CORRELATION OF THE INSTRUMENTS

Table 5.8 illustrates correlations between the instruments.

Table 5.8: Correlations between the Instruments

	Tug	vas	LCI	ABIS
Total ABIS		r=-0.57 p=0.03 *		
Total P-Scale	r=0.52 p=0.05*			
Total BI		r=0.61 p=0.02*	r=0.73 p=0.001*	r=-0.48 p=0.07

p≤0.05 considered significant.

Table 5.8 shows that at least four instruments correlated significantly with each other with LCI correlating strongly with the BI. Spearman's correlation test was performed and revealed a significant inverse correlation between ABIS and VAS (p=0.03), BI and VAS (p=0.02), P-scale and TUG (p=0.05), LCI and BI (p=0.001).

5.13 DISCUSSION OF THE PILOT STUDY RESULTS

The ABIS showed excellent internal consistency in these studies, alpha=0.88 (Breakey, 1997; Safaz et al., 2010), alpha=0.84 (Bumin et al., 2009). This was also found in this study. The LCI has show excellent internal consistency in previous studies, alpha=0.95 (Larsson et al., 2009; Franchignoni et al., 2004) and this was also found in this study.

The ABIS and the LCI are instruments that were designed for people with LLA and this might explain why they have done well in this regard unlike the P-scale, BI and EQ-5D which are generic instruments. However, the P-scale also showed excellent internal consistency in this study as well as in van Brakel et al's study, alpha=0.92 (van Brakel et al., 2006). However, their study was on leprosy patients and not people with LLA.

The BI has shown excellent internal consistency in previous studies, alpha=0.87 at admission and 0.92 at discharge for stroke patients undergoing rehabilitation (Finch et al, 2002) but these were not people with LLA. In this study, good internal consistency was found.

The EQ-5D has also showed strong internal consistency, alpha=0.7 (Rushnell et al., 2006). However, their study was on inflammatory bowel syndrome (IBS) patients and in this study there was mild internal consistency.

In the literature, TUG correlates strongly (r=-0.75) with LCI and EQ-5D correlates strongly (r= 0.84) with LCI (Larsson et al., 2009). However, this was not the case in this study. This may be because of the small sample size in this pilot study.

The EQ-5D has been shown to have a moderate correlation with BI, r=0.512, p=0.001 (Pinto et al., 2011). However, their study was on stroke patients. In our study, good and significant correlation was seen for these outcome measures.

ABIS shows no correlation (r=-0.17) with time since amputation (Breakey, 1997) and this was the case in this study too. Although one must be wary of making strict conclusions from the outcomes in this study, it could be that, this is the case but a study with more participants would conclude better.

5.14 LIMITATIONS OBSERVED IN THE PILOT STUDY

The researcher did not anticipate the difficulty in follow up. Participants did not come back to return the ED. They were contacted telephonically and confirmed that they encountered no difficulties in performing the exercises and using the ED but did not have money to come back and also didn't have any appointment pending. This further meant that a test-retest was not possible.

5.15 CONCLUSION

The above outcome measures demonstrated that they were appropriate for use in the main study. Four outcome measures correlated well with each other making it rational to use for this population. All the outcome measures showed excellent internal consistency except the EQ-5D and the BI which showed mild and good internal consistency respectively. Furthermore, the researcher was happy with how to use the OMs and each test session took about 25-40 minutes.

CHAPTER 6

6. RESULTS OF THE RANDOMISED CONTROLLED TRIAL

6.1 INTRODUCTION

This chapter presents the results of the randomised controlled trial (RCT) done to test the effect of the intervention described in Chapter 5 and Appendix AD. Comparisons between the experimental group (Group 2) and the control group (Group 1) in participation restriction, activity limitation, QOL, body image and risk of falling are presented. In addition within group changes in Groups 1 and 2 can be seen in Appendix ia. The comparison of participants who survived and those who died at three and six months as well as survival rates between the groups is presented. The flow of participants through the study is illustrated in Figure 6.1. The results have been presented in this manner to ensure clarity and ease of understanding.

6.2 FLOW OF PARTICIPANTS THROUGH THE STUDY

A loss to follow up of 27.9% (n=43) was incurred throughout the whole study. Both Group 1, the control and Group 2, the intervention group had (n=63) at three months, and n=62 and n=59 at six months respectively. Figure 6.1 illustrates the flow of participants throughout the study.

Figure 6.1 illustrates the flow of the total sample throughout the study.

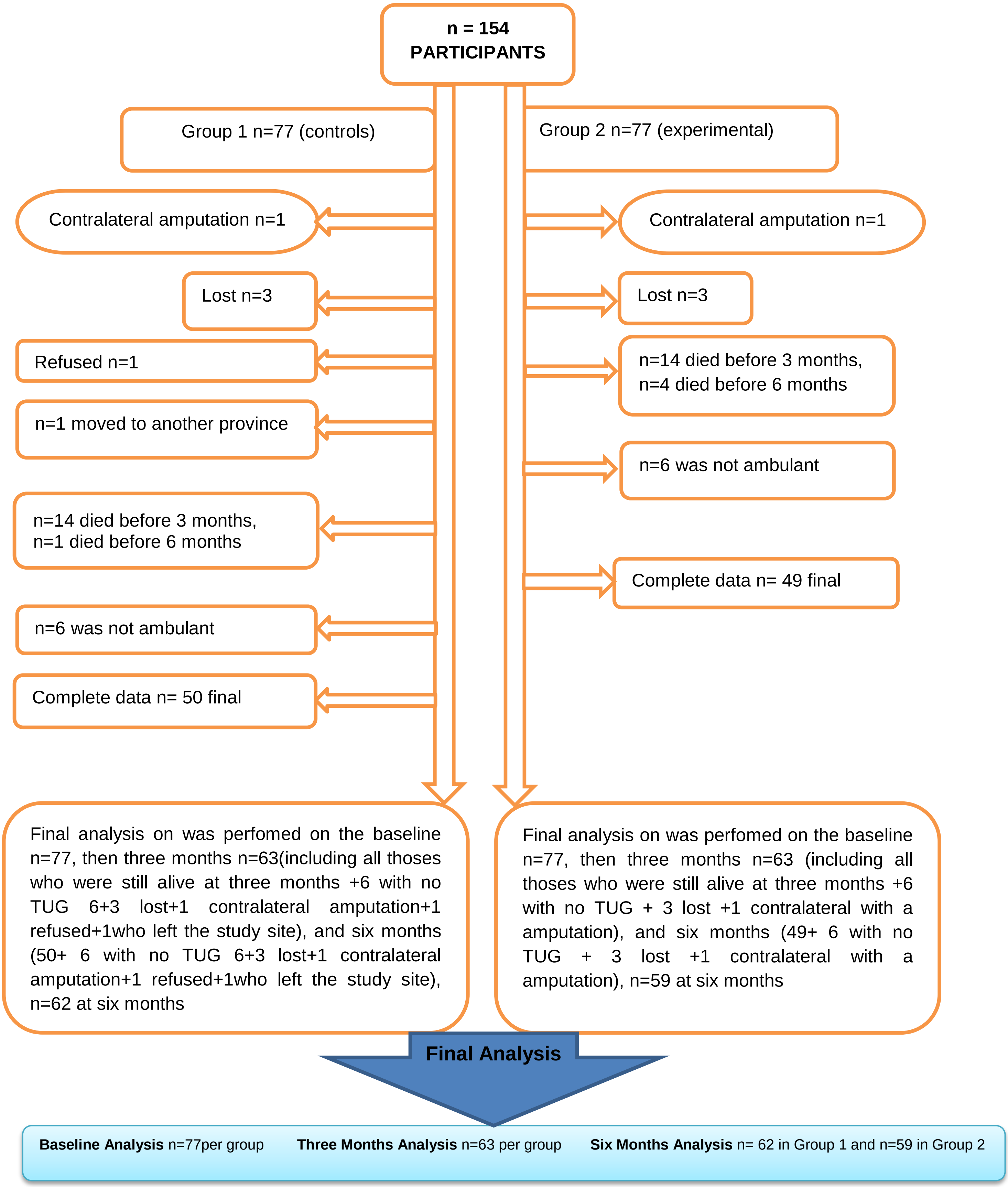


Figure 6.1: Flow of the Total Sample throughout the Study

6.3 DEMOGRAPHIC CHARACTERISTICS OF THE PARTICIPANTS

The demographic characteristics of the two groups are illustrated in Table 6.1.

Table 6.1: Demographic Characteristics of the Two Groups

Demographic Profile				
		Control group n=77	**Intervention group n=77**	**p-value**
Age	Age Mean (±SD)	57.78(9.66)	58.58(9.92)	0.611
	25th percentile Median 75th percentile	51 58 65	54 58 65	0.505
Gender	Male	51(66.2)	49(63.6)	0.433
	Female	26(33.8)	28(36.4)	
Transport mode	Own car	19(24.7)	17(22.1)	0.923
	Relative's car	9(11.7)	7(9.1)	
	Public transport	47(61)	51(66.2)	
	Hire private transport	2(2.6)	2(2.6)	
	Other			
Income	Private pension	2(2.6)	1(1.3)	0.541
	Old age pension	26(33.8)	25(32.5)	
	Disability grant	6(7.8)	7(9.1)	
	Still employed	29(37.7)	22(28.6)	
	Other	14(18.2)	22(28.6)	
Cigarette Smokers	Yes	49(63.6)	38(49.4)	0.052
	No	28(36.4)	39(50.6)	
Alcohol consumption	Yes	31(40.3)	34(44.2)	0.372
	No	46(59.7)	43(55.8)	

$p \leq 0.05$ is significant. (Fisher's exact test)

Table 6.1 shows that there were no significant differences in demographic characteristics between the two groups.

The clinical characteristics of the two groups are illustrated in Table 6.2.

Table 6.2: Clinical Characteristics of Groups

Clinical Profile				
		Control group n=77 n(%)	**Intervention group n=77 n(%)**	**p-value**
Level of amputation	BKA	44(57.1)	60(77.9)	0.005
	AKA	33(42.9)	17(22.1)	
HPT	Yes	42(54.5)	50(64.9)	0.125
	No	35(45.5)	27(35.1)	
Heart disease	Yes	5(6.5)	6(7.8)	0.500
	No	72(93.5)	71(92.2)	
Diabetes	Yes	46(59.7)	50(64.9)	0.309
	No	31(40.3)	27(35.1)	
PVD	Yes	39(50.6)	30(39)	0.097
	No	38(49.4)	47(61)	
Arthritis	Yes	3(3.9)	5(6.5)	0.360
	No	74(96.1)	72(93.5)	
Other (HIV, asthma, renal disease etc)	Yes	5(6.5)	9(11.7)	0.201
	No	72(93.5)	68(88.3)	

$p \leq 0.05$ is significant. (Fisher's exact tests)

Table 6.2 shows that there was generally no significant difference between the two groups but the intervention group had a significantly higher proportion of participants with a BKA than the control group.

6.4 PARTICIPATION RESTRICTION

Table 6.3 illustrates the participation levels of the two groups from the preoperative period to six months.

Table 6.3: Participation Levels of the Two Groups from the Preoperative Period to Six Months

P-Scale									
	Baseline			3 months			6 months		
	Control group n=77	Intervention group n=77	p-value	Control group n=63	Intervention group n=63	p-value	Control group n=62	Intervention group n=59	p-value
25th percentile **Median** **75th percentile**	0 0 0	0 0 5	0.038	10 28 41	6 18 27	0.004	1.75 15 30	0 15 25	0.280

p≤0.05 is significant

The groups were not comparable at baseline with the intervention group demonstrating significantly more participation restriction (p=0.038). However, intervention group demonstrated significantly less (p=0.004) participation restriction at three months postoperatively compared to the controls. In fact, the intervention group median score shows mild participation restriction while the control group median score shows moderate participation restriction during this follow up period (see Appendix O). Both groups show mild participation restriction by six months postoperatively. The baseline difference in level of amputation between the two groups had no influence (was excluded as a confounder) on postoperative participation levels (participation restriction) of the groups when this outcome was adjusted for level of amputation (see Appendix iia Table 1).

Table 6.4 illustrates the participation levels of the two groups from preoperative to six months item by item.

Table 6.4: Participation Levels at Baseline Three Months and Six Months Item by Item

	P-Scale										
			Baseline			3 months			6 months		
Item no.	**Item**	**Item level**	**Control group =77 n (%)**	**Intervention group n (%)**	**p-value**	**Control group =63 n (%)**	**Intervention group n (%)**	**p-value**	**Control group n (%)**	**Intervention group n (%)**	**p-value**
1	Do you have equal opportunity as your peers to find work?	0	69(89.6)	62(80.5)		37(58.7)	38(60.3)		37(59.7)	38(64.4)	
		1							1(1.6)	1(1.7)	
		2	1(1.3)	1(1.3)		1(1.6)					
		3			0.130		1(1.6)	1.000		1(1.7)	0.751
		5	7(9.1)	14(18.2)		25(39.7)	24(38.1)		24(38.7)	19(32.2)	
2	Do you work as hard as your peers do? (same hours, type of work etc)	0	71(92.2)	63(81.2)		39(61.9)	37(58.7)		37(59.7)	40(67.8)	
		1		1(1.3)		1(1.6)			1(1.6)		
		2					1(1.6)				
		3		1(1.3)	0.107		1(1.6)	0.890	24(38.7)		0.450
		5	6(7.8)	12(15.6)		23(36.5)	24(38.1)			19(32.2)	
3	Do you contribute to the household economically in a similar way to your peers?	0	67(87)	58(75.3)		36(57.1)	39(61.9)		39(62.9)	38(64.4)	
		1									
		2		1(1.3)							
		3	2(2.6)	2(2.6)	0.209	1(1.6)	4(6.3)	0.284			0.507
		5	6(7.8)	16(20.8)		26(41.3)	20(31.7)		23(37.1)	21(35.6)	
4	Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	73(94.8)	58(75.3)		30(47.6)	45(71.4)		39(62.9)	48(81.4)	
		1	1(1.3)				4(6.3)		2(3.2)		
		2	1(1.3)	1(1.3)		1(1.6)			2(3.2)	1(1.7)	
		3	1(1.3)	2(2.6)	0.904	9(14.3)	3(4.8)	0.0020 *	2(3.2)	3(5.1)	0.082
		5	1(1.3)	16(20.8)		2336.5)	11(17.5)		17(27.4)	7(11.9)	
5	Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	75(97.4)	73(94.8)		22(34.9)	38(60.3)		42(67.7)	42(71.2)	
		1	1(1.3)				1(1.6)				
		2			0.120		1(1.6)		1(1.6)	1(1.7)	
		3	1(1.3)			6(9.5)	3(4.8)	0.009	2(3.2)	2(3.4)	0.938
		5		4(5.2)		35(55.6)	20(31.7)		17(27.4)	14(23.7)	
6	Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	76(98.7)	73(94.8)		22(349)	36(57.1)		38(61.3)	40(67.8)	
		1					1(1.6)		1(1.6)	1(1.7)	
		2		1(1.3)		2(3.2)	1(1.6)		1(1.6)	1(1.7)	
		3	1(1.3)	3(3.9)	0.182	6(9.5)	4(6.3)	0.063	1(1.6)		0.887
		5				33(52.4)	21(33.3)		21(33.9)	17(28.8)	

Item no.	Item	Item level	Baseline: Control group =77 n (%)	Baseline: Intervention group n (%)	Baseline: p-value	3 months: Control group =63 n (%)	3 months: Intervention group n (%)	3 months: p-value	6 months: Control group n (%)	6 months: Intervention group n (%)	6 months: p-value
7	Are you as socially active as your peers are? (e.g. in religious/community affairs)	0	75(97.4)	75(97.4)	0.497	33(52.4)	38(60.3)	0.718	44(71)	44(74.6)	0.716
		1					1(1.6)				
		2	1(1.3)	2(2.6)		1(1.6)				1(1.7)	
		3	1(1.3)			5(7.9)	4(6.3)		1(1.6)		
		5				24(38.1)	20(31.7)		17(27.4)	14(23.7)	
8	Do you have the same respect in the community as your peers?	0	77(100)	76(98.7)	0.500	58(92.1)	60(95.1)	0.615	60(96.8)	56(94.9)	0.608
		1									
		2					1(1.6)		1(1.6)		
		3		1(1.3)		2(3.2)	1(1.6)			1(1.7)	
		5				3(4.8)	1(1.6)		1(1.6)	2(3.4)	
9	Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	77(100)	75(97.4)	0.248	53(84.1)	59(93.7)	0.227	56(90.3)	54(91.5)	0.419
		1					1(1.6)				
		2				2(3.2)	1(1.6)			1(1.7)	
		3				3(4.8)			4(6.5)	1(1.7)	
		5		2(2.6)		5(7.9)	2(3.2)		2(3.2)	3(5.1)	
10	Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?	0	75(97.4)	76(98.7)	1.000	48(76.2)	51(81)	0.467	49(79)	52(88.1)	0.385
		1				1(1.6)	2(3.2)		1(1.6)		
		2	1(1.3)				2(3.2)		1(1.6)	1(1.7)	
		3				3(4.8)	2(3.2)		3(4.8)		
		5	1(1.3)	1(1.3)		11(17.5)	6(9.5)		8(12.9)	6(10.2)	
11	Do you visit other people in the community as often as other people do?	0	76(98.7)	73(94.8)	0.183	34(54)	44(69.8)	0.0010 *	46(74.2)	48(81.4)	0.637
		1					3(4.8)				
		2					2(3.2)		2(3.2)		
		3		4(5.2)		11(17.5)	1(1.6)		3(4.8)	3(5.1)	
		5	1(1.3)			18(28.6)	13(20.6)		11(17.7	8(13.6)	
12	Do you move around inside and outside the house and around the village / neighbourhood just as other people do?	0	76(98.7)	74(96.1)	0.245	36(57.1)	45(71.4)	0.022	46(74.2)	51(86.4)	0.293
		1					2(3.2)				
		2				1(1.6)	1(1.6)		2(3.2)		
		3	1(1.3)			9(14.3)	1(1.6)		4(6.5)	2(3.4)	
		5		3(3.9)		17(27)	14(22.2)		10(16.1)	6(10.2)	

	P-Scale										
			Baseline			3 months			6 months		
Item no.	Item	Item level	Control group =77 n (%)	Intervention group n (%)	p-value	Control group =63 n (%)	Intervention group n (%)	p-value	Control group n (%)	Intervention group n (%)	p-value
13	In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	74(96.1)	75(97.4)	1.000	29(46)	46(73)	0.006	45(72.6)	47(79.7)	0.298
		1					1(1.6)				
		2				2(3.2)	1(1.6)			2(3.4)	
		3	1(1.3)			9(14.3)	2(3.2)		4(6.5)	3(5.1)	
		5	2(2.6)	2(2.6)		23(36.5)	13(20.6)		13(21)	7(11.9)	
14	In your home, do you do household work?	0	74(96.1)	74(96.1)	1.000	36(57.1)	40(63.5)	0.039	43(69.3)	39(66.1)	0.814
		1					3(4.8)			1(1.7)	
		2	2(2.6)			4(6.3)			3(4.8)	1(1.7)	
		3		1(1.3)		11(17.5)	5(7.9)		5(8.1)	6(10.2)	
		5	1(1.3)	2(2.6)		12(19)	15(23.8)		11(17.7)	12(20.3)	
15	In family discussions, does your opinion count?	0	74(96.1)	76(98.7)	0.747	60(95.2)	61(96.8)	0.746	61(98.4)	56(94.9)	0.172
		1					1(1.6)				
		2								1(1.7)	
		3	2(2.6)			2(3.2)			1(1.6)		
		5	1(1.3)	1(1.3)		1(1.6)	1(1.6)			2(3.4)	
16	Do you help other people (e.g. neighbours, friends or relatives)?	0	76(98.7)	74(96.1)	0.370	47(74.6)	59(93.7)	0.005	55(88.7)	55(93.2)	0.129
		1				1(1.6)	2(3.2)				
		2		1(1.3)		3(4.8)					
		3	1(1.3)			3(4.8)	1(1.6)		1(1.6)	3(5.1)	
		5		2(2.6)		9(14.3)	1(1.6)		6(9.7)	1(1.7)	
17	Are you comfortable meeting new people?	0	76(98.7)	75(97.4)	0.497	59(93.7)	62(98.4)	0.428	58(93.5)	55(93.2)	0.284
		1							1(1.6)		
		2				2(3.2)				2(3.4)	
		3	1(1.3)							1(1.7)	
		5		2(2.6)		2(3.2)	1(1.6)		3(4.8)	1(1.7)	
18	Do you feel confident to try to learn new things?	0	76(98.7)	75(97.4)	0.497	60(95.2)	62(98.4)	0.746	58(98.3)	56(94.9)	0.334
		1							1(1.6)		
		2				1(1.6)	1(1.6)				
		3	1(1.3)			1(1.6)				2(3.4)	
		5		2(2.6)		1(1.6)			3(4.8)	1(1.7)	

*p≤0.0028 is significant (Fisher’s exact test-Bonferroni corrected).

The groups showed no difference in proportion of participation scores item by item at baseline and at six months follow up for all items. However, items 4 and 11 demonstrated a significant difference in proportion of participation levels at three months postoperatively between the groups with the intervertion group performing better than the control group in these aspects of participation (that is the intervertion group experienced less participation restriction).

6.5 ACTIVITY LIMITATION

Table 6.5 illustrates the activity (BI) (Appendix H) levels of the two groups from the preoperative period to six months.

Table 6.5: Activity (BI) Levels at Baseline, Three and Six Months

BI									
	Baseline			**3 months**			**6 months**		
	Control group n=77	Intervention group n=77	Mann-Whitney U p-value	Control group n=63	Intervention group n=63	Mann-Whitney U P-value	Control group n=62	Intervention group n=59	Mann-Whitney U p-value
25th percentile **Median** **75th percentile**	20 20 20	20 20 20	0.096	16 18 19	18 18 20	0.039	18 18 20	18 18 20	0.638

p≤0.05 is significant.

The groups were comparable at baseline. However, the intervertion group demonstrated significantly lower (p=0.039) activity limitation levels at three months postoperatively compared to control group. At six months follow up, the levels of activity was similar between groups. In fact, both groups show high median BI scores (see Appendix BI).The baseline difference in level of amputation between the two groups had no influence on postoperative activity levels (activity limitation) of the groups as measured by the Barthel Index when this outcome was adjusted for level of amputation (see Appendix iia Table 2).

Table 6.6 illustrates the levels of activity limitation of the two groups from preoperative to six months- item by item.

Table 6.6: Activity (BI) Levels at Baseline, Three and Six Months - Item by Item

	BI										
			Baseline			3 months			6 months		
Item no	**Item**	**Level**	**Control group =77 n (%)**	**Intervention group n=77 n (%)**	**p-value**	**Control group n=63 n (%)**	**Intervention group n=63 n (%)**	**p-value**	**Control group 1 n=62 n (%)**	**Intervention group n=59 n (%)**	**p-value**
1	Bowels	0			0.752	1(1.6)	1(1.6)	0.746	1(1.6)		1.000
		1	1(1.3)	1(1.3)		2(3.2)			1(1.6)		
		2	76(98.7)	76(98.7)		60(95.2)	62(98.4)		60(96.8)	59(100)	
2	Bladder	0			0.752	1(1.6)	1(1.6)	1.000	1(1.6)	1(1.7)	0.119
		1	1(1.3)	1(1.3)		2(3.2)	1(1.6)		4(6.5)		
		2	76(98.7)	76(98.7)		60(95.2)	61(96.8)		57(91.9)	58(98.3)	
3	Grooming	1	77(100)	77(100)	Constant	63(100)	63(100)	Constant	62(100)	59(100)	Constant
4	Toilet use	0			0.248	1(1.6)		0.440			0.260
		1		2(2.6)		2(3.2)	5(7.9)		2(3.2)		
		2	77(100)	75(97.4)		60(95.2)	58(92.1)		60(96.8)	59(100)	
5	Feeding	2	77(100)	77(100)	Constant	63(100)	63(100)	Constant	62(100)	59(100)	Constant
6	Transfer	1			0.248	3(4.8)		0.126	2(3.2)		0.056
		2	2(2.6)			4(6.3)	2(3.2)			3(5.1)	
		3	75(97.4)	77(100)		56(88.9)	61(96.8)		60(96.8)	56(94.9)	
7	Mobility	1			0.221	7(11.1)	5(7.9)	0.035	4(6.5)	4(6.8)	1.000
		2	2(2.6)	2(2.6)		16(25.4)	6(9.5)		6(9.7)	58.5)	
		3	75(97.4)	75(97.4)		40(63.5)	52(82.5)		52(83.9)	50(84.7)	
8	Dressing	1	1(1.3)		0.500	2(3.2)	1(1.6)	0.500			Constant
		2	76(98.7)	77(100)		61(98.8)	62(98.4)		62(100)	59(100)	
9	Stairs	0	4(5.2)	2(2.6)	0.052	41(65.1)	33(52.4)	0.355	31(50)	32(54.2)	0.379
		1	5(6.5)			10(15.9)	14(22.2)		12(19.4)	6(10.2)	
		2	68(88.3)	75(97.4)		12(19)	16(25.4)		19(30.6)	21(35.6)	
10	Bathing	0	1(1.3)		0.500	3(4.8)	1(1.6)	0.309	1(1.6)	1(1.7)	0.740
		1	76(98.7)	77(100)		60(95.2)	62(98.4)		61(98.4)	58(98.3)	

*p≤0.005 is significant (Fisher's exact test-Bonferroni corrected).

The groups show no difference in function from baseline to six months follow up, item by item.

Table 6.7 illustrates the levels of activity limitation of the two groups at three months and at six months.

Table 6.7: Activity (MLCI) (Appendix AN) Levels at Baseline, Three and Six Months

	MLCI					
	3 months			6 months		
	Control group n=63	Intervention group n=63	Mann-Whitney U p-value	Control group n=62	Intervention group n=59	Mann-Whitney Up-value
25th percentile Median 75th percentile	13 21 30	20 24 38	0.005	19 24 36	22 24 40	0.255

$p \leq 0.05$ is significant.

The intervertion group demonstrated significantly lower ($p=0.005$) activity limitation levels at three months postoperatively compared to the control group. At six months follow up, the levels of activity showed no significant ($p=0.255$) differences between the groups. The baseline difference in level of amputation between the two groups had no influence on postoperative activity levels (activity limitation) of the groups as measured by the Standard MLCI when this outcome was adjusted for level of amputation (see Appendix ia Table 2d and e and Figure 3 and 4).

Table 6.8 illustrates the levels of activity limitation (MLCI) of the two groups from three to six months item by item.

Table 6.8: Activity (MLCI) Levels at Three and Six Months Item by Item

			3 months			6 months		
Item no.	Item	Level	Control group n=63 n (%)	Intervention group n=63 n (%)	p-value	Control group n=62 n (%)	Intervention group n=59 n (%)	p-value
1	Get up from a chair	1	2(3.2)	1(1.6)	1.000	1(1.7)	1(1.7)	0.805
		2	2(3.2)	2(3.2)		1(1.7)	2(3.4)	
		3	59(93.7)	60(95.2)		60(96.8)	56(94.9)	
2	Pick up an object from the floor when you are standing up with your walking aid	0	5(7.9)	1(1.6)	0.234	2(3.2)		0.739
		1	6(9.5)	7(11.1)		3(4.8)	4(6.8)	
		2	9(14.3)	5(7.9)		3(4.8)	2(3.4)	
		3	43(68.3)	50(79.5)		54(87.1)	53(89.8)	
3	Get up from the floor (e.g. if you fell)	0	5(7.9)		0.013	2(3.2)		0.044
		1	13(20.6)	7(11.1)		7(11.3)	8(13.6)	
		2	11(17.5)	7(11.1)		8(12.9)	1(1.7)	
		3	34(54)	49(77.8)		45(72.6)	50(84.7)	
4	Walk in the house	0	5(7.9)	5(7.9)	0.225	5(8.1)	4(6.8	0.854
		1	6(9.5)	4(6.3)		3(4.8)	1(1.7)	
		2	6(9.5)	1(1.6)		2(3.2)	1(1.7)	
		3	46(73)	53(84.1)		52(83.9)	53(89.8)	
5	Walk outside on even ground	0	10(15.9)	6(9.5)	0.061	5(8.1)	4(6.8)	0.709
		1	4(6.3)	3(4.8)		4(6.5)	2(3.4)	
		2	9(14.3)	2(3.2)		3(4.8)	1(1.7)	
		3	40(63.5)	53(82.5)		50(80.6)	52(88.1)	
6	Walk outside on uneven ground (e.g. grass, gravel, slope)	0	15(23.8)	8(12.7)	0.0030*	10(16.1)	4(6.8)	0.123
		1	11(17.5)	5(7.9)		6(9.7)	2(3.4)	
		2	10(15.9)	3(4.8)		5(8.1)	3(5.1)	
		3	27(42.9)	47(74.6)		41(66.1)	50(84.7)	
7	Walk outside in inclement weather (e.g. rain, wet surface)	0	32(50.8)	14(22.2)	0.0020*	16(25.8)	6(10.2)	0.129
		1	10(15.9)	12(19)		9(14.5)	14(23.7)	
		2	9(14.3)	8(12.7)		7(11.3)	8(13.6)	
		3	12(19)	29(46)		30(48.4)	31(52.5)	
8	Go up the stairs with a hand-rail	0	40(63.5)	32(50.8)	0.047	32(51.6)	30(50.8)	0.194
		1	7(11.1)	4(6.3)		6(9.7)	1(1.7)	
		2	8(12.7)	6(9.5)		8(12.9)	6(10.2)	
		3	8(12.7)	21(33.3)		16(25.8)	22(37.3)	

			3 months			6 months		
Item no.	Item	Level	Control group n=63 n (%)	Intervention group n=63 n (%)	p-value	Control group n=62 n (%)	Intervention group n=59 n (%)	p-value
9	Go down the stairs with a hand-rail	0	40(63.5)	33(52.4)	0.068	32(51.6)	31(52.5)	0.229
		1	6(9.5)	3(4.8)		6(9.7)	1(1.7)	
		2	9(14.3)	7(11.1)		8(12.9)	6(10.2)	
		3	8(12.7)	20(31.7)		16(25.8)	21(35.6)	
10	Step up a sidewalk curb	0	39(61.9)	31(49.2)	0.276	32(51.6)	32(54.2)	0.367
		1	5(7.9)	3(4.8)		5(8.1)	1(1.7)	
		2	6(9.5)	7(11.1)		5(8.1)	3(5.1)	
		3	13(20.6)	22(34.9)		20(32.3)	23(39)	
11	Step down a sidewalk curb	0	39(61.9)	31(49.2)	0.226	32(51.6)	31(52.5)	0.343
		1	7(11.1)	4(6.3)		5(8.1)	1(1.7)	
		2	4(6.3)	7(11.1)		5(8.1)	3(5.1)	
		3	13(20.6)	21(33.3)		20(32.3)	24(40.7)	
12	Go up a few steps (stairs) without a rail-hand	0	44(69.8)	33(52.4)	0.055	33(53.2)	32(54.2)	0.047
		1	7(11.1)	4(6.3)		9(14.5)	1(1.7)	
		2	4(6.3)	8(12.7)		6(9.7)	5(8.5)	
		3	8(12.7)	18(28.6)		14(22.6)	21(35.6)	
13	Go down a few steps (stairs) without a rail-hand	0	45(71.4)	34(54)	0.090	33(53.2)	31(52.5)	0.119
		1	6(9.5)	4(6.3)		9(14.5)	2(3.4)	
		2	4(6.3)	9(14.3)		6(9.7)	5(8.5)	
		3	8(12.7)	16(25.4)		14(22.6)	21(35.6)	
14	Walk while carrying an object	0	12(19)	11(17.5)	0.526	8(12.9	7(11.9)	0.309
		1	11(17.5)	6(9.5)		9(14.5)	3(5.1)	
		2	9(14.3)	8(12.7)		5(8.1)	8(13.6)	
		3	31(49.2)	38(60.3)		40(64.5)	41(69.5)	

*p≤0.0036 is significant (Fisher's exact test-Bonferroni corrected).

The intervertion group performed better than the control group on item 6 and 7 demonstrating a significant difference in proportion of activity levels within the items of the MLCI at three months postoperatively.

Table 6.9 illustrates the levels of activity limitation (see 4.5.6 MLCI Basic Subscale) of the two groups at three months and at six months.

Table 6.9: Activity (MLCI Basic Subscale) Levels at Three and Six Months

	MLCI Basic subscale					
	3 months			**6 months**		
	Control group n=63	Intervention group n=63	Mann-Whitney U p-value	Control group n=62	Intervention group n=59	Mann-Whitney U p-value
25th percentile **Median** **75th percentile**	7 9 17	9 11 21	0.040	9 9 21	9 11 21	0.447

p≤0.05 is significant.

The intervertion group demonstrated significantly lower (p=0.040) activity limitation levels at three months postoperatively compared to the intervention group in the total MLCI Basic Subscale score. At six months follow up, the levels of activity show no significant difference between the groups. The baseline difference in level of amputation between the two groups had no influence on postoperative activity levels (activity limitation) of the groups as measured by the Basic MLCI Subscale when this outcome was adjusted for level of amputation (see Appendix ia Table 2g and h and Figure 5 and 6).

Table 6.10 illustrates the levels of activity limitation (see 4.5.6) MLCI Basic Subscale) of the two groups at three months and at six months item by item.

Table 6.10: Activity (MLCI Basic Subscale) Levels at Three and Six Months - Item by Item

			MLCI Basic subscale					
			3 months			6 months		
Item no	Item	**Level**	**Control group n=63 n (%)**	**Intervention group n=63 n (%)**	**p-value**	**Control group n=62 n (%)**	**Intervention group n=59 n (%)**	**p-value**
1	Get up from a chair	1	2(3.2)	1(1.6)	1.000	1(1.6)	1(1.7)	0.805
		2	2(3.2)	2(3.2)		1(1.6)	2(3.4)	
		3	59(93.7)	60(95.2)		60(96.8)	56(94.9)	
4	Walk in the house	0	5(7.9)	5(7.9)	0.225	5(8.1)	4(6.8	0.854
		1	6(9.5)	4(6.3)		3(4.8)	1(1.7)	
		2	6(9.5)	1(1.6)		2(3.2)	1(1.7)	
		3	46(73)	53(84.1)		52(83.9)	53(89.8)	
5	Walk outside on even ground	0	10(15.9)	6(9.5)	0.061	5(8.1)	4(6.8)	0.709
		1	4(6.3)	3(4.8)		4(6.5)	2(3.4)	
		2	9(14.3)	2(3.2)		3(4.8)	1(1.7)	
		3	40(63.5)	53(82.5)		50(80.6)	52(88.1)	
8	Go up the stairs with a hand-rail	0	40(63.5)	32(50.8)	0.047	32(51.6)	30(50.8)	0.194
		1	7(11.1)	4(6.3)		6(9.7)	1(1.7)	
		2	8(12.7)	6(9.5)		8(12.9)	6(10.2)	
		3	8(12.7)	21(33.3)		16(25.8)	22(37.3)	
9	Go down the stairs with a hand-rail	0	40(63.5)	33(52.4)	0.068	32(51.6)	31(52.5)	0.229
		1	6(9.5)	3(4.8)		6(9.7)	1(1.7)	
		2	9(14.3)	7(11.1)		8(12.9)	6(10.2)	
		3	8(12.7)	20(31.7)		16(25.8)	21(35.6)	
10	Step up a sidewalk curb	0	39(61.9)	31(49.2)	0.276	32(51.6)	32(54.2)	0.367
		1	5(7.9)	3(4.8)		5(8.1)	1(1.7)	
		2	6(9.5)	7(11.1)		5(8.1)	3(5.1)	
		3	13(20.6)	22(34.9)		20(32.3)	23(39)	
11	Step down a sidewalk curb	0	39(61.9)	31(49.2)	0.226	32(51.6)	31(52.5)	0.343
		1	7(11.1)	4(6.3)		5(8.1)	1(1.7)	
		2	4(6.3)	7(11.1)		5(8.1)	3(5.1)	
		3	13(20.6)	21(33.3)		20(32.3)	24(40.7)	

*p≤0.0071 is significant (Fisher's exact test-Bonferroni corrected).

There was no significant difference between the two groups item by item in the basic MLCI.

Table 6.11 illustrates the levels of activity limitation (see 4.5.6) MLCI Advanced Subscale) of the two groups at three months and at six months.

Table 6.11: Activity (MLCI Advanced Subscale) Levels at Three and Six Months

	MLCI Advanced subscale					
	3 months			6 months		
	Control group n=63	Intervention group n=63	Mann-Whitney U p-value	Control group n=62	Intervention group n=59	Mann-Whitney U p-value
25th percentile	6	10		10	13	
Median	11	15	0.001	15	15	0.128
75th percentile	14	19		18	19	

$p \leq 0.05$ is significant.

The intervertion group demonstrated significantly lower (p=0.001) activity limitation levels at three months postoperatively compare to the control group in the total MLCI Advanced score. At six months follow up, the levels of activity were similar between groups. The baseline difference in level of amputation among the two groups had no influence on postoperative activity levels (activity limitation) at three months as measured by the Advanced MLCI Subscale (see Appendix ia Table 2j and Figure 7).

Table 6.12 illustrates the levels of activity limitation (MLCI Advanced Subscale) of the two groups from three to six months item by item.

Table 6.12: Activity (MLCI Advanced Subscale) Levels at Three and Six Months - Item by Item

	MLCI Advanced subscale-								
			3 months			6 months			
Item no.	**Item**	**Level**	**Control group n (%)**	**Intervention group n (%)**	**p-value**	**Control group n (%)**	**Intervention group n (%)**	**p-value**
2	Pick up an object from the floor when you are standing up with your walking aid	0	5(7.9)	1(1.6)	0.234	2(3.2)		0.739
		1	6(9.5)	7(11.1)		3(4.8)	4(6.8)	
		2	9(14.3)	5(7.9)		3(4.8)	2(3.4)	
		3	43(68.3)	50(79.5)		54(87.1)	53(89.8)	
3	Get up from the floor (e.g. if you fell)	0	5(7.9)		0.013	2(3.2)		0.044
		1	13(20.6)	7(11.1)		7(11.3)	8(13.6)	
		2	11(17.5)	7(11.1)		8(12.9)	1(1.7)	
		3	34(54)	49(77.8)		45(72.6)	50(84.7)	
6	Walk outside on uneven ground (e.g. grass, gravel, slope)	0	15(23.8)	8(12.7)	0.0030*	10(16.1)	4(6.8)	0.123
		1	11(17.5)	5(7.9)		6(9.7)	2(3.4)	
		2	10(15.9)	3(4.8)		5(8.1)	3(5.1)	
		3	27(42.9)	47(74.6)		41(66.1)	50(84.7)	
7	Walk outside in inclement weather (e.g. rain, wet surface)	0	32(50.8)	14(22.2)	0.0020*	6(9.7)	6(10.2)	0.129
		1	10(15.9)	12(19)		9(14.5	14(23.7)	
		2	9(14.3)	8(12.7)		7(11.3)	8(13.6)	
		3	12(19)	29(46)		30(48.4)	31(52.5)	
12	Go up a few steps (stairs) without a rail-hand	0	44(69.8)	33(52.4)	0.055	33(53.2)	32(54.2)	0.047
		1	7(11.1)	4(6.3)		9(14.5	1(1.7)	
		2	4(6.3)	8(12.7)		6(9.7)	5(8.5)	
		3	8(12.7)	18(28.6)		14(22.6)	21(35.6)	
13	Go down a few steps (stairs) without a rail-hand	0	45(71.4)	34(54)	0.090	33(53.2)	31(52.5)	0.119
		1	6(9.5)	4(6.3)		9(14.5	2(3.4)	
		2	4(6.3)	9(14.3)		6(9.7)	5(8.5)	
		3	8(12.7)	16(25.4)		14(22.6)	21(35.6)	
14	Walk while carrying an object	0	12(19)	11(17.5)	0.526	8(12.9)	7(11.9)	0.309
		1	11(17.5)	6(9.5)		9(14.5	3(5.1)	
		2	9(14.3)	8(12.7)		5(8.1)	8(13.6)	
		3	31(49.2)	38(60.3)		40(64.5)	41(69.5)	

*p≤0.0071 is significant (Fisher's exact test-Bonferroni corrected).

The intervertion group was better than the control group on item 6 and 7 demonstrating a significant difference in proportion of activity levels at three months postoperatively as measured by the MLCI advanced subscale.

6.6 BODY IMAGE

Table 6.13 illustrates the levels of perceived body image disturbance (MABIS) (Appendix L) of the two groups at three months and at six months.

Table 6.13: Perceived Body Image Disturbance of the Two Groups

	MABIS					
	3 months			6 months		
	Control group n=63	Intervention group n =63	Mann-Whitney U p-value	Control group n=62	Intervention group n= 59	Mann-Whitney U p-value
25th percentile	20	25	0.201	18	22	0.060
Median	28	35		25.5	39	
75th percentile	40	43		40	44	

$p \leq 0.05$ is significant.

Body image perception showed no significant difference between the groups, showing low body image disturbances at both assessment times.

Table 6.14 illustrates the levels of body image disturbance between the two groups from three to six month- item by item.

Table 6.14: Body Image Disturbance between the Two Groups - Item by Item

Item no	Item	Item level	MABIS 3 months Control group =63 n (%)	MABIS 3 months Intervention Group =63 n (%)	MABIS 3 months p-value	MABIS 6 months Control group =62 n (%)	MABIS 6 months Intervention group =59 n (%)	MABIS 6 months p-value
1	Because I am an amputee, I feel more anxious about my physical appearance in social situations than when I am alone	1	36(57.1)	32(50.8)	0.825	38(61.3)	27(45.8)	0.124
		2	5(7.9)	4(6.3)		4(6.5)	6(10.2)	
		3	8(12.7)	13(20.6)		9(14.5)	15(25.4)	
		4	3(4.8)	3(4.8)		1(1.6)	5(8.5)	
		5	11(17.5)	11(17.5)		10(16.1)	6(10.2)	
2	I avoid wearing shorts in public	1	44(69.8)	29(46)	0.025	41(66.1)	25(42.4)	0.022
		2		5(7.9)		5(8.1)	8(13.6)	
		3	8(12.7)	12(19)		6(9.7)	17(28.8)	
		4	1(1.6)	3(4.8)		2(3.2)	4(6.8)	
		5	10(15.9)	14(22.2)		8(12.9)	5(8.5)	
3	I like my overall physical appearance	1	35(61.9)	29(46)	0.091	36(58.1)	24(40.7)	0.121
		2	5(7.9)	4(6.3)		6(9.7)	9(15.3)	
		3	8(12.7)	16(25.4)		10(16.1)	17(28.8)	
		4	1(1.6)	6(9.5)		2(3.2)	5(8.5)	
		5	10(15.9)	8(12.7)		8(12.9)	4(6.8)	
4	It concerns me that the loss of my limb impairs my body's functional capabilities in various activities of daily living.	1	37(58.7)	24(38.1)	0.087	30(48.4)	22(37.3)	0.267
		2	4(6.3)	8(12.7)		8(12.9)	9(15.3)	
		3	6(9.5)	14(22.2)		9(14.5)	13(22)	
		4	6(9.5)	4(6.3)		5(8.1)	10(16.9)	
		5	10(15.9)	13(20.6)		10(16.1)	5(8.5)	
5	Because I am an amputee, I feel more anxious about my physical appearance on a daily basis	1	38(57.1)	26(41.3)	0.349	34(54.8)	26(44.1)	0.369
		2	5(7.9)	4(6.3)		6(9.7)	7(11.9)	
		3	6(9.5)	12(19)		9(14.5)	13(22)	
		4	6(9.5)	7(11.1)		3(4.8)	7(11.9)	
		5	10(15.9)	14(22.2)		10(16.1)	6(10.2)	
6	I experience a phantom limb	1	3(4.8)	1(1.6)	0.848	2(3.2)	2(3.4)	0.577
		2	1(1.6)	1(1.6)		7(11.3)	2(3.4)	
		3	5(7.9)	3(4.8)		8(12.9)	8(13.6)	
		4	13(20.6)	14(22.2)		11(17.7)	13(22)	
		5	21(65.1)	44(69.8)		34(54.8)	34(57.6)	

Item no	Item	Item level	3 months: Control group =63 n (%)	3 months: Intervention Group =63 n (%)	3 months: p-value	6 months: Control group =62 n (%)	6 months: Intervention group =59 n (%)	6 months: p-value
			MABIS					
7	Since losing my limb, it bothers me that I no longer conform to the society's ideal of normal appearance	1	37(58.7)	26(41.3)	0.058	35(56.5)	21(35.6)	0.135
		2	5(7.9)	12(19)		8(12.9)	12(20.3)	
		3	5(7.9)	13(20.6)		11(17.7)	17(28.8)	
		4	3(4.8)	2(3.2)		3(4.8)	6(10.2)	
		5	13(20.6)	10(15.9)		5(8.1)	3(5.1)	
8	It concerns me that the lost of my limb impairs my ability to protect myself from harm	1	35(55.6)	24(38.1)	0.088	31(50)	22(37.3)	0.027
		2	6(9.5)	11(17.5)		6(9.7)	10(16.9)	
		3	9(14.3)	13(20.6)		9(14.5)	18(30.5)	
		4	1(1.6)	6(9.5)		6(9.7)	7(11.9)	
		5	12(19)	9(14.3)		10(16.1)	2(3.2)	
9	The loss of my limb makes me think of myself as disabled	1	33(52.4)	25(39.7)	0.046	39(62.9)	14(23.7)	0.0001*
		2	3(4.8)	13(20.6)		5(8.1)	8(13.6)	
		3	10(15.9)	7(11.1)		8(12.9)	21(35.6)	
		4	4(6.3)	8(12.7)		3(4.8)	10(16.9)	
		5	13(20.6)	10(15.9)		7(11.3)	6(10.2)	
10	When I am walking, people notice my limp	1	32(50.8)	25(39.7)	0.069	32(51.6)	16(27.1)	0.001*
		2	3(4.8)	7(11.1)		7(11.3)	8(13.6)	
		3	5(7.9)	12(19)		7(11.3)	21(35.6)	
		4	6(9.5)	10(15.9)		4(6.5)	10(16.9)	
		5	17(27)	9(14.3)		12(19.4)	4(6.8)	
11	I avoid situations where my physical appearance can be evaluated by others (e.g. avoid social situations, swimming pool or beach activities, physical intimacy)	1	41(65.1)25	31(49.2)	0.081	42(67.7)	25(42.4)	0.0030*
		2	3(4.8)4	4(6.3)		4(6.5)	5(8.5)	
		3	5(7.9)11	14(22.2)		6(9.7)	17(28.8)	
		4	3(4.8)9	7(11.1)			5(8.5)	
		5	11(17.5)	7(11.1)		10(16.1)	7(11.9)	
12	People treat me as a disabled	1	25(39.7)	17(27)	0.451	36(58.1)	21(35.6)	0.006
		2	4(6.3)	7(11.1)		2(3.2)	6(10.2)	
		3	11(17.5)	13(20.6)		6(9.7)	14(23.7)	
		4	9(14.3)	14(22.2)		5(8.1)	12(20.3)	
		5	14(22.2)	12(19)		13(21)	6(10.2)	

Item no	Item	Item level	MABIS 3 months Control group =63 n (%)	Intervention Group =63 n (%)	p-value	6 months Control group =62 n (%)	Intervention group =59 n (%)	p-value
13	I like the appearance of my stump anatomy	1	35(55.6)	27(42.9)	0.020	37(59.7)	23(39)	0.0001*
		2	3(4.8)	7(11.1)		4(6.5)	8(13.6)	
		3	6(9.5)	18(28.6)		8(12.9)	19(32.2)	
		4	3(4.8)	3(4.8)		1(1.6)	7(11.9)	
		5	16(25.4)	8(12.7)		12(19.4)	2(3.4)	
14	I feel I must have four normal limbs in order to be physically attractive	1	40(63.5)	31(49.2)	0.099	45(72.6)	23(39)	0.0001*
		2	3(4.8)	5(7.9)		3(4.8)	8(13.6)	
		3	5(7.9)	15(23.8)		3(4.8)	15(25.4)	
		4	4(6.3)	5(7.9)		2(3.2)	9(15.3)	
		5	11(17.5)	7(11.1)		9(14.5)	4(6.8)	
15	It is important the size of my prosthesis and remaining anatomy of the affected limb are the same size as the other limb once I get it	1	32(50.8)	31(49.2)	0.025	36(58.1)	26(44.1)	0.008
		2	2(3.2)	7(11.1)		4(4.8)	6(10.2)	
		3	3(4.8)	11(17.5)		6(9.7)	17(28.8)	
		4	7(11.1)	3(4.8)		4(6.5)	7(11.9)	
		5	19(30.2)	11(17.5)		12(19.4)	3(5.1)	
16	I avoid looking into a full-length mirror in order not to see my stump anatomy	1	42(66.7)	38(60.3)	0.318	48(77.4)	36(61)	0.007
		2	6(9.5)	7(11.1)		5(8.1)	4(6.8)	
		3	4(6.3)	11(17.5)		3(4.8)	12(20.3)	
		4	3(4.8)	1(1.6)		1(1.6)	6(10.2)	
		5	8(12.7)	6(9.5)		5(8.1)	1(1.7)	

*p≤0.0031 is significant (Fisher's exact test-Bonferroni corrected).

The groups were not significantly different item by item at three months. The control group was better than intervention group at six months on items 9-11, 13 and 14.

6.7 QUALITY OF LIFE

Table 6.15 illustrates the QOL (EQ-5D) (Appendix E) of the two groups at baseline three and six months.

Table 6.15: Quality of Life Item Scores of the Two Groups at Baseline Three and Six Months

EQ-5D									
	Baseline			3 months			6 months		
	Control group n=77	Intervention group n=77	Mann-Whitney U p-value	Controls group n=63	Intervention group n=63	Mann-Whitney U p-value	Control group n=62	Intervention group n=59	Mann-Whitney U p-value
VAS **25th percentile** **Median** **75th percentile**	55 70 85	60 70 87.5	0.926	30 60 80	50 80 80	0.001	57.5 70 80	65 75 85	0.082
Utility index **25th percentile** **Median** **75th percentile**	0.028 0.264 0.725	0.193 0.264 0.796	0.068	0.264 0.725 0.796	0.689 0.796 0.796	0.033	0.443 0.796 0.850	0.725 0.796 1.000	0.244

p≤0.05 is significant.

The groups were comparable at baseline on both VAS and index scores. However, the intervention group demonstrated significantly superior (p=0.001) VAS and a significant (p=0.033) index score of QOL at three months postoperatively compared to the control group indicating that the intervention group had a better QOL. At six months follow up, the QOL scores were similar (high) between the groups. The baseline difference in level of amputation between the two groups had no influence on postoperative QOL of the groups as measured by the EQ-5D VAS and EQ-5D Index (see Appendix iia Table 3 and 4).

Table 6.16 illustrates the QOL item scores of the two groups at baseline three and six months.

Table 6.16: QOL Item Scores of the Two Groups at Baseline Three and Six Months

EQ-5D										
		Baseline			3months			6 months		
Item	Item level	Control group =77 n (%)	Intervention group =77 n (%)	p-value	Control group =63 n (%)	Intervention group =63 n (%)	p-value	Control group =62 n (%)	Intervention group =59 n (%)	p-value
Mobility	1	73(94.8)	75(97.4)	0.341	42(66.7)	53(84.1)	0.037	51(82.3)	50(84.7)	0.753
	2	4(5.2)	2(2.6)		15(23.8)	5(7.9)		8(12.9)	5(8.5)	
	3				6(9.5)	5(7.9)		3(4.8)	4(6.8)	
Self-care	1	75(97.4)	75(97.4)	0.690	58(92.1)	61(96.8)	0.220	60(96.8)	57(96.6)	0.672
	2	2(2.6)	2(2.6)		5(7.9)	2(3.2)		2(3.2)	2(3.4)	
Usual Activities	1	76(98.7)	76(98.7)	0.752	51(81)	51(81)	0.268	56(90.3)	52(88.1)	0.901
	2	1(1.3)	1(1.3)		12(19)	9(14.3)		5(8.1)	5(8.5)	
	3					3(4.8)		1(1.6)	2(3.4)	
Pain/ Discomfort	1	10(13)	13(16.9)	0.364	19(30.2)	13(20.6)	0.044	25(40.3)	2542.4)	0.791
	2	18(23.4)	24(31.2)		32(50.8)	45(71.4)		28(45.2)	28(47.5)	
	3	49(63.6)	40(51.9)		12(19)	5(7.9)		9(14.5)	6(10.2)	
Anxiety/Depression	1	32(41.6)	39(50.6)	0.227	31(49.2)	41(65.1)	0.039	44(71)	44(74.6)	0.418
	2	17(22.1)	20(26)		17(27)	17(27)		12(19.4)	13(22)	
	3	28(36.4)	18(23.4)		15(23.8)	5(7.9)		6(9.7)	2(3.2)	

*p≤0.01 is significant (Fisher's exact test-Bonferroni corrected).

The groups show no significant differences from baseline to six months follow up, item by item.

6.8 BALANCE (RISK OF FALLING)

Table 6.17 illustrates comparison of the ability to balance (risk of falling) (Appendix R TUG) of the two groups at three months and at six months.

Table 6.17: Balance (Risk of Falling) of the Two Groups at Three Months and at Six Months

	TUG					
	3 months			6 months		
	Control group n=63	Intervention group n=63	Mann-Whitney U p-value	Control group n=62	Intervention group n=59	Mann-Whitney U p-value
25th percentile	25	19	0.003	19	13	0.046
Median	34	24		25.5	21	
75th percentile	45	36		36	32	

$p \le 0.05$ is significant.

The intervention group demonstrated significantly less risk of falling (better ability to balance) at three months (p=0.036) and six months (p=0.046) postoperatively compared to the control group. The baseline difference in level of amputation between the two groups had no influence on postoperative risk of falling of the groups when this outcome was adjusted for level of amputation (see Appendix iia Table 5b and c and Figure 12 and 13).

6.9 ASSOCIATION BETWEEN BASELINE DEMOGRAPHIC, CLINICAL CHARACTERISTICS AND FUNCTIONAL OUTCOMES

This section reports associations between baseline (demographic and clinical) characteristics and functional outcomes. In this report only the functional outcomes that were significantly different between the groups were tested. Table 6.18 illustrates the association between functional outcomes and participant characteristics.

Table 6.18: Multiple Regression to Test Association between Functional Outcomes and Participant Characteristics

Outcome: BI 3 months	B	Std. Error	Beta	t	p-value
(Constant)	21.283	1.957		10.873	.000
Intervention group	1.001	.302	.289	3.310	.001
Age	-.057	.022	-.303	-2.571	.012
Female gender	-1.148	.310	-.313	-3.707	.000
Travel	-.180	.163	-.096	-1.107	.271
Income	.036	.160	.025	.227	.821
Alcohol drinking	-.096	.312	-.027	-.307	.760
Amputation level	-.048	.126	-.037	-.383	.703
Heart disease	.953	.582	.134	1.637	.105
Diabetes	.064	.644	.018	.099	.921
PVD	-.376	.630	-.107	-.597	.552
Outcome: P-Scale 3 months					
(Constant)	30.967	15.678		1.975	.051
Intervention group	-10.847	3.269	-.318	-3.318	.001
Age	.028	.174	.015	.158	.875
Amputation level	.543	1.368	.042	.397	.692
Diabetes	.149	6.731	.004	.022	.982
PVD	9.239	6.830	.268	1.353	.179
Outcome: EQ-5D index 3 months					
(Constant)	.146	.266		.548	.585
Intervention group	.159	.063	.243	2.513	.014
Amputation level	.005	.027	.019	.181	.857
Diabetes	.172	.132	.253	1.303	.195
PVD	.105	.132	.159	.796	.428
Income	.040	.026	.143	1.548	.125
Alcohol drinking	-.088	.065	-.131	-1.358	.178
Outcome: EQ-5D VAS 3 months					
(Constant)	68.940	19.060		3.617	.000
Intervention group	20.018	4.498	.402	4.450	.000
Amputation level	.114	1.819	.006	.063	.950
Diabetes	7.998	5.031	.155	1.590	.115
Age	-.670	.240	-.251	-2.786	.006
Outcome: TUG 3 months					
(Constant)	-47.709	45.555		-1.047	.298
Intervention group	-17.992	7.177	-.241	-2.507	.014
Age	1.564	.532	.375	2.938	.004
Female gender	14.039	7.530	.175	1.864	.066
Income	.745	3.747	.024	.199	.843
Alcohol drinking	5.850	7.449	.077	.785	.434
Amputation level	-2.359	3.104	-.084	-.760	.449
Diabetes	9.944	18.125	.129	.549	.585
PVD	17.022	18.714	.225	.910	.365

Outcome: BI 3 months	B	Std. Error	Beta	t	p-value
Outcome: TUG 3 months					
(Constant)	462.512	280.651		1.648	.103
Intervention group	40.739	64.472	.066	.632	.529
Amputation level	-9.710	24.002	-.042	-.405	.687
Age	-3.200	3.452	-.093	-.927	.356
Other	-249.593	99.327	-.252	-2.513	.014
Outcome: MLCI 3 months					
(Constant)	41.835	12.550		3.333	.001
Intervention group	8.918	1.994	.374	4.472	.000
Age	-.420	.144	-.324	-2.914	.004
Female gender	-8.354	2.045	-.331	-4.084	.000
Income	.290	1.046	.029	.277	.782
Alcohol drinking	-.837	2.051	-.034	-.408	.684
Amputation level	.688	.826	.076	.833	.407
Diabetes	1.987	4.106	.080	.484	.630
PVD	-.085	4.102	-.004	-.021	.984
Outcome: BMLCI 3 months					
(Constant)	25.486	7.009		3.636	.000
Intervention group	3.969	1.068	.312	3.716	.000
Age	-.223	.076	-.322	-2.918	.004
Female gender	-5.293	1.139	-.394	-4.649	.000
Income	.089	.559	.017	.159	.874
Amputation level	.173	.445	.036	.389	.698
Diabetes	.405	2.218	.031	.183	.855
PVD	-.925	2.316	-.072	-.399	.690
Smoking	.308	1.152	.024	.267	.790
HPT	-.214	1.154	-.017	-.186	.853
Outcome: AMLCI 3 months					
(Constant)	16.578	6.515		2.545	.012
Intervention group	4.846	1.055	.402	4.596	.000
Age	-.197	.075	-.300	-2.620	.010
Female gender	-3.236	1.098	-.254	-2.947	.004
Income	.219	.544	.043	.403	.688
Amputation level	.525	.429	.115	1.222	.225
Diabetes	1.603	2.133	.128	.751	.454
PVD	.600	2.140	.049	.280	.780
Smoking	.338	1.201	.028	.282	.779
Alcohol drinking	-.983	1.151	-.079	-.854	.395

Being in the intervention group was associated with better activity levels (high BI scores, higher MLCI scores including its subscales at 3 months), better balance ability/lower risk of falling (lower TUG scores at 3 months), better participation levels (lower P-scale scores at 3 months), better QOL (Index and VAS scores at 3 months). Being older was associated with poorer activity levels (lower BI and MLCI at 3 months) and poor balance (high TUG scores at 3 months). Being female was associated with better activity levels (high BI and MLCI scores at 3 months). Absence of diabetes and other conditions (e.g. Renal disease, HIV etc.) was associated with better QOL (high VAS at 3 months) and good balance (lower TUG at 6 months) respectively.

6.10 SUMMARY OF THE MAIN FINDINGS OF THE RANDOMISED CONTROLLED TRIAL

At three months postoperatively, the intervention group reported less participation restriction (higher participation levels) less activity limitation (higher activity levels), better quality of life, and better balance (less risk of falling) compared to the control group. Perceived body image disturbance was similar and low for both groups. Both groups were generally similar for most outcomes (overall scores of outcome measures) at six months except for risk of falling, where the intervention group still did better.

6.11 SURVIVAL ANALYSIS DURING THE STUDY

6.11.1 Survival Time of the Sample

Table 6.19 illustrates mean and median survival by age for the whole group (n=154).

Table 6.19: Mean and Median Survival by Age for the Whole Group

Mean				Median			
Estimate (age)	Std. Error	95% Confidence Interval		Estimate (age)	Std. Error	95% Confidence Interval	
		Lower Bound	Upper Bound			Lower Bound	Upper Bound
58.2	.816	56.610	59.809	58	1.158	55.730	60.270

Table 6.19 shows that the average survival age was 58 years through out the study period.

Figure 6.2 illustrates survival by age for the whole sample.

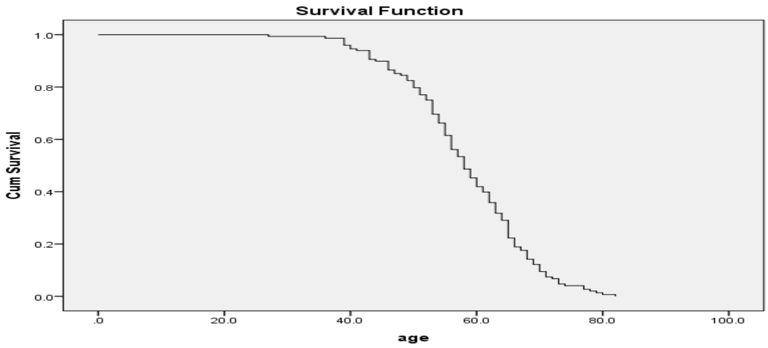


Figure 6.2: Survival Curve (Kaplan-Meier curve) by Age for the Whole Sample

Figure 6.2 shows that the average survival age was 58 years and survival decreases with increasing age.

Figure 6.3 illustrates survival hazard by age for the whole sample.

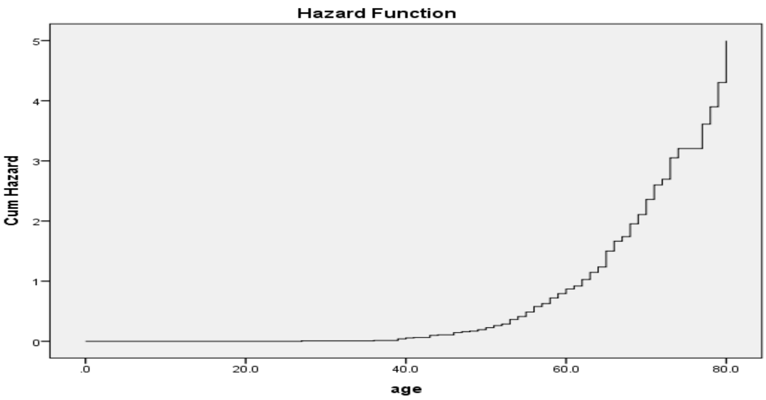


Figure 6.3: Cox Proportional Hazard by Age for the Whole Sample

Figure 6.3 shows that the survival hazard gradually increased with the age of the sample.

6.11.2 **Differences between People who Died and Those who Survived**

6.11.2.1 **Baseline comparison of people who died by three months and those who survived by three months**

Table 6.20 illustrates the baseline age, BI, P-Scale, EQ-5D VAS and Index of survivors and those who died.

Table 6.20: Age, BI, P-Scale, EQ-5D VAS and Index of Survivors and Those Who Died by Three Months

		Baseline		
		Survivors n=120	Deceased by 3 months n=28	Mann-Whitney U p-value
Age	25th percentile Median 75th percentile	52.3 62.5 65	51.8 62.5 65	0.326
Barthel index	25th percentile Median 75th percentile	20 20 20	20 20 20	0.654
P-Scale	25th percentile Median 75th percentile	0 0 0	0 0 9.5	0.093
EQ-5D index	25th percentile Median 75th percentile	0.193 0.264 0.796	0.028 0.193 0.565	0.086
EQ-5D VAS	25th percentile Median 75th percentile	66 77.5 80	50 70 80	0.174

$p \leq 0.05$ is significant

Table 6.20 shows that there were no significant differences in the median age, BI, P-Scale, EQ-5D index and VAS by three months between the survivors and those who had died.

Table 6.21 illustrates the baseline clinical characteristics of survivors and those who died by three months.

Table 6.21: Clinical Characteristics of Survivors and Those Who Died by Three Months

Clinical Profile (Baseline) n=120 Survivors, n=28 Died				
		n(%)	**n(%)**	**P-value**
Level of amputation	BKA	85(70.8)	16(57.1)	0.121
	AKA	35(29.2)	12(42.9)	
Smoking	Yes	61(50.8)	21(75)	0.016
	No	59(49.2)	7(25)	
Drinking	Yes	45(37.5)	17(60.7)	0.022
	No	75(62.5)	11(39.3)	
HPT	Yes	72(60)	18(64.3)	NS
	No	48(40)	10(35.7)	
Heart disease	Yes	8(6.7)	3(10.7)	NS
	No	112(93.3)	25(89.3)	
Diabetes	Yes	76(63.3)	17(60.7)	NS
	No	44(36.7)	11(39.3)	
PVD	Yes	51(42.5)	13(46.4)	NS
	No	69(57.5)	15(53.6)	
Arthritis	Yes	6(5)	2(7.1)	NS
	No	114(95)	26(92.9)	
Other (HIV, asthma, renal disease etc)	Yes	12(10)	2(7.1)	NS
	No	108(90)	26(92.9)	

Fisher's exact $p \leq 0.05$ is significant, NS-Not significant

Table 6.21 shows that there were significantly more smokers and drinkers among the group that died compared to the survivors.

Table 6.22 illustrates the baseline participation by items of the P-scale at three months for survivors and those who died.

Table 6.22: Participation by Items of the P-Scale for Survivors and those who Died by Three Months

P-Scale n=120 survivors, n=28 died				p-value
Item	Item Level	Baseline		
		n(%)	n(%)	
Do you have equal opportunity as your peers to find work?	0	105(87.5)	23(82.1)	NS
	1	1(0.8)		
	2		1(3.6)	
	5	14(11.7)	4(14.3)	
Do you work as hard as your peers do? (same hours, type of work etc)	0	107(89.2)	24(85.7)	NS
	1	1(0.8)		
	3		1(3.6)	
	5	12(10)	3(10.7)	
Do you contribute to the household economically in a similar way to your peers?	0	98(81.7)	24(85.7)	NS
	2	1(0.8)		
	3	4(3.3)		
	5	17(14.2)	4(14.3)	
Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	116(96.7)	23(82.1)	0.0010*
	1	2(1.7)		
	2	1(0.8)		
	3	1(0.8)	1(3.6)	
	5		4(14.3)	
Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	118(98.3)	24(85.7)	0.0020*
	1	1(0.8)		
	3	1(0.8)		
	5		4(14.3)	
Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	119(99.2)	24(85.7)	0.0020*
	2		1(3.6)	
	3	1(0.8)		
	5		3(10.7)	
Are you as socially active as your peers are? (e.g. in religious/community affairs)	0	119(99.2)	25(89.3)	0.011
	2		1(3.6)	
	3	1(0.8)		
	5		2(7.1)	
Do you have the same respect in the community as your peers?	0	119(99.2)	28(100)	NS
	3	1(0.8)		
Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	120(100)	26(92.9)	0.035
	5		2(7.1)	
Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?	0	118(98.3)	27(96.4)	NS
	2	1(0.8)		
	5	1(0.8)	1(3.6)	

P-Scale n=120 survivors, n=28 died					p-value
Item	Item Level	Baseline			
		n(%)	n(%)		
Do you visit other people in the community as often as other people do?	0	118(98.3)	25(89.3)	0.047
	5	2(1.7)	3(10.7)	
Do you move around inside and outside the house and around the village/neighbourhood just as other people do?	0	119(99.2)	25(89.3)	0.006
	3	1(0.8)		
	5		3(10.7)	
In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	118(98.3)	25(89.3)	0.022
	3	1(0.8)		
	5	1(0.8)	3(10.7)	
In your home, do you do household work?	0	116(96.7)	25(89.3)	NS
	3	3(2.5)		
	5	1(0.8)	3(10.7)	
In family discussions, does your opinion count?	0	116(96.7)	28(100)	NS
	3	2(1.7)		
	5	2(1.7)		
Do you help other people (e.g. neighbours, friends or relatives)?	0	118(98.3)	26(92.9)	NS
	2		1(3.6)	
	3	1(0.8)		
	5	1(0.8)	1(3.6)	
Are you comfortable meeting new people?	0	118(98.3)	27(96.4)	NS
	3	1(0.8)		
	5	1(0.8)	1(3.6)	
Do you feel confident to try to learn new things?	0	118(98.3)	27(96.4)	NS
	3	1(0.8)		
	5	1(0.8)	1(3.6)	

*p≤0.0028 is significant (Fisher's exact test-Bonferroni corrected).

Table 6.22 shows significant differences in item 4,5,6 with survivors showing lower participation restriction (less difficulties) than those who died.

Table 6.23 illustrates the baseline activity levels by items of the BI for survivors and those who died by three months.

Table 6.23: Activity levels by items of the BI for survivors and those who died by three months

		Baseline		
Item	Item level	n=120 survivors n(%)	n=28 died n(%)	p-value
Bowels	1	2(1.7)	28(100)	NS
	2	118(98.3)		
Bladdler	1	2(1.7)	28(100)	NS
	2	118(98.3)		
Grooming	1	120(100)	28(100)	Constant
Toilet use	1	1(0.8)	1(3.6)	NS
	2	119(99.2)	27(96.4)	
Feeding	2	120(100)	28(100)	Constant
Transfer	2	1(0.8)	28(100)	NS
	3	119(99.2)		
Mobility	2	5(4.2)	1(3.6)	NS
	3	115(95.8)	27(96.4)	
Dressing	1	120(100)	1(3.6)	NS
	2		27(96.4)	
Stairs	0	4(3.3)	1(3.6)	NS
	1	3(2.5)	2(7.1)	
	2	113(94.2)	25(89.3)	
Bathing	0	120(100)	1(3.6)	NS
	1		27(96.4)	

Fisher's exact p≤0.05 is significant. Constant indicates no variation, NS-Not significant

Table 6.23 shows that there were no significant differences in BI item scores between the survivors and those who died.

Table 6.24 illustrates quality of life by items of the EQ-5D for survivors and those who died by three months.

Table 6.24: Quality of Life by Items of the EQ-5D for Survivors and Those who Died at Three Months

Item	Item level	Baseline n=120 survivors n(%)	Baseline n=28 died n(%)	p-value
Mobility	1	115(95.8)	28(100)	NS
	2	5(4.2)		
Self-care	1	118(98.3)	26(92.9)	NS
	2	2(1.7)	2(7.1)	
Usual Activities	1	119(99.2)	27(96.4)	NS
	2	1(0.8)	1(3.6)	
Pain/ Discomfort	1	19(15.8)	2(7.1)	NS
	2	33(27.5)	6(21.4)	
	3	68(56.7)	20(71.4)	
Anxiety/Depression	1	55(45.8)	12(42.9)	NS
	2	31(25.8)	5(17.9)	
	3	34(28.3)	11(39.3)	

Fisher's exact p≤0.05 is significant, NS-Not significant

Table 6.24 shows that there were no significant differences in EQ-5D item scores between the survivors and those who died.

6.11.2.2 **Predictors of death by three months postoperatively**

Table 6.25 illustrates death prediction using a univariate logistic regression.

Table 6.25: Prediction of Death by Three Months

Univariate Logistic Regression (Three Months Death Prediction)						
	B	**S.E.**	**Wald**	**df**	**p-value**	**Exp(B)**
Smoking(yes)	1.065	.473	5.070	1	.024	2.902
Constant	-2.132	.400	28.433	1	.000	.119
Alcohol drinking(yes)	.946	.430	4.831	1	.028	2.576
Constant	-1.920	.323	35.349	1	.000	.147
Total P-Scale	.046	.020	5.107	1	.024	1.047
Constant	-1.669	.238	49.027	1	.000	.188

Constant indicates a reference variable in the regression model.

Table 6.25 shows that a participant who was a smoker was 2.9 times more likely to die compared to a non-smoker (p=0.024). A participant who drank alcohol was 2.6 times more likely to die compared to a non-drinker (p=0.028).Table 6.23 further shows that a participant had a 4.7% chance of dying for every unit increase in total P-scale score (p=0.024).

Table 6.26 illustrates death prediction using a bivariate logistic regression.

Table 6.26: Prediction of Death by Three Months (Bivariate Logistic Regression)

Bivariate Logistic Regression (3 months death prediction)						
	B	**S.E.**	**Wald**	**df**	**p-value**	**Exp(B)**
Total P-Scale	.045	.021	4.802	1	.028	1.046
BI total	-.052	.287	.033	1	.855	.949
Constant	-.629	5.700	.012	1	.912	.533
Total P-Scale	.045	.020	5.003	1	.025	1.046
EQ5D index	-1.004	.682	2.165	1	.141	.367
Constant	-1.305	.325	16.065	1	.000	.271
Total P-Scale	.040	.022	3.410	1	.065	1.041
EQ5D VAS	-.007	.010	.545	1	.460	.993
Constant	-1.129	.759	2.210	1	.137	.323
Total P-Scale	.049	.021	5.460	1	.019	1.050
Age	.025	.022	1.224	1	.269	1.025
Constant	-3.145	1.373	5.245	1	.022	.043

Constant indicates a reference variable in the regression model.

Table 6.26 shows that a participant has a 4.6% chance of dying for every unit increase in total P-scale score adjusted for BI total score or EQ-5D index (p=0.028 and 0.025 respectively). A participant has a 5% increase in chance of dying for every unit in total P-scale score adjusted for age (p=0.019).

6.11.2.3 **Survival time by groups by three months**

Table 6.27 illustrates survival times for the groups by three months.

Table 6.27: Means and Medians for Survival Times by Three Months

Group	**Mean**				**Median**			
	Estimate (age)	**Std. Error**	**95% Confidence Interval**		**Estimate (age)**	**Std. Error**	**95% Confidence Interval**	
			Lower Bound	**Upper Bound**			**Lower Bound**	**Upper Bound**
Control	57.8	1.143	55.557	60.037	58	1.720	54.629	61.371
Intervention	58.6	1.171	56.326	60.918	58	1.290	55.472	60.528
Overall	58.2	.816	56.610	59.809	58	1.158	55.730	60.270

Table 6.27 shows a fairly similar average age of survival for both groups by three months.

Figure 6.4 illustrates survival comparing the groups by three months.

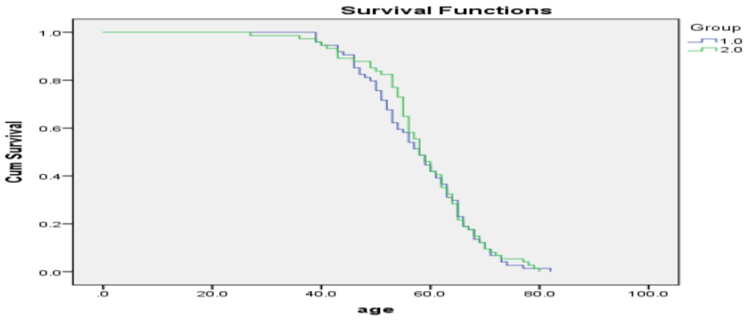


Figure 6.4: Kaplan-Meier Survival Curves Comparing the Groups by Three Months

The overall comparison test for equality of survival distributions for the different levels of group, Log Rank (Mantel-Cox) showed a chi-square of 0.125, 1 (df), p=0.723 indicating that survival was not significantly different between the groups as examined by age.

Figure 6.5 illustrates hazard function comparing the groups by three months.

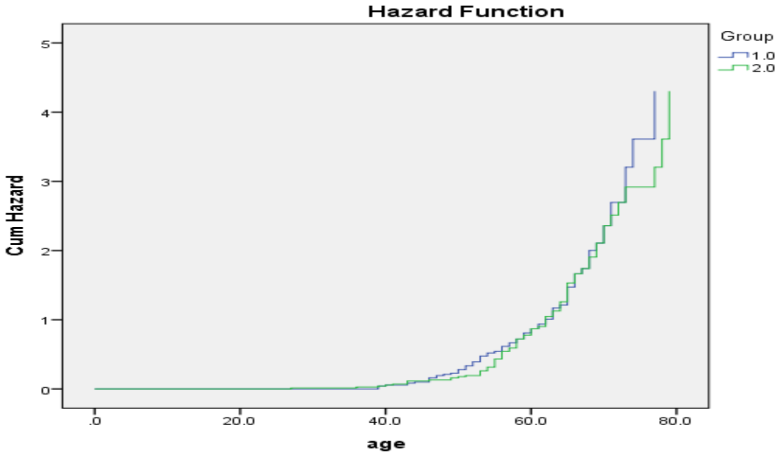


Figure 6.5: Cox Proportional Hazard Comparing the Groups by Three Months

Figure 6.5 shows that both groups had a similar hazard (risk of dying) by three months.

6.11.3 Baseline Comparison of People who Died by Six Months and Those who Survived

6.11.3.1 Baseline comparison of people who died by six months and those who urvived at six months

Table 6.28 illustrates the Age, BI, P-Scale, EQ-5D VAS and Utility index of survivors and those who died by six months.

Table 6.28: Age, BI, P-Scale, EQ-5D VAS and Index of Survivors and Those who Died

		Baseline		
		Survivors n=115	Deceased by 6 months n=33	Mann-Whitney U p-value
Age	25th percentile Median 75th percentile	52 58 65	62 62 65	0.575
Barthel index	25th percentile Median 75th percentile	20 20 20	20 20 20	0.907
P-Scale	25th percentile Median 75th percentile	0 0 0	0 0 9	0.061
EQ-5D Index	25th percentile Median 75th percentile	0.193 0.264 0.796	0.028 0.264 0.761	0.22
EQ-5D VAS	25th percentile Median 75th percentile	60 75 90	50 70 80	0.142

$p \leq 0.05$

Table 6.28 shows that there were no significant differences in the median age, BI, P-Scale, EQ-5D index and VAS by six months between the survivors and those who had died.

Table 6.29 illustrates the clinical characteristics of survivors and those who died by six months.

Table 6.29: Clinical Characteristics of Survivors and Those Who Died by Six Months

Baseline				
		n=115 survivors n(%)	**n=33 died n(%)**	**p-value**
Level of amputation	BKA	83(72.2)	18(54.5)	0.046
	AKA	32(27.8)	15(45.5)	
Smoking	Yes	58(50.4)	24(72.7)	0.018
	No	57(49.6)	9(27.3)	
Drinking	Yes	43(37.4)	19(57.6)	0.031
	No	72(62.6)	14(42.4)	
HPT	Yes	69(60)	21(63.6)	NS
	No	46(40)	12(36.4)	
Heart disease	Yes	7(6.1)	4(12.1)	NS
	No	108(93.9)	29(87.9)	
Diabetes	Yes	73(63.5)	20(60.6)	NS
	No	42(36.5)	13(39.4)	
PVD	Yes	49(42.6)	15(45.5)	NS
	No	66(57.4)	18(54.4)	
Arthritis	Yes	6(5.2)	2(6.1)	NS
	No	109(94.8)	31(93.9)	
Other (HIV, asthma, renal disease etc)	Yes	11(9.6)	3(9.1)	NS
	No	104(90.4)	30(90.9)	

$p \leq 0.05$ is significant, NS-Not significant (Fisher's exact test).

Table 6.29 illustrates that there were significant differences in level of amputation, smoking habits and drinking habits between the survivors and those who died by six months. The survivors had a higher proportion of BKA and the deceased had a higher proportion of AKA. The deceased had more smokers and drinkers.

Table 6.30 illustrates Participation by items of the P-scale for survivors and those who died by six months.

Table 6.30: Participation by Items of the P-Scale for Survivors and Those who Died by Six Months

P-Scale				
		Baseline		
Item	Item Level	n=115 survivors n(%)	n=33 dead n(%)	p-value
Do you have equal opportunity as your peers to find work?	0	100(87)	28(84.8)	NS
	1	1(0.9)		
	2		1(3)	
	5	14(12.2)	4(12.1)	
Do you work as hard as your peers do? (same hours, type of work etc)	0	102(88.7)	29(87.9)	NS
	1	1(0.9)		
	3		1(3)	
	5	12(10.4)	3(9.1)	
Do you contribute to the household economically in a similar way to your peers?	0	94(81.7)	28(84.8)	NS
	2	1(0.9)		
	3	3(2.6)	1(3)	
	5	17(14.8)	4(12.1)	
Do you make visits outside your village/neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	111(96.5)	28(84.8)	0.003
	1	2(1.7)		
	2	1(0.9)		
	3	1(0.9)	1(3)	
	5		4(12.1)	
Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	113(98.3)	29(87.9)	0.0020*
	1	1(0.9)		
	3	1(0.9)		
	5		4(12.1)	
Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	114(99.1)	29(87.9)	0.004
	2	1(0.9)	1(3)	
	3			
	5		3(9.1)	
Are you as socially active as your peers are? (e.g. in religious/community affairs)	0	114(99.1)	30(90.9)	0.018
	2		1(3)	
	3	1(0.9)		
	5		2(6.1)	
Do you have the same respect in the community as your peers?	0	115(100)	32(97)	NS
	3		1(3)	

P-Scale				
		Baseline		
Item	**Item Level**	**n=115 survivors n(%)**	**n=33 dead n(%)**	**p-value**
Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	115(100)	31(93.9)	0.049
	5		2(6.1)	
Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?	0	113(98.3)	32(97)	NS
	2	1(0.9)		
	5	1(0.9)	1(3)	
Do you visit other people in the community as often as other people do?	0	113(98.3)	30(90.9)	0.074
	5	2(1.7)	3(9.1)	
Do you move around inside and outside the house and around the village/ neighbourhood just as other people do?	0	114(99.1)	30(90.9)	0.010
	3	1(0.9)		
	5		3(9.1)	
In your village/neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	113(98.3)	30(90.9)	0.035
	3	1(0.9)		
	5	1(0.9)	3(9.1)	
In your home, do you do household work?	0	111(96.5)	31(93.9)	NS
	3	3(2.6)		
	5	1(0.9)	2(6.1)	
In family discussions, does your opinion count?	0	111(96.5)	115(100)	NS
	3	2(1.7)		
	5	2(1.7)		
Do you help other people (e.g. neighbours, friends or relatives)?	0	114(99.1)	30(90.9)	0.018
	2		1(3)	
	3	1(0.9)		
	5		2(6.1)	
Are you comfortable meeting new people?	0	114(99.1)	31(93.9)	0.049
	3	1(0.9)		
	5		2(6.1)	
Do you feel confident to try to learn new things?	0	114(99.1)	31(93.9)	0.049
	3	1(0.9)		
	5		2(6.1)	

*p≤0.0028 is significant (Fisher's exact test-Bonferroni corrected).

Table 6.30 shows that there were significant differences in proportions of item scores 5 (item 5 taking part in major festivals e.g. weddings indicating that the survivors had less participation restrictions compared to those who died.

Table 6.31 illustrates activity levels by item of the BI for survivors and those who died by six months.

Table 6.31: Activity Levels by Item of the BI for Survivors and those who Died by Six Months

		Baseline		
Item	**Item level**	**n=115 survivors n(%)**	**n=33 died n(%)**	**p-value**
Bowels	1	2(1.7)		NS
	2	113(98.3)	33(100)	
Bladdler	1	2(1.7)		NS
	2	113(98.3)	33(100)	
Grooming	1	115(100)	33(100)	Constant
Toilet use	1	1(0.9)	1(3)	NS
	2	114(99.1)	32(97)	
Feeding	2	115(100)	33(100)	Constant
Transfer	2	1(0.9)		NS
	3	114(99.1)	33(100)	
Mobility	2	5(4.3)	1(3)	NS
	3	110(95.7)	32(97)	
Dressing	1	115(100)	1(3)	NS
	2		32(97)	
Stairs	0	4(3.5)	1(3)	NS
	1	3(2.6)	2(6.1)	
	2	108(93.9)	30(90.9)	
Bathing	0	115(100)	1(3)	NS
	1		32(97)	

p≤0.05 is significant. Constant indicates no variation. NS - no significant

Table 6.31 shows that there was no significant difference in BI item scores between the survivors and those who died.

Table 6.32 illustrates QOL by item of the EQ-5D for survivors and those who died by six months.

Table 6.32: Quality of Life by Item of the EQ-5D for Survivors and those who Died by Six Months

		Baseline		
Item	**Item level**	**n=115 survivors n(%)**	**n=33 died n(%)**	**p-value**
Mobility	1	110(95.7)	33(100)	NS
	2	5(4.3)		
Self-care	1	113(98.3)	31(93.9)	NS
	2	2(1.7)	2(6.1)	
Usual Activities	1	114(99.1)	32(97)	NS
	2	1(0.9)	1(3)	
Pain/ Discomfort	1	19(16.5)	2(6.1)	NS
	2	30(26.1)	9(27.3)	
	3	66(57.4)	22(66.7)	
Anxiety/Depression	1	51(44.3)	16(48.5)	NS
	2	31(27)	5(15.2)	
	3	33(28.7)	12(36.4)	

p≤0.05 is significant, NS no significant.

Table 6.32 shows that there were no significant differences in EQ-5D item scores between the survivors and those who died.

6.11.3.2 **Predictors of Death by Six Months Postoperatively**

Table 6.33 illustrates death prediction using a univariate logistic regression.

Table 6.33: Prediction of Death by Six Months using a Univariate Logistic Regression

Univariate logistic regression (six months death prediction)						
	B	**S.E.**	**Wald**	**Df**	**p-value**	**Exp(B)**
Smoking(yes)	.963	.433	4.949	1	.026	2.621
Constant	-1.846	.359	26.482	1	.000	.158
Alcohol drinking(yes)	.821	.402	4.180	1	.041	2.272
Constant	-1.638	.292	31.433	1	.000	.194
Amputation level	-.771	.407	3.589	1	.058	.463
Constant	-.758	.313	5.863	1	.015	.469
Total P-Scale	.044	.020	4.820	1	.028	1.045
Constant	-1.446	.223	42.087	1	.000	.236
VAS	-.014	.009	2.728	1	.099	.986
Constant	-.258	.617	.175	1	.676	.773

Constant indicates a reference variable in the regression model.

Table 6.33 shows that a participant who was a smoker was 2.6 times more likely to die compared to a non-smoker (p=0.026). A participant who was an alcohol drinker is 2.3 times more likely to die compare to a non-drinker (p=0.041). Table 6.32 further shows that a participant has a 4.5% chance of dying for every unit increase in total P-scale score (p=0.028). Amputation level and VAS scores were not found to be significant predictors of death in the univariate regression analysis.

Table 6.34 illustrates death prediction using a bivariate logistic regression at six months.

Table 6.34: Prediction of Death by Six Months using a Bivariate Logistic Regression

Bivariate Logistic Regression (Six Months Death Prediction)						
	B	**S.E.**	**Wald**	**Df**	**p-value**	**Exp(B)**
Amputation level(BKA)	-.800	.412	3.762	1	.052	.449
VAS	-.015	.009	2.906	1	.088	.985
Constant	.298	.687	.188	1	.665	1.347
Total P-Scale	.045	.020	4.810	1	.028	1.046
BI total	.032	.288	.012	1	.912	1.033
Constant	-2.081	5.724	.132	1	.716	.125
Total P-Scale	.044	.020	4.701	1	.030	1.045
EQ5Dindex	-.599	.612	.958	1	.328	.550
Constant	-1.217	.313	15.097	1	.000	.296
Total P-Scale	.046	.021	4.912	1	.027	1.047
Age	.009	.021	.193	1	.660	1.009
Constant	-1.980	1.240	2.548	1	.110	.138
Total P-Scale	.045	.020	5.009	1	.025	1.046
Smoke	-1.000	.445	5.060	1	.024	.368
Constant	-1.071	.262	16.692	1	.000	.343
Total P-Scale	.050	.021	5.532	1	.019	1.051
Alcohol drinking	-.946	.418	5.120	1	.024	.388
Constant	-.973	.288	11.410	1	.001	.378
Total P-Scale	.038	.022	3.136	1	.077	1.039
VAS	-.009	.010	.805	1	.369	.991
Constant	-.828	.714	1.345	1	.246	.437

Constant indicates a reference variable in the regression model.

Table 6.34 shows that a participant had a 4.5 to 5.1% chance of dying for every unit increase in total P-scale score adjusted for BI total score (p=0.028), EQ5D index (p=0.030), age (p=0.027), smoking (p=0.025) or drinking (0.019). A participant had a 36.8% and 38.8% reduction in the chance of dying if they do not smoke or drink adjusted for total P-scale (p=0.024) for both smoking and drinking.

In conclusion, participants who died were mainly smokers, drinkers and survival (or death) was evenly distribute between the groups (see Appendix va), showing that both groups lost participants in a uniform manner. Increasing participation restriction, smoking, and drinking were preoperative predictors of death.

Table 6.35 illustrates survival times for the groups by six months.

Table 6.35: Means and Medians for Survival Times by Six Months

Group	Mean				Median			
	Estimate (Age)	Std. Error	95% CI		Estimate (Age)	Std. Error	95% CI	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
Control	57.779	1.100	55.623	59.936	58.000	1.595	54.873	61.127
Intervention	58.584	1.131	56.368	60.801	58.000	1.196	55.655	60.345
Overall	58.182	.787	56.639	59.724	58.000	1.034	55.973	60.027

The overall comparison test for equality of survival distributions for the different levels of group, Log Rank (Mantel-Cox) showed a Chi-square of 0.132, 1 (df), p=0.716 indicating that survival was not significantly different between the groups as examined by age.

Figure 6.6 illustrates survival of the groups by age by six months

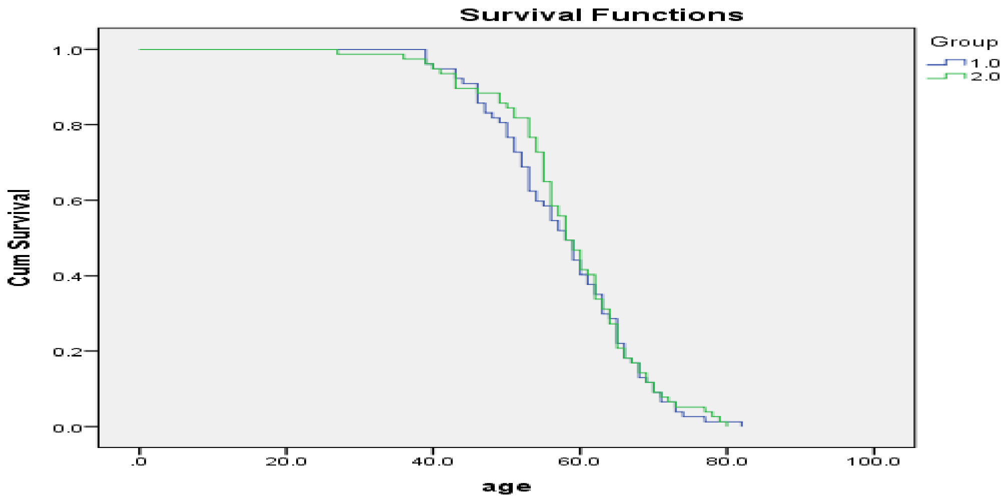


Figure 6.6: Survival Curve (Kaplan-Meier) of the Groups by Age

Figure 6.6 shows the trends of the two groups with group 1 (blue line) initially showing better survival around age 40, Group 2 (green line- intervetion group) showing slight resilience before age 60 but this evens out just after age 60. There was no difference in survival of the two groups.

Figure 6.7 illustrates survival hazard of the groups by age.

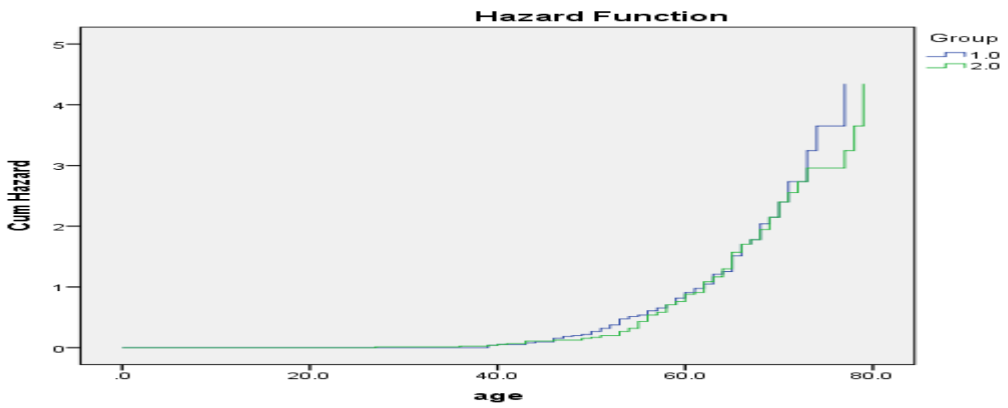


Figure 6.7: Cox Proportional Hazard of the Groups by Age

Figure 6.7 shows that the survival hazard was relatively similar and increasing with age of the two groups.

Table 6.36 illustrates prediction of death by level of alcohol consumption.

Table 6.36: Prediction of Death by Level of Alcohol Consumption.

Exposure to alcohol	B	S.E.	Wald	df	p-value	Exp(B)
Alcohol			4.028	4	.402	
Alcohol 1	19.491	20,096.755	.000	1	.999	291,685,751.906
Alcohol 2	20.104	20,096.755	.000	1	.999	538,496,772.749
Alcohol 3	20.392	20,096.755	.000	1	.999	717,995,696.998
Alcohol 4	42.406	44,937.227	.000	1	.999	2,609,783,967,996,807,200.000
Constant	-21.203	20,096.755	.000	1	.999	.000

Exposure to alcohol: 1= A few times a month, 2= Once a week, 3=3-4 times a week, 4= every day.

The findings using logistic regression analysis show no significant (p>0.05) relationship to predict death as a result of exposure to alcohol during this study.
Table 6.37 illustrates prediction of death by level of amount of smoking.

Table 6.37: Prediction of Death by Level of Smoking

Exposure to smoking	B	S.E.	Wald	df	p-value	Exp(B)
Smoking			4.838	5	.436	
Smoking 1	-1.723	1.455	1.401	1	.236	.179
Smoking 2	-1.558	1.517	1.054	1	.305	.211
Smoking 3	-1.022	1.467	.485	1	.486	.360
Smoking 4	-.916	1.494	.376	1	.540	.400
Smoking 5	-.511	1.592	.103	1	.748	.600
Constant	.000	1.414	.000	1	1.000	1.000

Exposure to alcohol: 1= 1-5 cigarettes per day, 2= 6-10 cigarettes per day, 3=11-20 cigarettes per day, 4= 21-30 cigarettes per day, 5= Over 30 cigarettes per day

The findings using logistic regression analysis shows no significant (p>0.05) relationship to predict death as a result of exposure to smoking during this study.

6.12 EXERCISE DIARIES

Unfortunately, only eight (8) diaries were returned by the participations. Thus the return rate was regarded as inadequate for analysis.

6.13 CONCLUSION

The results of the RCT show that the 12 weeks intervention improved participation, activity, QOL and balance following LLA. The results further show that survival is poor following LLA in this population, and that smoking, drinking and poor preoperative participation levels result in death following LLA.

CHAPTER 7

7. DISCUSSION OF THE RANDOMISED CONTROLLED TRIAL

7.1 INTRODUCTION

This chapter presents a discussion of the main findings from Chapter 6. The results are discussed in accordance with the main aim of the study. The aim was to determine the impact of a self-administered exercise programme (home programme) administered postoperatively on function and other selected outcomes three months and six months after a LLA. This RCT evaluated the benefits of using this programme to improve participation levels (reduce participation restriction), activity levels (reduce activity limitation), quality of life levels, perceived body image disturbance and balance (reduce risk of falling) in persons in the intermediate stage of rehabilitation following a LLA. The intervention resulted in significantly greater participation levels (reduced participation restriction), activity levels (reduced activity limitation), quality of life levels and balance in the intervention compared to the control group. Perceived body image disturbances were similarly low in both groups. Lower limb amputation patients, who are discharged from tertiary hospitals without the opportunity to receive intermediate term in-patient rehabilitation, will benefit from this programme if returning home and to their community. Not only was balance improved (reduced risk of falling) after the intervention but it was maintained up to six months thereafter.

Survival is poor following a LLA in the Johannesburg metropolitan tertiary hospitals and persons, who die before six months are mainly those who smoke tobacco, consume alcohol and have participation restrictions preoperatively.

The results from the P-Scale have been discussed under participation restriction, those from the BI and MLCI and its subscales have been collapsed and discussed under activity limitation, the MABIS results have been discussed under body image disturbance, and EQ-5D results have been discussed under quality of life, and finally the results of the TUG have been discussed under balance/ risk of falling. The death results have been discussed under survival.

7.2 PARTICIPATION RESTRICTION

Both groups experienced a significant increase in participation restriction (decreased participation levels) from baseline to six months postoperatively (Appendix ia Table 1a shows within group change in participation from baseline to six months) and an increase in participation restriction (decreased participation levels) from baseline to three months postoperatively. The control group showed a further improvement in participation from three to six months postoperatively while the intervention group remained relatively the same (maintained their participation levels) during this period (Appendix ia Table 1a) plateauing compared to the controls. Czerniecki et al. (2012) and Norvell et al. (2011, found that function declines from the preoperative to postoperative state and then improves again. Fortington et al. (2013b) reported that aspects of life such as physical function, social function and pain improve with time in people with LLA. These findings support the improvement seen in the control group from three to six months and that the intervention group did better at three months despite this spontaneous ('natural') improvement that is expected following a LLA.

Although the groups were generally comparable and highly functional at baseline, and both experienced an increase in participation restriction (decreased participation levels), the intervention group showed better participation levels compared to control group at three months postoperatively. This may be attributed to the intervention received by the intervention group making them more able to cope and participate in life situations. At six months follow up, the participation levels were relatively similar between the groups with both groups showing mild participation restriction. The intervention is beneficial from discharge and patients regained their functional independence three months earlier than the controls. The use of the intervention can be likened to being given a 'head start'. The intervention group may have found it difficult to do better than the control from three to six months because they started from a significantly lower participation level (Table 6.3; p=0.038) at baseline than that of the controls. However, this shows that it is important to intervene early in order to have a positive outcome (Moxey et al., 2012) and possibly get patients to achieve their functional independence early so as to potentially minimise negative outcome such as the burden of dependency on family and care givers during these early days of rehabilitation. This will allow further management to continue from a higher baseline and thus potentially make it easier to return to close to preoperative participation levels. Bragaru et al. (2013a) found that older age, smoking and vascular causes have a negative influence on participation (e.g. in sports). Both groups had an average age of just below 60 and all had LLA of vascular cause, they were of similar demographic and clinical profiles except for the level of amputation which was excluded as a confounder of participation restriction (Appendix iia Table 1- showing that the amputation level did not influence the functional outcome). This means that the intervention was effective irrespective of level of amputation. The plateauing of the intervention group after three months may either mean that they need a different programme if they are to gain a higher participation level but there is the possibility that the intervention group reached its optimal participation levels, considering that people with LLA from a low socioeconomic setting such as in this study often have the worst outcomes as found by Venermo et al. (2013).

Preoperative factors independently associated with maintenance of independent living status are; age (younger), lower levels of amputation, independent ambulatory status, absence of coronary artery disease (CAD), and absence of dementia (Taylor et al., 2005). Taylor et al. (2005) reported that preoperative factors independently associated with failure to maintain independent living status in decreasing order are; age≥70, age 60-69, level of amputation, homebound ambulatory status, and presence of dementia (Taylor et al., 2005). Here the groups were comparable by all the above-mentioned factors except level of amputation (which was excluded as a confounder in participation outcomes) and demented participants did not participate in this study because it was anticipated that they may be at a disadvantage as regards following the explanations in the study.

Sinha et al. (2013, reported that being a male and an older person with LLA result in being more socially adjusted, being younger results in less restriction in function and social life while being employed results in less restriction in function, less restriction in athletic performance and social life. More comorbidities result in more functional restriction. In this study, the groups were comparable for these factors (gender and age) and thus, were not expected to differ based on them. Senra et al. (2011) found that people with LLA report perceiving themselves as impaired, as a result, they use assistive devices and adapt their lives to the new life (living with an amputation) while the majority often does not accept their new situation and this may explain the better participation levels obtained by the intervention group receiving the programme and being more participatory than the controls. This means that the intervention group used the programme in order to overcome restrictions in function and adapt their lives to the new life as a person living with an amputation in a similar way as found by Senra et al. (2011). They found that persons with LLA learn to adapt their lives to the new life of living with a leg amputation. In this study, the intervention promoted the above mentioned (socially adjusted, less restricted in function and social life, less restricted in recreational activities, adapt their lives to the new life) constructs of participation as measured by the P-scale again reiterating its solid benefits for persons with a LLA during the intermediate stage of rehabilitation. These constructs of participation as identified by Senra et al. (2011) are similar to our findings in Table 6.4; items 4 pertains to economic contribution to the household; item 11 visiting other people. Both were significantly better in the intervention group (see Appendix O- showing the Participation scale). These findings support the use of the intervention and that the intervention should be accepted as standard care in situations like in this study.

Ephraim et al. (2006) reported that people with LLA are more likely to perceive persistent barriers (to participation) in policies, physical/structural (environment), attitudes/support as well as services/assistance. People with LLA perceive persistent barriers as greater than that of the general disabled population except in the areas of work/school and services/assistance (Ephraim et al., 2006). Again these constructs of participation from Ephraim et al. (2006) support our findings when one looks at item 11 (visiting around the community). The results show that the intervention group were better than the control group in these aspects of participation (Table 6.4). Ephraim et al. (2006) further reported that females with LLA were less likely to perceive persistent barriers (to participation) in physical/ structural (environment). In this study, the gender findings were similar across groups and thus did not play a role in this outcome (Appendix iib - showing that gender did not affect the functional outcome). Ephraim et al. (2006) argued that a possible explanation for their findings was that women have lower expectations than men regarding regaining physical activity thus may report less barriers/ inhibition in environmental aspects as they do not perceive that they need many facilities.

The participants in this study are largely from a poor socioeconomic background especially given the catchment area of the hospitals as seen by Godlwana et al. (2012). Poverty in people with LLA is a predictor of increased perceived barriers in the environment with poor people with LLA being two to three and a half times more likely to perceive these barriers in policies including accessing services (Ephraim et al. 2006). In this study, the programme helped the intervention group to overcome these barriers in its environment although both groups were from the same poor socioeconomic background. Although accessing services is a challenge in this population, the programme gave them the abilities needed for self-management using an affordable method, without having the burden of transport costs to a rehabilitation facility as expressed in the findings by Godlwana and Stewart (2013) on a sample from this same study setting.

The groups had similar pain compared to the intervention group implying that the intervention was not able reduce pain. The exercise (See Appendix AD section A, Figure 5 A and B - showing the education given to the participants and the stretching exercises) on stump handling and stretching the hip flexors was ineffective in reducing pain during this stage of rehabilitation and although it promoted more participation, unlike in the findings by Ephraim et al. (2006) who found that people with LLA with stump pain were about twice as likely to perceive barriers in physical/structural aspects of the environment than those who reported no pain. The same was true of people with LLA with back pain, but in this study, pain did not restrict participation or result in in perceived barriers compared to the control group.

Livingstone et al. (2011) found that people with LLA have diminished capacity to actively participate in their routine functions (e.g. farming) due to role restrictions. Restricted social contact was also reported. Social participation is poor due to impaired mobility, inability or reluctance to drive, embarrassment in social situation due to poor balance (Livingstone et al., 2011) and this is similar to Coffey et al. (2014) who found that people with LLA have high levels of disability during the first six months after discharge from the hospital. In this study, items 4,11, the control group was significantly inferior to the intervention group on the P-scale. These are items referring to social participation e.g. visiting. Schoppen et al. (2003) reported that people with LLA encounter considerable restrictions in daily functioning and in this study, these items scored higher in the intervention than in the control group. These may have been why the intervention group performed better than the control group as the intervention had a protective effect making this a useful programme to use or adopt for LLA patients. Although participation declined from baseline to three months post amputation in both groups, the exercise programme seems to have enabled the intervention group to decline less compared to the controls, as regards the extent of decline, although this did not carry over to six months meaning that more reminders to do the programme may be needed to benefit the groups after the 12 week intervention. In this study, the intervention group reported better participation at three months as well as better QOL compared to the controls. These findings concur with those by Asano et al. (2008) who found that participation is an important factor in predicting perceived QOL after LLA.

7.3 ACTIVITY LIMITATION

A within group comparison (Appendix ia Table 2a- shows within group change in activity levels from baseline to six months) shows that both groups experienced increased activity limitation (declining activity levels) from baseline to three months postoperatively. The control group further shows a decrease in activity limitation (increasing activity levels/recovery) from three to six months postoperatively while no change was detected in the intervention group during this period. Patients have reduced mobility during the first six months post amputation and physical function remains below that of population norms (Fortington et al., 2013b; Czerniecki et al., 2012; Glemne et al., 2012), similarly in this study premorbid state was better than postoperative status. People with LLA report difficulties like loss of basic skills, loss of functional independence and ADL function as well as impaired mobility and diminished activity levels (Senra et al., 2011; Livingstone et al., 2011). Following these limitations, people with LLA tend to realise these limitations and use adaptation styles to reduce their physical limitations (Livingstone et al., 2011). This means that people with LLA have a mammoth task to relearn basic aspects of function (ADL) in order to regain functional independence postoperatively, and this intervention facilitated and enabled the intervention group to reduce activity limitation and regain functional independence especially exercises Figure 1,2,3,4 and 8 of Appendix AD (showing treatment to improve standing balance, the ability to sit to stand, plantarflexor and hip extensor muscle strengthening exercises) as these specific exercises focus on functional aspects like transfers, balance and mobility.

When comparing the groups, the groups were similar at baseline (BI scores). However, the intervention group demonstrated less activity limitation (BI and MLCI standard basic and advanced subscale scores) at three months postoperatively compared to the control group. This shows that the intervention was successful in reducing activity limitation although it did not carry over to six months and this can be attributed to the exercises mentioned immediately above. At six months follow up, the levels of activity were similar between the groups thus showing that more reminders about the intervention may be needed to carry the effect of the intervention through to six months and possibly after six months as well. The outcome at three months may be attributed to the intervention program as it was administered from discharge to three months. These findings are similar to Wegener et al. (2009) showing again that a self-management programme improves activity levels (reduces functional limitation).

Both groups struggled with stairs (BI item 9 and MLCI items on stairs) at three months although they were comparable at baseline. This implies that the intervention was not effective in improving stair climbing and this is possibly because there was a need for this self-administered programme to be safe and thus it did not included exercises or tasks that involved stair negotiation. Hobara et al. (2012) report that age is inversely correlated with the ability to climb stairs; meaning that the older the person with LLA the poorer their stair climbing ability. Inability to walk up or down inclines or rough terrains arise due to poor balance following LLA and their findings are similar to those in this study. The intervention group did better than the controls because the programme contained tasks that included strengthening antigravity muscles as seen in the exercises mentioned above. The intervention successfully ensured that the experimental group recovered much better than the controls following a LLA by improving functional independence and reducing activity limitation. The baseline difference in level of amputation between the groups was excluded as a confounder in activity limitation outcomes as measured by the BI, MLCI, basic MLCI and advanced at three months (Appendix iia Table 2; Appendix ia Table 2d and Figure 3, Table 2e and Figure 4, Table 2g and Figure 5, Table 2h and Figure 6 and Table 2j and Figure 7).

The findings show that both groups were having difficulty with activities assessed in item 9-13 (items pertaining to stairs) and coping with item 1, 4 and 5 (see Appendix AK) of the MLCI. The intervention group did better than the control group on item 6, 7 (see Appendix AK) demonstrating a significant difference in activity levels at three months postoperatively showing again that the intervention was worthwhile and should be adopted as part of rehabilitation for people with LLA and this activity was promoted by exercise (Figure 2,6,8,9 of Appendix AD).

Factors influencing maintenance of preoperative ambulation are being of a younger age, a lower level of amputation, male gender, absence of CAD, absence of dementia, being ambulatory preoperatively (Taylor et al., 2005). Failure of ambulation is associated with age equal to or over 70, age 60-69, bilateral amputation, End Stage Renal Disease (ESRD) and being homebound (Taylor et al., 2005). In this study, age, gender, comorbidities (examples being heart conditions, PVD, HPT, renal disease etc.), preoperative ambulation were not different between the two groups and as a result did not influence activity limitation (Appendix iib).

Traballesi et al. (2007) found that age and stump problems correlate negatively with mobility (as measured by the BI). Mobility (as measured by the LCI) levels are higher in patients with an ideal stump and lower in those with a combination of stump pain and flexion deformities (Traballesi et al., 2007). The groups in this study were comparable by age, impairments such as stump problems and contractures were not measured, however one would expect more stump problems in a group with more BKAs as they are susceptible to revisions (Wong, 2005) and more contractures as there are two joints (hip and knee) (Engstrom and Van de Ven, 1999). Fleury et al. (2013) reported that age of a person with LLA influences gait re-education (activity limitation). The presence of comorbidities, poor premorbid function, higher levels of amputation, poor state of the contralateral leg and poor motivation have a negative influence on gait re-education (Fleury et al., 2013). The above citations support the findings of this study in that the exercises (Figure 5, 6, 7 and 9 of Appendix AD) focused on the impairments around the stump and thus helped the intervention group to do better than the controls. Gait re-education is not always possible in all patients with LLA due to vascular problems, some may only achieve independence in transfers and wheelchair dexterity (Fleury et al. 2013). The results of their study are similar to these findings in that 12 participants were not able to walk but the intervention group was better than the control group despite both groups having high premorbid function unlike the study by Fleury et al. (2013) who reported that high preoperative function resulted in better post operative function, which was not the case with control group relative to the intervention group in this study. From this, it can be deduced that the intervention was successful and achieved the desired effect on mobility earlier than the control group.

7.4 BODY IMAGE DISTURBANCE

Body image perception (overall) revealed no difference between the groups, showing low body image disturbances at both assessment periods. The control group reported significantly less body image disturbance than Group 2 (item 9-11, 13-14) at six months postoperatively. These findings agree with those by Couture et al. (2012) reiterating that body image varies across patients and indeed it is a broad concept, including a range of socio-psychologic components regarding both how persons with amputations look and how they think they look (Flannery and Faria 1999). From their study, one may appreciate why this study had no conclusive position on the subject of body image between the groups as it is such a dynamic and complex matter. While the groups were not different overall, there were some differences based on specific items of the MABIS. The person's perception of how they look will influence their subjective well-being. Body image disturbance is evident when the patient cannot accept their current body image and clings onto the old body image which is not the same as the current reality (Flannery and Faria, 1999). The results of this study may suggest that our participants (overall) had accepted the new image in both groups and this outcome cannot be attributed to the intervention. This implies that a different intervention focusing on body image is needed if one is to improve body image but our results suggest that both groups did not need an intervention to improve body image.

Unwin et al. (2009) found that amputation and demographic factors were not related to psychological adjustment outcomes following LLA. Hope at the beginning of rehabilitation is related to positive mood, while hope and social support are related to general adjustment (Unwin et al., 2009). This may potentially suggest that our sample had hope in rehabilitation or were positive about their rehabilitation outcomes and thus had minimal body image disturbance or they were content with their body image and required no management for body image.

Anxiety and depression are directly correlated to body image disturbance (Coffey et al., 2009). Senra et al. (2011) found that people with LLA report changes in identity as well as affective and asexual life. In this study, both groups reported low body image disturbances. However this study differs from Coffey et al. (2009), anxiety/ depression was worse in the control compared to the intervention group even though body image disturbance was similar and social experience differences in the two samples are the possible reason for this variation, especially that the groups may have had different individual social experiences or interactions in the community during the study period. Godlwana and Stewart (2013) found that some members of the community may at times say unkind things to a person with LLA and this may potentially result in body image disturbances. Both groups reported no difference at three months on item 14 (physical attractiveness) of the MABIS but at six months, the intervention group was inferior in this outcome. This may be because this group was doing well in general functional independence outcomes and aiming higher, setting new rehabilitation goals and having more ambitions for their recovery. Patients with a high QOL report less body anxiety (Dajpratham et al., 2011) and this further explains why these groups have minimal body image disturbance, regardless of the group even though Group 2's QOL was much better than the control group.

7.5 QUALITY OF LIFE

The control group showed a decline in QOL (VAS) from baseline to three months postoperatively and an improvement (recovery) in QOL (VAS) from three to six months postoperatively while the intervention group exhibited no change (within group comparison Appendix ia Table 4a) thus maintaining their preoperative status. Both groups experienced a significant decline in QOL from baseline to six months post-operatively, both groups experienced an improvement in QOL (EQ-5D Index) from baseline to three months postoperatively. The control group further showed an improvement in QOL (EQ-5D Index) from three to six months postoperatively while no change was detected in the intervention group during this period (Appendix ia Table 4b) indicating that the intervention group reached a plateau because they were highly functional earlier and seemed not to reach new heights in QOL after three months.

The intervention group demonstrated superior QOL (EQ-5D VAS and EQ-5D index) (between group comparison - Table 6.15) scores at three months postoperatively compared to the control group. At six months follow up, the QOL scores were similar (high) between the groups. This implies that the intervention was successful in improving the quality of life as well as the mobility, pain and anxiety/depression. In this regard, the intervention showed that it could be used as part of current care for LLA patients in South Africa in similar situations. Norvell et al. (2011) reported a decline over time in mobility from the premorbid state to a year after LLA. Being 65 year or older, having an alcohol disorder, being hypertensive, having been treated for are all associated with lower success in regaining mobility postoperatively. Participants in this study were comparable by age, alcohol consumption, hypertension and anxiety or depression at baseline but at three months, the intervention group was better than the controls on depressive/anxiety symptoms thus emerging better on the abovementioned domains of QOL suggesting that the intervention helped them, although these improvements did not carry over to six months. These findings are similar to Wegener et al. (2009) showing again that a self-management programme improves depressive symptoms. More reminders about the programme may potentially have helped the intervention group to be better than the control at six months.

Depression and participation in ADL are modifiable characteristics influencing QOL (Asano et al., 2008). Higher QOL was reported by those with lower depression scores (Asano et al., 2008). The findings are different to those of this study. The intervention seems not to have helped the intervention group to overcome the depression although they practiced enough to help them improve their QOL. A patient may report reduced QOL post operatively, then improve with time as they adapt to the amputation (Asano et al., 2008). This was the case in this study as both groups reported reductions in QOL (EQ-5D index) from baseline to three months, then improved from three to six months although the intervention group was better than the controls at three months. The intervention resulted in better recovery of the intervention group at three months. The more mobile the patient the better their QOL is (Asano et al., 2008). Again the intervention group in this study reported not difference in being more mobile and had better VAS on the EQ-5D than the control group. This reiterates that the intervention was successful in assisting the experimental group to recover better than the control group and start enjoying better QOL earlier that the control group even though the index score were not significantly different. Norvell et al. (2011) reported that patients with amputations who achieve mobility success are more likely to be satisfied with life (QOL) than those who do not.

This was the case in this study even though the intervention group were not better mobility in (Index) but subsequent overall QOL at three months.

People with LLA who have phantom pain report a poorer QOL than those with no phantom pain (Van der Schans et al., 2002). Walking and stump pain are important determinants of QOL following LLA. The findings by Van der Schans et al. (2002) are different to those of this study in that the intervention group experienced similar pain at three months compared to the control group and but still did better than the control group on VAS and Index scores of the EQ-5D. Wegener et al. (2009) also reported that a self-management group rated the intervention as very helpful ($p<0.01$) in managing pain and improving their confidence ($p<0.05$) to improve their QOL. This tells us that it was worth implementing the intervention and it could be used as part of standard care for people with LLA in order to improve their lives even in situations where it did not significantly reduce pain.

Gender, age, aetiology, level of amputation and stump pain showed no significant differences between the groups with low or higher HRQOL in the study by Dajpratham et al. (2011). In this study, the groups were similar by gender, age and aetiology but not by level of amputation, which again highlights the lack of consensus about the impact of level of amputation on outcomes of people with LLA as already touched on earlier in this chapter, as we know from this study that level of amputation did not impact on the results. However, Dajpratham et al. (2011) was an observational study not a tested intervention.

Senra et al. (2011) found that people with LLA report feelings of inferiority and problems related to well-being. Those who report stump pain associate it with poor quality of life and poor adjustment to the new life. Coffey et al. (2009) revealed that anxiety and depression scores are high in patients with AKA compared to BKA. Shorter time since LLA, as well as having comorbidities results in a higher possibility of psychological disorders (Nunes et al., 2012). In this study there was an even distribution of gender and comorbidities. Time since operation was the same for both groups.

Amputation is associated with pain relief from primary pathology (e.g. tissue loss related pain), depression, sleep disorder, anxiety and irritability. Anxiety and depression are high during hospitalization for LLA and drop at discharge (Singh et al., 2009). Singh et al. (2009) report that anxiety and depression are often present at admission and then a recurrence of symptoms is seen post amputation meaning that the same patients that were having anxiety and depression account for its postoperative incidence. There is no association between gender, vascular cause and age with depression or anxiety (Singh et al., 2009) and this is similar to the findings in this study as the sample was comparable. In this study, the groups were comparable by preoperative levels of anxiety and depressive symptoms andt at three months the intervention seems not to have lessened anxiety and depression implying that the intervention did not change symptoms of anxiety and depression. The increased functional independence lowered symptoms of anxiety and depression and promoted more psychological wellness in both groups.

In this study, QOL was comparable between the two groups at six months, confirming the findings by Fortington et al. (2013b) that vitality and perceived change in health improve with time in people with LLA. Most of the improvement in these QOL domains is seen at six months post amputation (Fortington et al., 2013b). The intervention group was already recovering better at three months suggesting that it is an excellent bridge from baseline to six months making it useful in protecting patients from deterioration.

7.6 BALANCE (RISK OF FALLING)

The intervention group demonstrated a lower risk of falling (better ability to balance) at three months postoperatively compared to the control group. A close look at the programme show that exercises (Figure 1, 2, 3, 4, 8 Appendix AD) contributed to the improvement in balance as these exercises focus intensely on activities such as sit to stand and back, transfers, as well as single leg standing. Biswas et al. (2010, found that therapeutic practice and training for co-ordination of movements helps improve balance and gait in LLA, thus improving mobility. Many factors impact on postoperative mobility in LLA but balance and hip strength are the most important as these are the aspects that support walking (Raya et al., 2010). This intervention had these components (Figure 1, 2, 3, 4, 5, 6, 9 Appendix AD) and this has been helpful in the recovery of the experimental group addressing both functional and non-functional (impairment related) hip muscle strength. The intervention (Appendix AD Figure 1, 2, 3, 4, 8) has exercises that focus on training for co-ordination of movements, hip control, balance and gait thus improving mobility as seen in Biswas et al. (2010, .

Being older, having a vascular amputation, higher level of amputation, longer duration since amputation results in poor walking (Raya et al., 2010) and in this study the difference in walking between the groups is attributed to the intervention. Van

Velzen et al. (2006) found that physical capacity (muscle strength and balance) as well as walking ability (walking velocity and symmetry) deteriorates considerably, following LLA. Aerobic capacity of people with LLA is lower than that of able-bodied people. The number of people with LLA who are able to regain ambulatory status post LLA ranges from 56% to 97% (van Velzen et al., 2006). Similarily in this study, the majority regained ambulatory status and the intervention group benefited from the intervention in a similar way as reported in these studies as the groups were similar in age, aetiology and time since amputation. The intervention helped the intervention group to regain physical capacity (muscle strength and balance), walking ability (walking velocity and symmetry), as well as ambulatory status reported by Van Velzen et al. (2006).

Schoppen et al. (2003) report that people with LLA perform poorly in ADLs (e.g. mobility) and instrumented activities of daily living (IADL) (e.g. an outcome measure based ADL like the TUG test). The study by Schoppen et al. (2003) revealed that patients with LLA have TUG score mean of 23.9 seconds (SD 13.2) and median 21.3 seconds. In this study, both groups (at three months) had a median TUG above 21.3 seconds as reported by Schoppen et al. (2003) but the intervention group median was significantly better than that of the control group, meaning that the intervention, especially sit to standing, single leg standing, turning, as well as the transfers were beneficial. The participants from the intervention group obtained a similar outcome to Schoppen et al. (2003) and this strengthens the findings that the programme is worthwhile. The experimental group may well have been confident in getting up/down, turning and standing because of the practice they got from the intervention. Balance at two weeks is an important predictor of ADL during the intermediate stage of rehabilitation (Schoppen et al., 2003) as people with LLA with good balance as early as two weeks post operatively are more independent in ADL later on during the intermediate stage of rehabilitation and those with poor balance at this time perfom poorly during the intermediate stage (Schoppen et al., 2003).

Balance is poor following LLA, especially in those amputated due to vascular reasons (Miller et al. 2002), and this may be because of the overall health, physical status and age of this population as opposed to people with LLA as a result of trauma. Balance may differ across various patient characteristics (e.g. age, gender, cause of amputation, mobility device used, comorbidities, problems of the contralateral leg, perceived health, ADL limitation) except social support and family support, level of amputation, joint pain and recent fall (last 12 months) (Miller et al., 2002). People with LLA due to vascular problems have poorer balance compared to nonvascular related causes especially in situations such as; walking in crowded areas, sweeping the floor, reaching while on their toes, walking around the house, getting in and out of the car and reaching at eye level. On the other hand, as a person with LLA; being male and being able to walk without concentrating, having fewer limitations in ADL, fewer symptoms of depression, and no fear of falling are all independently related to good balance (Miller et al., 2002). In this study the intervention in the experimental group resulted in better balance, fewer limitations in ADL and fewer symptoms of depression.

Miller et al. (2002) also found that using a walking device, fear of falling, having to concentrate while walking were all independently related to poor balance. This may have been the case in this study, as the participants were still using walking devices and the anxiety levels were high at three months for the control group, the experimental group had minimal fear, were able to perform the tasks needed in physical functioning with minimal concentration and thus had good balance compared to the controls because they were familiar with the demands and coordination of being upright and moving about. This good balance carried over to six months.

7.7 SURVIVAL FOLLOWING A LOWER LIMB AMPUTATION

The Groups were generally similar at baseline except that the intervention group had a higher proportion of BKA. Equality of survival distributions indicates that survival was not significantly different between the groups, initially showing better survival around age 40 for both groups then the intervention group (Figure 6.6 green line) showing slight resilience before age 60 but this evened out just after age 60, showing no difference in survival for the groups. The average survival of LLA patients in this study is 58 regardless of gender. Survival (death rate remains high) remains poor in this study setting (Johannesburg) compared to the international literature (Karam et al., 2013, Hershkovitz et al., 2012, Papazafizopoulou et al., 2009, Wong, 2005, Eskelinen et al., 2004, Leung and Wong, 2004). Godlwana et al. (2011) is the only study that shows a higher death rate than this study and it was undertaken in the same study setting. Social habits (smoking and drinking) as well as high participation restriction are associated with poor survival in this study. These findings on social habits are similar to those by Godlwana et al. (2011). Sadly, the death rate in this study is comparable to a death rate seen at one year following a LLA in the international literature (Dillingham and Pezzin, 2008, Otiniano et al., 2003) meaning that in Johannesburg the death rate is so high that it is reached at half the time as seen in the international literature.

7.8 DIFFERENCES BETWEEN PEOPLE WHO DIED AND THOSE WHO SURVIVED

The main differences between people who died and those who survived was that the group who died comprised mostly of people who were cigarette (tobacco) smokers, those who consumed alcohol (alcohol drinkers), a higher level of amputation (AKA), and those with high participation restriction levels compared to the survivors. Cigarette (tobacco) smoking, alcohol consumption (alcohol drinking) and poor preoperative function have been identified as modifiable characteristics in order to reduce the possibility of death following a LLA (Calle-Pascual et al., 1997, Godlwana et al., 2011).

Death was evenly distributed between the groups. The participants who died experienced more difficulty with participation, such as visiting (neighbours, village, public facilities such as shops and religious places) and community affairs like weddings, recreational involvement. The findings are somewhat similar to those of Gallagher et al. (2011) who reported that mostly, environmental barriers to LLA include climate, physical environment and income. Participation restriction is most expressed in sports/physical recreation as well as leisure/ cultural activities (Gallagher et al. 2011) and these findings are similar to those of this study in the constructs of social participation in recreation/ sports as well as cultural activities such as weddings.

A participant had a 44.9% difference in the study by Godlwana et al. (2011), with older people with LLA more in the group that died. Taylor et al. (2005) reported that preoperative factors independently associated with survival are; age (the younger the better), level of amputation (the lower the better), absence of ESRD, absence of dementia, absence of peripheral arterial disease (PAD), preoperative independent ambulatory status, preoperative independent living status and absence of CAD all have as a better outcome while bilateral reduction in chance of (marginally insignificant) dying as a result of the level of amputation adjusted for VAS. These findings are similar to Wong (2005) who found that higher levels of amputation result in poor survival. Participants had a reduced chance of dying if they did not smoke (36.8% reduction) or drink (38.8% reduction) adjusted for total P-scale. These findings are similar to the findings by Godlwana et al. (2011). In this study, there were no significant differences by age, comorbidities, and ambulation status between those who survived and those who died whereas age was significantly amputation or being male has the worst outcome. Preoperative factors independently associated with death are; age 70 or older, age 60-69, high level of amputation, bilateral amputation, dementia, presence of PAD, poor preoperative ambulatory status (nonambulatory), and presence of CAD all have the worst outcome (Taylor et al. 2005).

In this study, item 5 of the EQ-5D (Anxiety/Depression) revealed no difference between those who died and those who survived. This is similar to Singh et al. (2009) that there is no association between mortality and depression or anxiety.

7.9 CLINICAL CHARACTERISTICS

The groups were similar by comorbidities but they were different by level of amputation although this did not influence the majority of the outcomes as shown in Appendix ia and iia. The intervention group had more participants with a BKA than the controls. This may be because, generally, BKA is the commonest level of amputation. This is especially so because one of the aims of the operation is to preserve as much leg length as possible. Moreover, the study did not record level of amputation at the follow up points, thus it cannot be guaranteed that some of the participants in the control group had not been revised to AKA as lower levels of amputation have higher rates of revision (Wong 2005). In the literature there is no consensus on LLA outcomes based on the anatomical level of amputation and in this study; level of amputation was excluded as a confounder in outcomes as seen in Appendix ia and iia. Basu et al. (2008) and Czerniecki et al. (2012) found no association between level of amputation and ambulation. Ambulation was reported to decline following LLA (with BKA, AKA and TMT) from premorbid to post amputation with no significant differences among the groups (Czerniecki et al., 2012) but Cox et al. (2011) reported higher QOL and functional independence among BKA's compared to AKA's. This study was different from Czerniecki et al. (2012) in that it did not include patients with a TMT amputation. This implies that there is more to it than level of amputation, so level of amputation does not matter when all other characteristics are comparable. In this study, level of amputation was excluded as a confounder in the analysis of the results and in the literature (Suckow et al., 2012, Czerniecki et al., 2012, Basu et al., 2008, Pell et al., 1993). Pell et al. (1993) showed that quality of life of a person with LLA is most highly associated with lower extremity function and mobility, not necessarily length of the stump.

Older age was associated with poor functional outcomes. This is a natural tendency and these results are similar to those of Taylor et al (2005). Being female was associated with reduced functional outcome and this is similar to findings by Miller (2002). The absence of diabetes or other conditions (e.g. renal disease, HIV) was associated with higher functional outcome, these results are similar to those of Taylor et al (2005). The level of amputation was not associated with any of the fanctiional outcomes unlike in the study by Raya et al (2010), and these results show the lack of consensus on the role of level of amputation as found in studies by Czerniecki et al., 2012) and Norvell et al (2011).

7.10 LIMITATIONS OF THE STUDY

The poor return rate of the exercise diaries was a limitation in the analysis of results as this study could not comment on the role of having to diarise the exercises activities performed. A diary return rate of about 15% (8 out for 55 patrticints was not good enough even though it was five times better that the less that 3% reported by Crosbie (2006).

The high death rate was a limitation to this study. However, as seen in Chapter 2 Table 2.1, mortality is high in this poputation and more so in Johannesburg. Further to this, mortality is an outcome of LLA.

A participant leaving the study site to relocate to their province of birth and participants lost to follow up, thus not traceable during follow up were limitations to getting more data for this study. However, participants do move around especially in our case, the participants in Johannesburg may be migrant labourours from the former homelands and they may consider is better to return to the province of birth when they have stabilised from the operation and/ or may be “boarded” from their employment. There was also the difficulty of having to follow up participants by going to their homes where at times their streets are not properly sign posted. There was also the problem of untraceable physical addresses which has been reported as a limitation in this study setting previously (Godlwana et al., 2012).

Attriction is always a problem in follow up studies and in this study we were able to get 72% of the participants at six months. This did not affect the power of the study adversely as the sample size calculation (section 4.3.3) provided for this limitation by overestimating the sample as per recommendations from previous research in this population (Godlwana 2009). Further to this, an intention to treat analysis was employed in an efford to preserve the power of the study, preserve randomisation, mininise bias and the study had good follow up levels, which also gives it power.

The study did not happen without process challenges. Tracing of participants during follow up did not always go as planned and as a result the researcher drove to the participants’ homes as some could not make appointments even thought these were generally always scheduled as the same day they were coming for check ups at the hospital. Due to transport problems, the drivers of the transport hired by the participants or a relative were often in a hurry and thus interviews were sometimes conducted with this as a worrying factor of the part of the researcher as the researcher was worried that the patient may be rushing through questions so that he/she accommodates the relationship with their transport person. Despite these challenges, steps were taken to ensure that participants were as comfortable as possible during the interviews.

The various test performed during date analysis were generally the necessary tests to answer the objectives of the study. Typer I errors were avoided by setting a more stringent level of significance using the Bonferroni correction method.

7.11 CONCLUSION

This discussion provides evidence that the intervention improved all functional outcomes in participants with LLA. The improvements were greater than those obtained from standard care. This means that the intervention was beneficial in improving, participation levels (reduced participation restriction), activity levels (reduced activity limitation), quality of life levels and balance (reduced risk of falling) in persons in the intermediate stage of rehabilitation following a lower limb amputation. The self-administered exercise programme (home programme) resulted in significantly high functional levels in all the above outcomes regardless of level of amputation. Thus, this intervention could be accepted as part of rehabilitation for people with LLA in similar settings as the ones in Johannesburg.

Survival is poor following a LLA in the Johannesburg metropolitan tertiary hospitals and persons who demise by six months are mainly those who smoke tobacco, consume alcohol and have participation restriction preoperatively.

CHAPTER 8

8. CONCLUSIONS

8.1 INTRODUCTION

The main conclusion is that the intervention proved successful in reducing participation restriction (increasing participation levels), reducing activity limitation (increasing activity levels), improving quality of life as well as reducing the risk of falling (improving balance) in this study. The intervention had no impact on body image disturbance.

8.2 Main conclusions

8.2.1 Conclusions on the Main Findings of the RCT.

Table 8.1 Summary of the findings of the randomised controlled trial.

Study Objectives	**Findings**
To compare pre and postoperative levels of participation restriction between the intervention and the control group.	The intervention group showed lower levels of participation than the control group at baseline. At three months follow up the intervention group showed higher levels of participation than the control group and at six month the groups were similar.
To compare pre and postoperative levels of activity limitation between the groups.	The groups were similar at baseline. However, at three months follow up the intervention group showed higher activity levels than the control group and at six month the groups were similar.
To compare the perceived body image between the groups.	The groups were similar showing low body image disturbance.
To compare pre and postoperative quality of life (QOL) between the groups.	The groups were similar at baseline. However, at three months follow up the intervention group showed higher QOL levels than the control group and at six month the groups were similar.
To compare balance and falls prediction (risk of falling) between the groups.	The intervention group showed lower risk of falling than the control group.
To compare survival rate between the groups including a comparison of their preoperative (baseline) characteristics.	Mortality rate is high in Johannesburg following LLA and smoking and alcohol drinking is highly associated with poor survival.
To establish the relationship between function, body image, participation and compliance with home exercises (using the Exercise diary (ED)) in these patients.	Objective not tested due to a poor return rate of the diaries

8.2.2 Hypothesis Testing

Table 8.2 Summary of hypotheses testing.

Hypotheses	Outcome
The postoperative levels of participation restriction, activity limitation, QOL, Risk of falling will be not significantly improve in the intervention compared to the control group.	Evidence rejects the null hypothesis
The intervention group will not experience/report significantly less perceived body image disturbance than the control group.	Evidence retains the null hypothesis

Answering the Research Question

What is the impact of a self-administered postoperative exercise programme (home programme) on function and other selected outcomes three months and six months after a LLA?

Answer: Evidence shows that a self-administered postoperative exercise programme (home programme) on function three months and six months after a LLA improves postoperative levels of participation restriction, activity limitation, QOL, risk of falling however is not able to improve participant body image.

8.2.3 The Impact of this Work

The results of this work show that patients who are unable to diligently attend physiotherapy following LLA can successfully implement the home exercise programme tested in this thesis and improve their functional outcomes.

8.3 RECOMMENDATIONS

8.3.1 Recommendations for Future Research

8.3.1.1 A multicenter study or a national study testing this intervention should be considered to improve the generalisability of these results.

8.3.1.2 Future research could consider longer follow up with weekly telephone reminders to study whether the effects found in this study can be maintained for longer periods.

8.3.1.3 A long term follow-up of survival and QOL study needs to be conducted to determine if LLA improves QOL and survival in the long term.

8.3.1.4 A study to examine the cost effectiveness of LLA operations in South Africa the many demands on the healthcare system would be valuable.

8.3.1.5 A study to examine the rate of return to work after LLA operations in South Africa, given that so many people, once they have an amputation, may end up without an income and become dependent on state disability pensions, should be considered.

8.3.1.6 A study to examine energy expenditure during ambulation; stump problems and health of the contralateral leg in the LLA population could be considered.

8.3.1.7 Collaborative research on the role of HIV in people with LLA in terms of long term outcomes should be conducted.

8.3.1.8 More stringent follow up to collect the diaries is needed in future studies. This will enable researchers to test the role of the ED in this programme and thus potentially explain whether it is worth having the ED in the management of these patients.

8.3.2 Recommendations for Practice

The intervention could be included as part of standard care for people with lower limb amputations especially as a discharge pack. Given the lack of rehabilitation centres for patients who use the public health care system in South Africa, the results of this study give a realistic alternative to rehabilitation approaches in under resourced situations.

REFERENCES

Abou-Zamzam, A. M., Teruya, T. H., Killen, D. & Ballard, J. L. 2003. Major lower extremity amputation in an Academic Vascular Center. *Annals of Vascular Surgery, International Journal of Vascular Surgery,* 17**,** 86-90.

Alvarsson, A., Sandgren, B., Wendel, C., Alvarsson, M. & Brismar, K. 2012. A retrospective analysis of amputation rates in diabetic patients: can lower extremity amputations be further prevented? *Cardiovascular Diabetology,* Open access.

Amosun, S. L., Mutimura, E. & Frantz, J. M. 2005 Health promotion needs of physically disabled individuals with lower limb amputation in Rwanda. *Disability and Rehabilitation,* 27**,** 837-847.

Asano, M., Rushton, P., Miller, W. C. & Deathe, A. B. 2008. Predictors of quality of life amog individuals who have a lower limb amputation. *Prosthetics and Orthotics International,* 32**,** 231-243.

Back-Pettersson, S. & Bjorkelund, C. 2005. Care of elderly lower limb amputees, as described in medical and nursing records. *Scandinavian Journal of Caring Science,* 19**,** 337-343.

Barbarin, O. & Richter, L. 2001. Economic status, community danger and psychological problems among South African children. *Childhood,,* 8**,** 115-133.

Barton, G. R., Sach, T. H., Doherty, M., Avery, A. J., Jenkinson, C. & Muir, K. R. 2008. An assessment of the dicriminative ability of the EQ-5D index, SF-6D, and EQ VAS, using sociodemoraphic factors and clinical conditions. *Europian ournal of Health Economics,* 9**,** 237-249.

Basu, N. N., Fassiadis, N. & Mcirvine, A. 2008. Mobility one yea after unilateral lower limb amputation: a modern, UK institutional report *Interactive Cardiovascular and thoracic surgery,* 7**,** 1024-1027.

Biswas, D., Roy, S. K., Lenka, P. K. & Kumar, R. 2010. Energy cost and gait effiiency of below-knee amputee and normal subject with similar physical parameter & quality of life: a comparative study. *Online Journal of Health and Allied Sciences,* 9**,** 1-4.

Bosmans, J. C., Suurmeijer, T. P. B. M., Hulsink, M., Van Der Schans, C. P., Geertzen, J. H. B. & Dijkstra, P. U. 2007. Amputation, phantom pain and subjective well-being: a qualitative study. *International Journal of rehabilitation Research,* 30**,** 1-8.

Bragaru, M., Meulenbelt, H. E. J., Dijkers, P. M., Geertzen, J. H. B. & Dekker, R. 2013a. Sports participation of Dutch lower limb amputees. *Prosthetics and Orthotics International,* 0**,** 1-5.

Bragaru, M., Van Wilgen, C. P., Geertzen, J. H. B., Ruijs, G. J. B., Dijkers, P. M. & Dekker, R. 2013b. Barriers and Facilitatoras of Participation in Sports: A qualitative Study on Dutch individuals with Lower limb amputation. *Public Library of Science,* 8**,** 1-8.

Breakey, J. W. 1997. Body image: The lower limb amputation. *Journal of prosthesis and orthosis,* 9**,** 58-66.

Broomhead, P., Dawes, P., Hancock, A., Unia, P., Blundell, A. & Davies, V. 2006 Clinical guidelines for the pre and post operative physiotherapy management of adults with lower limb amputation. *In:* PHYSIOTHERAPY, T. C. S. O. (ed.). British Association of Chartered Society of Physiotherapists in Amputee Rehabilitation.

Buckley, C. M., O'farrell, A., Canavan, R. J., Lynch, A. D., De La Harpe, D. V., Bradley, C. P. & Perry, I. J. 2012. Trends in the incidence of lower limb amputations in people with and without diabetes over a five-year period in the Republic of Ireland. *PLOS ONE,* 7**,** e41492.

Bumin, G., Bayramlar, K. & Sener, Y. Y. G. 2009. Cross cultural adaptation and reliability of the Turkish version of Amputee Body image Scale (ABIS). *Journal of Back and Musculoskeletal rehabilitation,* 22**,** 11-16.

Burger, H. & Marincek, C. 2007. Return to work after lower limb amputation. *Disability and Rehabilitation,* 29**,** 1323-1329.

Calle-Pascual, A. L., Redondo, M. J., Ballesteros, M., Martinez-Salinas, M. A., Diaz, J. A., De Matis, P., Calle, J. R., Gil, E., Jimenez, M., Serrano, F. J., Martinez-Alvarez, P. J. & Maranes, J. P. 1997. Nontraumatic lower extremity amputations in diabetic and non-diabetic subjects in Madrid, Spain. *Diabetes & Metabolism,* 23**,** 519-523

Clark, R., Gray, D. B. & Holman, R. 2002. Estimating utility values for health state in type 2 Diabetic patients using the EQ-5D (UKPDS 62). *Medical Decision Making,* 22**,** 340-349.

Coffey, L., Gallagher, P. & Desmond, D. 2013a. A prospective study of the importance of life goal characteristics and goal adjustment capacities in longer term psychological adustment to lower limb amputation. *Clinical Rehabilitation,* 0**,** 1-10.

Coffey, L., Gallagher, P. & Desmond, D. 2014. Goal pursuit and goal adjustment as predictors of disability and quality of life among individuals with a lower limb amputation: A prospective study. *Archives of Physical Medicine and Rehabilitation,* 95**,** 244-252.

Coffey, L., Gallagher, P., Desmond, D. & Ryall, N. 2013b. Goal pursuit, goal adjustment, and affective well-being following lower limb amputation *British Journal of Health Psychology*.

Coffey, L., Gallagher, P., Horgan, O., Desmond, D. & Maclachlan, M. 2009. Psychosocial adjustments to diabetes-related lower limb amputation. *Diabetic Medicine,* 26**,** 1063-1067.

Couture, M., Desrosiers, J. & Caron, C. D. 2012. Coping with lower limb amputation due to vascular disease in the hospital, rehabilitation and home setting. *International Scholar Research Network Rehabilitation*.

Cox, P. S. T., Williams, S. K. P. & Weaver, S. R. 2011. Life after Lower Extremety Amputation in Diabetes. *West Indian Medical Journal,* 60**,** 536-540.

Czerniecki, J. M., Turner, A. P., Williams, R. M., Hakimi, K. N. & Norvell, D. C. 2012. Mobility changes in individuals with dysvascular amputation from the presurgical period to 12 months postamputation. *Archives of Physical Medicine and Rehabilitation,* 93**,** 1766-1773.

Dajpratham, P., Tantiniramai, S. & Liukkanapichonchut, P. 2011. Health related quality of life among the Thai people with unilateral lower limb amputation. *Journal of Medical Association of Thailand,* 94**,** 250-255.

Dawson, J., Boller, I., Doll, H., Lavis, G., Sharp, R., Cooker, P. & Jenkinson, C. 2012. Responsiveness of the Manchester-Oxford foot questionnaire (MOXFQ) compared with AOFAS, SF-36 andEQ-5D assessment following foot and ankle surgery. *Journal of Bone and Joint surgery,* 94-B**,** 215-221.

De Godoy, J. M. P., De Godoy, M. F., Batigalia, F., Travolo, A. R. F. & Monteiro, E. H. F. 2005. Lower-extremity amputation: a 6-year follow-up study in Brazil,. *Journal of Orthopaedic Surgery,* 13**,** 164-166

Deans, S. A., Mcfadyen, A. K. & Rowe, P. J. 2008. Physical activity and quality of life : a study of a lower-limb amputee population. *Prosthetics and Orthotics International,* 32**,** 186-200.

Desmond, D. M. & Maclachlan, M. 2006. Coping strategies as predictors of psychosocial adaptation in a sample of elderly veterans with acquired lower limb amputation. *Social Science& Medicine,* 62**,** 208-216.

Dhillon, V., Hurst, N., Hannan, J. & Nuki, G. 2005. Association of low general health status, measure progressively by Euroqol EQ-5D, with osteoporosis, independent of a history of prior fracture. *Osteoporosis International,* 16 483-489.

Dillingham, T. R. & Pezzin, L. E. 2008. Rehabilitation Setting and Associated Mortality and Medical Stability Among Persons With Amputations. *Archives of Physical Medicine and Rehabilitation,* 89**,** 1038-1045.

Dillingham, T. R., Pezzin, L. E. & Mackenzie, E. J. 2002. Racial differences in the Incidence of limb loss secondary to Peripheral Vascular Disease: A Population Study. *Archives of Physical Medicine and Rehabilitation,* 83**,** 1252-7.

Dos Santos, V. P., Alves, C. a. S., Lopes, C. F. & De Araújo Filho, J. S. 2013. Gender-related differences in critical limb ischemia due to peripheral arterial occlusive disease. *Sociedade Brasileira de Angiologia e de Cirurgia Vascular*.

Engkasan, J. P., Ehsan, F. M. & Chung, T. Y. 2012. Ability t return to driving after major lower limb amputation. *Journal of Rehabilitation and Medicine,* 44**,** 19-23.

Engstrom, B. & Van De Ven, C. 1999. *Therapy for amputees, 3rd* Edinburgh, Churchill Livingston 11-43.

Ephraim, P. L., Mackenzie, E. J., Wegener, S. T., Dillingham, T. R. & Pezzin, L. E. 2006. Environmental Barriers Experienced by Amputees: The Craig Hospital Inventory of Envitonmental Factors-Short Form. *Archives of Physical Medicine and Rehabilitation,* 87**,** 328-333.

Eskelinen, E., Lepantalo, M., Hietala, E. M., Sell, H., Kauppila, L., Maenpaa, I., Pitkanen, J., Salminen-Peltola, P., Leutola, S., Eskilinen, A., Kiviola, A., Tukiainen, E., Lukinmaa, A., Brasken, P. & Railo, M. 2004. Lower extremity amputations in Finland in 2000 and trends up to 2001. *European Journal of Vascular and Endovascular Surgery,* 27**,** 193-200.

Feinglass, J., Rucker-Whitaker, C., Linquist, L., Mccarthy, W. J. & Pearce, W. H. 2005. Racial differences in primary and repeat lower extremity amputation: Results from a multihospital study. *Journal of Vascular Surgery,* 41**,** 823-829.

Ferguson, H. J. M., Nightingale, P., Pathak, R. & Jayatunga, A. P. 2010. The Influend of Socio-economic Deprivation on Rates of Major Lower Limb Amputation Secondary to Peripheral Arterial Disease. *European Journal of Vascular and Endovascular Surgery,* 40**,** 76-80.

Finch, E., Brooks, D., Stratford, P. W. & Mayo, N. E. 2002. *Physical rehabilitation outcome measures, a guide to enhance clinical decision making, 2nd*, Lippincott Williams& Wilkins, 87-89, 125-129.

Fisher, K. & Hanspal, R. 1998a. Body image and patients with amputations: does the prosthesis maintain the balance? *International Journal of Rehabilitation Research,* 21**,** 355-363.

Flannery, C. J. & Faria, H. S. 1999. Limb loss: Alterations in body image. *Journal of vascular Nursing,* 17**,** 100-106.

Fleury, A. M., Salih, S. A. & Peel, N. M. 2013. Rehabilitation of older vascular amputee: A review of literature. *Geriatrics Gerontology international,* 13**,** 264-273.

Fortington, L. V., Dijkers, P. U., Bosman, J. C., Post, W. J. & Geertzen, J. H. B. 2013b. Change in health-related qualityof life in the first 18 months after lower limb amputation: a prospective, longitudinal study. *Journal of Rehabilitation and Medicine,* 45**,** 587-594.

Fortington, L. V., Geertzen, J., Van Netten, J. J., Postema, K., Rommers, G. M. & Dijkers, P. U. 2013a. Short and Long term mortality rates after lower limb amputation. *European Journal of Vascular and Endovascular Surgery,* 46**,** 124-131.

Fortington, L. V., Rommers, G. M., Postema, K., Van Netten, J. J., Geertzen, J. H. B. & Dijkers, P. M. 2013c. Lower limb amputation in Northern Netherlands: Unchanged incidence from 1991-1992 to 2003-2004. *Prosthetics and Orthotics International,* 37**,** 305-310.

Franchignoni, F., Orlandini, D., Ferriero, G. & Moscato, T. A. 2004. Reliability, validity, and Responsiveness of the Locomoto capabilities index in aults with lower-limb amputation undergoing prosthetic training. *Archives of Physical Medicine and Rehabilitation,* 85**,** 743-748.

Gallagher, P., O'donovan, M.-A., Doyle, A. & Desmont, D. 2011. Environmental barries, activity limitations and participation restrictions experienced by peole with major limb amputation. *Prosthetics and Orthotics International,* 35**,** 278-284.

Gauthier-Gagnon, C. & Grise, M. C. 1998. The Locomotor Capabilities Index: Content validity. *Journal of Rehabilitation Outcomes Measure,* 2**,** 40-46.

Glemne, M., Ramstrand, N., Crafoord, J. & Nygren, L. 2012. Preoperative characteristics and functional outcomes of lower limb amputees treated at Southern Alvsoborg Hospital, Sweden *Prosthetics and Orthotics International,* 37**,** 298-304.

Godlwana, L. 2009. *The Impact of Lower Limb Amputation on Quality of Life: A study done in the Johannesburg Metropolitan area, South Africa*

Godlwana, L., Nadasan, T. & Puckree, T. 2008. Global trends in incidence of lower limb amputation: A review of the literature. *South African Journal of Physiotherapy,* 64**,** 8-11.

Godlwana, L. & Stewart, A. 2013 The impact of lower limb amputation on community reintegration of a population in Johannesburg: a qualitative perspective. *South African Journal of Physiotherapy,* Special edition**,** 48-54.

Godlwana, L., Stewart, A. & Musenga, E. 2012. Quality of life following a major lower limb amputation in Johannesburg, South africa. *South African Journal of Physiotherapy,* 68**,** 17-22.

Godlwana, L., Stewart, A. & Musenge, E. 2011. Differences in characteristics between people with lower limb amputation who died before 12 weeks and those who survived: Short report. *South African Journal of Physiotherapy,* 67**,** 44-47.

Haig, A. J., Jayarajan, S., Maslowki, E., Yamakawa, K. S., Tinney, M., Beier, K. P., Juang, D., Chan, L., Boggess, T., Loar, J., Owusu-Ansah, B. & Kalpakjian, C. 2009. Development of a Language-Independent Functional Evaluation. *Archives of Physical Medicine and Rehabilitation,* 90**,** 2074-2080.

Henke, P. K. 2009. Contemporary Management of Acute Limb Ischemia: Factors Associated with Amputation and In-Hospital Mortality. *Seminars in Vascular Surgery,* 22**,** 34-40.

Hennis, A. J. M., Fraser, H. S., Jonnalagadda, R., Fuller, J. & Chaturvedi, N. 2004. Explanations for the high risk of Diabetes-Related Amputation in a Caribbean population of black African descent and potential for prevention. *Diabetes Care,* 27**,** 2636-2641.

Henry, A. J. 1993. *A descriptive survey of lower-limb amputees admitted at Tygerberg hospital (1985-1987).* MSc, University of Stellenbosch

Henry, A. J., Hevelone, N. D., Belkin, M. & Nguyen, L. L. 2011. Socioeconomic and hospital-related predictors of amputation for critical limb ischemia. *Journal of Vascular Surgery,* 53**,** 330-339.

Hershkovitz, A., Dudkiewicz, I. & Brill, S. 2012. Rehabilitation outcome of post-acute lower geriatric amputees. *Disability and Rehabilitation*.

Hobara, H., Kobayashi, Y., Tominaga, S., Nakamura, T., Yamasaki, N. & Ogata, T. 2012. factors affecting stair-ascent patterns in unilateral transfemoral amputation. *Prosthetics and Orthotics International,* 0**,** 1-5.

Holzer, L. A., Sevelda, S., Fraberger, F., Bluder, O., Kickinger, W. & Holzer, G. 2014. Body image and self-esteem in lower-limb amputees. *PLOS ONE,* 9**,** e92943.

Hoshino, J., Ubara, Y., Ohara, K., Ohta, E., Suwabe, T., Higa, Y., Nakanishi, S., Sawa, N., Katori, H., Takemoto, F. & Takaichi, K. 2008. Changes in the acivities of daily living (ADL) in relation to the level of amputation of patients undergoing lower extremity amputation for arteriosclerosis obliterans (ASO) *Circulation Journal,* 72**,** 1495-1498.

Houlden, H., Edward, M., Mcneil, J. & Greenwood, R. 2006. Use the Barthel Index and the Functional Independence Measure during early inpatient rehabilitaion after single incident brain injury. *Clinical Rehabilitation,* 20**,** 153-159.

Hsieh, Y.-W., Wang, C.-H., Wu, S.-C., Chen, P.-C., Sheu, C.-F. & C-L., H. 2007. Establlishing the minimal clinical importannt differences of the Barthel Index in Stoke patients. *Neurorehabilitation and neural repair,* 21**,** 233-238.

Johannesson, A., Larsson, G., Ramstrand, N., Turkiewicz, A., Wirehn, A. & Atroshi, I. 2009. Incidence of Lower-Limb Amputation in the Diabetic and Nondiabetic General Population. *Diabetes Care,* 32**,** 275-280.

Jones, W. S., Patel, M. R., Dai, D., Vemulapalli, S., Subherwal, S., Stafford, J. & Peterson, E. D. 2013. High Mortality risks after Major lower extremity amputation in medicare patients with peripheral artery disease. *American Heart Journal,* 165**,** 809-815.

Kamel, E. H. 2000. *The thoughts and feelings of patients submitted to an amputation of a limb about the operation.* MMed research report, Medical University of Southern Africa.

Karam, J., Shepard, A. & Rubinfeld, I. 2013. Predictors of operative mortality followiong major lower extremity amputation using the National Surgery Quality Improvement Program public use data. *Journal of Vascular Surgery***,** 1-7.

Kelly, M. & Dowling, M. 2008. Patietnt rehabilitation following lower limb amputation. *Nursing standards,* 22**,** 35-40.

Khan, S. A., Qianyi, R. L., Liu, E. L., Ng, E. L., Fook-Chong, S. & Tan, G. E. 2013. Effects of anaesthetic techhnique on mortaility following major lower limb extremity amputation: a prospective score-match observational study. *The Association of Anaesthesitists of Great Britain and Ireland,* 68**,** 612-620.

Kitchel, T. & Ball, A. 2014. Quantitative Theoretiral and Conceptual Framework Use in Agricultural Education Research. *Journal of Agricultural Education,* 55**,** 186-199.

Kontodimopoulos, N., Pappa, E., Niakas, D., Yfantopoulos, J., Dimitrakaki, C. & Tountas, Y. 2008. Validity of the EuroQol (EQ-5D) instrument in a Greek general population. *Value in Health,* 11**,** 1162-1169.

Lai, F. H., Wong, E., Wong, S. K., Soo, A. K., Yip, K. T., Chan, C. K. & Tse, P. L. 2005. Development and validity of a Body Image Assessment for patients after lower limb amputatuion - the chinese amputauion body image scale- CABIS -. *Asian journal of occupational therapy,* 4**,** 1-11.

Larsson, B., Johannesson, A., Andersson, I. H. & Atroshi, I. 2009. The locomotor capabilities index: validity and reliability of the Swedish version inadults with lower limb amputation. *Health and quality of life outcome,* 7**,** 1-9.

Lazzarini, P. A., O'rourke, A. R., Russel, A. W., Clark, D. & Kuys, S. S. 2012. What are the key conditions associated with lower limb amputations in a major Australian teaching hospital? *Journal of foot and ankle research,* 5**,** Open Acess.

Leggetter, S., Chaturvedi, N., Fuller, J. H. & Edmonds, M. E. 2002. Ethnicity and Risk of Diabetes-Related Lower Extremety Amputation. *Archives of Internal Medicine,* 162**,** 73-78.

Leung, H. B. & Wong, W. C. 2004. Preoperative and rehabilitation outcome after lower-limb amputation in elderly Chinese patients in Hong Kong. *Journal of Orthopaedic Surgery,* 12**,** 102-109.

Liao, K., Weng, S., Hsing, C., Liu, C., Wang, J., Huang, K. & Chu, C. 2013. The amputation and mortality rates of diabetic patients with critical limb ischemia: A nationwide population-based follow-up study in Taiwan. *Formosan Journal of Surgery,* 46**,** 79-86.

Liles, D. R., Kallen, M. A., Petersen, L. A. & Bush, R. L. 2006. Quality of life and peripheral arterial disease. *Journal of Surgical Research,* 136 294-301.

Lin, F.-J., Samp, J., Munoz, A., Wong, P. S. & Pickard, A. S. 2013. Evaluating change using patient-reported outcome measure in Knee replacement: complementary nature of the EQ-5D index and VAS scores. *European Journal of Health Economics*.

Livingstone, W., Van De Mortel, T. F. & Taylor, B. 2011. A path of perceptual resilience: Exploring the experience of a diabetic-related amputation through grounded theory *Contemporary nurse,* 39**,** 20-30.

Louwagie, G. M., Bachmann, M. O., Meyer, K., Booysen, F. R., Fairall, L. R. & Heunis, C. 2007 Highly active antiretroviral treatment and health related quality of life in South African adults with human immunodeficiency virus infection: A cross-sectional analytical study. *BioMed Central Public Health,* 7**,** Open Acess.

Ma, Y., Mazumdar, M. & Memtsoudis, S. G. 2012. Beyond repeated measures ANOVA: advanced statistical methods for the analysis of longitudinal data in anesthesia research. *Regional Anesthesia and Pain Medicine,* 37**,** 99-105.

Magasi, S. & Post, M. W. 2010. A comparative review of contemporary participation measures' psychometric properties and content coverage. *Archives of Physical Medicine and Rehabilitation,* 91**,** 17-28.

Marshall, C. & Stansby, G. 2010. Amputation and rehabilitation. *Vascular Surgery II,* 28**,** 284-287.

Mayosi, B. M. & Benatar, S. R. 2014. Health and health care in South Africa- 20 Years after Mandela. *The New England Journal of Medicine,* 371**,** 1345-1353.

Mcintyre, D., Thiede, M. & Birch, S. 2009. Access as a policy-relevant concept in low and middle income countries *Health Economics, Policy and Law,* 4**,** 179-193.

Miller, W. C., Speechley, M. & Deathe, A. B. 2002. Balance confidence among people with lower limb amputation. *Physical Therapy,* 82**,** 856-865.

Montori, V. M. & Guyatt, G. H. 2001. Intention-to-treat principle. *Canadian Medical Association Journal,* 165**,** 1339-1341.

Moss, S. E., Klien, R. & Klien, B. E. K. 1999. The 14-year incidence of lower extremity amputations in a diabetic population. *Diabetes Care,* 22**,** 951-959.

Moxey, P. W., Hofman, D., Hinchliffe, R. J., Jones, K., Thompson, M. M. & Holt, P. J. E. 2010. Epidemiology study of lower limb amputation in England between 2003 and 2008. *British Journal of Surgery,* 97**,** 1348-1358.

Moxey, P. W., Hofman, D., Hinchliffe, R. J., Poloniecki, J., Loftus, I. M., Thompson, M. M. & Holt, P. J. 2012. Delay influences outcome after lower limb amputation. *European Journal of Vascular and Endovascular Surgery,* 44**,** 485-490.

Nather, A., Bee, C. S., Huak, C. Y., Chew, J. L. L., Lin, C. B., Neo, S. & Sim, E. Y. 2008. Epidemiology of diabetic foot problems and predictive factors for limb loss. *Journal of Diabetes and Its Complications,* 22**,** 77-82.

Nehler, M. R., Coll, J. R., Hiatt, W. R., Regensteiner, J. G., Schickel, G. T., Klenke, W. A., Strecker, P. K., Anderson, W. M., Jones, D. N., Whitehill, T. A., Moskowitz, S. & Krupski, W. C. 2003. Functional outcomes in a comtemporary series of lower limb amputations. *Journal of Vascular surgery,* 38**,** 7-14.

Norvell, D. C., Turner, A. P., Williams, R. M., Hakimi, K. M. & Czerniecki, J. M. 2011. Defining successful mobility after lower limb extremity amputation for complications of peripheral vascular disease and diabetes. *Journal of Vascular Surgery,* 54**,** 412-419.

Nunes, M. A., De Barros Jr, N., Miranda Jr, F. & Baptista-Silva, J. C. 2012. Common Mental disorders in patients undergoing lower limb amputation: A population based sample. *World journal of surgery,* 36**,** 1011-1015.

Ohtar, T., Ishioashi, H., Hosaka, M. & Sugimoto, I. 2004. Clinical and social consequences of Buerger disease. *Journal of Vascular Surgery,* 39**,** 176-180.

Otiniano, M. E., Du, X., Ottenbacher, K., Black, S. A. & Markides, K. S. 2003. Lower limb amputations in diabetic Mexican American elders incidence, prevalence and correlates. *Journal of Diabetes and its Complications,* 17**,** 59-65.

Papazafizopoulou, A., Tentolouris, N., Soldatos, R.-P., Liapis, C. D., Dounis, E., Kostakis, A. G., Bastounis, E. & Katsilambros, N. 2009. Mortality in Diabetic and nondiabetic amputations performed from 1996 to 2005 in a tertiary hospital population: a 3 year follow-up study. *Journal of Diabetes and its Complications,* 23**,** 7-11

Parker, S. L., Adogwa, O., Mendenhall, S. K., Shau, D. N., Anderson, W. N., Cheng, J. S., Devin, C. J. & Mcgirt, M. J. 2012. Determination of minimum clinically important difference (MCID) in pain, disability, and quality of life after revision fusion for symptomatic pseudoarthrosis. *The Spine Journal,* 12**,** 1122-1128.

Peacock, J. M., Keo, H. H., Duval, S., Baumgartner, I., Oldenburg, N., Jaff, M. R., Henry, T. D., Yu, X. & Hirsch, A. T. 2011. The Incidence and Health Economic Burden of Ischemic Amputation in Minnesota, 2005-2008 *Preventing Chronic Disease,* 8**,** 1-8.

Peek, M. E. 2011. Gender Differences in Diabetes-related Lower Extremity Amputations. *Clinical Orthopaedics and Related Research,* 469**,** 1951–1955.

Pell, J. P., Donnan, P. T., Fowkes, F. G. R. & Ruckey, C. V. 1993 Quality of life following lower limb amputation for peripheral arterial disease. *European Journal of Vascular Surgery,* 7**,** 448-451.

Pernot, H. F. M., Winnubst, G. M. M., Cluitmans, J. J. M. & De Witte, L. P. 2000. Amputees in Limburg: incidence, morbidity and mortality, prosthetic supply, care utilization and functional level after one year. *Prosthetics and Orthotics International,* 24**,** 90-96.

Pinto, B. E., Maso, I., Vilela, R. N. R., Santos, L. C. & Oliveira-Filho, J. 2011. Validation of the EuroQol quality of life questionnaire on Stroke victims. *Arquivos de Neuro-psiquiatria,* 69**,** 320-323.

Polgar, S. & Thomas, S. A. 2008. *Introduction to research in the health sciences, 5th ed*, Churchill Livingstone, 197-226.

Raya, M. A., Gailey, R. S., Fiebert, I. M. & Roach, K. E. 2010. Impairment variables predicting activity limitations in an individual with lower limb amptation. *Prosthetics and Orthotics International,* 34**,** 73-84.

Resnick, H. E., Carter, E. A., Lindsay, R., Henly, S. J., Ness, F. K., Welty, T. K., Lee, E. T. & Howard, B. V. 2004. Relations of all lower-extremity amputation to all-cause and cardiovascular disease mortality in American Indians. *Diabetes Care,* 27**,** 1286-1293.

Resnik, L. & Borgia, M. 2011. Reliability of Outcome Measures for People With Lower-Limb Amputations: Distinguishing True Change From Statistical Error. *Physical Therapy,* 91**,** 555-565.

Robinson, V., Sansam, K., Hirst, L. & Neumann, V. 2010. Major Lower limb amputation-what, why and how to achieve the best results. *Orthopaedics and Trauma,* 24**,** 276-285.

Rushton, P. W. & Miller, W. C. 2002. Goal attained scaling in the rehabilitation of patients with lower-extremity amputation: a pilot study. *Archives of Physical Medicine and Rehabilitation,* 83**,** 771-775.

Safaz, I., Yilmaz, B., Goktepe, A. S. & Yazicioglu, K. 2010. Turkish Version of The Amputee body Image Scale and Relationship with Quality of Life. *Bulletin of Clinical Psychopharmacology,* 20**,** 79-83.

Salavati, M., Mazaheri, M., Khosrozadeh, F., Mousavi, S. M. E., Negahban, H. & Shojaei, H. 2011. The Persian version of locomotor capabilities index: translation, reliability and validity in individuals with lower limb amputation. *Quality of Life Research,* 20**,** 1-7.

Schoppen, T., Boonstra, A., Groothoff, J. W., De Vries, J., Goeken, L. N. & Eisma, W. H. 1999. The timed "up and go" test: Reliabilty and validity in persons with unilateral lower limb amputation. *Archives of Physical Medicine and Rehabilitation,* 80**,** 825-828.

Schoppen, T., Boonstra, A., Groothoff, J. W., De Vries, J., Goeken, L. N. & Eisma, W. H. 2003. Physical, Mental, and Social Predictors of Functional Outcome in Unilateral Lower-Limb Amputees. *Archives of Physical and Rehabilitation Medicine,* 84**,** 803-11.

Senra, H., Oliveira, R. A. & Leal, I. V., C. 2011. Beyond the body image: a qualitative study on how adults experience lower limb amputation. *Clinical Rehabilitation,* 26**,** 180-191.

Singh, R., Ripley, D., Pentland, B., Todd, I., Hunter, J., Hutton, L. & Philip, A. 2009. Depression and anxiety symptoms after lower limb amputation: the rise and fall. *Clinical Rehabilitation,* 23**,** 281-286.

Sinha, R., Van Heuvel, W. J. A. & Arokiasamy, P. 2013. Adjustments to amputuion and an artificial limb in lower limb amputees. *Prosthetics and Orthotics International,* 0**,** 1-7.

Smyth, R. 2004. Exploring the usefulness of a conceptual framework as a research tool: A researcher's reflections. *Issues in Educational Research,* 14**,** 167-180.

Spichler, E. R. S., Spichler, D., Lessa, I., Costa E Forti, A., Franco, L. J. & Laporte, E. R. 2001. Capture-recapture method to estimate lower-extremity amputation rates in Rio de Janeiro, Brazil. *Pan American Journal of Public Health,* 10**,** 334-340.

Stewart, A., Noakes, T., Eales, C., Becker, P. & Veriawa, Y. 2005. Adherence to cardiovascular risk factor modification in patients with hypertension. *Cardivascular Journal of South Africa* 16**,** 102-107.

Stineman, M. G., Kwong, P. L., Kurichi, J. E., Prvu-Bettger, J. A., Vogel, W. B., Maislin, G., Bates, E. B. & Reker, D. M. 2008. The Effectiveness of Inpatient Rehabilitation in the Acute Postoperative phase of Care After Trastibial of transfemoral Amputation: Study of an intergrated health care delivery system. *Archives of Physical Medicine and Rehabilitation,* 89**,** 1863-1872.

Suckow, B. D., Goodney, P. P., Cambria, R. A., Bertges, D. J., Eldrup-Jorgensen, J., Indes, J. E., Schanzer, A., Stone, D. H., Kraiss, L. W. & Cornenwett, J. L. 2012. Predicting Functional Status Following Amputation After Lower Extremety Bypass. *Annals of Vascular Surgery,* 26**,** 67-78.

Taylor, S. M., Kalbaugh, C. A., Blackhusrt, D. W., Hamontree, S. E., Cull, D. L., Messich, H. S., Robertson, R. T., Langan, E. M., York, J. W., Carsten, C. G., Snyder, B. A., Jackson, M. R. & Youkey, J. R. 2005. Preoperative clinical factors predict postoperative functional outcomes after major lower limb amputation: An analysis of 553 consecutive patients. *Journal of Vascular Surgery,* 42**,** 227-234.

The Global Lower Extremity Amputation (Glea) Study Group 2000. Epidemiology of lower extremity amputation in centers in Europe, North America and East Asia. *British Journal of Surgery,* 87**,** 328-37.

Traballesi, M., Porcacchia, P., Averna, T., Angioni, G., Lubich, S., Di Meo, F. & Brunelli, S. 2007. Prognostic factors in prosthetic rehabilitation of bilateral dysvascular above-knee amputee: is the stumop condition an influencing factor? *Europa Medicophysica,* 43**,** 1-6.

Treweek, S. P. & Condie, M. E. 1998. Three measure of functional outcome for lower limb amputees: a retrospective study. *Prosthetics and Orthotics international,* 22**,** 178-185.

Tseng, C. 2006. Prevalence of lower-extremety amputation among patients with diabetes mellitus: Is height a factor? *Chinese Medical Association Journal,* 174**,** 1-5.
Unwin, J., Kacperek, L. & Clarke, C. 2009. A prospective study of positive adjustment to lower limb amputation. *Clinical Rehabilitation,* 23**,** 1044-1050.
Van Brakel, W. H., Anderson, A. M., Mutatkar, R. K., Bakirtzief, Z., Nicholls, P. G., Raju, M. S. & Das-Pattanayak, R. K. 2006. The Participation Scale: Measuring a key concept in public health. *Disability and Rehabilitation,* 28**,** 193-203.
Van Der Schans, P. C., Geertzen, J. H. B., Schoppen, T. & Dijksstra, P. U. 2002. Phantom Pain and Health-Related Quality of Life in Lower Limb Amputees. *Journal of pain and symptom management,* 24**,** 429-436.
Van Der Sluis, C. K., Hartman, P. P., Schoppen, T. & Dijkstra, P. U. 2009. Job adjustments, job satisfaction and health experience in upper and lower limb amputees. *Prosthetics and Orthotics International,* 33**,** 41-51.
Van Velzen, J. M., Van Bennekom, C. a. M., Polomski, W., Slootman, J. R., Van Der Wounde, L. H. V. & Houdijk, H. 2006. Physical capacity and walking ability after lower limb amputation: a systematic review. *Clinical Rehabilitation,* 20**,** 999-1106.
Venermo, M., Manderbacka, K., Ikonen, T., Keskimaki, I., Winell, K. & Sond, R. 2013. Amputations and socioeconomic position among persons with diabetes mellitus, a population-based register study. *British Medical Journal Open Access,* 3**,** 1-7.
Wegener, S. T., Mackenzie, E. J., Ephraim, P., Ehde, D. & Williams, R. 2009. Self-management improves outcomes in persons with limb loss. *Archives of Physical Medicine and Rehabilitation,* 90**,** 373-381.
Whyte, A. S. & Niven, A. C. 2001. Variation in Phantom Limb Pain: Results of a Diary Study. *Journal of pain and Symptom Management,* 22**,** 947-953.
Wiens, B. L. & Zhao, W. 2007. The role of intention to treat in analysis of noninferiority studies. *Clinical Trials* 4**,** 286–291.
Witsø, E., Lium, A. & Lydersen, S. 2010. Lower limb amputations in Trondheim, Norway. *Acta Orthopaedica,* 81**,** 737-744.
Wong, M. W. N. 2005. Lower extremity amputation in Hong Kong. *Hong Kong Medical Journal,* 11**,** 147-152.
World Health Organisation 2001. *International classification of functioning, disability and health: ICF,* Geneva, WHO Publishing, 2-25
Wouters, E., Heunis, C., Van Rensburg, D. & Meulemans, H. 2009. Physical and emotional health outcomes after 12 month of public-sector antiretroviral treatment in the Free State Province of South Africa: a longitudinal study using structural equation modeling. *BioMed Central Public Health,* 9**,** 103.
Yang, Y. J., Tsai, L. S., Wu, Y. H., Hseih, Y. W., Hseih, C. L. & Howe, T. H. 2008 The competence of fieldwork students in administering the Barthel Index. *Hong Kong Journal of Occupational Therapy,* 18**,** 28-33.
Zidarov, D., Swaine, B. & Gauthier-Gagnon, C. 2009b. Life Habits and Prosthetic Profle of Persons With Lower-Limb Amputation During Rehabilitation and at 3-Month Follow-up. *Archives of Physical Medicine and Rehabilitation,* 90**,** 1953-1959.
Zidarov, D., Swaine, B. & Gauththier-Gognon, C. 2009a. Quality of life of persons with lower limb amputation during rehabilitation and at 3-months follow up. *Archives of Physical Medicine and Rehabilitation,* 90**,** 634-645.

APPENDIX A1

PARTICIPANT'S CONTACT DETAILS LEAFLET

Participant's code:……………………………………………………………………………………

Instruction: To be kept separate from the participant's questionnaires

The information in this box will only be used for follow up purposes.

Physical address of the participant: --

Telephone numbers of the participant: ---

APPENDIX A2

THEATRE REGISTER DATA ABSTRACTION SHEET

Patient	Age	Sex	Level of amputation

APPENDIX B

PARTICIPANT'S CODE:……………………………………………………………………………

INSTRUCTIONS: The interviewer must fill in or mark (X) as appropriate

SECTION 1: DEMOGRAPHIC DETAILS

1.1 **Age.________ Date of birth .______________**

1.2 **Race:**

African	**Coloured**	**Indian**	**White**	**Other.**

1.3 **Gender:**

male	female

1.4 **How far is the nearest clinic/hospital from your home? _____________**

1.5 **How do you travel?**

Own car	Relative's car	Public transport	Hire private transport	Other, please specify

1.6 **Where do you get your money for travel?** _________________________

1.7 **Occupation.______________________**

Income:

Private pension	Old age pension	Disability grant	Still employed	Other, please specify

1.8 **Smoking history: did you smoke?**

Before the operation	yes	no

After the operation	yes	no

If yes, how often per day?

1-5	6-10	11-20	21-30	Over 30

1.9 **Do you drink alcoholic drinks**?

Before the operation	yes	no

After the operation	yes	no

1.10 **If yes, how often do you drink?**

A few times a month	Once a week	3-4 times a week	everyday

SECTION 2: MEDICAL INFORMATION

2.1 **What is the reason for your amputation?** ________________________________

2.2 **What amputation will you have?** Left – state date of OP

Toe	TMT	Mid T	Symes	BKA	TKnee	GS	AKA	Hip	HQ
1	2	3	4	5	6	7	8	9	10

Right – state date of OP

Toe	TMT	Mid T	Symes	BKA	TKnee	GS	AKA	Hip	HQ
1	2	3	4	5	6	7	8	9	10

2.3. **Do you have any of these conditions?**

Hypertension 1	Arthritis 2	Chronic heart disease 3	Diabetes 4	Peripheral vascular disease 5	Others, please specify 6

2.4 **If yes, are you on treatment as prescribed by the doctor?**

Yes	No

APPENDIX C
(SOTHO)

PARTICIPANT'S CODE:………………………………………………………………………………

INSTRUCTIONS: The interviewer must fill in or mark (X) as appropriate

SECTION 1: DEMOGRAPHIC DETAILS

1.1 **Dijara (Mengwaga).___________ Letsatsi la matswalo .______________Lebitso la sepetlele.**______________

1.2 **Mohlobo:**

Motho o ntsho	O Coloured	Mo India	Motho o mosweo	O mongwe

1.3 **Bongwe:**

monna	mosadi

1.4 **Sepetlele kapa kliniki ya kgaufi e kgole ha kaakang le lehae la hao?** __________

1.5 **O tsamaya/sepela ka eng?**

Koloi ya ka	Koloi ya wa leloko	Dinamelwa tsa setshaba	Ke hira sepalangwa/koloi	Sengwe, hlalosa:

1.6 **O thola/fumana kae tshelete ya ho tsamaya/sepela?**_______________________

1.7 **Mosebetsi.**_______________________

Mogolo:

Phenshene ye ke ikeleditseng yona	Phenshene ya botsofadi	Mphiwafela wa bohole	Ke sa sebetsa/bereka	Sengwe, hlalosa:

1.8 **Ka ho khoha: O ne o kgoha motsoko?**

Pele o etsa karo/opereshene	Eya	Aowa	Moraho ha ho etsa karo/opereshene	Eya	Aowa

Ha ebe o ne o kgoha, o ne o kgoha ha kae ka letsatsi?

1-5	6-10	11-20	21-30	Over 30

1.9 **O nwa dinotagi/bojwala naa?**

Pele o etsa karo/opereshene	Eya	Aowa	Moraho ha ho etsa karo/opereshene	Eya	Aowa

1.10 **Ha ebe o ya nwa, o nwa ha kae?**

Ga mmalwanyana ka kgwedi	Ha nngwe ka beke	3-4 ka beke	matsatsi ohle

SECTION 2: MEDICAL INFORMATION

2.1 **Lebaka le etsang hore o kgaolwe seripa sa mmele ke lefeng?**_______________

2.2 **Seripa sa hao sa mmele se ilo kgaola/segwa ho fihla kae?** Left – state date of OP

Toe	TMT	Mid T	Symes	BKA	TKnee	GS	AKA	Hip	HQ
1	2	3	4	5	6	7	8	9	10

Right – state date of OP

Toe	TMT	Mid T	Symes	BKA	TKnee	GS	AKA	Hip	HQ
1	2	3	4	5	6	7	8	9	10

2.3 **Naa o na le malwetsi a latelang?**

Madi a maholo	Bolowetsi bja marapo	Bolwetsi bja sebaka se setelele bja pelo	Bolwetsi bja tswekere	Bolwetsi bja methapo ya madi	Mangwe, hlalosa,

2.4. **Ha o na le bo bong bja malwetsi a ka hodimo, a naa o fumana kalafi ho tswa ho Ngaka?**

Eya	Aowa

APPENDIX D

(ZULU)

PARTICIPANT'S CODE:……………………………………………………………………………

IMIYALO: Umhloli kafanele agcwalise ngo (X) ngokufanele

INGXENYE 1: IMININGWANO NGAWE

1.1 **Iminyaka yakho_______ Usuku lokuzalwa.________ Igama Lesibhedlela______**

1.2 **Ubuhlanga:**

owomdabu	**Ungum Coloured**	**uyiIndia**	**ungumlungu**	**Omunye umhlobo**

1.3 **Ubulili:**

isilisa	isifazane

1.4 **Ikude kangakanani ikliniki noma isbhedlela esiseduzane nasekhaya? ________**

1.5 **Ufika kanjani ezindaweni?**

Ngemoto yakho	Ngemoto yesihlobo	Izimoto zawonkewonke	Uqasha imoto eqondene nawe	Okunye, ngicela ucacise

1.6 **Uyitholaphi imali yokugibela? ________________________**

1.7 **Umsebenzi.________________________**

Umholo:

Impesheni eqondene nawe	Impesheni yokuguga	Impesheni yokulimala/ukugula	Usasebenza	Okunye, ngicela ucacise

1.8 **Ububhema ugwayi**?

Ngaphambi kokusikwa	yebo	cha	Emveni kokusikwa	yebo	cha

Uma kunjalo, ubhema kangaki ngosuku?

1-5	6-10	11-20	21-30	Over 30

1.9 **Uyaphuza uphuzo oludakayo?**

Ngaphambi kokusikwa	yebo	cha	Emveni kokusikwa	yebo	cha

1.10 **Uma kunjalo, uphuza kangaki?**

Izikhathi ezimbalwa ngenyanga	Kanye ngeviki	Kathathu noma kane ngeviki	Nsukuzonke

INGXENYE 2:

2.1 **Yini imbangela yokunqunywa?** ____

2.2 **Uzonqunywa kuphi?** Left – state date of OP

Toe	TMT	Mid T	Symes	BKA	TKnee	GS	AKA	Hip	HQ
1	2	3	4	5	6	7	8	9	10

Right – state date of OP

Toe	TMT	Mid T	Symes	BKA	TKnee	GS	AKA	Hip	HQ
1	2	3	4	5	6	7	8	9	10

2.3 **Unazo yini ezinye zalezigulo?**

i high blood	Isifo samathambo	Isifo senhliziyo	ushukela	Isifo semithambo yegazi	okunye

2.4 **Uma kunjalo, ziyelashwa yini ngudokotela?**

Yebo	Cha

APPENDIX E
EQ-5D (ENGLISH)

HEALTH QUESTIONNAIRE

(English version for South Africa)

By placing a tick in one box in each group below, please indicate which statements best describe your own state of health TODAY.

Mobility
I have no problems in walking about ❑
I have some problems in walking about ❑
I am confined to bed ❑

Self-Care
I have no problems with self-care ❑
I have some problems washing or dressing myself ❑
I am unable to wash or dress myself ❑

Usual Activities (*e.g. work, study, housework, family or leisure activities)*
I have no problems with performing my usual activities ❑
I have some problems with performing my usual activities ❑
I am unable to perform my usual activities ❑

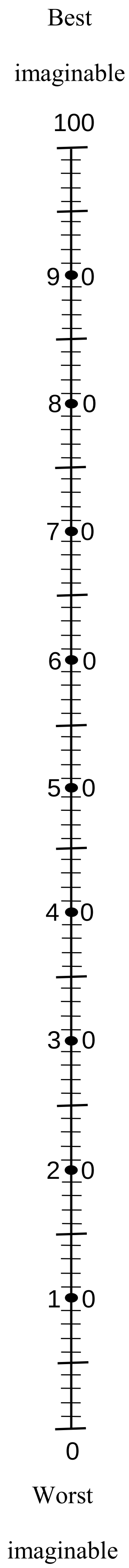
Pain/Discomfort
I have no pain or discomfort ❑
I have moderate pain or discomfort ❑
I have extreme pain or discomfort ❑

Anxiety/Depression
I am not anxious or depressed ❑
I am moderately anxious or depressed ❑
I am extremely anxious or depressed ❑

To help people say how good or bad their state of health is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale, in your opinion, how good or bad your own health is today. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your state of health is today.

Your own state of health



APPENDIX F

EQ-5D (SOTHO)

LENANE LA DIPOTSO LA TSA BOPHELO BO BOTLE
(Phetolelo ya Sesotho)
(Sesotho version for South Africa)
(Best available)

Ka ho tshwaya ka hara lebokoso le le leng sehlopheng se seng le se seng mona tlase, bontsha hle hore na ke dipolelo dife tse hlalosang ka botlalo boemo ba bophelo ba hao kajeno.

Ho tsamaya
Ha ke na bothata ba ho tsamaya ☐
Ke na le bothata bo itseng ba ho tsamaya ☐
Ke hlola betheng ☐

Ho itlhokomela
Ha ke na bothata ba ho itlhokomela ☐
Ke na le bothata bo itseng ka ho itlhatswa kapa ho itentsha/ikapesa ☐
Ha ke kgone ho itlhatswa kapa ho itentsha/ikapesa ☐

Mesebetsi ya setlwaheli *(mohlala: mosebetsi, boithuto, mosebetsi wa ka tlung, mesebetsi ya lelapa, kapa ya ho iketla)*

Ha ke na bothata ba ho etsa mesebetsi ya ka ya setlwaheli ☐
Ke na le bothata bo itseng ho etsa mesebetsi ya ka ya setlwaheli ☐
Ha ke kgone ho etsa mesebetsi ya ka ya setlwaheli ☐

Ho opelwa le ho se ikutlwe monate

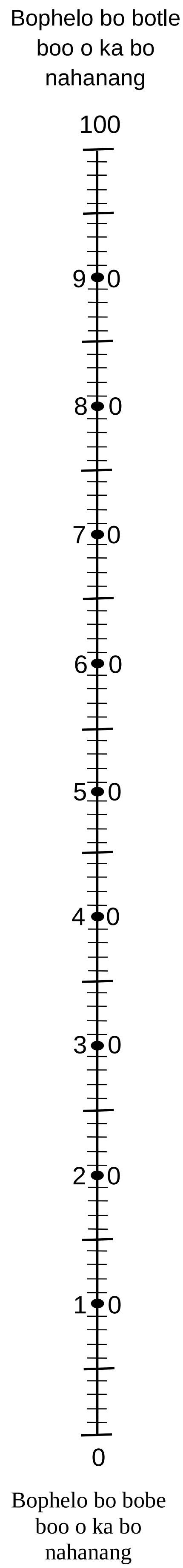
Ha ke opelwe kapa ho se ikutlwe monate ☐
Ha ke opelwe hakaalo kapa ho se ikutlwe monate ☐
Ke opelwa hampe kapa ha ke ikutlwe monate ho hang ☐

Ho tshwenyeha kapa ho wa ha maikutlo
Ha kea tshwenyeha kapa hona ho wa maikutlo ☐
Ha kea tshwenyeha hakaalo kapa ke wele maikutlo ☐
Ke tshwenyehile hampe kapa ke wele maikutlo haholo ☐

Ho thusa batho ho bolela hore na boemo ba bophelo bo botle kapa bo bobe, re takile sekala (se batlang se tshwana le themometa) seo ho sona boemo bo botle haholo boo o ka bo nahanang bo tshwailweng ka 100 boemo bo bobe ka ho fetisisa boo o ka bo nahanang bo tshwailweng ka 0.

Re ne re ka rata ha o ne o ka bontsha sekaleng sena ka moo bophelo ba hao bo leng botle kapa bo leng bobe ka teng kajeno, ho ya ka wena. Etsa hona hle ka ho seha mola ho tloha lebokosong hle ka tlase ho ya fihla kae kapa kae sekaleng ho bontsha ka moo boemo ba hao ba bophelo bo leng botle ka teng kapa bo leng bobe ka teng kajeno.

Boemo ba hao ba bophelo



APPENDIX G

EQ-5D (ZULU)

UHLELO LWEMIBUZO NGEMPILO

(Zulu version for South Africa)

Ngokufaka uphawu ebhokisini elilodwa kulelo nalelo qoqo elingezansi, sicela ukhombise ukuthi yisiphi isitatimende esichaza kahle kakhulu isimo sempilo yakho namhlanje.

Ukuhamba/ukunyakaza

Anginazinkinga ukuzihambahambela ☐
Nginezinkinga ezithile ukuzihambahambela ☐
Ngihlala ngisembhedeni/ngisocansini ☐

Ukuzinakekela

Anginazinkinga ngokuzinakekela ☐
Nginezinkinga ezithile zokuzigeza noma ukuzigqokisa ☐
Angikwazi ukuzigeza noma ukuzigqokisa ☐

Imisebenzi ejwayelekile (*isibonelo: ukusebenza, ukutadisha, umsebenzi wasendlini, imisebenzi yomndeni noma eyokungcebeleka)*

Anginazinkinga ukwenza imisebenzi yami eyejwayelekile ☐
Nginezinkinga ezithile ukwenza imisebenzi yami eyejwayelekile ☐
Angikwazi ukwenza imisebenzi yami eyejwayelekile ☐

Izinhlungu/ukungaphatheki kahle

Anginazinhlungu noma ukungaphatheki kahle ☐
Nginezinhlungu noma ukungaphatheki kahle okulingene nje ☐
Nginobuhlungu obedlulele nokungaphatheki kahle ☐

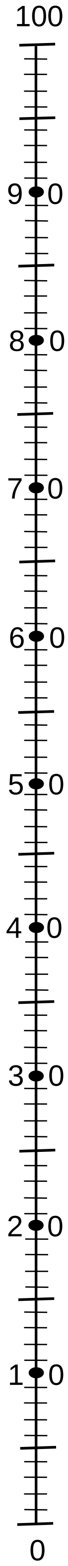
Ixhala/ukudangala

Anginalo ixhala noma ukudangala ☐
Nginexhala noma ukudangala okulingene nje ☐
Nginexhala nokudangala ngokweqile ☐

Ukuze sisize abantu basho ukuthi isimo sempilo yabo sihle noma sibi kangakanani, sidwebe isikali (esifana netemometha) okuqoshwe kuso isimo esihle kakhulu ongase usicabange sabekwa ku 100 naleso esibi kakhulu saba ku- 0.

Singathanda ukuba ukhombise kulesi sikali ukuthi yinhle noma yimbi kangakanani impilo yakho namhlanje, ngokwakho ukubona. Siza wenze lokhu ngokudweba umugqa osuka ebhokisini ngezansi uye kunoma yiliphi izinga esikalini elikhombisa ukuthi sihle noma sibi kangakanani isimo sempilo yakho namhlanje.

Isimo sempilo esihle kakhulu ongasicabanga



Isimo sempilo esimbi kakhulu ongasicabanga

Isimo sakho
Sempilo
namhlanje

APPENDIX H

BARTHEL INDEX (ENGLISH)

BARTHEL ADL INDEX

Bowels 0 = incontinent (or needs to be given enema)
1 = occasional accident (once a week)
2 = continent

Bladder 0 = incontinent, or catheterised and unable to manage alone
1 = occasional accident (maximum once per 24 hours)
2 = continent

Grooming 0 = needs help with personal care
1 = independent face/ hair/ teeth/ shaving (implements provided)

Toilet use 0 = dependent
1 = needs some help, but can do something alone
2 = independent (on and off, dressing, wiping)

Feeding 0 = unable
1 = needs help cutting, spreading butter, etc.
2 = independent

Transfer (bed to chair and back)
0 = unable, no sitting balance
1 = major help (one or two people, physical)
2 = minor help (verbal or physical)
3 = independent

Mobility 0 = immobile
1 = wheelchair dependent, including corners
2 = walks with help of one person (verbal or physical)
3 = independent (but may use any aid; for example, stick)

Dressing 0 = dependent
1 = needs help but can do about half unaided
2 = independent (including buttons, zips, laces, etc.)

Stairs 0 = unable
1 = needs help (verbal, physical, carrying aid)
2 = independent

Bathing 0 = dependent
1 = independent (or in shower)

Total 0-20 Total**……/20**

APPENDIX I

BARTHEL INDEX (SOTHO)

LENANE LA BARTHEL ADL

Mala:	0 = ho sitwa ho itshwara / ho itaola (o hloka ho nehwa sepeiti/ lehlaka) 1 = kotsi ka mohlomong (ha nngwe ka beke) 2 = ho itshwara / itaola
Senya:	0 = ho sitwa ho itshwara, kapa o kentswe lelana mme ha o kgone ho le sebedisa o le mong 1 = kotsi ka mohlomong (boholo ha nngwe dihoreng tse 24) 2 = ho itshwara / itaola
Ho itlhwekisa	0 = o hloka thuso ya ho itlhwekisa 1 = o ikemetse mabapi le sefahleho/ moriri/ meno/ ho kuta ditedu (ha ho nehelanwe ka disebediswa)
Ho sebedisa ntlwana	0 = o tshepetse 1 = o hloka thuso e itseng, empa o ka etsa ntho e itseng o le mong 2 = o ikemetse (ka nako tse ding, ho tena, ho itlhakola (fefa)
Ho ja	0 = ha o kgone 1 = o hloka thuso ya ho seha, ho tlotsa sereledi, jj. 2 = o ikemetse
Ho fetisetsa (ho tloha betheng ho ya setulong le ho kgutlela)	0 = ha o kgone, ha ho tekatekano ya ho dula 1 = thuso e kgolo (motho a le mong kapa ba babedi, matla) 2 = thuso e nyane (ya ho bua kapa matla) 3 = o ikemetse
Ho tsamaya	0 = ha o kgone ho tsamaya 1 = o tshepetse ho setulo sa ho tsamaya, ho kenyeletsa dihuku 2 = o tsamaya ka thuso ya motho a le mong (ka puo kapa matla) 3 = o ikemetse (empa o ka sebedisa sesebediswa sa thuso (aid) sefe kappa sefe; mohlala, seikokotlelo)
Ho tena /apara	0 = o tshepetse 1 = o hloka thuso empa o ka etsa halofo ya ho tena o sa thuswa 2 = o ikemetse (ho kenyeletsa dikonopo, diziphu, maqhwele, jj.)
Ditepisi (mehato)	0 = ha o kgone 1 = o hloka thuso (ka puo, matla, thuso ya ho rwala) 2 = o ikemetse
Ho tola	0 = o tshepetse 1 = o ikemetse (kapa ka shawareng)

paloyohle 0-20

APPENDIX J

BARTHEL INDEX (ZULU)

i-INDEKSI KA - BARTHEL YOKWENZA OKUHAMBISANA NEMPILO YANSUKU ZONKE (I-ADL)

Amathumbu 0 = ukuhluleka ukuzilawula (kumbe udinga ukuchathwa)
1 = ingozi ethe gqwa (kanye ngesonto)
2 = uyakwazi ukuzilawula

Isinyi 0 = uyehluleka ukuzilawula, kumbe usebenzisa ikhathetha futhi awukwazi ukuzenzela uwedwa
1 = ingozi ethe gqwa (akudluli kusikhawu esisodwa emahoreni angama 24)
2 = uyakwazi ukuzilawula

Ukuzicwala 0 = udinga usizo ngokuzilungisa
1 = uyazilungisa ubuso/izinwele/amazinyo/ukushefa (iziilungisi zihlinzekiwe)

Ukusebenzisa indlu yangasese
0 = udinga ukwelekelwa
1 = udinga ukwelekelwa okuthize, kodwa kukhona okwazi ukuzenzela ngokwakho
2 = awudingi ukwelekelwa (kuyaguqu-guquka, ukuzigqokisa, ukuzesula)

Ukuzifunza 0 = awukwazi
1 = udinga usizo ukusika, ukugcoba ibhotela, etc.
2 = awudingi ukwelekelwa

Ukuzithutha(kusuka embhedeni kuya esihlalweni nokubuya)
0 = awukwazi, angikwazi ukuzihlalela
1 = Kudingakala usizo olukhulu (lomuntu oyedwa kumbe ababili, izikhwepha)
2 = Kudingakala usizo oluncane (ngenkulumo kumbe ngezikhwepha)
3 = awudingi ukwelekelwa

Ukunyakaza 0 = akunyakazeki
1 = udinga usizo lwesihlalo esihambayo, kumbandakanya amajika
2 = uhamba ngokwelekelelwa umuntu oyedwa (ngenkulumo kumbe ngezikhwepha)
3 = awudingi ukwelekelwa (kepha ungayisebenzisa noma iyiphi insiza; isibonelo, udondolo)

Ukugqoka 0 = udinga ukwelekelwa
1 = udinga usizo kepha uyakwazi ukugqoka isigamu ngaphandle kosizo
2 = awudingi ukwelekelwa (kumbandakanya izinkinobho, awoziphu, imichilo, njalo njalo.)

Izitebhiso 0 = awukwazi
1 = udinga usizo (ngenkulumo, ngezikhwepha, nosizo lokuthwalwa)
2 = awudingi ukwelekelwa

Ukuzigeza 0 = udinga ukwelekelwa
1 = awudingi ukwelekelwa (kumbe eshaweni)

sekukonke 0-20

APPENDIX K

ORIGINAL ABIS

1. …….Because I am an amputee, I feel more anxious about my physical appearance in social situations than when I am alone
2. ……..I avoid wearing shorts in public because my prosthesis would be seen
3. **R** ……..I like my overall physical appearance when wearing a prosthesis
4. ……..It concerns me that the lost of my limb impairs my body's functional capabilities in various activities of daily living.
5. ……..I avoid looking into a full-length mirror in order not to see my prosthesis
6. ……..Because I am an amputee, I feel more anxious about my physical appearance on a daily basis
7. ……..I experience a phantom limb
8. ……..Since losing my limb, it bothers me that I no longer conform to the society's ideal of normal appearance
9. ……..It concerns me that the lost of my limb impairs my ability to protect myself from harm
10. ………When I am not wearing my prosthesis, I avoid situations where my physical appearance can be evaluated by others (e.g. avoid social situations, swimming pool or beach activities, physical intimacy)
11. ………The loss of my limb makes me think of myself as disabled
12. **R** ………I like my physical appearance when not wearing a prosthesis
13. ………..When I am walking, people notice my limp
14. ……….When I am wearing my prosthesis, I avoid situations where my physical appearance can be evaluated by others (e.g. avoid social situations, swimming pool or beach activities, physical intimacy)
15. ………People treat me as a disabled
16. **R** ………I like the appearance of my stump anatomy
17. ………I wear baggy clothing in an attempt to hide my prosthesis
18. ………I feel I must have four normal limbs in order to be physically attractive
19. ………It is important the size of my prosthesis and remaining anatomy of the affected limb are the same size as the other limb
20. ………I avoid looking into a full-length mirror in order not to see my stump anatomy

APPENDIX L

ENGLISH MABIS

1. …….Because I am an amputee, I feel more anxious about my physical appearance in social situations than when I am alone
2. ……..I avoid wearing shorts in public
3. **R**……..I like my overall physical appearance
4. ……..It concerns me that the loss of my limb impairs my body's functional capabilities in various activities of daily living.
5. ……..Because I am an amputee, I feel more anxious about my physical appearance on a daily basis
6. ……..I experience a phantom limb
7. ……..Since losing my limb, it bothers me that I no longer conform to the society's ideal of normal appearance
8. ……..It concerns me that the lost of my limb impairs my ability to protect myself from harm
9. ………The loss of my limb makes me think of myself as disabled
10. ………..When I am walking, people notice my limp
11. ………. I avoid situations where my physical appearance can be evaluated by others (e.g. avoid social situations, swimming pool or beach activities, physical intimacy)
12. ………People treat me as a disabled
13. **R** ………I like the appearance of my stump anatomy
14. ………I feel I must have four normal limbs in order to be physically attractive
15. ………It is important the size of my prosthesis and remaining anatomy of the affected limb are the same size as the other limb once I get it
16. ………I avoid looking into a full-length mirror in order not to see my stump anatomy

1-none of the time, 2-rarely, 3-some of the time, 4-most of the time, 5-all of the time

APPENDIX M

SOTHO MABIS

1. …….Hobane ke kgaotswe seripa sa mmele, ke ikutlwa ke tshwenyeha ka tsela yeo ke shebahalang mo hara batho ho feta ha ke le mong
2. ……..Ke etsa hore ke se ke ka tenya/apara marokgo a makgutsane ha ke le hara batho
3. **R** ……..Ke rata tsela yeo ke shebahalang ka yona ka kakaretso
4. ……..Ke tshwenyeha ka hore ho lahlehelwa ke seripa sa mmele ho thibela ho nka karolo ha mmele wa ka mo diketsong tsa tsatsi le tsatsi
5. …….. Hobane ke kgaotswe seripa sa mmele, ke ikutlwa ke tshwenyeha ka tsela yeo ke shebahalang tsatsi le tsatsi
6. ……..Ke utlwa leoto le seng teng
7. ……..Ho tloha nako yeo ke lahlehetsweng ke karolo ya mmele, ke tshwenyeha ka hore ha ke sa shebeha/bonwa ka tsela yeo setshaba se lebelletseng hore motho ya feletseng o tlamehile a shebahale ka teng
8. …….. Ke tshwenyeha ka hore ho lahlehelwa ke seripa sa mmele ho mpaledisa/ntshitisa ho ka itshireletsa hore ke se ke ka lemala
9. ………Ho lahlehelwa ke karolo ya mmele waka ho nketsa hore ke nahane hore ke motho ya holofetseng
10. ………..Ha ke tsamaya/sepela, batho ba lemoha ho hlotsa ha ka
11. ………. Ke etsa hore ke se ke ka ba mo dibakeng tseo seemo sa mmele waka se ka hlahlojwang/lekolwang ke batho ba bang (mohlala: Ke etsa ho re ke se ke ka ba mo hara batho, mo ho nang le diketso tsa ho rutha matangwaneng kapa lewatle, dikamano tse tsamaisanang le tsa thobalano)
12. ………Batho ba nkuka/nka jwale ka motho ya holofetseng
13. **R** ………Ke rata tsela yeo karolo ya ka e kgaotsweng e shebahalang ka teng
14. ………Ke ikutlwa hore ke tlamehile ke be le maoto le matsoho a feletseng a sebetsang hantle hore ke kgone ho ba le kgohedi ho batho ba bang
15. ………Ho bohlokwa hore karolo ya mmele ya maiketsetso yeo ke tla e fumanang le karolo ya ka ya mmele e setseng ha ke kgaolwa e lekane le karolo ya mmele e sa kgaolwang
16. ………Ke etsa hore ke se ke ka sheba/lebelela ka seiponeng se bontshang mmele kaofela hore ke se ke ka bona tsela yeo setho sa ka sa mmele se kgaotsweng se shebahalang ka teng

1-none of the time, 2-rarely, 3-some of the time, 4-most of the time, 5-all of the time

APPENDIX N

ZULU MABIS

1. …….Ngoba nginqanyulwe isitho somzimba ngizizwa ngikhathazeka ngendlela engibukeka ngayo phakathi kwabantu kunokuba ngingedwa.
2. ……Ngiyakugwena ukuqoka izingubo ezimfishane/noma isikhindi emphakathini.
3. **R** ……Ngiyayithanda indlela umzimba wami obukeka ngayo.
4. …Kuyangikhathaza ukulahlekelwa isitho sami somzimba ngoba kukhubaza ukusebenza komzimba wami emisebenzini eyahlukahlukene yansukuzonke.
5. ……. Ngoba nginqanyulwe isitho somzimba ngizizwa ngikhathazekile ngendlela engibukeka ngayo nsukuzonke.
6. ……..Umuzwa wesitho sami esingasekho ngisawuzwa.
7. …….Selokhu ngalahlekelwa isitho sami somzimba, kuyangikhathaza ukuthi angisakwazi ukubukeka ngendlela umphakathi ocabanga ukuthi yindlela ejwayelekile ukuthi abantu babukeke ngayo.
8. …… Kuyangikhathaza ukulahlekelwa isitho somzimba ngoba kungenza ngingakwazi ukuzivikela ezingozini/ebungozini.
9. …..Ukulahlekelwa kwami isitho somzimba kungenza ngizicabange/ngizizwe njengomuntu okhubazekileyo.
10. ….Uma ngihamba abantu bayabona futhi kubacacele ukuthi ngiyaqhuga.
11. …..Ngiyazigwema izindawo lapho ukubukeka kwami kuzongehlulelisa ngabantu (isibonelo, izindawo zomphakathi, izindawo zokubhukuda, nezindawo lapho okufanele ukuthi kukhunyulwe khona)
12. ……Abantu bangithathisa okumuntu okhubazekileyo.
13. **R** …….Ngiyithanda indlela isitho sami sokufakelwa esibukeka ngayo.
14. …..Ngicabanga ukuthi kufanele ngibe nazo zonke izitho zomzimba ukuze umzimba wami ubukeke kahle.
15. …..Kusemqoka noma kubalulekile ukuthi isitho sami sokufakelwa nesendalo zilingane.
16. ……Ngiyakugwema ukuzibuka eziibukweni ezinde ukuze ngingaboni isitho sami sokufakelwa.

1-none of the time, 2-rarely, 3-some of the time, 4-most of the time, 5-all of the time

APPENDIX O

P-SCALE ENGLISH

no	P-Scale	Not spec/not answered	Yes	Sometimes	No	Irrelevant/ I do no want to, I do not have to	No problem	Small	Medium	Large	Score
1	Do you have equal opportunity as your peers to find work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
2	Do you work as hard as your peers do? (same hours, type of work etc)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
3	Do you contribute to the household economically in a similar way to your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
4	Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
5	Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
6	Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
7	Are you as socially active as your peers are? (e.g. in religious/community affairs)		0			0					

	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
8	Do you have the same respect in the community as your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
9	Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
10	Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
11	Do you visit other people in the community as often as other people do?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
12	Do you move around inside and outside the house and around the village / neighbourhood just as other people do?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
13	In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
14	In your home, do you do household work?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

15	In family discussions, does your opinion count?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
16	Do you help other people (e.g. neighbours, friends or relatives)?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
17	Are you comfortable meeting new people?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	
18	Do you feel confident to try to learn new things?		0			0					
	[if sometimes or no] How big a problem is it to you?						1	2	3	5	

Comment

Total

Name :______________________________

Age :______________________________ Gender:__________

Interviewer :____

Date of interview : _________/____________/________

Grades of participation

No significant restriction	Mild restriction	Moderate restriction	Severe restriction	Extreme restriction
1-12	13-22	23-32	33-52	52-90

APPENDIX P

P-SCALE SOTHO

No	P-Scale	Ga e ya arabiwa	Eya	Ka dinako tse dingwe	Aowa	Ha e tsamaisane le nna/Ha ke nyake, Ha ke hapeletsehe	Ha hona bothata	Nnyane	Magareng	Kgolo	Sekoro
1	Naa o na le monyetla wa ho thola/fumana mosebetsi go tshwana le balekane ba hao?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
2	Naa o sebetsa haholo ho feta balekane ba hao? (dihora tse tshwanang, mofuta wa mosebetsi etc)		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
3	Naa o kgona ho neelana ka tshjelete mo lelapeng ka tsela e tshwanang le ya balekane ba hao?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
4	Naa o etela/tshjakela ka ntle ha motse wa hao/baagisaneng ho tshwana le balekane ba hao? (ntle le ha o eya ho thola kalafi) Mohlala: mabenkeleng, mmarakeng		0			0					

	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
5	Naa o nka karolo mo meletlong e meholo kapa dihlabelong ho tshwana le balekane ba hao? (Mohlala: manyalo, mafu, meletlo ya sedumedi)		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
6	Naa o nka karolo haholo mo ho ithabiseng feela/dintho tsa setjhaba ka kakaretso ho tshwana le balekane ba hao? (Mohlala: dipapadi, ho bua/bolela, dikopano)		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
7	Naa o nka karolo mo dinthong tsa setjhaba ho tshwana le balekane ba hao? (Mohlala: mo nthong tsa sedumedi/taba tsa motseng)		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
8	Naa o thola hlompho ho tswa ho setjhaba ka tsela e tshwanang le eo e fumanwang ke balekane ba hao?		0			0					

	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
9	Naa o na le monyetla wa ho ihlokomela ka bo wena? (tsela eo o shebahalang ka yona, ho fepa mmele, tsa maphelo, etc.) ho tshwana le balekane ba hao?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
10	Naa o na le menyetla e tshwanang le ya balekane ba hao ho qala/thoma dikamano tsa nako e telele le molekane wa bophelo johle?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
11	Naa o etela batho ba bang mo motseng ho tshwana le ka tsela eo ba bang ba etsang?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
12	Naa o tsamayatsamaya ka hara ntlu le ka ntle ho ntlu le baagisaneng ba hao ho tshwana le batho ba bang?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	

13	Mo motseng wa hao/boagisaneng, naa o etela tulo tsa setjhaba ho tshwana le batho ba bang? (Mohlala: dikolo, mabenkele, dikantoro, mmaraka le mabenkele a tee/kofi)		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
14	Ka lapeng la hao, naa o etsa mosebetsi wa ka ntlung?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
15	Mo dipuisanong tsa lelapa, a naa se o se nahanang se nkelwa hlohong?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
16	Naa o thusa batho ba bang (Mohlala: baagisane, bakgotse kapa ba leloko)?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	
17	Naa o ikutlwa o lokolohile hore o ka kopana le batho ba o sa ba tsebeng?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	

18	Naa o utlwa o itshepa ho ka leka ho ithuta ntho tse ntjha/o sa ditsebeng ?		0			0					
	[Ha eba ka dinako tse dingwe kapa aowa] Ke bothata bo kakang/kae ho wena?						1	2	3	5	

Tshwaelo

Yohle

Lebitso :______________________________

Dijara/mengwaga :______________________________ Bong:___________

Mmotsa dipotso :____

tsatsi la ho botswa dipotso : _________/____________/________

Grades of participation

No significant restriction	Mild restriction	Moderate restriction	Severe restriction	Extreme restriction
1-12	13-22	23-32	33-52	52-90

APPENDIX Q

P-SCALE ZULU

No	P-Scale	Not spec/not answered	Yes	Sometimes	No	Irrelevant/ I do no want to, I do not have to	No problem	Small	Medium	Large	Score
1	Kungabe unamathuba alinganayo yini okuthola umsebengi nabantu abasezingeni lakho?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
2	Kungabe usebenza ngokuzikhandla ngendlela elinganayo nabantu abasezingeni lakho? (amahora alinganayo, inhlobo yomsebenzi njalonjalo)		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
3	Kungabe unegalelo noma ulekelela elinganayo nontanga bakho ekhaya kini ngokwezimali?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
4	Kungabe uvakashe yini ezindaweni ezingaphandle kwalapha uhlala khona noma komakhelwane njengoba kwenza abantu abasezingeni lakho? (ngaphandle kokuya kodokotela nasezitolo)		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
5	Kungabe uyalibamba iqhaza emicimbini nasemigubheni eqavile njengabantu abasezingeni lakho? (isibonelo, emishadweni, emincwabeni nasemigidini yezenkolo)		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
6	Kungabe **uyalibamba** iqhaza elilinganayo kwezokuzithokozisa, nasezintweni zomphakathi njengabantu abasezingeni lakho? (isibonelo, imihlangano, ezemidlalo)		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	

7	Kungabe uneqhaza elilinganayo **yini** emphakathini njengabantu abasezingeni lakho? (Isibonelo enkolo, ezomphakathi njalonjalo)		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
8	Kungabe uthola ukuhlonipheka okulinganayo nabantu abasezingeni lakho emphakathini?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
9	Kungabe unethuba elanele lokuzinakekela wena siqu sakho njegabantu abasezingeni lakho? (isibonelo, indlela obukeka ngayo,ukudla okudlayo, nangokwempilo-nje)		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
10	Kungabe unethuba elilinganayo lokuqala nokugcina isikhathi eside ubudlelwane nomuntu uphilisana naye empilweni njengabantu abasezingeni lakho?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
11	Kungabe uyakwazi yini ukuvakashela abantu endaweni yangakini kaningi njengoba abanye abantu benza?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
12	Kungabe uhamba uphume ungena endlini noma nasendaweni lapho uhlala khona njengoba kwenza abanye abantu?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
13	Endaweni ohlala kuyo ngabe uvakashela izindawo zomphakathi njengoba kwenza abanye abantu? (Isibonelo, ezikoleni, ezitolo,emahhovisi,ezindaweni zokuthenga nezokudla noma zokuphuza itiye)		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
14	Ekhaya uyawenza yini umsebenzi wasendlini?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	

15	Ezingxoxweni zomndeni ngabe umbono wakho ubalulekile?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
16	Kungabe uyabasiza yini abanye abantu? (isibonelo,omakhelwane, abangani noma izihlobo)		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
17	Kungabe uzizwa ukhululekile yini ukudibana nabantu ongabajwayele?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	
18	Kungabe uzizwa unesibindi sokuzama ukufunda izinto ezintsha?		0			0					
	(uma kwenzeka kuwe noma kungenzeki) Kuyinkinga engakanani kuwe?						1	2	3	5	

Comment

Total

Name :______________________________

Age :______________________________ Gender:_________

Interviewer :____

Date of interview : _________/____________/________

Grades of participation

No significant restriction	Mild restriction	Moderate restriction	Severe restriction	Extreme restriction
1-12	13-22	23-32	33-52	52-90

APPENDIX R

TIMED UP AND GO ENGLISH

TIMED GET UP AND GO TEST

Measures mobility in people who are able to walk on their own (assistive device permitted)

Name_________________________
Date__________________________
Time to Complete________________**seconds**

Instructions:
The person may wear their usual footwear and can use any assistive device they normally use.

1. Have the person sit in the chair with their back to the chair and their arms resting on the arm rests.
2. Ask the person to stand up from a standard chair and walk a distance of 10 ft. (3m).
3. Have the person turn around, walk back to the chair and sit down again.

Timing begins when the person starts to rise from the chair and ends when he or she returns to the chair and sits down.

The person should be given 1 practice trial and then 3actual trial. The times from the three actual trials are averaged.

Predictive Results
<u>Seconds Rating</u>
<10 Freely mobile
<20 Mostly independent
20-29 Variable mobility
>30 Impaired mobility

Source: Podsiadlo, D., Richardson, S. The timed ‘Up and Go’ Test: a Test of Basic Functional Mobility for Frail Elderly Persons. *Journal of American Geriatric Society*. 1991; 39:142-148

APPENDIX S

TIMED UP AND GO SOTHO

TIMED GET UP AND GO TEST

Measures mobility in people who are able to walk on their own (assistive device permitted)

Name_________________________

Date__________________________

Time to Complete________________**seconds**

Ditaelo:

Motho a ka jwara/apara dieta/dihlako tja gagwe tja ka mehla ebile a ka shomisha/sebedisa thupa ya gagwe ya go tsamaya/sepela ye a tlwaetjeng go e shomisha/sebedisa.

1. Motho a dule mo setolong a etshegetse mosetolong.
2. Kopa motho a eme mo setolong a tsamaye botelele ba maoto a masome (of 10 ft. /3m).
3. Kopa motho a rotologe, a boe a dule fatshe.

Palo ya nako e simololа ga motho a ema mo setolong e be a fela ga a dula fatshe

Motho o tswanetse go fewa nako ya go leka di taelo tse a tlo fewang tsona (3 actual trials). The times from the three actual trials are averaged.

Predictive Results

Seconds Rating

<10 Freely mobile

<20 Mostly independent

20-29 Variable mobility

>30 Impaired mobility

Source: Podsiadlo, D., Richardson, S. The timed 'Up and Go' Test: a Test of Basic Functional Mobility for Frail Elderly Persons. *Journal of American Geriatric Society*. 1991; 39:142-148

APPENDIX T

TIMED UP AND GO ZULU

TIMED GET UP AND GO TEST
(ISIKHATHI ESIBEKIWE SOKUVUKA NOKUYA E-THESTINI)

Izikalo zokuhamba kwabantu abakwaziyo ukuzihambela ngokwabo (Izinsiza kuhamba zivumelekile)

Igama:
Usuku:
Isikhathi sokuqeda__________________ngamasekhondi

Imiqathango/imithetho:

Umuntu angagqoka izicathulo zakhe asebenzise nezinto zokumsiza ajwayele ukuzisebenzisa

1. Hlalisa umuntu esitulweni nezingalo zakhe azibeke ezingalweni zesitulo
2. Cela umuntu ukuthi asukume esitulweni ahambe ibanga elingamagxathu ayishumi (10ft)3m
3. Cela umuntu ukuthi ajike ahambe aphindele esitulweni ayohlala phansi.

Qala ukubala isikhathi uma umuntu eqala ukusukuma esitulweni uqede uma umuntu esebuyele wahlala phansi esitulweni futhi.

Umuntu kumelwe anikwe ithuba lokuzama ukwenza lokhu ngaphambi kukuba kuthestwe.

Imiphumela engalindeleka

Amasekhondi Amazinga
<10 Freely mobile (Ukuhamba ngaphandle kosizo)
<20 Mostly independent (Udinga usizo)
20-29 Variable mobility (Ukuhamba okushintshashintshayo)
>30 Impaired mobility (Ongakwazi ukuhamba)

Source: Podsiadlo, D., Richardson, S. The timed ‘Up and Go’ Test: a Test of Basic Functional Mobility for Frail Elderly Persons. *Journal of American Geriatric Society*. 1991; 39:142-148

APPENDIX U

PERMISSION LETTER TO HOSPITALS

University of the Witwatersrand
Department of Physiotherapy

The Hospital Manager/CEO: ……….Hospital

Dear Prof/Dr/Sir/Madam

APPLICATION FOR PERMISSION TO CONDUCT A STUDY AT YOUR HOSPITAL.

My name is Lonwabo Godlwana, a lecturer and a PhD student in the Department of Physiotherapy at the University of the Witwatersrand. I am requesting permission to conduct a study that is for my PhD.

Title of study: The epidemiology and functional outcomes after a major lower limb amputation (LLA) in Johannesburg.

Aim of the study: To determine the impact of a self administered exercise programme (Home programme) administered postoperatively on selected outcomes three months and six months after a LLA and establish the two incidence and prevalence of disease related LLA operations. **Methods:** a RCT**.** The Barthel index to measure function (BI), Modified Locomotor Capabilities Index (MLCI),Modified Amputee Body Image Scale (MABIS), Participation Scale (P-Scale), Euroqol EQ-5D quality of life (EQ-5D), Timed Up and Go test (TUG) will be used to gather data from the participants. The control group will get the standard rehabilitation from your hospital and the intervention group with get an additional exercise programme and an Exercise Diary (ED). The intervention will be from discharge until 3 months since amputation. A research assistant (a physiotherapist) will administer the intervention and the researcher will do all the testing. All participant data will be kept confidential. A theatre register records will be reviewed to gather data on the prevalence and incidence of LLA

The study has been approved by the University of the Witwatersrand Ethics Committee. Ethical clearance no……………... attached is a copy of the participant information sheet and Ethical Clearance Certificate.

Kind regards

Researchers:
Lonwabo L Godlwana-Researcher
Tel: 011 717 3707/072 373 2156
Fax: 011 717 3719
Email: Lonwabo.Godlwana@wits.ac.za

Supervisor: Prof AV Stewart
Tel: 011 717 3718
Email:aimee.stewart@wits.ac.za

APPENDIX V1

ETHICAL CONSIDERATIONS

ETHICAL APPROVAL FROM THE UNIVERSITY OF THE WITWATERSRAND

M110124M110124

UNIVERSITY OF THE WITWATERSRAND, JOHANNESBURG
Division of the Deputy Registrar (Research)

HUMAN RESEARCH ETHICS COMMITTEE (MEDICAL)
R14/49 Mr Lonwabo Lungile Godiwana

CLEARANCE CERTIFICATE	M110124
PROJECT	Functional Outcomes after a major Lower Limb Amputation (LLA) in Johannesburg: A Single Blinded Randomized Controlled Trial
INVESTIGATORS	Mr Lonwabo Lungile Godiwana.
DEPARTMENT	Department of Physiotherapy
DATE CONSIDERED	28/01/2011
DECISION OF THE COMMITTEE*	Approved unconditionally

Unless otherwise specified this ethical clearance is valid for 5 years and may be renewed upon application.

DATE 22/02/2011 CHAIRPERSON ....
(Professor PE Cleaton-Jones)

*Guidelines for written 'informed consent' attached where applicable
cc: Supervisor : Professor Aimee Stewart

DECLARATION OF INVESTIGATOR(S)

To be completed in duplicate and ONE COPY returned to the Secretary at Room 10004, 10th Floor, Senate House, University.
I/We fully understand the conditions under which I am/we are authorized to carry out the abovementioned research and I/we guarantee to ensure compliance with these conditions. Should any departure to be contemplated from the research procedure as approved I/we undertake to resubmit the protocol to the Committee. I agree to a completion of a yearly progress report.

PLEASE QUOTE THE PROTOCOL NUMBER IN ALL ENQUIRIES. .

APPENDIX V2

HOSPITAL PERMISSIONLETTERS

17-APR-2011 23:50 From:PAEDS/BARA 0119389374 To:0865534780 P.1/1

Appendix V2

MEDICAL ADVISORY COMMITTEE

CHRIS HANI BARAGWANATH HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 14 April 2011

TITLE OF PROJECT:

UNIVERSITY: Witwatersrand

Functional outcomes after major lower limb amputation in Johannesburg: a single blinded randomised controlled trial

Principal Investigator Mr L Godlwana

Department: Physiotherapy

Supervisor (If relevant):. Prof A Stewart

Permission Head Department (where research conducted) Yes

Date of start of proposed study: May 2011

Date of completion of data collection July 2013

The Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- The researchers complying with the HoD's request not to impose additional tasks on the Department.
- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

PROF. JOHN PETTIFOR
MBBCh, FCP (S.A.)
CHIEF PAEDIATRICIAN

DR. P. [illegible]

Recommended	Approved/~~Not Approved~~
(On behalf of the MAC)	Hospital Management
Date: 14 April 2011	Date: 15 APR 2011

health and
social development
Department: Health and Social Development
GAUTENG PROVINCE

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Office of the CEO
Enquiries: L. Mngomezulu
Tell: (011): 488-3792
Fax: (011) 488-3753
Date: 20th September 2011

Mr. Lonwabo Lungile Godlwana
Lecturer
University of the Witwatersrand

Dear Mr. Godlwana

RE: "Functional outcomes after a major lower limb amputation (LLA) in Johannesburg: a single blinded randomized controlled trial"

Permission is granted for you to conduct the above research as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister in Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Yours sincerely

Dr. Barney Selebano
Chief Executive Officer

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

EDENVALE REGIONAL HOSPITAL

Department of Health
Lefapha la Maphelo
Departement van Gesondheid
Umnyango wezeMphilo

☎: (011) 321 6001
Fax: (011) 443 6162

23rd July 2014

Dear Lonwabo Godlwana

Permission is hereby granted to you to collect data from the theatre registration book regarding patient that had received lower limbs amputations.

Regards,

Dr Jann-Kruger
HOD Surgery

Chief Executive Officer, Edenvale General Hospital ,Modderfontein Road, Private Bag x1005 Edenvale 1610
Tel: (011) 321 6001, Fax (011) 443 6162

health and
social development
Department: Health and Social Development
GAUTENG PROVINCE

PERMISION FOR RESEARCH

DATE: 17.6.14

NAME OF RESEARCH WORKER: Lonwabo L. Godlwana (Mr)

CONTACT DETAILS OF RESEARCH (INCLUDE ALTERNATE RESEARCHER):
072 373 2156 cell, office 011 717 3707
Prof A Stewart (Supervisor): 082 330 9513

TITLE OF RESEARCH PROJECT Functional outcomes after a lower limb amputation (LLA) in Johannesburg: A single blinded RCT

OBJECTIVES OF STUDY (Briefly or include a protocol):
To establish the 2 year prevalence of lower limb amputation (vascular) in Johannesburg

METHODOLOGY (Briefly or include a protocol):
Review of hospital statistics on vascular LLA over a 2 year period.

THE APPROVAL BY THE SUPERINTENDENT IS STRICTLY ON THE BASIS OF THE FOLLOWING:

(i) CONFIDENTIALITY OF PATIENTS MAINTAINED: Yes
(ii) NO COSTS TO THE HOSPITAL: Yes
(iii) APPROVAL OF HEAD OF DEPARTMENT: Yes
(iv) APPROVAL BY ETHICS COMMITTEE OF UNIVERSITY: Yes

SUPERINTENDENT PERMISION

Signature: [signature] Date: 23/06/2014

SUBJECT TO ANY RESTRICTIONS: Financial impact on the hospital!

Helen Joseph Hospital
Perth Road
Tel: 011 489 1011

Private Bag X47
Auckland Park
2006

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

MEDICAL ADVISORY COMMITTEE
CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

PERMISSION TO CONDUCT RESEARCH

Date: 09 June 2014

TITLE OF PROJECT: Functional outcomes after a major lower limb amputation (LLA) in Johannesburg: A single blinded randomized controlled trial

UNIVERSITY: Witwatersrand

Principal Investigator: LL Godlwana

Department: Physiotherapy

Supervisor (If relevant): A Stewart

Permission Head Department (where research conducted): Yes

Date of start of proposed study: on going as permission was granted earlier
Date of completion of data collection: December 2015

he Medical Advisory Committee recommends that the said research be conducted at Chris Hani Baragwanath Hospital. The CEO /management of Chris Hani Baragwanath Hospital is accordingly informed and the study is subject to:-

- Permission having been granted by the Committee for Research on Human Subjects of the University of the Witwatersrand.
- the Hospital will not incur extra costs as a result of the research being conducted on its patients within the hospital
- the MAC will be informed of any serious adverse events as soon as they occur
- permission is granted for the duration of the Ethics Committee approval.

Permission had been granted in 2013, but the researcher needs further information

Recommended
(On behalf of the MAC)
Date: 09 June 2014

Approved/Not Approved
Hospital Management
Date: 09/06/14

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

CHRIS HANI BARAGWANATH ACADEMIC HOSPITAL

Directorate: Department of Surgery

☎011 933 8804 / 9267 / 8386

011 938 2002

1st August 2014

Prof Y Jeenah
Head – Psychiatric Dept.
CH Baragwanath Hospital

Dear Prof Jeenah

RE: Permission for Research Project from Vascular Unit

Title: 'Functional outcomes after a Major Lower Limb Amputation in Johannesburg Metro.

I hereby ask for permission in support for Mr Lonwabo L Godlwana to conduct a research project and to use patients records as a study. I have studied Mr Gondlwana' research product for functional outcomes after major lower limb amputation in diabetic and vascular limbs.

Collection of statistics and we do not have any objection to his research providing all other requirements are met.

Please also note that the study will be at no additional cost to the hospital.

Please find enclose details of the study.

Yours faithfully

Dr A Arain
Head of Vascular Surgery,
Chris Hani Baragwanath Academic Hospital

cc. Prof MD Smith- Head – Dept. of Surgery
Dr Maseko- Deputy CEO
Prof. Velaphi – HOD Paediatrics

GAUTENG PROVINCE
HEALTH
REPUBLIC OF SOUTH AFRICA

Enq: Ms P. Ngwenya
Tel: 011 681 2002
Fax: 086 623 6947

Dear Lonwabo

Permission is hereby granted for you to conduct your research at South Rand Hospital.

Kind regards

Mrs. MC. Makhetha
Chief Executive Office
Date: 26/05/2014

SUID RANDSE HOSPITAAL
P/SAK X1
ROSETTENVILLE
2014 -05- 2 6
P/BAG X1
ROSETTENVILLE
SOUTH RAND HOSPITAL

GAUTENG PROVINCE

HEALTH
REPUBLIC OF SOUTH AFRICA

CHARLOTTE MAXEKE JOHANNESBURG ACADEMIC HOSPITAL

Enquiries:
Ms. L. Mngomezulu
Office of the Director: Clinical Services
Tel: (011) 488-3365
Fax: (011) 488-3753
25th July 2014

Mr. Lonwabo Gondlwana
Department of Physiology
University of the Witwatersrand

Dear Mr. Gondlwana

RE: **"Functional outcomes after a major lower Limb Amputations (LLA) in Johannesburg: A single blinded randomized controlled trail"**

Permission is granted for you to conduct the above recruitment activities as described in your request provided:

1. Charlotte Maxeke Johannesburg Academic hospital will not in anyway incur or inherit costs as a result of the said study.
2. Your study shall not disrupt services at the study sites.
3. Strict confidentiality shall be observed at all times.
4. Informed consent shall be solicited from patients participating in your study.

Please liaise with the Head of Department and Unit Manager or Sister In Charge to agree on the dates and time that would suit all parties.

Kindly forward this office with the results of your study on completion of the research.

Supported / not supported

Dr. S. Ngobese
Acting Director: Clinical Services
DATE: 25/07/2014

Approved / not approved

Ms. G. Bogoshi
Chief Executive Officer
DATE: 28/07/2014

Charlotte Maxeke Johannesburg Academic Hospital

Vascular Unit	Ward 395
Level 9, Orange Block	Telephone: (011) 488 3395

Consultants: Prof. M Veller, Dr. J Pilai, Dr. I Cassimjee, Dr. T Monareng

Re: Mr. Lonwabo Gondlwana

23/07/2014

To whom it may concern,

The above mentioned is a physiotherapist who is associated with the Department of Physiotherapy at the University of Witwatersrand.

Mr. Godlwana is currently embarking on research towards his PHD which involves the observation and study of functional outcomes within patients whom have undergone limb amputations.

The Department of Vascular Surgery (Charlotte Maxeke JHB Academic Hospital), give Mr. Gondlwana full permission and indemnity to compile his research, by working with and studying the patient population in ward 395.

Sincerely,

Dr. J Pillai

Dr. I Cassimjee

(Consultant Vascular Surgeons)

APPENDIX W

INFORMATION DOCUMENT (ENGLISH)

Study title: The epidemiology and functional outcomes after a major lower limb amputation (LLA) in Johannesburg

Hello - my name is Lonwabo Godlwana and I am doing research on the functional outcomes after a leg amputation

Introduction
We, Lonwabo Godlwana and Prof AV Stewart, are doing research on the functional outcomes after a leg amputation. Research is the process to learn the answers to a question. In this way we want to learn what are the differences in the functional outcomes after a leg amputation when you get the usual treatment at the hospital compared to those who will get an additional exercise programme to do at home as well as lifestyle modification advice

Invitation to participate: We are inviting you to take part in this research study.

What is involved in the study? You will be required to undergo interviews (the interview is about 45 minutes) before going for the operation. This will be about your details, functional abilities, participation in your usual activities and quality of life. At three and six months after the operation you will again give us another interview also about 45 minutes on the some topics so we can see if there is a difference after the amputation. In addition there will be questions on body image and you will also be asked to perform a task where you will stand from a chair and walk to a point 3m away and back the chair during which you will be allowed to use your walking device. You may also be selected to participate in a group that will receive exercises to do from discharge till three months.

Risks of being involved in the study: there are no invasive tests or treatments in the study. You will be required to answer questions in an interview and it you are in the group that has to do our exercises at home, the exercises allow the use of your walking devise when done in standing. If you happen to need psychological support, you will be referred to the psychologists (CH Baragwanath Hospital 011 933 8934)

Benefits of being in the study: the results of the study may help in improving the methods used to care for people with a leg amputation. The results of the study will be availed to you once the study has been completed. However there are no direct benefits.

Participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which you are otherwise entitled and you may discontinue at anytime without penalty or loss of benefit to which you are otherwise entitled. You will still get the usual hospital treatment.

Reimbursements "for out of pocket" expenses. All interviews will be scheduled on the some day as your visit to the hospital. In the event of you being required to visit only for this study, a taxi fare (to a maximum R100) will be provided after the interview.

Confidentiality: All information will be kept confidential and you will not be identified by name.

Contact details of researchers:
Lonwabo L Godlwana-Researcher
Tel: 011 717 3707/072 373 2156
Fax: 011 717 3719
Email: Lonwabo.Godlwana@wits.ac.za

Supervisor: Prof AV Stewart
Tel: 011 717 3718
Email:aimee.stewart@wits.ac.za

Contact details of REC administration and chair for reporting complaints: Prof P Cleaton. Jones Wits Research Office, 10th Floor Senate House, East Campus at 011-717-1234 Fax: 011-339-5708

APPENDIX X

INFORMATION DOCUMENT (SOTHO)

LENGWALO LA HLAHISO LESEDING

Sehloho sa patlisiso: Functional outcomes after a major lower limb amputation (LLA) in Johannesburg: a single blinded randomised controlled trial

Ho iketsetsa dintho moraho ha ho kgaolwa/segwa leoto

Dumelang- Lebitso la ka ke Lonwabo Godlwana ke etsa dipatlisiso ka ha ho iketsetsa dintho moraho ha ho kgaolwa/segwa leoto

Matseno
Rena, Lonwabo Godlwana le Prof AV Stewart, re etsa dipatlisiso ka ha ho iketsetsa dintho moraho ha ho kgaolwa/segwa leoto. Dipatlisiso ke tsela feela ya ho re nea/fa dikarabo/diphetolo ho potso. Ka tsela ye re nyaka/batla ho ithuta hore phapang ke eng mo ho iketsetseng dintho moraho ha ho kgaolwa leoto ha o fumana kalafi e tlwaelehileng sepetlela ha ho bapiswa le bao ba tla fumana kalafi e kenyeletsang le lenane la ho ikwetlisa hae le hlahiso leseding ka tsa ho fetola maphelo a bona.

Ho memiwa ho nka karolo: Re ho mema ho nka karolo mo dipatlisisong tsena.

Ho kenyeleditsweng mo dipatlisisong tsena? O tla tshwanela hore o be le nako ya ho botswa dipotso (nako e ka bang metsotso e 45) pele o etswa karo ya mmele. Se e tla ba ka ha tsela yeo o iketsetsang dintho ka yona, ho nka karolo ha hao mo dinthong tse tlwaelehileng mo bophelong ba hao, le maemo a bophelo ba hao. Mo kgweding ya boraro le ya botshelela moraho ha ho etsa karo ya mmele o tla botswa dipotso hape tse tla nkang metsotso e ka bang 45. Dipotso tsena di tla botswa gore re tsebe ha eba ho na le phapang moraho ha ho kgaolwa leoto. Hape ho tla ba le dipotso mabapi le tsela yeo o shebang mmele wa hao ka teng ebile o tla kopiwa hore o nke karolo mo ho emeng ho tloha setulong o be o sepela/tsamaya ho fihla ho 3m go tswa setulong le ho kgutlela setulong o sebedisa thupa/thobane ya hao ya ho sepela/tsamaya ha ho hlokahala. O ka kgethwa hape go nka karolo mo sehlopheng se tla fumana kwetliso yeo ba tla e etsa hae ho tloha ka nako yeo ba lokollwang sepetlele ho fihlela nako ya dikgwedi tse tharo kapa o ka tswela pele ka kalafi ya sepetlela sa CH Baragwanath ye e tlwaelehileng.

Kotsi ya ho nka karolo mo dipatlisisong tsena: Ha hona diteko tsa mmele kapa kalafi tse kenelelang mmeleng mo dipatlisisong tse. O tla tshwanela feela ke ho araba/fetola dipotso ha o botswa/botsiswa ebile ha o le sehlopheng se tlamehileng ho etsa boikwetliso ba rona hae, boikwetliso bona bo ho dumella hore o ka sebedisa thupa/thobane ha o ikwetlisa o emeletse. Ha ho ka tholwa hore maikutlo a hao a amehile hoo o hlokang thuso, o tla romelwa ho Mosaekolotsi (CH Baragwanath Hospital 011 933 8934).

Mohola wa ho nka karolo dipatlisisong tsena: Dikarabo tse fumanwang ho tswa ho dipatlisiso tsena di ka thusa ho kaonafatsa tsela tseo di sebediswang ho hlokomela batho bao ba kgaotsweng leoto. O ka fumana dikarabo tse fumanweng mo dipatlisisong tsena ha ho feditswe ho etswa dipatlisiso. Hlokomela hore ha hona thuso yeo e tobileng wena feela.

O na le boikgethelo mo ho nkeng karolo, ha o hana ho nka karolo o ka se fumane kotlo kapa ho lahlehelwa ke ditokelo tseo di ho tshwanetseng le hona o ka tlohela ho nka karolo nako efe kapa efe ntle le kotlo kapa ho lahlehelwa ke ditokelo tseo di ho tshwanetseng. O tla tswela pele ho fumana kalafi ye tlwaelehileng ya hao.

Moputso ho tseo di ka hlokang hore o sebedise tshelete ho tswa potleng ya hao. O tla botswa dipotso ka matsatsi ao o neng o tlamehile ho tla sepetlele ka ona. Ha ho ka etsahala hore o tle sepetlela ho tlo botswa dipotso bakeng sa dipatlisiso tsena feela o tla fiwa/neiwa tshelete ya taxi (e sa feteng R100) moraho ha ho botswa dipotso.

Ho tla etswa ka hohle hohle hore hlahiso leseding yeo o tla fanang ka yona e bolokehe/e se ke ya tsejwa ke bohle le lebitso la hao le ka se ke la sebediswa dipatlisisong tsena.

Tsela ya ho ikopanya le babatlisisi:

Lonwabo L Godlwana-Mmatlisisi
Tel: 011 717 3707/072 373 2156
Fax: 011 717 3719
Email: Lonwabo.Godlwana@wits.ac.za

Supervisor: Prof AV Stewart
Tel: 011 717 3718
Email:aimee.stewart@wits.ac.za

Tsela ya ho ikopanya le bakwaledi ba REC le modulasetulo wa bona ho kenya tletlebo/sello: Prof P Cleaton. Jones Wits Research Office, 10th Floor Senate House, East Campus at 011-717-1234 Fax: 011-339-5708

APPENDIX Y

INFORMATION DOCUMENT (ZULU)

Study title: The epidemiology and functional outcomes after a major lower limb amputation (LLA) in Johannesburg
Ngiyanibingelela. – Igama lami uLonwabo Godlwana ngenza inhlolovo mayelana nabantu abanqunywe umlenze nokubona ukuthi bayakwazi yini ukuzenzele izinto empilweni (QOL)

Isingeniso
Thina, Lonwabo Godlwana and Prof AV Stewart, senza inhlolovo mayelana nezinga lokuthinteka kokukwazi ukuzenzela izinto empilweni emva kokunqunywa komlenze. Inhlolovo iyidlela yokuthola izimpendulo emibuzweni esinayo. Ngalendlela sifuna ukuthola umehluko kwindlela abantu abakwazi ukwenza ngayo izinto empilweni emva kokunqumywa umlenze, uma bethola ukwelashwa esibhedlela ngendlela eyejwayelekile nakulabo abathola amaphepha anemininingwane eyengeziwe yokuzivocavoca emakhaya namacebo okushitsha indlela abenza ngayo izinto ezimpilweni zabo.

Isimemo sokuba yingxenye: Siyanimema ukuba nibe yingxenye yalenhlolovo.
Yini enyenziwayo kuloluphenyo? Kuzofanele ubuzwe imibuzo ngaphambi kokunqunywa (imizuzwana ewu-45). Lokho kuzobe kumayelana nemininingwane yakho, ngendlela owenza ngayo izinto, indlela owenza ngayo izinto empilweni yakho nangokweneliseka ngempilo yakho. Emveni kwezinyanga ezintathu noma eziyisithupha uphinda futhi ubuzwe imibuzo isikhathi futhi esiyimizuzwana ewu-45 kuzo futhi izihloko ezifanayo ukuze sibone ukuthi ukhona yini umehluko emveni kokunqunywa. Ngaphezu kwaleyo mibuzo kuyoba khona umbuzo mayelana nedlela oban ngayo umzimba wakho uyophinde ucelwe ukuthi usukume esitulweni uhmbe ibanga elingi-3m uphinde ubuyele esitulweni, uyovunyelwa ukusebenzisa insiza kuhamba yakho. Kungenzeka ukuba uqokwe ube yingxenye yeqembu eliyoqhubeka lizivocavoce isikhathi esiyizinyaga ezintathu likhishiwe esibhedlela.

Izingozi zokuba yingxenye yophenyo. Akukho ukuhlolwa komzimba ngisho okuhlukumezayo kuloluphenyo. Uzodingeka ukuba uphendulo imibuzo noma uma useqenjini eliyozivocavoca emakhaya alo, uma uzivocavoca umile uvumelekile ukusebenzisa izinsiza kuhamba.Uma udinga uxhaso ngokwenqondo, uzothunyelwa kwabasebenza ngenqondo, (Johannesburg Hospital 011 488 4481, Baragwanath Hospital 011 933 8934) .

Imihlomulo yokuba yingxenye yophenyo: Imiphumela yaloluphenyo ingasiza ukuthuthukisa izindlela ezisetshenziswayo ukunakekela esibasizayo emveni kokunqunywa imilenze. Imiphumela yaloluphenyo izovezwa kuwena emveni kokuba uphenyo seluqediwe.Ayikho eminye imihlomulo ezoza kuwe ngaphandle kwalena esibaluliwe ngenhla.

Awuphoqiwe ukuba yingxenye yalenhlolovo: ukwenqaba ekubeni yingxenye akunasijeziso okukanye ukulahlekelwa amalungelo akho ukwelashwa njalonjalo, kanti ungayeka noma yinini uma ufuna.Uyoqhubeka nokwelashwa esibhedlela.

Ukukhokhelwa kwezimo eziphezu kwamandla. Zonke izinhlelo zemibuzo zizohlelwa ngosuku olufanayo lokuvakashela kwakho esibhedlela. Uma kufanele uvakashe nje maqondana nophenyo kuphela, imali yokugibela itekisi uyonikezwa emva kokuphendula imibuzo (ingafika ku-R100).
Imfihlo: Lonke ulwazi olutholakayo luyoba yimfihlo.

Contact details of researchers:
Lonwabo L Godlwana-Researcher
Tel: 011 717 3707/072 373 2156
Fax: 011 717 3719
Email: Lonwabo.Godlwana@wits.ac.za

Supervisor: Prof AV Stewart
Tel: 011 717 3718
Email:aimee.stewart@wits.ac.za

Contact details of REC administration and chair for reporting complaints: Prof P Cleaton. Jones Wits Research Office, 10th Floor Senate House, East Campus at 011-717-1234 Fax: 011-339-5708

APPENDIX Z

PARTICIPANT INFORMED CONSENT (ENGLISH)

DECLARATION

I……………………………………………………. (Full names of participant) hereby confirm that I understand the contents of the information sheet about this study and the nature of the research project, and I consent to participating in the research project. I have been given the opportunity to ask questions from the researcher. I understand that I am at liberty to withdraw from the project at any time, should I so desire with no penalty or lost of benefit to which I am otherwise entitled.

SIGNATURE OF PARTICIPANT:

…………………………………………. Date……………

SIGNATURE OF WITNESS (in the case where the participant puts a mark (X))

…………………………………………. Date……………

Contact details of researchers:

Lonwabo L Godlwana-Researcher
Tel: 011 717 3707/072 373 2156
Fax: 011 717 3719
Email: Lonwabo.Godlwana@wits.ac.za

Supervisor: Prof AV Stewart
Tel: 011 717 3718
Email:aimee.stewart@wits.ac.za

APPENDIX AA

PARTICIPANT INFORMED CONSENT (SOTHO)

LENGWALO LA HO DUMELA HO NKA KAROLO LA MONKAKAROLO

KANO

Nna………………………………………………. (Mabitso ka botlalo a monkakarolo) ke dumela hore ke utlisisa dikahare tsa lengwalo la hlahiso leseding ka ha dipatlisiso tsena, ebile ke dumela ho nka karolo mo dipatlisisong tsena. Ke neilwe/filwe monyetla wa ho botsa/botsisa mmatlisisi dipotso. Ke utlwisisa hore ke lokolohile hore nka ikgohela moraho mo dipatlisisong ka nako efe kapa efeng, ha ke batla/nyaka ntle le kotlo kapa ho lahlehelwa ke ditokelo tse di ntshwanetseng.

SAENILWE KE MONKAKAROLO:

……………………..…………………..….   Letsatsi……………..

SAENILWE KE PAKI (ka sebaka seo monkakarolo a sebedisang letshwao (X))

……………………..…………………..….   Letsatsi……………..

Tsela ya ho ikopanya le babatlisisi:

Lonwabo L Godlwana-Mmatlisisi
Tel: 011 717 3707/072 373 2156
Fax: 011 717 3719
Email: Lonwabo.Godlwana@wits.ac.za

Supervisor: Prof AV Stewart
Tel: 011 717 3718
Email:aimee.stewart@wits.ac.za

APPENDIX AB

PARTICIPANT INFORMED CONSENT (ZULU)

SIVUMELWANO SOKUBA YINGXENYE YENHLOLOVO

Sawubona

Igama lakho litholakale ezincwadini zasesibhedlela …………….……..…hospital), lapho okubekwe ukuthi uzohlinzwa umlenze wakho. Sicela imvume yakho ukuba sihlangane ngengxoxiswano mayelana nempilo yakho ngaphambi nangemva kokunqunywa kwakho.

ISIVUMELWANO

Mina ……..........................(amagama aphelele kothatha ingxenye) ngiyaqiniseka ukuthi ngiyaqondisisa inqikithi yephepha lesivumelwano mayelana naloluphenyo kanye nenqubo yalenhlolovo. Kanti futhi ngiyavuma ukuba yingxenye yalenhlolovo. Ngilitholile ithuba lokubuza kwinhloli. Ngiyaqondisisa ukuthi ngingayeka nomanini kulenhlolovo uma ngifisa ngaphandle kokujeziswa noma ukulahlekelwa amalungelo ami.

SIGNATURE OF PARTICIPANT:

……………………..…………………..….   Usuku ……………..

Ufakazi (lapho oyingxenye ubeka u (X)

……………………..…………………..….   Usuku ……………..

Imininingwano yabancwaningi:

Lonwabo L Godlwana-Researcher
Tel: 011 717 3707/072 373 2156
Fax: 011 717 3719
Email: Lonwabo.Godlwana@wits.ac.za

Supervisor: Prof AV Stewart
Tel: 011 717 3718
Email:aimee.stewart@wits.ac.za

APPENDIX AC

BI SAMPLE SIZE-MAIN OUTCOME MEASURE

ENTER INPUTS HERE… (asterisked items are compulsory)	effect to be detected*:		2
	SD*:		3
	alpha (suggest 5%)*:		5
	power (suggest 80%)*:		90
	non-compliance (%):		15
	dropouts (%):		15
	intraclass correlation co-efficient		0
	mean cluster size		0
	correlation (r) with covariate:		0
ANSWER IS RETURNED HERE…			
	n (per group):		77
	width of confidence interval:		+/- 0.62

APPENDIX AD

INTERVENTION ENGLISH

Lifestyle modification aspects:

Smoking, drinking, keeping active (physical), safety and the prevention of falls, positive perception about body image

Exercises on the following aspects:

Functional exercises

Transfers, positioning, mobility.

Non-functional exercises

Elbow extensors, knee extensors, hip extensors

Controls

Will get the current protocol received by CHBH and CMJAH patients.

Intervention group- all exercises to be done twice a day

Will get the current protocol received by CHBH and CMJAH patients in addition to the following:

Section A

Education on Lifestyle modification:

Negative impact smoking and drinking on the CVS, healing, and general vitality including potential falls related to drinking.

The positive impact of being active (physical).

Importance of safety and the prevention of falls, including awareness about the stump and the potential risk of losing balance or of poor balance and stability, feeling that the amputated limb still exists and forgetting that its not there and attempting to take a step in it and thus falling

Positive perception about body image. Participants will be encourage to handle the stump in order to desensitize it and accept it.

How to care for the stump and the remaining limb to avoid trauma

Section B-

Exercises – <u>do these two times a day.</u> ***Where possible an extra person/ relative or other carer can assist you during these exercises especially when upright (eg standing) or during transfers.***

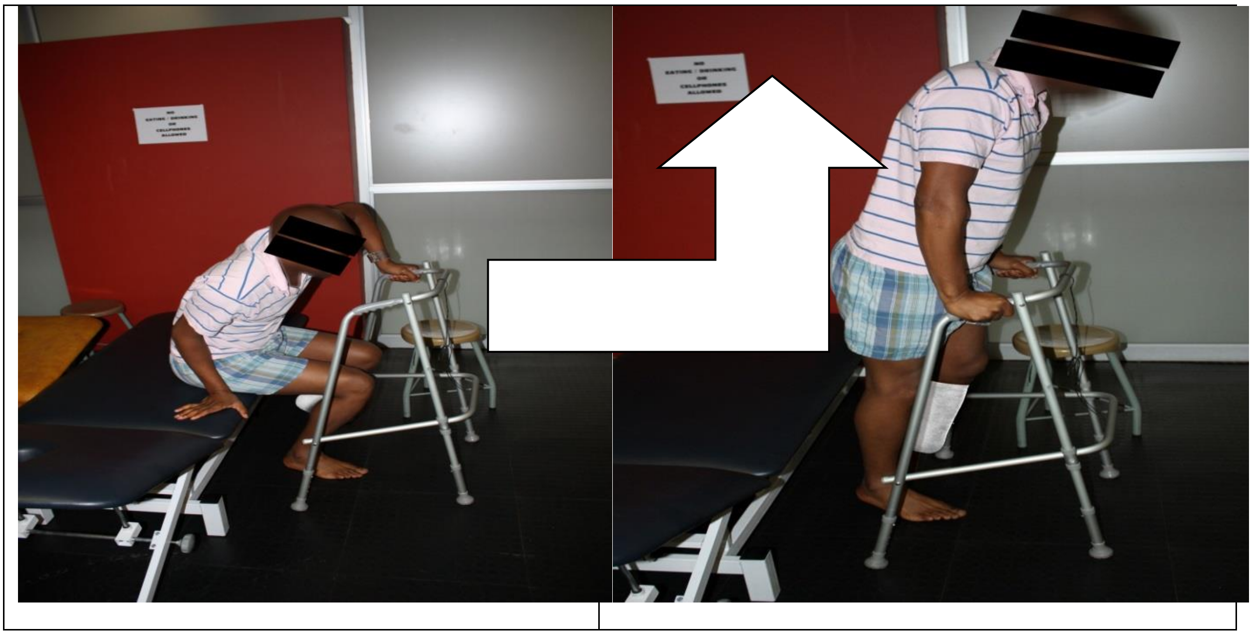
Functional Exercises/ upright

Standing balance: **Stand on the leg and maintain standing**. *Safety*-This must be done next to two supporting surfaces eg a chair and a table/ walking frame/ crutches or next to you bed at home so that if you get tired or you are about you fall you can hold on to one of these and or sit. **Alternatively, please ensure that your walking frame or crutches are readily available to catch your balance during the exercise.** Try to stand 10 repetitions for about 5 seconds and progress by increasing time as you feel you can do more. In the beginning you may need an extra person/ relative or other carer to be next to you during this exercise

Figure 1

In sitting: **practice the action of sitting to standing and back. Use the arms to assist you.** *Safety* as in the first exercise for balance. Do 10 repetitions initially and progress to 30 as tolerated. **Alternatively, please ensure that your walking frame or crutches are readily available to catch your balance during the exercise.**

Figure 2



Ankle/calf exercises- in standing (*<u>Safety</u>* as in the first exercise for balance). **Attempt to stand on toe toes and come down slowly.** Do 10 repetitions initially and progress to 30 as tolerated. Eccentric and concentric plantarflexors. **Alternatively, please ensure that your walking frame or crutches are readily available to catch your balance during the exercise. Figure 3**

<u>Transfers:</u> always ensure you have somebody available to help during transfers (*<u>for safety)</u>*, however, **as much as possible do the transfer on your own.** <u>Safety-</u> plan your transfer and ensure that the surfaces you are transferring between are in close proximity. Always remember that you have one leg so that you won't use the stump side to put weight and end up falling. **Alternatively, please ensure that your walking frame or crutches are readily available to catch your balance during the exercise. Figure 4**

Section C-

Non functional exercises/ not upright even if functional

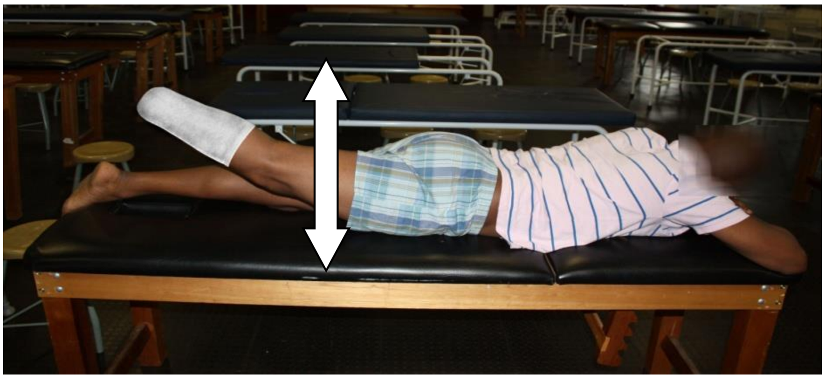
Positioning: **Lie on your stomach**. In bed, keep your hips and knees straight and you can be on your elbows if you can tolerate (this will promote the hip stretch). Maintain this position for 10 minute initially and progress to 30 minute as tolerated.

Figure 5A

Figure 5B

Lie on your stomach: do hip stretches 20-30 times

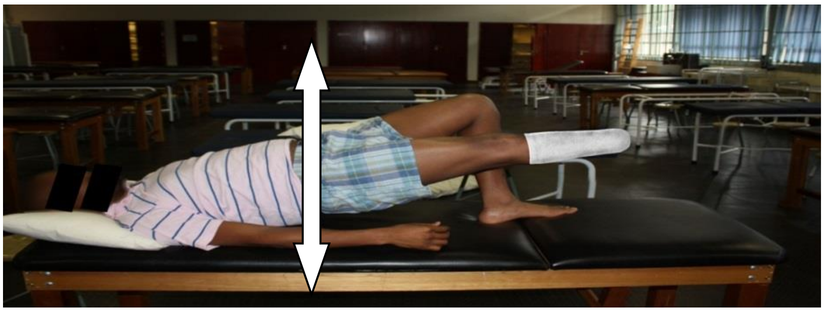
Figure 6



When **lying on your back**: do not put a pillow or pillows under your stump so that the stump leg is straight.

Figure 7

<u>Hip exercises:</u> **lie on your back, bend your good leg and lift you bum by tightening your bums and making a space between you and the bed**. Do 10 repetitions initially and progress to 30 as tolerated. Concentric hip extensors **Figure 8**



Lie on your back, lift your leg up while keeping it straight and down slowly. Do the same with the stump. Eccentric and concentric hip flexors (SLR). **Figure 9A**

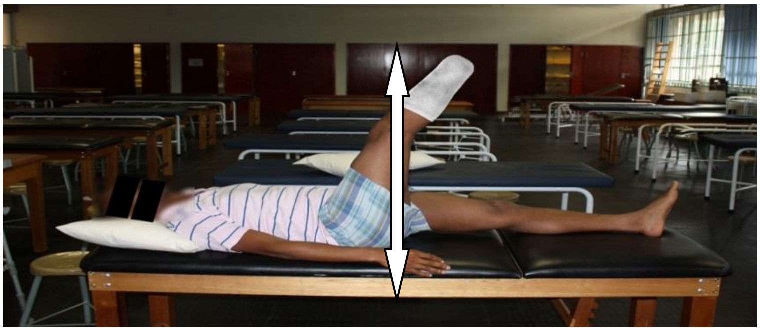
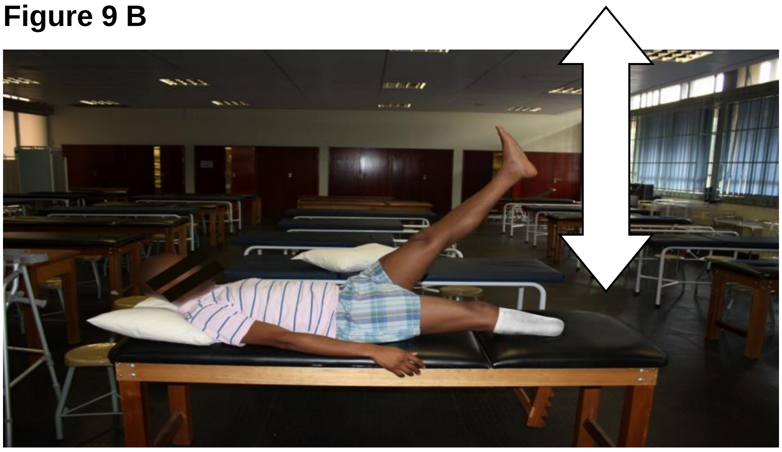


Figure 9 B



APPENDIX AE

INTERVENTION SOTHO

Ka ha ho fetola maemo a tsa bophelo:

Ho kgoha/tsuba, ho nwa, ho ba matjato (tsa mmele), polokeho le ho thibela ho wa, ho bona seemo sa mmele ka tsela e hantle

Ho ikwetlisa ho maemo a latelang:

Ho ikwetlisa ho tsamaisanang le tshebediso ya mmele

Ho theoha le ho palama dintho, ho beyakanya mmele/ditho tsa mmele, ho sepela/ho itshitshinya,

Ho ikwetlisa ho sa tsamaisaneng le tshebediso ya mmele

Ho otlolla sekhu, ho otlolla letolo/lengwele, ho otlolla letheka

Ba sa fumaneng/tholeng ikwetliso

Ba tla fumana tse etswang ke bakudi ba CHB le CMJAH ka mehla.

Sehlopha se sa fumaneng/tholeng ikwetliso

Ba tla fumana tse etswang ke bakudi ba CHB le CMJAH ka mehla ba fumane hape tse latelang:

Karolo A

Thuto ka ha ho fetola maemo a tsa bophelo:

Tsela e mpe eo ho tsuba le ho nwa di amang amadi le pelo, ho fola/alafeha, le ho phela hantle ka kakaretso ho kenyeletsa le kgoneho ya ho wa ho tsamayelanang le ho nwa

Tsela e ntle eo ho ba matjato ho ka amang mmele ka yona (tsa mmele),

Bohlokwa ba ho bolokeha le ho thibela ho wa, ho kenyeletsa le ho tseba ka ha karolo eo e kgaotsweng le ho kgonahala ha kotsi ya ho thekatheka kapa ho thekatheka le ho ikema, ho utlwa e kare karolo eo e kgaotseng e sale hona/teng le ho lebala hore karolo eo ha e gona/teng le ho leka ho hata ka leoto le seng teng ho etsang hore o we.

Ho bona seemo sa mmele ka tsela e hantle. Banka karolo ba tla rotloetswa/kgothaletswa ho tshwara karolo e kgaotsweng/ripilweng ho re e tlwaele ho tshwariwa le hore ba tsebe ho e amohela.

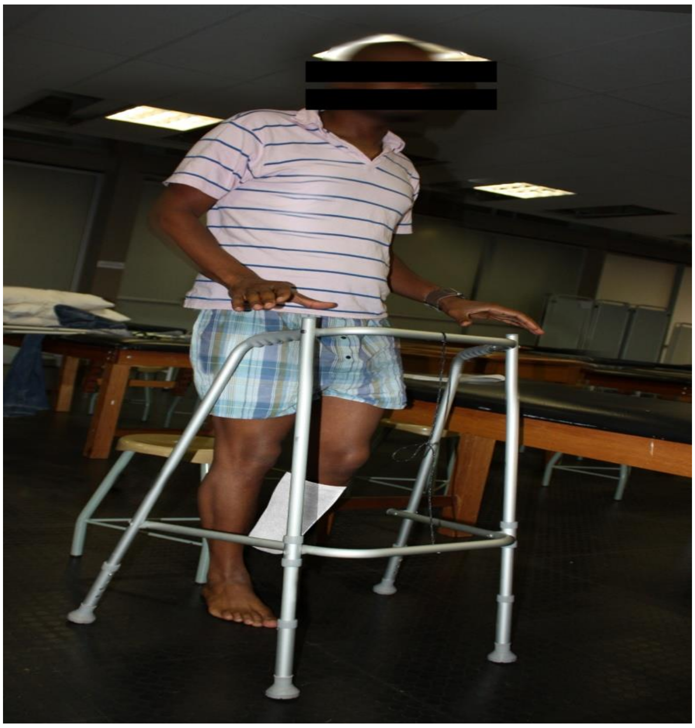
Ho re ba ka hlokomela jwang karolo e kgaotsweng ya mmele le leoto/letsoho le sa amehang ho thibela ho lemala/gobala.

Karolo B

Boikwetliso – etsa/dira tsena ha bedi ka letsatsi. **Mo ho kgonehang motho e mong/wa leloko kapa e mong wa bahlokomedi a ka ho thusa ha o etsa ikwetliso ena haholo ha o emeletse (mohlala: o emeletse ka maoto) kapa ha o theoha kapa o palama dintho.**

Ho ikwetlisa ho tsamaisanang le tshebediso ya mmele/o emeletse

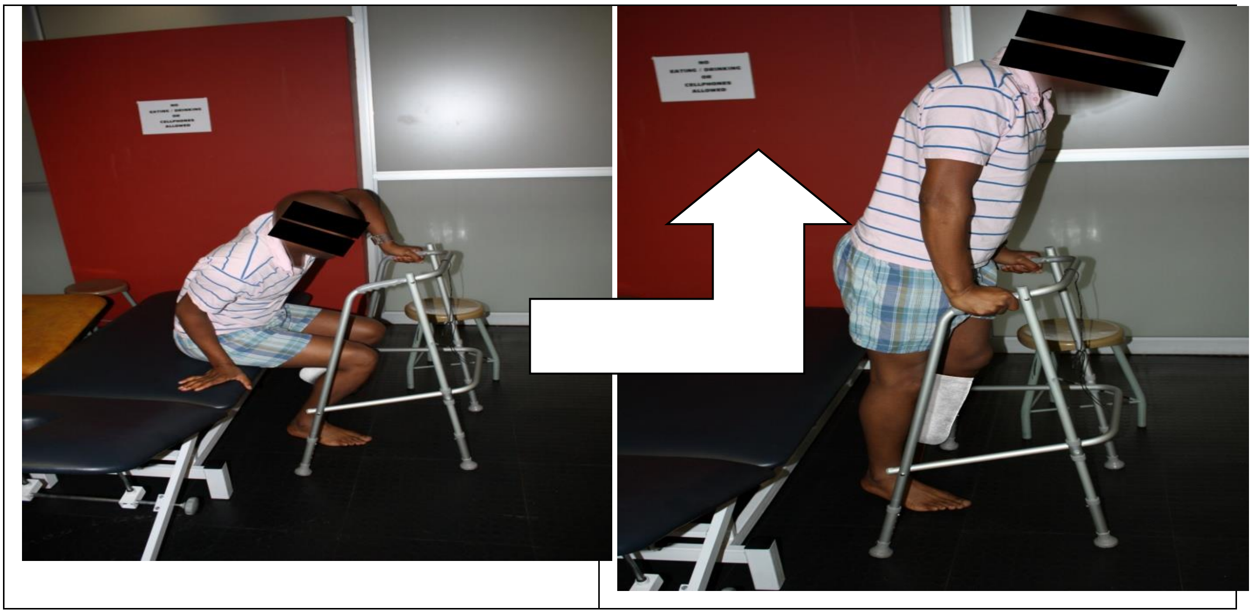
Ho thekatheka ha o emeletse: **Ema ka leoto le le leng/teye o eme jwale.** *Tsa polokeho* – Sena se tlamehilwe ho etswa haufi le baka tse pedi mo o ka intshwarelelang, mohlala setulo le tafola haufi le bethe/mpete wa hao ka hae hore ha o kgathala kapa ha o utlwa e kare o tla wa o kgone ho itshwarelela ho enngwe ya tsena kapa ho dula. **Kapa , hle etsa ho re foreyeme ya hao ya ho tsamaya kapa dithupa tsa ho tsamaya di fumaneha ha bonolo ho re o kgone ho itshwarelela ha ho ka etsahala hore o thekatheke ha o ntse o ikwetlisa.** Leka ho ema metsotswana e ka bang 5 o tswelele ka ho oketsa nako ha o utlwa ho re o ka etsa ho feta moo. Mathomong o ka hloka motho e mong/wa leloko kapa e mong wa bahlokomedi ho ba haufi le wena ha o ikwetlisa.



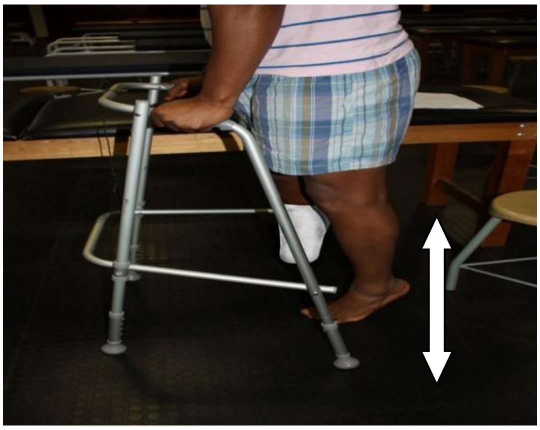
Setshwantsho 1

O ntse/dutse: **leka mokgwa/tsela ya ho dula o emelela. Sebedisa matsoho ho ho thusa.** *Polokeho* e tshwana le ya ikwetliso ya mathomo ya tsa thekatheko. Thoma ka ho phetha/buseletsa ha 10 o tswelele ho fihla ho 30 ho ya le ka moo o kgonang. **Etsa ho re foreyeme ya hao ya ho tsamaya kapa dithupa tsa ho tsamaya di fumaneha ha bonolo ho re o kgone ho itshwarelela ha ho ka etsahala hore o thekatheke ha o ntse o ikwetlisa.**

Setshwantsho 2



Ho kwetlisa kokoilane/lenakaila- o emeletse (*__Polokeho__* e tshwana le ya ikwetliso ya mathomo ya tsa thekatheko). **Leka ho ema ka menwana ya maoto mme o theohe ha nnyane.** Thoma ka ho phetha/buseletsa ha 10 o tswelele ho fihla ho 30 ho ya le ka moo o kgonang. <u>Eccentric and concentric plantarflexors</u> **Etsa ho re foreyeme ya hao ya ho tsamaya kapa dithupa tsa ho tsamaya di fumaneha ha bonolo ho re o kgone ho itshwarelela ha ho ka etsahala hore o thekatheke ha o ntse o ikwetlisa.** Setshwantsho 3



<u>Ho theoha le ho palama dintho:</u> etsa ho re ka mehla o be le motho ya tla ho thusang ha o <u>theoha le ho palama dintho</u> (<u>hore o bolokehe</u>), **empa, leka ka hohle hole hore o theohe le ho palama dintho ka bowena/ntle le thuso.** <u>Polokeho-</u> beyakanya ho theoha le ho palama dintho ha hao ho etsa hore mo o theohelang kapa o palamelang teng ke kgaufi le kgaufi. Hopola ka mehla hore o na le leoto letee hore o se ke wa sebedisa hlakore le kgaotsweng ho beya boima bja mmele wa feletsa o wele. **Etsa ho re foreyeme ya hao ya ho tsamaya kapa dithupa tsa ho tsamaya di fumaneha ha bonolo ho re o kgone ho itshwarelela ha ho ka etsahala hore o thekatheke ha o ntse o ikwetlisa.**

Setshwantsho 4

Karolo C

Ho ikwetlisa ho sa tsamaisaneng le tshebediso ya mmele/o sa emelela le ha ho tsamaisana le tshebediso ya mmele

<u>Ho beyakanya mmele/ditho tsa mmele:</u> **Robala ka mpa**. Mpeteng, letheka le mangwele/dikhuru di tshwanetse go dula di otlolohile o ka itshetleha ka dingalo/dijabana ge o kgona (sena se tla etsa hore letheka le otlolohe). Thoma ka ho ba jwale metsotso ye 10 o tswelele ho fihla ho ye 30 ho ya le ka moo o kgonang.

Setshwantsho 5 A

Setshwantsho 5 B

Robala ka mpa: otlolla letheka la hao 20-30 times

Setshwantsho 6

Ha o **robetse ka mokokotlo**: o se ke wa beya mosamelo ka tlase ha karolo e kgaotsweng ya mmele hore karolo ya leoto e kgaotsweng e otlolohe.

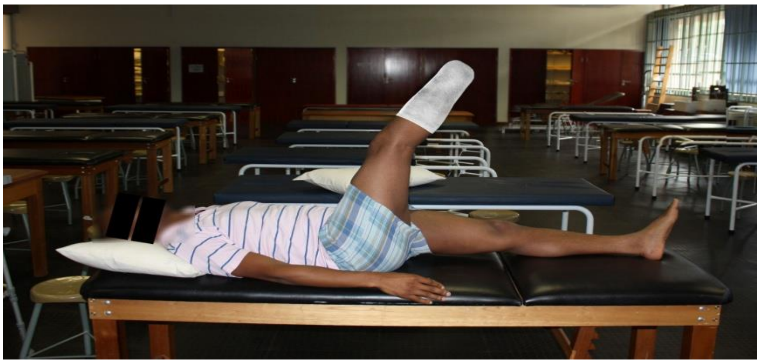
Setshwantsho 7

Boikwetliso ba letheka: **robala ka mokokotlo, thinya/koba leoto la hao le phetseng hantle mme o phahamise leraho empa o tiise maraho o etsa hore ho be le sekaka mahareng ha hao le mpete.** Thoma ka ho phetha/buseletsa ha 10 o tswelele ho fihla ho 30 ho ya le ka moo o kgonang. Concentric hip extensors.

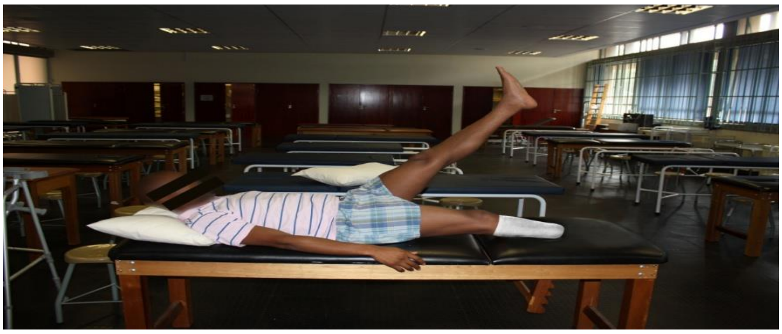
Setshwantsho 8

Robala ka mokokotlo, phahamisa leoto la hao o etse hore le dule le otlolohile o be o le theose ka bonya/ha nnyane. Etsa jwale le ka leoto le kgaotsweng. Eccentric and concentric hip flexors (SLR).

Setshwantsho 9 A



Setshwantsho 9 B



APPENDIX AF

INTERVENTION ZULU

Izindlela zokushintsha indlela ophila ngayo:

Ukubhema, ukuphuza, ukuhlala ngokuzivocavoca, izindlela eziphephile zokuvikela ukuwa, indlela elungile yokubheka umzimba wakho.

Smoking, drinking, keeping active (physical), safety and the prevention of falls, positive perception about body image

Izindlela ezahlukene zokuzivocavoca

Ukuzivocavova ngokwenza izinto zakho zemihla

Ukushitsha indawo ubuhlezi kuyo uye kwenye,ukuhlala, ukuhamba.

Ukujima

Ukuzithutha, indlela yokuhlala, ukuzinyakazisa,

Ukuzijimisa

Ukusebenzisa indololwani, amadolo, amanyonga

Iqembu elizonakekelwa ngokwejwayelekile

Kuzotholakala inqubo etholwa iziguli e-CHB ne CMJAH

Bazothola ukunakekelwa ngendleya yase CHB ne CMJAH.

Iqembu elizotho ukwelashwa ngokwengeziwe:

Kuzotholakala inqubo etholwa iziguli e-CHB ne CMJAH kwengezwe ngalokhu okulandelayo:

Ingxenye A

Imfundiso ngendlela yokushitsha indlela ophila ngayo:

Imiphumela emibi ukubhema nokuphuza okulimaza ngayo intliziyo nemithambo, ukwelapheka, nama general vitality including potential falls related to drinking

Imiphumela emihle yokuhlala ngokuzivocavoca,

Ukubaluleka kokuphepha nokuvikela ukuwa, kuhlanganisa nokwazi kabanzi nge-stump kanye namathuba amaningi obungozi bokuwa noma ukungakwazi ukuma kahle okungadala ukuthi uwe, nokuzwa sengathi ilunga lomzimba elinqunyiwe lisekhona nokukhohlwa ukuthi alisekho uzame ukuhamba ngalo libe lingekho okungaholela ekutheni uwe.

Izindlela ezinhle zokubheka umzimba wakho. Abantu ababambe iqhaza bayokhuthazwa ukthi babambenoma bacumbaze i-stump ukwehlisa ukuthi sisheshe sizwele nokusamukela.

Sinakekelwa kanjani i-stump namanye amalunga omzimba ukuvikela ukulimala

.

Ingxenye -B

Ukuzivocavoca – **Zivocavoce kabili ngosuku.** ***Uma kungenzeka umuntu/ isihlobo noma umuntu okusizayo angakusiza uma uzivocavoca ngendlela elandelayo, ikakhulukazi uma umile noma usuka kwenye indawo uya kwenye.***

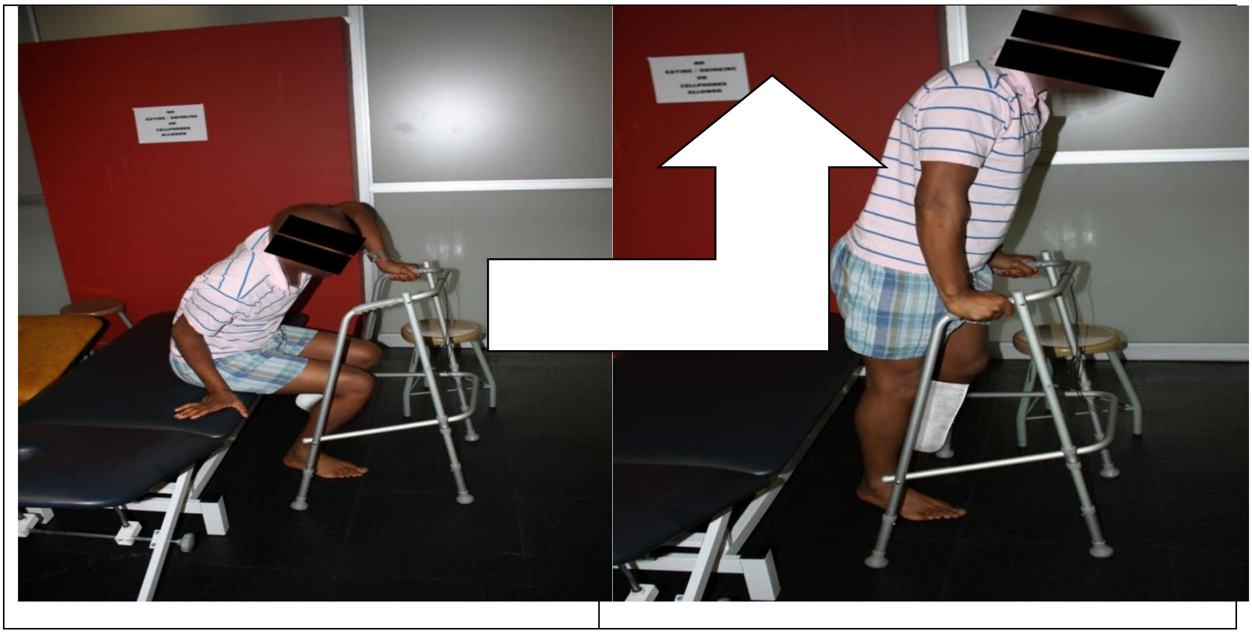
Ukuzijimisa

Ukuma: **Yima ngomlenze owodwa qhubeka ume imizuzwana.** Ukuphepha-Lokho kumele kwenziwe eduze kwezinto ezimbili zokubambelela isibonelo, isitulo netafula noma eduze kombede endlini yakho ukuze uma ukhathala noma uzwa sengathi ufuna ukuwa ukwazi ukubambelela kwezinye zalezizinto noma uhlale kuzo. **Qiniseka ukuthi izinsiza kuhamba zakho ziseduze nawe uma uzidinga ngenkathi uzivocavoca.** Zama ukuma amasekhondi amahlanu(5) qhubeka wenyuse isikhathi uma uzizwa ukuthi ungakwazi ukuqhubeka ume. Ekuqaleni ungamdinga omunye umuntu/isihlobo noma umuntu okusizayo abe seduze nawe uma uzivocavoca.

Isithombe 1

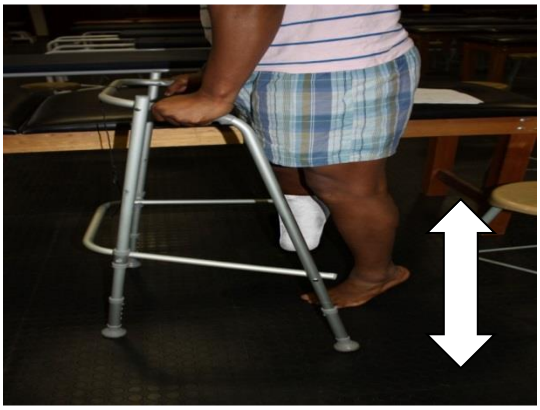
Uma uhleli: **Sukuma ume uphinde uhlale phansi (phindaphinda lokho). Sebenzisa izingalo zakho ukukusiza wenze lokho.** *Ukuphepha* **njengasekuqaleni uzivocavocela ukuma kahle.** Phindaphinda lokho ka-shumi (10) ekuqaleni uqhubeke uye emashumini amathathu (30) uma ukwazi. **Qiniseka ukuthi izinsiza kuhamba zakho ziseduze nawe uma uzidinga ngenkathi uzivocavoca.**

Isithombe 2



Ukuvocavoca iqakala- Uma umile (Ukuphepha, **njengasekuqaleni uzivocavocela ukuma kahle)**. Zama ukuma ngeminwe yezinyawo wehle kancane**.** Phindaphinda lokho ka-shumi (10) ekuqaleni uqhubeke uye emashumini amathathu (30) uma ukwazi. **Qiniseka ukuthi izinsiza kuhamba zakho ziseduze nawe uma uzidinga ngenkathi uzivocavoca.**

Isithombe 3



ukuzithutha: Ngasosonke isikhathi zama ukuhlala unomuntu ongakusiza uma wenza ama-transfers (*Ukuphepha)*, zama ngakho konke ukwenza i-transfer ngokwakho**. Ukuphepha-** Hlela i-transfer yakho uqiniseke ukuthi indawo o-transferring phakathi kwazo zisondeleni futhi ziseduze kwakho. Ngasosonke isikhathi khumbula ukuthi unomlenze owodwa ukuze ungazimeleli kwi-stump okungeza ukuthi uwe. **Qiniseka ukuthi izinsiza kuhamba zakho ziseduze nawe uma uzidinga ngenkathi uzivocavoca.**

Isithombe 4

Ingxenye C-

Ukujimela embhedeni(Non functional exercises/ not upright even if functional)

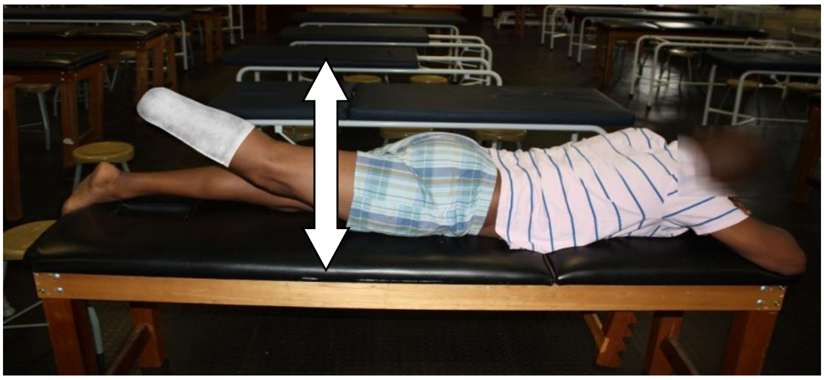
<u>Uqala la:</u> **Lala ngesisu**. Embedeni , Gcina ama-hips kanye namadolo eqondile ugobise nezindololwane uma ungakwazi (lokho kuzokhuthaza ukudonseka kwe-hip). Yini ngalendlela imizuzu eyishumi (10) ekuqaleni uqhubekele emashumini amathathu (30) uma ungakwazi.

Isithombe 5 A

Isithombe 5 B

Lala ngesisu: Yenza i-hip stretches imizuzu engamashumi amabili kuya kwamathathu (20-30)

Isithombe 6

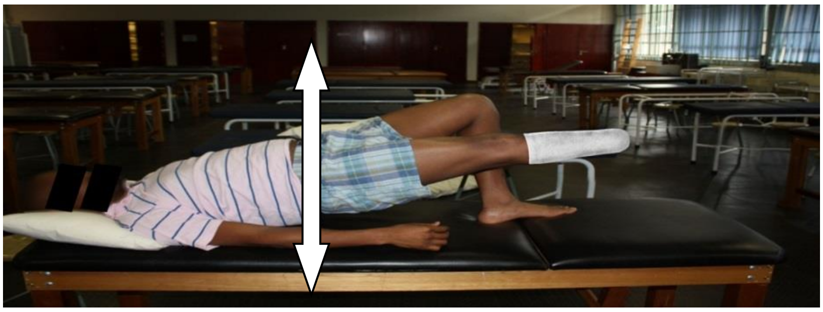


Uma ulele ngomqolo: Ungabeki umqamelo noma imiqamelo ngaphansi kwe-stump sakho ukuze i-stump somlenze siqonde.

Isithombe 7

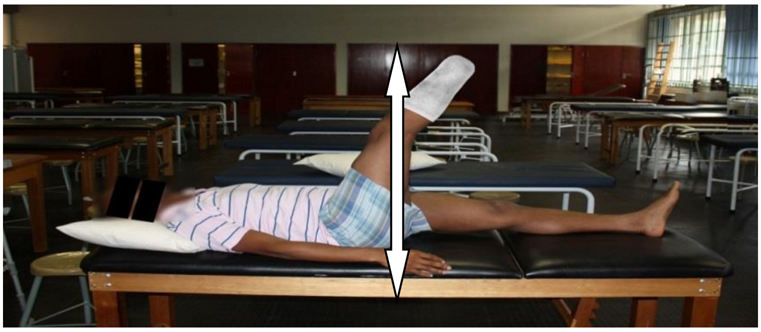
<u>Ukujimisa inyonga:</u> **Uma ulele ngomqolo, Gobisa idolo lomlenze ongalimele phakamisa izinqe zakho uziqinise uvule isikhale phakathi kwakho nombede.** Phindaphinda lokho ka-shumi (10) ekuqaleni uqhubeke uye emashumini amathathu (30) uma ukwazi.

Isithombe 8

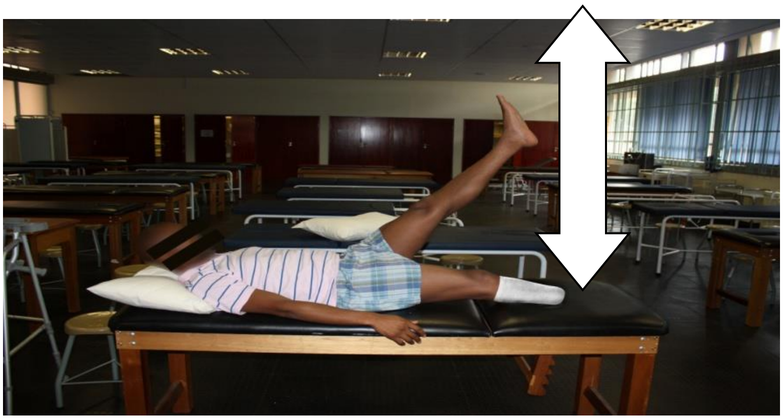


Uma ulele ngomqolo, phakamisa umlenze wakho uwugcine uqondile bese uwubuyisela phansi kancane. Yenza okufanayo nge-stump.

Isithombe 9 A



Isithombe 9 B



APPENDIX AG

EXERCISE DIARY ENGLISH

Instructions for use-From discharge until 3 month after the operation. Please tick (√) twice a day if you did them twice for each exercise.

Example 1

Week 1

Exercises done	Monday	Tuesday	Wednesday	Thursday	Friday	**Saturday**	**Sunday**
Section A	√			√			
Section B	√√	√√	√√	√√	√√	√	√√
Section C	√√	√√	√√	√√	√√	√	√√

This sampled week reports that you reminded yourself on the education on lifestyle modification on Monday and Thursday on week 1 and you performed the physical exercises twice a day every day except on Saturday of this week you did them once a day.

Example 2

Week 8

Exercises done	Monday	Tuesday	Wednesday	Thursday	Friday	**Saturday**	**Sunday**
Section A							
Section B	√√	√√	√√	√√	√√	√√	√√
Section C	√√	√√	√√	√√	√√	√√	√√

This sampled week reports that you during week 8 you performed the physical exercises twice a day every day.

APPENDIX AH

EXERCISE DIARY SOTHO

Tsatsi puka ya ikwetliso –

Ditaelo tsa tshebediso- Ho tloha ha o lokollwa sepetlele ho fihlela nakong ya kgwedi tse 3 moraho ha ho etswa karo/opereshene. Hle tshwaya (√) habedi ka letsatsi ha o di entse habedi ho ikwetliso efe kapa efe.twice a day if you did them twice for each exercise.

Mohlala 1

Beke 1

Ikwetliso e enstwe	Mantaha/ Mosupoloho	Labobedi	Laboraro	Labone	Labohlano	**Mokibelo**	**Sontaha**
Karolo A	√			√			
Karolo B	√√	√√	√√	√√	√√	√	√√
Karolo C	√√	√√	√√	√√	√√	√	√√

Beke ena e kgethilweng e bontsha hore o ekgopoditse ka ha ho ithuta ka ho fetola maemo a tsa bophelo ka Mantaha le Labone ka beke 1 ebile o ikwetlisitse mmele habedi ka letsatsi tsatsi le lengwe le le lengwe ntle le ka Mokibelo wa beke ena moo o di entseng ha tee/nngwe ka lestatsi. Mohlala 2

Beke 8

Ikwetliso e enstwe	Mantaha/ Mosupoloho	Labobedi	Laboraro	Labone	Labohlano	**Mokibelo**	**Sontaha**
Karolo A							
Karolo B	√√	√√	√√	√√	√√	√√	√√
Karolo C	√√	√√	√√	√√	√√	√√	√√

Beke ena e kgethilweng e bontsha hore nakong ya beke 8 o ikwetlisitse mmele habedi ka letsatsi tsatsi le lengwe le le lengwe.

APPENDIX AI

EXERCISE DIARY ZULU

Uhlelo lokuzivicavicaExercise diary –

Imithetho yokusebenzisa loluhlelo-Ukuphuma esibhedlela kuze kube izinyanga ezintathu emva kokunqunywa. Sicela umake (√) kabili ngosuku uma uzivocavoce kabili uhla ngalunye lokuzivocavoca.

Isibonelo 1

Isonto 1

ExUkuzivocavoca ukwenziwe	UMsobuluko	ULwesibili	ULwesithathu	ULwesinu	ULwesihlanu	UMgqibelo	Isonto
Ingxenye A	√			√			
Ingxenye B	√√	√√	√√	√√	√√	√	√√
Ingxenye c	√√	√√	√√	√√	√√	√	√√

Lesisibonelo seviki sisho ukuthi uzikhumbuze ngokwakho ukuzifundisa ngezindlela zokushintsha izinto empilweni yakho ngo-Msombuluko nango-Lwesine esotweni lokuqala nanokuthi uzivocavocile kabili ngosuku nsukuzonke ngaphandle ko-Mgqibelo kuleliviki uzivocavoce kanye ngosuku.

Example 2

Week 8

ExUkuzivocavoca ukwenziwe	UMsobuluko	ULwesibili	ULwesithathu	ULwesinu	ULwesihlanu	UMgqibelo	Isonto
Ingxenye A	√			√			
Ingxenye B	√√	√√	√√	√√	√√	√√	√√
Ingxenye c	√√	√√	√√	√√	√√	√√	√√

Lesisibonelo seviki sisho ukuthi evikini lesishiyagalombili (8) uzivocavoce kabili ngosuku nsukuzonke.

APPENDIX AJ

STANDARD LCI

The common question is "whether or not you wear your prosthesis at the present time, would you say that you are able to do the following activities with your prosthesis on? "

		0	1	2	3
1	Get up from a chair				
2	Pick up an object from the floor when you are standing up with your prosthesis				
3	Get up from the floor (e.g. if you fell)				
4	Walk in the house				
5	Walk outside on even ground				
6	Walk outside on uneven ground (e.g. grass, gravel, slope)				
7	Walk outside in inclement weather (e.g. snow, rain, ice)				
8	Go up the stairs with a hand-rail				
9	Go down the stairs with a hand-rail				
10	Step up a sidewalk curb				
11	Step down a sidewalk curb				
12	Go up a few steps (stairs) without a rail-hand				
13	Go down a few steps (stairs) without a rail-hand				
14	Walk while carrying an object				

Total __________

Key:

0= No, 1=yes if someone helps me, 2= yes if someone is near me,3= yes, alone

APPENDIX AK

MODIFIED LCI

The common question is “whether or not you wear your prosthesis at the present time, would you say that you are able to do the following activities (walking aid included)?”

		0	1	2	3
1	Get up from a chair				
2	Pick up an object from the floor when you are standing up with your walking aid				
3	Get up from the floor (e.g. if you fell)				
4	Walk in the house				
5	Walk outside on even ground				
6	Walk outside on uneven ground (e.g. grass, gravel, slope)				
7	Walk outside in inclement weather (e.g. rain, wet surface)				
8	Go up the stairs with a hand-rail				
9	Go down the stairs with a hand-rail				
10	Step up a sidewalk curb				
11	Step down a sidewalk curb				
12	Go up a few steps (stairs) without a rail-hand				
13	Go down a few steps (stairs) without a rail-hand				
14	Walk while carrying an object				

Total __________

Key: 0= No, 1=yes if someone helps me, 2= yes if someone is near me,3= yes, alone

APPENDIX AL

MODIFIED LCI SOTHO

Potso/potsiso ye tlwaelehileng ke hore “naa o apara/jwara kapa ha o apare/jware karolo ya mmele ya maiketsetso nakong ya jwale, naa o ka re o kgona go etsa/dira dintho tse latelang (ho kenyeletsa thobane/thupa ya ho sepela/tsamaya)?”

		0	1	2	3
1	Ho emelela ho tswa setulong				
2	Ho nopa/thwala ntho fatshe ha o emelela o sebedisa thobane/thupa ya hao ya ho sepela/tsamaya				
3	Ho phahama ho tloha fatshe (mohlala: moraho ha hore o we)				
4	Ho tsamaya/sepela ka mo ntlong/hara ntlu				
5	Ho tsamaya/sepela ka ntle mo lebaleng le lekalekanelang				
6	Ho tsamaya/sepela ka ntle mo lebaleng le sa lekalekanelang (mohlala: jwang, majwe/maswika/mmoto)				
7	Ho tsamaya/sepela ka ntle ha boemo ba leratadima bo le bobe/bogale (mohlala: pula, lebala le kolobileng/metsi)				
8	Ho palama direpudi/ditepisi o itshwareletse mo sekokotlelong				
9	Ho theoha/foloha direpudi/ditepisi o itshwareletse mo sekokotlelong				
10	Ho palama/namela mmotwana/setepe sa ka mo thoko/hlakoreng ha tsela				
11	Ho theoha/foloha mmotwana/setepe sa ka mo thoko/hlakoreng ha tsela				
12	Ho palama/namela direpudi/ditepisi tse mmalwanyana ntle le ho itshwarelela mo sekokotlelong				
13	Ho theoha/foloha direpudi/ditepisi tse mmalwanyana ntle le ho itshwarelela mo sekokotlelong				
14	Ho sepela/tsamaya o rwele/tshwere ntho/morwalo				

Key:

0= Aowa/, 1=Eya ha ho na le motho ya nthusang, 2= Eya ha ho na le motho haufi le nna,3= Eya, ke le mong/noshi

APPENDIX AM

MODIFIED LCI ZULU

Umbuzo ojwayelekile "uyawugqoka noma awuwugqoki umlenze wokufakelwa manje, noma ungathi uyakwazi ukwenza lezinto ezilandelayo (ngezinduku)? ”

		0	1	2	3
1	Ukusukuma esitulweni				
2	Ukucosha into phansi uma umile ngomlenze wakho wokufakelwa.				
3	Ukuvuka phansi (isibonela, uma kade uwile)				
4	Ukuhamba endlini				
5	Ukuhamba phandle emhlabeni olinganayo				
6	Ukuhamba phandle emhlabeni ongalingani (isibonela, etshanini, emhlabeni onamatshe,endaweni eyehlelayo)				
7	Ukuhamba phandle esimweni sezulu esingesihle (isibonela, emvuleni,endaweni emanzi)				
8	Ukwenyuka izitebhisi ngento yokubambelela				
9	Ukwehla izitebhisi ngento yokubambelela				
10	Step up a sidewalk curb				
11	Step down a sidewalk curb				
12	Ukwenyuka izitebhisi ezimbalwa ngaphandle kwento yokubambelela.				
13	Ukwehla izitebhisi ezimbalwa ngaphandle kwento yokubambelela.				
14	Ukuhamba uphethe into ezandleni				

Key:

0= No, 1=Yebo, uma kukhona ongisizayo, 2= Yebo, uma kukhona oseduze kwami,3= Yebo, ngingedwa

APPENDIX OF RESULTS

APPENDIX ia

ADJUSTING FOR BASELINE DIFFERENCES

Key when reading the graphs:

Amputation level 5- BKA

Amputation level 8-AKA

On the horizontal axis (where 1 and 2 appears with an outcome measure) 1 is the three months follow up and 2 is the six months follow up

totPS0 – total P-scale at baseline (total P-scale at time zero)

BI0 – total BI at baseline (total BI at time zero)

mlcitot3- total MLCI at three months

bmlcitot3- total basic MLCI at three months

bmlcitot6- total basic MLCI at six months

amlcitot3- total advanced MLCI at three months

amlcitot6- total advanced MLCI at six months

totmab3- total MABIS at three months

totmab6- total MABIS at six months

eq5dindex0- EQ-5D index at baseline (at time zero)

VAS0- EQ-5D VAS at baseline (at time zero)

tug3- TUG at three months

tug6- TUG at six months

1. **Participation restriction**

Table 1a illustrates the within group comparisons of P-Scale

Table 1a: within group comparisons of P-Scale

P-Scale						
	Baseline to 3months			3-six months		Baseline to 6months
	25th percentile Median 75th percentile At baseline	25th percentile Median 75th percentile at three months	Related samples Wilcoxon signed rank test p-value	25th percentile Median 75th percentile at six months	Related samples Wilcoxon signed rank test p-value	Related samples Friedman's 2 way ANOVA test p-value
Group1 n=62	0 0 0	10 26.5 41.25	0.0001	1.75 15 30	0.0001	0.0001
Group2 n=59	0 0 5	6 15 28	0.0001	0 15 25	0.102	0.0001

$p \leq 0.05$ is significant.

Table 1a shows that both groups experienced significant changes (p=0.0001) in participation restriction from baseline to six months postoperatively as revealed by the Friedman's 2 way ANOVA. A post hoc test to determine where the change was, shows that both groups experienced a significant increase (p=0.0001) in participation restriction from baseline to three months postoperatively. Group 1 further shows a significant decrease (p=0.001) in participation restriction from three to six months postoperatively while no significant change (p=0.102) was detected in Group 2 during this period.

Examination of the influence of baseline difference in level of amputation on P-scale outcomes

Generalised Linear Model (GLM) Repeated measure Analysis of Covariance (RM ANCOVA) was used to adjust for the baseline difference in level of amputation on participation (Group 1, n=62; Group 2, n=59).

Table 1b illustrates tests of between-subjects effects transformed variable: Average P-Scale

Table 1b: Between-subjects effects transformed variable: Average P-Scale

Source	Type III Sum of Squares	df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Intercept	56726.719	1	56726.719	140.128	0.0001	.545	140.128	1.000
Group	2840.637	1	2840.637	7.017	0.009	.057	7.017	.748
Amputation level	614.709	1	614.709	1.518	0.220	.013	1.518	.231
Baseline P-Scale	560.643	1	560.643	1.385	0.242	.012	1.385	.215
Error	47364.082	117	404.821					

p≤0.05 is significant.

Table 1b shows that although the groups were not similar by level of amputation, this played no significant (p=0.220) role in participation restriction outcomes of the two groups.

Figure 1 illustrates the variance of participation restriction from three months (1) to six months (2) for the groups.

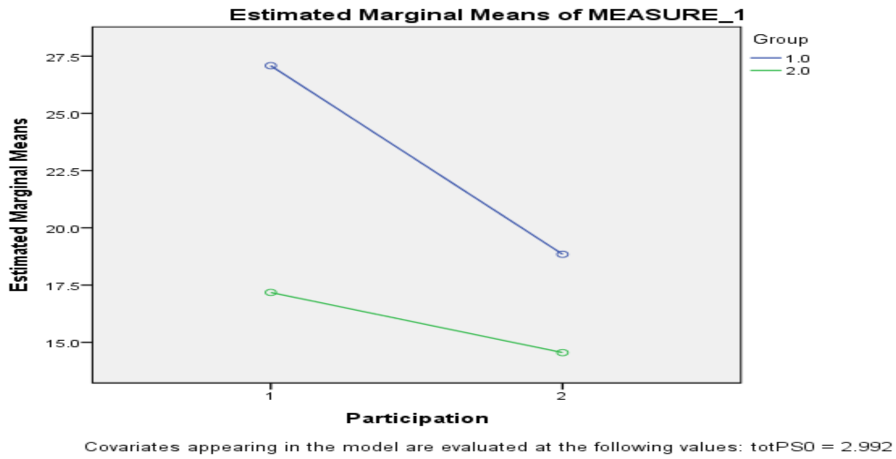


Figure 1: Variance of participation restriction from three months (1) to six months (2) for the groups.

Footnote: in the figure, Measure_1 is P-scale, in the horizontal axis 1 is three months and 2 is six months period.

Figure 1 shows a steep decline in participation restriction (increasing participation levels) in Group 1 compared to Groups 2 from three to six months. This means that although the intervention helped Group 2 to be less restricted in participation at three months compared to Group 1, Group 1 had a natural recovery and caught up with Group 2 by six months indicating that Group 2 did not lose function from three to six months.

2. Activity limitation

Table 2a illustrates the within group comparisons of the BI

Table 2a: within group comparisons of the BI

BI						
	Baseline to 3months			3-six months		Baseline to 6months
	25^{th} percentile Median 75^{th} percentile At baseline	25^{th} percentile Median 75^{th} percentile At three months	Related samples Wilcoxon signed rank test p-value	25^{th} percentile Median 75^{th} percentile At six months	Related samples Wilcoxon signed rank test p-value	Related samples Friedman's 2 way ANOVA test p-value
Group1 n=62	20 20 20	16 18 19	0.0001	18 18 20	0.001	0.0001
Group2 n=59	20 20 20	18 18 20	0.0001	18 18 20	0.180	0.0001

p≤0.05 is significant.

Table 2a shows that both groups experienced significant changes (p=0.0001) in activity limitation from baseline to six months postoperatively as revealed by the Friedman's 2 way ANOVA. A post hoc test to determine where the change was, shows that both groups experienced a significant increase (p=0.0001) in activity limitation from baseline to three months postoperatively. Group 1 further shows a significant decrease (p=0.001) in activity limitation from three to six months postoperatively while no significant change (p=0.180) was detected in Group 2 during this period indicating that Group 2 maintained their activity levels because of the intervention.

Examination of the influence of baseline difference in level of amputation on BI outcomes

Generalised Linear Model (GLM) Repeated Measure Analysis of Covariance (RM ANCOVA) was used to adjust for the baseline difference in level of amputation on activity limitation (BI) (Group 1, n=62; Group 2, n=59).

Table 2b illustrates tests of between-subjects effects transformed variable: Average BI total

Table 2b: between-subjects effects transformed variable: Average BI total

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Intercept	67.741	1	67.741	15.965	0.000	.120	15.965	.977
Group	7.368	1	7.368	1.737	0.190	.015	1.737	.257
Amputation level	.041	1	.041	.010	0.922	.000	.010	.051
Baseline BI	6.272	1	6.272	1.478	0.226	.012	1.478	.226
Error	496.436	117	4.243					

p≤0.05 is significant.

The table shows that although the groups were not similar by level of amputation, this played no significant (p=0.922) role in activity limitation outcomes of the two groups.

Figure 2 illustrates the variance of activity limitation from three months (1) to six months (2) for the groups.

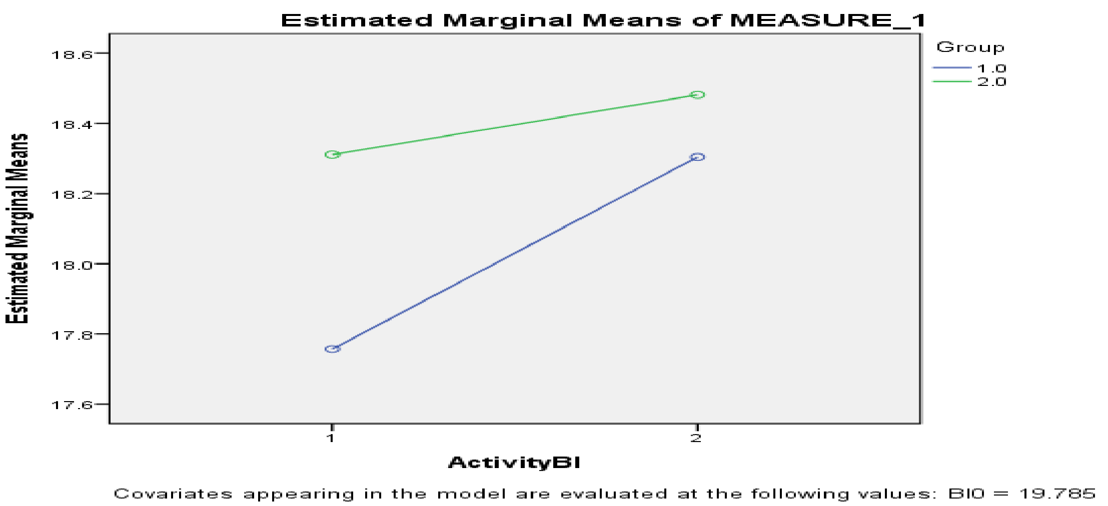


Figure 2: Variance of activity limitation from three months (1) to six months (2) for the groups

Footnote: in the figure, Measure_1 is BI, in the horizontal axis 1 is three months and 2 is six months period.

Figure 2 shows a step decline in activity limitation (increasing activity levels) in Group 1 compared to Groups 2 from three months (1) to six months (2).

Table 2c illustrates the within group comparisons total MLCI.

Table 2c: within group comparisons total MLCI

	total MLCI 3-six months		
	25th percentile Median 75th percentile at three months	25th percentile Median 75th percentile at 6 months	Related samples Wilcoxon signed rank test p-value
Group1 n=62	13 21 30	19 24 36	0.000
Group2 n=59	20 24 38	22 24 40	0.029

p≤0.05 is significant.

Both groups show a significant decrease (Group 1, p=0.0001; Group 2, p=0.029) in activity limitation from three to six months postoperatively.

Examination of the influence of baseline difference in level of amputation on MLCI outcomes

Generalised Linear Model (GLM) univariate regression Analysis of Variance (ANOVA) was used to adjust for the baseline difference in level of amputation on activity limitation (MLCI at 3months) (Group 1, n=62; Group 2, n=59).

Table 2d illustrates tests of between-subjects effects using MLCI three months as a dependent variable.

Table 2d: between-subjects effects using MLCI three months as a dependent variable

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	1244.442	2	622.221	5.028	0.008	.079	10.056	.807
Intercept	62497.103	1	62497.103	505.020	0.000	.811	505.020	1.000
Group	1216.903	1	1216.903	9.833	0.002	.077	9.833	.875
Amputation level	197.658	1	197.658	1.597	0.209	.013	1.597	.241
Error	14602.715	118	123.752					
Total	89042.000	121						
Corrected Total	15847.157	120						

$p \leq 0.05$ is significant.

Table 2d shows that although the groups were not similar by level of amputation, this played no significant (p=0.209) role at the three months activity limitation (MLCI) outcomes of the two groups.

Figure 3 illustrates the variance of activity limitation at three months (5 is BKA and 8 is AKA) for the groups.

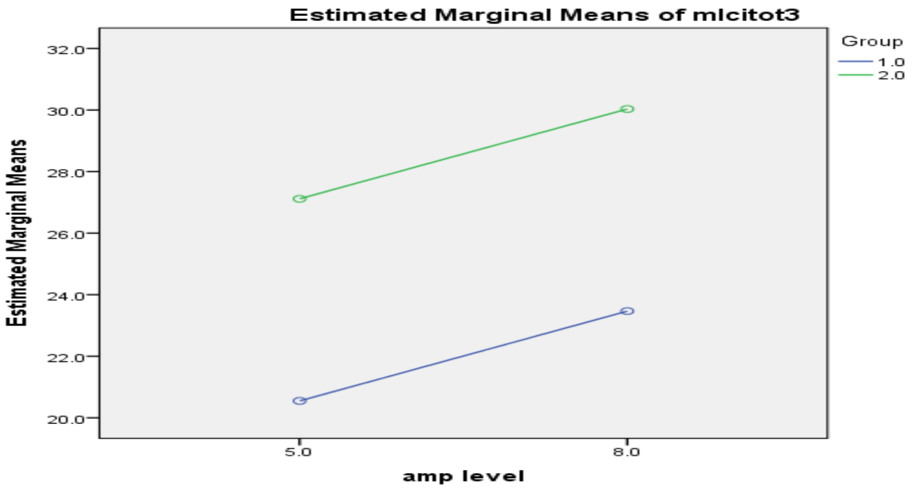


Figure 3: variance of activity limitation at three months (5 is BKA and 8 is AKA in the figure) for the groups

Footnote: in the figure, mlcitot3 is the total MLCI at three months, in the horizontal axis 5 is BKA and 8 is AKA.

Figure 3 shows a gradual decrease in activity limitation (increasing activity levels levels) in both groups from between these with a BKA(5) and those with AKA (8). This implies that groups performed in a similar (hence the lines/traces are parallel) way as viewed by level of amputation.

Generalised Linear Model (GLM) Repeated measure Analysis of Covariance (RM ANCOVA) was used to adjust for the baseline difference in level of amputation on activity limitation (MLCI) (Group 1, n=62; Group 2, n=59).
Table 2e illustrates tests of between-subjects effects using MLCI at six months as a dependent variable**.**

Table 2e: between-subjects effects using MLCI at six months as a dependent variable

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	9285.026	3	3095.009	64.064	0.0001	.622	192.193	1.000
Intercept	1083.643	1	1083.643	22.431	0.0001	.161	22.431	.997
Group	211.356	1	211.356	4.375	0.039	.036	4.375	.546
Amputation level	150.017	1	150.017	3.105	0.081	.026	3.105	.416
MLCI at 3months	9109.754	1	9109.754	188.565	0.0001	.617	188.565	1.000
Error	5652.395	117	48.311					
Total	107464.000	121						
Corrected Total	14937.421	120						

$p \leq 0.05$ is significant.

Table 2e shows that although the groups were not similar by level of amputation, this played no significant (p=0.081) role in activity limitation (MLCI) outcomes of the two groups. However, the three months MCLI had a significant influence (p=0.0001) on the six months MLCI, meaning that having a good MLCI score at three months meant a good score at six months.

Figure 4 illustrates the variance of activity limitation between BKA(5) and AKA(8) for the groups.

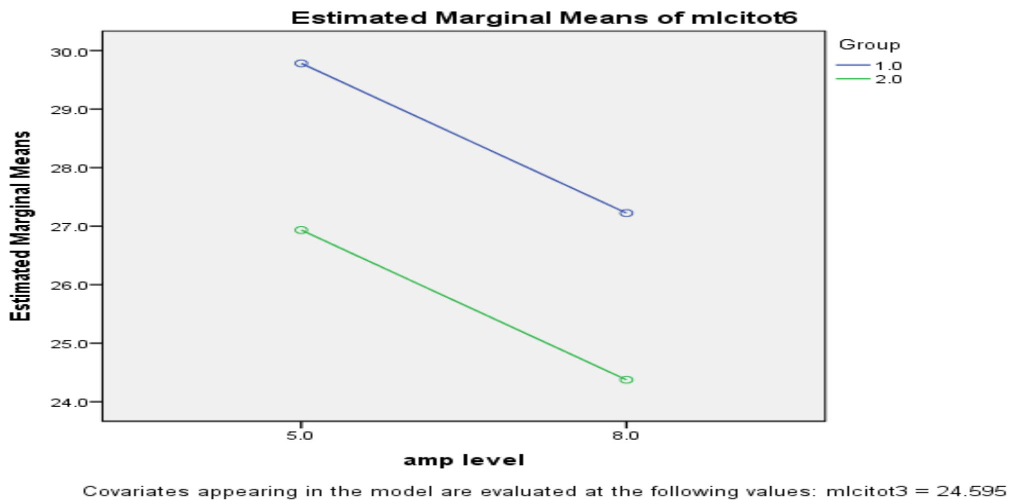


Figure 4: Variance of activity limitation between BKA(5) and AKA(8) for the groups.

Footnote: in the figure, mlcitot6 is the total MLCI at three months, in the horizontal axis 5 is BKA and 8 is AKA.

Figure 4 shows a increased in activity limitation (decreasing activity levels levels) in both groups from between these with a BKA (5) and those with AKA (8).

Table 2f illustrates the within group comparisons on basic MLCI.

Table 2f: within group comparisons on basic MLCI

Basic MLCI 3-six months			
	25th percentile Median 75th percentile at three months	25th percentile Median 75th percentile at six months	Related samples Wilcoxon signed rank test p-value
Group1 n=62	7 9 17	9 9 21	0.001
Group2 n=59	9 11 21	9 11 21	0.303

p≤0.05 is significant.

Group 1 shows a significant decrease (p=0.001) in activity limitation (increase in activity levels) from three to six months postoperatively while Group 2 experienced no significant change (p=0.303) in activity limitation during this period. This implies that although Groups 2 outperformed Group1 at three months (Mann-Whitney results), their ability to gain activity levels reached a plateau, which indicates that the intervention was only effective until three months but importantly, they maintained their activity level. Generalised Linear Model (GLM) univariate regression Analysis of Variance (ANOVA) was used to adjust for the baseline difference in level of amputation on activity limitation (basic MLCI at three months) (Group 1, n=62; Group 2, n=59).

Table 2g illustrates tests of between-subjects effects using basic MLCI three months as a dependent variable.

Table 2g: Between-subjects effects using basic MLCI three months as a dependent variable.

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power[b]
Corrected Model	185.462[a]	2	92.731	2.468	0.089	.040	4.936	.488
Intercept	15023.267	1	15023.267	399.817	0.000	.772	399.817	1.000
Group	184.486	1	184.486	4.910	0.029	.040	4.910	.594
Amputation level	19.838	1	19.838	.528	0.469	.004	.528	.111
Error	4433.894	118	37.575					
Total	22551.000	121						
Corrected Total	4619.355	120						

$p \leq 0.05$ is significant.

Table 2g shows that although the groups were not similar by level of amputation, this played no significant (p=0.469) role on three months activity limitation (basic MLCI) outcomes of the two groups.

Figure 5 illustrates the variance of activity limitation (basic MLCI) at three months (5 is BKA and 8 is AKA) for the groups**.**

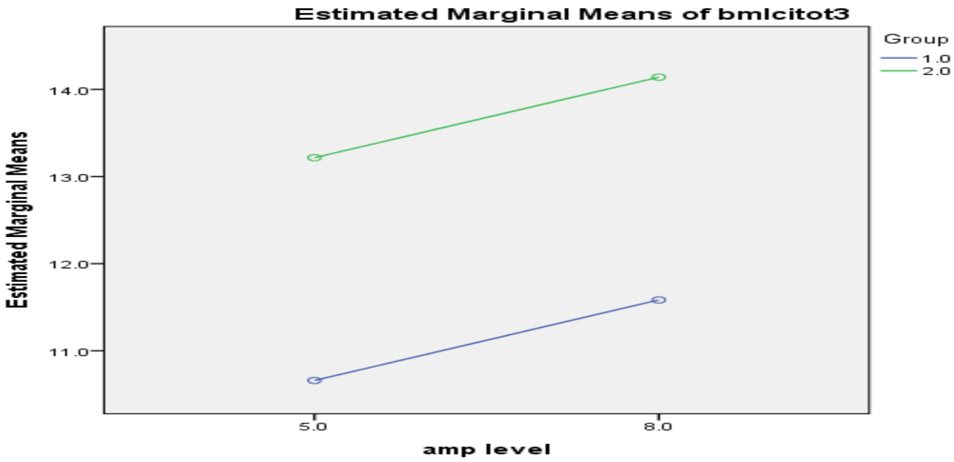


Figure 5 Variance of activity limitation (basic MLCI) at three months (5 is BKA and 8 is AKA) for the groups.

Footnote: in the figure, bmlcitot3 is the total MLCI basic subscale at three months, in the horizontal axis 5 is BKA and 8 is AKA.

Figure 5 shows a gradual decrease in activity limitation (increased activity levels) in both groups between those with a BKA (5) and those with AKA (8).

Generalised Linear Model (GLM) Repeated measure Analysis of Covariance (RM ANCOVA) was used to adjust for the baseline difference in level of amputation on activity limitation (basic MLCI) (Group 1, n=62; Group 2, n=59).

Table 2h illustrates tests of between-subjects effects using basic MLCI six months as a dependent variable.

Table 2h: Between-subjects effects using basic MLCI six months as a dependent variable

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	2923.956	3	974.652	63.297	0.000	.619	189.892	1.000
Intercept	225.694	1	225.694	14.657	0.000	.111	14.657	.967
Group	44.952	1	44.952	2.919	0.090	.024	2.919	.395
Amputation level	16.771	1	16.771	1.089	0.299	.009	1.089	.179
Basic MLCI at three months	2904.098	1	2904.098	188.602	0.000	.617	188.602	1.000
Error	1801.564	117	15.398					
Total	25909.000	121						
Corrected Total	4725.521	120						

p≤0.05 is significant.

Table 2h shows that although the groups were not similar by level of amputation, this played no significant (p=0.299) role in activity limitation (basic MLCI) outcomes of the two groups.

Figure 6 illustrates the variance of activity limitation (basic MLCI) from three to six months (5 is BKA and 8 is AKA) for the groups.

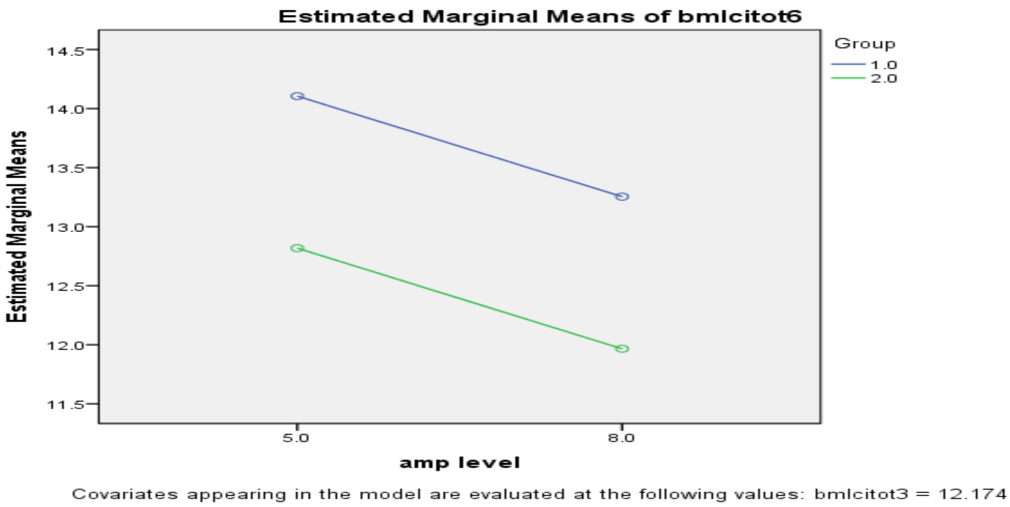


Figure 6: Variance of activity limitation (basic MLCI) from three to six months (5 is BKA and 8 is AKA) for the groups.

Footnote: in the figure, bmlcitot6 is the total MLCI basic subscale at six months, in the horizontal axis 5 is BKA and 8 is AKA.

Figure 6 shows a gradual increase in activity limitation (decreased activity levels) in both groups from between these with a BKA (5) and those with AKA (8).

Table 2i illustrates within group comparisons of Advanced MLCI.

Table 2i: Within group comparisons of Advanced MLCI

Advance MLCI 3-six months			
	25th percentile Median 75th percentile at three months	25th percentile Median 75th percentile at six months	Related samples Wilcoxon signed rank test P-value
Group1 n=62	6 11.5 14	10 15 18	0.0001
Group2 n=59	11 15 19	13 15 19	0.030

p≤0.05 is significant.

Both groups shows a significant decrease (Group 1, p=0.0001; Group 2, p=0.030) in activity limitation (increased activity levels) from three to six months postoperatively.
Generalised Linear Model (GLM) univariate regression Analysis of Variance (ANOVA) was used to adjust for the baseline difference in level of amputation on activity limitation (advanced MLCI at three months) (Group 1, n=62; Group 2, n=59).
Table 2j illustrates tests of between-subjects effects using advanced MLCI three months as a dependent variable.

Table 2j: Between-subjects effects using advanced MLCI three months as a dependent variable

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	471.906	2	235.953	7.848	0.001	.117	15.696	.948
Intercept	16237.072	1	16237.072	540.076	0.000	.821	540.076	1.000
Group	453.757	1	453.757	15.093	0.000	.113	15.093	.971
Amputation level	92.257	1	92.257	3.069	0.082	.025	3.069	.412
Error	3547.598	118	30.064					
Total	22689.000	121						
Corrected Total	4019.504	120						

p≤0.05 is significant.

Table 2j shows that although the groups were not similar by level of amputation, this played no significant (p=0.082) role on three months activity limitation (advanced MLCI) outcomes of the two groups.

Figure 7 illustrates the variance of activity limitation (advanced MLCI) at three months (5 is BKA and 8 is AKA) for the groups.

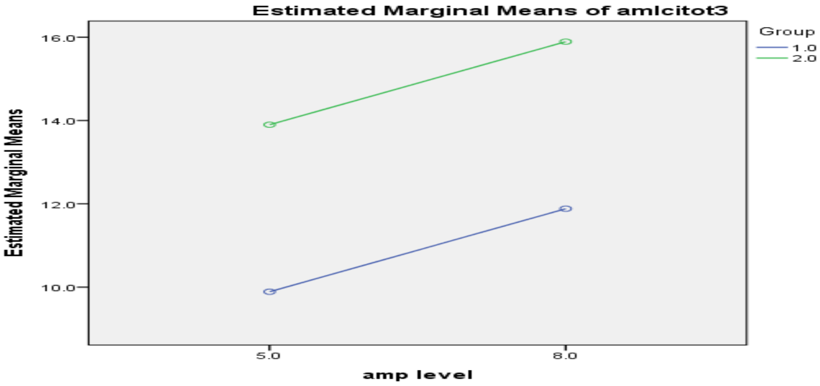


Figure 7: Variance of activity limitation (advanced MLCI) at three months (5 is BKA and 8 is AKA) for the groups

Footnote: in the figure, amlcitot3 is the total MLCI advanced subscale at three months, in the horizontal axis 5 is BKA and 8 is AKA.

Figure 7 shows a gradual decrease in activity limitation (increased activity levels) in both groups from between these with a BKA (5) and those with AKA (8).

Generalised Linear Model (GLM) Repeated measure Analysis of Covariance (RM ANCOVA) was used to adjust for the baseline difference in level of amputation on activity limitation (advanced MLCI) (Group 1, n=62; Group 2, n=59).

Table 2k illustrates tests of between-subjects effects using advanced MLCI six months as a dependent variable.

Table 2k: Between-subjects effects using advanced MLCI six months as a dependent variable

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	1903.842	3	634.614	51.437	0.000	.569	154.312	1.000
Intercept	464.214	1	464.214	37.626	0.000	.243	37.626	1.000
Group	44.721	1	44.721	3.625	0.059	.030	3.625	.471
Amputation level	56.103	1	56.103	4.547	0.035	.037	4.547	.562
Advanced MLCI at three months	1828.354	1	1828.354	148.194	0.000	.559	148.194	1.000
Error	1443.497	117	12.338					
Total	28484.000	121						
Corrected Total	3347.339	120						

p≤0.05 is significant.

Table 2k shows that as the groups were not similar by level of amputation, that played a significant (p=0.035) role in activity limitation (advanced MLCI) outcomes of the two groups. This may mean that based on the level of amputation, participants will only vary at six months regarding their performance in the advanced MLCI.

Figure 8 illustrates the variance of activity limitation (advanced MLCI) from three to six months (5 is BKA and 8 is AKA) for the groups.

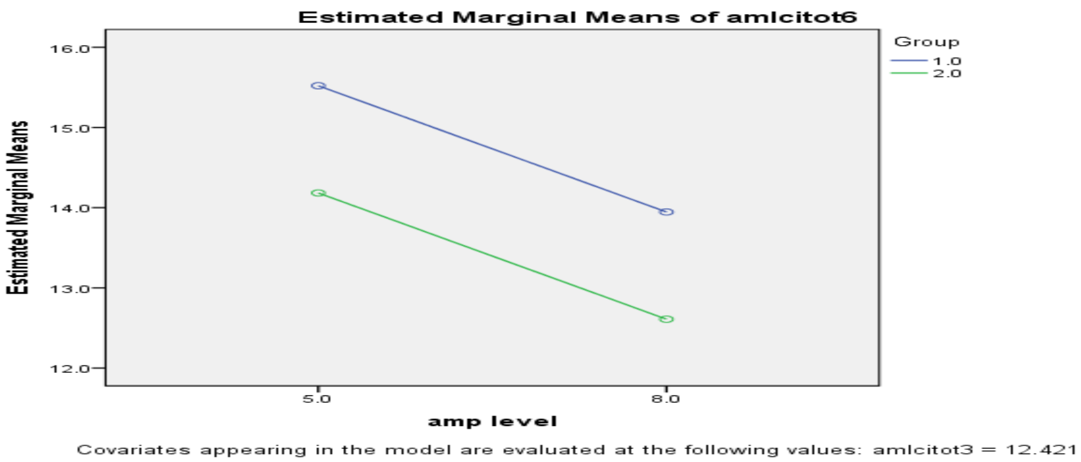


Figure 8: Variance of activity limitation (advanced MLCI) from three to six months (5 is BKA and 8 is AKA) for the groups.

Footnote: in the figure, amlcitot6 is the total MLCI advanced subscale at six months, in the horizontal axis 5 is BKA and 8 is AKA.

Figure 8 shows a gradual increase in activity limitation (decreased activity levels) in both groups from between these with a BKA (5) and those with AKA (8).

3. Body image

Table 3a illustrates a within group comparisons of MABIS.

Table 3a within group comparisons of MABIS

MABIS 3-six months			
	25^{th} percentile Median 75^{th} percentile at three months	25^{th} percentile Median 75^{th} percentile at six months	Related samples Wilcoxon signed rank test P-value
Group1 n=62	20 28 42	18 25.5 40	0.150
Group2 n=59	23 35 43	22 39 44	0.997

p≤0.05 is significant.

Table 3a illustrates that both groups show no significant change in body image disturbance from three to six months.

Examination of the influence of baseline difference in level of amputation on MABIS outcomes

Generalised Linear Model (GLM) univariate regression Analysis of Variance (ANOVA) was used to adjust for the baseline difference in level of amputation on body image (MABIS at three months) (Group 1, n=62; Group 2, n=59).

Table 3b illustrates tests of between-subjects effects using MABIS three months as a dependent variable.

Table 3b: Between-subjects effects using MABIS three months as a dependent variable

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	1388.294	2	694.147	3.268	0.042	.052	6.537	.612
Intercept	105164.162	1	105164.162	495.153	0.000	.808	495.153	1.000
Group	1.633	1	1.633	.008	0.930	.000	.008	.051
Amputation level	1271.010	1	1271.010	5.984	0.016	.048	5.984	.680
Error	25061.706	118	212.387					
Total	169334.000	121						
Corrected Total	26450.000	120						

p≤0.05 is significant.

Table 3b shows that although the groups were similar by body image, level of amputation had a significant (p=0.016) influencing role on three months body image (MABIS) outcomes of the two groups.

Figure 9 illustrates the variance of body image (MABIS) at three months (5 is BKA and 8 is AKA) for the groups.

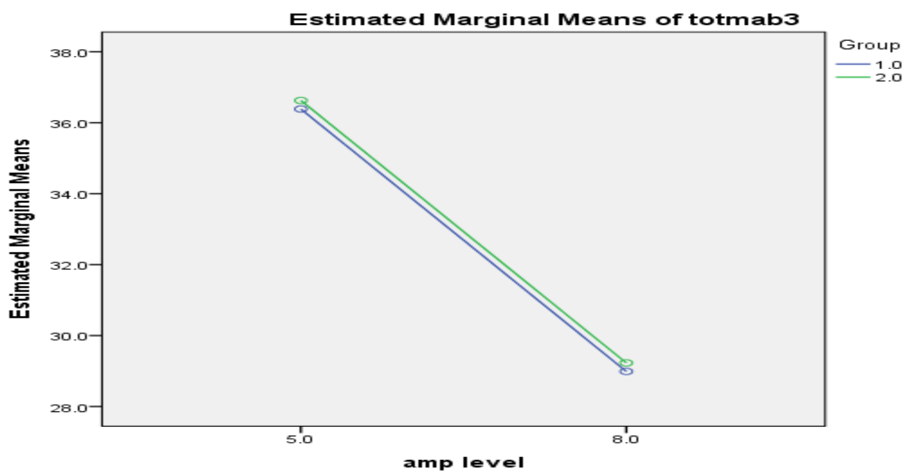


Figure 9: Variance of body image (MABIS) at three months (5 is BKA and 8 is AKA) for the groups.

Footnote: in the figure, totmab3 is the total MABIS at three months, in the horizontal axis 5 is BKA and 8 is AKA.

Figure 9 shows a gradual decrease in body image disturbance in both groups between these with a BKA (5) and those with AKA (8).

4. Quality of life (QOL).

Table 4a illustrates a within group comparisons of the EQ-5D VAS**.**

Table 4a: Within group comparisons of the EQ-5D VAS

VAS						
	Baseline to 3months			3-six months		Baseline to 6months
	25th percentile Median 75th percentile at baseline	25th percentile Median 75th percentile at three months	Related samples Wilcoxon signed rank test p-value	25th percentile Median 75th percentile at 6months	Related samples Wilcoxon signed rank test p-value	Related samples Friedman's 2 way ANOVA test p-value
Group1 n=62	50 70 80	30 60 80	0.002	57.5 70 80	0.0001	0.004
Group2 n=59	60 80 90	50 80 80	0.416	65 75 85	0.167	0.366

$p \leq 0.05$ is significant.

Table 4a shows that Group 1 experienced significant changes (p=0.004) in QOL (VAS) from baseline to six months postoperatively while Group 2 exhibited no significant (p=0.366) change as revealed by the Friedman's 2 way ANOVA. A post hoc test to determine where the change was for Group 1, shows that a significant decline occurred (p=0.002) in QOL (VAS) from baseline to three months postoperatively and a significant improvement (recovery) (p=0.0001) in QOL (VAS) from three to six months postoperatively.

Table 4b illustrates a within group comparisons of the EQ-5D Index.

Table 4b: Within group comparisons of the EQ-5D Index

Index						
		Baseline to 3months		3-six months		Baseline to 6months
	25th percentile Median 75th percentile at three months	25th percentile Median 75th percentile at six months	Related samples Wilcoxon signed rank test P-value	25th percentile Median 75th percentile	Related samples Wilcoxon signed rank test P-value	Related samples Friedman's 2 way ANOVA test P-value
Group1 n=62	0.028 0.264 0.725	0.264 0.725 0.796	0.008	0.443 0.796 0.850	0.006	0.000
Group2 n=59	0.193 0.291 0.796	0.725 0.796 0.796	0.004	0.725 0.796 1.000	0.109	0.002

$p \leq 0.05$ is significant.

Table 4b shows that both groups experienced significant changes (Group 1, p=0.0001; Group 2, p=0.002) in QOL (EQ-5D Index) from baseline to six months postoperatively as revealed by the Friedman's 2 way ANOVA. A post hoc test to determine where the change was, shows that both groups experienced a significant improvement (Group 1, p=0.008; Group 2, p=0.004) in QOL (EQ-5D Index) from baseline to three months postoperatively. Group 1 further shows a significant improvement (p=0.006) in QOL (EQ-5D Index) from three to six months postoperatively while no significant change (p=0.109) was detected in Group 2 during this period indicating that Group 2 reached a point of saturation, this implies that the exercise intervention was only useful from baseline until three months.

Examination of the influence of baseline difference in level of amputation on EQ-5D outcomes

Generalised Linear Model (GLM) Repeated measure Analysis of Covariance (RM ANCOVA) was used to adjust for the baseline difference in level of amputation on quality of life (EQ-5D Index) (Group 1, n=62; Group 2, n=59).

Table 4c illustrates tests of between-subjects effects transformed variable: Average EQ-5D Index**.**

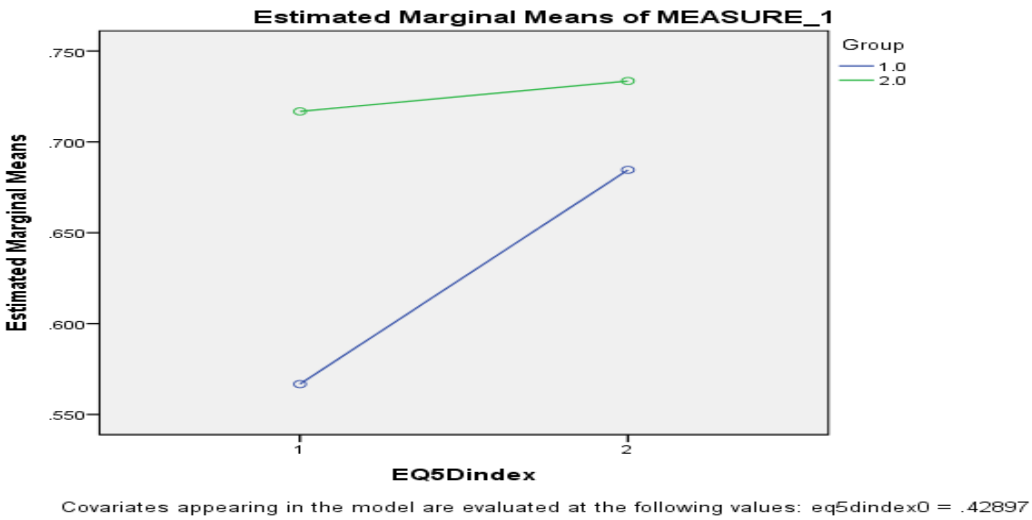
Table 4c: Between-subjects effects transformed variable: Average EQ-5D Index

Source	Type III Sum of Squares	Df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Intercept	33.716	1	33.716	250.880	0.000	.682	250.880	1.000
Group	.542	1	.542	4.030	0.047	.033	4.030	.512
Amputation level	.041	1	.041	.306	0.581	.003	.306	.085
EQ-5D index at baseline	.231	1	.231	1.721	0.192	.014	1.721	.256
Error	15.724	117	.134					

p≤0.05 is significant.

Table 4c shows that although the groups were not similar by level of amputation, this played no significant (p=0.581) role in QOL EQ-5D Index outcomes of the two groups.

Figure 10 illustrates the variance of QOL EQ-5D index from three months (1) to six months (2) for the groups.



Footnote: in the figure, Measure_1 is the total EQ-5D Index, in the horizontal axis 1 is at three months and 2 is at six months.

Figure 10 Variance of QOL EQ-5D index from three months (1) to six months (2) for the groups.

Figure 10 shows a steep increase in QOL (EQ-5D Index) in Group 1 compared to Group 2 from three months (1) to six months (2).

Generalised Linear Model (GLM) Repeated measure Analysis of Covariance (RM ANCOVA) was used to adjust for the baseline difference in level of amputation on quality of life (EQ-5D VAS) (Group 1, n=62; Group 2, n=59).

Table 4d illustrates tests of between-subjects effects transformed variable: Average EQ-5D VAS.

Table 4d: Between-subjects effects transformed variable: Average EQ-5D VAS.

Source	Type III Sum of Squares	df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power[a]
Intercept	57727.906	1	57727.906	87.619	0.000	.428	87.619	1.000
Group	8023.007	1	8023.007	12.177	0.001	.094	12.177	.933
Amputation level	440.620	1	440.620	.669	0.415	.006	.669	.128
EQ-5D VAS at baseline	2689.495	1	2689.495	4.082	0.046	.034	4.082	.518
Error	77085.431	117	658.850					

$p \leq 0.05$ is significant.

Table 4d shows that although the groups were not similar by level of amputation, that played no significant (p=0.415) role in QOL VAS outcomes of the two groups.

Figure 11 illustrates the variance of QOL VAS from three months (1) to six months (2) for the groups.

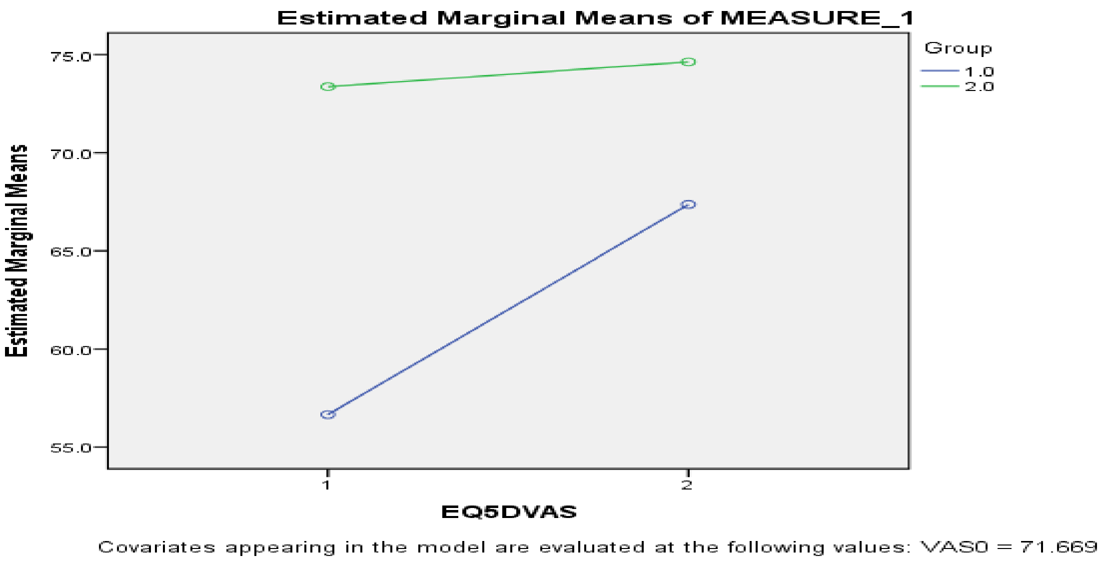


Figure 11: Variance of QOL VAS from three months (1) to six months (2) for the groups

Footnote: in the figure, Measure 1 is the total EQ-5D VAS, in the horizontal axis 1 is three months and 2 is six months period.

Figure 11 shows a steep increase in QOL (EQ-5D VAS) in Group 1 compared to Group 2 from three months (1) to six months (2). This implies that although Group 2 is significantly better than Group 1 at three months (Mann-Whitney test) if observation point one of the above figure, they plateaued indicating that they did not lose function from three to six months.

5. Balance (risk of falling)

Table 5a illustrates a within group comparisons of TUG

Table 5a within group comparisons of TUG

TUG 3-six months			
	25th percentile Median 75th percentile at three months	25th percentile Median 75th percentile at six months	Related samples Wilcoxon signed rank test P-value
Group1 n=62	25.75 34 45.25	19 25.5 36	0.0001
Group2 n=59	19 24 36	13 21 32	0.0001

$p \leq 0.05$ is significant.

Both groups show a significant reduction ($p=0.0001$) in risk of falling (improvement in balance) from three to six months postoperatively.

Examination of the influence of baseline difference in level of amputation on TUG outcomes

Generalised Linear Model (GLM) univariate regression Analysis of Variance (ANOVA) was used to adjust for the baseline difference in level of amputation on risk of falling (balance (TUG test at three months) (Group 1, n=62; Group 2, n=59).

Table 5b illustrates a test of between-subjects effects using TUG at three months as a dependent variable.

Table 5b between-subjects effects using TUG at three months as a dependent variable

Source	Type III Sum of Squares	df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power
Corrected Model	5652.058	2	2826.029	2.489	0.087	.040	4.978	.491
Intercept	124995.012	1	124995.012	110.099	0.000	.483	110.099	1.000
Group	4559.056	1	4559.056	4.016	0.047	.033	4.016	.511
Amputation level	2434.653	1	2434.653	2.145	0.146	.018	2.145	.306
Error	133965.116	118	1135.298					
Total	315102.000	121						
Corrected Total	139617.174	120						

p≤0.05 is significant.

Table shows that although the groups were not similar by level of amputation, this played no significant (p=0.146) role on three months risk of falling outcomes of the two groups. Figure 12 illustrates the variance of risk of falling at three months (5 is BKA and 8 is AKA) for the groups**.**

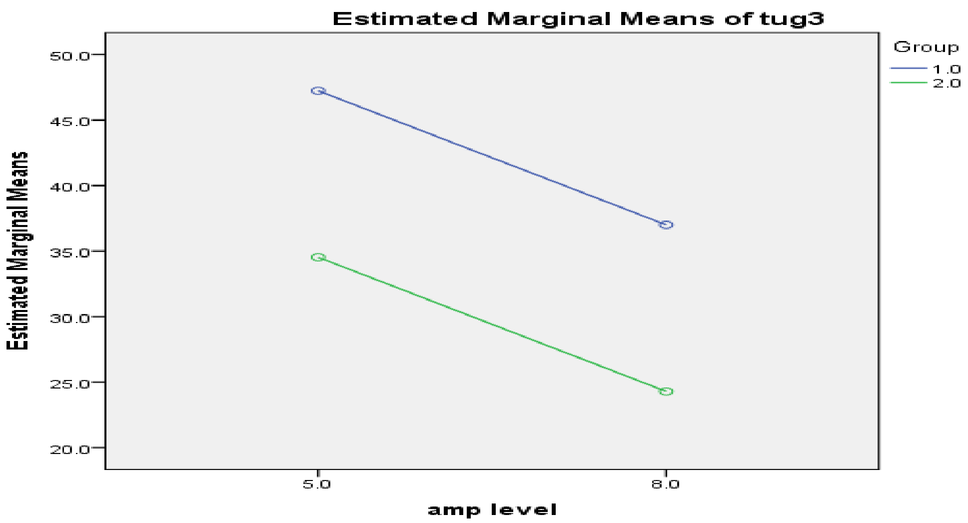


Figure 12: Variance of risk of falling at three months (5 is BKA and 8 is AKA) for the groups

Footnote: in the figure, tug3 is the totalTUG at three months, in the horizontal axis 5 is BKA and 8 is AKA.

Figure 12 shows a gradual decrease in risk of falling in both groups between these with a BKA (5) and those with AKA (8).

Generalised Linear Model (GLM) Repeated measure Analysis of Covariance (RM ANCOVA) was used to adjust for the baseline difference in level of amputation on risk of falling (TUG) (Group 1, n=62; Group 2, n=59).

Table 5c illustrates tests of between-subjects effects dependent variable: TUG at six months.

Table 5c: Between-subjects effects dependent variable: TUG at six months

Source	Type III Sum of Squares	df	Mean Square	F	p-value	Partial Eta Squared	Noncent. Parameter	Observed Power[b]
Corrected Model	56830.116[a]	3	18943.372	64.619	0.000	.624	193.858	1.000
Intercept	1987.339	1	1987.339	6.779	0.010	.055	6.779	.733
Group	55.776	1	55.776	.190	0.664	.002	.190	.072
Amputation level	73.847	1	73.847	.252	0.617	.002	.252	.079
TUG at three months	53527.120	1	53527.120	182.591	0.0001	.609	182.591	1.000
Error	34298.933	117	293.153					
Total	205465.250	121						
Corrected Total	91129.050	120						

$p \leq 0.05$ is significant.

Table 5c shows that although the groups were not similar by level of amputation, this played no significant ($p=0.617$) role on risk of falling outcomes of the two groups.

Figure 13 illustrates the variance of risk of falling (TUG) from three to six months (5 is BKA and 8 is AKA) for the groups.

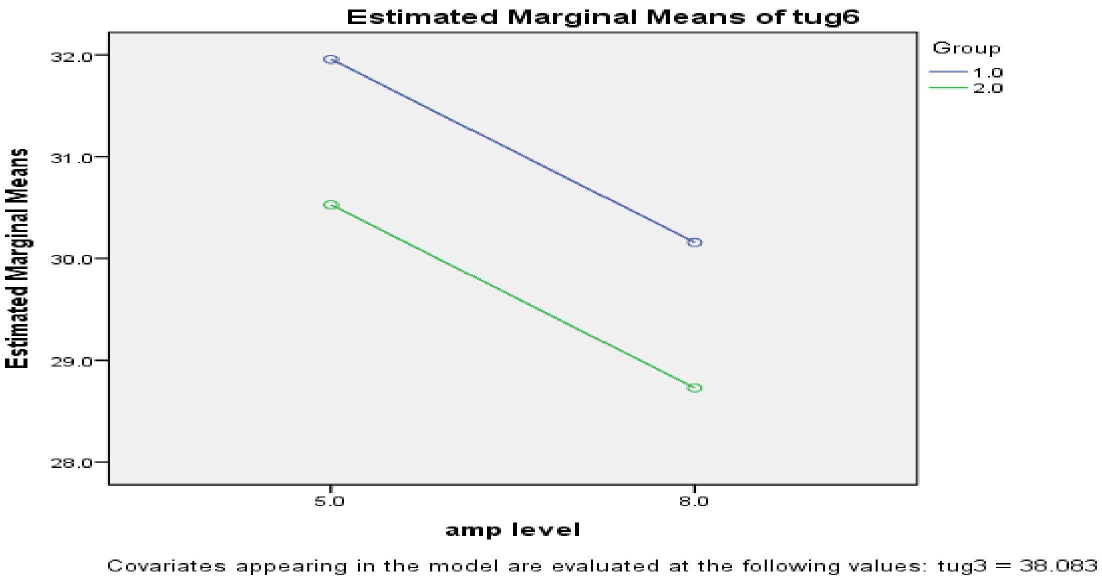


Figure 13: Variance of risk of falling (TUG) from three to six months (5 is BKA and 8 is AKA) for the groups.

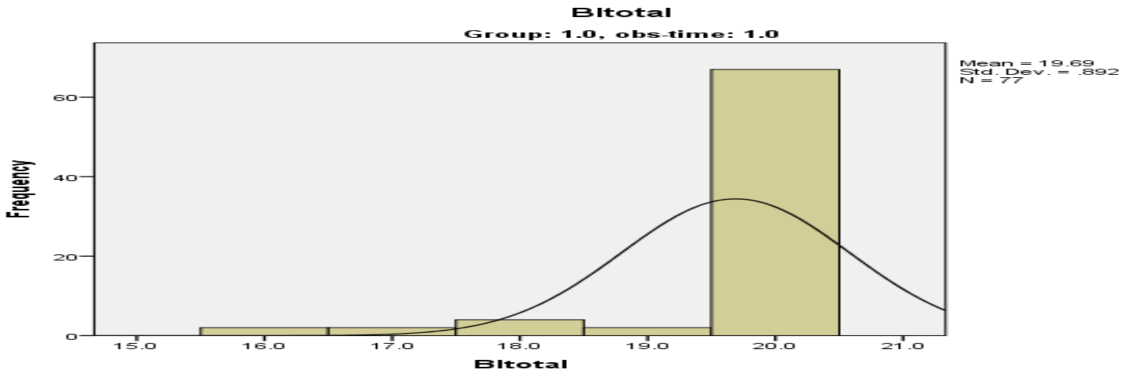
Footnote: in the figure, tug6 is the totalTUG at six months, in the horizontal axis 5 is BKA and 8 is AKA

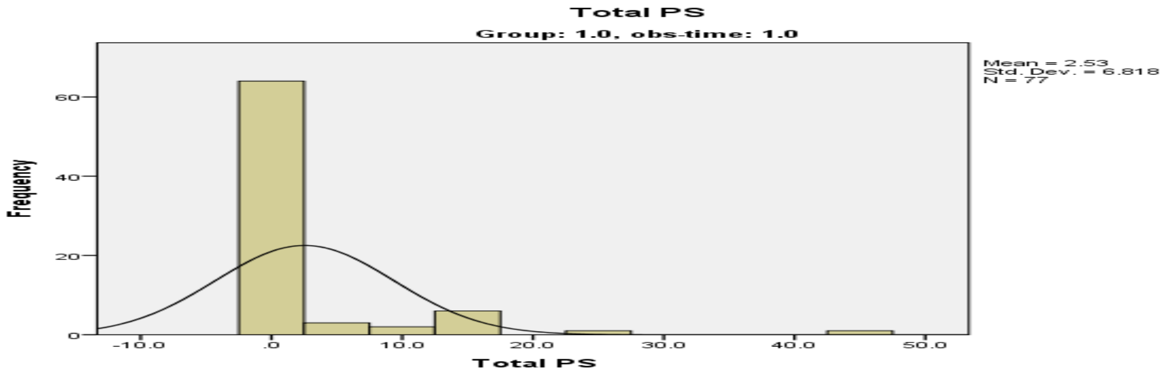
Figure 13 shows a gradual decrease in risk of falling in both groups between these with a BKA (5) and those with AKA (8).

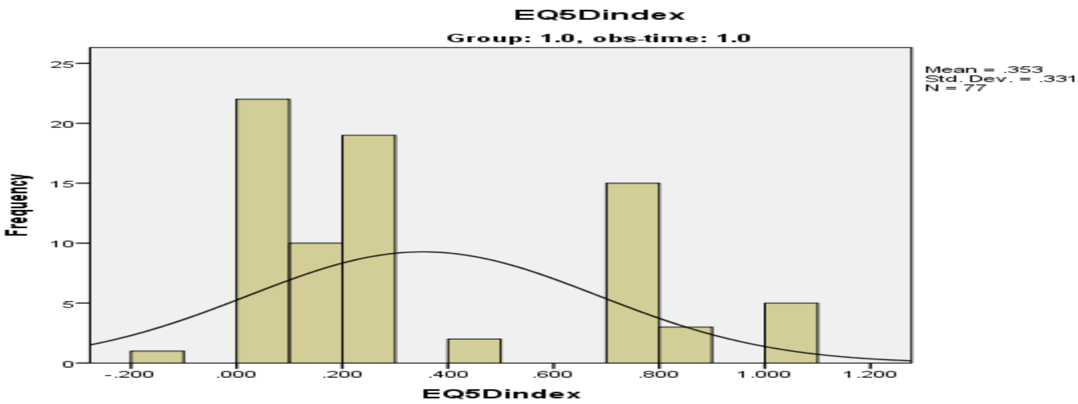
APPENDIX ib

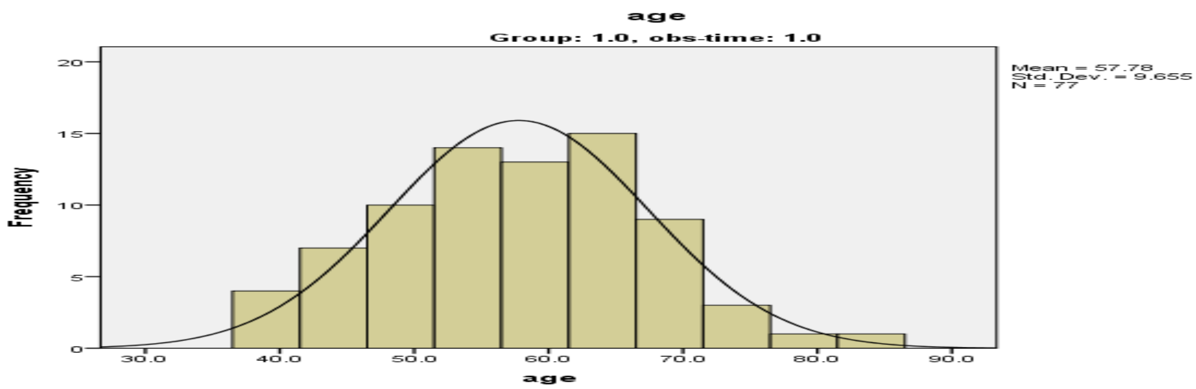
DISTRIBUTION OF THE DATA

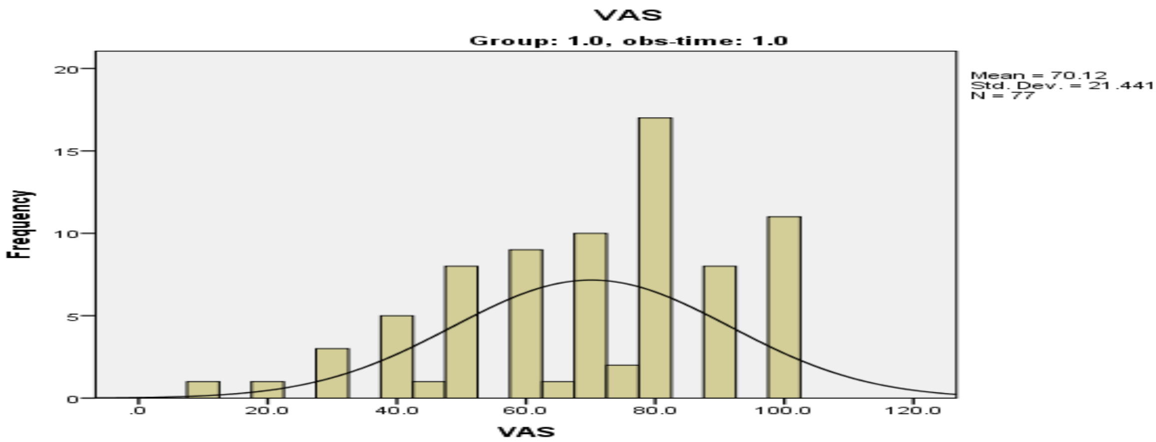
DISTRIBUTION OF DATA

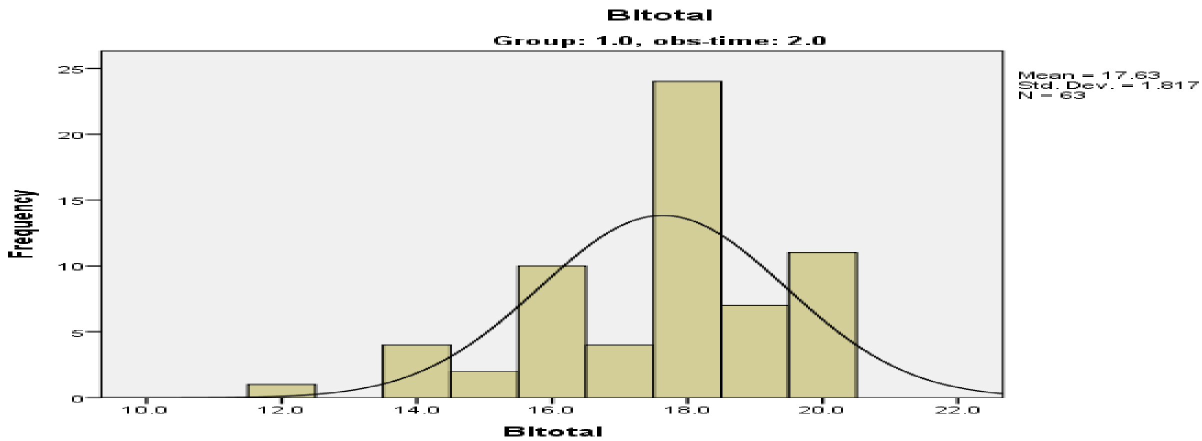


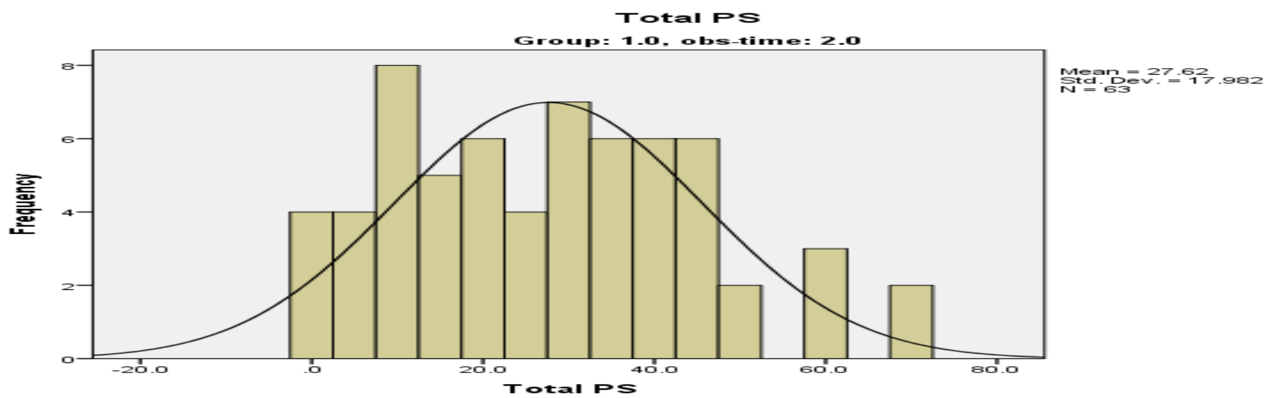


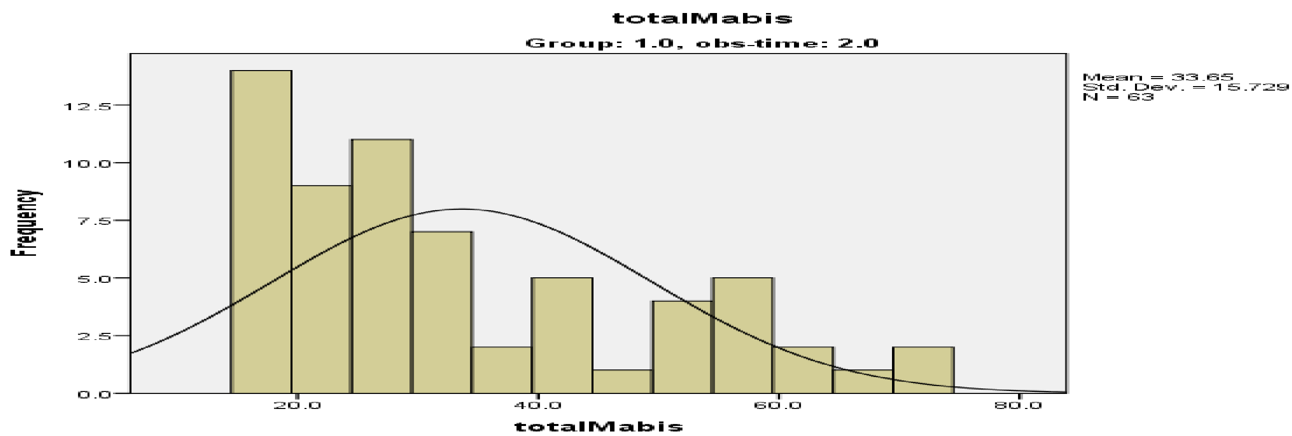


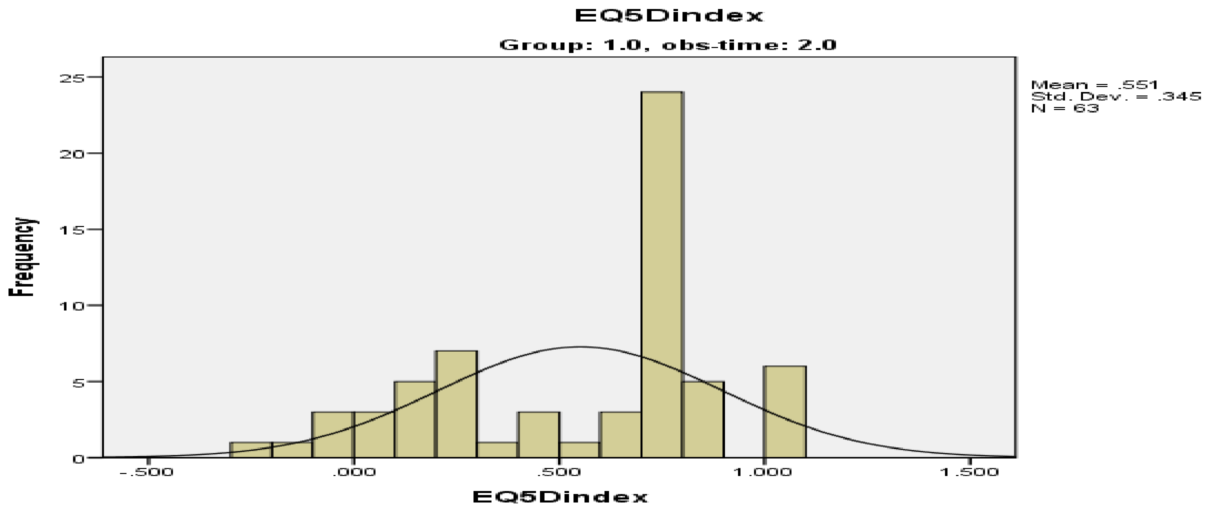



VAS
Group: 1.0, obs-time: 1.0
Mean = 70.12
Std. Dev. = 21.441
N = 77
Frequency
VAS

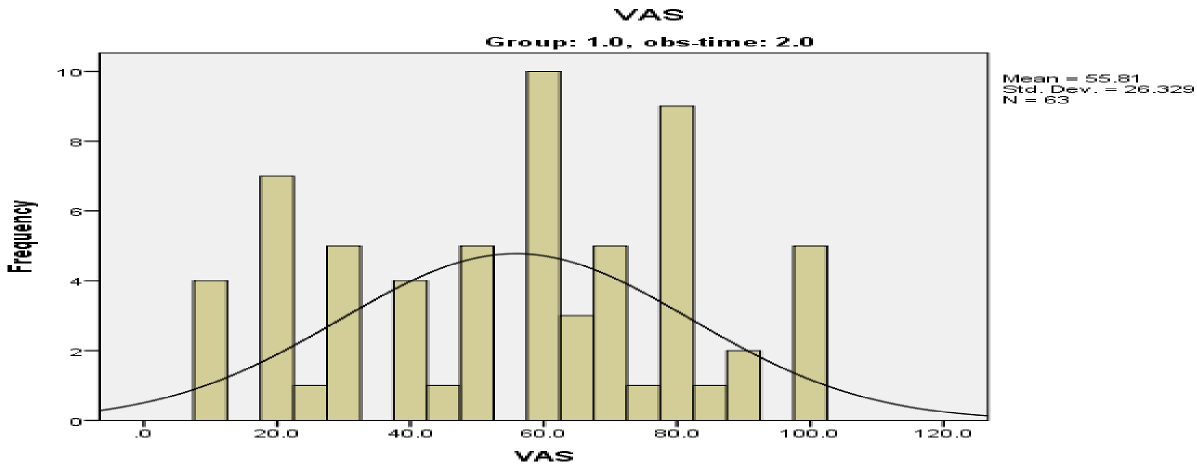

BItotal
Group: 1.0, obs-time: 2.0
Mean = 17.63
Std. Dev. = 1.817
N = 63
Frequency
BItotal


Total PS
Group: 1.0, obs-time: 2.0
Mean = 27.62
Std. Dev. = 17.982
N = 63
Frequency
Total PS

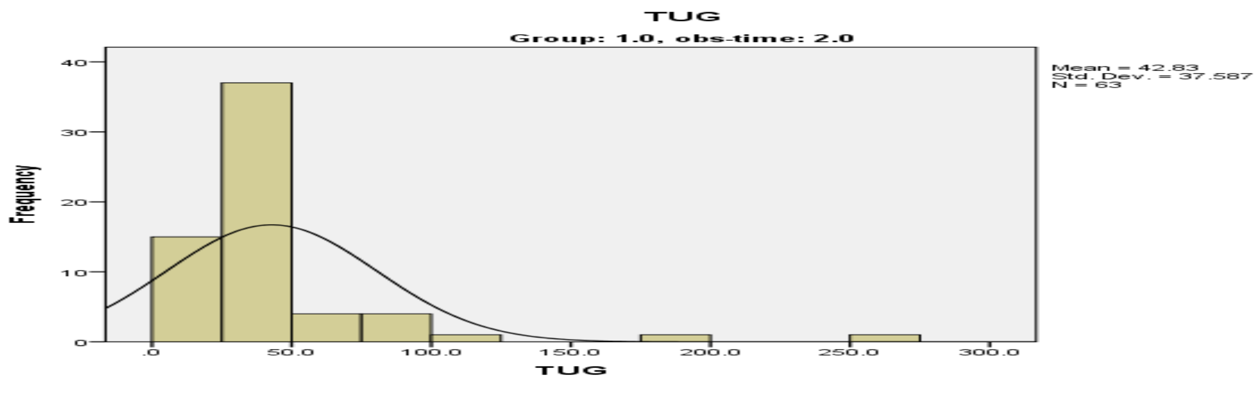

totalMabis
Group: 1.0, obs-time: 2.0
Mean = 33.65
Std. Dev. = 15.729
N = 63
Frequency
totalMabis



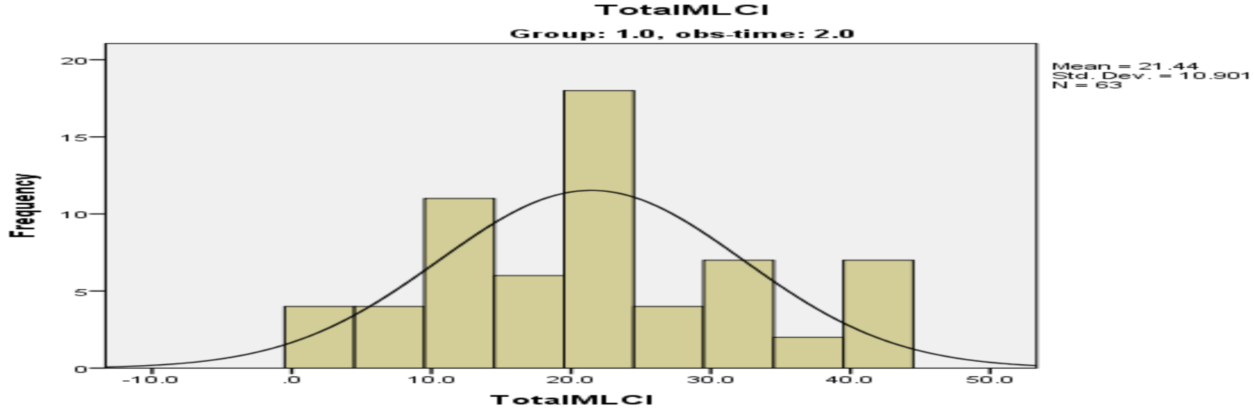
EQ5Dindex
Group: 1.0, obs-time: 2.0
Mean = .551
Std. Dev. = .345
N = 63
Frequency
25
20
15
10
5
0
-.500
.000
.500
1.000
1.500
EQ5Dindex



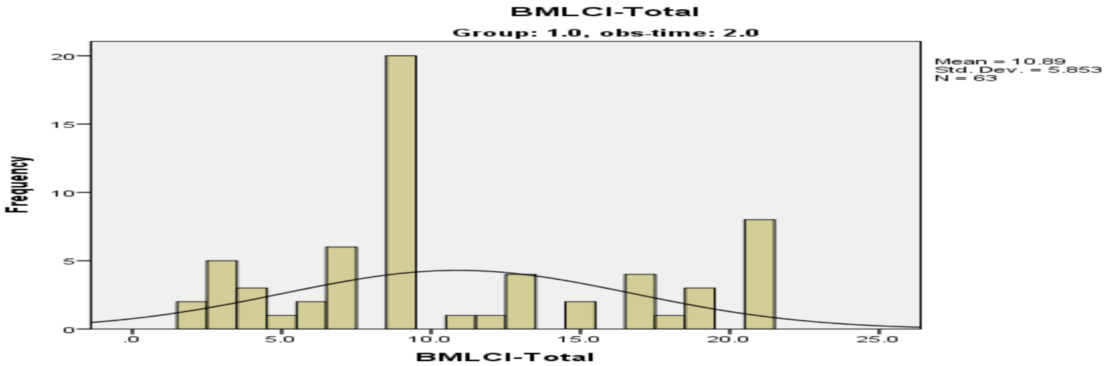
VAS
Group: 1.0, obs-time: 2.0
Mean = 55.81
Std. Dev. = 26.329
N = 63
Frequency
10
8
6
4
2
0
.0
20.0
40.0
60.0
80.0
100.0
120.0
VAS

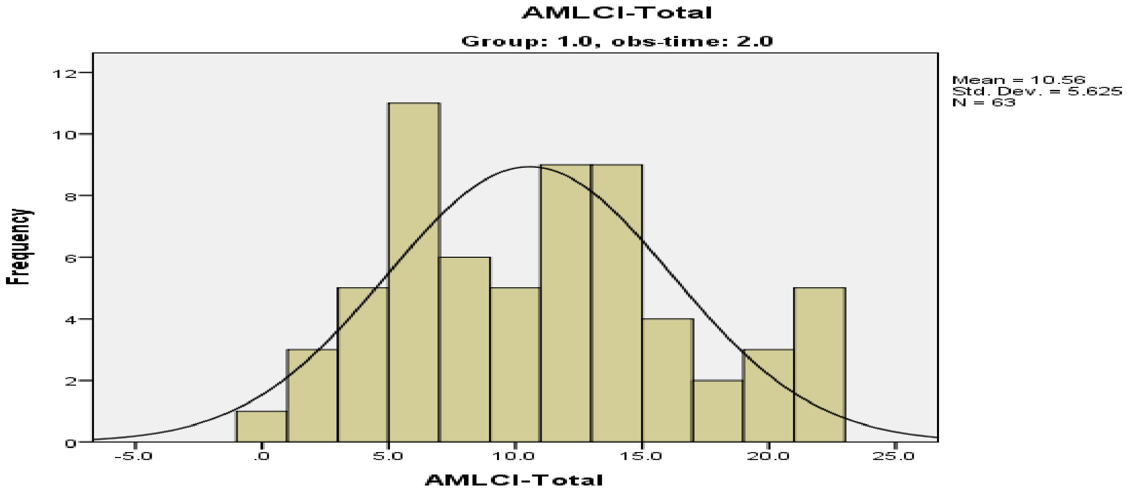


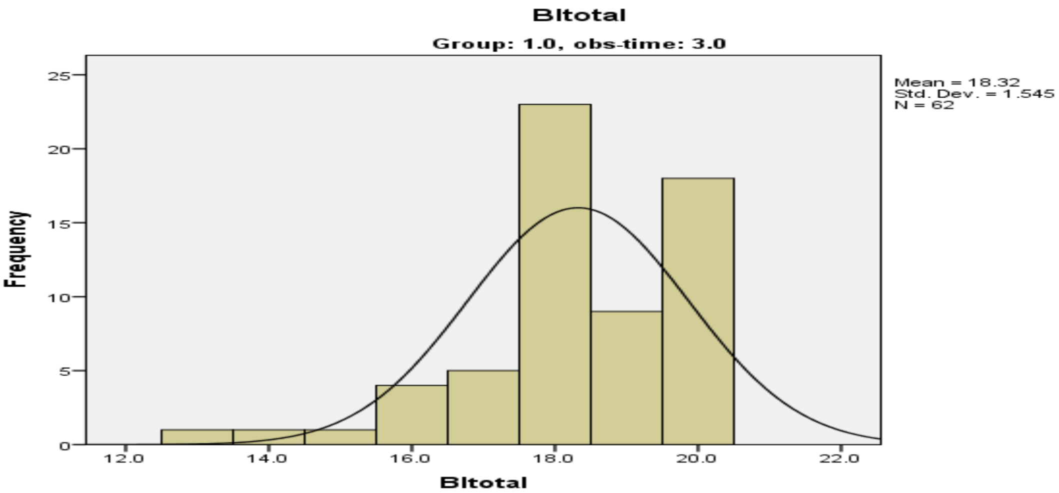
TUG
Group: 1.0, obs-time: 2.0
Mean = 42.83
Std. Dev. = 37.587
N = 63
Frequency
40
30
20
10
0
.0
50.0
100.0
150.0
200.0
250.0
300.0
TUG

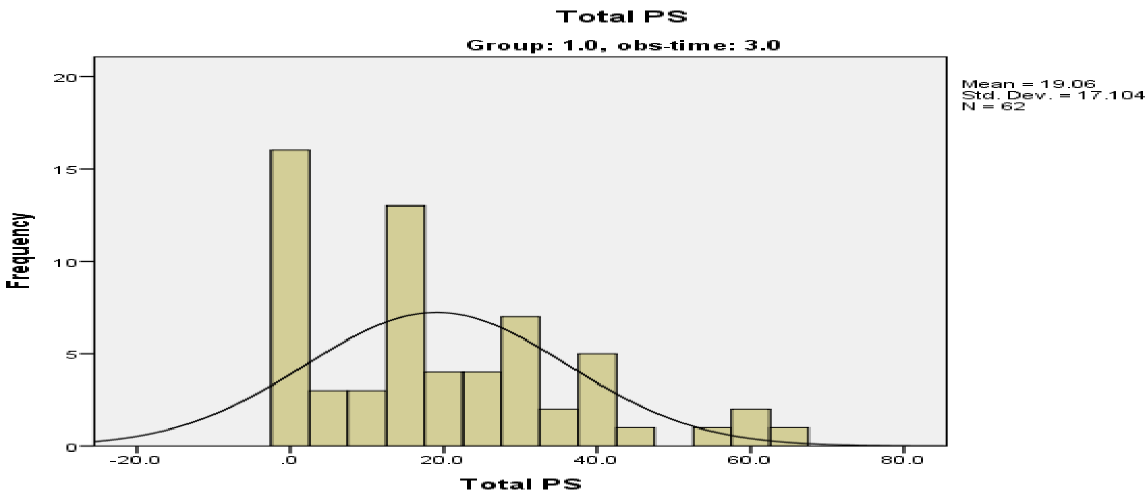


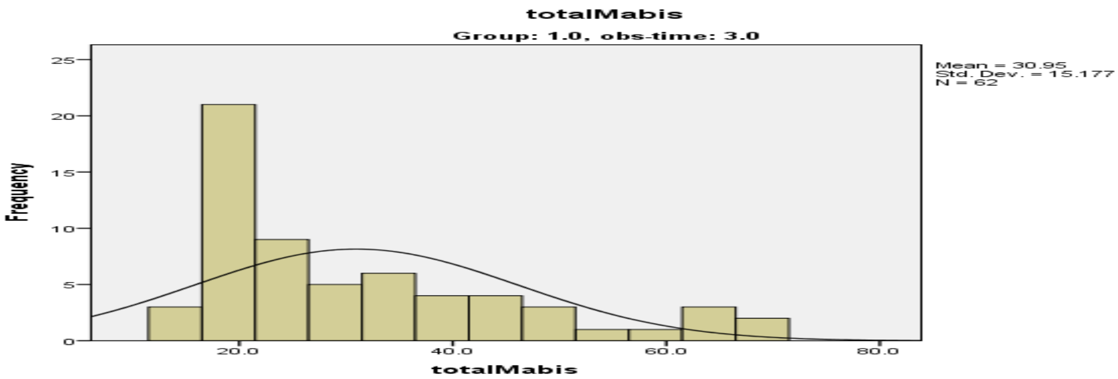
TotalMLCI
Group: 1.0, obs-time: 2.0
Mean = 21.44
Std. Dev. = 10.901
N = 63
Frequency
20
15
10
5
0
-10.0
.0
10.0
20.0
30.0
40.0
50.0
TotalMLCI

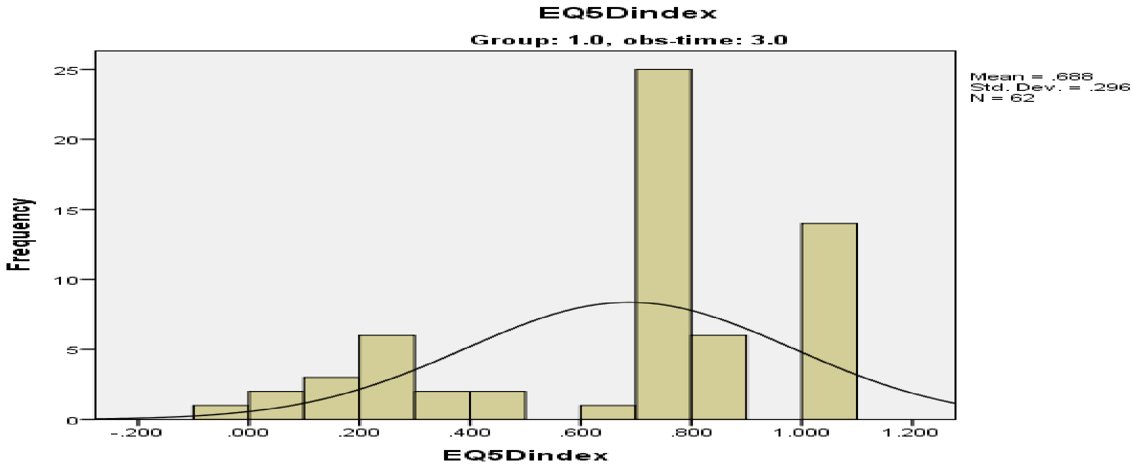

BMLCI-Total
Group: 1.0, obs-time: 2.0
Mean = 10.89
Std. Dev. = 5.853
N = 63
Frequency
BMLCI-Total

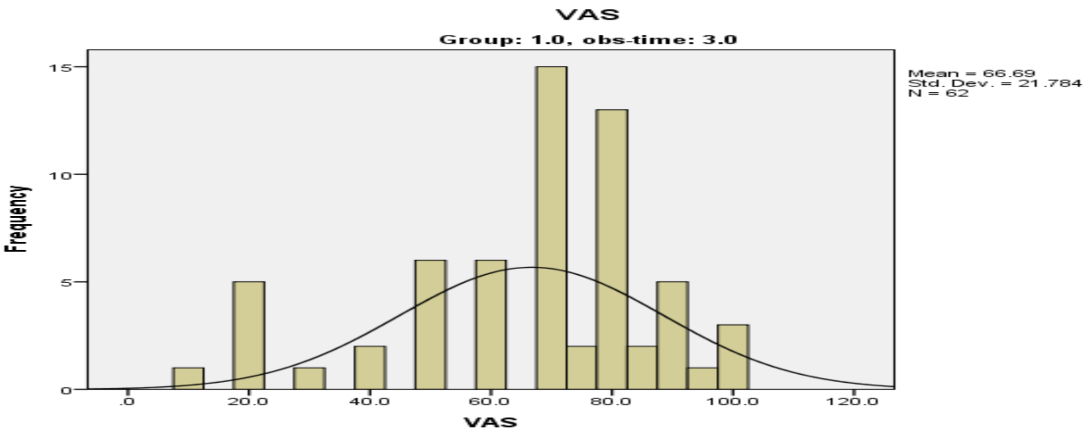

AMLCI-Total
Group: 1.0, obs-time: 2.0
Mean = 10.56
Std. Dev. = 5.625
N = 63
Frequency
AMLCI-Total

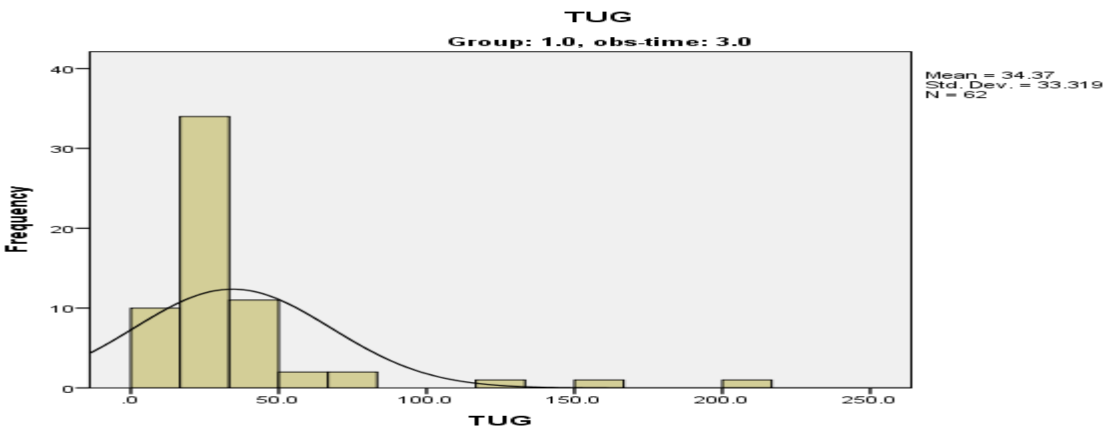

BItotal
Group: 1.0, obs-time: 3.0
Mean = 18.32
Std. Dev. = 1.545
N = 62
Frequency
BItotal

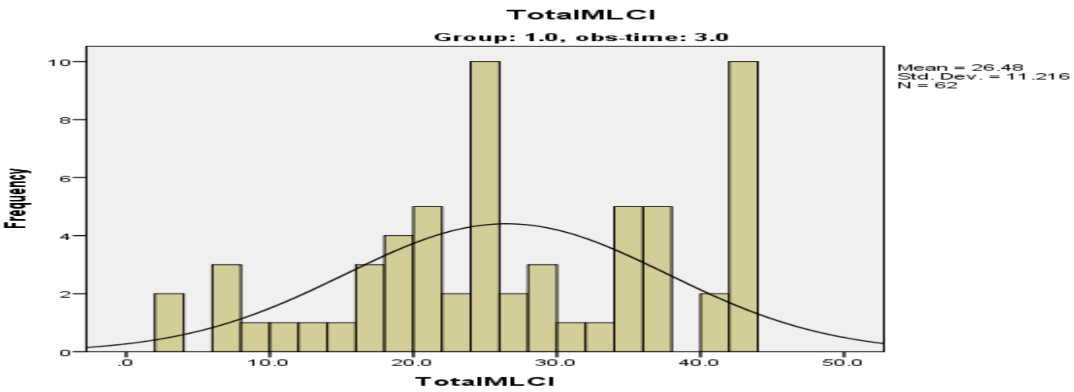

Total PS
Group: 1.0, obs-time: 3.0
Mean = 19.06
Std. Dev. = 17.104
N = 62
Frequency
Total PS

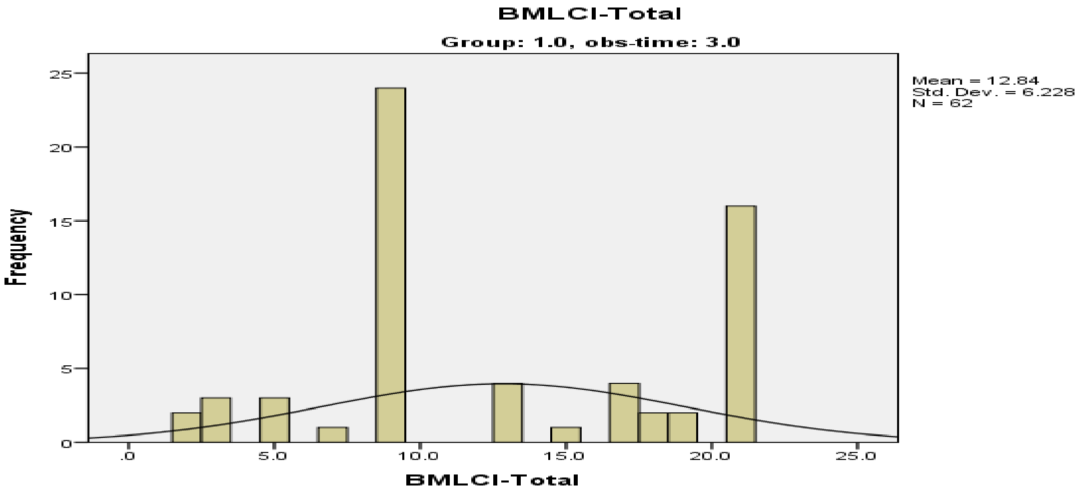

totalMabis
Group: 1.0, obs-time: 3.0
Mean = 30.95
Std. Dev. = 15.177
N = 62
Frequency
totalMabis

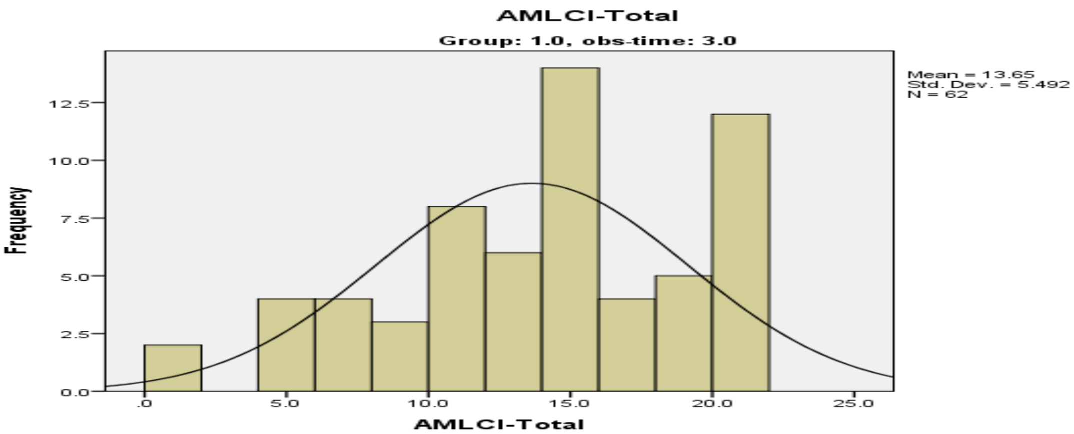

EQ5Dindex
Group: 1.0, obs-time: 3.0
Mean = .688
Std. Dev. = .296
N = 62
Frequency
EQ5Dindex

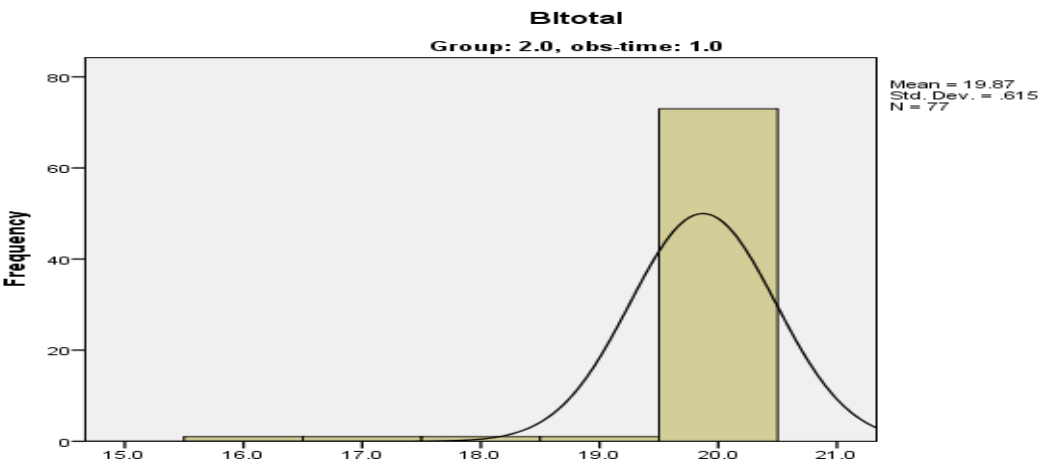

VAS
Group: 1.0, obs-time: 3.0
Mean = 66.69
Std. Dev. = 21.784
N = 62
Frequency
VAS

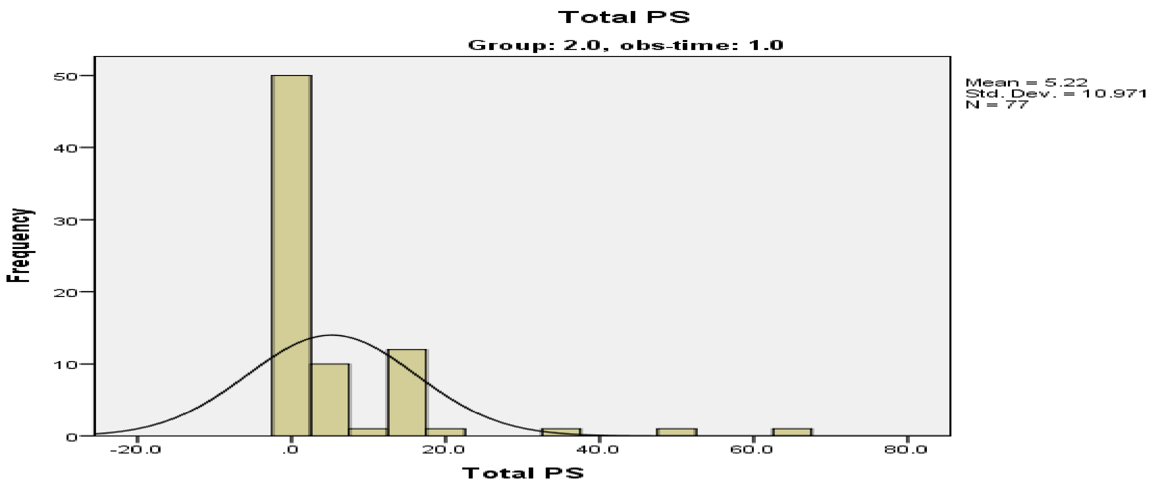

TUG
Group: 1.0, obs-time: 3.0
Mean = 34.37
Std. Dev. = 33.319
N = 62
Frequency
TUG

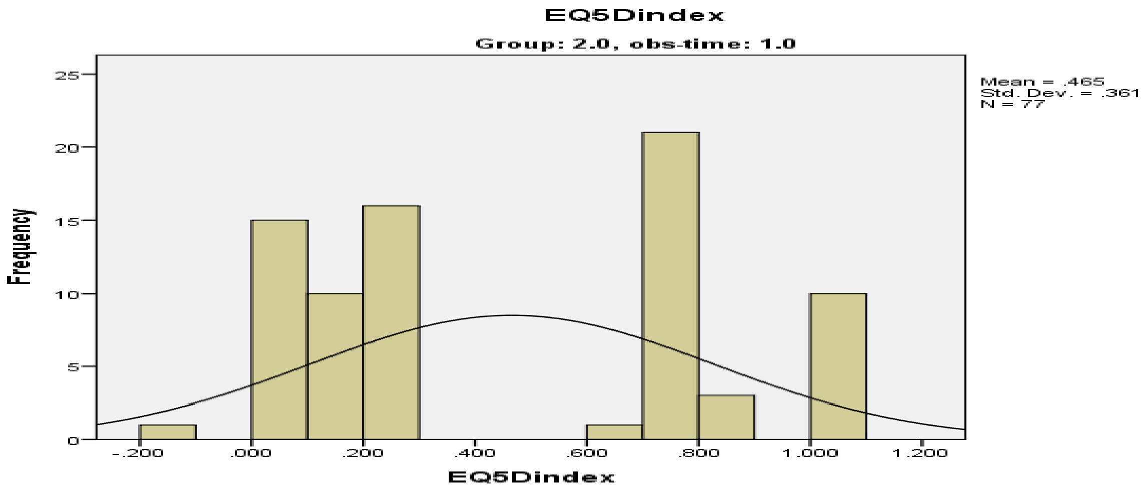

TotalMLCI
Group: 1.0, obs-time: 3.0
Mean = 26.48
Std. Dev. = 11.216
N = 62
Frequency
TotalMLCI

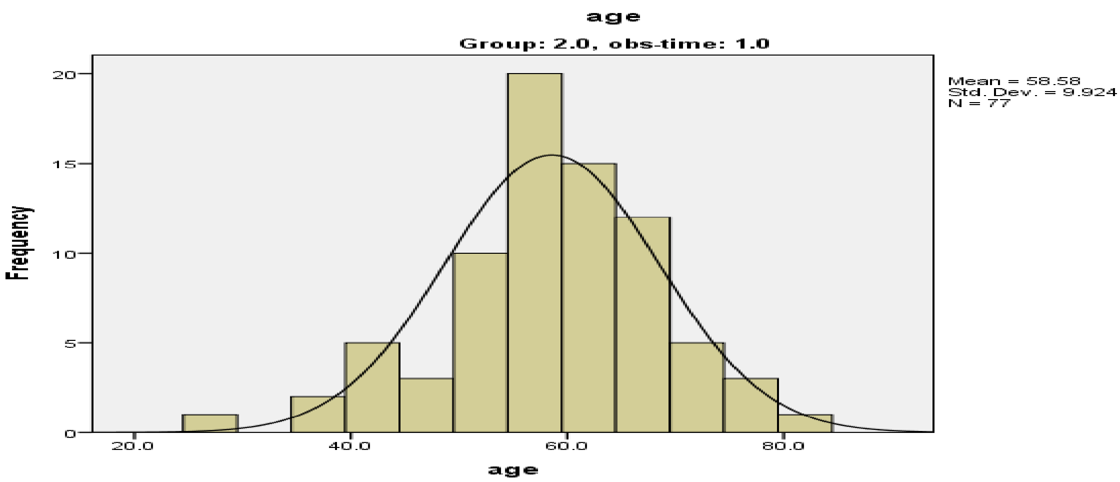

BMLCI-Total
Group: 1.0, obs-time: 3.0
Mean = 12.84
Std. Dev. = 6.228
N = 62
Frequency
BMLCI-Total

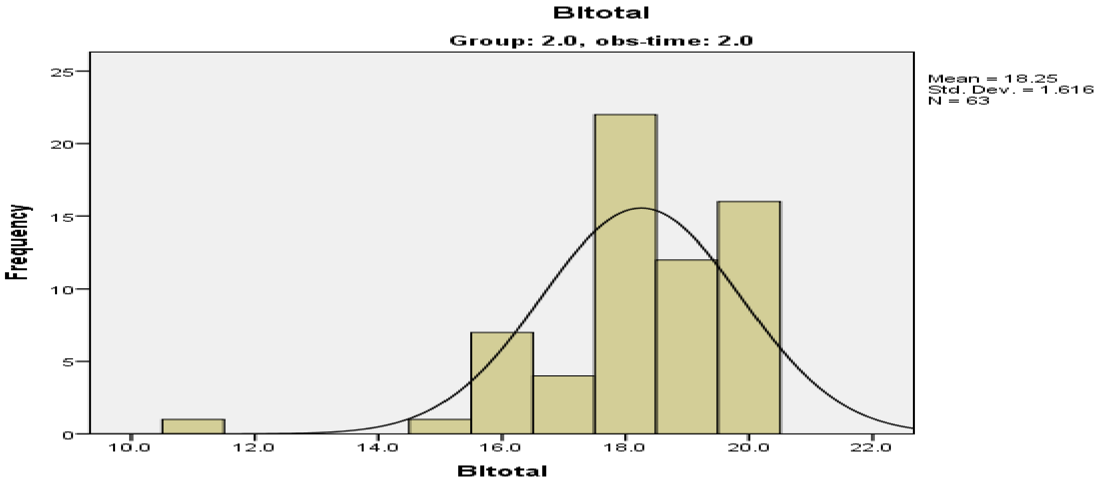

AMLCI-Total
Group: 1.0, obs-time: 3.0
Mean = 13.65
Std. Dev. = 5.492
N = 62
Frequency
AMLCI-Total

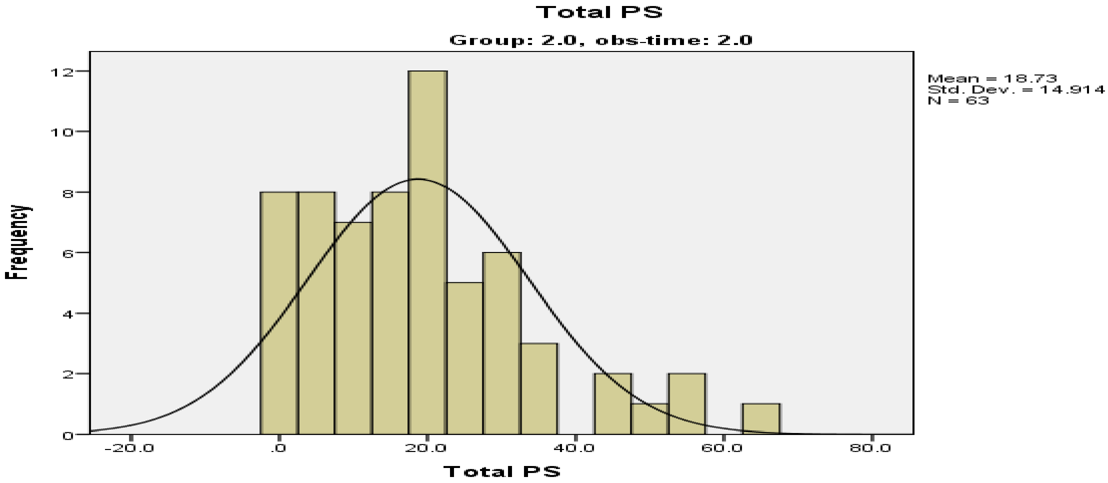

BItotal
Group: 2.0, obs-time: 1.0
Mean = 19.87
Std. Dev. = .615
N = 77
Frequency
BItotal

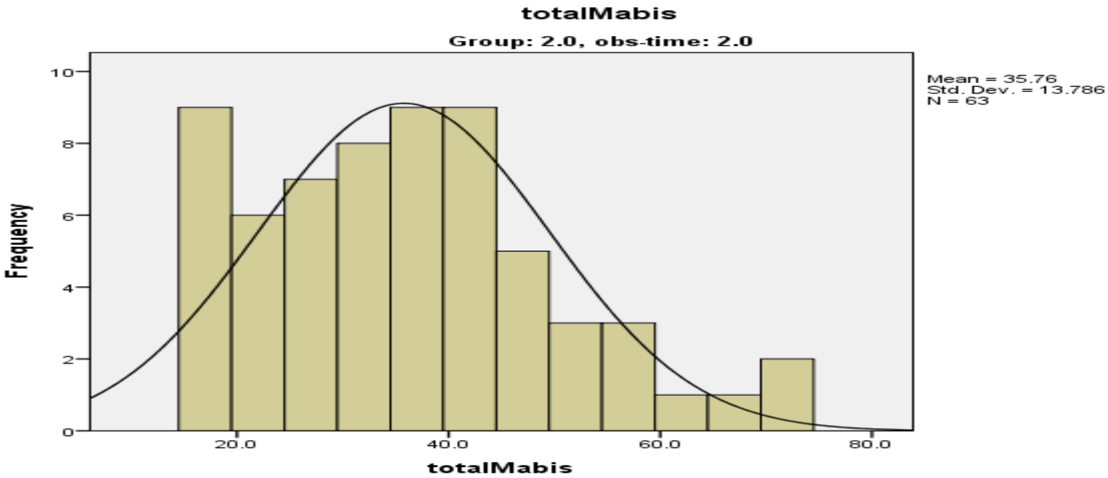

Total PS
Group: 2.0, obs-time: 1.0
Mean = 5.22
Std. Dev. = 10.971
N = 77
Frequency
0
10
20
30
40
50
-20.0
.0
20.0
40.0
60.0
80.0
Total PS

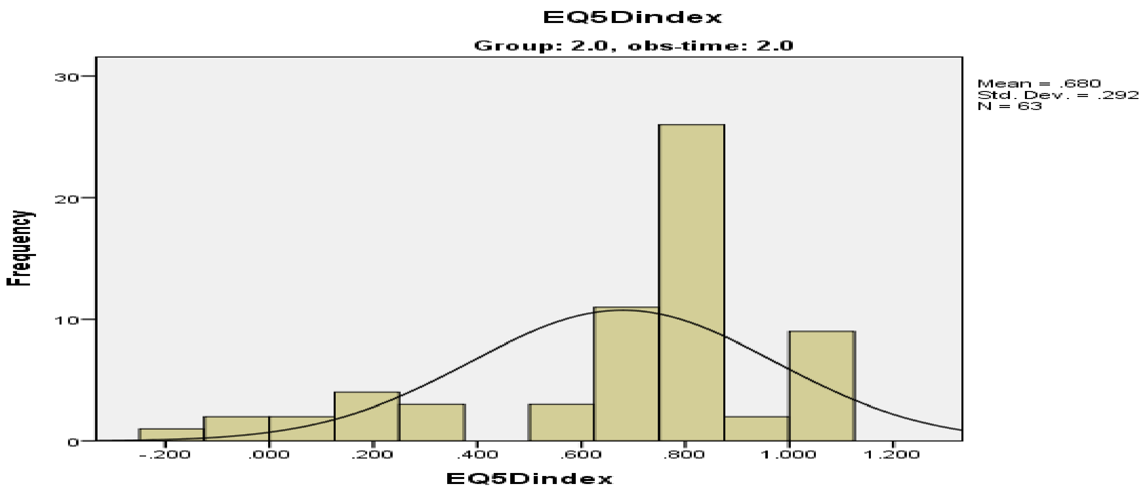

EQ5Dindex
Group: 2.0, obs-time: 1.0
Mean = .465
Std. Dev. = .361
N = 77
Frequency
0
5
10
15
20
25
-.200
.000
.200
.400
.600
.800
1.000
1.200
EQ5Dindex

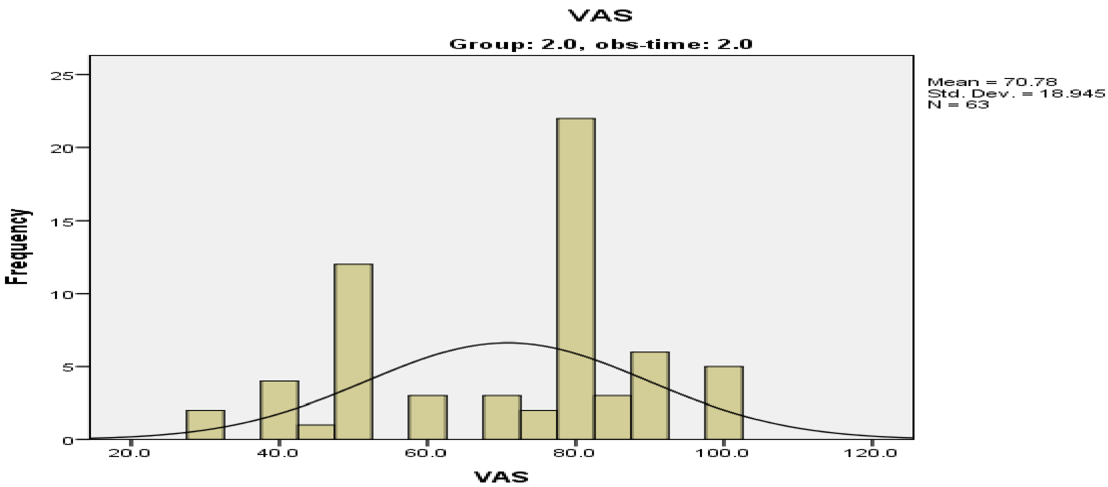

age
Group: 2.0, obs-time: 1.0
Mean = 58.58
Std. Dev. = 9.924
N = 77
Frequency
0
5
10
15
20
20.0
40.0
60.0
80.0
age

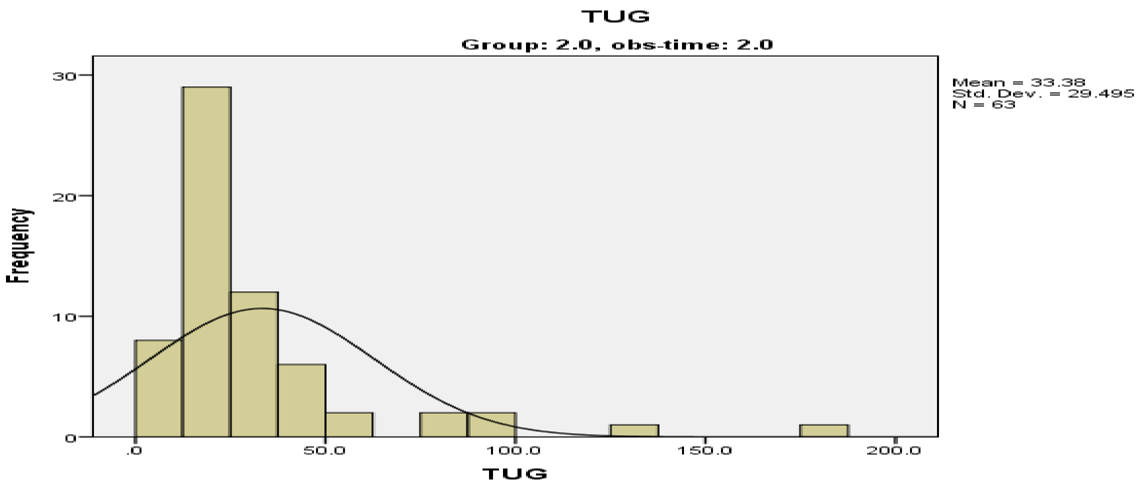

BItotal
Group: 2.0, obs-time: 2.0
Mean = 18.25
Std. Dev. = 1.616
N = 63
Frequency
BItotal

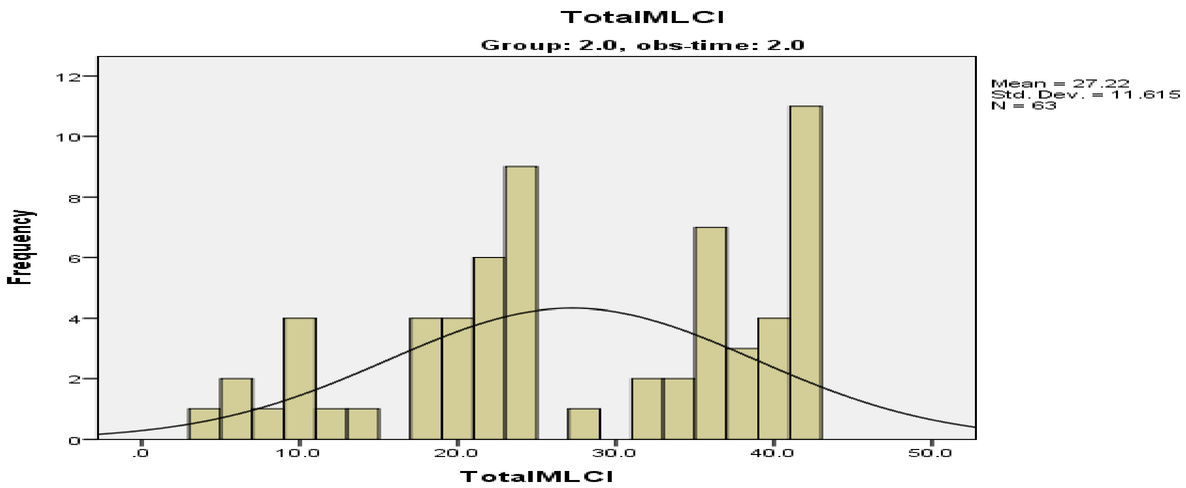

Total PS
Group: 2.0, obs-time: 2.0
Mean = 18.73
Std. Dev. = 14.914
N = 63
Frequency
Total PS

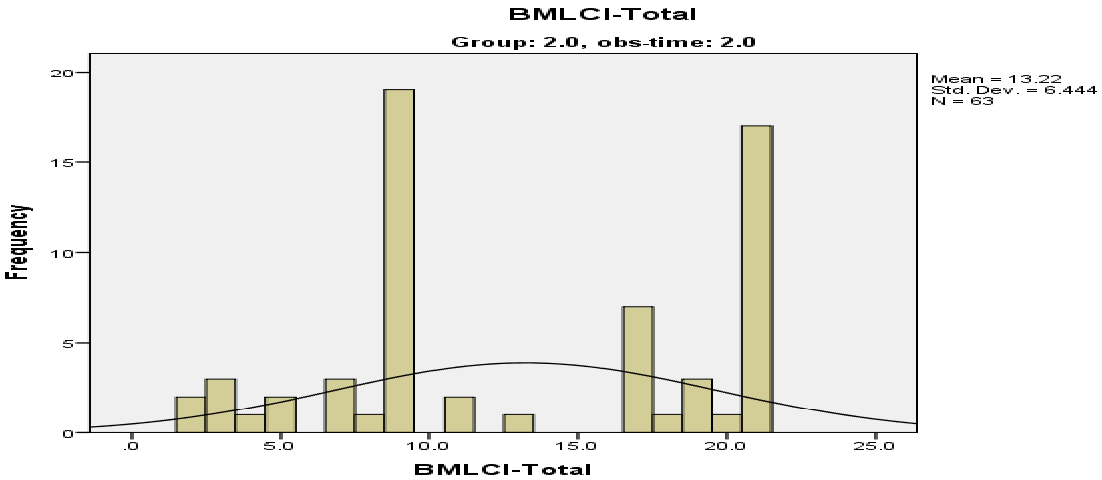

totalMabis
Group: 2.0, obs-time: 2.0
Mean = 35.76
Std. Dev. = 13.786
N = 63
Frequency
totalMabis

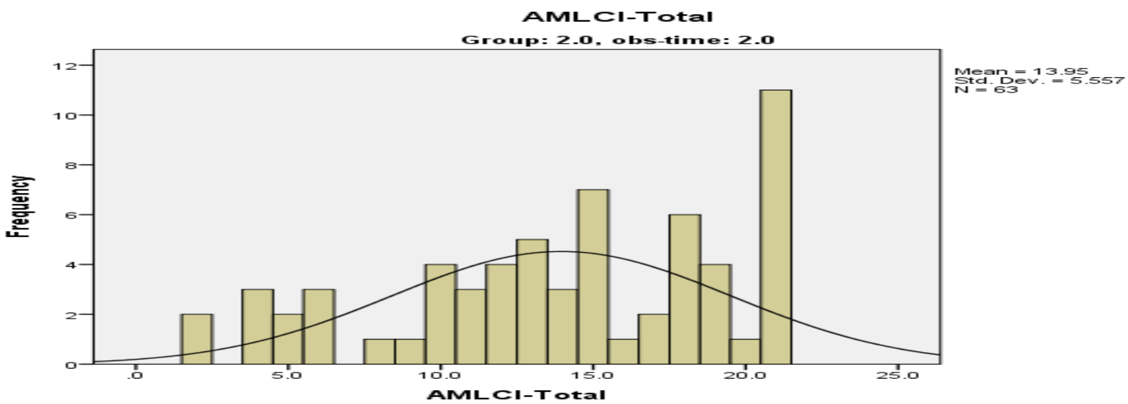

EQ5Dindex
Group: 2.0, obs-time: 2.0
Mean = .680
Std. Dev. = .292
N = 63
Frequency
30
20
10
0
-.200
.000
.200
.400
.600
.800
1.000
1.200
EQ5Dindex

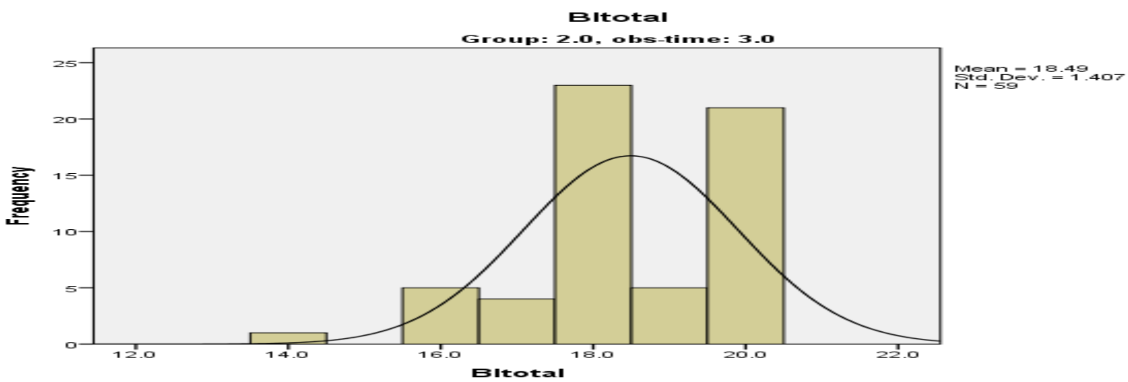

VAS
Group: 2.0, obs-time: 2.0
Mean = 70.78
Std. Dev. = 18.945
N = 63
Frequency
25
20
15
10
5
0
20.0
40.0
60.0
80.0
100.0
120.0
VAS

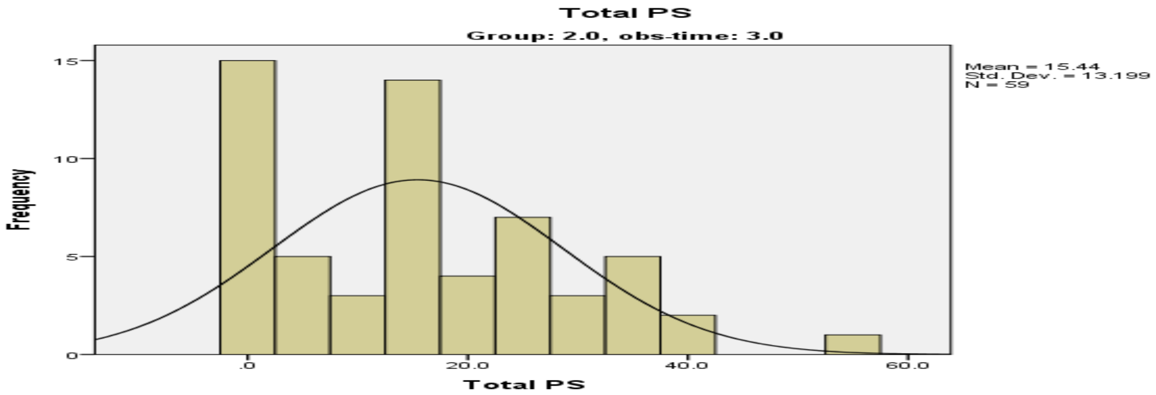

TUG
Group: 2.0, obs-time: 2.0
Mean = 33.38
Std. Dev. = 29.495
N = 63
Frequency
30
20
10
0
.0
50.0
100.0
150.0
200.0
TUG


TotalMLCI
Group: 2.0, obs-time: 2.0
Mean = 27.22
Std. Dev. = 11.615
N = 63
Frequency
TotalMLCI

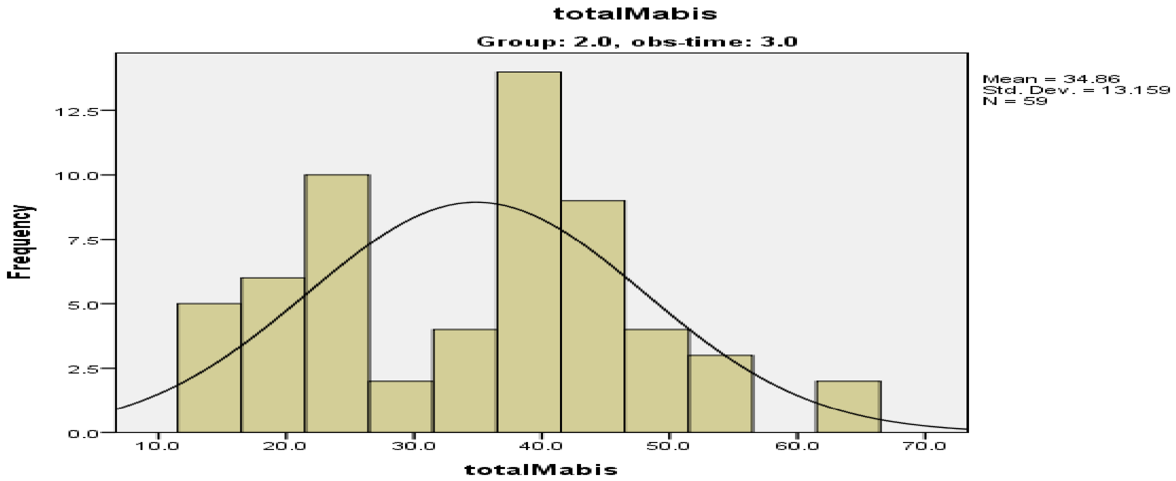

BMLCI-Total
Group: 2.0, obs-time: 2.0
Mean = 13.22
Std. Dev. = 6.444
N = 63
Frequency
BMLCI-Total


AMLCI-Total
Group: 2.0, obs-time: 2.0
Mean = 13.95
Std. Dev. = 5.557
N = 63
Frequency
AMLCI-Total

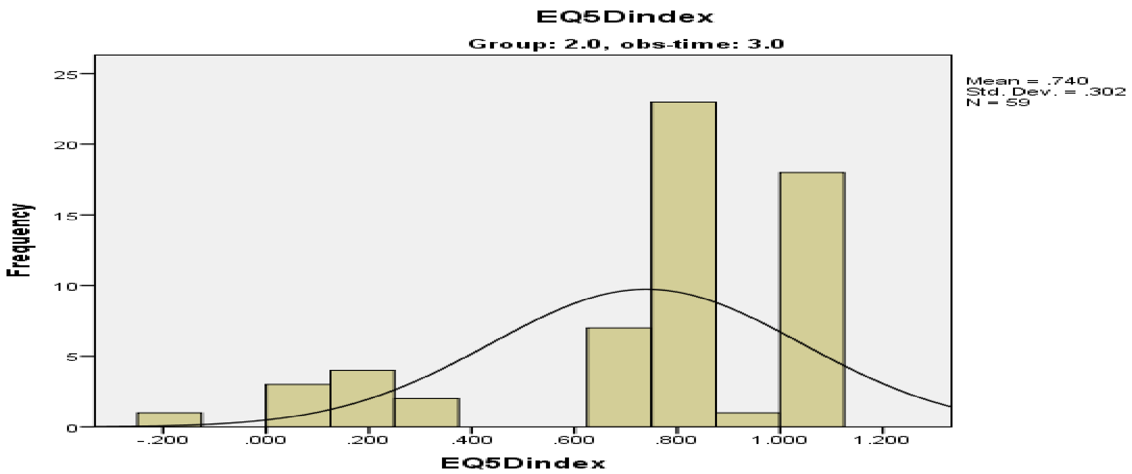

BItotal
Group: 2.0, obs-time: 3.0
Mean = 18.49
Std. Dev. = 1.407
N = 59
Frequency
BItotal



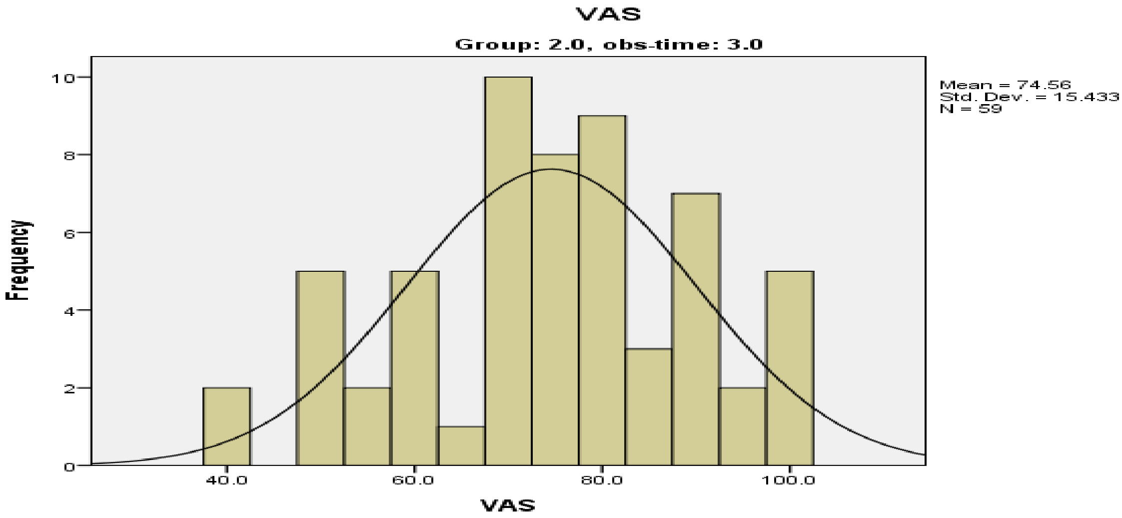
Total PS
Group: 2.0, obs-time: 3.0
Mean = 15.44
Std. Dev. = 13.199
N = 59
Frequency
Total PS

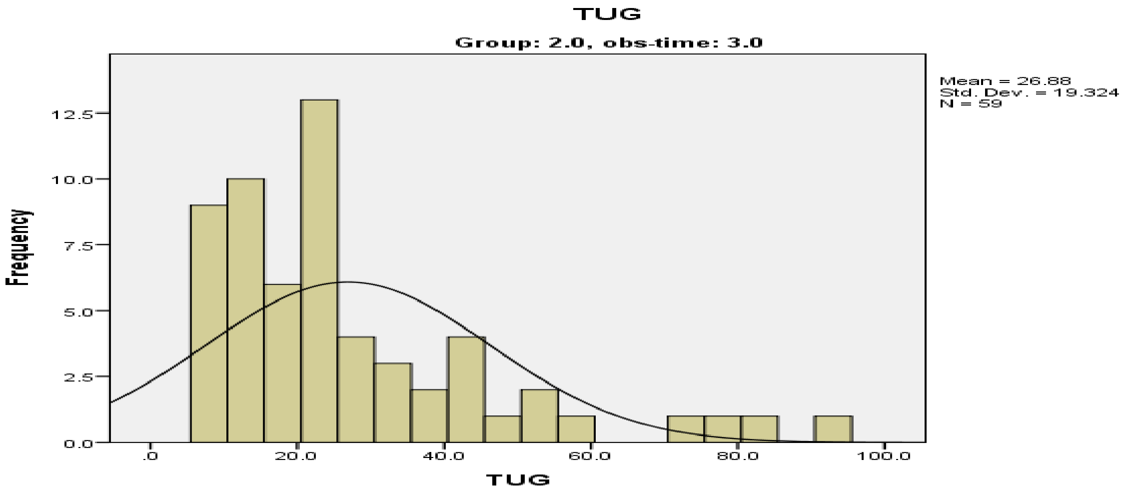


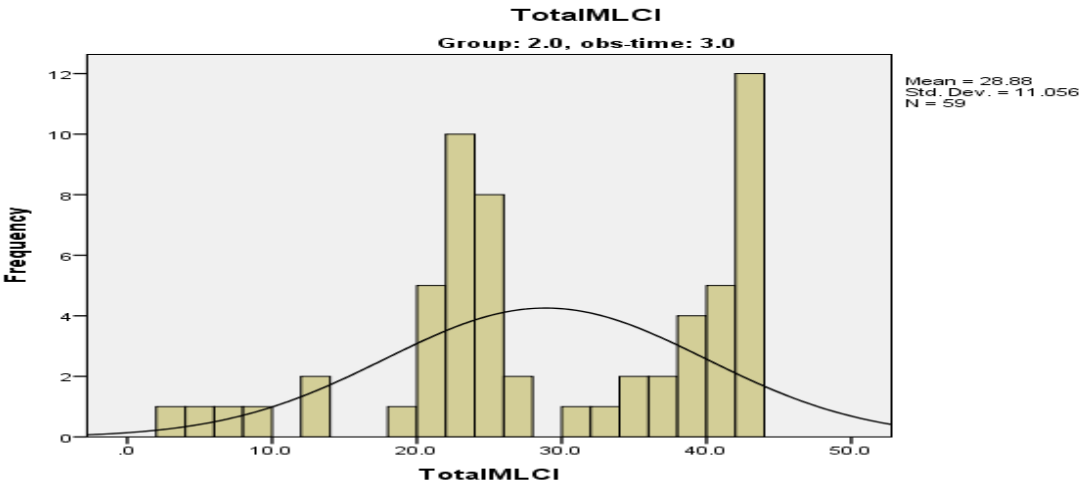
totalMabis
Group: 2.0, obs-time: 3.0
Mean = 34.86
Std. Dev. = 13.159
N = 59
Frequency
totalMabis

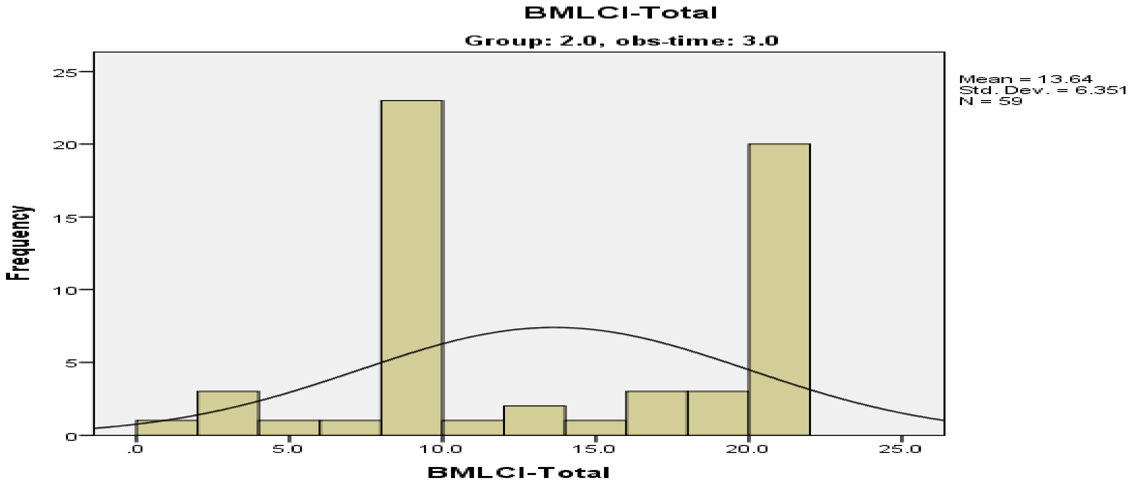


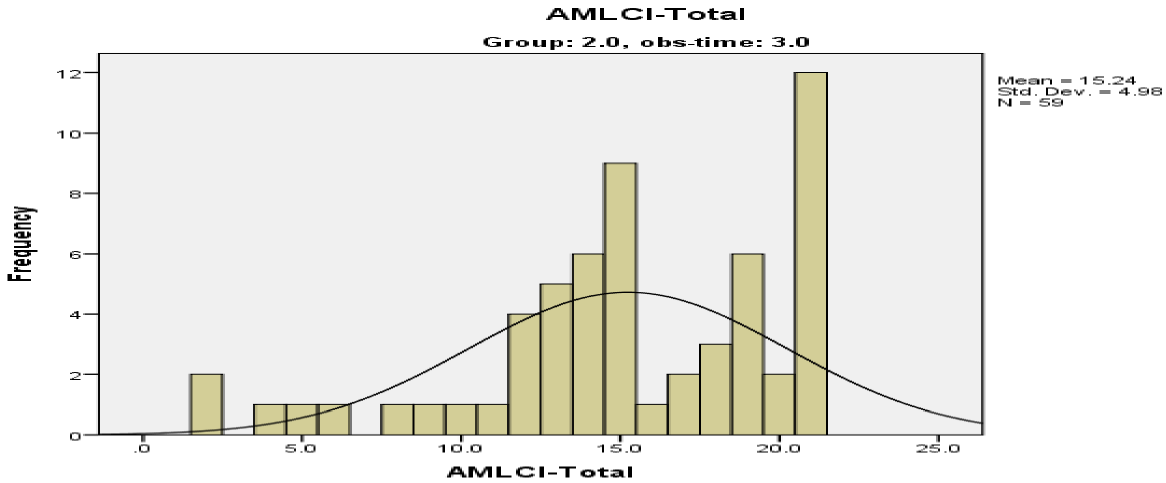
EQ5Dindex
Group: 2.0, obs-time: 3.0
Mean = .740
Std. Dev. = .302
N = 59
Frequency
EQ5Dindex


VAS
Group: 2.0, obs-time: 3.0
Mean = 74.56
Std. Dev. = 15.433
N = 59
Frequency
0
2
4
6
8
10
40.0
60.0
80.0
100.0
VAS


TUG
Group: 2.0, obs-time: 3.0
Mean = 26.88
Std. Dev. = 19.324
N = 59
Frequency
0.0
2.5
5.0
7.5
10.0
12.5
.0
20.0
40.0
60.0
80.0
100.0
TUG


TotalMLCI
Group: 2.0, obs-time: 3.0
Mean = 28.88
Std. Dev. = 11.056
N = 59
Frequency
0
2
4
6
8
10
12
.0
10.0
20.0
30.0
40.0
50.0
TotalMLCI


BMLCI-Total
Group: 2.0, obs-time: 3.0
Mean = 13.64
Std. Dev. = 6.351
N = 59
Frequency
25
20
15
10
5
0
.0
5.0
10.0
15.0
20.0
25.0
BMLCI-Total


AMLCI-Total
Group: 2.0, obs-time: 3.0
Mean = 15.24
Std. Dev. = 4.98
N = 59
Frequency
12
10
8
6
4
2
0
.0
5.0
10.0
15.0
20.0
25.0
AMLCI-Total

APPENDIX iia

GEE ADJUSTING FOR BASELINE AMPUTATION LEVEL

Table 1 illustrates parameter estimates of dependent variable: P-Scale total.

Table 1 Parameter estimates of dependent variable: P-Scale total.

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	P-value
(Intercept)	5.965	1.5723	2.884	9.047	14.394	1	0.000
[Amputation level=5.0]	-.956	1.4665	-3.830	1.919	.425	1	0.515
[Amputation level=8.0]	0	.	.	.	.	.	.
[Group=1.0]	-2.887	1.4109	-5.652	-.122	4.187	1	0.041
[Group=2.0]	0	.	.	.	.	.	.
(Scale)	83.782						

Table 1 shows that level of amputation has no significant (p=0.515) role in P-scale outcome

Table 2 illustrates parameter estimates of dependent variable: BI total.

Table 2 Parameter estimates of dependent variable: BI total.

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	P-value
(Intercept)	19.955	.0998	19.759	20.151	39989.710	1	0.000
[Amputation level=5.0]	-.109	.1224	-.349	.131	.790	1	0.374
[Amputation level=8.0]	0	.	.	.	.	.	.
[Group=1.0]	-.204	.1244	-.448	.039	2.699	1	0.100
[Group=2.0]	0	.	.	.	.	.	.
(Scale)	.588						

Table 2 shows that level of amputation has no significant (p=0.374) role in BI outcome.

Table 3 illustrates parameter estimates of dependent variable: EQ-5D VAS

Table 3: Parameter estimates of dependent variable: EQ-5D VAS

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	Df	P-value
(Intercept)	69.783	3.9651	62.012	77.554	309.741	1	0.000
[Amputation level=5.0]	.062	3.8727	-7.528	7.652	.000	1	0.987
[Amputation level=8.0]	0	.	.	.	.	.	.
[Group=1.0]	.299	3.5898	-6.737	7.334	.007	1	0.934
[Group=2.0]	0	.	.	.	.	.	.
(Scale)	487.170						

Table 3 shows that level of amputation has no significant (p=0.987) role in EQ-5D VAS outcome.

Table 4 illustrates parameter estimates of dependent variable: EQ-5D Index.

Table 4: Parameter estimates of dependent variable: EQ-5D Index

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	p-value
(Intercept)	.539	.0646	.412	.666	69.708	1	0.000
[Amputation level=5.0]	-.095	.0627	-.217	.028	2.276	1	0.131
[Amputation level=8.0]	0	.	.	.	.	.	.
[Group=1.0]	-.132	.0548	-.239	-.025	5.799	1	0.016
[Group=2.0]	0	.	.	.	.	.	.
(Scale)	.119						

Table 4 shows that level of amputation has no significant (p=0.131) role in EQ-5D Index outcome.

APPENDIX iib

GEE TO EXCLUDE AGE, GENDER AND COMORBIDITIES AS CONFOUNDERS

Table iib 1 illustrates the effect of gender, level of amputation, comorbidities and age on BI outcome.

Table iib: 1 Effect of gender, level of amputation, comorbidities and age on BI outcome.

Dependent variable:BI

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	p-value
(Intercept)	19.574	.3892	18.812	20.337	2529.655	1	.000
male	.013	.0982	-.179	.206	.018	1	.894
female	0	.	.	.	.	.	.
BKA	-.252	.1567	-.559	.056	2.577	1	.108
AKA	0	.	.	.	.	.	.
HPT=.0	.154	.1382	-.116	.425	1.250	1	.264
HPT=1.0	0	.	.	.	.	.	.
Arthritis=.0	-.346	.3458	-1.024	.331	1.003	1	.316
Arthritis=1.0	0	.	.	.	.	.	.
CHD=yes	-.317	.4105	-1.122	.487	.597	1	.440
CHD=no	0	.	.	.	.	.	.
PVD=yes	.096	.1002	-.101	.292	.914	1	.339
PVD=no	0	.	.	.	.	.	.
Diabetes=yes	.510	.1704	.176	.844	8.966	1	.003
Diabetes=no	0	.	.	.	.	.	.
other=yes	.087	.1503	-.207	.382	.338	1	.561
other=no	0	.	.	.	.	.	.
age	-.001	.0069	-.014	.013	.018	1	.892
(Scale)	.567						

Footnote: PVD and diabetes are not regarded as comorbidities in this study, they are regarded as actual aetiologic conditions.

Table iib 1 shows that gender, level of amputation, comorbidities and age all had no significant effect of BI

Table iib 2 illustrates the effect of gender, level of amputation, on P-Scale outcome.

Table iib 2: Effect of gender, level of amputation, on P-Scale outcome

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	p-value
(Intercept)	5.402	1.6972	2.076	8.729	10.132	1	.001
male	-2.098	1.8203	-5.665	1.470	1.328	1	.249
female	0	.	.	.	.	.	.
BKA	-.242	1.5603	-3.301	2.816	.024	1	.876
AKA	0	.	.	.	.	.	.
(Scale)	84.781						

Table iib 2 shows that gender and level of amputation had no significant effect of P-Scale

Table iib 3 illustrates the effect of gender, level of amputation, on BI outcome.

Table iib 3: Effect of gender, level of amputation, on BI outcome

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	p-value
(Intercept)	19.855	.1092	19.641	20.069	33061.016	1	.000
Male	-.054	.1180	-.285	.177	.210	1	.647
Female	0	.	.	.	.	.	.
BKA	-.060	.1221	-.299	.180	.238	1	.625
AKA	0	.	.	.	.	.	.
(Scale)	.598						

Table iib 3 shows that gender and level of amputation had no significant effect of BI

Table iib 4 illustrates the effect of gender, level of amputation, on EQ-5D index outcome.

Table iib 4: Effect of gender, level of amputation, on EQ-5D index outcome

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	p-value
(Intercept)	.418	.0670	.287	.549	38.880	1	.000
Male	.053	.0588	-.062	.168	.810	1	.368
Female	0	.	.	.	.	.	.
BKA	-.064	.0641	-.190	.062	.997	1	.318
AKA	0	.	.	.	.	.	.
(Scale)	.122						

Table iib 4 shows that gender and level of amputation had no significant effect of EQ-5D index

Table iib 5 illustrates the effect of gender, level of amputation, on EQ-5D outcome.

Table iib 5: Effect of gender, level of amputation, on EQ-5D VAS outcome

Parameter	B	Std. Error	95% Wald Confidence Interval		Hypothesis Test		
			Lower	Upper	Wald Chi-Square	df	p-value
(Intercept)	68.454	4.3667	59.895	77.012	245.750	1	.000
Male	2.385	3.9668	-5.390	10.159	.361	1	.548
Female	0	.	.	.	.	.	.
BKA	-.042	3.7855	-7.461	7.377	.000	1	.991
AKA	0	.	.	.	.	.	.
(Scale)	485.871						

Table iib 5 shows that gender and level of amputation had no significant effect of EQ-5D VAS

APPENDIX iiia

ITT DEATHS EXCLUDED FROM BASELINE, LOST PARTICIPANTS DATA IMPUTED

Introduction

These results are of all the participants (including all those who were followed up as well as those whore were lost during follow up but were not confirmed dead) excluding all those who died. These result show that the outcome of the RCT is generally similar regardless of method of date analysis, be it PPA or ITT inclusive of those who died as presented is chapter 6.

Demographic characteristics of the participants

Tables 1 illustrate the demographic characteristics of the two groups.

Tables 1 demographic characteristics of the two groups

Demographic profile, Group 1 n=62, Group 2 n=59				
		Group1 n(%)	Group2 n(%)	p-value
Age	25th percentile Median 75th percentile	50 57 62.25	54 59 65	0.115
Gender	Male	43(69.4)	37(62.7)	0.281
	Female	19(30.6)	22(37.2)	
Transport mode	Own car	18(29)	14(23.7)	0.809
	Relative's car	6(9.7)	5(8.5)	
	Public transport	36(58).1	39(66.1)	
	Hire private transport	2(3.2)	1(1.7)	
	Other			
Income	Private pension	2(3.2)		0.564
	Old age pension	18(29)	21(35.6	
	Disability grant	6(9.7)	5(8.5)	
	Still employed	24(38.7)	18(30.5)	
	Other	12(19.4)	15(25.4)	
Cigarette Smokers	Yes	37(59.7)	26(44.1)	0.062
	No	35(40.3)	33(55.9)	
Alcohol consumption	Yes	21(33.9)	25(42.4)	0.219
	No	41(66.1	34(57.6)	

p≤0.05 is significant. Fisher's exact test- , There was no significant difference in the age of the two groups for any of the demographic characteristics.

Tables 2 illustrate the clinical characteristics of the groups.

Tables 2 clinical characteristics of the groups

Clinical profile, Group 1 n=62, Group 2 n=59				
		Group1 n(%)	Group2 n(%)	P-value
Level of amputation	BKA	39(59.7)	49(83.1)	0.004
	AKA	25(40.3)	10(16.9)	
HPT	Yes	33(53.2)	38(64.4)	0.144
	No	29(46.8)	21(35.6)	
Heart disease	Yes	3(4.8)	4(6.8	0.472
	No	59(95.2)	55(93.2)	
Diabetes	Yes	36(58.1)	40(67.8)	0.179
	No	26(41.9)	19(32.2)	
PVD	Yes	32(51.6)	22(37.3)	0.080
	No	30(48.4)	37(62.7)	
Arthritis	Yes	1(1.6)	5(8.5)	0.092
	No	61(98).4	54(91.5)	
Other (HIV, asthma, renal disease etc)	Yes	4(6.5)	7(11.9)	0.237
	No	58(93.5)	55(88.1)	

p≤0.05 is significant. Fisher's exact tests- ,

Group 2 had a significantly more participants with a BKA than Group 1.

Participation restriction

Table 3 illustrates the participation levels of the two groups from the preoperative period to six months.

Table 3: Participation levels of the two groups from the preoperative period to six months

P-Scale									
	Baseline			three months			six months		
	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value
25th percentile Median 75th percentile	0 0 0	0 0 5	0.371	10 26.5 41.25	6 10 28	0.006	1.75 15 30	0 15 25	0.280

$p \leq 0.05$ is significant.

The groups were comparable at baseline. However, Group 2 demonstrated significantly better (p=0.004) participation levels at three months postoperatively compare to Group 1. In fact, the Group 2 median score shows no significant participation restriction while the Group 1 median score shows moderate participation restriction during this follow up period. At six months follow up, the participation levels are similar both groups. Both groups show mild participation restriction by six months postoperatively.

Table 4 illustrates the participation levels of the two groups from preoperative to six months item by item.

Table 4: Participation levels of the two groups from preoperative to six months item by item

P-Scale, Group 1 n=62, Group 2 n=59										
		Baseline			3months			six months		
Item	Item level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
1 Do you have equal opportunity as your peers to find work?	0	55(88.7)	48(81.4)	0.364	37(59.7)	34(57.6)	0.925	37(59.7)	38(64.4)	0.751
	1		1(1.6)					1(1.6)	1(1.7)	
	3					1(1.7)			1(1.7)	
	5	7(11.3)	10(16.9)		25(40.3)	24(40.7)		24(38.7)	19(32.2)	
2 Do you work as hard as your peers do? (same hours, type of work etc)	0	56(90.3)	49(83.1)	0.340	39(62.9)	33(55.9)	0.574	37(59.7)	40(67.8)	0.450
	1		1(1.7)					1(1.6)		
	2					1(1.7)				
	3					1(1.7)		24(38.7)		
	5	6(9.7)	9(15.3)		23(37.1)	24(40.7)			19(32.2)	
3 Do you contribute to the household economically in a similar way to your peers?	0	52(83.9)	45(76.3)	0.471	35(56.5)	35(59.3)	0.294	39(62.9)	38(64.4)	0.507
	2		1(1.7)							
	3	2(3.2)	1(1.7)		1(1.6)	4(6.8)				
	5	8(15.9)	12(20.3)		26(41.9)	20(33.9)		23(37.1)	21(35.6)	
4 Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	59(95.2)	58(98.3))	1.000	30(48.4)	42(71.2)	0.003	39(62.9)	48(81.4)	0.082
	1	1(1.6)	1(1.7)			4(6.8)		2(3.2)		
	2	1(1.6)			1(1.6)			2(3.2)	1(1.7)	
	3	1(1.6)			8(12.9)	3(5.1)		2(3.2)	3(5.1)	
	5				23(37.1)	10(16.9)		17(27.4)	7(11.9)	
5 Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	60(96.8)	59(100)	1.000	22(35.5)	36(61)	0.009	42(67.7)	42(71.2)	0.938
	1	1(1.6)				1(1.7)				
	2					1(1.7)		1(1.6)	1(1.7)	
	3	1(1.6)			5(8.1)	3(5.1)		2(3.2)	2(3.4)	
	5				35(56.5)	18(30.5)		17(27.4)	14(23.7)	
6 Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	61(98.4)	59(100)	1.000	22(35.5)	35(59.3)	0.046	38(61.3)	40(67.8)	0.887
	1							1(1.6)	1(1.7)	
	2				2(3.2)	1(1.7)		1(1.6)	1(1.7)	
	3	1(1.6)			5(8.1)	4(6.8)		1(1.6)		
	5				33(53.1)	19(32.2)		21(33.9)	17(28.8)	
7 Are you as socially active as your peers are? (e.g.	0	61(98.4)	59(100)	0.512	33(53.2	35(59.3)	0.787	44(71)	44(74.6)	0.716

P-Scale, Group 1 n=62, Group 2 n=59										
		Baseline			3months			six months		
in religious/community affairs)	1					1(1.7)				
	2				1(1.6)				1(1.7)	
	3	1(1.6)			4(6.5)	4(6.8)		1(1.6)		
	5				24(38.7)	19(32.2)		17(27.4)	14(23.7)	
8 Do you have the same respect in the community as your peers?	0	62(100)	59(100)	Constant	57(91.9)	56(94.9)	0.712	60(96.8)	56(94.9)	0.608
	2					1(1.7)		1(1.6)		
	3				2(3.2)	1(1.7)			1(1.7)	
	5				3(4.8)	1(1.7)		1(1.6)	2(3.4)	
9 Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	62(100)	59(100)	Constant	53(85.5)	55(93.2)	0.390	56(90.3)	54(91.5)	0.491
	1					1(1.7)				
	2				2(3.2)	1(1.7)			1(1.7)	
	3				2(3.2)			4(6.5)	1(1.7)	
	5				5(8.1)	2(3.4)		2(3.2)	3(5.1)	
10 Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?	0	60(96.8)	59(100)	1.000	48(77.4)	48(71.2)	0.395	49(79)	52(88.1)	0.385
	1					1(1.7)		1(1.6)		
	2	1(1.6)				2(3.4)		1(1.6)	1(1.7)	
	3				3(4.8)	2(3.4)		3(4.8)		
	5	1(1.6)			11(17.7)	6(10.2)		8(12.9)	6(10.2)	
11 Do you visit other people in the community as often as other people do?	0	61(98.4)	58(98.3)	1.000	34(54.8)	48(81.4)	0.004	46(74.2)	48(81.4)	0.637
	1					2(3.4)				
	2					2(3.4)		2(3.2)		
	3				10(16.1)	1(1.7)		3(4.8)	3(5.1)	
	5	1(1.6)	1(1.7)		18(29)	12(20.3)		11(17.7	8(13.6)	
12 Do you move around inside and outside the house and around the village / neighbourhood just as other people do?	0	61(98.4)	59(100)	1.000	36(58.1)	44(74.6)	0.031	46(74.2))	51(86.4)	0.293
	1					1(1.7				
	2				1(1.6)	1(1.7		2(3.2)		
	3	1(1.6)			9(14.5	1(1.7)		4(6.5)	2(3.4)	
	5				16(25.8)	12(20.3)		10(16.1)	6(10.2)	
13 In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	60(96.8)	59(100)	1.000	29(46.8)	44(74.6)	0.009	45(72.6)	47(79.7)	0.298
	2				2(3.2)	1(1.7)			2(3.4)	
	3	1(1.6)			8(12.9)	2(3.4)		4(6.5)	3(5.1)	
	5	1(1.6)			23(37.1)	12(20.3)		13(21)	7(11.9)	
14 In your home, do you do household work?	0	59(95.2)	58(98.3)	1.000	36(58.1)	39(66.1)	0.119	43(69.3)	39(66.1)	0.814

P-Scale, Group 1 n=62, Group 2 n=59										
		Baseline			3months			six months		
	1					2(3.4)			1(1.7)	
	2				3(4.8)			3(4.8)	1(1.7)	
	3	2(3.2)	1(1.7)		11(17.7)	5(8.5)		5(8.1)	6(10.2)	
	5	1(1.6)			12(19.4)	13(22)		11(17.7)	12(20.3)	
15 In family discussions, does your opinion count?	0	59(95.2)	58(98.3)	0.746	59(95.2)	58(98.3)	0.746	61(98.4)	56(94.9)	0.172
	2								1(1.7)	
	3	2(3.2)			2(3.2)			1(1.6)		
	5	1(1.6)	1(1.7)		1(1.6)	1(1.7)			2(3.4)	
16 Do you help other people (e.g. neighbours, friends or relatives)?	0	61(98.4)	59(100)	0.512	47(75.8)	56(94.9)	0.009	55(88.7)	55(93.2)	0.129
	1				1(1.6)	1(1.7)				
	2				3(4.8)					
	3	1(1.6)			2(3.2)	1(1.7)		1(1.6)	3(5.1)	
	5				9(14.5)	1(1.7)		6(9.7)	1(1.7)	
17 Are you comfortable meeting new people?	0	61(98.4)	59(100)	0.512	58(93.5)	59(100)	0.246	58(93.5)	55(93.2)	0.284
	1							1(1.6)		
	2				2(3.2)				2(3.4)	
	3	1(1.6)							1(1.7)	
	5				2(3.2)			3(4.8)	1(1.7)	
18 Do you feel confident to try to learn new things?	0	61(98.4)	59(100)	0.512	59(95.2)	58(98.3)	1.000	58(98.3)	56(94.9)	0.334
	1							1(1.6)		
	2				1(1.6)	1(1.7)				
	3	1(1.6)			1(1.6)				2(3.4)	
	5				1(1.6)			3(4.8)	1(1.7)	

*p≤0.0028 is significant (Fisher's exact test-Bonferroni corrected).

The groups show no significant difference in participation scores item by item from baseline to six months follow up item by items.

Activity limitation

Table 5 illustrates the activity (BI) levels of the two groups from the preoperative period to six months.

Table 5: Activity (BI) levels of the two groups from the preoperative period to six months

BI									
	Baseline			three months			six months		
	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value
25th percentile Median 75th percentile	20 20 20	20 20 20	0.136	16 18 19	18 18 20	0.038	18 18 20	18 18 20	0.638

$p \leq 0.05$ is significant.

The groups were comparable at baseline. However, Group 2 demonstrated significantly less (p=0.043) activity limitation levels (higher activity levels) at three months postoperatively compare to Group 1. At six months follow up, the levels of activity similar amongst both groups.

Table 6 illustrates the levels activity limitation of the two groups from preoperative to six months item by item.

Table 6: Levels activity limitation of the two groups from preoperative to six months item by item

BI (Group 1, n=62, Group 2, n=59)										
		Baseline			3months			six months		
Item	Level	Group1 n (%)	Group 2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
1 Bowel	0			0.740	1(1.6)	1(1.7)	1.000	1(1.6)		1.000
	1	1(1.6)	1(1.7)		1(1.6)			1(1.6)		
	2	61(98.4)	58(98.3)		60(96.8)	58(98.3)		60(96.8)	59(100)	
2 Bladder	0			0.740	1(1.6)	1(1.7)	1.000	1(1.6)	1(1.7)	0.119
	1	1(1.6)	1(1.7)		2(3.2)	1(1.7)		4(6.5)		
	2	61(98.4)	58(98.3)		59(95.2)	57(96.6)		57(91.9)	58(98.3)	
3 Grooming	1	62(100)	59(100)	Constant	62(100)	59(100)	Constant	62(100)	59(100)	Constant
4 Toilet use	0			0.488	1(1.6)		0.432			0.260
	1		1(1.7)		2(3.2)	4(6.8)		2(3.2)		
	2	62(100)	58(98.3)		59(95.2)	55(93.2)		60(96.8)	59(100)	
5 Feeding	2	62(100)	59(100)	Constant	62(100)	59(100)	Constant	62(100)	59(100)	Constant
6 Transfers	1			0.260	2(3.2)		0.210	2(3.2)		0.056
	2	2(3.2)			4(6.5)	1(1.7)			3(5.1)	
	3	60(96.8)	59(100)		56(90.3)	58(98.3)		60(96.8)	56(94.9)	
7 Mobility	1			0.364	6(9.7)	5(8.5)	0.031	4(6.5)	4(6.8)	1.000
	2	4(6.5)	2(3.4)		16(25.8)	5(8.5)		6(9.7)	58.5)	
	3	58(93.5	57(96.6)		40(64.5)	49(83.1)		52(83.9)	50(84.7)	
8 Dressing	1		59(100)	Constant	2(3.2)	1(1.7)	0.519			Constant
	2	62(100)			60(96.8)	58(98.3)		62(100)	59(100)	
9 Stairs	0	4(6.5)	1(1.7)	0.133	40(64.5)	30(50.8)	0.332	31(50)	32(54.2)	0.379
	1	3(4.8)			10(16.1)	14(23.7)		12(19.4)	6(10.2)	
	2	55(88.7)	58(98.3)		12(19.4)	15(25.4)		19(30.6)	21(35.6)	
10 Bathing	0			Constant	2(3.2)	1(1.7)	.0519	1(1.6)	1(1.7)	0.740
	1	62(100)	59(100)		60(96.8)	58(98.3)		61(98.4)	58(98.3)	

*p≤0.005 is significant (Fisher's exact test-Bonferroni corrected).

The groups show no significant difference from baseline to six months follow up, item by item.

Table 7 illustrates the levels activity limitation of the two groups at the three months and to six month period.

Table 7: Levels activity limitation of the two groups at the three months and to six month period

	MLCI					
	three months			six months		
	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value
25th percentile Median 75th percentile	13 21 30	20 24 38	0.004	19 24 36	22 24 40	0.255

p≤0.05 is significant.

Group 2 demonstrated significantly less (p=0.009) activity limitation levels (higher activity levels) at three months postoperatively compare to Group 1. At six months, the levels of activity showed no significant differences between both groups.

Table 8 illustrates the levels activity limitation (MLCI) of the two groups from three to six months.

Table 8: Levels activity limitation (MLCI) of the two groups from three to six months

Item	Level	3months			six months		
		Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
1 Get up from a chair	1	1(1.7)	1(1.7)	1.000	1(1.7)	1(1.7)	0.805
	2	2(3.2)	2(3.4)		1(1.7)	2(3.4)	
	3	59(95.2)	56(94.9)		60(96.8)	56(94.9)	
2 Pick up an object from the floor when you are standing up with your walking aid	0	4(6.5)	1(1.7)	0.289	2(3.2)		0.739
	1	6(9.7)	6(10.2)		3(4.8)	4(6.8)	
	2	9(14.5)	4(6.8)		3(4.8)	2(3.4)	
	3	43(69.4)	48(81.4)		54(87.1)	53(89.8)	
3 Get up from the floor (e.g. if you fell)	0	5(8.1)		0.007	2(3.2)		0.044
	1	12(19.4)	5(8.5)		7(11.3)	8(13.6)	
	2	11(17.7)	6(10.2)		8(12.9)	1(1.7)	
	3	34(54.8)	48(81.4)		45(72.6)	50(84.7)	
4 Walk in the house	0	5(8.1)	5(8.5)	0.258	5(8.1)	4(6.8	0.854
	1	5(8.1)	3(5.1)		3(4.8)	1(1.7)	
	2	6(9.7)	1(1.7)		2(3.2)	1(1.7)	
	3	46(74.2)	50(84.7)		52(83.9)	53(89.8)	
5 Walk outside on even ground	0	9(14.5)	6(10.2)	0.088	5(8.1)	4(6.8)	0.709
	1	4(6.5)	2(3.4)		4(6.5)	2(3.4)	
	2	9(14.5)	2(3.4)		3(4.8)	1(1.7)	
	3	40(64.5)	49(83.1)		50(80.6)	52(88.1)	
6 Walk outside on uneven ground (e.g. grass, gravel, slope)	0	15(24.2)	8(13.6)	0.002*	10(16.1)	4(6.8)	0.123
	1	10(16.1)	4(6.8)		6(9.7)	2(3.4)	
	2	10(16.1)	2(3.4)		5(8.1)	3(5.1)	

Item	Level	3months Group1 n (%)	3months Group2 n (%)	3months p-value	six months Group1 n (%)	six months Group2 n (%)	six months p-value
	3	27(43.5)	45(76.3)		41(66.1)	50(84.7)	
7 Walk outside in inclement weather (e.g. rain, wet surface)	0	31(50)	13(22)	0.003*	16(25.8)	6(10.2)	0.129
	1	10(16.1)	11(18.6)		9(14.5)	14(23.7)	
	2	9(14.5)	7(11.9)		7(11.3)	8(13.6)	
	3	12(19.4)	28(47.5)		30(48.4)	31(52.5)	
8 Go up the stairs with a hand-rail	0	39(62.9)	29(49.2)	0.052	32(51.6)	30(50.8)	0.194
	1	7(11.3)	4(6.8)		6(9.7)	1(1.7)	
	2	8(12.9)	6(10.2)		8(12.9)	6(10.2)	
	3	8(12.9)	20(33.9)		16(25.8)	22(37.3)	
9 Go down the stairs with a hand-rail	0	39(62.9)	30(50.8)	0.080	32(51.6)	31(52.5)	0.229
	1	6(9.7)	3(5.1)		6(9.7)	1(1.7)	
	2	9(14.5)	7(11.9)		8(12.9)	6(10.2)	
	3	8(12.9)	19(32.2)		16(25.8)	21(35.6)	
10 Step up a sidewalk curb	0	38(61.3)	28(47.5)	0.267	32(51.6)	32(54.2)	0.367
	1	5(8.1)	3(5.1)		5(8.1)	1(1.7)	
	2	6(9.7)	7(11.9)		5(8.1)	3(5.1)	
	3	13(21)	21(35.6)		20(32.3)	23(39)	
11 Step down a sidewalk curb	0	38(61.3)	28(47.5)	0.217	32(51.6)	31(52.5)	0.343
	1	7(11.3)	4(6.8)		5(8.1)	1(1.7)	
	2	4(6.5)	7(11.9)		5(8.1)	3(5.1)	
	3	13(21)	20(33.9)		20(32.3)	24(40.7)	

		3months			six months		
Item	**Level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
12 Go up a few steps (stairs) without a rail-hand	0	43(69.4)	30(50.8)	0.055	33(53.2)	32(54.2)	0.047
	1	7(11.3)	4(6.8)		9(14.5)	1(1.7)	
	2	4(6.5)	8(13.6)		6(9.7)	5(8.5)	
	3	8(12.9)	17(28.8)		14(22.6)	21(35.6)	
13 Go down a few steps (stairs) without a rail-hand	0	44(71)	31(52.5)	0.084	33(53.2)	31(52.5)	0.119
	1	6(9.7)	4(6.8)		9(14.5)	2(3.4)	
	2	4(6.5)	9(15.3)		6(9.7)	5(8.5)	
	3	8(12.9)	15(25.4)		14(22.6)	21(35.6)	
14 Walk while carrying an object	0	11(17.7)	11(18.6)	0.138	8(12.9	7(11.9)	0.309
	1	11(17.7)	3(5.1)		9(14.5)	3(5.1)	
	2	9(14.5)	7(11.9)		5(8.1)	8(13.6)	
	3	31(50)	38(64.4)		40(64.5)	41(69.5)	

*p≤0.0036 is significant (Fisher’s exact test-Bonferroni corrected).

Group 2 outperformed Group 1 on item 6 and 7 demonstrating a significant difference in activity levels (showing less activity limitation) at three months postoperatively.

Table 9 illustrates the levels of activity limitation (MLCI Basic subscale) of the two groups at three months period to six months**.**

Table 9: Activity limitation (MLCI Basic subscale) of the two groups at three months period to six months

	MLCI Basic subscale					
	three months			six months		
	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value
25th percentile	7	9		9	9	
Median	9	11	0.043	9	11	0.447
75th percentile	17	21		21	21	

p≤0.05 is significant.

Group 2 demonstrated significantly less (p=0.043) activity limitation levels at three months postoperatively compare to Group 1 in the total MLCI basic subscale scores. At six months follow up, the levels of activity show no significant difference amongst both groups.

Table 10 illustrates the levels activity limitation (MLCI Basic subscale) of the two groups at three months period to six months by item.

Table 10: Activity limitation (MLCI Basic subscale) of the two groups at three months period to six months by item

		MLCI Basic subscale- Group 1 (n=62), Group 2 (n=59)					
		3months			six months		
Item	Level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
1 Get up from a chair	1	1(1.6)	1(1.7)	1.000	1(1.6)	1(1.7)	0.805
	2	2(3.2)	2(3.4)		1(1.6)	2(3.4)	
	3	59(95.2)	56(94.9)		60(96.8)	56(94.9)	
4 Walk in the house	0	5(8.1)	5(8.5)	0.258	5(8.1)	4(6.8	0.854
	1	5(8.1)	3(5.1)		3(4.8)	1(1.7)	
	2	6(9.7)	1(1.7)		2(3.2)	1(1.7)	
	3	46(74.2)	50(84.7)		52(83.9)	53(89.8)	
5 Walk outside on even ground	0	9(14.5)	6(10.2)	0.088	5(8.1)	4(6.8)	0.709
	1	4(6.5)	2(3.4)		4(6.5)	2(3.4)	
	2	9(14.5)	2(3.4)		3(4.8)	1(1.7)	
	3	40(64.5)	49(83.1)		50(80.6)	52(88.1)	
8 Go up the stairs with a hand-rail	0	39(62.9)	29(49.2)	0.052	32(51.6)	30(50.8)	0.194
	1	7(11.3)	4(6.8)		6(9.7)	1(1.7)	
	2	8(12.9)	6(10.2)		8(12.9)	6(10.2)	
	3	8(12.9)	20(33.9)		16(25.8)	22(37.3)	
9 Go down the stairs with a hand-rail	0	39(62.9)	30(50.8)	0.080	32(51.6)	31(52.5)	0.229
	1	6(9.7)	3(5.1)		6(9.7)	1(1.7)	
	2	9(14.5)	7(11.9)		8(12.9)	6(10.2)	
	3	8(12.9)	19(32.2)		16(25.8)	21(35.6)	
10 Step up a sidewalk curb	0	38(61.3)	28(47.5)	0.267	32(51.6)	32(54.2)	0.367
	1	5(8.1)	3(5.1)		5(8.1)	1(1.7)	
	2	6(9.7)	7(11.9)		5(8.1)	3(5.1)	
	3	13(21)	21(35.6)		20(32.3)	23(39)	

		MLCI Basic subscale- Group 1 (n=62), Group 2 (n=59)					
		3months			six months		
Item	**Level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
11 Step down a sidewalk curb	0	38(61.3)	28(47.5)	0.217	32(51.6)	31(52.5)	0.343
	1	7(11.3)	4(6.8)		5(8.1)	1(1.7)	
	2	4(6.5)	7(11.9)		5(8.1)	3(5.1)	
	3	13(21)	20(33.9)		20(32.3)	24(40.7)	

*p≤0.0071 is significant (Fisher's exact test-Bonferroni corrected).

Both groups demonstrated insignificant differences in item outcomes when assessed using the basic MLCI as both three and six months.

Table 11 illustrates the levels activity limitation (MLCI Advanced subscale) of the two groups at three months period to six months.

Table 11: Activity limitation (MLCI Advanced subscale) of the two groups at three months period to six months

	MLCI Advanced subscale					
	three months			six months		
	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value
25th percentile Median 75th percentile	6 11.5 14	11 15 19	0.001	10 15 18	13 15 19	0.128

$p \leq 0.05$ is significant.

Group 2 demonstrated significantly less ($p=0.002$) activity limitation levels (high activity levels) at three months postoperatively compare to Group 1 in the total MLCI advanced scores. At six months follow up, the levels of activity show an insignificant difference between the groups.

Table 12 illustrates the levels activity limitation (MLCI Advanced subscale) of the two groups from preoperative to six months item by item.

Table 12: Activity limitation (MLCI Advanced subscale) of the two groups from preoperative to six months item by item

MLCI Advanced subscale- Group 1 (n=62), Group 2 (n=59)							
		3months			six months		
Item	**Level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
2 Pick up an object from the floor when you are standing up with your walking aid	0	4(6.5)	1(1.7)	0.289	2(3.2)		0.739
	1	6(6.7)	6(10.2)		3(4.8)	4(6.8)	
	2	9(14.5)	4(6.8)		3(4.8)	2(3.4)	
	3	43(69.4)	48(81.4)		54(87.1)	53(89.8)	
3 Get up from the floor (e.g. if you fell)	0	5(8.1)		0.007*	2(3.2)		0.044
	1	12(19.4)	5(8.5)		7(11.3)	8(13.6)	
	2	11(17.7)	6(10.2)		8(12.9)	1(1.7)	
	3	34(54.8)	48(81.4)		45(72.6)	50(84.7)	
6 Walk outside on uneven ground (e.g. grass, gravel, slope)	0	15(24.2)	8(13.6)	0.002*	10(16.1)	4(6.8)	0.123
	1	10(16.1)	4(6.8)		6(9.7)	2(3.4)	
	2	10(16.1)	2(3.4)		5(8.1)	3(5.1)	
	3	27(43.5)	45(76.3)		41(66.1)	50(84.7)	
7 Walk outside in inclement weather (e.g. rain, wet surface)	0	31(50)	14(23.7)	0.003*	6(9.7)	6(10.2)	0.129
	1	10(16.1)	11(18.6)		9(14.5	14(23.7)	
	2	9(14.5)	7(11.9)		7(11.3)	8(13.6)	
	3	12(19.4)	27(45.8)		30(48.4)	31(52.5)	
12 Go up a few steps (stairs) without a rail-hand	0	43(69.3)	30(50.8)	0.055	33(53.2)	32(54.2)	0.047

MLCI Advanced subscale- Group 1 (n=62), Group 2 (n=59)							
		3months			six months		
Item	**Level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
	1	7(11.3)	4(6.8)		9(14.5	1(1.7)	
	2	4(6.5)	8(13.6)		6(9.7)	5(8.5)	
	3	8(12.9)	17(28.8)		14(22.6)	21(35.6)	
13 Go down a few steps (stairs) without a rail-hand	0	44(71)	31(52.3)	0.084	33(53.2)	31(52.5)	0.119
	1	6(9.7)	4(6.4)		9(14.5	2(3.4)	
	2	4(6.5)	9(15.3)		6(9.7)	5(8.5)	
	3	8(12.9)	15(25.4)		14(22.6)	21(35.6)	
14 Walk while carrying an object	0	11(17.7)	11(18.6)	0.138	8(12.9)	7(11.9)	0.309
	1	11(17.7)	3(5.1)		9(14.5	3(5.1)	
	2	9(14.5)	7(11.9)		5(8.1)	8(13.6)	
	3	31(50)	38(64.4)		40(64.5)	41(69.5)	

*p≤0.0071 is significant (Fisher's exact test-Bonferroni corrected).

Group 2 outperformed Group 1 on item 3,6 and 7 demonstrating a significant difference in activity levels at three months postoperatively.

Body image

Table 13 illustrates the levels of perceived body image disturbance of the two groups at three months period to six months.

Table 13: Perceived body image disturbance of the two groups at three months period to six months

	MABIS					
	three months			six months		
	Group 1 n=62	Group 2 n =59	Mann-Whitney U p-value	Group1 n=62	Group 2 n= 59	Mann-Whitney U p-value
25th percentile	20	23		18	22	
Median	28	35	0.248	25.5	39	0.060
75th percentile	42	43		40	44	

p≤0.05 is significant.

Body image perception showed no significant difference amongst both groups, showing low body image disturbance at both assessment periods.

Table 14 illustrates the levels of body image disturbance among the two groups from three to six months.

Table 14: Perceived body image disturbance among the two groups from three to six months

Item	MABIS- Group 1 (n=62), Group 2 (n=59)						
		3months			six months		
	Item level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
1 Because I am an amputee, I feel more anxious about my physical appearance in social situations than when I am alone	1	36(58.1)	31(52.5)	0.745	38(61.3)	27(45.8)	0.124
	2	5(8.1)	4(6.8)		4(6.5)	6(10.2)	
	3	7(11.3)	12(20.3)		9(14.5)	15(25.4)	
	4	3(4.8)	3(5.1)		1(1.6)	5(8.5)	
	5	11(17.7)	9(15.3)		10(16.1)	6(10.2)	
2 I avoid wearing shorts in public	1	44(71)	28(47.5)	0.026	41(66.1)	25(42.4)	0.022
	2		5(8.5)		5(8.1)	8(13.6)	
	3	8(12.9)	11(18.6)		6(9.7)	17(28.8)	
	4	1(1.6)	3(5.1)		2(3.2)	4(6.8)	
	5	9(14.5)	12(20.3)		8(12.9)	5(8.5)	
3 I like my overall physical appearance	1	39(62.9)	29(49.2)	0.066	36(58.1)	24(40.7)	0.121
	2	5(8.1)	4(6.8)		6(9.7)	9(15.3)	
	3	8(12.9)	14(23.7)		10(16.1)	17(28.8)	
	4		5(8.5)		2(3.2)	5(8.5)	
	5	10(16.1)	12(20.3)		8(12.9)	4(6.8)	
4 It concerns me that the loss of my limb impairs my body's functional capabilities in various activities of daily living	1	37(58.1)	24(40.7)	0.134	30(48.4)	22(37.3)	0.267
	2	3(4.8)	5(8.5)		8(12.9)	9(15.3)	
	3	6(9.7)	14(23.7)		9(14.5)	13(22)	
	4	6(9.7)	4(6.8)		5(8.1)	10(16.9)	
	5	10(16.1)	12(20.3)		10(16.1)	5(8.5)	
5 Because I am an amputee, I feel more anxious about my physical appearance on a daily basis	1	36(58.1)	26(44.1)	0.496	34(54.8)	26(44.1)	0.369
	2	4(6.5)	3(5.1)		6(9.7)	7(11.9)	
	3	6(9.7)	11(18.6)		9(14.5)	13(22)	
	4	6(9.7)	7(11.9)		3(4.8)	7(11.9)	
	5	10(16.1)	12(20.3)		10(16.1)	6(10.2)	

Item	MABIS- Group 1 (n=62), Group 2 (n=59)						
		3months			six months		
	Item level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
6 I experience a phantom limb	1	3(4.8)	1(1.7)	0.729	2(3.2)	2(3.4)	0.577
	2	1(1.6)	1(1.7)		7(11.3)	2(3.4)	
	3	5(8.1)	2(3.4)		8(12.9)	8(13.6)	
	4	13(21)	14(23.7)		11(17.7)	13(22)	
	5	40(64.5)	41(69.5)		34(54.8)	34(57.6)	
7 Since losing my limb, it bothers me that I no longer conform to the society's ideal of normal appearance	1	37(59.7)	25(42.4)	0.034	35(56.5)	21(35.6)	0.135
	2	5(8.1)	10(16.9)		8(12.9)	12(20.3)	
	3	4(6.5)	13(22)		11(17.7)	17(28.8)	
	4	3(4.8)	1(1.7)		3(4.8)	6(10.2)	
	5	13(21)	10(16.9)		5(8.1)	3(5.1)	
8 It concerns me that the lost of my limb impairs my ability to protect myself from harm	1	35(56.5)	24(40.7)	0.132	31(50)	22(37.3)	0.027
	2	6(9.7)	10(16.9)		6(9.7)	10(16.9)	
	3	8(12.9)	12(20.3)		9(14.5)	18(30.5)	
	4	1(1.6)	5(8.5)		6(9.7)	7(11.9)	
	5	12(19.4)	8(13.6)		10(16.1)	2(3.2)	
9 The loss of my limb makes me think of myself as disabled	1	33(53.2)	23(39)	0.071	39(62.9)	14(23.7)	0.0001*
	2	3(4.8)	12(20.3)		5(8.1)	8(13.6)	
	3	9(14.5)	7(11.9)		8(12.9)	21(35.6)	
	4	4(6.5)	7(11.9)		3(4.8)	10(16.9)	
	5	13(21)	10(16.9)		7(11.3)	6(10.2)	
10 When I am walking, people notice my limp	1	32(51.6)	23(39)	0.055	32(51.6)	16(27.1)	0.001*
	2	2(3.2)	6(10.2)		7(11.3)	8(13.6)	
	3	5(8.1)	12(20.3)		7(11.3)	21(35.6)	
	4	6(9.7)	9(15.3)		4(6.5)	10(16.9)	
	5	17(27.4)	9(15.3)		12(19.4)	4(6.8)	

Item	MABIS- Group 1 (n=62), Group 2 (n=59)						
		3months			six months		
	Item level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
11 I avoid situations where my physical appearance can be evaluated by others (e.g. avoid social situations, swimming pool or beach activities, physical intimacy)	1	41(66.1)	29(49.2)	0.034	42(67.7)	25(42.4)	0.003*
	2	3(4.8)	4(6.8)		4(6.5)	5(8.5)	
	3	4(6.5)	14(23.7)		6(9.7)	17(28.8)	
	4	3(4.8)	6(10.2)			5(8.5)	
	5	11(17.7)	6(10.2)		10(16.1)	7(11.9)	
12 People treat me as a disabled	1	25(40.3)	16(27.1)	0.423	36(58.1)	21(35.6)	0.006
	2	4(6.5)	6(10.2)		2(3.2)	6(10.2)	
	3	10(16.1)	12(20.3)		6(9.7)	14(23.7)	
	4	9(14.5)	14(23.7)		5(8.1)	12(20.3)	
	5	14(22.6)	11(18.6)		13(21)	6(10.2)	
13 I like the appearance of my stump anatomy	1	35(56.5)	26(44.1)	0.020	37(59.7)	23(39)	0.0001*
	2	3(4.8)	6(10.2)		4(6.5)	8(13.6)	
	3	6(9.7)	17(28.8)		8(12.9)	19(32.2)	
	4	2(3.2)	3(5.1)		1(1.6)	7(11.9)	
	5	16(25.8)	7(11.9)		12(19.4)	2(3.4)	
14 I feel I must have four normal limbs in order to be physically attractive	1	4064.5)	29(49.2)	0.050	45(72.6)	23(39)	0.0001*
	2	3(4.8)	5(8.5)		3(4.8)	8(13.6)	
	3	4(6.5)	14(23.7)		3(4.8)	15(25.4)	
	4	4(6.5)	5(8.5)		2(3.2)	9(15.3)	
	5	11(17.7)	6(10.2)		9(14.5)	4(6.8)	
15 It is important the size of my prosthesis and remaining anatomy of the affected limb are the same size as the other limb once I get it	1	32(51.6)	31(52.5)	0.037	36(58.1)	26(44.1)	0.008
	2	2(3.2)	6(10.2)		4(4.8)	6(10.2)	
	3	3(4.8)	10(16.9)		6(9.7)	17(28.8)	

Item	MABIS- Group 1 (n=62), Group 2 (n=59)						
		3months			six months		
	Item level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
	4	7(11.3)	3(5.1)		4(6.5)	7(11.9)	
	5	18(29)	9(15.3)		12(19.4)	3(5.1)	
16 I avoid looking into a full-length mirror in order not to see my stump anatomy	1	42(67.7)	37(62.7)	0.411	48(77.4)	36(61)	0.007
	2	5(8.1)	7(11.9)		5(8.1)	4(6.8)	
	3	4(6.5)	9(15.3)		3(4.8)	12(20.3)	
	4	3(4.8)	1(1.7)		1(1.6)	6(10.2)	
	5	8(12.9)	5(8.5)		5(8.1)	1(1.7)	

*p≤0.0031 is significant (Fisher's exact test-Bonferroni corrected).

Group 1 reported significantly less body image disturbance than Group 2 (item 9,10,11, 13 and 14) at six months.

Quality of life

Table 15 illustrates the quality of life (EQ-5D VAS scores and EQ-5D utility index total scores) of the two groups from the preoperative period to six months.

Table 15: Quality of life (EQ-5D VAS scores and EQ-5D utility index total scores) of the two groups from the preoperative period to six months

EQ-5D									
	Baseline			three months			six months		
	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value
VAS 25th percentile Median 75th percentile	50 70 90	60 80 90	0.199	30 60 80	50 80 80	0.000	57.5 70 80	65 75 85	0.082
Utility index 25th percentile Median 75th percentile	0.028 0.264 0.725	0.193 0.291 0.796	0.054	0.264 0.725 0.796	0.725 0796 0.796	0.020	0.443 0.796 0.850	0.725 0.796 1.000	0.244

p≤0.05 is significant.

The groups were comparable at baseline on both VAS and index scores. However, Group 2 demonstrated significantly superior (p=0.000) VAS and (p=0.020) index scores of QOL at three months postoperatively compare to Group 1. At six months follow up, the QOL scores were insignificantly different between the groups.

Table 16 illustrates the QOL item scores of the EQ-5D of the two groups from preoperative to six months.

Table 16: QOL item scores of the EQ-5D of the two groups from preoperative to six months

EQ-5D- Group 1 (n=62), Group 2 (n=59)										
		Baseline			3months			six months		
Item	Item level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
1 Mobility	1	58(93.5	57(96.6)		42(67.7)	50(84.7)		51(82.3)	50(84.7)	
	2	4(6.5)	2(3.4)	0.364	14(22.6)	4(6.8)	0.041	8(12.9)	5(8.5)	0.753
	3				6(9.7)	5(8.5)		3(4.8)	4(6.8)	
2 Self-care	1	61(98.4)	58(98.3)	0.740	58(93.5	57(96.6)	0.364	60(96.8)	57(96.6)	0.672
	2	1(1.7)	1(1.7)		4(6.5)	2(3.4)		2(3.2)	2(3.4)	
3 Usual activities	1	61(98.4)	59(100)		51(82.3)	48(81.4)		56(90.3)	52(88.1)	
	2	1(1.7)		0.512	11(17.7)	8(13.6)	0.232	5(8.1)	5(8.5)	0.901
	3					3(5.1)		1(1.6)	2(3.4)	
4 Pain/discomfort	1	10(16.1)	11(18.6)		19(30.6)	12(20.3)		25(40.3)	2542.4)	
	2	14(22.6)	19(32.2)	0.371	32(51.6)	44(74.1)	0.019	28(45.2)	28(47.5)	0.791
	3	38(61.3)	29(49.2)		11(17.7)	3(5.1)		9(14.5)	6(10.2)	
5 Anxiety/Depression	1	24(38.7)	31(52.5)		30(48.4)	40(67.8)		44(71)	44(74.6)	
	2	15(24.2)	17(28.8)	0.074	17(27.4)	16(627.1)	0.008*	12(19.4)	13(22)	0.418
	3	23(37.1)	11(18.6)		15(24.2)	3(5.1)		6(9.7)	2(3.2)	

*p≤0.01 is significant (Fisher's exact test-Bonferroni corrected).

The groups show no significant difference in at baseline and at six months follow up, item by item. However, Group 2 outperformed Group 1 on item 5 demonstrating a significant difference in anxiety/ depression respectively (p=0.008 respectively).

Balance (risk of falling)

Table 17 illustrates the ability to balance, thus risk of falling of the two groups at three months period to six months.

Table 17: Balance (risk of falling) of the two groups at three months period to six months

	TUG					
	three months			six months		
	Group1 n=62	Group2 n=59	Mann-Whitney U p-value	Group1 n=62	Group2 n=59	Mann-Whitney U p-value
25th percentile Median 75th percentile	24.5 34 45.25	19 24 36	0.003	19 25.5 36	13 21 32	0.046

$p \leq 0.05$ is significant.

Group 2 demonstrated a significantly less (p=0.003) risk of falling (better ability to balance) at three months postoperatively compare to Group 1. At six months follow up, there was no significant difference in balance between the groups.

APPENDIX iva

PPA RESULTS- EXCLUDES LOST AND DEMISED PARTICIPANTS

Introduction

These results are of all the participants who completed the study, those who demised or were lost during follow up are not in the analysis (missing data). These results show that the outcome of the RCT is generally similar to the analysis using ITT as presented is chapter 6 and Appendix iiia.

Demographic characteristics of the participants

Tables 1 illustrate the demographic characteristics of the two groups.

Tables 1 Demographic characteristics of the two groups.

Demographic profile, Group 1 n=56, Group 2 n=55				
		Group 1 n=56 n(%)	Group 2 n=55 n(%)	p-value
Age	25th percentile Median 75th percentile	49.3 56.5 64.8	54 59 66	0.111
Gender	Male	39(69.6)	34(61.8)	0.428
	Female	17(30.4)	21(38.2)	
Transport mode	Own car	18 (32.1)	13(23.6)	0.615
	Relative's car	6(10.7)	5(9.1)	
	Public transport	30 (53.6)	36(65.5)	
	Hire private transport	2(3.6)	1(1.8)	
	Other			
Income	Private pension	1(1.8)		0.842
	Old age pension	17(30.4)	20(36.4)	
	Disability grant	6(10.7)	5(9.1)	
	Still employed	21(37.5)	17(30.9)	
	Other	11(19.6)	13(23.6)	
Cigarette Smokers	Yes	35(62.5)	22(40)	0.014
	No	21(37.5)	33(60)	
Alcohol consumption	Yes	19(33.9)	23(41.8)	0.254
	No	37(66.1)	32(58.2)	

$p \leq 0.05$ is significant. The age was examined using Mann-Whitney U test and the categorical data was examined using Fisher's exact test -

There was no significant difference in the age of the two groups. There was no significant difference in the proportions of gender, transport mode used, income and alcohol drinking habits between the two groups. However, Group 1 had a significantly more smokers than Group 2.

Tables 2 illustrates the clinical characteristics of the groups.

Tables 2: Clinical characteristics of the groups

Clinical profile, Group 1 n=56, Group 2 n=55				
		Group1 n(%)	Group2 n(%)	P-value
Level of amputation	BKA	34(60.7)	47(85.5)	0.003
	AKA	22(39.3)	8(14.5)	
HPT	Yes	31(55.4)	36(65.5)	0.186
	No	25(44.6)	26(34.5)	
Heart disease	Yes	3(5.4)	4(7.3)	0.490
	No	53(94.6)	51(92.7)	
Diabetes	Yes	31(55.4)	39(70.9)	0.066
	No	25(44.6)	16(29.1)	
PVD	Yes	30(53.6)	18(32.7)	0.021
	No	26(46.4)	37(67.3)	
Arthritis	Yes	1(1.8)	5(9.1)	0.099
	No	55(98.2)	50(90.9)	
Other (HIV, asthma, renal disease etc)	Yes	4(7.1)	7(12.7)	0.253
	No	52(92.9)	48(87.3)	

$p \leq 0.05$ is significant. Fisher's exact tests-

Notably, Group 2 had a significantly more participants with a BKA and less PVD than Group 1.

Participation restriction

Table 3 illustrate a within group comparison of participation restriction from baseline to six months.

Table 3: Within group comparison of participation levels

P-Scale						
	Baseline to 3months			3-six months		Baseline to 6months
	25th percentile Median 75th percentile At baseline	25th percentile Median 75th percentile at three months	Related samples Wilcoxon signed rank test p-value	25th percentile Median 75th percentile at six months	Related samples Wilcoxon signed rank test P-value	Related samples Friedman's 2 way ANOVA test p-value
Group1 n=56	0.000 0.000 0.000	15 30 42	0.0001	8.5 16.5 30	0.001	0.0001
Group2 n=55	0.000 0.000 5.000	10 20 28	0.0001	5 15 26	0.102	0.0001

p≤0.05 is significant.

Table 3 shows that both groups experienced significant changes (p=0.0001) in participation restriction from baseline to six months postoperatively as revealed by the Friedman's 2 way ANOVA. A post hoc test to determine where the change was, shows that both groups experienced a significant increase (p=0.0001) in participation restriction from baseline to three months postoperatively. Group 1 further shows a significant improvement (p=0.001) in participation restriction from three to six months postoperatively while no significant change (p=0.102) was detected in Group 2 during this period.

Table 4 illustrates the comparison of participation levels of the two groups from baseline to six months.

Table 4: Participation levels of the two groups from baseline to six months.

P-Scale									
	Baseline			three months			six months		
	Group1 n=56	Group2 n=55	p-value	Group1 n=56	Group2 n=55	P-value	Group1 n=56	Group2 n=55	P-value
25th percentile Median 75th percentile	0.000 0.000 0.000	0.000 0.000 5.000	0.281	15 30 42	10 20 28	0.004	8.5 16.5 30	5 15 26	0.15

p≤0.05 is significant.

The groups were homogeneous at baseline and comparable at baseline. However, Group 2 demonstrated significantly better (p=0.004) participation levels at three months postoperatively compare to Group 1. In fact, the Group 2 median score shows mild participation restriction while the Group 1 median score shows moderate participation restriction during this follow up period. At six months follow up, the participation levels are similar between both groups. Both groups show mild participation restriction by six months postoperatively.

Table 5 illustrates the participation levels by item from baseline to six months

Table 5: Participation levels by item (P-Scale)

P-Scale, Group 1 n=56, Group 2 n=55										
		Baseline			**3months**			**six months**		
Item	**Item level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
1 Do you have equal opportunity as your peers to find work?	0	51(91.1)	45(81.8)	0.26	31(55.4)	30(54.5)	1.000	31(55.4)	34(61.8)	0.715
	1		1(1.8)					1(1.8)	1(1.8)	
	3					1(1.8)			1(1.8)	
	5	5(8.9)	9(16.4)		25(44.6)	24(43.6)		24(42.9)	19(34.5)	
2 Do you work as hard as your peers do? (same hours, type of work etc)	0	52(92.9)	46(83.6)	0.178	33(58.9)	29(52.7)	0.598	31(55.4)	36(65.5)	0.382
	1							1(1.8)		
	2		1(1.8)			1(1.8)				
	3					1(1.8)				
	5	4(7.1)	8(14.5)		23(41.1)	24(43.6)		24(42.9)	19(34.5)	
3 Do you contribute to the household economically in a similar way to your peers?	0	48(85.7)	43(78.2)	0.164	29(51.8)	31(56.4)	0.282	33(58.9)	34(61.8)	0.453
	2		1(1.8)							
	3	2(3.6)			1(1.8)	4(7.3)				
	5	6(10.7)	11(20)		26(46.4)	20(36.4)		23(41.1)	21(38.2)	
4 Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	53(94.6)	54(98.2)	1.000	24(42.9)	38(69.1)	0.002*	33(58.9)	44(80)	0.053
	1	1(1.8)	1(1.8)			4(7.3)		2(3.6)	0(0)	
	2	1(1.8)			1(1.8)			2(3.6)	1(1.8)	
	3	1(1.8)			8(14.3)	3(5.5)		2(3.6)	3(5.4)	
	5				23(41.1)	10(18.2)		17(30.4)	7(12.7)	

P-Scale, Group 1 n=56, Group 2 n=55										
Item		Baseline			3months			six months		
5 Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	54(96.4)	55(100)	1.000	22(39.3)	32(58.2)	0.092	36(64.3)	38(69.7)	0.936
	1	1(1.8)				1(1.8)				
	2					1(1.8)		1(1.8)	1(1.8)	
	3	1(1.8)			5(8.9)	3(5.5)		2(3.6)	2(3.6)	
	5				29(51.9)	18(32.7)		17(30.4)	14(25.5)	
6 Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	55(98.2)	55(100)	0.505	22(39.3)	31(56.4)	0.351	32(57.1)	36(65.5)	0.868
	1							1(1.8)	1(1.8)	
	2				2(3.6)	1(1.8)		1(1.8)	1(1.8)	
	3	1(1.8)			5(8.9)	4(7.3)		1(1.8)		
	5				27(48.2)	19(34.5)		21(37.5)	17(30.9)	
7 Are you as socially active as your peers are? (e.g. in religious/community affairs)	0	55(98.2)	55(100)	0.505	27(48.2)	31(56.4)	0.635	38(67.9)	40(72.7)	0.636
	1					1(1.8)				
	2				1(1.8)				1(1.8)	
	3	1(1.8)			4(7.1)	4(7.3)		1(1.8)		
	5				24(42.9)	19(34.5)		17(30.4)	14(25.5)	
8 Do you have the same respect in the community as your peers?	0	56(100)	55(100)	Constant	50(89.3)	52(94.5)	0.613	54(96.4)	52(94.5)	0.711
	2					1(1.8)		1(1.8)		
	3				2(3.6)	1(1.8)			1(1.8)	
	5				3(5.4)	1(1.8)		1(1.8)	2(3.6)	

P-Scale, Group 1 n=56, Group 2 n=55										
Item		**Baseline**			**3months**			**six months**		
9 Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	56(100)	55(100)	Constant	47(83.9)	51(92.7)	0.317	50(89.3)	50(90.9)	0.595
	1					1(1.8)				
	2				2(3.6)	1(1.8)			1(1.8)	
	3				2(3.6)			4(7.1)	1(1.8)	
	5				5(8.9)	2(3.6)		2(3.6)	3(5.5)	
10 Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?	0	54(96.4)	55(100)	1.000	42(75)	44(80)	0.361	43(76.8)	48(87.3)	0.334
	1					1(1.8)		1(1.8)		
	2	1(1.8)				2(3.6)		1(1.8)	1(1.8)	
	3				3(5.4)	2(3.6)		3(5.4)		
	5	1(1.8)			11(19.6)	6(10.9)		8(14.3)	6(10.9)	
11 Do you visit other people in the community as often as other people do?	0	55(98.2)	54(98.2)	0.748	28(50)	38(69.1)	0.003	40(71.4)	44(80)	0.571
	1					2(3.6)				
	2					2(3.6)		2(3.6)		
	3				10(17.9)	1(1.8)		3(5.4)	3(5.5)	
	5	1(1.8)	1(1.8)		18(32.1)	12(21.8)		11(19.6)	8(14.5)	
12 Do you move around inside and outside the house and around the village / neighbourhood just as other people do?	0	55(98.2)	55(100)	0.505	30(53.6)	40(72.7)	0.022	40(71.4)	47(85.5)	0.249
	1					1(1.8)				
	2				1(1.8)	1(1.8)		2(3.6)		
	3	1(1.8)			9(16.1)	1(1.8)		4(7.1)	2(3.6)	
	5	0(0)	0(0)		16(28.6)	12(21.8)		10(17.9)	6(10.9)	

P-Scale, Group 1 n=56, Group 2 n=55										
Item		**Baseline**			**3months**			**six months**		
13 In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	54(96.4)	55(100)	NS	23(41.1)	40(72.7)	0.004	39(69.6)	43(78.2)	0.275
	2				2(3.6)	1(1.8)			2(3.6)	
	3	1(1.8)			8(14.3)	2(3.6)		4(7.1)	3(5.5)	
	5	1(1.8)			23(41.1)	12(21.8)		13(23.2)	7(12.7)	
14 In your home, do you do household work?	0	54(96.4)	54(98.2)	1.000	30(53.6)	35(63.6)	0.102	37(66.1)	35(63.6)	0.834
	1					2(3.6)			1(1.8)	
	2				3(5.4)			3(5.4)	1(1.8)	
	3	1(1.8)	1(1.8)		11(19.6)	5(9.1)		5(8.9)	6(10.9)	
	5	1(1.8)			12(21.4)	13(23.6)		11(19.6)	12(21.8)	
15 In family discussions, does your opinion count?	0	53(94.6)	54(98.2)	0.745	53(94.6)	54(98.2)	0.745	55(98.2)	52(94.5)	0.241
	2								1(1.8)	
	3	2(3.6)			2(3.6)			1(1.8)		
	5	1(1.8)	1(1.8)		1(1.8)	1(1.8)			2(3.6)	
16 Do you help other people (e.g. neighbours, friends or relatives)?	0	55(98.2)	55(100)	0.505	41(73.2)	52(94.5)	0.006	49(87.5)	51(92.7)	0.113
	1				1(1.8)	1(1.8)				
	2				3(5.4)				1(1.8)	
	3	1(1.8)			2(3.6)	1(1.8)		1(1.8)		
	5				9(16.1)	1(1.8)		6(10.7)	2(3.6)	
17 Are you comfortable meeting new people?	0	55(98.2)	55(100)	0.505	52(92.9)	55(100)	0.118	52(92.9)	51(92.7)	0.366
	1							1(1.8)	0(0)	
	2				2(3.6)				2(3.6)	
	3	1(1.8)							1(1.8)	
	5				2(3.6)			3(5.4)	1(1.8)	

P-Scale, Group 1 n=56, Group 2 n=55										
Item		**Baseline**			**3months**			**six months**		
18 Do you feel confident to try to learn new things?	0	55(98.2)	55(100)	0.505	53(94.6)	54(98.2)	1.000	52(92.9)	52(94.5)	0.366
	1							1(1.8)		
	2				1(1.8)	1(1.8)				
	3	1(1.8)			1(1.8)				2(3.6)	
	5				1(1.8)			3(5.4)	1(1.8)	

*p≤0.0028 is significant (Fisher's exact test-Bonferroni corrected).

The groups show no difference in proportion of participation scores item by item at baseline and at six months follow up for most items. However, items 4 demonstrated a significant difference in proportion of participation levels at three months postoperatively between both groups with Group 2 performing Group 1 in this aspect of participation.

Activity limitation

Table 6 illustrate a within group comparison of activity limitation (BI) from baseline to six months.

Table 6: Within group comparison of activity levels (BI)

BI						
	Baseline to 3months			3-six months		Baseline to 6months
	25th percentile Median 75th percentile At baseline	25th percentile Median 75th percentile At three months	Related samples Wilcoxon signed rank test p-value	25th percentile Median 75th percentile At six months	Related samples Wilcoxon signed rank test p-value	Related samples Friedman's 2 way ANOVA test p-value
Group1 n=56	20 20 20	16 18 19	0.0001	18 18 20	0.001	0.0001
Group2 n=55	20 20 20	18 18 20	0.0001	18 18 20	0.18	0.0001

$p \leq 0.05$ is significant.

Table 6 shows that both groups experienced significant changes (p=0.0001) in activity limitation from baseline to six months postoperatively as revealed by the Friedman's 2 way ANOVA. A post hoc test to determine where the change was, shows that both groups experienced a significant increase (p=0.0001) in activity limitation from baseline to three months postoperatively. Group 1 further shows a significant improvement (p=0.001) in activity limitation from three to six months postoperatively while no significant change (p=0.18) was detected in Group 2 during this period.

Table 7 illustrates the levels of activity limitation (BI) of the two groups from the preoperative period to six months.

Table 7: Activity limitation (BI) of the two groups from the baseline to six months

BI									
	Baseline			three months			six months		
	Group1 n=56	Group2 n=55	P-value	Group1 n=56	Group2 n=55	P-value	Group1 n=56	Group2 n=55	P-value
25th percentile	20	20	0.31	16	18	0.043	18	18	0.653
Median	20	20		18	18		18	18	
75th percentile	20	20		19	20		20	20	

$p \leq 0.05$ is significant.

The groups were comparable by activity levels at baseline. However, Group 2 demonstrated significantly less (p=0.043) activity limitation levels at three months postoperatively compare to Group 1. At six months follow up, the levels of activity similar amongst both groups.

Table 8 illustrates the levels activity limitation of the two groups from baseline to six months item by item.

Table 8: Activity limitation (BI) of the two groups from baseline to six months item by item

BI (Group 1, n=56, Group 2, n=55)										
		Baseline			3months			six months		
Item	**Level**	**Group 1 n (%)**	**Group 2 n (%)**	**p-value**	**Group 1 n (%)**	**Group 2 n (%)**	**p-value**	**Group 1 n (%)**	**Group 2 n (%)**	**p-value**
1 Bowel	0			0.748	1(1.8)		1.000	1(1.8)		1.000
	1	1(1.8)	1(1.8)		1(1.8)	1(1.8)		1(1.8)		
	2	55(98.2)	54(98.2)		54(96.4)	54(98.2)		54(96.4)	55(100)	
2 Bladder	0			0.748	1(1.8)	1(1.8)	1.000	1(1.8)		0.118
	1	1(1.8)	1(1.8)		2(3.6)	1(1.8)		4(7.1)	1(1.8)	
	2	55(98.2)	54(98.2)		53(94.6)	53(96.4)		51(91.1)	54(98.2)	
3 Grooming	1	56(100)	55(100)	Constant	56(100)	55(100)	Constant	56(100)	55(100)	Constant
4 Toilet use	0			0.495	1(1.8)		0.557			0.252
	1		1(1.8)		2(3.6)	4(7.3)		2(3.6)		
	2	56(100)	54(98.2)		53(94.6)	51(92.7)		54(96.4)	55(100)	
5 Feeding	2	56(100)	55(100)	Constant	56(100)	55(100)	Constant	56(100)	55(100)	Constant
6 Transfer	1			0.505	2(3.6)		0.129			0.088
	2	1(1.8)			4(7.1)	1(1.8)		2(3.6)	3(5.5)	
	3	55(98.2)	55(100)		50(89.3)	54(98.2)		54(96.4)	52(94.5)	
7 Mobility	1			0.509	6(10.7)	5(9.1)	0.025	4(7.1)	4(7.3)	1.000
	2	3(5.4)	2(3.6)		16(28.6)	5(9.1)		6(10.7)	5(9.1)	
	3	53(94.6)	53(96.4)		34(60.7)	45(81.8)		46(82.1)	46(83.6)	
8 Dressing	1			Constant	2(3.6)	1(1.8)	0.507			Constant
	2	56(100)	55(100)		54(96.4)	54(98.2)		56(100)	55(100)	
9 Stairs	0	3(5.4)		0.237	34(60.7)	26(47.3)	0.391	25(44.6)	28(50.9)	0.350
	1	2(3.6)	1(1.8)		10(17.9)	14(25.5)		12(21.4)	6(10.9)	
	2	51(91.1)	54(98.2)		12(21.4)	15(27.3)		19(33.9)	21(38.2)	
10 Bathing	0			Constant	2(3.6)	1(1.8)	0.507	1(1.8)	1(1.8)	0.748
	1	56(100)	55(100)		54(96.4)	54(98.2)		55(98.2)	54(98.2)	

*$p \leq 0.005$ is significant (Fisher's exact test-Bonferroni corrected).

The groups show no significant difference from baseline to six months follow up, item by item.

Table 9 illustrate a within group comparison of activity limitation (total MLCI) from baseline to six months.

Table 9: Within group comparison of activity levels (total MLCI)

	total MLCI 3-six months		
	25th percentile Median 75th percentile		Related samples Wilcoxon signed rank test P-value
Group1 n=56	13 21 31.5	19 26.5 36	0.0001
Group2 n=55	20 31 39	22 26 41	0.029

p≤0.05 is significant.

Table 9 shows both groups experienced a significant decrease (Group 1 p=0.0001; Group 2 p=0.029) in activity limitation from three to six months postoperatively.

Table 10 illustrates the levels activity limitation (MLCI) of the two groups from baseline to six months.

Table 10: Activity limitation (MLCI) of the two groups from baseline to six months

	MLCI					
	three months			six months		
	Group1 n=56	Group2 n=55	P-value	Group1 n=	Group2 n=	P-value
Mean (±SD)	21.8 (11.3)	27.9 (11.9)	0.007	26.8 (11.8)	29.3 (11.4)	0.261
25th percentile Median 75th percentile	13 21 31.5	20 31 39	0.009	19 26.5 36	22 26 41	0.214

p≤0.05 is significant.

Group 2 demonstrated significantly less (p=0.009) activity limitation levels at three months postoperatively compare to Group 1. At six months follow up, the levels of activity showed no significant differences between both groups.

Table 11 illustrates the levels activity limitation (MLCI) of the two groups from baseline to six months item by item.

Table 11: Activity limitation (MLCI) of the two groups from baseline to six months item by item

Item	Level	3months Group1 n (%)	3months Group2 n (%)	3months p-value	six months Group1 n (%)	six months Group2 n (%)	six months p-value
1 Get up from a chair	1	1(1.8)	1(1.8)	0.604	1(1.8)	1(1.8)	0.807
	2	2(3.6)	2(3.6)		1(1.8)	2(3.6)	
	3	53(94.6)	52(94.5)		54(96.4)	52(94.5)	
2 Pick up an object from the floor when you are standing up with your prosthesis	0	4(7.1)	1(1.8)	0.239	2(3.6)		0.715
	1	6(10.7)	6(10.9)		3(5.4)	4(7.3)	
	2	9(16.1)	4(7.3)		3(5.4)	2(3.6)	
	3	37(66.1)	44(80)		48(85.7)	49(89.1)	
3 Get up from the floor (e.g. if you fell)	0	5(8.9)		0.004	2(3.6)		0.035
	1	12(21.4)	5(9.1)		7(12.5)	8(14.5)	
	2	11(19.6)	6(10.9)		8(14.3)	1(1.8)	
	3	28(50)	44(80)		39(69.6)	46(83.6)	
4 Walk in the house	0	5(8.9)	5(9.1)	0.22	5(8.9)	4(7.3)	0.728
	1	5(8.9)	3(5.5)		3(5.4)	1(1.8)	
	2	6(10.7)	1(1.8)		2(3.6)	1(1.8)	
	3	40(71.4)	46(83.6)		46(82.1)	49(89.1)	
5 Walk outside on even ground	0	9(16.1)	6(10.9)	0.061	5(8.9)	4(7.3)	0.612
	1	4(7.1)	2(3.6)		4(7.1)	2(3.6)	
	2	9(16.1)	2(3.6)		3(5.4)	1(1.8)	
	3	34(60.7)	45(81.8)		44(78.6)	48(87.3)	
6 Walk outside on uneven ground (e.g. grass, gravel, slope)	0	15(26.8)	8(14.5)	0.001*	10(17.9)	4(7.3)	0.089
	1	10(17.9)	4(7.3)		6(10.7)	2(3.6)	

		3months			six months		
Item	**Level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
	2	10(17.9)	2(3.6)		5(8.9)	3(5.5)	
	3	21(37.5)	41(74.5)		35(62.5)	46(83.6)	
7 Walk outside in inclement weather (e.g. rain, wet surface)	0	25(44.6)	13(23.6)	0.044	16(28.6)	6(10.9)	0.118
	1	10(17.9)	11(20)		9(16.1)	14(25.5)	
	2	9(16.1)	7(12.7)		7(12.5)	8(14.5)	
	3	12(21.4)	24(43.6)		24(42.9)	27(49.1)	
8 Go up the stairs with a hand-rail	0	33(58.9)	25(45.5)	0.055	26(46.4)	26(47.3)	0.197
	1	7(12.5)	4(7.3)		6(10.7)	1(1.8)	
	2	8(14.3)	6(10.9)		8(14.3)	6(10.9)	
	3	8(14.3)	20(36.4)		16(28.6)	22(40)	
9 Go down the stairs with a hand-rail	0	33(58.9)	26(47.3)	0.09	26(46.4)	27(49.1)	0.224
	1	6(10.7)	3(5.5)		6(10.7)	1(1.8)	
	2	9(16.1)	7(12.7)		8(14.3)	6(10.9)	
	3	8(14.3)	19(34.5)		16(28.6)	21(38.2)	
10 Step up a sidewalk curb	0	32(57.1)	24(43.6)	0.305	26(46.4)	28(50.9)	0.346
	1	5(8.9)	3(5.5)		5(8.9)	1(1.8)	
	2	6(10.7)	7(12.7)		5(8.9)	3(3.3)	
	3	13(23.2)	21(38.2)		20(35.7)	23(41.8)	
11 Step down a sidewalk curb	0	32(57.1)	24(43.6)	0.232	26(46.4)	27(49.1)	0.34
	1	7(12.5)	4(7.3)		5(8.9)	1(1.8)	
	2	4(7.1)	7(12.7)		5(8.9)	3(5.5)	
	3	13(23.2)	20(36.4)		20(35.7)	24(43.6)	
12 Go up a few steps (stairs) without a rail-hand	0	37(66.1)	26(47.3)	0.063	27(42.8)	28(50.9)	0.044

		3months			six months		
Item	Level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
	1	7(12.5)	4(7.3)		9(16.1)	1(1.8)	
	2	4(7.1)	8(14.5)		6(10.7)	5(9.1)	
	3	8(14.3)	17(30.9)		14(25)	21(38.2)	
13 Go down a few steps (stairs) without a rail-hand	0	38(67.9)	27(49.1)	0.098	27(42.8)	27(49.1)	0.113
	1	6(10.7)	4(7.3)		9(16.1)	2(3.6)	
	2	4(7.1)	9(16.4)		6(10.7)	5(9.1)	
	3	8(14.3)	15(27.3)		14(25)	21(38.2)	
14 Walk while carrying an object	0	11(19.6)	11(20)	0.103	8(14.3)	7(12.7)	0.288
	1	11(19.6)	3(5.5)		9(16.1)	3(5.5)	
	2	9(16.1)	7(12.5)		5(8.9)	8(14.5)	
	3	25(44.6)	34(61.8)		34(60.7)	37(67.3)	

*p≤0.0036 is significant (Fisher's exact test-Bonferroni corrected).

Group 2 outperformed Group 1 on item 6 demonstrating a significant difference in activity levels at three months postoperatively.
Table 12 illustrate a within group comparison of activity limitation (Basic MLCI) from baseline to six months.

Table 12: Within group comparison of activity levels (Basic MLCI)

	basic MLCI 3-six months		
	25th percentile Median 75th percentile		Related samples Wilcoxon signed rank test P-value
Group1 n=56	7 9 17	9 13 21	0.001
Group2 n=55	9 17 21	9 12 21	0.303

p≤0.05 is significant.

Table 12 shows that Group 1 shows a significant decrease (p=0.001) in activity limitation from three to six months postoperatively while Group 2 experienced maintained their activity levels during this period.

Table 13 illustrates the levels activity limitation (Basic MLCI) of the two groups from baseline to six months.

Table 13: Activity limitation (Basic MLCI) of the two groups from baseline to six months

	MLCI Basic subscale					
	three months			six months		
	Group1 n=56	Group2 n=55	P-value	Group1 n=56	Group2 n=55	P-value
25th percentile Median 75th percentile	7 9 17	9 17 21	0.045	9 13 21	9 12 21	0.507

p≤0.05 is significant.

Group 2 demonstrated significantly less (p=0.045) activity limitation levels at three months postoperatively compare to Group 1 in the total MLCI basic subscale scores. At six months follow up, the levels of activity show no significant difference between groups.
Table 14 illustrates the levels activity limitation (Basic MLCI) of the two groups from baseline to six months item by item.

Table 14: Activity limitation (Basic MLCI) of the two groups from baseline to six months item by item

		MLCI Basic subscale- Group 1 (n=56), Group 2 (n=55)					
		3months			six months		
Item	**Level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
1 Get up from a chair	1	1(1.8)	1(1.8)	0.604	1(1.8)	1(1.8)	0.807
	2	2(3.6)	2(3.6)		1(1.8)	2(3.6)	
	3	53(94.6)	52(94.5)		54(96.4)	52(94.5)	
4 Walk in the house	0	5(8.9)	5(9.1)	0.220	5(8.9)	4(7.3)	0.728
	1	5(8.9)	3(5.5)		3(5.4)	1(1.8)	
	2	6(10.7)	1(1.8)		2(3.6)	1(1.8)	
	3	40(71.4)	46(83.6)		46(82.1)	49(89.1)	
5 Walk outside on even ground	0	9(16.1)	6(10.9)	0.061	5(8.9)	4(7.3)	0.612
	1	4(7.1)	2(3.6)		4(7.1)	2(3.6)	
	2	9(16.1)	2(3.6)		3(5.4)	1(1.8)	
	3	34(60.7)	45(81.8)		44(78.6)	48(87.3)	
8 Go up the stairs with a hand-rail	0	33(58.9)	25(45.5)	0.055	26(46.4)	26(47.3)	0.197
	1	7(12.5)	4(7.3)		6(10.7)	1(1.8)	
	2	8(14.3)	6(10.9)		8(14.3)	6(10.9)	
	3	8(14.3)	20(36.4)		16(28.6)	22(40)	
9 Go down the stairs with a hand-rail	0	33(58.9)	26(47.3)	0.090	26(46.4)	27(49.1)	0.224
	1	6(10.7)	3(5.5)		6(10.7)	1(1.8)	
	2	9(16.1)	7(12.7)		8(14.3)	6(10.9)	
	3	8(14.3)	19(34.5)		16(28.6)	21(38.2)	
10 Step up a sidewalk curb	0	32(57.1)	24(43.6)	0.305	26(46.4)	28(50.9)	0.346
	1	5(8.9)	3(5.5)		5(8.9)	1(1.8)	
	2	6(10.7)	7(12.7)		5(8.9)	3(3.3)	
	3	13(23.2)	21(38.2)		20(35.7)	23(41.8)	
11 Step down a sidewalk curb	0	32(57.1)	24(43.6)	0.232	26(46.4)	27(49.1)	0.340
	1	7(12.5)	4(7.3)		5(8.9)	1(1.8)	
	2	4(7.1)	7(12.7)		5(8.9)	3(5.5)	
	3	13(23.2)	20(36.4)		20(35.7)	24(43.6)	

*p≤0.0071 is significant (Fisher's exact test-Bonferroni corrected).

Both groups demonstrated relatively insignificant differences in item outcomes when assessed using the basic MLCI.

Table 15 illustrate a within group comparison of activity limitation (Advanced MLCI) from baseline to six months.

Table 15: Within group comparison of activity levels (Advanced MLCI)

	Advance MLCI 3-six months		
	25th percentile Median 75th percentile		Related samples Wilcoxon signed rank test P-value
Group1 n=56	6 10 14.8	10 14.5 18	0.0001
Group2 n=55	10 15 19	13 15 20	0.030

p≤0.05 is significant.

Table 15 shows that both groups shows a significant decrease (Group 1, p=0.0001; Group 2, p=0.030) in activity limitation (increasing activity levels) from three to six months postoperatively.

Table 16 illustrates the levels activity limitation (Advanced MLCI) of the two groups from baseline to six months item by item.

Table 106: Activity limitation (Advanced MLCI) of the two groups from baseline to six months item by item

	MLCI Advanced subscale					
	three months			**six months**		
	Group1 n=56	Group2 n=55	P-value	Group1 n=56	Group2 n=55	P-value
25th percentile Median 75th percentile	6 10 14.8	10 15 19	0.002	10 14.5 18	13 15 20	0.107

p≤0.05 is significant.

Group 2 demonstrated significantly less (p=0.002) activity limitation levels at three months postoperatively compare to Group 1 in the total MLCI advanced scores. At six months follow up, the levels of activity show insignificant difference between groups.

Table 17 illustrates the levels activity limitation (Advanced MLCI) of the two groups from baseline to six months item by item.

Table 17: Activity limitation (Advanced MLCI) of the two groups from baseline to six months item by item

MLCI Advanced subscale- Group 1 (n=56), Group 2 (n=55)							
		3months			six months		
Item	**Level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
2 Pick up an object from the floor when you are standing up with your walking aid	0	4(7.1)	1(1.8)	0.239	2(3.6)		0.715
	1	6(10.7)	6(10.9)		3(5.4)	4(7.3)	
	2	9(16.1)	4(7.3)		3(5.4)	2(3.6)	
	3	37(66.1)	44(80)		48(85.7)	49(89.1)	
3 Get up from the floor (e.g. if you fell)	0	5(8.9)		0.004	2(3.6)		0.035
	1	12(21.4)	5(9.1)		7(12.5)	8(14.5)	
	2	11(19.6)	6(10.9)		8(14.3)	1(1.8)	
	3	28(50)	44(80)		39(69.6)	46(83.6)	
6 Walk outside on uneven ground (e.g. grass, gravel, slope)	0	15(26.8)	8(14.5)	0.001*	10(17.9)	4(7.3)	0.089
	1	10(17.9)	4(7.3)		6(10.7)	2(3.6)	
	2	10(17.9)	2(3.6)		5(8.9)	3(5.5)	
	3	21(37.5)	41(74.5)		35(62.5)	46(83.6)	
7 Walk outside in inclement weather (e.g. rain, wet surface)	0	25(44.6)	13(23.6)	0.044	16(28.6)	6(10.9)	0.118
	1	10(17.9)	11(20)		9(16.1)	14(25.5)	
	2	9(16.1)	7(12.7)		7(12.5)	8(14.5)	
	3	12(21.4)	24(43.6)		24(42.9)	27(49.1)	
12 Go up a few steps (stairs) without a rail-hand	0	37(66.1)	26(47.3)	0.063	27(42.8)	28(50.9)	0.044
	1	7(12.5)	4(7.3)		9(16.1)	1(1.8)	
	2	4(7.1)	8(14.5)		6(10.7)	5(9.1)	
	3	8(14.3)	17(30.9)		14(25)	21(38.2)	

13 Go down a few steps (stairs) without a rail-hand	0	38(67.9)	27(49.1)	0.098	27(42.8)	27(49.1)	0.113
	1	6(10.7)	4(7.3)		9(16.1)	2(3.6)	
	2	4(7.1)	9(16.4)		6(10.7)	5(9.1)	
	3	8(14.3)	15(27.3)		14(25)	21(38.2)	
14 Walk while carrying an object	0	11(19.6)	11(20)	0.103	8(14.3)	7(12.7)	0.288
	1	11(19.6)	3(5.5)		9(16.1)	3(5.5)	
	2	9(16.1)	7(12.5)		5(8.9)	8(14.5)	
	3	25(44.6)	34(61.8)		34(60.7)	37(67.3)	

*p≤0.0036 is significant (Fisher's exact test-Bonferroni corrected).

Group 2 outperformed Group 1 on item 6 demonstrating a significant difference in activity levels and what is that significant difference in proportion at three months postoperatively on the two tailed test as measured by the MLCI advanced subscale. Group 2 continued to perform well on item 3 at six months.

Body Image

Table 18 illustrate a within group comparison of perceived body image from three to six months.

Table 18: Within group comparison of perceived body image from three to six months

	MABIS 3-six months		
	25th percentile Median 75th percentile		Related samples Wilcoxon signed rank test P-value
Group1 n=56	22.2 29.5 48	20.3 27.5 41.5	0.150
Group2 n=55	26 35 45	22 39 44	0.828

$p \leq 0.05$ is significant.

There was no si

gnificant change in body image disturbance from three to six months in both groups.

Table 19 illustrate a between groups comparison of perceived body image from three to six months.

Table 19: Perceived body image from three to six months between groups

	MABIS					
	three months			six months		
	Group1 n=56	Group2 n =55	P-value	Group1 n=56	Group2 n= 51	P-value
25th percentile Median 75th percentile	22.2 29.5 48	26 35 45	0.316	20.3 27.5 41.5	22 39 44	0.111

$p \leq 0.05$ is significant.

Body image perception showed no significant difference between both groups, showing low body image disturbances at both assessment periods.

Table 20 illustrate a between groups comparison of perceived body image (MABIS) from three to six months item by item.

Table 20: Perceived Body Image (MABIS) from Three to Six Months Item by item Between Groups

		MABIS- Group 1 (n=56), Group 2 (n=55)					
		3months			six months		
Item	Item level	Group1 n (%)	Group2 n (%)	p-value	Group1 n (%)	Group2 n (%)	p-value
1 Because I am an amputee, I feel more anxious about my physical appearance in social situations than when I am alone	1	30(53.6)	27(49.1)	0.781	32(57.1)	23(41.8)	0.142
	2	5(8.9)	4(7.3)		4(7.1)	6(10.9)	
	3	7(12.5)	12(21.8)		9(16.1)	15(27.3)	
	4	3(5.4)	3(5.5)		1(1.8)	5(9.1)	
	5	11(19.6)	9(16.4)		10(17.9)	6(10.9)	
2 I avoid wearing shorts in public	1	38(67.9)	24(43.6)	0.032	35(62.5)	21(38.2)	0.026
	2		5(9.1)		5(8.9)	8(14.5)	
	3	8(14.3)	11(20)		6(10.7)	17(30.9)	
	4	1(1.8)	3(5.5)		2(3.6)	4(7.3)	
	5	9(16.1)	12(21.8)		8(17.9)	5(9.1)	
3 I like my overall physical appearance	1	33(58.9)	25(45.5)	0.075	30(53.6)	20(36.4)	0.138
	2	5(8.9)	4(7.3)		6(10.7)	9(16.4)	
	3	8(14.3)	14(25.5)		10(17.9)	17(30.9)	
	4		5(9.1)		2(3.6)	5(9.1)	
	5	10(17.9)	7(12.7)		8(14.3)	4(7.3)	
4 It concerns me that the loss of my limb impairs my body's functional capabilities in various activities of daily living.	1	31(55.4)	20(36.4)	0.115	24(42.9)	18(32.7)	0.301
	2	3(5.4)	5(9.1)		8(14.3)	9(16.4)	
	3	6(10.7)	14(25.5)		9(16.1)	13(23.6)	
	4	6(10.7)	4(7.3)		5(8.9)	10(18.2)	

		MABIS- Group 1 (n=56), Group 2 (n=55)					
		3months			six months		
	5	10(17.9)	12(21.8)		10(17.9)	5(9.1)	
5 Because I am an amputee, I feel more anxious about my physical appearance on a daily basis	1	30(53.6)	22(40)	0.54	28(50)	22(40)	0.406
	2	4(7.1)	3(5.5)		6(10.7)	7(12.7)	
	3	6(10.7)	11(20)		9(16.1)	13(23.6)	
	4	6(10.7)	7(12.7)		3(5.4)	7(12.7)	
	5	10(17.9)	12(21.8)		10(17.9)	6(10.9)	
6 I experience a phantom limb	1	3(5.4)	1(1.8)	0.702	2(3.6)	2(3.6)	0.556
	2	1(1.8)	1(1.8)		7(12.5)	2(3.6)	
	3	5(8.9)	2(3.6)		8(14.3)	8(14.5)	
	4	13(23.2)	14(25.5)		11(19.6)	13(23.6)	
	5	34(60.7)	37(67.3)		28(50)	30(54.6)	
7 Since losing my limb, it bothers me that I no longer conform to the society’s ideal of normal appearance	1	31(55.4)	21(38.2)	0.04	29(51.8)	17(30.9)	0.155
	2	5(8.9)	10(18.2)		8(14.3)	12(21.8)	
	3	4(7.1)	1323.6		11(19.6)	17(30.9)	
	4	3(5.4)	1(1.8)		3(5.4)	6(10.9)	
	5	13(23.2)	10(18.2)		5(8.9)	3(5.5)	
8 It concerns me that the lost of my limb impairs my ability to protect myself from harm	1	29(51.8)	20(36.4)	0.151	25(44.6)	18(32.7)	0.031
	2	6(10.7)	10(18.2)		6(10.7)	10(18.2)	
	3	8(14.3)	12(21.3)		9(16.1)	18(32.7)	
	4	1(1.8)	5(9.1)		6(12.7)	7(12.7)	
	5	13(23.2)	8(14.5)		10(17.9)	2(3.6)	
9 The loss of my limb makes me think of myself as disabled	1	27(48.2)	19(34.5)	0.081	33(58.9)	14(25.5)	0.003

		MABIS- Group 1 (n=56), Group 2 (n=55)					
		3months			six months		
	2	3(5.4)	12(21.8)		5(8.9)	8(14.5)	
	3	9(16.1)	7(12.7)		8(14.3)	17(30.9)	
	4	4(7.1)	7(12.7)		3(5.4)	10(18.2)	
	5	13(23.2)	10(18.2)		7(12.5)	6(10.9)	
10 When I am walking, people notice my limp	1	26(46.4)	19(34.5)		26(46.4)	16(29.1)	
	2	2(3.6)	6(10.9)		7(12.5)	8(14.5)	
	3	5(8.9)	12(21.8)	0.063	7(12.5)	17(30.9)	0.01
	4	6(10.7)	9(16.4)		4(7.1)	10(18.2)	
	5	17(30.4)	9(16.4)		12(21.4)	4(7.3)	
11 I avoid situations where my physical appearance can be evaluated by others (e.g. avoid social situations, swimming pool or beach activities, physical intimacy)	1	35(62.5)	25(45.5)		36(64.3)	21(38.2)	
	2	3(5.4)	4(7.3)	0.04	4(7.1)	5(9.1)	0.004
	3	4(7.1)	14(25.5)		6(10.7)	17(30.9)	
	4	3(5.4)	6(10.9)		0(0)	5(9.1)	
	5	11(19.6)	6(10.9)		10(17.9)	7(12.7)	
12 People treat me as a disabled	1	19(33.9)	12(21.8)		30(53.6)	17(30.9)	
	2	4(7.1)	6(10.9)		2(3.6)	6(10.9)	
	3	10(17.9)	12(21.8)	0.471	6(10.7)	14(25.5)	0.006
	4	9(16.1)	14(25.5)		5(8.9)	12(21.8)	
	5	14(25)	11(20)		13(23.2)	6(10.9)	
13 I like the appearance of my stump anatomy	1	29(51.8)	22(40)		31(55.4)	19(34.5)	
	2	3(5.4)	6(10.9)	0.023	4(7.1)	8(14.5)	0.0001*
	3	6(10.7)	17(30.9)		8(14.3)	19(34.5)	

	MABIS- Group 1 (n=56), Group 2 (n=55)						
		3months			six months		
	4	2(3.6)	3(5.5)		1(1.8)	7(12.7)	
	5	16(28.6)	7(12.7)		12(21.4)	2(3.6)	
14 I feel I must have four normal limbs in order to be physically attractive	1	34(60.7)	25(45.5)	0.056	39(69.6)	19(34.5)	0.0001*
	2	3(5.4)	5(9.1)		3(5.4)	8(14.5)	
	3	4(7.1)	14(25.5)		3(5.4)	15(27.3)	
	4	4(7.1)	5(9.1)		2(3.6)	9(16.4)	
	5	11(19.6)	6(10.9)		9(16.1)	4(7.3)	
15 It is important the size of my prosthesis and remaining anatomy of the affected limb are the same size as the other limb once I get it	1	26(46.4)	27(49.1)	0.036	30(53.6)	22(40)	0.01
	2	2(3.6)	6(10.9)		4(7.1)	6(10.9)	
	3	3(5.4)	10(18.2)		6(10.7)	17(30.9)	
	4	7(12.5)	3(5.5)		4(7.1)	7(12.7)	
	5	18(32.1)	9(16.4)		12(21.4)	3(5.5)	
16 I avoid looking into a full-length mirror in order not to see my stump anatomy	1	36(64.3)	33(60)	0.424	42(75)	32(58.2)	0.008
	2	5(8.9)	7(12.7)		5(8.9)	4(7.3)	
	3	4(7.1)	9(16.4)		3(5.4)	12(21.8)	
	4	3(5.4)	1(1.8)		1(1.8)	6(10.9)	
	5	8(14.3)	5(9.1)		5(8.9)	1(1.8)	

*p≤0.0031 is significant (Fisher's exact test-Bonferroni corrected).

Table 20 illustrates the levels of body image disturbance between the two groups from three to six months. Group 1 reported significantly less body image disturbance than Group 2 (item 13 and 14) at three months.

Quality of Life

Table 21 illustrate a within group comparison of QOL (EQ-5D VAS) from baseline to six months.

Table 21: Within group comparison of QOL (EQ-5D VAS) from baseline to six months

VAS						
	Baseline to 3months			**3-six months**		**Baseline to 6months**
	25th percentile Median 75th percentile at baseline	**25th percentile Median 75th percentile at three months**	**Related samples Wilcoxon signed rank test P-value**	**25th percentile Median 75th percentile at 6months**	**Related samples Wilcoxon signed rank test P-value**	**Related samples Friedman's 2 way ANOVA test P-value**
Group1 n=56	52.5 70 90	30 60 80	0.002	50 70 80	0.001	0.016
Group2 n=55	60 80 90	50 80 85	0.316	60 75 90	0.177	0.190

$p \leq 0.05$ is significant.

Table 21 shows that Group 1 experienced significant changes (p=0.016) in QOL (VAS) from baseline to six months postoperatively while Group 2 exhibited no significant change as revealed by the Friedman's 2 way ANOVA. A post hoc test to determine where the change was for Group 1, shows that a significant decline (p=0.002) in QOL (VAS) from baseline to three months postoperatively and a significant improvement (recovery) (p=0.001) in QOL (VAS) from three to six months postoperatively.

Table 22 illustrate a within group comparison of QOL (EQ-5D Index) from baseline to six months.

Table 22 Within group comparison of QOL (EQ-5D Index) from baseline to six months

Index						
	Baseline to 3months			**3-six months**		**Baseline to 6 months**
	25th percentile Median 75th percentile		**Related samples Wilcoxon signed rank test P-value**	**25th percentile Median 75th percentile**	**Related samples Wilcoxon signed rank test P-value**	**Related samples Friedman's 2 way ANOVA test P-value**
Group1 n=56	0.028 0.264 0.725	0.235 0.725 0796	0.008	0.362 0.796 0.963	0.014	0.0001
Group2 n=55	0.193 0.264 0.796	0.725 0.796 0.796	0.003	0.725 0.796 1	0.121	0.008

$p \leq 0.05$ is significant.

Table shows that both groups experienced significant changes (Group 1, p=0.0001; Group 2, p=0.008) in QOL (EQ-5D Index) from baseline to six months postoperatively as revealed by the Friedman's 2 way ANOVA. A post hoc test to determine where the change was, shows that both groups experienced a significant improvement (Group 1, p=0.008; Group 2, p=0.003) in QOL (EQ-5D Index) from baseline to three months postoperatively. Group 1 further shows a significant improvement (p=0.014) in QOL (EQ-5D Index) from three to six months postoperatively while no significant change (p=0.121) was detected in Group 2 during this period.

Table 23 illustrate a between groups comparison of QOL (EQ-5D VAS and Index) from baseline to six months**.**

Table 23: Quality of life (EQ-5D VAS and Index) from baseline to six months

EQ-5D									
	Baseline			**three months**			**six months**		
	Group1 n=56	**Group2 n=55**	**P-value**	**Group1 n=56**	**Group2 n=55**	**P-value**	**Group1 n=56**	**Group2 n=55**	**P-value**
VAS 25^{th} percentile Median 75^{th} percentile	52.5 70 90	60 80 90	0.293	30 60 80	50 80 85	0.001	50 70 80	60 75 90	0.118
Utility index 25^{th} percentile Median 75^{th} percentile	0.028 0.264 0.725	0.193 0.264 0.796	0.106	0.235 0.725 0.796	0.725 0.796 0.796	0.054	0.362 0.796 0.963	0.725 0.796 1	0.246

p≤0.05 is significant.

The groups were homogeneous at baseline on both VAS and index scores. However, Group 2 demonstrated significantly superior (p=0.001) VAS and a marginally insignificant (p=0.054) index scores of QOL at three months postoperatively compared to Group 1. At six months follow up, the QOL scores were insignificantly different between the groups.

Table 24 illustrate a between groups comparison of QOL (EQ-5D items) from baseline to six months item by item**.**

Table 24: Quality of life (EQ-5D items) from baseline to six months item by item

EQ-5D- Group 1 (n=56), Group 2 (n=55)										
		Baseline			3months			six months		
Item	**Item level**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**	**Group1 n (%)**	**Group2 n (%)**	**p-value**
1 Mobility	1	53(94.6)	53(96.4)	0.509	36(64.3)	46(83.6)	0.031	45(80.4)	46(83.6)	0.75
	2	3(5.4)	2(3.6)		14(25)	4(7.1)		8(14.3)	5(9.1)	
	3				6(10.7)	5(9.1)		3(5.4)	4(7.3)	
2 Self-Care	1	55(98.2)	54(98.2)	0.748	52(92.9)	53(96.4)	0.348	54(96.4)	53(96.4)	0.684
	2	1(1.8)	1(1.8)		4(7.1)	2(3.6)		2(3.6)	2(3.6)	
3 Usual activities	1	55(98.2)	55(100)	0.505	45(80.4)	44(80)	0.248	50(89.3)	48(87.3)	0.901
	2	1(1.8)			11(19.6)	8(14.5)		5(8.9)	5(9.1)	
	3					3(5.5)		1(1.8)	2(3.6)	
4Pain/discomfort	1	8(14.3)	11(20)	0.550	19(33.9)	12(21.8)	0.009*	25(44.6)	24(45.5)	0.755
	2	14(25)	16(29.1)		26(46.4)	40(72.7)		22(39.3)	25(43.6)	
	3	34(60.7)	28(50.9)		11(19.6)	3(5.5)		9(16.1)	6(10.9)	
5 Anxiety/ depression	1	22(39.3)	28(50.9)	0.179	30(53.6)	36(65.5)	0.008*	38(67.9)	40(72.7)	0.411
	2	14(25)	16(29.1)		11(19.6)	16(29.1)		12(21.4)	13(23.6)	
	3	20(35.7)	11(20)		15(26.8)	3(5.5)		6(10.7)	2(3.6)	

p≤0.01 is significant.

The groups show no significant differences at baseline and at six months follow up, item by item. However, Group 2 out-performed Group 1 on item 4 and 5 demonstrating significantly less pain/discomfort (p=0.009) and having less anxiety/ depression respectively (p=0.008).

Balance (risk of falling)

Table 25 illustrate a within group comparison of balance (risk of falling) (TUG) from 3to six months.

Table 25 balance (risk of falling) (TUG) from three to six months

TUG 3-six months			
	25th percentile Median 75th percentile		Related samples Wilcoxon signed rank test p-value
Group1 n=50	21 33.5 46.8	18.5 25 36.5	0.0001
Group2 n=49	15.5 24 40.5	11.5 20 38.5	0.005

p≤0.05 is significant.

Table 25 shows that both groups shows a significant reduction (Group 1, p=0.0001; Group 2, p=0.005) in risk of falling (improvement in balance) from three to six months postoperatively. Table 26 illustrate a between groups comparison of balance (risk of falling) (TUG) from 3to six months.

Table 26 Balance (risk of falling) (TUG) from three to six months.

	TUG					
	three months			six months		
	Group1 n=50	Group2 n=49	p-value	Group1 n=50	Group2 n=49	p-value
25th percentile Median 75th percentile	21 33.5 46.8	15.5 24 40.5	0.036	18.5 25 36.5	11.5 20 38.5	0.154

p≤0.05 is significant.

Group 2 demonstrated a significantly less (p=0.036) risk of falling (better ability to balance) at three months postoperatively compare to Group 1. At six months follow up, there was no significant difference in balance between groups.

APPENDIX va

SHOWING THAT THE SURVIVORS WERE SIMILAR IRRESPECTIVE OF THE GROUP AND AND SO WERE THOSE WHO DIED

Table 1 illustrates survivors at three months analysed by age and baseline function per group.

Table 1: Survivors at three months analysed by age and baseline function per group.

		Baseline		
		Group 1, n=60	**Group 2, n=60**	**p value**
Age	25th percentile Median 75th percentile	50 57 64.8	54 58 65	NS
Barthel index	25th percentile Median 75th percentile	20 20 20	20 20 20	NS
P-Scale	25th percentile Median 75th percentile	0 0 0	0 0 5	NS
EQ-5D index	25th percentile Median 75th percentile	0.028 0.264 0.725	0.193 0.264 0.796	0.07
EQ-5D VAS	25th percentile Median 75th percentile	50 70 90	60 80 90	NS

All Fisher's exact p>0.05, NS- not significant

Table 1 shows that there were no significant differences between the groups among those who survived at three months.

Table 2 illustrates survivors at three months analysed by baseline clinical profiles per group.

Table 2: Survivors at three months analysed by by baseline clinical profiles per group

Clinical profile (Baseline) Group 1 n=60, Group 2 n=60				
		Group 1 n(%)	**Group 2 n(%)**	**p-value**
Level of amputation	BKA	36(60)	49(81.7)	0.008
	AKA	24(40)	11(18.3)	
Smoking	Yes	36(60)	25(41.7)	0.034*
	No	24(40)	35(58.3)	
Drinking	Yes	20(33.3)	35(58.3)	0.225
	No	40(66.7)	25(41.7)	
HPT	Yes	34(56.7)	38(63.3)	NS
	No	26(43.3)	22(36.7)	
Heart disease	Yes	3(5)	5(8.3)	NS
	No	57(95)	55(91.7)	
Diabetes	Yes	35(58.3)	41(68.3)	NS
	No	25(41.7)	19(31.7)	
PVD	Yes	5(8.3)	21(35)	0.07
	No	55(91.7)	39(65)	
Arthritis	Yes	1(1.7)	5(8.3)	NS
	No	59(98.3)	55(91.7)	
Other (HIV, asthma, renal disease etc)	Yes	5(8.3)	7(11.7)	NS
	No	55(91.7)	53(88.3)	

Fisher's exact p≤0.05 is significant , NS- not significant

Table 2 shows that there were no significant differences between the groups among those who survived except that Group 2 had a significantly more of smokers and BKAs.

Table 3 illustrates survivors at three months analysed by baseline Participation per group.

Table 3 Survivors at three months analysed by baseline Participation per group.

P-Scale Group 1 n=60 , Group 2 n=60				
		Baseline		
Item	**Item Level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Do you have equal opportunity as your peers to find work?	0	55(91.7)	50(83.3)	NS
	1		1(1.7)	
	2			
	5	5(8.3)	9(15)	
2 Do you work as hard as your peers do? (same hours, type of work etc)	0	56(93.3)	51(85)	NS
	1		1(1.7)	
	5	4(6.7)	8(13.3)	
3 Do you contribute to the household economically in a similar way to your peers?	0	52(86.7)	46(76.7)	NS
	2		1(1.7)	
	3	2(3.3)	2(3.3)	
	5	6(10)	11(18.3)	
4 Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	57(95)	59(98.3)	NS
	1	1(1.7)	1(1.7)	
	2	1(1.7)		
	3	1(1.7)		
5 Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	58(96.7)	60(100)	NS
	1	1(1.7)		
	3	1(1.7)		
6 Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	59(98.3)	60(100)	NS
	3	1(1.7)		

P-Scale Group 1 n=60 , Group 2 n=60				
		Baseline		
Item	**Item Level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
7 Are you as socially active as your peers are? (e.g. in religious/community affairs)	0	59(98.3)	60(100)	
	3	1(1.7)		
8 Do you have the same respect in the community as your peers?	0	60(100)	59(98.3)	NS
	3		1(1.7)	
9 Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	60(100)	60(100)	1.000
	5			
10 Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?	0	58(69.7)	60(100)	NS
	2	1(1.7)		
	5	1(1.7)		
11 Do you visit other people in the community as often as other people do?	0	59(98.3)	59(98.3)	NS
	5	1(1.7)	1(1.7)	
12 Do you move around inside and outside the house and around the village / neighbourhood just as other people do?	0	59(98.3)	60(100)	NS
	3	1(1.7)		
	5			
13 In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	58(96.7)	60(100)	NS
	3	1(1.7)		
	5	1(1.7)		
14 In your home, do you do household work?	0	57(95)	59(98.3)	NS
	3	2(3.3)	1(1.7)	

P-Scale Group 1 n=60 , Group 2 n=60				
		Baseline		
Item	Item Level	Group 1 n(%)	Group 2 n(%)	p-value
	5	1(1.7)		
15 In family discussions, does your opinion count?	0	57(95)	59(98.3)	NS
	3	2(3.3)		
	5	1(1.7)	1(1.7)	
16 Do you help other people (e.g. neighbours, friends or relatives)?	0	59(98.3)	59(98.3)	NS
	3	1(1.7)		
	5		1(1.7)	
17 Are you comfortable meeting new people?	0	59(98.3)	59(98.3)	NS
	3	1(1.7)		
	5		1(1.7)	
18 Do you feel confident to try to learn new things?	0	59(98.3)	59(98.3)	NS
	3	1(1.7)		
	5		1(1.7)	

Fisher's exact $p<0.05$ is significant

Table 3 shows that there was no significant difference in participation between the two groups among the survivors.

Table 4 illustrates survivors at three months analysed by baseline activity levels per group.

Table 4: Survivors at three months analysed by baseline activity (BI) levels per group

BI Group 1 n= 60, Group 2 n=60				
		Baseline		
Item	Item level	Group 1 n(%)	Group 2 n(%)	p-value
1 Bowel	1	1(1.7)	1(1.7)	NS
	2	59(98.3)	59(98.3)	
2 Bladder	1	1(1.7)	1(1.7)	NS
	2	59(98.3)	59(98.3)	
3 Grooming	1	60(100)	60(100)	Constant
4 Toilet use	1		1(1.7)	NS
	2	60(100)	59(98.3)	
5 Feeding	2	60(100)	60(100)	Constant
6 Transfer	2	1(1.7)		NS
	3	59(98.3)	60(100)	
7 Mobility	2	3(5)	2(3.3)	NS
	3	57(95)	58(96.7)	
8 Dressing	2	60(100)	60(100)	Constant
9 Stairs	0	3(5)	1(1.7)	NS
	1	3(5)		
	2	54(90)	59(98.3)	
10 Bathing	1	60(100)	60(100)	Constant

Fisher's exact p≤0.05 is significant

Table 4 shows that there were no significant differences in BI item scores between the two groups among the survivors.

Table 5 illustrates survivors at three months analysed by baseline QOL levels per group.

Table 5: Survivors at three months analysed by baseline QOL levels per group

Item	Item level	Baseline Group 1 n=60, Group 2 n=60 Group 1 n(%)	Group 2 n(%)	p-value
1 Mobility	1	57(95)	58(96.7)	NS
	2	3(5)	2(3.3)	
2 Self-Care	1	59(98.3)	59(98.3)	NS
	2	1(1.7)	1(1.7)	
3 Usual activities	1	59(98.3)	60(100)	NS
	2	1(1.7)		
4 Pain/ discomfort	1	8(13.3)	11(18.3)	NS
	2	15(25)	18(30)	
	3	37(61.7)	31(51.7)	
5 Anxiety/ depression	1	23(38.3)	32(53.3)	NS
	2	15(25)	16(26.7)	
	3	22(36.7)	12(20)	

Fisher's exact $p<0.05$ is significant

Table 5 shows that there were no significant differences in EQ-5D item scores between the two groups among the survivors at baseline.Those who died at three months were generally similar irrespective of the group.

Table 6 illustrates that those who died at three months analysed by age and baseline function per group.

Table 6: Those who died at three months analysed by age and baseline function per group

		Baseline		
		Group 1, n=14	Group 2, n=14	P value
Age	25th percentile Median 75th percentile	53.3 64 69.5	48.5 58.5 65	NS
Barthel index	25th percentile Median 75th percentile	20 20 20	20 20 20	NS
P-Scale	25th percentile Median 75th percentile	0 0 5	0 6 20	0.039
EQ-5D index	25th percentile Median 75th percentile	0.028 0.229 0.379	0.028 0.193 0.691	NS
EQ-5D VAS	25th percentile Median 75th percentile	67.5 80 82	35 60 72.5	0.021

Fisher's exact $p \leq 0.05$ is significant , NS- not significant

Table 6 shows that patients who died from Group 2 had significantly more participation restriction (p=0.039) and significantly lower (p=0.021) QOL (VAS) than those from Group 1.

Table 7 illustrates those who died at three months analysed by baseline clinical profiles per group.

Table 7: Participants who died at three months analysed by baseline clinical profiles per group

Clinical profile (Baseline) Group 1 n=14, Group 2 n=14				
		Group 1 n(%)	Group 2 n(%)	P-value
Level of amputation	BKA	7(50)	9(64.3)	NS
	AKA	7(50)	5(35.7)	
Smoking	Yes	11(78.6)	10(71.4)	NS
	No	3(21.4)	4(28.6)	
Drinking	Yes	9(64.3)	8(57.1)	NS
	No	5(35.7)	6(42.9)	
HPT	Yes	8(57.1)	10(71.4)	NS
	No	6(42.9)	4(28.6)	
Heart disease	Yes	2(14.2)	1(7.1)	NS
	No	12(85.7)	13(92.9)	
Diabetes	Yes	9(64.3)	8(57.1)	NS
	No	5(35.7)	6(42.9)	
PVD	Yes	7(50)	6(42.9)	NS
	No	7(50)	8(57.1)	
Arthritis	Yes	2(14.3)		NS
	No	12(85.7)	14(100)	
Other (HIV, asthma, renal disease etc)	Yes		2(14.3)	NS
	No	14(100)	12(85.7)	

Fisher's exact $p<0.05$ is significant, NS- not significant

Table 7 shows that there were no significant differences in clinical profiles between the two groups among those who died at three months.

Table 8 illustrates participants who died at three months analysed by baseline participation per group.

Table 8: Participants who Died at Three Months Analysed by Baseline Participation per Group

P-Scale Group 1 n=14 , Group 2 n= 14				
		Baseline		
Item	Item level	Group 1 n(%)	Group 2 n(%)	p-value
1 Do you have equal opportunity as your peers to find work?	0	13(92.9)	10(71.4)	0.098**
	2	1(7.1)		
	5		4(28.6)	
2 Do you work as hard as your peers do? (same hours, type of work etc)	0	14(100)	10(71.4)	0.098**
	3		1(7.1)	
	5		3(21.4)	
3 Do you contribute to the household economically in a similar way to your peers?	0	14(100)	10(71.4)	0.049*
	5		4(28.6)	
4 Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	13(92.9)	10(71.4)	
	3		1(7.1)	
	5	1(7.1))	3(21.4)	
5 Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	14(100)	10(71.4)	0.049*
	5		4(28.6)	
6 Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	14(100)	10(71.4)	0.098
	2		1(7.1)	
	5		3(21.4)	
7 Are you as socially active as your peers are? (e.g. in religious/community affairs)	0	13(92.9)	12(85.7)	NS
	2	1(7.1)		
	5		2(14.3)	
8 Do you have the same respect in the community as your peers?	0	14(100)	14(100)	Constant
9 Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	14(100)	12(85.7)	NS
	5		2(14.3)	
10 Do you have the same opportunities as your peers to start or maintain a	0	14(100)	13(92.9)	NS

long-term relationship with a life partner?				
	5		1(7.1)	
11 Do you visit other people in the community as often as other people do?	0	14(100)	11(78.6)	NS
	5		3(21.3)	
12 Do you move around inside and outside the house and around the village / neighbourhood just as other people do?	0	14(100)	11(78.6)	NS
	5		3(21.3)	
13 In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	13(92.9)	12(85.7)	NS
	5	1(7.1)	2(14.3)	
14 In your home, do you do household work?	0		12(85.7)	NS
	5		2(14.3)	
15 In family discussions, does your opinion count?	0	14(100)	14(100)	Constant
16 Do you help other people (e.g. neighbours, friends or relatives)?	0	14(100)	12(85.7)	NS
	2		1(7.1)	
	5		1(7.1)	
17 Are you comfortable meeting new people?	0	14(100)	13(92.9)	NS
	5		1(7.1)	
18 Do you feel confident to try to learn new things?	0	14(100)	13(92.9)	NS
	3		1(7.1)	

Fisher’s exact $p \leq 0.05$ is significant, NS- not significant

Table 8 shows that there were significant differences in P-Scale item 3and5 scores of patients who died from both groups with Group 2 showing more participation restriction in these items.

Table 9 illustrates participants who died at three months analysed by baseline activity levels per group.

Table 9: Participants who Died at Three Months Analysed by Baseline Activity (BI) Levels per Group

BI Group 1 n=14 , Group 2 n=14					
		Baseline			
Item	**Item level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Bowel	2	14(100)	14(100)	Constant
2 Bladder	1			
	2	14(100)	14(100)	Constant
3 Grooming	1	14(100)	14(100)	Constant
4 Toilet use	1		1(7.1)	NS
	2	14(100)	13(92.9)	
5 Feeding	2	14(100)	14(100)	Constant
6 Transfer	3	14(100)	14(100)	Constant
7 Mobility	2	1(7.1)		NS
	3	13(92.9)	14(100)	
8 Dressing	1	1(7.1)		NS
	2	13(92.9)	14(100)	
9 Stairs	0	2(14.3)	1(7.1)	NS
	1	12(85.7)		
	2		13(92.9)	
10 Bathing	0	1(7.1)		NS
	1	13(92.9)	14(100)	

Fisher's exact p≤0.05 is significant, NS- not significant

Table 9 shows that there were no significant differences in BI item scores between the two groups among those who died at three months.

Table 10 illustrates particicpants who died at three months analysed by baseline QOL levels per group.

Table 10: Participants who Died at Three Months Analysed by Baseline QOL Levels per Group.

		Baseline Group 1 n=14 , Group 2 n=14		
Item	**Item level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Mobility	1	14(100)	14(100)	Constant
2 Self-Care	1	13(92.9)	13(92.9)	NS
	2	1(7.1)	1(7.1)	
3 Usual activity	1	14(100)	13(92.9)	NS
	2		1(7.1)	
4 Pain/discomfort	1		2(14.3)	NS
	2	3(21.4)	3(21.4)	
	3	11(78.6)	9(64.3)	
5 Anxiety/depression	1	7(50)	5(35.7)	NS
	2	2(14.3)	3(21.4)	
	3	5(35.7)	6(42.9)	

Fisher's exact p≤0.05 is significant, NS- not significant

Table 10 shows that there were no significant differences in EQ-5D item scores between the two groups among those who died at three months.

Table 11 illustrates survivors at six months analysed by age and baseline function per group**.**

Table 11: Survivors at Six Months Analysed by Age and Baseline Function per Group

		Baseline		
		Group 1, n=59	**Group 2, n=56**	**P value**
Age	25th percentile Median 75th percentile	50 57 65	54.3 58.5 65.8	NS
Barthel index	25th percentile Median 75th percentile	20 20 20	20 20 20	NS
P-Scale	25th percentile Median 75th percentile	0 0 0	0 0 4.8	NS
EQ-5D index	25th percentile Median 75th percentile	0.028 0.264 0.725	0.193 0.264 0.796	0.061
EQ-5D VAS	25th percentile Median 75th percentile	50 70 90	60 80 90	NS

Fisher's exact $p \leq 0.05$ is significant, NS- not significant

Table 11 shows that there were no significant differences in age, BI, P-scale, EQ-5D index and VAS between the survivors from the two groups.

Table 12 illustrates survivors at six months analysed by baseline clinical profiles per group.

Table 12: Survivors at Six Months Analysed by Baseline Clinical Profiles per Group

Clinical profile (Baseline) Group 1 n=59, Group 2 n=59				
		Group 1 n(%)	**Group 2 n(%)**	**P-value**
Level of amputation	BKA	36(61)	47(83.9)	0.005**
	AKA	23(39)	9(16.1)	
Smoking	Yes	35(59.3)	23(41.1)	0.038*
	No	24(40.7)	33(58.9)	
Drinking	Yes	19(32.2)	24(42.9)	NS
	No	40(67.8)	32(57.1)	
HPT	Yes	33(55.9)	36(64.3)	NS
	No	26(44.1)	20(35.7)	
Heart disease	Yes	3(5.1)	4(7.1)	NS
	No	56(94.9)	52(92.9)	
Diabetes	Yes	34(57.6)	39(69.6)	NS
	No	25(42.4)	17(30.4)	
PVD	Yes	30(50.8)	19(33.9)	0.050*
	No	29(49.2)	37(66.1)	
Arthritis	Yes	1(1.7)	5(8.9)	0.092
	No	58(98.3)	51(91.1)	
Other (HIV, asthma, renal disease etc)	Yes	4(6.8)	7(12.5)	NS
	No	55(93.2)	49(87.5)	

Fisher's exact $p<0.05$ is significant, NS- not significant

Table 12 shows that Group 2 survivors has significantly more BKAs, less smokers and less PVDs.

Table 13 illustrates survivors at six months analysed by baseline participation levels per group.

Table 13: Survivors at Six Months analysed by Baseline Participation levels per Group

P-Scale Group 1 n= 59, Group 2 n=56					
Item		Baseline			
	Item level	Group 1 n(%)	Group 2 n(%)	p-value
1 Do you have equal opportunity as your peers to find work?	0	54(91.5)	46(82.1)	NS
	1		1(1.8)	
	5	4(8.5)	9(16.1)	
2 Do you work as hard as your peers do? (same hours, type of work etc)	0	55(93.2)	47(83.9)	NS
	1		1(1.8)	
	5	4(6.8)	8(14.3)	
3 Do you contribute to the household economically in a similar way to your peers?	0	51(86.4)	43(76.8)	NS
	2		1(1.8)	
	3	2(3.4)	1(1.8)	
	5	6(10.2)	11(19.6)	
4 Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	56(94.9)	55(98.2)	NS
	1	1(1.7)	1(1.8)	
	2	1(1.7)		
	3	1(1.7)		
5 Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	57(96.6)	56(100)	NS
	1	1(1.7)		
	3	1(1.7)		
6 Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	58(98.3)	56(100)	NS
	3	1(1.7)		

P-Scale Group 1 n= 59, Group 2 n=56				
Item		Baseline		
	Item level	Group 1 n(%)	Group 2 n(%)	p-value
7 Are you as socially active as your peers are? (e.g. in religious/community affairs)	0	58(98.3)	56(100)	NS
	3	1(1.7)		
8 Do you have the same respect in the community as your peers?	0	59(100)	56(100)	Constant
9 Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	59(100)	56(100)	Constant
10 Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?	0	57(96.6)	56(100)	NS
	2	1(1.7)		
	5	1(1.7)		
11 Do you visit other people in the community as often as other people do?	0	58(98.3)	55(98.2)	NS
	5	1(1.7)	1(1.8)	
12 Do you move around inside and outside the house and around the village / neighbourhood just as other people do?	0	58(98.3)	56(100)	NS
	3	1(1.7)		
13 In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	57(96.6)	56(100)	NS
	3	1(1.7)		
	5	1(1.7)		
14 In your home, do you do household work?	0	56(94.9)	55(98.2)	NS
	3	2(3.4)	1(1.8)	
	5	1(1.7)		
15 In family discussions, does your opinion count?	0	56(94.9)	55(98.2)	NS
	3	2(3.4)		
	5	1(1.7)	1(1.8)	
16 Do you help other people (e.g. neighbours, friends or relatives)?	0	58(98.3)	56(100	NS

P-Scale Group 1 n= 59, Group 2 n=56					
Item		**Baseline**			
	Item level	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
	3	1(1.7)		
17 Are you comfortable meeting new people?	0	58(98.3)	56(100	NS
	3	1(1.7)		
18 Do you feel confident to try to learn new things?	0	58(98.3)	56(100	NS
	3	1(1.7)		

Fisher's exact p≤0.05 is significant, NS- not significant

Table 13 shows that there were no significant differences in P-scale item scores between the two groups among those who survived.

Table 14 illustrates survivors at six months analysed by baseline activity levels per group.

Table 14 Survivors at six months analysed by baseline activity levels per group.

BI Group 1 n=59 , Group 2 n=56				
		Baseline		
Item	**Item level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Bowel	1	1(1.7)	1(1.8)	NS
	2	58(98.3)	55(98.2)	
2 Bladder	1	1(1.7)	1(1.8)	NS
	2	58(98.3)	55(98.2)	
3 Grooming	1	59(100)	56(100)	Constant
4 Toilet use	1		1(1.8)	NS
	2	59(100)	55(98.2)	
5 Feeding	2	59(100)	56(100)	
6 Transfer	2	1(1.7)		NS
	3	58(98.3)	56(100)	
7 Mobility	2	3(5.1)	2(3.6)	NS
	3	56(94.9)	54(96.4)	
8 Dressing	2	59(100)	56(100)	Constant
9 Stairs	0	3(5.1)	1(1.8)	NS
	1	3(5.1)		
	2	53(89.8)	55(98.2)	
10 Bathing	1	59(100)	56(100)	Constant

Fisher's exact $p \leq 0.05$ is significant

Table 14 shows that there were no significant differences in BI item scores between the two groups among those who died.

Table 15 illustrates survivors at six months analysed by baseline QOL levels per group.

Table 15: Survivors at Six Months Analysed by Baseline QOL Levels per Group.

		Baseline Group 1 n=59 , Group 2 n=56		
Item	**Item level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Mobility	1	56(94.9)	54(96.4)	NS
	2	3(5.1)	2(3.6)	
2 Self-Care	1	58(98.3)	55(98.2)	NS
	2	1(1.7)	1(1.8)	
3 Usual activity	1	58(98.3)	56(100)	NS
	2	1(1.7)		
4 Pain/discomfort	1	8(13.6)	11(19.6)	NS
	2	14(23.7)	16(28.6)	
	3	37(62.7)	29(51.8)	
5 Anxiety/depression	1	22(37.3)	29(51.8)	NS
	2	15(25.4)	16(28.6)	
	3	22(37.3)	11(19.6)	

Fisher's exact $p \leq 0.05$ is significant, NS- not significant

Table 15 shows in a sub-analysis that there were no significant differences in EQ-5D item scores of patients who died from both groups.

Death at six months analysed by group

Table 16 illustrates survivors at six months analysed by age and baseline function per group.

Table 16: Survivors at Six Months Analysed by Age and Baseline Function per Group

		Baseline		
		Group 1, n=15	**Group 2, n=18**	**P value**
Age	25th percentile Median 75th percentile	53 63 69	48.5 58 64.3	NS
Barthel index	25th percentile Median 75th percentile	20 20 20	20 20 20	NS
P-Scale	25th percentile Median 75th percentile	0 0 0	0 5 15	0.030
EQ-5D index	25th percentile Median 75th percentile	0.028 0.264 0.725	0.028 0.229 0.796	NS
EQ-5D VAS	25th percentile Median 75th percentile	70 80 80	37.5 60 80	0.018

Fisher's exact $p \leq 0.05$ is significant, NS- not significant

Table 16 shows that patients who died had significantly higher VAS in Group 1 than those from Group 2. The table further shows that patients who died in had significantly less participation restriction in Group 1 than those from Group 2.

Table 17 illustrates survivors at six months analysed by baseline clinical profiles per group.

Table 17: Survivors at Six Months Analysed by by Baseline Clinical Profiles per Group

Clinical profile (Baseline) Group 1 n=15, Group 2 n=18				
		Group 1 n(%)	**Group 2 n(%)**	**P-value**
Level of amputation	BKA	7(46.7)	11(61.9)	NS
	AKA	8(53.3)	7(38.1)	
Smoking	Yes	12(80)	12(66.7)	NS
	No	3(20)	6(33.3)	
Drinking	Yes	10(66.7)	9(50)	NS
	No	5(33.3)	9(50)	
HPT	Yes	9(60)	12(66.7)	NS
	No	6(40)	6(33.3)	
Heart disease	Yes	2(13.3)	2(11.1)	NS
	No	13(86.7)	16(88.9)	
Diabetes	Yes	10(66.7)	10(55.6)	NS
	No	5(33.3)	8(44.4)	
PVD	Yes	7(46.7)	10(55.6)	NS
	No	8(53.3)	8(44.4)	
Arthritis	Yes	2(13.3)		NS
	No	13(86.7)	18(100)	
Other (HIV, asthma, renal disease etc)	Yes	1(6.7)	2(11.1)	NS
	No	14(93.3)	16(88.9)	

Fisher's exact p≤0.05 is significant, NS –not significant

Table 17 shows in a sub-analysis that there were no significant differences in clinical profiles of patients who died from both groups.

Table 18 illustrates survivors at three months analysed by baseline Participation per group.

Table 18: Survivors at Three Months Analysed by Baseline Participation per Group

P-Scale Group 1 n=15 , Group 2 n= 18				
Item		**Baseline**		
	Item level	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Do you have equal opportunity as your peers to find work?	0	14(93.3)	14(77.8)	NS
	2	1(6.7)		
	5		4(22.2)	
2 Do you work as hard as your peers do? (same hours, type of work etc)	0	15(100)	14(77.8)	NS
	3		1(5.6)	
	5		3(16.7)	
3 Do you contribute to the household economically in a similar way to your peers?	0	15(100)	13(72.2)	0.069
	3		1(5.6)	
	5		4(22.2)	
4 Do you make visits outside your village / neighbourhood as much as your peers do? (except for treatment) e.g. bazaars, markets	0	14(93.3)	13(72.2)	NS
	3		1(5.6)	
	5	1(6.7)	4(22.2)	
5 Do you take part in major festivals and rituals as your peers do? (e.g. weddings, funerals, religious festivals)	0	15(100)	14(77.8)	0.075
	5		4(22.2)	
6 Do you take as much part in casual recreational/social activities as do your peers? (e.g. sports, chat, meetings)	0	15(100)	14(77.8)	NS
	2		1(5.6)	
	5		3(16.7)	
7 Are you as socially active as your peers are? (e.g. in religious/community affairs)	0	14(93.3)	16(88.9)	NS
	2	1(6.7)		

P-Scale Group 1 n=15 , Group 2 n= 18				
Item		Baseline		
	Item level	Group 1 n(%)	Group 2 n(%)	p-value
	5		2(11.9)	
8 Do you have the same respect in the community as your peers?	0	15(100)	17(94.4)	NS
	3		1(5.6)	
9 Do you have opportunity to take care of yourself (appearance, nutrition, health, etc.) as well as your peers?	0	15(100)	16(88.9)	NS
	5		2(11.9)	
10 Do you have the same opportunities as your peers to start or maintain a long-term relationship with a life partner?	0	15(100)	17(94.4)	NS
	5		1(5.6)	
11 Do you visit other people in the community as often as other people do?	0	15(100)	15(83.3)	NS
12 Do you move around inside and outside the house and around the village / neighbourhood just as other people do?	0	15(100)		NS
	5		3(16.7)	
13 In your village / neighbourhood, do you visit public places as often as other people do? (e.g. schools, shops, offices, market and tea/coffee shops)	0	14(93.3)	16(88.9)	NS
	3			
	5	1(6.7)	2(11.9)	
14 In your home, do you do household work?	0	15(100)	16(88.9)	NS
	5		2(11.9)	
15 In family discussions, does your opinion count?	0	15(100)	18(100)	Constant
16 Do you help other people (e.g. neighbours, friends or relatives)?	0	15(100)	15(83.3)	NS
	2		1(5.6)	
	5		2(11.1)	
17 Are you comfortable meeting new people?	0	15(100)	16(88.9)	NS
	5		2(11.9)	

P-Scale Group 1 n=15 , Group 2 n= 18					
Item		**Baseline**			
	Item level	**Group 1 n(%)**	**Group 2 n(%)**		**p-value**
18 Do you feel confident to try to learn new things?	0	15(100)	16(88.9)		NS
	5		2(11.9)		

Fisher's exact p≤0.05 is significant, NS- not significant

Table 18 shows in a sub-analysis that there were no significant differences in P-Scale scores of patients who died from both groups.

Table 19 illustrates survivors at three months analysed by baseline activity levels per group.

Table 19: Survivors at three months analysed by baseline activity (BI) levels per group

BI Group 1 n= 15, Group 2 n=18				
		Baseline		
Item	**Item level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Bowel	2	15(100)	18(100)	Constant
2 Bladder	2	15(100)	18(100)	Constant
3 Grooming	1	15(100)	18(100)	Constant
4 Toilet use	1		1(5.6)	NS
	2	15(100)	17(94.4)	
5 Feeding	2	15(100)	18(100)	Constant
6 Transfer	3	15(100)	18(100)	Constant
7 Mobility	2	1(6.7)		NS
	3	14(93.3)	18(100)	
8 Dressing	1	1(6.7)		
	2	14(93.3)	18(100)	NS
9 Stairs	0		1(5.6)	NS
	1	2(13.3)		
	2	13(86.7)	17(94.4)	
10 Bathing	0	1(6.7)		NS
	1	14(93.3)	18(100)	

Fisher's exact p≤0.05 is significant, NS- not significant

Table 19 shows in a sub-analysis that there were no significant differences in BI item scores of patients who died from both groups.

Table 20 illustrates particiapnts who died at six months analysed by baseline activity levels per group.

Table 20: Particiapnts who died at six months analysed by baseline activity levels per group

BI Group 1 n= 15, Group 2 n=18				
		Baseline		
Item	**Item level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Bowel	2	15(100)	18(100)	Constant
2 Bladder	2	15(100)	18(100)	Constant
3 Grooming	1	15(100)	18(100)	Constant
4 Toilet use	1		1(5.6)	NS
	2	15(100)	17(94.4)	
5 Feeding	2	15(100)	18(100)	Constant
6 Transfer	3	15(100)	18(100)	Constant
7 Mobility	2	1(6.7)		NS
	3	14(93.3)	18(100)	
8 Dressing	1	1(6.7)		
	2	14(93.3)	18(100)	NS
9 Stairs	0		1(5.6)	NS
	1	2(13.3)		
	2	13(86.7)	17(94.4)	
10 Bathing	0	1(6.7)		NS
	1	14(93.3)	18(100)	

Fisher's exact p≤0.05 is significant, NS- not significant

Table 20 shows in a sub-analysis that there were no significant differences in BI item scores of patients who died from both groups.

Table 21 illustrates particiapnts who died at six months analysed by baseline QOL levels per group.

Table 21: Particiapnts who died at six months analysed by baseline QOL levels per group

		Baseline Group 1 n=15 , Group 2 n=18		
Item	**Item level**	**Group 1 n(%)**	**Group 2 n(%)**	**p-value**
1 Mobility	1	15(100)	18(100)	Constant
2 Self -Care	1	14(93.3	17(94.4)	NS
	2	1(6.7)	1(5.6)	
3 Usual activity	1	15(100)	17(94.4)	NS
	2		1(5.6)	
4 pain/ discomfort	1		2(11.1)	NS
	2	4(26.7)	5(27.8)	
	3	11(17.3)	11(61.1)	
5 Anxiety/ depression	1	8(53.3)	8(44.4)	NS
	2	2(13.3)	3(16)	
	3	5(33.3)	7(38.9)	

Fisher's exact p≤0.05 is significant, NS-not significant

Table 21 shows in a sub-analysis that there were no significant differences in EQ-5D item scores of patients who died from both groups.

APPENDIX vi

STANDARD TREATMENT FROM CHBH AND CMJAH AS AVAILED BY THE DEPARTMENTS

AMPs OPD Protocol

PURPOSE:

To provide a guideline in the physiotherapy assessment and management of amputee patients post discharge from hospital

Location: Physiotherapy out-patient department, new building

Time: Wednesday 13:00-15:00
Friday 11:00-12:00

REFERRAL CRITERIA:

- Patients with lower limb amputations (traumatic or vascular)
- Patients that from part of our catchment
- If the patient lives outside of our catchment they need to be referred to the appropriate clinic for ongoing follow up and rehab. Patients who have special needs and do not form part of CHBAH's catchment may be seen at our OPD provided the case is discussed with the Head of Section
- If patient is not walking when discharged, then can be booked within the first week depending on availabity of appointments on the next Wednesday
- Walking patients can be booked 3 weeks post discharge
- Only a maximum of 8 patients can be booked if two therapist are working. If one therapist is working only 4 patients can be booked
- Patients must be book within the available time slots in the diary

PROCEDURE:

Assessment – see **Appendix A**: Amputation Follow Up

AIMS OF ASSESSMENT

To establish what the concerns of the patient are and to identify the functional ability of the patient

Subjective Assessment

Read the patient's file before commencing the assessment.

A discharge summary may be attached (see **Appendix B**: Amputation Discharge Summary). This will assist in guiding, verifying and contextualizing the information obtained during the assessment.

Interview the patient regarding:

- His/ her main concerns
- Functional abilities and participation restrictions
- Home environment
- Compliance with medication and home exercise program

Objective Assessment

This should be performed in a practical environment. Removal of excess clothing will assist in providing more accurate findings.

Verify the subjective findings through observation and a functional assessment

Observation

- Quality of movement
- Posture
- Wound and wound healing (signs of infection incl. hot, red, swollen)
- Coning of stump
- Patients choice of footwear

Functional Assessment

- Assess the patients functional abilities from different starting positions (not necessarily in this order) i.e. supine, prone, long sitting, high sitting, 4 point and 2 point (as indicated), standing, transitions, transfers, gait and stairs.
- If the patient has a prosthetic, assessment with the prosthetic needs to be done incl weight bearing on the prosthetic, weight shift over the prosthetic, gait
- Keep strength, ROM of joints, co-ordination and balance in mind while assessing the patient (see **Appendix B:** Amputation Follow Up)
- This will assist in allowing a goal directed assessment of the patients impairment so as to optimize time

Assessment Implications

Following the assessment, the therapist should be able to:
1. direct their treatment in the most effective way to achieve goals set
2. decide if referral to other members of the MDT is required
3. order the appropriate assistive device

TREATMENT

Aims of Treatment

1. To achieve goals set and
2. To increase participation and decrease activity limitations

Principles of Treatment

- Treatment should always be goal orientated
- In order to achieve the goals set, the activity may need to be broken down into components i.e. address the impairment in order to achieve the activity
- The caregiver has to be an active role player and participant in therapy so as to allow continuity and ongoing therapy at home

Prosthetics

HEP

Discharge criteria

Once a patient is independently mobile with a prosthetic, he/she may be discharged from our OPD. If unsure about discharge please discuss the patient with your supervisor.

References

Protocol Generated by: Maitreyi Rama (PD1)

AMPUTEE PROTOCOL

RESPONSIBILITY

1.THE PATIENT's ARE SUPPOSED TO HELP THEMSELVES APPROXIMATELY NINETY FIVE PER CENT AND THE FAMILY .THE PHYSIOS. THE PEOPLE AROUND YOU ARE ONLY FIVE PER CENT

INDEPENDENTLY

2. THE PATIENTS ARE THE ONES THEY SUPPOSED TO BATHE THEMSELVES. TO TAKE THEMSELVES TO THE TOILET. TO MOVE AROUND BY THEMSELVES .

REHABILILITATION

3.IN ORDER TO ACHIEVE OUR FUTURE , TOWARDS OUR REHAB . WE ARE SUPPOSE TO BE POSITIVE TO OUR REHAB BECAUSE IT IS FOR OUR OWN GOOD . TO MEET SOME CHALLENGES THAT ARE GOING TO COME ACROSS IN OUR LIFE

BE- ACTIVE . BE - CONFIDENT . AND BE - INDEPENDENT .

REHABILITATION OF AMPUTEE

AMPUTATION

AIMS OF AMPUTATIONS

AMPUTATION IS PERFORMED WHEN:

1. ARTERIAL RECONSTRUCTIVE SURGERY HAS FAILED OR TECHNICALLY IMPOSSIBLE.
2. THE STATE OF LIMB IS NOT FUNCTIONING PROPERLY.
3. AMPUTATION SHOULD BE ACCEPTED AS A FORM OF TREATMENT
4. IN CASE OF PVD OR DIABETIC SEPSIS THE AMPUTATIONWILL RELIEVE THE PAINFUL INFECTED LIMB SOMETIMES LIFE THREATENING EXTREMITY

CAUSES OF AMPUTATION

- CAN BE CONGENITAL OR ACQUIRED
- CONGENITAL ; DUE TO DEFORMITY IN INFANCY : PT BORN WITH SEVERELY DERFORMED LIMB OR LIMBS
- ACQUIRED ; DUE TO PERIPHERAL DISEASE ;
- ARTERIAL DISEASE
- TRAUMA –MVA ,TRAIN ACCIDENTS OR MACHINE ACCIDENTS IN FACTORIES
- BULLET WOUNDS
- DEEP BURNS : ELECTRICAL ,ACID ;FIRE ;WATER
- MALIGNACY -TUMOURS
- METABOLIC-DIABETIC GIVING RISE TO ULCERS AND
- INFECTION –DUE TO BONE DISEASE

LOWER LIMB LEVEL OF AMPUTATIONS

-TOES
-TRANS-METATARSAL
-SYMES; THROUGH ANKLE
-BKA
-TKA

-GRITTI STOKES –FEMORRAL CONDYLES
-MID-THIGH OR AKA
-THA – HIP ARTICULATION
-HEMIPELVECTOMY ;HIND QUARTER THIS IS USED MAINLY IN THE TRAUMA OR MALIGNANCY NOT COMMON IN PVD

MAIN PROBLEMS –POST OP

-WEAKNESS OF STUMP MUSCLES
-STIFFNESS OF JOINTS
-POOR BALANCE
-POOR AMBULATION
-CONTRACTURES
-SWELLING
-ADHERENT SCARS
-PAINFUL STUMP
-PHANTOM LIMB PAIN
-BADLY SHAPED STUMP

REHABILITATION PROGRAMME

-WORD OF ENCOURAGEMENT
-FUTURE UNCERTAIN
-SOCIAL WORKER, FAMILY ,FRIENDS ,THERAPIST INVOLVEMENT.
-HOME PROGRAM ENCOURAGEMENT

POST –OPERATIVE STAGES DIVIDED IN TWO STAGES

-PRE-PROSTHETIC STAGE
-PROSTHETIC STAGE

PRE –PROSTHETIC STAGE

-AIMS OF TREATMENT
-TO PREVENT DEFORMITIES
-TO CONTROL STUMP OEDEMA
- TO ~~M~~MAINTAIN MUSCLE STRENGTH
- TO MAINTAIN JOINT MOBILITY
- TO IMPROVE BALANCE
- TO TEACH TRANSFERS
- TO RE-EDUCATE GAIT
- TO RESTORE FUNCTIONAL INDEPENDENCE
- TO TEACH CONING OF THE LIMB
- TO CONTROL PHANTHOM LIMB PAIN.
- TO TEACH WALKING WITH PNEUMATIC LEG

ASSESSMENT

SUBJECTIVE
OBJECTIVE

GENERAL EXAMINATION

- CARDIAC CONDITION
- RESPIRATORY
- VISION
- STUMP STATE (a) GUILLOTINE OR CLOSED
  (b)SWELLING

(c) OOZING
(d) SENSATION
(e) PAIN
(f) TEMPERATURE

FUNCTIONAL ABILITY

- BED MOBILITY – ROLLING, BRIDGING, MOVING UP AND DOWN
- BALANCE REACTIONS – STATIC & DYNAMIC.
- TRANSFERS FROM –
  BED TO CHAIR/WHEELCHAIR,
  SITTING TO STANDING
  LYING TO SITTING
- WALKING WITH OR WITHOUT AIDS.
- JOINT MOBILITY – BOTH LIMBS UN-AFFECTED AND AFFECTED.
- MUSCLE STRENGTH – UPPER & LOWER LIMBS.
  TRUNK AND ABDOMEN.

TREATMENT

1. DEEP BREATHING EXERCISES.
2. CIRCULATORY EXERCISES.
3. MOBILISING JOINTS – EXT. & FLEX.
4. STRENGTHENING OF U & L LIMBS
5. BED MOBILITY ACTIVITIES
6. TRUNK STABILITY
7. TRANSFERS
8. STUMP OEDEMA CONTROL (ELEVATION)
9. RE-EDUCATION OF GAIT

- BETWEEN PARALLEL BARS
- WITH WALKER
- CRUTCHES/AXILLIARY OR ELBOW
- PNEUMATIC LEG.

PROSTHETIC STAGE

FACTOR TO BE CONSIDERED BEFORE
SUPPLYING A PROSTHESIS

1. AGE AND PHYSICAL CONDITION – OLD AND FRAIL MAYBE UNSUITABLE.
2. MENTAL CONDITION – PATIENT MUST BE WELL MOTIVATED AND NOT CONFUSED.
3. LEVEL OF AMPUTATION – BILATERAL A.K.A. ESPECIALLY HIGH LESION ESPECIALLY OLD.
4. GENERAL CONDITION – CARDIAC CEREBRAL, COMBINATION OF UNCONTROLLED CHRONIC DIABETIC AND HYPERTENSIVE. CHRONIC DISEASES, EPILEPTIC , RENAL, POOR VISION, UNDEPENDANT PATIENT
5. STUMP MUST BE IN GOOD CONDITION.
6. FUNCTIONAL NO FRACTURES.
7. PROPERLY CONED SHAPE.
8. SCAR NO ADHERENT
9. PROPERLY HEALED ESPECIALLY MID-PART
10. NO OEDEMA
11. JOINT FULL R.O.M.
12. GOOD SENSATION
13. PROPERLY HEALING GOOD BLOOD SUPPLY.

PHANTOM PAIN REDUCTION

- MASSAGE OF STUMP
- TAPING OF STUMP
- PERCUSSION OF STUMP

GROUP THERAPY ALSO PROMOTE THE PATIENT TO BE INDEPENDENT . ABI~~L~~ITY TO COPE AND TO FACE SOME CHALLENGES AND OBSTACLES THAT COME ACROSS IN THEIR LIVES

WE ARE ABLE , WE CARE AND WE ARE PROUD OF OURSELVES

APPENDIX vii

EQ-5D INDEX VALUES

Scoring EQ-5D health states

Values for the 243 health states defined by the EuroQoL classification have been calculated using a regression model. The following worked example indicates how these coefficients are to be used so as to compute the estimated values for each state.

Calculating EQ-5D state scores - a worked example

EuroQoL dimension	Level 2	Level 3
Mobility	0.069	0.314
Self-care	0.104	0.214
Usual activity	0.036	0.094
Pain / discomfort	0.123	0.386
Anxiety / depression	0.071	0.236
	Constant = 0.081	N3 = 0.269

The arithmetic needed to recover the estimated value for any health state from this table of decrements is given by the following example:

Taking health state 1 1 2 2 3

Full health (1 1 1 1 1) = 1.0

Constant term (for any dysfunctional state)(subtract 0.081)

Mobility	- level 1(subtract 0)
Self-care	- level 1(subtract 0)
Usual activity	- level 2(subtract 0.036)
Pain / discomfort	- level 2(subtract 0.123)
Anxiety / depression	- level 3(subtract 0.236)

Level 3 occurs within at least 1 dimension(subtract N3 parameter 0.269)

Hence the estimated value for state 1 1 2 3 3 is given by

1.0 - 0.081 - 0.036 - 0.123 - 0.236 - 0.269 = **.255**

Estimated weights for EQ-5D health states

1 1 1 1 1	1.000
1 1 1 1 2	0.848
1 1 1 1 3	0.414
1 1 1 2 1	0.796
1 1 1 2 2	0.725
1 1 1 2 3	0.291
1 1 1 3 1	0.264
1 1 1 3 2	0.193
1 1 1 3 3	0.028
1 1 2 1 1	0.883
1 1 2 1 2	0.812
1 1 2 1 3	0.378
1 1 2 2 1	0.760
1 1 2 2 2	0.689
1 1 2 2 3	0.255
1 1 2 3 1	0.228
1 1 2 3 2	0.157
1 1 2 3 3	-0.008
1 1 3 1 1	0.556
1 1 3 1 2	0.485
1 1 3 1 3	0.320
1 1 3 2 1	0.433
1 1 3 2 2	0.362
1 1 3 2 3	0.197
1 1 3 3 1	0.170
1 1 3 3 2	0.099
1 1 3 3 3	-0.066
1 2 1 1 1	0.815
1 2 1 1 2	0.744
1 2 1 1 3	0.310
1 2 1 2 1	0.692
1 2 1 2 2	0.621

1	2	1	2	3	0.187
1	2	1	3	1	0.160
1	2	1	3	2	0.089
1	2	1	3	3	-0.076
1	2	2	1	1	0.779
1	2	2	1	2	0.708
1	2	2	1	3	0.274
1	2	2	2	1	0.656
1	2	2	2	2	0.585
1	2	2	2	3	0.151
1	2	2	3	1	0.124
1	2	2	3	2	0.053
1	2	2	3	3	-0.112
1	2	3	1	1	0.452
1	2	3	1	2	0.381
1	2	3	1	3	0.216
1	2	3	2	1	0.329
1	2	3	2	2	0.258
1	2	3	2	3	0.093
1	2	3	3	1	0.066
1	2	3	3	2	-0.005
1	2	3	3	3	-0.170
1	3	1	1	1	0.436
1	3	1	1	2	0.365
1	3	1	1	3	0.200
1	3	1	2	1	0.313
1	3	1	2	2	0.242
1	3	1	2	3	0.077
1	3	1	3	1	0.050
1	3	1	3	2	-0.021
1	3	1	3	3	-0.186
1	3	2	1	1	0.400
1	3	2	1	2	0.329
1	3	2	1	3	0.164
1	3	2	2	1	0.277
1	3	2	2	2	0.206
1	3	2	2	3	0.041
1	3	2	3	1	0.014

1	3	2	3	2	-0.057
1	3	2	3	3	-0.222
1	3	3	1	1	0.342
1	3	3	1	2	0.271
1	3	3	1	3	0.106
1	3	3	2	1	0.219
1	3	3	2	2	0.148
1	3	3	2	3	-0.017
1	3	3	3	1	-0.044
1	3	3	3	2	-0.115
1	3	3	3	3	-0.280
2	1	1	1	1	0.850
2	1	1	1	2	0.779
2	1	1	1	3	0.345
2	1	1	2	1	0.727
2	1	1	2	2	0.656
2	1	1	2	3	0.222
2	1	1	3	1	0.195
2	1	1	3	2	0.124
2	1	1	3	3	-0.041
2	1	2	1	1	0.814
2	1	2	1	2	0.743
2	1	2	1	3	0.309
2	1	2	2	1	0.691
2	1	2	2	2	0.620
2	1	2	2	3	0.186
2	1	2	3	1	0.159
2	1	2	3	2	0.088
2	1	2	3	3	-0.077
2	1	3	1	1	0.487
2	1	3	1	2	0.416
2	1	3	1	3	0.251
2	1	3	2	1	0.364
2	1	3	2	2	0.293
2	1	3	2	3	0.128
2	1	3	3	1	0.101
2	1	3	3	2	0.030
2	1	3	3	3	-0.135

2	2	1	1	1	0.746
2	2	1	1	2	0.675
2	2	1	1	3	0.241
2	2	1	2	1	0.623
2	2	1	2	2	0.552
2	2	1	2	3	0.118
2	2	1	3	1	0.091
2	2	1	3	2	0.020
2	2	1	3	3	-0.145
2	2	2	1	1	0.710
2	2	2	1	2	0.639
2	2	2	1	3	0.205
2	2	2	2	1	0.587
2	2	2	2	2	0.516
2	2	2	2	3	0.082
2	2	2	3	1	0.055
2	2	2	3	2	-0.016
2	2	2	3	3	-0.181
2	2	3	1	1	0.383
2	2	3	1	2	0.312
2	2	3	1	3	0.147
2	2	3	2	1	0.260
2	2	3	2	2	0.189
2	2	3	2	3	0.024
2	2	3	3	1	-0.003
2	2	3	3	2	-0.074
2	2	3	3	3	-0.239
2	3	1	1	1	0.367
2	3	1	1	2	0.296
2	3	1	1	3	0.131
2	3	1	2	1	0.244
2	3	1	2	2	0.173
2	3	1	2	3	0.008
2	3	1	3	1	-0.019
2	3	1	3	2	-0.090
2	3	1	3	3	-0.255
2	3	2	1	1	0.331
2	3	2	1	2	0.260

2	3	2	1	3	0.095
2	3	2	2	1	0.208
2	3	2	2	2	0.137
2	3	2	2	3	-0.028
2	3	2	3	1	-0.055
2	3	2	3	2	-0.126
2	3	2	3	3	-0.291
2	3	3	1	1	0.273
2	3	3	1	2	0.202
2	3	3	1	3	0.037
2	3	3	2	1	0.150
2	3	3	2	2	0.079
2	3	3	2	3	-0.086
2	3	3	3	1	-0.113
2	3	3	3	2	-0.184
2	3	3	3	3	-0.349
3	1	1	1	1	0.336
3	1	1	1	2	0.265
3	1	1	1	3	0.100
3	1	1	2	1	0.213
3	1	1	2	2	0.142
3	1	1	2	3	-0.023
3	1	1	3	1	-0.050
3	1	1	3	2	-0.121
3	1	1	3	3	-0.286
3	1	2	1	1	0.300
3	1	2	1	2	0.229
3	1	2	1	3	0.064
3	1	2	2	1	0.177
3	1	2	2	2	0.106
3	1	2	2	3	-0.059
3	1	2	3	1	-0.086
3	1	2	3	2	-0.157
3	1	2	3	3	-0.322
3	1	3	1	1	0.242
3	1	3	1	2	0.171
3	1	3	1	3	0.006
3	1	3	2	1	0.119

3	1	3	2	2	0.048
3	1	3	2	3	-0.117
3	1	3	3	1	-0.144
3	1	3	3	2	-0.215
3	1	3	3	3	-0.380
3	2	1	1	1	0.232
3	2	1	1	2	0.161
3	2	1	1	3	-0.004
3	2	1	2	1	0.109
3	2	1	2	2	0.038
3	2	1	2	3	-0.127
3	2	1	3	1	-0.154
3	2	1	3	2	-0.225
3	2	1	3	3	-0.390
3	2	2	1	1	0.196
3	2	2	1	2	0.125
3	2	2	1	3	-0.040
3	2	2	2	1	0.073
3	2	2	2	2	0.002
3	2	2	2	3	-0.163
3	2	2	3	1	-0.190
3	2	2	3	2	-0.261
3	2	2	3	3	-0.426
3	2	3	1	1	0.138
3	2	3	1	2	0.067
3	2	3	1	3	-0.098
3	2	3	2	1	0.015
3	2	3	2	2	-0.056
3	2	3	2	3	-0.221
3	2	3	3	1	-0.248
3	2	3	3	2	-0.319
3	2	3	3	3	-0.484
3	3	1	1	1	0.122
3	3	1	1	2	0.051
3	3	1	1	3	-0.114
3	3	1	2	1	-0.001
3	3	1	2	2	-0.072
3	3	1	2	3	-0.237

3 3 1 3 1	-0.264
3 3 1 3 2	-0.335
3 3 1 3 3	-0.500
3 3 2 1 1	0.086
3 3 2 1 2	0.015
3 3 2 1 3	-0.150
3 3 2 2 1	-0.037
3 3 2 2 2	-0.108
3 3 2 2 3	-0.273
3 3 2 3 1	-0.300
3 3 2 3 2	-0.371
3 3 2 3 3	-0.536
3 3 3 1 1	0.028
3 3 3 1 2	-0.043
3 3 3 1 3	-0.208
3 3 3 2 1	-0.095
3 3 3 2 2	-0.166
3 3 3 2 3	-0.331
3 3 3 3 1	-0.358
3 3 3 3 2	-0.429
3 3 3 3 3	-0.594

Unconscious [-0.402]
Note : this value is the mean observed score. It does not result from the regression model.

Source : A1 TARIFF BASED ON UK SURVEY (1993)