INCIDENCE AND REHABILITATION OF LOWER LIMB AMPUTATION IN CANADA, AND FEASIBILITY OF A NOVEL TRAINING PROGRAM

by

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Abstract

Background: There is a dearth of evidence about lower limb amputation (LLA) incidence, rehabilitation, and practice in Canada. Such data are crucial for assessing the burden of the disability and making informed healthcare decisions. We know from the literature that the current resource-intensive rehabilitation model is costly and perhaps not sustainable. This highlights the need for exploring interventions that are less resource-intensive and, therefore, more cost-effective.

Purpose: To gain an understanding about the incidence of LLA, current practices, and rehabilitation services provided in Canada and to design and evaluate a novel approach that may ultimately provide cost-effective LLA rehabilitation.

Methods: Five studies were conducted. Studies 1-2) analyses of Canadian data to determine the incidence of LLA and the provision of inpatient rehabilitation services from 2006 to 2011; studies 3-4) a Canadian survey to describe prosthetic rehabilitation practices and to explore therapists' perspectives about the use of commercial games, particularly the Nintendo Wii Fit, in rehabilitation; and study 5) a feasibility randomized controlled trial (RCT) to evaluate the use of Wii Fit intervention (named Wii.n.Walk) in LLA rehabilitation.

Results: The age-adjusted incidence of LLA was 22.9 per 100,000 individuals. Although there was a decline in the incidence rates, the number of LLAs increased for older age categories. In total, 18.0% (n=2,902/16,114) of the individuals received inpatient

rehabilitation in Canada over the study years. When asked about the use of commercial games, 43.9% (n=36/82) of the therapists indicated that they use the Wii Fit in rehabilitation. Our feasibility RCT showed the intervention adherence was 83.4%. No adverse events occurred.

Conclusions: Although the age-adjusted incidence rates have declined, the number of LLAs has increased in individuals older than 50. Given the increase in number of LLAs and the fact that only 18% of individuals receive inpatient rehabilitation, there is a need for other service deliveries. The Wii Fit is prevalently used in prosthetic rehabilitation in Canada and was found to be feasible for LLA rehabilitation. A future powered RCT is required to provide more evidence about the efficacy and cost-effectiveness of the Wii Fit in prosthetic rehabilitation.

Preface

The research studies for this dissertation were coordinated and conducted at GF Strong Rehabilitation Research Lab in Vancouver, British Columbia, Canada. The five studies (Chapters 2 to 6) reported in this dissertation were designed by Bita Imam, in consultation with Dr. William C. Miller (supervisor), and Drs. Janice J. Eng, Tal Jarus, and Heather Finlayson (supervisory committee members).

Data for studies in Chapters 2 and 3 were obtained from the Canadian Institute of Health Information and the National Reporting Rehabilitation System. Ethics approval for the protocol of Chapters 2 and 3 was obtained from the Clinical Research Ethics Board of the University of British Columbia (H13-01304), Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal (CRIR-883-1013), and Commission to Access Information In Quebec (file no: 1008136). I was responsible for study design, preparation and submission of ethics and grant documents, data collection and analysis, chapters and manuscripts write up, and dissemination of findings. Versions of Chapters 2 and 3 will be submitted for peer-reviewed publications.

Ethical approval for Chapters 4 and 5 was obtained by the Clinical Research Ethics Board of the University of British Columbia (H15-00580). My involvement included study design, survey development and refinement, participant recruitment, data collection and analysis, chapters and manuscripts write up, and dissemination of results. Versions of Chapters 4 and 5 will be submitted for peer-reviewed publications.

The protocol for Chapter 6 was approved by the Clinical Research Ethics Board at the University of British Columbia (H11-01246) and Vancouver Coastal Health Authority (V11-01246). The study was registered with ClinicalTrials.gov (identifier NCT01715662) on October 15th, 2012 and updated on November 27th, 2014. A version of Chapter 6 has been published in the journal of Clinical Rehabilitation with the following citation: Imam, B., Miller, W.C., Finlayson, H., Eng, J.J., & Jarus, T. (2017). A randomized controlled trial to evaluate the feasibility of the Wii Fit for improving walking in older adults with lower limb amputation. *Clinical Rehabilitation, 31,* 82-92. My role in this study included study conception and design, ethics and grant preparation and submission, participant recruitment, study coordination, training of the evaluators and the control group trainer, Wii.n.Walk intervention administration, data analysis, dissemination, and chapter and manuscript write up.

WCM supervised all the research projects, provided ongoing guidance on concept formation and interpretation of results, and reviewed and edited the study documents, thesis chapters, and manuscripts that arose from this dissertation. JJE contributed to the design of the feasibility RCT and the interpretation of results in Chapter 6, provided feedback and editing on the manuscript from Chapter 6, and assisted with survey refinement in Chapters 4 and 5. TJ provided expertise on the design of the feasibility RCT and contributed to editing of the manuscript from Chapter 6. HF assisted with study design and interpretation of results from Chapters 2 and 3, participated in design of the survey in Chapters 4 and 5 and the feasibility RCT in Chapter 6, helped with participant medical screening for the feasibility RCT, and provided feedback and editing on the manuscript from Chapter 6.

Table of Contents

List of Tables

List of Figures

List of Abbreviations

2MWT: 2 Minute Walk Test

ABC: Activities-specific Balance Confidence

ACSM: American College of Sport Medicine

ANCOVA: Analysis of Covariance

ANOVA: Analysis of Variance

BMI: Body Mass Index

CCI: Canadian Classification of Health Interventions

CI: Confidence Interval

CIHI: Canadian Institute of Health Information

CONSORT: Consolidated Standards of Reporting Trials

DAD: Discharge Abstract Database

FIM: Functional Independence Measure

ICD-10: 10th Revision of the International Statistical Classification of Diseases and Related Health Problems

LCI-5: The Locomotor Capabilities Index in Amputees

LLA: Lower Limb Amputation

MMSE: Mini Mental State Examination

NRS: National Rehabilitation Reporting System

PASE: Physical Activity Scale for the Elderly

RCT: Randomized Controlled Trial

SAM: Modus Health Stepwatch^{TM} Activity Monitor

SCS: Socket Comfort Scale

SD: Standard Deviation

SE: Standard Error

SPPB: Short Physical Performance Battery

WWT: Walking While Talking Test

Glossary

Age-adjustment or age-standardization: is an epidemiological analysis method that removes age confounding and allows the rate of a disease or event to be compared across various populations that have different age structure (Hoem, 1987; Inskip, Beral, Fraser, & Haskey, 1983).

Direct method of age-adjustment: is a method of age-adjustment by multiplying age-specific rates by age-specific weights in a standard population (Lee & Liaw, 1999).

Cohen's effect size: is the ratio of the difference in the mean values between the experimental and control group (change score) to the pooled standard deviation. Cohen's d effect size values are defined as: <0.2= trivial effect; 0.2 to 0.5 = small effect; 0.5 to 0.8 = medium effect; > 0.8= large effect (Cohen, 1998).

Dedicated amputee rehabilitation program: is a rehabilitation program that only enrols individuals with amputation.

Distal lower limb amputations: are amputations that are farther from the central portion of the body. For example, toe amputations are distal to knee amputations.

Feasibility randomized controlled trial: is usually conducted prior to a subsequent larger-scale efficacy trial in order to evaluate whether it is feasible to proceed to the larger trial. It

also allows preliminary evaluation of the treatment effect and calculation of the required sample size for the larger trial.

Functional independence: is defined in this dissertation as the individual's independence level for carrying out activities of daily living.

Incidence: is the rate of an occurrence of new cases of a specific disease or an event in a population at risk during a specified period of time (MacMahon & Trichopoulos, 1996).

Intention to treat analysis: is an analysis method in which all randomized participants are included in the analysis and are analyzed in their assigned groups, regardless of whether they received the allocated intervention or not.

Knee disarticulation amputation: is a knee joint amputation.

Major lower limb amputations: include hip and pelvis, transfemoral, knee disarticulation, transtibial, and ankle amputations (Lusardi & Nielsen, 2007).

Minimal clinically important difference: is the smallest change in the outcome that is considered clinically important (Angst, Aeschlimann, & Stucki, 2001; Hays & Woolley, 2000).

Minor lower limb amputations: include foot and toe amputations (Lusardi & Nielsen, 2007).

Odds ratio: is the odds of an outcome or an event in an exposed group, compared to the odds of the outcome or the event in a non-exposed group. An odds ratio of greater than 1 represents an increased probability of the event in the exposed group compared to the non-exposed, while an odds ratio of less than 1 indicates a reduced probability of the event in the exposed group. An odds ratio of 1 suggests no difference in the probability between the exposed and non-exposed group.

Per protocol analysis: includes and analyzes the data only for those who received and completed the allocated intervention

Proximal lower limb amputations: are amputations that are closer to the central portion of the body. For example, knee amputations are proximal to toe amputations.

Prosthetic rehabilitation: is defined as the fitting of a prosthesis and training to use and walk with the prosthesis. Prosthetic rehabilitation is critical for helping individuals reach functional independence (Gauthier-Gagnon & Grise, 2006; Webster et al., 2014).

Relative risk: is the ratio of probability of an occurrence of a disease or an event in an exposed group to the probability of the disease or event in a non-exposed group. A relative risk of greater than 1 indicates that the probability of the disease/event is greater in the

exposed group. A relative risk of less than 1 specifies that the probability of the disease/event is smaller in the exposed group relative to the non-exposed group. When relative risk is 1, there is no difference in probability of the disease/event between the exposed and the non-exposed group (Portney & Watkins, 2009).

Self-efficacy: is the belief an individual has in their ability to successfully accomplish a task (Bandura, 1997)

Telehealth: is the delivery of health services through telecommunication technologies.

Transfemoral amputation: is an above knee amputation.

Transtibial amputation: is a below knee amputation.

Acknowledgements

I would like to start by thanking my supervisor, Dr. Bill Miller, for believing in me and helping me grow and follow my dream. Bill, thank you for your encouragement and extraordinary mentorship. I have been very fortunate to have a supervisor like you who directed me to the path of success and motivated me to work hard to reach above and beyond. Your leadership skills and research expertise are admirable and I am grateful for having had the opportunity to work with you and learn from you. My supervisory committee members, Drs. Janice J. Eng, Tal Jarus, and Heather Finlayson, thank you for your expertise and tremendous support and encouragement. You have been remarkable role models for me. Heather, special thanks to you for being so accommodating in assisting me with participant screening for my feasibility RCT. I enjoyed every minute of working with you.

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Dedication

To my family who has been incredibly supportive throughout this journey:

Mom, Dad, my sister Tina, and my husband Kamran,

this achievement would have been impossible without you.

Love you,

Bita

1 Introduction

1.1 Epidemiology of lower limb amputation

Lower limb amputation (LLA) is a disabling condition that affects the health and quality of life of individuals (Knezevic et al., 2015). LLA is costly to global healthcare systems (Dillingham, Pezzin, & Shore, 2005) and recognized as a public health issue (Ephraim, Dillingham, Sector, Pezzin, & Mackenzie, 2003). The annual cost of acute and post-acute care for LLAs in the United States (US) exceeds four billion dollars (Dillingham, Pezzin, & Shore, 2005). The average cost of hospitalization per client in the US is 50,000 dollars (Lusardi & Nielsen, 2007). Another US study reported that the two-year costs of LLAs, between 1994 to 1997 and from surgery to follow-up visits post-discharge from rehabilitation, is $50,000 for foot amputations, $86,000 for transtibial amputations, $110,000 for transfemoral amputations, and $112,00 for knee disarticulation amputations (Mackenzie et al., 2007).

In order to better understand the burden and impact of LLA on healthcare systems, it is important to conduct epidemiological studies to obtain an estimate of the size of the problem. There have been a number of studies that assessed the epidemiology of LLA across the world. These studies have evaluated the incidence rates, causes, and levels of LLA. Determining baseline epidemiological values is useful for comparing rates across countries, planning and managing preventive and rehabilitative care, and developing strategies for healthcare cost reduction.

1.1.1 Causes of lower limb amputation

The causes of LLA are numerous but can be generally classified by the following areas: 1) complications associated with distal neuropathy and peripheral vascular disease; 2) trauma; 3) osteosarcoma (i.e. bone cancer); and 4) congenital limb deformities (Lusardi & Nielsen, 2007).

Distal neuropathy and peripheral vascular disease are the main culprits of LLA in Western countries (Dawes, Iqbal, Steinmetz, & Mayo, 2010; Fosse, 2009; Frieden, 2005; Lusardi & Nielsen, 2007). The common contributors of peripheral vascular disease are similar to those of cardiovascular and cerebrovascular disease and include smoking, obesity, inactivity, hypertension, and high serum cholesterol and triglyceride levels (Lusardi & Nielsen, 2007). Distal neuropathy and peripheral vascular disease are common in individuals with diabetes and account for 80% of the LLAs in Western countries (Carmona et al., 2005; Frieden, 2005; Lusardi & Nielsen, 2007). The prevalence of peripheral vascular disease is almost four times greater in individuals with diabetes (Beckman, Creager, & Libby, 2002). In the US, diabetes is present in 9.3% (29.1 million) of the population, and complications associated with diabetes make up more than 50% of LLAs (Centres for Disease Control and Prevention, 2014). Similarly, in Canada, 9.3% (3.4 million) of the population has diabetes (Canadian Diabetes Association, 2015), and the disease is estimated to be responsible for more than 60% of the LLAs (Canadian Institute of Health Information, 2012). Peripheral vascular disease and diabetes are more prevalent in older adults and in males (Lusardi & Nielsen 2007). Therefore, the incidence of LLA is considerably greater in older adults and in males.

The age at which an initial LLA occurs is typically between 51 and 69 years old. Generally there is a greater incidence among individuals over the age of 50, with a sharp increase after the age of 75 (Lusardi & Nielsen, 2007).

The second leading cause of LLA in Western countries is trauma, which accounts for 16.4% of LLAs in the US (Dillingham, Pezzin, & Mackenzie, 2002). The most common trauma-related LLAs are the result of injuries involving industrial machinery, power tools and appliances, firearms, and motor vehicle accidents (Lusardi & Nielsen, 2007). Males are at a substantially higher risk of trauma-related LLAs because they are more likely to participate in risky behaviours (Dillingham, Pezzin, & Mackenzie, 1998). In Western countries, there has been a recent reduction in the rate of trauma-related LLAs mainly due to improved occupational safety standards and implementation of safety guidelines (Lusardi & Nielsen, 2007; Varma, Stineman, & Dillingham, 2014).

The other, less common, causes of LLAs are cancer and congenital defects. Cancer-related LLAs comprise about 0.9% of the LLA cases (Dillingham, Pezzin, & Mackenzie, 2002). The incidence of LLA due to cancer has decreased significantly with recent improvements in surgical techniques and treatments (Lusardi & Nielsen, 2007). Lastly, congenital limb deformities account for almost 0.8% of the LLA cases (Dillingham, Pezzin, & Mackenzie, 2002). In Western countries, the incidence of congenital-related LLAs has remained relatively unchanged over time (Lusardi & Nielsen, 2007).

1.1.2 Levels of lower limb amputation

The levels of LLA, from most proximal (closest to the central portion of the body) to most distal (farthest from the central portion of the body), are classified as: hip and pelvis, transfemoral (above the knee), knee disarticulation (at the knee), transtibial (below the knee), ankle, foot, and toe amputations (Lusardi & Nielsen, 2007). The levels of LLAs are further subdivided into two categories: major and minor. Major LLAs include hip and pelvis, transfemoral, knee disarticulation, transtibial, and ankle amputations. Minor LLAs are foot and toe amputations (Lusardi & Nielsen, 2007). In the US, toe amputations are the most common level of LLAs and account for approximately 33% of the cases. The second most common level in the US is transtibial amputations, which account for 28% of the cases. Transfemoral amputations are almost as frequent as transtibial amputations and occur in 26% of the cases. Foot and ankle amputations constitute approximately 11% of the LLAs. Lastly, knee disarticulation, and hip and pelvis amputations account for about 1% of the cases in the US (Dillingham, Pezzin, & Mackenzie, 2002).

Vascular disease can affect both limbs. Approximately 50% of individuals with vascular-related LLAs undergo amputations of the contralateral limb within three-to-five years of the initial amputation (Lusardi & Nielsen, 2007). Meltzer et al. (2002) reported that between 25-45% of individuals with LLA have bilateral amputations at the transtibial level, or the transfemoral level, or a combination of transtibial in one limb and transfemoral in the other limb.

Generally, distal LLAs and preservation of the knee joint are preferred over proximal LLAs because distal LLAs are associated with reduced healing time, lower costs, shorter rehabilitation time, and greater possibility of the individual achieving prosthetic walking and independence (Frieden, 2005; Stewart & Condie, 1996). Ideally, the ratio of the incidence of transtibial to transfemoral amputations should not be below 2.5 (Dormandy, Heeck, & Vig, 1999). In the US, the reported ratio is 1.1 because of the higher incidence of transfemoral amputations (Dillingham, Pezzin, & Mackenzie, 2002). In Canada, this ratio has not been determined; however, for the province of Quebec, it has been found to be between 1.09 and 1.19 (Dawes, Iqbal, Steinmetz, & Mayo, 2010). Although the ideal goal is to preserve the knee, in vascular-related amputations there is a trade-off between saving the knee and the risk of the infection spreading if the surgeon decides to keep the knee. From a rehabilitation standpoint, transtibial amputations are preferred over higher levels of amputation (Davis & Datta, 2003; Jeans, Brown, & Karol, 2011); however, surgeons may opt for higher levels of amputation in vascular-related cases to prevent infection from spreading and, therefore, increase the chance of healing and survival.

1.1.3 Incidence of lower limb amputation

The incidence of LLA is known for several countries and, as Table 1.1 shows, it varies notably across the world (Moxey et al., 2011).

Table 1.1. Worldwide incidence of LLA

Country	Year	Incidence per 100,000 (Population)	Statistical analysis	Reference
France	2003	158 (in individuals with diabetes) 13 (in individuals without diabetes)	Age- and sex-adjusted	Fosse (2009)
Switzerland	1990-1999	42 (in individuals >65 years old)	Crude	Carmona et al. (2005)
Australia	2000-2010	35 to 39 (all LLAs)	Age-adjusted	Dillon, Kohler, & Peeva (2014)
Netherland	2003-2004	8.8 (all age groups) 23.6 (>45 years old)	Age-adjusted	Fortington et al. (2013)
United States	1988 1996	36.99 (vascular LLAs); 3.21 (trauma LLAs) 44.92 (vascular LLAs); 2.07 (trauma LLAs)	Age-adjusted	Dillingham, Pezzin, & Mackenzie (2002)
Germany	2005	31 (all LLAs)	Age-adjusted	Trautner, Haastert, Mauckner, Gatcke, & Giani (2007)
Sweden	1997-2006	195 (in individuals with diabetes) 23 (in individuals without diabetes)	Crude	Johannesson et al. (2009)
Ireland	2005 2009	144.2 (in individuals with diabetes); 12.0 (in individuals without diabetes) 175.7 (in individuals with diabetes); 9.2 (in individuals without diabetes)	Age-adjusted	Buckley et al. (2012)
United Kingdom	2004 2008	275 (in individuals with diabetes); 13.6 (in individuals without diabetes) 250 (in individuals with diabetes); 11.9 (in individuals without diabetes)	Crude	Vamos et al. (2010)

The reason for the variability in incidence rates has been mainly attributed to the geographical differences in the incidence of diabetes and vascular disease (Moxey et al., 2011). Countries with a greater incidence of diabetes tend to have a greater incidence of LLA (Moxey et al., 2011). The age-adjusted incidence rates of LLA in individuals with diabetes are usually between eight to twenty eight times greater than those without diabetes (Johannesson et al., 2009; Lusardi & Nielsen, 2007; Reiber et al., 1995; Van Houtum & Lavery, 1996). In the US, individuals with diabetes are twenty eight times more likely to have a LLA than individuals without diabetes (Lusardi & Nielsen, 2007). In other countries this ratio is smaller. For example, in Sweden, individuals with diabetes are eight times more likely to have a LLA than individuals without diabetes (Johannesson et al., 2009).

Despite the increase in the rate of diabetes (Wild, Roglic, Green, Sicree, & King, 2004), the majority of recent studies have reported a decline or no change in the *age-adjusted incidence rates* of LLA in Western countries (Dillon, Kohler, & Peeva, 2014; Holstein, Ellitsgaard, Olsen, & Ellitsgaard, 2000; Schofield, Yu, Jain, & Leese, 2009; Vamos et al., 2010; van Houtum, Rauwerda, Ruwaard, Schaper, & Bakker, 2004; Wang et al., 2009). In the United Kingdom (UK), the LLA rates in diabetic populations have declined from 275 to 250 per 100,000, from year 2004 to 2008 (Vamos et al., 2010). Similarly, in non-diabetic individuals, the rates have declined from 13.6 to 11.9 per 100,000 (Vamos et al., 2010). In the US, although earlier studies have shown an increase in the incidence rates, recent data, from 1998 to 2006, have shown a 37% decrease in age-adjusted rates in individuals with diabetes (Wang et al., 2009).

1.1.4 How big is the problem in Canada?

Although LLA epidemiological data exist for several countries, these data (including age-adjusted incidence rates by province, sex, level, and cause of amputation) are unknown for Canada. As a result, we do not have an understanding of how big the problem is in Canada. As stated above, we know from the literature that the main cause of LLA in Western countries is related to complications from diabetes and vascular disease, but we do not know to what extent these chronic diseases lead to LLA in Canada. Furthermore, we do not have evidence-based data regarding possible temporal changes in the LLA incidence rates in Canada that could reflect improvement/lack of improvement in diabetes prevention and disease management. The absence of Canadian epidemiological data limits one's ability to make informed healthcare decisions regarding LLA prevention strategies and rehabilitation services.

1.2 Impairments associated with lower limb amputation

LLA may be associated with physical and psychological changes, affecting the individual's quality of life (Horgan & MacLachlan, 2004). The International Classification of Functioning, Disability and Health (ICF) provides a useful framework for understanding the changes that follow LLA as well as the relationships that exist among the variables (World Health Organization, 2001) (Figure 1.1).

The ICF describes disability and functioning as by-products of interactions between *health conditions* and *contextual factors*. Health conditions are an individual's diagnoses and co-

morbidities, whereas contextual factors are the environmental (e.g. social support, living conditions, etc.) and personal (e.g. age, sex, education level, etc.) factors. According to the ICF, human functioning can be explained as three distinct components: *body function and structure*, *activities*, and *participation*. Disability is therefore defined as dys-functioning at one or more of these components (World Health Organization, 2001).

Impairments in *body function and structure* refer to problems with physiological or psychological functions. Limitations in *activities* are difficulties in executing an action or a task. Restrictions in *participation* are problems an individual may face in involvement in life situations (World Health Organization, 2001). There are bi-directional relationships between *body functions and structure*, *activities*, and *participation*. For example, changes in *body function* affect *activities*, and vice versa (World Health Organization, 2001).

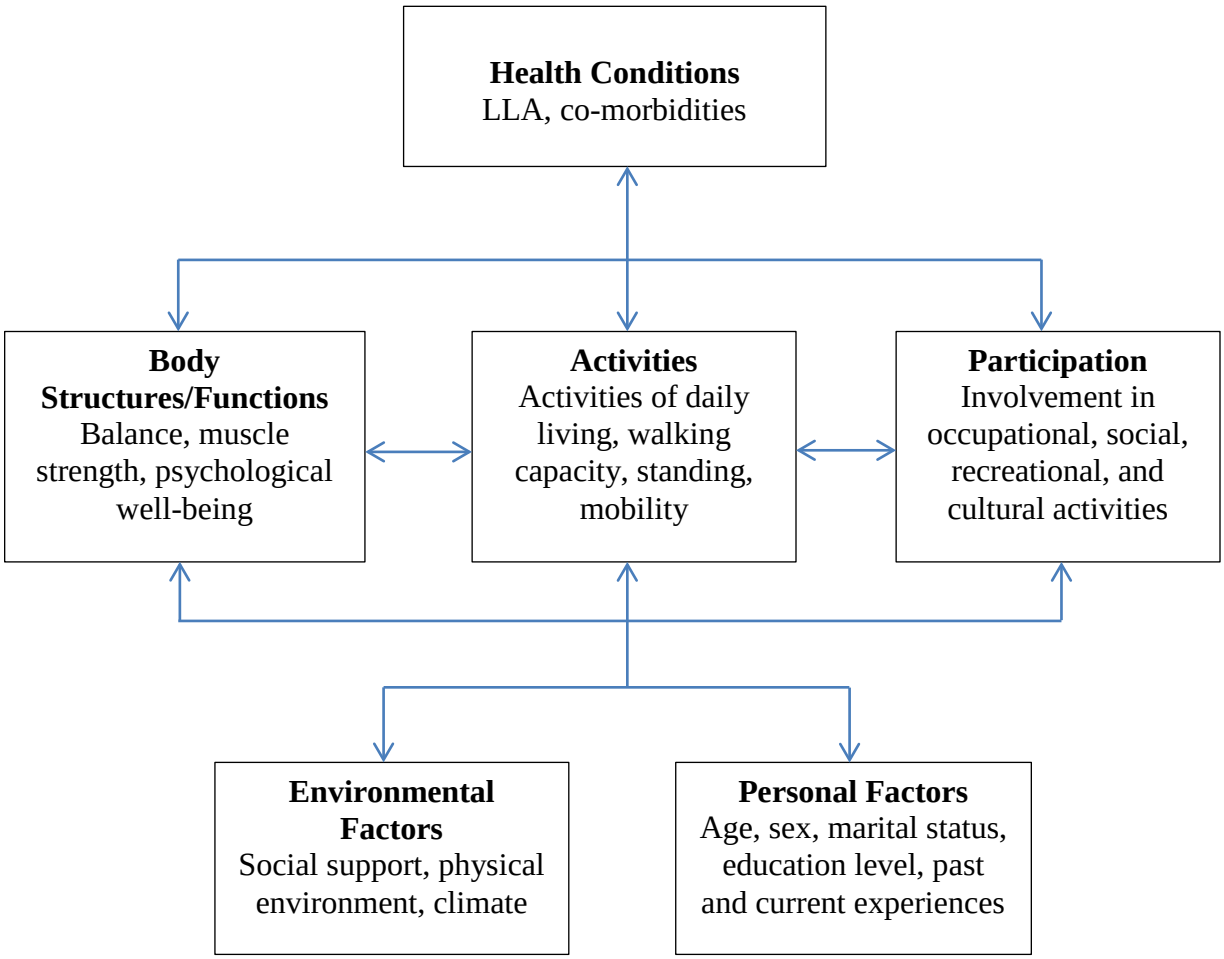

Figure 1.1. International Classification of Functioning, Disability and Health (ICF) framework to describe functioning and disability in individuals with LLA

LLA affects all three components of functioning (i.e. *body function and structure*, *activities*, and *participation*). At the level of *body function and structure*, LLA leads to impairments in balance, muscle strength, walking velocity, and gait symmetry, all of which contribute to decreasing walking capacity (Van Velzen et al., 2006). Walking capacity is the strongest determinant of health-related quality of life and the best predictor of prosthetic mobility in

individuals with LLA (van der Schans, Geertzen, Schoppen, & Dijkstra, 2002). Furthermore, cognitive impairment and depression are common in individuals with LLA (Bhutani, Bhutani, Chhabra, & Uppal, 2016; Coffey, O'Keeffe, Gallagher, Desmond, & Lombard-Vance, 2012). Impairments in *body function and structure* lead to restrictions in *activities* and *participation*. In individuals with LLA, daily activities such as prolonged standing and walking long distances (i.e. walking capacity) are largely limited (Gallagher, O'Donovan, Doyle, & Desmond, 2011). Similarly, participation in sport, leisure/cultural and recreational activities, as well as occupational activities may be restricted (Gallagher, O'Donovan, Doyle, & Desmond, 2011). Restrictions in activities and participation are influenced by environmental, personal, and health factors (World Health Organization, 2001). As an example, environmental factors such as climate affect the volume of the residual limb by causing it to swell or to shrink. The changes in the volume of residual limb influence prosthetic use and ultimately mobility and participation levels (Gallagher & MacLachlan, 2001). Likewise, health factors such as co-morbidities play a role in individuals' functioning after LLA. Comorbidities are common in the majority of older adults with LLA and mainly include diabetes and peripheral neuropathy (80.6%), hypertension (68.2%), ischaemic heart disease (66.2%), and hemiplegia (8-18%) (Hamamura et al., 2009; Hebert et al., 2009; Lusardi & Nielsen, 2007). Individuals with LLA that have a higher number of comorbidities often have greater limitations in activities and participation (Hamamura et al., 2009).

1.3 Lower limb amputation rehabilitation

Following LLA, individuals need to undertake rehabilitation to restore lost capacities and regain functional independence (Hamamura et al., 2009; Hebert et al., 2009). LLA

rehabilitation is divided into nine phases, each with a set of treatment goals: preoperative, operative, acute post-surgical, pre-prosthetic, prosthetic prescription and fabrication, prosthetic rehabilitation, community integration, vocational rehabilitation, and follow up (Esquenazi & DiGiacomo, 2001). The goals of the pre-operative phase are client education, treatment plan development, and discussion about outcomes and expectations. The goals of the operative and acute post-surgical phases are wound healing, pain control, emotional support, and residual limb shaping. The goals of the pre-prosthetic phase are increasing muscle strength, flexibility and range of motion, improving cardiovascular conditions, and teaching clients how to stand and ambulate without prosthesis. Once the client is able to ambulate safely without prosthesis but with crutches, the client will be progressed to prosthetic rehabilitation, which involves fitting of a prosthesis and training how to use and walk with the prosthesis (Esquenazi & DiGiacomo, 2001). Prosthetic rehabilitation is crucial because prosthetic use has been linked to improvements in physical and psychological outcomes (Schaffalitzky, Gallagher, Maclachlan, & Ryall, 2011).

Globally, there are different models of care for LLA rehabilitation with varying periods of inpatient and/or outpatient rehabilitation. In the US, individuals with transtibial amputation require between four to six weeks of rehabilitation to achieve basic mobility (Uustal, 2009). Individuals with transfemoral amputation usually require around six to twelve weeks of rehabilitation. Finally, individuals with bilateral amputation typically require twelve weeks of rehabilitation or longer. Individuals with higher-level amputation necessitate longer rehabilitation periods because of the energy expenditure required for prosthetic walking (Goktepe, Cakir, Yilmaz, & Yazicioglu, 2010). These individuals walk with heavier

prostheses, which lead to increased energy costs for ambulation (Goktepe, Cakir, Yilmaz, & Yazicioglu, 2010). This increased energy cost impacts prosthetic control and leads to limitation in functional abilities. As a result, people with a higher-level amputation need a longer period of rehabilitation to build the physical strength for walking. Older age also affects the length of rehabilitation (Kurichi et al., 2013). Older adults require a longer rehabilitation period to achieve a comparable level of mobility with younger individuals (Lusardi & Nielsen, 2007).

LLA rehabilitation, particularly inpatient rehabilitation, is costly and resource-intensive. A US study reported that the average cost of inpatient rehabilitation in veterans with LLA is about $45,000 (Kurichi et al., 2013). Although we do not have concrete data, we know that there has been a recent contextual shift in rehabilitation service delivery from inpatient to outpatient and/or home rehabilitation to reduce the costs (Meier & Heckman, 2014). Meier and Heckman (2014) reported that the inpatient LLA rehabilitation in the US, in an effort to save money, has been mostly eliminated.

1.3.1 What do we know about LLA rehabilitation in Canada?

In Canada, there is a dearth of evidence-based data about LLA rehabilitation. It is unclear how many individuals receive inpatient rehabilitation in Canada and what the length of their rehabilitation is. As a result, we are unable to determine the demand and impact of rehabilitation service delivery on the healthcare system in Canada. Furthermore, no data are available for Canada about what is being currently done in LLA rehabilitation or in what setting (i.e. inpatient, outpatient, home, or hybrid) services are being provided. Having an

evidence-based understanding of the current practices is critical for informed decision-making, promoting best practices, and maintaining quality of care while reducing healthcare costs. National survey studies are great tools to learn about current practices across Canada. The results from national studies can help us understand what LLA rehabilitation practices and service deliveries looks like in Canada and learn if any novel, cost-effective forms of rehabilitation are being used in practice.

1.3.2 What are other ways LLA rehabilitation can be delivered?

As stated above, we know that the current hospital-based rehabilitation delivery is costly and may not be sustainable as the demand for rehabilitation continues to increase (Meier & Heckman, 2014; Zeidler, Mittendorf, Vahldiek, Zeidler, & Merkesdal, 2008). The number of individuals with LLA is expected to increase due to the increase in the aging Canadian population. Statistics Canada projects that the proportion of seniors aged 65 years and older is going to grow from 14% in 2009 to 25% by 2036 (Statistics Canada, 2015). As a result, it is worthwhile to explore innovative interventions and rehabilitation delivery forms that are less resource intensive and enable access to rehabilitation by a larger number of individuals at a low cost. Such programs may lead to earlier discharges from hospital-based rehabilitation and allow rehabilitation to continue beyond discharge. For instance, numerous studies have reported on the feasibility and efficacy of home-based rehabilitation in different client populations (Crotty, Whitehead, Gray, & Finucane, 2002; Robins et al., 2016; Tsauo, Leu, Chen, & Yang, 2005). These programs enable clients to progress from a dependent hospital-based rehabilitation to an independent rehabilitation with less reliance on therapists and more focus on empowering the client to be in control of their own health and

rehabilitation outcomes. One innovative strategy for providing home-based rehabilitation may be the use of interactive video gaming technology. These gaming software allow clients to engage in interactive exercises in their home and receive real-time feedback from the device throughout the activities without reliance on the therapist. Over the past few years, there has been a growing interest by therapists and researchers in the use of commercial gaming technology in the area of rehabilitation. Commercial games are attractive because they not only provide an interactive form of exercise but also are available to the general public at a low cost. One of the top-selling and most prevalent commercial games used in rehabilitation is the Nintendo Wii Fit. We do not have empirical data about the prevalence of use of the Wii Fit in LLA rehabilitation; however we know that it is informally being used for prosthetic rehabilitation at our local rehabilitation clinic and other clinics in Canada. Although therapists already use these games in practice, evidence for the efficacy of the use of Wii Fi in prosthetic rehabilitation is still lacking. We also do not have data about the therapists' experience and perspectives about using these games. This is not an evidence-based practice. As a result, randomized controlled trials are required to evaluate the use of these games in prosthetic rehabilitation. Furthermore, national survey studies can be useful in learning about the prevalence of the Wii Fit in prosthetic rehabilitation across facilities in Canada as well as therapists' experience and perspectives about the use of these games in practice.

1.4 Wii Fit rehabilitation from Social Cognitive Theory

Social Cognitive Theory by Bandura (1997) is a useful theory for understanding behavior changes and has provided the foundation of several effective interventions for improving

health-related outcomes (Basen-Engquist et al., 2011; Brassington, Atienza, Perczek, DiLorenzo, & King, 2002; Stacey, James, Chapman, Courneya, & Lubans, 2015). According to the Social Cognitive Theory, learning is improved through enhancing self-efficacy (Bandura, 1997). Self-efficacy refers to an individual's perception about their abilities to perform a task. The higher the individual's self-efficacy, the more likely the behavior will be learned and adopted. Self-efficacy is enhanced through four main sources: *vicarious learning*, *mastery experience*, *verbal persuasion,* and *physiological state*.

Vicarious learning refers to learning by watching and imitating others. Observing others accomplishing certain tasks with desirable outcomes provides a sense of self-efficacy to the learner (or observer) that they, too, are capable of succeeding at that task (Bandura, 1997). This is referred to as *outcome expectations*. The more similar (e.g. age, sex) the observer is to the model being observed, the greater the likelihood of expecting similar outcomes and subsequent modeling and vicarious learning. This is the basis of peer-based learning. The Wii Fit games provide an opportunity for *vicarious learning* by allowing the client to play the games in a group setting against their peers. Group training has various inherent benefits including enhancing social interaction, social support, peer modeling, and thereby *vicarious learning* (Bandura, 1997).

Mastery experience is learning through practicing. Accomplishing easy tasks increases the individual's self-efficacy for learning more complex tasks. Experiencing incremental success provides the individual with a sense of achievement, motivation, and self-efficacy, thereby enhances learning in anticipation for future success (Bandura, 1977). The Wii Fit games may

promote *mastery experience* by requiring clients to initially complete the easy precursor (or beginner) levels before more challenging levels are introduced. The harder levels of the games are initially locked and only become unlocked through practice and completion of the easier precursor levels.

Verbal persuasion is providing encouragement and positive feedback to the client for a successful performance. The Wii Fit games provide real-time visual and auditory encouragement to the client after a successful accomplishment of a task.

The *physiological state* is concerned about the individual's arousal state. High levels of anxiety and stress have negative impacts on performance. Playing the Wii Fit games provide an enjoying and interactive learning environment, thereby helping to reduce the anxiety and stress associated with learning. In Chapter 6, we will report data on our Wii Fit intervention that uses the principles of Social Cognitive Theory to improve outcomes in older adults with LLA.

1.5 Summary

There is a lack of evidence-based data on the incidence and rehabilitation of LLA in Canada. We know from the literature that the main cause of LLA in Western countries is complications from diabetes and vascular disease. However, without knowing the incidence of LLA, we cannot determine the effect and size of the problem in Canada. Furthermore, without assessing evidence-based data on LLA rehabilitation and practice (e.g. number of individuals receiving rehabilitation in Canada, rehabilitation delivery forms, etc.), we are

limited in our understanding about the demand and impact on rehabilitation services. As a result, it is difficult to make any informed healthcare decisions about managing preventive and rehabilitative services and promoting best practices (Ward, 2013).

Based on the information above, we can safely assume that with the aging population and the continued growth in the incidence of diabetes, the current costly resource-intensive rehabilitation model may not be sustainable. There is a need to look to other forms of delivery to reduce healthcare costs and make rehabilitation available to a larger number of individuals with LLA. The solution may lie in designing rehabilitation models that help clients progress from the dependent inpatient setting to less costly and more accessible independent home rehabilitation. An example is a home-based program that uses commercially available physical activity games as a form of rehabilitation. Recently there has been a rise in the use of commercial games, particularly the Nintendo Wii Fit, in the area of prosthetic rehabilitation. As the use of these games is growing, randomized controlled trials are required to evaluate their efficacy. Additionally, it is important to learn how widely these games are being used and therapists' perspectives on their use.

1.6 Research objectives

The objectives of this dissertation are addressed in the following chapters.

In Chapter 2, we define the incidence of LLA in Canada (by age, sex, level, and cause of LLA) and investigate temporal changes in the incidence rates. We present findings for six-year data (2006 to 2011) obtained from the Canadian Institute of Health Information.

In Chapter 3, we determine the proportion of individuals with LLA that received inpatient rehabilitation in Canada from 2006 to 2011. Through analyzing data from the Canadian Institute of Health Information and the National Rehabilitation Reporting System, we detail the percentage of individuals that received inpatient rehabilitation, the length of their stay, and their functional status level at the time of discharge from rehabilitation.

In Chapter 4, we develop an understanding of prosthetic rehabilitation and the nature of the therapies that clients received during their period of rehabilitation in Canada. We report data on a cross-sectional survey that targeted prosthetic rehabilitation facilities in Canada.

In Chapter 5, we explore therapists' perspectives about the use of commercial games (mainly the Wii Fit in lower limb prosthetic rehabilitation). We surveyed physical therapists and occupational therapists who work with individuals with LLA in Canada. We describe data on prevalence of use, as well as therapists' perceived barriers/challenges and benefits associated with using the Wii Fit games for prosthetic rehabilitation in Canada.

In Chapter 6, we present data from a feasibility study of a randomized controlled trial that evaluated the use of the Wii Fit for improving walking capacity in older adults with LLA. Results for feasibility indicators including: enrolment rate, retention rate, adherence, safety, adverse event rate, and participants' perceived benefits from the intervention are described. Furthermore, findings for clinical outcomes of walking capacity, balance, balance confidence, participation in physical activity, prosthetic use, and mobility are discussed.

2 Incidence of Lower Limb Amputation in Canada

2.1 Introduction

As stated in Chapter 1, the lower limb amputation (LLA) incidence data are unknown for Canada. As a result, incidence rates from other countries, particularly the United States (US), are commonly used to support health care planning and research initiatives. Lawee and Csima (1992) and Dawes, Iqbal, Steinmetz, & Mayo (2010) reported the only Canadian studies of the incidence of LLA to date. Lawee and Csima (1992) examined the incidence of LLA in individuals living with diabetes in Ontario, from 1987 to 1988, using the US's diabetes population statistics. The reported annual incidence rate was 440 per 100,000 individuals (Lawee & Csima, 1992). In another study, Dawes, Iqbal, Steinmetz, & Mayo (2010) reported the incidence of LLAs in Quebec and found that there were 15,992 LLAs from 1996 to 2004.

While providing some insight, the above two regionally oriented studies (Dawes, Iqbal, Steinmetz, & Mayo, 2010; Lawee & Csima, 1992) have important limitations that justify the need for our current study. First, they only provide regional data without any indication of national rates. Data at the national level is critical because health and health-related behaviours, such as obesity, diabetes, and smoking rates, are variable across provinces, and this variability could impact incidence rates (Canadian Community Health Survey, 2009; Statistics Canada, 2013). Additionally, understanding the incidence rates from both national and provincial perspectives is essential for developing national/provincial strategies to inform health policy and manage preventive and rehabilitation services. The second limitation, for

the Ontario study specifically, is that the data are outdated and provided only for diabetes-related LLAs at a single point in time (Lawee & Csima, 1992). Reporting on variations in the rates over a period of time (e.g. at least a few years) rather than a single time point would be valuable because it would provide information about changes in the burden and profile of the disease. Third, no information is provided for the incidence by level or other causes of LLA. Fourth, the reported incidence is unadjusted and only represents the crude rate. Unadjusted crude rates are not ideal because they do not allow a fair comparison with the rates from other countries or rates across different years (Hoem, 1987; Inskip, Beral, Fraser, & Haskey, 1983). Recently Kayssi, de Mestral, Forbes, & Roche-Nagle (2016) reported on LLAs in Canada from 2006 to 2009. According to this study, 5,342 individuals underwent a LLA for vascular reasons with 81% of those being related to complications associated with diabetes. Although this study provided important information about LLA in Canada, data pertaining to Quebec, trauma, and pediatric cases were excluded. In addition, the incidence rate of LLA, as well as the incidence rates by age, sex, province, and level and cause of LLA were not reported.

Therefore, the primary objective of this study was to determine the age-adjusted incidence rate of LLA in Canada per 100,000 individuals. As explained in Chapter 1, age is an important confounder. The age-adjusted rates will remove the effect of age confounding and allow a fair comparison of the rates across years or with other countries that have a different age structure.

The secondary objectives were to provide the age-adjusted incidence rates of LLA by ten Canadian provinces, sex, level, and cause of amputation per 100,000 individuals. We chose to examine the rates by sex, level, and cause of amputation because these are important variables that affect the incidence rates (Chapter 1). Provincial rates give a clear picture of the variability in the incidence rates across Canada and are useful in developing national strategies to inform health policy and services. We also looked at the most recent six-year temporal changes in the age-adjusted incidence rates. Examining the temporal changes in rates will be helpful in understanding if the efforts in reducing the incidence rates (e.g. diabetes prevention, education, and management) have been effective. Furthermore, changes in the rates will be indicative of changes in the burden and profile of the disability. The tertiary objective was to assess the relative risk of LLA in individuals with diabetes compared to individuals without diabetes. As LLA is an important indicator of quality of care in individuals with diabetes, determining the value of relative risk will provide useful insights into the extent to which diabetes increases the risk of LLA in Canada.

2.2 Methods

2.2.1 Design and population

Data on all acute inpatient cases for individuals that have been discharged from the hospital with the recorded procedure codes for LLAs (from hip and pelvis to toes), from April 1st, 2006 to March 31st, 2012, were obtained from the Discharge Abstract Database (DAD) of the Canadian Institute of Health Information (CIHI). As CIHI releases data based on fiscal years, the most recent data that were available at the time of data request was for March 31st, 2012.

The start date was selected because the new coding systems, the 10th revision of the International Statistical Classification of Diseases and Related Health Problems (ICD-10-CA) and the Canadian Classification of Health Interventions (CCI), were implemented by 2006 in all Canadian provinces. All provinces, except Quebec, adopted the ICD-10-CA coding system in 2004. Thus, we selected 2006 as our start date to include Quebec's data.

We extracted the procedure codes from the CCI (Canadian Classification of Health Interventions, 2012) and used them to identify the LLA cases from the DAD (Table 2.1). Similarly, we extracted the diagnosis codes from the ICD-10-CA (International Statistical Classification of Diseases and Related Health Problems, 2012) and used these to determine the diagnoses (i.e. diabetes) for each patient (Table 2.2).

Table 2.1. Canadian Classification of Health Intervention (CCI) codes to identify LLA cases

Level of LLA	**CCI codes**
Hip and pelvis	1VA93; 1SQ93
Transfemoral	1VC91; 1VC93
Knee disarticulation	1VG93
Transtibial	1VQ93
Ankle	1WA93
Foot	1WE93; 1WI93; 1WJ93
Toe	1WK93; 1WL93; 1WM93; 1WN93

Table 2.2. International Statistical Classification of Diseases and Related Health Problems (ICD-10-CA) to identify the causes of LLA cases

Diagnosis	ICD-10-CA codes
Diabetes	E10; E11; E12; E13; E14; G590; G632; H280; H360; I792; M142; M146; N083
Other vascular diseases/ Infections	A04; A40; A41; A48; A52; G598; G630; G631; G633; G635; G636; G638; H368; I790; I791; I798; E74; G45; G46; G57; G60; G62; I12; I20; I21; I22; I23; I24; I25; I26; I27; I28; I30; I31; I32; I33; I34; I35; I36; I37; I38; I39; I40; I41; I42; I43; I44; I45; I46; I48; I49; I50; I51; I52; I60; I61; I62; I63; I64; I65; I66; I67; I68; I69; I70; I71; I72; I73; I74; I77; I78; I79; I80; I81; I82; I83; I84; I86; I87; I88; I89; I95; I97; I98; I99; J44; J69; J86; J96; L02; L08; L89; L95; L97; L98; M00; M05; M06; M10; M12; M15; M17; M19; M31; M46; M86; M87; M89; M96; N17; N18; R02; R09;T80; T81; T82; T84; T85; T87
Trauma	T34; T35; M84; S30; S32; S33; S34; S38; S39; S70; S72; S77; S78; S79; S80; S82; S83; S87; S88; S89; S90; S92; S97; S98; S99; T04; T05; T12; T13; T24; T25; T79; T93; T94; Z041; Z042; Z043; Z045; V01; V02; V03; V04; V05; V06; V07; V08; V09; V10; V11; V12; V13; V14; V15; V16; V17; V18; V19; V20; V21; V22; V23; V24; V25; V26; V27;V28; V29; V30; V31; V32; V33; V34; V35; V36; V37; V38; V39; V40; V41; V42; V43; V44; V45; V46; V47; V48; V49; V50; V51; V52; V53; V54; V55; V56; V57; V58; V59; V60; V61; V62; V63; V64; V65; V66; V67; V68; V69; V70; V71; V72; V73; V74; V75; V76; V77; V78; V79; V80; V81; V82; V83; V84; V85; V86; V87; V88; V89; V90; V91; V92; V93; V94; V95; V96; V97; V98; V99; W20; W21; W22; W23; W24; W25; W26; W27; W28; W29; W30; W31; W32; W33; W34; W35; W36; W37; W38; W39; W40; W41; W43; W44; W45; W49; W52; W54; W55; W56; W58; W59; W64; W85; W86; W87; X72; X73; X74; X82; X93; X94;X95; Y03; Y85; Y86; Y87
Cancer	C40; C41; C437; C447; C492; D16; D46; C795
Congenital	Q65; Q66; Q68; Q69; Q70; Q72; Q73; Q74; Q78; Q79; Q2731

The final data obtained from CIHI contained six Statistical Analysis System (SAS) files, each relating to a fiscal year. Each row corresponded to a LLA hospitalization visit containing one or more than one LLA procedure on a single individual. Each hospitalization visit contained a unique, meaningless patient identification code to allow tracking the number of individuals and if the individual had single or multiple LLAs over the study years. Variables including

sex, age, province, year, side of LLA (left, right, bilateral), level of amputation, and diagnoses were also obtained for each LLA case.

The CCI procedure codes recorded for each hospitalization visit indicated the levels of the LLA(s). The CCI data were decoded and aggregated by a statistician to accurately count the number of different levels of LLA. Seven categories were defined based on the CCI codes: hip and pelvis, transfemoral, knee disarticulation, transtibial, ankle, foot, and toes (Lusardi & Nielsen, 2007).

The following rules were used to correctly count the number of LLAs. When more than one LLA procedures were found in a single hospitalization visit for an individual on one limb, we only counted the highest level. For example, if both ankle and transtibial amputations were done on one limb in one visit, we only counted the transtibial amputation. If there were more than one LLA in a single hospitalization visit for an individual on both limbs (both left and right), we counted the highest level of LLA for each limb. Lastly, if there were more than one LLA in more than one visit for an individual we counted all of these LLAs separately. For example, if an individual had both ankle and transtibial amputations in two separate visits, both of these LLA were counted separately.

The ICD-10-CA (Table 2.2) diagnosis code(s) recorded in each hospitalization visit provided insights into the most probable cause of LLA. The ICD-10-CA data were decoded and aggregated by the statistician to allow categorizing the causes of LLAs. Consistent with other similar studies, five categories were defined using the ICD-10-CA codes: diabetes, other

vascular diseases/infections, trauma, cancer, and congenital disorders (Dawes, Iqbal, Steinmetz, & Mayo, 2010). The first recorded diagnosis (e.g. codes for trauma) was selected as the most probable cause of amputation with an exception for other vascular diseases/infections category. If the first diagnosis was vascular diseases/infections other than diabetes, we looked at the other diagnoses. The rationale behind this was that vascular diseases and infections in these individuals were likely to have been preceded with complications/infections associated with diabetes or trauma causes. If a code(s) for diabetes but no trauma was found, the cause was flagged as diabetes. If a code(s) for trauma but no diabetes were found, the cause was noted as trauma. If neither diabetes nor trauma codes were found, the cause was flagged as other vascular diseases/infections. Finally, if both diabetes and trauma were found, we reviewed the case thoroughly to decide what the likely cause has been.

After obtaining ethics approval from the Clinical Research Ethics Board of the University of British Columbia, the Centre for Interdisciplinary Research in Rehabilitation of Greater Montreal, and the Commission to Access Information in Quebec, the complete database was obtained from the CIHI in August 2014.

2.2.2 Data analyses

Demographic and descriptive data: the characteristics of LLAs in Canada and across the provinces were described using means and standard deviations (SD) and frequency (%).

In order to address the primary objective: age-specific crude national and provincial incidence rates were calculated for three age groups (0-49, 50-74, and 75+ years old) because generally the LLA incidence is expected to be different between these groups (Lusardi & Nielsen, 2007). To calculate the age-specific crude incidence rates, the number of new cases of LLA in a specific age group was divided by the size of the population in that specific age group. National and provincial population sizes from 2006 to 2011 were obtained from the 2011 Canadian Census (Statistics Canada, 2011).

Direct method of age-adjustment was used to adjust the amount that each age group contributed to the overall rate in each year, so that the overall rates were based on the same age structure and allowed for fair comparison of the rates over the study years or across provinces (Hoem, 1987; Inskip, Beral, Fraser, & Haskey, 1983). Direct method of adjustment was accomplished by first multiplying the age-specific rates by age-specific weights in a standard population (Lee & Liaw, 1999). Age-specific weights were taken from the weights for final post-censual Canadian population 2011. The final post-censual Canadian population in 2011 is the most recent Canadian standardized population and is recommended by Statistics Canada to be used for all age-adjustment statistics. The weighted rates were then summed across the age groups to give the total age-adjusted rate. Age-adjusted rates were calculated for each year separately per 100,000 individuals and were then averaged to derive the overall rate in Canada.

In order to address the secondary objectives: direct method of standardization was used to determine age-adjusted rates by province, sex, level, and cause of LLA. The rates were

calculated per 100,000 individuals. We presented the yearly rates as well as the overall averaged rate.

In order to address the tertiary objective: relative risk for diabetes-related LLAs was calculated by dividing the age-adjusted incidence rate of LLA in people with diabetes over the age-adjusted incidence rate of LLA in people without diabetes. The population of individuals with and without diabetes was obtained from Statistics Canada (Statistics Canada, 2013).

2.3 Results

Demographic and descriptive data: from April 1st 2006 to March 31st 2012, there were a total of 44,430 LLAs performed in Canada. The number of LLAs increased from 7,331 in 2006 to 7,708 in 2011. Mean (SD) age at amputation was 65.7 (16.6) years old, and 30,560 (68.8%) were males. More than half of the LLAs occurred in the 50-74 age category (n=24,400, 54.9%), followed by the age category of 75+ (n=13,773, 31.0%), and finally the age group 0-49 (n=6,257, 14.1%). The number of transtibial amputations was the highest (n=13,708, 30.9%) compared to the other levels. The number of ankle amputations was the lowest (n=241, 0.5%). The main cause of amputation was diabetes (n=29,087, 65%) (Table 2.3).

Table 2.3. Characteristics of LLA in Canada for fiscal years 2006 to 2011

	2006	**2007**	**2008**	**2009**	**2010**	**2011**	**Total**
Amputations *n*	7,331	7,190	7,466	7,367	7,368	7,708	44,430
Amputations (0-49 years old) *n (%)*	1,068 (14.6)	976 (13.6)	1,078 (14.4)	1,120 (15.2)	1,034 (14.0)	981 (12.7)	6,257 (14.1)
Amputations (50-74 years old) *n (%)*	4,002 (54.6)	3,933 (54.7)	3,982 (53.3)	4,045 (54.9)	4,053 (55.0)	4,385 (56.9)	24,400 (54.9)
Amputations (75+ years old) *n (%)*	2,261 (30.8)	2,281 (31.7)	2,406 (32.2)	2,202 (29.9)	2,281 (31.0)	2,342 (30.4)	13,773 (31.0)
Age *mean (SD)*	65.1 (16.9)	65.7 (16.2)	65.7 (16.7)	65.2 (16.7)	65.7 (16.9)	65.8 (16.1)	65.7 (16.6)
Sex (males) *n (%)*	5,007 (68.3)	4,903 (68.2)	5,032 (67.4)	5,201 (70.6)	5,106 (69.3)	5,311 (68.9)	30,560 (68.8)
Hip and pelvis amputations *n (%)*	47 (0.6)	42 (0.6)	56 (0.8)	47 (0.6)	61 (0.8)	56 (0.7)	309 (0.7)
Transfemoral amputations *n (%)*	1,786 (24.4)	1,787 (24.9)	1,821 (24.4)	1,735 (23.6)	1,743 (23.7)	1,731 (22.5)	10,603 (23.9)
Knee disarticulation amputations *n (%)*	74 (1.0)	77 (1.1)	85 (1.1)	95 (1.3)	86 (1.2)	49 (0.6)	466 (1.0)
Transtibial amputations *n (%)*	2,290 (31.2)	2,226 (31.0)	2,221 (29.7)	2,290 (31.1)	2,243 (30.4)	2,438 (31.6)	13,708 (30.9)
Ankle amputations *n (%)*	46 (0.6)	40 (0.6)	40 (0.5)	44 (0.6)	40 (0.5)	31 (0.4)	241 (0.5)
Foot amputations *n (%)*	2,098 (28.6)	2,039 (28.4)	2,216 (29.7)	1,898 (25.8)	1,887 (25.6)	2,084 (27.0)	12,222 (27.5)
Toe amputations *n (%)*	985 (13.4)	975 (13.6)	1,024 (13.7)	1,257 (17.1)	1,307 (17.7)	1,318 (17.1)	6,866 (15.4)
Diabetes amputations *n (%)*	4,620 (63.0)	4,637 (64.5)	4,843 (64.9)	4,874 (66.2)	4,883 (66.3)	5,229 (67.8)	29,086 (65.4)
Other vascular diseases/infections amputations *n (%)*	2,012 (27.4)	1,865 (25.9)	1,931 (25.9)	1,844 (25.0)	1,846 (25.1)	1,881 (24.4)	11,379 (25.6)
Trauma amputations *n (%)*	455 (6.2)	470 (6.5)	476 (6.4)	457 (6.2)	416 (5.6)	405 (5.3)	2,679 (6.0)
Cancer amputations *n (%)*	152 (2.1)	143 (2.0)	136 (1.8)	105 (1.4)	140 (1.9)	128 (1.7)	804 (1.8)

	2006	**2007**	**2008**	**2009**	**2010**	**2011**	**Total**
Congenital amputations *n (%)*	52 (0.7)	36 (0.5)	33 (0.4)	46 (0.6)	55 (0.7)	48 (0.6)	270 (0.6)
Alberta amputations *n (%)*	714 (9.8)	640 (8.9)	740 (9.9)	748 (10.2)	752 (10.2)	879 (11.4)	4,473 (10.1)
British Columbia amputations *n (%)*	837 (11.4)	873 (12.2)	867 (11.6)	866 (11.8)	903 (12.3)	970 (12.6)	5,316 (12.0)
Manitoba amputations *n (%)*	394 (5.4)	380 (5.3)	420 (5.6)	423 (5.8)	421 (5.7)	405 (5.3)	2,443 (5.5)
New Brunswick amputations *n (%)*	247 (3.4)	205 (2.9)	209 (2.8)	217 (3.0)	182 (2.5)	174 (2.3)	1,234 (2.8)
Newfoundland and Labrador amputations *n (%)*	214 (2.9)	203 (2.8)	197 (2.6)	177 (2.4)	219 (3.0)	187 (2.4)	1,197 (2.7)
Nova Scotia amputations *n (%)*	308 (4.2)	264 (3.7)	307 (4.1)	256 (3.5)	264 (3.6)	326 (4.2)	1,725 (3.9)
Ontario amputations *n (%)*	2,766 (37.8)	2,761 (38.5)	2,838 (38.1)	2,748 (37.4)	2,773 (37.7)	2,839 (36.9)	16,724 (37.7)
Prince Edward Island amputations *n (%)*	62 (0.8)	38 (0.5)	34 (0.5)	34 (0.5)	27 (0.4)	36 (0.5)	231 (0.5)
Quebec amputations *n (%)*	1,475 (20.1)	1,522 (21.2)	1,586 (21.3)	1,598 (21.7)	1,544 (21.0)	1,587 (20.6)	9,312 (21.0)
Saskatchewan amputations *n (%)*	305 (4.2)	293 (4.1)	251 (3.4)	283 (3.9)	275 (3.7)	300 (3.9)	1,707 (3.8)

Primary objective: The average age-adjusted rate of LLA in Canada was 22.9 per 100,000 (Table 2.4 and Figure 2.1).

Table 2.4. Crude, age-specific, and age-adjusted rates for fiscal years 2006 to 2011 (per 100,000) in Canada

	2006	2007	2008	2009	2010	2011	Overall
Crude	22.5	21.9	22.5	21.9	21.7	22.4	22.1
Age-specific (yrs)							
0-49	4.8	4.4	4.9	5.0	4.6	4.4	4.7
50-74	47.9	45.6	44.8	44.0	42.7	44.8	45.0
75+	111.5	109.7	113.1	101.5	102.9	103.5	107.0
Age-adjusted	24.1	23.1	23.4	22.5	22.0	22.4	22.9

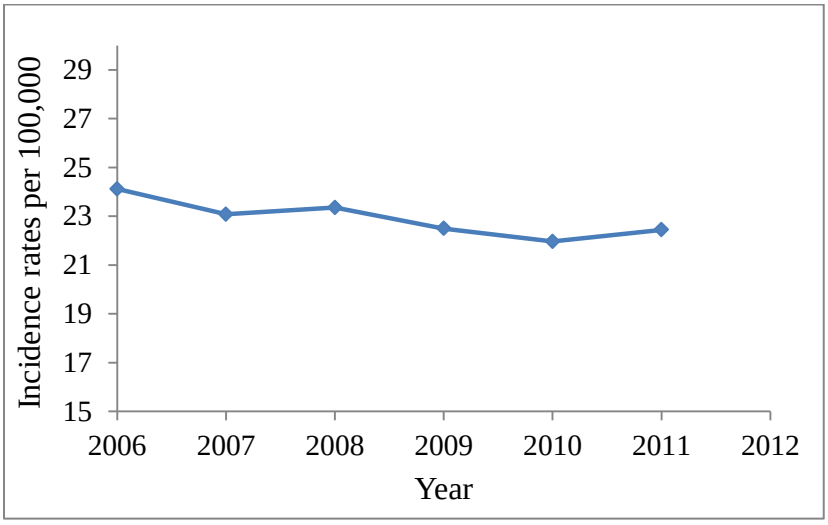

Figure 2.1. Age-adjusted LLA incidence rates in Canada per 100,000 individuals. Age-standardized to final post-censual Canadian population in 2011, direct method.

Secondary objective: Among all provinces, Quebec and British Columbia had the lowest age-adjusted LLA incidence rates (average rate from 2006 to 2011=19.6, and 20.1 per 100,000

individuals, respectively), while Newfoundland and Labrador had the highest rate (average rate from 2006 to 2011=37.9 per 100,000 individuals) (Table 2.5).

The average age-adjusted incidence rate over the study years in males was 34.0 per 100,000, whereas in females it was 13.2 per 100,000 (Figure 2.2).

As shown in Figure 2.3, among all levels of amputations, transtibial amputations had the highest rate (7.1 per 100,000), followed by foot amputations (6.3 per 100,000). The lowest rates belonged to ankle and knee disarticulation amputations (0.1 and 0.2 per 100,000, respectively). The transtibial/transfemoral incidence ratio increased from 2006 (1.28) to 2011 (1.41).

In terms of cause of amputation, diabetes-related amputations were the highest, with an average age-adjusted incidence rate of 15.0 per 100,000 (Figure 2.4). The second most common cause of amputation was the "other vascular diseases/infections" category (5.9 per 100,000) followed by trauma-related amputations (1.3 per 100,000).

Tertiary objective: The average age-adjusted incidence rate of LLA in people with diabetes was 280.5 per 100,000, whereas for people without diabetes it was 9.7 per 100,000 (relative risk=28.9).

Table 2.5. Age-specific and age-adjusted LLA rates for fiscal years 2006 to 2011 (per 100,000) by provinces

	2006	2007	2008	2009	2010	2011	Overall
AB							
Age-specific (yrs)							
0-49	6.7	5.6	6.7	7.3	5.2	7.2	6.5
50-74	46.5	40.4	45.5	40.6	48.3	51.5	45.5
75+	119.3	105.0	111.8	115.6	100.3	111.3	110.6
Age-adjusted	25.4	22.1	24.6	24.0	23.7	26.7	24.4
BC							
Age-specific (yrs)							
0-49	4.3	4.2	4.2	3.1	3.8	3.0	3.8
50-74	39.2	38.9	37.3	37.1	36.6	40.8	38.3
75+	94.3	102.2	99.1	103.6	104.4	108.3	102.0
Age-adjusted	20.2	20.5	19.9	19.4	19.8	20.7	20.1
MB							
Age-specific (yrs)							
0-49	7.6	6.8	9.9	9.5	8.1	8.9	8.5
50-74	77.5	74.3	80.1	73.3	72.7	71.9	75.0
75+	130.7	126.6	116.5	141.8	147.7	115.4	129.8
Age-adjusted	35.6	33.9	36.9	36.4	35.7	33.9	35.4
NB							
Age-specific (yrs)							
0-49	7.7	4.4	4.0	7.9	6.2	3.5	5.6
50-74	62.4	51.6	53.3	51.1	37.4	34.4	48.4
75+	154.1	139.5	135.9	119.1	121.2	137.8	134.6
Age-adjusted	32.9	26.7	26.8	27.5	22.7	21.1	26.3

	2006	2007	2008	2009	2010	2011	Overall
NL							
Age-specific (yrs)							
0-49	7.3	8.0	7.2	8.1	9.7	7.2	7.9
50-74	77.0	66.6	64.8	65.9	75.2	64.0	68.9
75+	244.8	241.2	227.7	135.1	187.3	159.2	199.2
Age-adjusted	42.8	40.1	38.1	32.9	40.0	33.4	37.9
NS							
Age-specific (yrs)							
0-49	5.9	4.5	5.1	4.8	5.0	7.0	5.4
50-74	68.9	48.9	59.8	51.0	50.8	61.1	56.8
75+	138.9	160.4	167.5	123.2	127.8	150.0	144.6
Age-adjusted	32.6	27.4	31.4	25.8	26.1	31.8	29.2
ON							
Age-specific (yrs)							
0-49	4.4	3.9	4.5	4.6	4.2	3.5	4.2
50-74	47.8	46.9	44.4	44.2	42.8	44.6	45.1
75+	113.6	113.1	117.9	99.9	102.4	101.1	108
Age-adjusted	23.9	23.3	23.3	22.1	21.7	21.7	22.7
PE							
Age-specific (yrs)							
0-49	3.3	9.0	3.4	4.5	2.3	4.5	4.5
50-74	75.6	40.4	51.4	47.6	27.6	40.1	47.1
75+	320.8	147.4	102.8	101.9	130.3	136.8	156.7
Age-adjusted	44.8	27.1	23.6	23.2	17.9	23.3	26.7

	2006	2007	2008	2009	2010	2011	Overall
QC							
Age-specific (yrs)							
0-49	3.5	3.6	3.9	4.3	4.1	3.9	3.9
50-74	40.6	40.7	38.9	40.7	36.5	37.0	39.1
75+	91.4	91.9	100.9	84.6	87.1	88.9	90.8
Age-adjusted	19.9	20.0	20.3	19.9	18.8	18.9	19.6
SK							
Age-specific (yrs)							
0-49	7.6	7.6	5.6	8.7	7.3	7.1	7.3
50-74	66.8	66.9	55.6	6.5	52.6	62.2	51.8
75+	117.3	94.9	88.3	103.5	100.9	93.6	99.8
Age-adjusted	31.7	30.2	25.3	27.6	26.4	28.5	28.3

AB=Alberta; BC=British Columbia; MB=Manitoba; NB=New Brunswick; NL= Newfoundland and Labrador; NS=Nova Scotia; ON=Ontario; PE=Prince Edward Island; QC=Quebec; SK=Saskatchewan

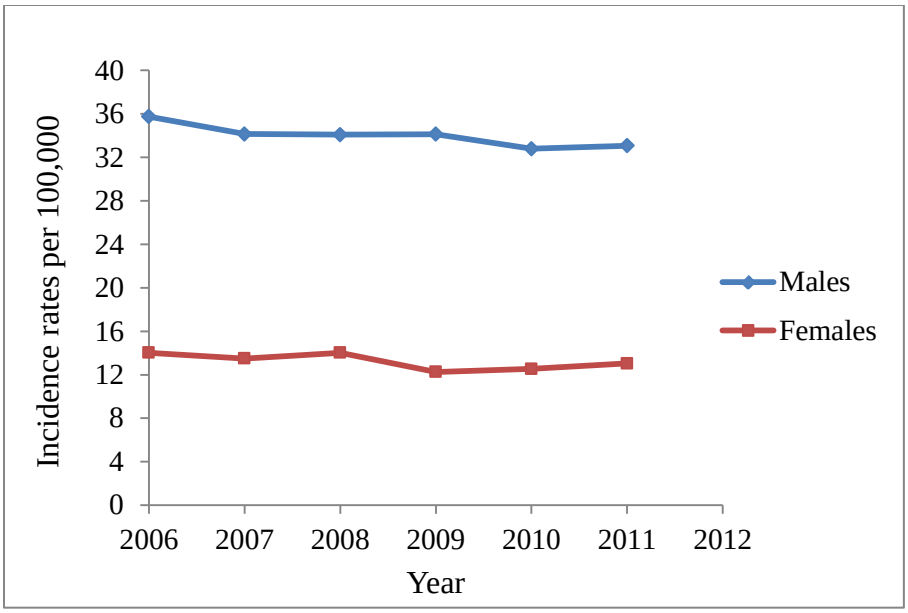

Figure 2.2. Age-adjusted LLA incidence rates in Canada by sex, per 100,000 individuals. Age-standardized final post-censual Canadian population in 2011, direct method.

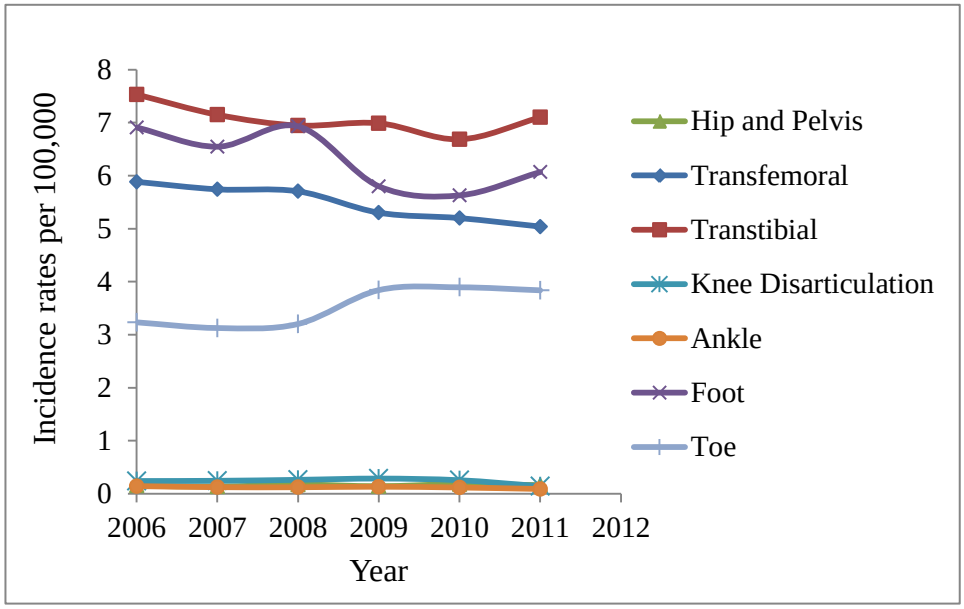

Figure 2.3. Age-adjusted LLA incidence rates in Canada by level of LLA, per 100,000 individuals. Age-standardized to final post-censual Canadian population in 2011, direct method.

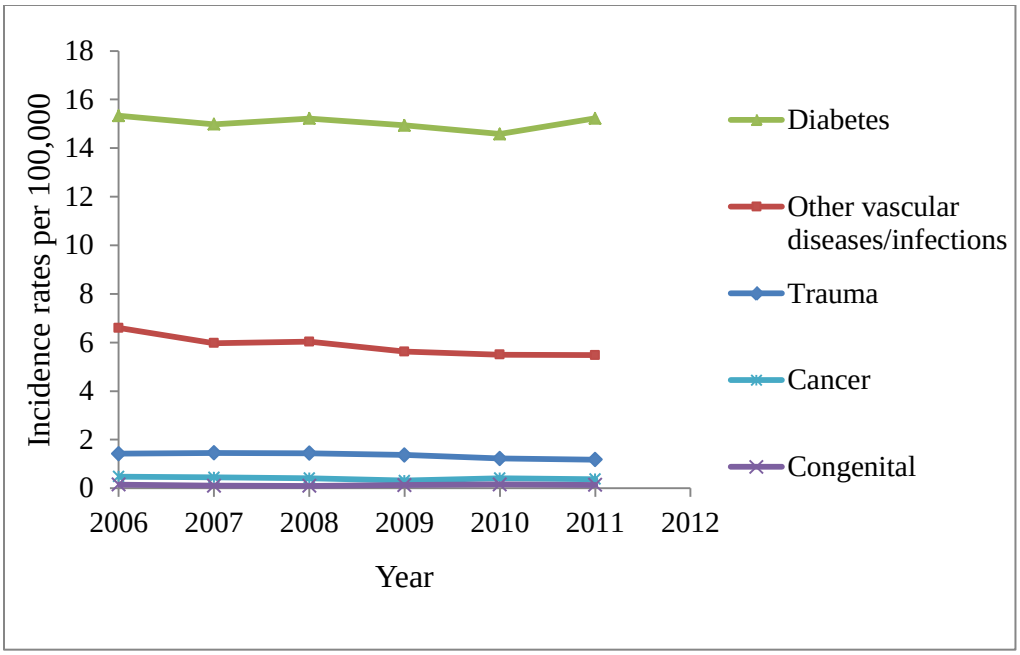

Figure 2.4. Age-adjusted LLA incidence rates in Canada by cause of LLA, per 100,000 individuals. Age-standardized to final post-censual Canadian population in 2011, direct method.

2.4 Discussion

This is the first study that reported on age-adjusted incidence rates of LLA in Canada and the ten provinces by sex, level, and cause of amputation. The results showed a decline in the age-adjusted incidence rates over the six-year period studied. Similarly, in all provinces, except for Alberta and British Columbia, the LLA age-adjusted incidence rates showed a decline. On average, the overall age-adjusted incidence rate was 2.6 times greater in males than in females. The age-adjusted transtibial to transfemoral incidence ratio showed an increase from 1.28 in 2006 to 1.41 in 2011. The main cause of LLA was diabetes (65% of LLAs). The

relative risk of LLA was 28.9 times greater in people with diabetes than in people without diabetes.

Because different statistical methods have been employed across studies for reporting incidence rates, it was difficult to compare the rates across different countries. The overall age-adjusted rate in our study (22.9 per 100,000) was larger (8.8 per 100,000) than that of some Western countries such as the Netherlands (Fortington et al., 2013) and smaller (92.5 per 100,000) than that of others such as Ireland (Buckley et al., 2012). The observed downturn in the age-adjusted LLA incidence rates is consistent with the recent literature (Belatti & Phistikul, 2013; Dawes, Iqbal, Steinmetz, & Mayo, 2010; Varma, Stineman, & Dillingham, 2014). In the US, the rates were reported to have declined from 2000 to 2010 (Belatti & Phistikul, 2013). It is interesting that although the age-adjusted LLA incidence rates have declined, the total number of LLAs increased in our data. A closer look at our data showed that because the Canadian population has grown from 2006 to 2011, the size of the denominator used in calculating the incidence rates has increased as well. As a result, because the size of the population has grown faster than the number of LLAs, the rates have declined despite the increase in the total number of LLAs. Other studies have reported similar trends. In a study that investigated the vascular-related LLA incidence rates in older adults in the US from 1956 to 1995, the authors reported a decline in the LLA incidence rates but an increase in the total number of LLAs (Fletcher et al., 2002). Likewise, Dawes, Iqbal, Steinmetz, & Mayo (2010) reported similar findings for the LLA incidence rates in Quebec.

Consistent with previous reports, the calculated incidence rate of LLA was greater in males than in females (Carmona et al., 2005; Dawes, Iqbal, Steinmetz, & Mayo, 2010; Fosse, 2009). This finding was not surprising because males tend to participate in high-risk activities (e.g. motor vehicle racing) more, which can significantly increase the chance of injury and traumatic LLAs. Furthermore, the rates of diabetes and vascular diseases are generally greater in males (Statistics Canada, 2013).

Diabetes accounted for more than 65% of the LLAs in our study. Despite the fact that diabetes related LLA incidence rates remained relatively stable in our study, the number of LLAs due to diabetes increased by 13% from 2006 to 2011 in our study. Similar trends were reported for the United Kingdom (UK) in years between 2004 and 2008 (Vamos et al., 2010). It is well known that individuals with diabetes have an inherent risk factor for foot disease (Lusardi & Nielsen, 2007). The nerve damage caused by diabetes can cause numbness and prevent the individual from feeling an injury. Furthermore, the lack of blood flow associated with diabetes-related peripheral vascular disease impedes the healing of ulcers and foot infections, which can lead to LLA. Proper foot screening and aggressive treatment of infections help prevent the occurrence of LLAs in this population (Canadian Diabetes Association Clinical Practice Guidelines Expert Committee, 2008). In 2007, 51% of individuals in Canada met the clinical guidelines for physicians' foot examinations, and this number continues to grow (Canadian Institute for Health Information, 2009; Sanmartin & Gilmore, 2008). Though this is encouraging, more prevention efforts need to be done to halt the increase in diabetes-related LLAs in Canada.

In terms of rates by Canadian provinces, our results showed that although the age-adjusted incidence rates continued to decrease for all provinces except for Alberta and British Columbia, the province of Newfoundland and Labrador showed the highest LLA rates compared to other provinces. This could be because the age-adjusted diabetes rate and diabetes risk factors such as obesity are reported to be the highest in this province (diabetes rate=8.3%; obesity and overweight rate=74.6%) compared to other provinces in Canada (Canadian Community Health Survey, 2009). British Columbia and Quebec had the lowest LLA rates, which may be due to their lower diabetes and obesity rates (Canadian Community Health Survey, 2009; Statistics Canada, 2013). However, despite the fact that British Columbia had one of the lowest aged-adjusted rates, it showed a 16% increase in the absolute number of new cases of LLA from 2006 to 2011. Likewise, in Alberta, there was a 23.1% increase in the number of new cases of LLA from 2006 to 2011. Statistics Canada shows that despite the historical lower rate of diabetes in these two provinces, the incidence of diabetes is increasing in British Columbia and Alberta perhaps due to having a higher concertation of certain ethnicities such as South Asians and Chinese that generally have higher risk factors for developing diabetes. This increase in the incidence of diabetes may explain the observed growth in the number and incidence of LLA in these two provinces.

Recent reports also showed a greater decline in proximal LLAs (e.g. transfemoral) compared to distal (e.g. transtibial) LLAs (Belatti & Phistikul, 2013). This is consistent with our study results; the ratio of transtibial to transfemoral amputations increased in this study. Distal LLAs and preservation of the knee joint are advantageous over proximal LLAs because they are associated with reduced mortality and healing time, decreased costs, shorter rehabilitation

time, and greater possibility of achieving prosthetic walking and independence for the individual. Optimally, the transtibial to transfemoral incidence ratio should be no less than 2.5 (Dormandy, Heeck, & Vig, 1999; Stewart & Condie, 1996). In the current study, this ratio was below the optimal level; however, the transtibial to transfemoral incidence ratio continued to increase over time, which indicates a decrease in the number of transfemoral amputations and perhaps the surgeons' increased efforts for preserving the knee joints. Future studies should investigate if this trend will help reduce mortality and complications and increase prosthetic walking in this population.

2.4.1 Limitations

This study had a number of limitations. First, there were some missing data (~5%). Although missing data can affect the precision of the statistics, the amount of missing data in our study was small and therefore the influence is likely small. Second, it was hard to determine the definitive cause of LLA because the direct cause of amputation was not reported. To address this, we reviewed the patient's comorbidities to derive the most probable cause of amputation. Third, CIHI releases data based on fiscal years, whereas Statistics Canada has the population data based on annual years. Thus, the calculated yearly incidence rates do not entirely reflect the annual rates or the fiscal rates. Fourth, this study did not estimate the prevalence of individuals living with LLA in Canada. While prevalence is usually assessed through surveying the population, a certain degree of bias is always associated with estimating prevalence using this method, as some individuals may choose not to complete the survey and will not be included in the final count. Furthermore, since mortality rates are high for the individuals with LLA, prevalence data may not give a clear picture of the burden of

LLA in Canada. Estimating incidence rates, however, will allow us to determine how patterns of LLA change over time and thereby inform health care planning for this population. Fifth, we have reported data until March 31st 2012 because it was the most recently complete data set that CIHI could release to us.

2.5 Conclusions

This study provided the first Canadian national and provincial age-adjusted incidence rates of LLA and a baseline for monitoring and evaluating moving forward. Understanding the incidence of LLA is essential to managing rehabilitation services for this population. Although the age-adjusted LLA incidence rates have decreased from April 1st 2006 to March 31st 2012, the number of LLAs has increased. The increase in the number of LLAs has important implications for social and healthcare costs. With the growing aging population, and the expected growth in the number of individuals living with LLA, it is imperative that adequate rehabilitation resources are available to this population and are allocated appropriately.

3 Provision of Inpatient Rehabilitation Services to Individuals with Major Lower Limb Amputation in Nine Canadian Provinces

3.1 Introduction

In Chapter 2, we established that there are approximately 7,400 new cases of LLA per year in Canada. More than half of these cases were shown to be major, defined as hip and pelvis, transfemoral, knee disarticulation, transtibial, and ankle amputations (Lusardi & Nielsen, 2007).

Major LLA rehabilitation is a multi-step process that starts with preoperative client education and assessment of needs, expectations, and goals followed by acute post-operative emotional support, stump and skin care training, early ambulation training, fabrication and fitting of a prosthesis, prosthetic training, and eventually vocational training and community integration (Esquenazi & DiGiacomo, 2001). In Canada, the models of major LLA rehabilitation vary. Some provinces/centres provide hospital stays and highly structured, resource-intense prosthetic rehabilitation by a multidisciplinary team of healthcare professionals, whereas others provide service on an ad hoc basis by teams of clinicians with limited exposure/knowledge (Deathe, Miller, & Speechley, 2002). Although no formal data exist, typical major LLA rehabilitation in Canada is postulated to involve up to six weeks of inpatient rehabilitation followed by outpatient follow-ups in some provinces and/or early supportive rehabilitation programs within the client's home (Deathe, Miller, & Speechley, 2002).

Esquenazi (2004) reported that a period of inpatient rehabilitation is critical for clients with major LLA for restoring function, shaping of the residual limb, fitting of the initial prosthesis, improving range of motion and muscle strength in preparation for prosthetic use, and early gait and prosthetic use training. An observational study that followed and compared the outcomes within the first postoperative year between individuals with major LLA that received and those that did not receive inpatient rehabilitation showed that those that received inpatient rehabilitation had a greater likelihood of one-year survival, and home discharge from the hospital (Stineman et al., 2008). This was attributed to improvements in mobility and general function through inpatient rehabilitation (Stineman et al., 2008). In another study, longer periods of inpatient rehabilitation were shown to be associated with improved physical function in individuals with trauma-related amputations (Pezzin, Dillingham, & Mackenzie, 2000).

Despite its noted health and functional benefits (Pezzin, Dillingham, & Mackenzie, 2000; Stineman et al., 2008), inpatient rehabilitation is associated with considerable costs resulting in burden on the healthcare system and the pressure to discharge clients early. As a consequence, some clients with major LLA do not receive any inpatient rehabilitation or are discharged prior to reaching sufficient levels of independence for performing daily activities (Meier & Heckman, 2014). The shortened period or lack of inpatient rehabilitation is reported to impose an important challenge for this population and may result in reduced mobility, poorer health, and increased mortality (Stineman et al., 2008).

No published data exist regarding the provision of inpatient rehabilitation services for clients with major LLA in Canada. It is unclear how many clients receive inpatient rehabilitation, how long the inpatient rehabilitation is for those that receive it, and what the clients' functional independence level is at the time of discharge from inpatient rehabilitation. In addition, we do not have empirical data about whether the provision or the length of inpatient rehabilitation is reducing in Canada. Gaining an understanding about the provision of inpatient rehabilitation services across Canada is imperative to supporting research initiatives, public policy decision making, and managing intervention and rehabilitation services provided to individuals with major LLAs (Dillingham, Pezzin, & Mackenzie, 2003). Such information would be helpful in planning and developing augmentative or alternative rehabilitation services based on the needs.

The primary objective of this study was to learn about the provision of inpatient rehabilitation services in Canada. To that end, we calculated the proportion of individuals with major LLA that receive inpatient rehabilitation in the nine provinces of Canada. For those that receive inpatient rehabilitation, we examined the length of their rehabilitation and their functional independence level for performing activities of daily living at the time of discharge from inpatient rehabilitation. To find out whether there have been any temporal and regional variations, we compared the most recent six years of data as well as provincial data. The secondary objective was to determine if there were differences in functional independence at the time of discharge for those that have had longer inpatient rehabilitation, controlling for important covariates. The goal of the secondary objective was to corroborate earlier findings that longer rehabilitation is associated with better functional outcomes in

individuals with major LLA (Pezzin, Dillingham, & Mackenzie, 2000; Stineman et al., 2008).

3.2 Methods

3.2.1 Design and population

To address the objectives, we conducted a secondary analysis of administrative data. The LLA records extracted from CIHI's Discharge Abstract Database (DAD) from April 1st 2006 to March 31st 2012 (see Chapter 2 for details) were linked with the data from the National Rehabilitation Reporting System (NRS) to gather information related to inpatient rehabilitation (Quebec inpatient rehabilitation data were not available). Although no formal definition of inpatient rehabilitation was provided by the NRS, our understanding is that inpatient rehabilitation is defined as an overnight stay in a rehabilitation hospital. The NRS collects inpatient rehabilitation data from specialized facilities as well as hospital rehabilitation units, programs and designated rehabilitation beds (National Rehabilitation Reporting System Metadata, Canadian Institute of Health Information). The LLA records contained unique meaningless identification codes that allowed us to count the number of individuals with major LLA. In addition to the individual's identification code, each LLA record had the following variables: age, sex, province, year of LLA, acute days of hospital stay post-LLA (i.e. days elapsed between hospital admission and discharge dates), level of LLA, and a list of up to twenty five co-morbidities. For each LLA record extracted from the DAD, the NRS database was searched to determine if the individual was admitted to inpatient rehabilitation post-LLA.

3.2.2 Outcome measurements

For individuals with any record of inpatient rehabilitation, the following variables were extracted from NRS and linked to the individual's DAD record: every active inpatient rehabilitation length of stay (i.e. actual days of inpatient rehabilitation, excluding days spent away from rehabilitation due to a service interruption and/or days spent waiting to be discharged), and total Functional Independence Measure (FIM) scores at the time of admission and discharge from inpatient rehabilitation facility. The FIM scores were used to determine the status of the individual's functional independence and the amount of assistance required by the individual to perform activities of daily living (Guide for the Uniform Data Set for Medical Rehabilitation, 1996). The FIM instrument contains eighteen items (thirteen motor tasks and five cognitive tasks) rated on a seven-point scale ranging from total assistance to complete independence in activities of daily living. The motor tasks include eating, grooming, bathing, upper body dressing, lower body dressing, toileting, bladder management, bowel management, bed to chair transfer, toilet transfer, shower transfer, locomotion, and stairs. The cognitive tasks include comprehension, expression, social interaction, problem solving, and memory. Total scores range from 18 to 126, with higher scores indicating higher level of function (Guide for the Uniform Data Set for Medical Rehabilitation, 1996). Panesar, Morrison, & Hunter (2001) have reported on the validity and sensitivity to change of the FIM scores in individuals with vascular-related LLA who are aged 44 to 85 years old. Evidence for validity has been shown by statistically significant correlations ($p<0.001$) with the Amputee Activity Score, which is an amputee specific measure to evaluate function in lower limb prosthetic users, as well as the Office of Population Censuses and Surveys Disability Scale, a measure of level of disability. Evidence

for sensitivity to change has been presented by statistically significant change (change score=11, $p<0.00001$) in the scores between admission and discharge from rehabilitation (Panesar, Morrison, & Hunter, 2001). Although not directly tested in the amputee population, evidence for test-retest (ICC=0.98) and inter-rater reliability (ICC=0.80-0.99) has been shown for the FIM in older adults (Glenny & Stolee, 2009; Hobart et al., 2001). We used the FIM because it was the sole instrument used by CIHI/NRS to collect information on functional independence.

3.2.3 Data analysis

Demographics and descriptive data: mean (SD) and frequency (%) were used to describe the study population (e.g. age, sex, days of acute hospital stay, and number of individuals with major LLA by province per fiscal year).

In order to address the primary objective: we calculated the frequency (%) of individuals that received inpatient rehabilitation in Canada and in each of the nine provinces separately by dividing the total number of individuals that received inpatient rehabilitation over the total number of individuals with major LLA. Mean (SD) days of inpatient rehabilitation was calculated to determine the average length of inpatient rehabilitation. Mean (SD) FIM scores at admission and discharge were calculated to determine the individuals' functional independence level at the time of admission and discharge from inpatient rehabilitation. The variations in provision of inpatient rehabilitation (%), the mean (SD) length of inpatient rehabilitation in days, and mean (SD) FIM scores at admission and discharge were presented for each fiscal year (2006 to 2011) as well as by the nine provinces.

In order to address the secondary objective: multiple linear regression analyses were used to determine the effect of the length of inpatient rehabilitation (independent variable) on FIM change scores from baseline to discharge (dependent variable). To provide the adjusted estimate of the effect of length of inpatient rehabilitation on FIM change scores by controlling for important covariates, we used the Kleinbaum's three-stage modeling strategy (Kleinbaum, Kupper, Nizam, & Muller, 2008; Kleinbaum & Klein, 2010): stage 1 (variable specification); stage 2 (interaction Assessment); and stage 3 (confounding Assessment).

Variable selection: the main independent variable was the length of inpatient rehabilitation, whereas the dependent variable was the FIM change scores. The potential covariates considered were: age, sex, level of LLA, and baseline FIM scores. These variables were considered to be potential covariates because we hypothesized that they may influence discharge FIM scores in individuals with major LLA. The covariates that showed a correlation of at least 0.20 with the dependent variable or a statistically significant ($p<0.05$) difference in the dependent variable using t-test or one-way ANOVA were kept in the model for further investigation (Kleinbaum, Kupper, Nizam, & Muller, 2008). Dummy variables were created for the categorical covariates sex and level of LLA.

Interaction assessment: two interaction terms were evaluated. An age x length of inpatient rehabilitation interaction term was examined because older individuals typically receive longer rehabilitation and therefore the association between the FIM change scores and length of inpatient rehabilitation may vary by age (Lusardi & Nielsen, 2007). The second interaction

term was between the level of LLA and the length of inpatient rehabilitation because higher levels of LLA are usually associated with longer rehabilitation, and therefore the relationship between the length of inpatient rehabilitation and the FIM may differ by level of LLA (Lusardi & Nielsen, 2007). Statistically significant interaction term(s) were kept in the final model ($p<0.05$).

Confounding assessment: we examined the effect of potential confounders to determine whether the association between the length of inpatient rehabilitation and FIM change scores remained statistically significant ($p<0.05$) in the presence of those confounders. The covariates that changed the magnitude of the unstandardized beta coefficient of the main independent variable by more than 10% were included as confounders in the final model (Kleinbaum, Kupper, Nizam, & Muller, 2008).

All regression assumptions were tested for the final model (Kleinbaum, Kupper, Nizam, & Muller, 2008). The residual plots were evaluated to assess outliers, normality, and homoscedasticity. Collinearity was detected if there was a correlation of 0.70 and higher between the independent variables or a variation inflation factor of greater than 10 (Kleinbaum, Kupper, Nizam, & Muller, 2008). When collinearity was observed, the variable with the higher correlation with the dependent variable was selected.

Unstandardized coefficients (b) and 95% confidence intervals (CI), standardized coefficients (β), standard error (SE), and percentage of variance explained (R^2) were calculated for the final regression model.

3.3 Results

Demographics and descriptive data: from April 1st 2006 to March 31st 2012, there were 16,114 new individuals with major LLAs in the nine provinces of Canada. Mean (SD) age at amputation was 65.5 (16.6) years old and 10,775 (66.9%) were males. Mean (SD) acute stay post-amputation was 28.8 (45.6) days. Ontario had the highest number of individuals with major LLA (n=7,604, 47.2%), whereas Prince Edward Island had the lowest (n=99, 0.6%) (Table 3.1).

Table 3.1. Demographics and descriptive data for individuals with major LLA in the nine Canadian provinces from fiscal year 2006 to 2011

	2006	**2007**	**2008**	**2009**	**2010**	**2011**	**Total**
n (%) of individuals	2,906 (18.0)	2,693 (16.7)	2,678 (16.6)	2,675 (16.6)	2,613 (16.2)	2,549 (15.8)	16,114
Mean (SD) age in years	65.1 (16.8)	65.6 (16.2)	65.4 (16.9)	65.2 (16.8)	66.02 (16.8)	65.5 (16.2)	65.5 (16.6)
n (%) males	1,924 (66.2)	1,787 (66.4)	1,754 (65.5)	1,825 (68.2)	1,768 (67.7)	1,717 (67.4)	10,775 (66.9)
Mean (SD) days of acute stay	28.3 (43.7)	29.8 (43.6)	27.8 (51.4)	29.6 (48.0)	28.9 (44.2)	28.5 (42.5)	28.8 (45.6)
n (%) of individuals in Alberta	357 (12.3)	322 (12.0)	354 (13.2)	369 (13.8)	328 (12.6)	374 (14.7)	2,104 (13.1)
n (%) of individuals in British Columbia	417 (14.3)	420 (15.6)	398 (14.9)	382 (14.3)	428 (16.4)	395 (15.5)	2,440 (15.1)
n (%) of individuals in Manitoba	203 (7.0)	182 (6.8)	180 (6.7)	189 (7.1)	188 (7.2)	183 (7.2)	1,125 (7.0)
n (%) of individuals in New Brunswick	105 (3.6)	91 (3.4)	105 (3.9)	109 (4.1)	76 (2.9)	71 (2.8)	557 (3.5)

	2006	2007	2008	2009	2010	2011	Total
n (%) of individuals in Newfoundland and Labrador	102 (3.5)	93 (3.5)	88 (3.3)	88 (3.3)	84 (3.2)	70 (2.7)	525 (3.3)
n (%) of individuals in Nova Scotia	153 (5.3)	132 (4.9)	159 (5.9)	121 (4.5)	124 (4.7)	134 (5.3)	823 (5.1)
n (%) of individuals in Ontario	1,373 (47.2)	1,291 (47.9)	1,247 (46.6)	1,252 (46.8)	1,249 (47.8)	1,192 (46.8)	7,604 (47.2)
n (%) of individuals in Prince Edward Island	28 (1)	22 (0.8)	11 (0.4)	16 (0.6)	9 (0.3)	13 (0.5)	99 (0.6)
n (%) of individuals in Saskatchewan	162 (5.6)	135 (5.0)	128 (4.8)	142 (5.3)	125 (4.8)	116 (4.6)	808 (5.0)

Primary objective: in total, 18.0% (n=2,902) of the individuals with major LLAs received inpatient rehabilitation in the nine provinces of Canada from April 1st 2006 to March 31st 2012. Years 2007 and 2008 had the lowest provision of inpatient rehabilitation (n=246, 9.1%; n=237, 8.8%, respectively). For individuals that received inpatient rehabilitation, the mean (SD) number of acute hospital stay was 27.9 (30.1) days, whereas the mean (SD) length of inpatient rehabilitation was 37.3 (25.2) days. The mean (SD) FIM score at admission to inpatient rehabilitation was 92.0 (17.2) and at discharge from inpatient rehabilitation was 106.8 (14.5) / 126. The mean (SD) FIM change score was 14.1 (11.5) (Table 3.2).

Table 3.2. Data for individuals with major LLA that received inpatient rehabilitation in the nine Canadian provinces from fiscal year 2006 to 2011

	2006	2007	2008	2009	2010	2011	Total
n (%) received inpatient rehabilitation	629 (21.6)	246 (9.1)	237 (8.8)	614 (23.0)	619 (23.7)	557 (21.9)	2,902 (18.0)
Mean (SD) age	65.0 (13.2)	62.2 (14.5)	64.0 (14.3)	63.5 (14.6)	65.4 (14.0)	64.3 (13.4)	64.3 (14.0)
n (%) males	435 (69.2)	169 (68.7)	166 (70)	444 (71.7)	444 (71.7)	405 (72.7)	2,063 (71.1)
Mean (SD) days of acute stay	26.1 (26.0)	33.9 (32.4)	29.5 (36.3)	27.0 (27.5)	27.8 (31.4)	27.8 (31.5)	27.9 (30.1)
Mean (SD) days of inpatient rehabilitation	37.4 (27.4)	42.5 (30.5)	43.3 (30.4)	37.1 (25.6)	35.6 (21.0)	35.8 (24.0)	37.3 (25.2)
Mean (SD) FIM at admission to rehabilitation	92.3 (17.5)	94.7 (17.3)	93.5 (16.8)	91.9 (17.0)	91.0 (17.0)	91.6 (17.4)	92.0 (17.2)
Mean (SD) FIM at discharge from rehabilitation	107.3 (14.4)	107.9 (14.3)	108.2 (13.8)	106.6 (14.5)	106.6 (14.2)	106.1 (15.2)	106.8 (14.5)

New Brunswick and British Columbia had the lowest provision of inpatient rehabilitation (n=8, 1.4% and n=118, 4.8%, respectively), whereas Nova Scotia and Ontario had the highest (n=235, 28.6% and n=1,779, 23.4%, respectively).

Newfoundland and Labrador had the longest mean (SD) days of inpatient rehabilitation stay (mean=62.6, SD=36.6 days), while Prince Edward Island had the shortest (mean=26.5, SD=9.2 days).

The mean (SD) FIM scores at admission to inpatient rehabilitation ranged from 73.5 (23.9) (New Brunswick) to 105.3 (12.8) (Prince Edward Island). The mean (SD) FIM scores at the

time of discharge from inpatient rehabilitation ranged from 90.9 (29.9) (New Brunswick) to 111.3 (12.9) (Prince Edward Island) /116 (Table 3.3).

Table 3.3. Canadian provincial data for individuals with major LLA that received inpatient rehabilitation from fiscal year 2006 to 2011 (excluding Quebec)

	AB	**BC**	**MB**	**NB**	**NL**	**NS**	**ON**	**PE**	**SK**
n (%) received inpatient rehabilitation	402 (19.1)	118 (4.8)	165 (14.7)	8 (1.4)	90 (17.1)	235 (28.6)	1779 (23.4)	15 (15.1)	89 (11.0)
Mean (SD) age	60.9 (15.5)	63.8 (15.1)	64.6 (14.4)	59.9 (7.2)	64.9 (12.5)	66.7 (12.4)	64.7 (13.6)	65.3 (16.4)	65.0 (14.5)
n (%) males	299 (74.4)	85 (72.0)	110 (66.7)	6 (75.0)	58 (64.4)	154 (65.5)	1278 (71.8)	11 (73.3)	61 (68.5)
Mean (SD) acute stay	35.4 (41.5)	38.7 (38.0)	31.9 (35.4)	28.8 (19.5)	44.1 (32.9)	29.7 (28.2)	24.3 (25.2)	23.8 (20.3)	24.4 (25.7)
Mean (SD) days of inpatient rehabilitation	41.8 (31.3)	32.8 (22.7)	48.0 (28.5)	43.8 (51.5)	62.6 (36.6)	40.9 (24.0)	34.9 (23.3)	26.5 (9.2)	32.8 (20.6)
Mean (SD) FIM at admission to rehabilitation	97.2 (14.4)	96.2 (15.7)	91.8 (17.8)	73.5 (23.9)	96.6 (17.1)	96.5 (17.8)	90.1 (17.2)	105.3 (12.8)	89.7 (18.4)
Mean (SD) FIM at discharge from rehabilitation	109.3 (14.2)	109.7 (13.4)	103.7 (15.5)	90.9 (29.9)	110.4 (13.7)	109.8 (14.8)	106.2 (14.2)	111.3 (12.9)	102.2 (17.3)

Secondary objective: neither of the specified interaction terms was found to be statistically significant and therefore not included in the final model. Moreover, none of the potential confounders, except for baseline FIM scores, changed the coefficient of the main independent variable by more than 10%. As a result, the final model included the effect of the length of inpatient rehabilitation (main independent variable) on FIM change scores

(dependent variable), adjusting for baseline FIM scores. The final model had an unstandardized coefficient of 0.1 (95% CI: 0.08, 0.1) and a standardized coefficient of 0.2 (p-value <0.00001). The standard error was 0.006. Adjusted R^2 was 0.31, indicating that 31% of the variations in the FIM change scores are explained by this model.

3.4 Discussion

This was the first study that investigated the provision of inpatient rehabilitation services for individuals with major LLA in nine Canadian provinces. Our findings showed that the provision of inpatient rehabilitation services remained relatively low during the study years with an average of 18%. Similar findings were reported for the United States (Dillingham, Pezzin, & Mackenzie, 2003; Dillingham & Pezzin, 2005). In 1997, 16% of the individuals with vascular amputations at Massachusetts hospital were admitted to inpatient rehabilitation (Dillingham & Pezzin, 2005). In another report, an even smaller proportion of vascular amputees (9.6%) received inpatient rehabilitation from 1986 to 1997 in Maryland statewide hospital (Dillingham, Pezzin, & Mackenzie, 2003). The reduced period of inpatient LLA rehabilitation has imposed a challenge for rehabilitation teams to decide how to provide enough therapy within such limited period of rehabilitation in order to achieve optimal functional outcomes (Meier & Heckman, 2014). Given the limited provision of inpatient rehabilitation services for individuals with major LLA and the continued effort to reduce healthcare costs, cost-effective and accessible augmentative models of care are required for this population.

The provision of inpatient rehabilitation services remained relatively stable over the six-year study period, except for the years 2007 and 2008, when there was a substantial decline (~9.0%). It went back up again in 2009 (~24.0%) and remained relatively stable for the subsequent years. It is not clear why this happened. Interestingly, the mean length of inpatient rehabilitation stay was the highest for the years 2007 and 2008 (42.5 and 43.3 days, respectively). This suggests that the provision of inpatient rehabilitation for these two years might have been low because the clients that were admitted stayed longer and as a consequence, decreased the availability of beds for new clients.

Although a low percentage of the individuals with major LLA received inpatient rehabilitation, our results showed that for those that received it, the mean length of inpatient rehabilitation stay (37.3 days) and the FIM scores at discharge (106.8 /126) seemed high. Previous studies in other countries have reported relatively similar findings. In Australia, the median length of inpatient rehabilitation in individuals with LLA from 1996 to 2010 has been reported to be 39 days (Hordacre et al., 2013), whereas in Singapore, from 1996 to 2005, it has been 45 days (Chen et al., 2013). It appears that although admission to inpatient rehabilitation is limited in Canada, and that, perhaps, individuals are selected based on a multitude of factors (e.g. age, amputation level, number of co-morbidities, etc.), the inpatient rehabilitation stay is relatively long and individuals are discharged with high FIM scores. However, a closer look at the data showed that these individuals were admitted with high FIM scores to inpatient rehabilitation (mean=92.0/126). At the time of discharge from inpatient rehabilitation, the FIM scores of these individuals increased by an average of 14.5 points, which is below the reported minimal clinically important difference of 22 (Beninato

et al., 2006). One possible explanation for the high admission FIM scores is that clients that are selected for inpatient rehabilitation are 'cherry picked' to succeed. Selecting clients for rehabilitation and allocating resources appropriately is a challenging task. It requires predicting who are most likely to succeed and benefit from the therapy while excluding those who are expected to fail (Wade, 2003). The current models that exist for client selection for rehabilitation are reported to be subjective and biased towards denying therapy from many clients who may benefit from it (Zucker et al., 2013). This may suggest that some frailer clients who have lower functional abilities and are predicted to 'not succeed' are not admitted to inpatient rehabilitation, thereby contributing to the high admission FIM scores.

Another explanation for the high FIM scores is perhaps the ceiling effects associated with the FIM. At discharge our data were highly skewed with more than 72% of the FIM data being larger than 100/126. As a result, it is plausible to argue that the FIM may not be an adequate instrument to measure client's functional independence and to make informed decisions about their admission/discharge to inpatient rehabilitation. Previous studies have reported on the FIM's ceiling effects and the admission scores' poor ability in predicting successful prosthetic rehabilitation and important outcomes specific to individuals with LLA (Leung, Rush, & Devlin, 1996). Furthermore, the other limitation of the FIM is that it does not include items on important elements of activities and participation, such as recreational and social activities (Nichol, Higgins, Gabbe, Murray, Cooper, & Cameron, 2011). Despite the limitations associated with the FIM, all Canadian inpatient rehabilitation centres that report to the CIHI/NRS are only required to collect FIM data. Deathe et al. (2002) that surveyed amputee rehabilitation centres in Canada reported that the most commonly used

standardized outcome measure is the FIM. They also found out that 31% of the centres do not use any formal outcome measures for client outcome evaluation (Deathe, Miller, & Speechley, 2002). Recently, in response to this issue, the Canadian Association of Physical Medicine & Rehabilitation Amputee Special Interest Group has reached a consensus on a minimum of eight outcome measures (e.g. Two Minute Walk Test) that should be completed for individuals with major LLA that participate in rehabilitation programs (Dudek, Deathe, Devlin, Hebert, & Payne, 2010). The implementation of this toolkit of outcome measures may help to better plan and guide clients' rehabilitation needs.

There were considerable variabilities in provincial provision of inpatient rehabilitation, suggesting differences in healthcare service delivery across Canada. It is not clear why the provision of inpatient rehabilitation services was very low for British Columbia (4.8%) and New Brunswick (1.4%). It may be plausible that LLA rehabilitation is mostly done at an outpatient or home-based setting at the centres in these provinces. The provincial variabilities could also be due to missing data. Submitting data to the NRS is voluntary for all provinces except for Ontario and Prince Edward Island. As a result, not all Canadian rehabilitation facilities report to the NRS. It is estimated that approximately 80% of the inpatient rehabilitation facilities in Canada (excluding Quebec) send data to the NRS. In British Columbia, a total of six inpatient rehabilitation facilities participate at the NRS data collection. Although the exact number of all Canadian facilities that provide inpatient amputee rehabilitation is unknown, our review of the 2011 version of the compendium of Canadian Healthcare Facilities that lists all healthcare facilities in Canada (Guide to Canadian Healthcare Facilities, 2011) revealed that there are at least eight inpatient amputee

rehabilitation facilities in British Columbia. As a result, the provincial variations observed in this study might have been due to the difference in the amount of missing data. Additionally, missing data may have resulted in underestimating the provision of inpatient rehabilitation in Canada. Having said that, even for Ontario and Prince Edward Island that have 100% data submission rates to the NRS, the provision of inpatient rehabilitation remains low (~23% and 15%, respectively). Future studies should investigate the reasons for low provision of inpatient rehabilitation among individuals with major LLA in Canada and its long-term impact on outcomes specific to this population.

The results for the secondary objective showed a fair association between the length of rehabilitation and FIM change scores. Individuals that had received a longer inpatient rehabilitation had a statistically significant higher FIM change scores from baseline to discharge with a standardized beta coefficient of 0.2 (p-value<0.00001) which indicates improvement in functional independence associated with longer inpatient rehabilitation. This is not surprising as evidence shows that longer rehabilitation is associated with better functional outcomes across a wide range of diagnoses (Ng et al., 2007). Nonetheless, our finding should be interpreted with caution because when sample size is large the chance of finding significance and type II error increases substantially. Furthermore, the improvement in FIM scores may not be clinically important because of the small magnitude of the beta coefficient (Keefe et al., 2013; Portney & Watkins, 2009). As noted earlier, the small gain in the FIM scores can be attributed to the ceiling effect of the FIM and the resultant small change in the scores from admission to discharge, particularly because our clients already had high FIM scores at admission.

3.4.1 Limitations

This study had a number of limitations. First, inpatient rehabilitation data for Quebec were not available. Additionally, because of the voluntary nature of data submission to the NRS in all provinces except for Ontario and Prince Edward Island, not all inpatient rehabilitation facilities report to the NRS. As a result, the data presented in this chapter do not uniformly reflect the full picture of inpatient rehabilitation in Canada. However, we used population data to report on the remaining nine provinces in Canada and provided valuable baseline knowledge about inpatient rehabilitation services across these provinces. It is estimated that approximately 80% of the inpatient rehabilitation facilities in Canada participate in NRS data collection. It is also known that all inpatient rehabilitation facilities in Ontario and Prince Edward Island submit data to the NRS. Second, because of the longitudinal nature of the data we might have had some individuals who had multiple amputations represented in the data more than once. We endeavored to minimize this limitation by tracking the individual's unique identifier code and deleting records that were represented more than once. Third, the only measure used by the NRS to measure function was the FIM. Given the reported limitations with the FIM (Leung, Rush, & Devlin, 1996), it may not have been the best measure of functional independence for this population. Furthermore, the lack of data on other amputee specific outcomes limited our ability to comment on other important health related outcomes (e.g. mobility, health-related quality of life) at the time of admission and discharge from rehabilitation. Fourth, prosthetic rehabilitation data were not available and limited our ability to understand the extent to which prosthetic rehabilitation was provided during inpatient rehabilitation. Nonetheless, this study was the first to investigate the

provision of inpatient amputee rehabilitation services in Canada. The national longitudinal data allowed us to broadly understand the utilization of inpatient rehabilitation services in the nine provinces of Canada which could be used to assist with management of rehabilitation services and policy decision makings. Future studies should investigate the provision of prosthetic rehabilitation in Canada using national surveys. Better understanding of national prosthetic rehabilitation services helps provide foundational data for policy makers and managers of rehabilitation services to promote best practices.

3.5 Conclusions

In conclusion, only a small proportion of individuals with major LLA received inpatient rehabilitation in nine Canadian provinces from April 1st 2006 to March 31st 2012. Given the low provision of inpatient rehabilitation shown in this chapter and the evidence that longer rehabilitation is associated with better functional outcomes, development of accessible and cost-effective augmentative or alternative rehabilitation approaches might be useful.

4 Canadian Survey About Lower Limb Prosthetic Rehabilitation

4.1 Introduction

The literature in health services regarding lower limb amputation (LLA) rehabilitation is somewhat lacking with detail around current practices and provision of care. We know from the existing literature that there is a trend from less inpatient to more outpatient and/or home-based rehabilitation in an effort to reduce healthcare costs (Lusardi & Nielsen, 2007; Meier & Heckman, 2014). However, we still speculate that there is considerable variability in Canada, where despite the universal healthcare system we have tremendous amount of individuality between provinces in healthcare delivery. The reason we need a better understanding of current LLA prosthetic rehabilitation practices is that it provides data to help policy makers and managers of rehabilitation services to ensure that they are promoting best practices.

Prosthetic rehabilitation, defined as fitting of a prosthesis and training to use and walk with the prosthesis, is critical for helping individuals with LLA reach functional independence (Gauthier-Gagnon & Grise, 2006; Webster et al., 2014). In Chapter 3, we showed that 18% of individuals with LLA receive inpatient rehabilitation services in Canada. Although this finding was useful, the LLA records extracted from the Canadian Institute of Health Information's (CIHI) discharge abstract database (DAD) did not provide data that allowed us to comment on *prosthetic* rehabilitation more specifically (i.e. the therapies clients receive during their rehabilitation). As a result, it was not possible to determine if prosthetic rehabilitation was provided to the clients during their inpatient stay, and if so, for how long.

In addition, the CIHI data provided no information about outpatient therapies or other approaches used to provide prosthetic rehabilitation.

Therefore, the objective of this chapter was to describe the prosthetic rehabilitation services provided to individuals with LLA across rehabilitation facilities in Canada. To that end, we described approaches used for prosthetic rehabilitation including models of care and types of therapy used. We also looked at the demographics of clients that get prosthetic rehabilitation in Canada.

4.2 Methods

4.2.1 Design and sample

This was a cross-sectional online survey designed to collect information from all ten Canadian provinces on public facilities that provide lower limb prosthetic rehabilitation. The three Canadian territories were not included because they do not have rehabilitation facilities.

The lower limb prosthetic rehabilitation facilities in Canada were identified through the two following sources:

1. The 2011 version of the compendium of Canadian Healthcare Facilities (Guide to Canadian Healthcare Facilities, 2011) was used to identify public facilities that provide rehabilitation. We identified these facilities by searching for the following phrases: ‘acute care hospitals’, ‘long term care facilities’, and ‘outpatient health

services centres' coupled with at least one of the following keywords that suggested rehabilitation centre or service: 'rehab', 'rehab ctr', 'reg rehab ctr', 'rehab serv'

2. The latest list (fiscal year 2013-2014) of all the facilities that had submitted rehabilitation data on LLAs was obtained from the National Rehabilitation Reporting (NRS). The NRS collects rehabilitation data from facilities in all Canadian provinces except for Quebec.

We used both sources to increase the chance of identifying more prosthetic facilities. Due to potential language barriers in identification of Quebec facilities from the compendium of Canadian healthcare facilities, a bilingual researcher who had extensive knowledge about the rehabilitation facilities in Quebec identified the rehabilitation facilities for Quebec.

All facilities identified were contacted to find out if they met the study inclusion criteria. Facilities were included if they: provided lower limb prosthetic rehabilitation; had a minimum of ten rehabilitation beds designated to any diagnosis; and had an annual minimum of five clients with LLA that received prosthetic rehabilitation.

Research assistants telephoned the rehabilitation department of each facility and asked to speak with the clinical practice leaders. The research assistants provided general details about the survey and asked about the eligibility of the facility from the practice leaders (see the eligibility criteria above). If the facility was ineligible, it was removed from the list. If the facility was eligible, the practice leaders were asked if they were willing for their facility to

participate in the survey. If the answer was yes, the email address of one representative from each facility was obtained to complete the survey.

The representatives were contacted by email. The message included an introductory study letter, details about the study, and a link to the survey. Dillman's Tailored Design Method was used to increase the response rate and build trust (Dillman, 2000). If participants opened the survey link, they were directed to the consent form. The consent form had the option of "I agree" to indicate consent. Participants were directed to the survey after providing consent. Reminder emails were sent to all participants at two, four and six weeks after initial email contact (Dillman, 2000), regardless of completion status, because the survey responses were anonymous. The study was approved by the Clinical Research Ethics Board at the University of British Columbia.

4.2.2 Survey development

The survey was developed in English based on the existing literature, our areas of interest, and clinical experience. The survey was refined through five iterations. The first iteration was reviewed by three Canadian clinical researchers: an occupational therapist/epidemiologist, a physiatrist, and a physical therapist. The second iteration was reviewed by ten Canadian researchers with various backgrounds in physical and occupational therapy. The third iteration was piloted with two therapists (a physical and an occupational therapist) who provided LLA prosthetic rehabilitation in Canada. Co-author BI then met with the two therapists with the goal of item refinement using a *think aloud* approach. The *think aloud* approach asks participants to think aloud as they respond to the survey questions,

thereby helping to provide insight as to whether the items are being construed as intended (Fonteyn, Kuipers, & Grobe, 1993). The *think aloud* technique has been shown to be useful in identifying problematic items in health-related survey design and outcome measure development (Bowden, Fox-Rushby, Nyandieka, & Wanjau, 2002; French, Cooke, McLean, Williams, & Sutton, 2007). We refined the survey items and their response categories based on the findings from the *think aloud* process. The fourth iteration of the survey was edited for clarity and grammar by three research assistants. The final iteration was reviewed and approved by the study investigators.

The final English version of the survey, the introductory study letter, and the reminder letters were translated into French by a bilingual research assistant. The French survey was back translated to English by another bilingual translator. The bilingual research assistant and BI reviewed the back translations. Discrepancies were reviewed and corrected.

The final survey consisted of a total of thirty three close-ended questions partitioned into three sections: 1) questions about the facilities' lower limb prosthetic rehabilitation; 2) questions about the use of commercial games in practice from therapists' perspective; and 3) demographics (Appendix A). In this Chapter, we will only present the results for the first section of the survey. The second and third sections will be discussed in Chapter 5.

Section one included fifteen close-ended questions about the details of the facilities' lower limb prosthetic rehabilitation. The questions addressed: the provision of inpatient and/or outpatient prosthetic rehabilitation; if the facility provide a dedicated prosthetic rehabilitation

program (i.e. programs that only enrol amputees) or not; the annual number of enrolled inpatient and/or outpatient clients with LLA; the number of inpatient and/or outpatient clinicians providing LLA prosthetic rehabilitation; the types of prosthetic rehabilitation therapies (e.g. flexibility, balance training, recreational program, return-to-work program, etc.) provided; the length of prosthetic rehabilitation program offered, by level of LLA; the annual number of clients fitted with a prosthetic limb; the age range of clients with LLA; and the type of healthcare providers (e.g. physical therapists, occupational therapists, physiatrists, prosthetists, etc.) that are part of the prosthetic rehabilitation team.

4.2.3 Data management and statistical analyses

The survey was generated and managed using Fluid Survey software (http://www.fluidsurveys.com, Ottawa, ON, Canada) which saves and stores data on a Canadian server. We added a “save and continue later” option to the survey to allow participants to save their responses at any point and complete the survey at a later date. The data were exported from the server into Microsoft Excel 2007 (Microsoft Corporation, USA) for decoding, organizing, and analyzing. We used summary statistics (mean, standard deviation, frequency, and percentage), and graphs (histogram and stacked column) to describe the sample and address the study objectives.

4.3 Results

4.3.1 Demographic and descriptive data

In total, 159 public rehabilitation facilities were identified and contacted for eligibility. Of those, 65 facilities met the eligibility criteria. The survey link was sent to a representative from each of the 65 facilities.

Of the 65 representatives that the survey link was sent to, 59 completed the survey (response rate=90.8%). The majority of the facilities were English speaking (n=46/59, 77.9%). All Canadian provinces were represented in the study (Figure 4.1). Ontario and Quebec had the greatest representation (n=25/59, 42.4%; n=13/59, 22.0%, respectively); Manitoba, Nova Scotia, and Newfoundland and Labrador had the lowest representation (n=1/59, 1.7% for each).

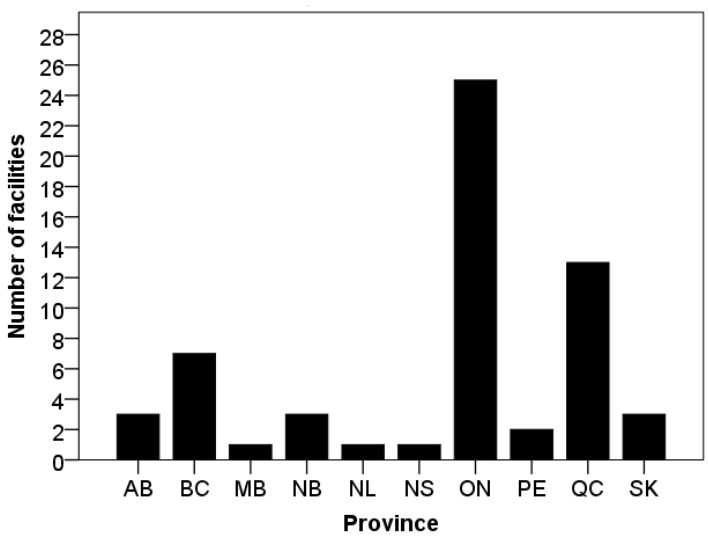

Figure 4.1. Number of participating facilities in each Canadian province (AB=Alberta; BC=British Columbia; MB=Manitoba; NB=New Brunswick; NL=Newfoundland and Labrador; NS=Nova Scotia; ON=Ontario; PE=Prince Edward Island; QC=Quebec; SK=Saskatchewan)

4.3.2 Prosthetic rehabilitation data

Approaches and types of service: the majority of the facilities (n=39/59, 66.1%) indicated that they provide both inpatient and outpatient lower limb prosthetic rehabilitation services, whereas some (n=10/59, 16.9%) indicated that they only provide inpatient or outpatient lower limb prosthetic rehabilitation services.

For facilities that provided inpatient prosthetic rehabilitation, 27/49 (55.1%) admitted clients under their general inpatient rehabilitation program, 10/49 (20.4%) admitted clients under a specific inpatient rehabilitation program (e.g. musculoskeletal), and 12/49 (24.5%) admitted clients to a dedicated amputee prosthetic rehabilitation program.

For facilities that provided outpatient prosthetic rehabilitation, 18/49 (36.7%) serviced clients through a dedicated amputee prosthetic rehabilitation program, 17/49 (34.7%) serviced clients through a specific outpatient rehabilitation program (e.g. musculoskeletal), and 14/49 (28.6%) serviced clients through their general outpatient rehabilitation prgoram.

The majority of facilities provided four to six weeks (n=22/49, 44.9%) of inpatient prosthetic rehabilitation for individuals with unilateral transtibial amputation. Similarly, most facilities provided four to six weeks of inpatient prosthetic rehabilitation (n=29/49, 59.2%) for individuals with unilateral transfemoral amputation. For individuals with bilateral transtibial amputation, 20/49 (40.8%) facilities provided four to six weeks of inpatient prosthetic rehabilitation, while 10/49 (20.4%) provided ten to twelve weeks of inpatient prosthetic rehabilitation. Lastly, for individuals with bilateral transfemoral amputation, most facilities provided ten weeks or longer inpatient prosthetic rehabilitation (n=30/49, 61.2%) (Figure 4.2).

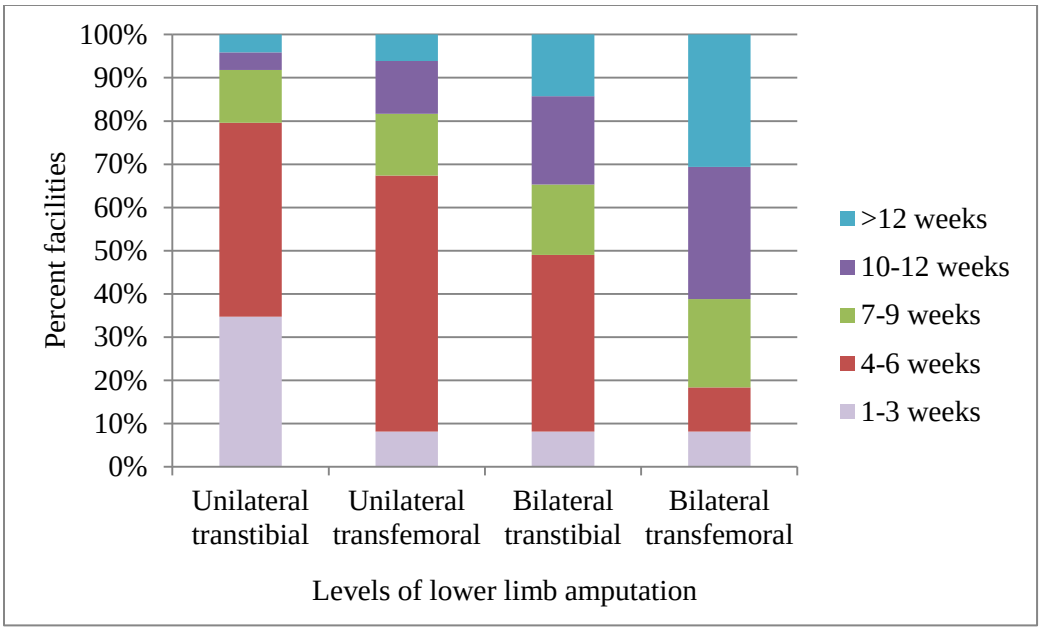

Figure 4.2. Length of inpatient prosthetic rehabilitation by level of LLA at prosthetic facilities in Canada (n=49)

For facilities that provided outpatient rehabilitation, the majority (n=16/49, 32.7%) provided four to six weeks of outpatient prosthetic rehabilitation to clients with unilateral transtibial amputation, and four to six weeks (n=15/49, 30.6%) or >twelve weeks (n=16/49, 32.7%) of rehabilitation to clients with unilateral tranfemoral amputation. For individuals with bilateral transtibial and transfemoral amputation, the majority of facilities provided >twelve weeks of outpatient prosthetic rehabilitation (n=17/49, 34.7%; n=29/49, 59.2%, respectively) (Figure 4.3).

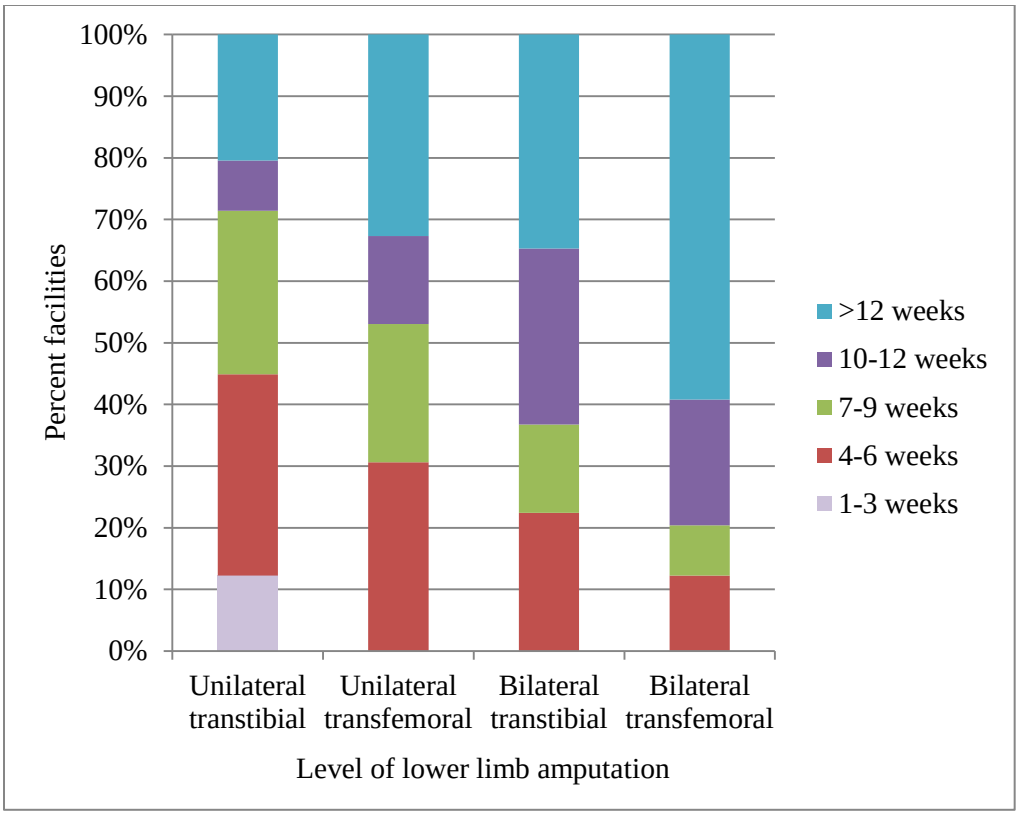

Figure 4.3. Length of outpatient prosthetic rehabilitation by level of LLA at prosthetic facilities in Canada (n=49)

Types of therapy: all facilities (n=59/59, 100%) provided balance and coordination training, gait training, and prosthetic fit education during client's prosthetic rehabilitation. About 57/59 (97%) provided flexibility and range of motion (i.e. muscle stretching), 55/59 (93.2%) provided cardiovascular training (i.e. aerobic fitness training), and 51/59 (86.4%) provided muscle strengthening. Twelve of the facilities (24.5%) specified the provision of "other" therapies, including: aquatic therapy, school integration program, nutritional education, stress management, phantom pain and body image education, home interventions and home visits, and gaming rehabilitation (Figure 4.4).

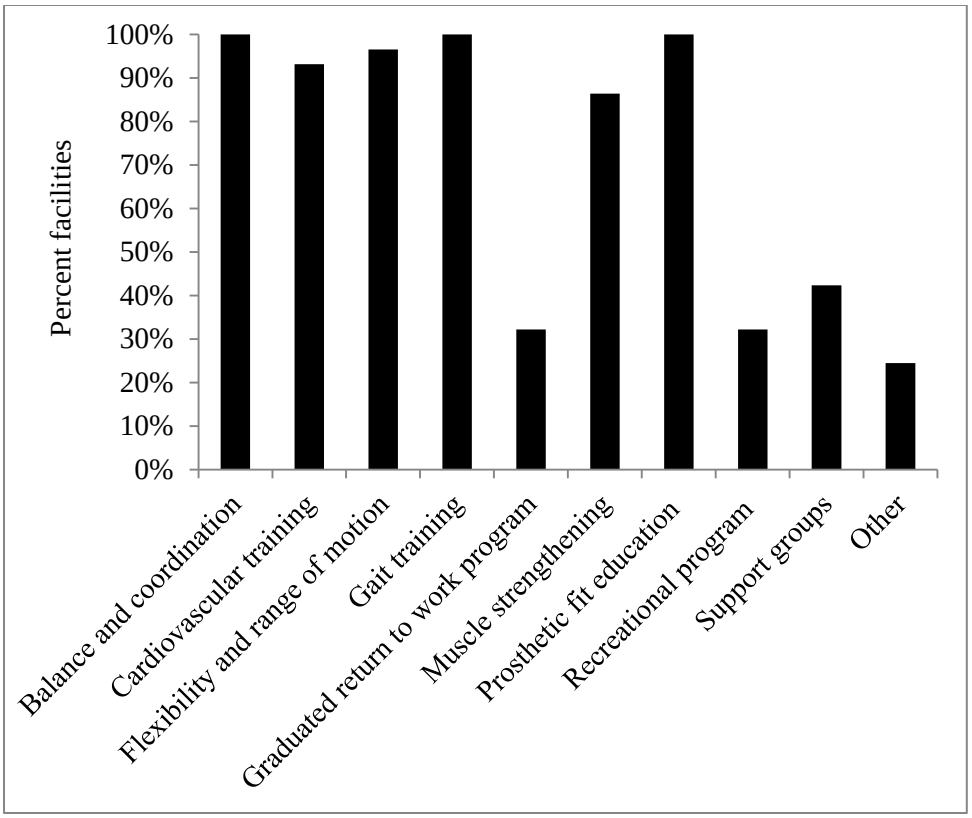

Figure 4.4. Types of therapy provided in lower limb prosthetic rehabilitation programs across facilities in Canada (n=59)

Focus of service: the majority of the facilities (n=57/59, 96.6%) provided prosthetic rehabilitation services to clients aged between 50-64 years old (Figure 4.5).

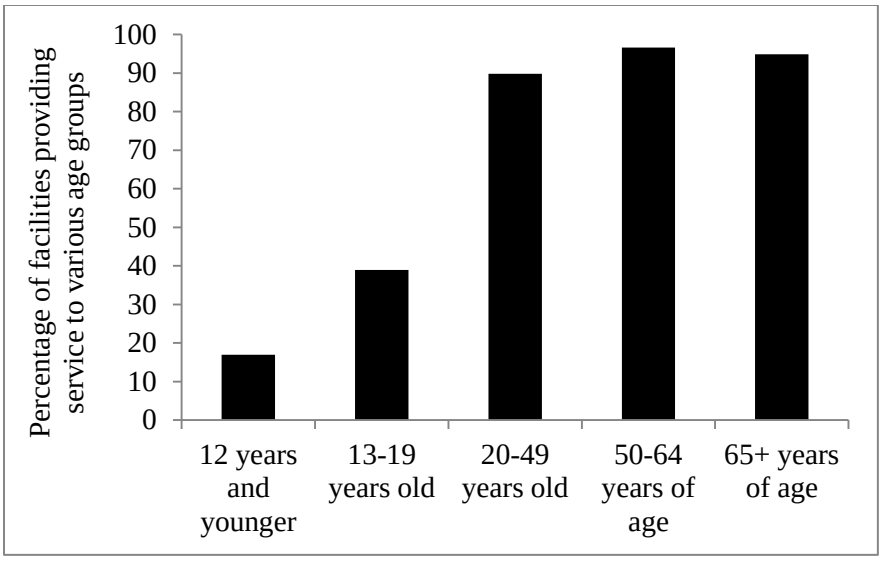

Figure 4.5. The percentage of Canadian facilities providing lower limb prosthetic rehabilitation services to various age groups (n=59). ***Respondents were asked to select all that apply.***

Annually, a mean of 30 (SD=30.5) clients with LLA were admitted as inpatients, and 23 (SD=19.4) clients were serviced as outpatients across the facilities in Canada. Of those admitted as inpatients, 23/30 (76.7%) were fitted with a prosthesis; and of those serviced as outpatients, 20.9/23.1 (90.6%) were fitted with a prosthesis.

Healthcare providers: an average of 4.5 (SD=3.1) healthcare providers (full time or part time) provided inpatient lower limb prosthetic rehabilitation, and an average of 3.3 (SD=3.1) healthcare providers (full time or part time) provided outpatient lower limb prosthetic rehabilitation across these facilities in Canada.

The majority of the facilities indicated that they have a physical therapist (n=58/59, 98.3%), an occupational therapist (n=52/59, 88.1%), and a prosthetist (n=52/59, 88.1%) on their team. Forty-seven (79.7%) facilities reported that they have a social worker and 45/59 (76.3%) reported that they have a nurse (Figure 4.6) on their team. Twenty-one (35.6%) facilities specified having "other" healthcare professionals as part of their team, including: hospitalist, educator specialist, rehabilitation assistant, kinesiologist, care coordinator, speech therapist, and sexologist.

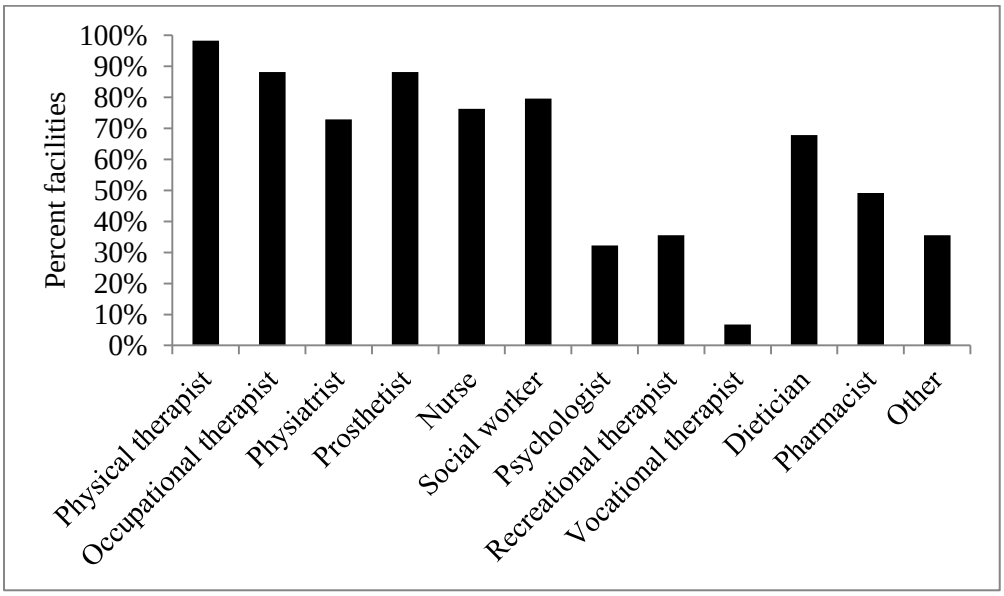

Figure 4.6. Types of healthcare providers comprising prosthetic rehabilitation teams across prosthetic facilities in Canada

4.4 Discussion

National clinical survey studies provide insight into current practices and the provisions of health services across the country, thereby illuminating geographic and professional

variation in clinical practice. With a greater understanding about current practices and rehabilitation service provision, we may be more successful at promoting best practices as well as managing and allocating rehabilitation services.

In this study, Canadian public facilities that provide lower limb prosthetic rehabilitation were surveyed about the nature of their prosthetic rehabilitation programs. The response rate of 91% was excellent. The results indicated that the majority of the facilities across Canada provide both inpatient and outpatient prosthetic rehabilitation. For facilities that provide inpatient rehabilitation, most clients are admitted to the facility's general inpatient program; however, for facilities providing outpatient rehabilitation, clients are mostly serviced at dedicated amputee outpatient programs. In terms of the length of prosthetic rehabilitation (whether inpatient or outpatient), the results showed that the majority of facilities provided between one to three weeks or four to six weeks of prosthetic rehabilitation to clients with unilateral transtibial amputation. The length of rehabilitation was longer (majority four to six weeks) for clients with unilateral transfemoral amputation. For clients with bilateral transtibial amputation, the majority of facilities provided four to six weeks of rehabilitation, while for clients with bilateral transfemoral amputation the majority provided ten to twelve or >twelve weeks of prosthetic rehabilitation. Our findings were similar to the US data that showed the length of prosthetic rehabilitation for clients with transtibial amputation is the shortest and it is approximately between four to six weeks; for clients with transfemoral amputation, rehabilitation is longer (between six to twelve weeks); and lastly for clients with bilateral transfemoral amputation, it is more than twelve weeks (Uustal, 2009). Generally, clients with a higher level or bilateral amputation require longer periods of prosthetic

rehabilitation. This is due to the fact that higher levels of amputation are associated with a greater degree of loss of function (Uustal, 2009). Additionally, energy expenditure for prosthetic walking increases significantly for higher level and for bilateral amputations because of the increasing weight of the prosthesis (Goktepe, Cakir, Yilmaz, & Yazicioglu, 2010). Compared to able-bodied individuals, the energy expenditure associated with prosthetic walking increases by 40%-60% for clients with unilateral transtibial amputation, 90%-120% for clients with unilateral transfemoral amputation, 60%-100% for clients with bilateral transtibial amputation, and >200% for clients with bilateral transfemoral amputation (Pinzur, Gold, Schwartz, & Gross, 1992; Vllasolli et al., 2014). This notable increase in energy expenditure highlights the importance of prosthetic rehabilitation in helping clients build the fitness level required for prosthetic walking (Goktepe, Cakir, Yilmaz, & Yazicioglu, 2010).

Our results showed that a high percentage of the clients (77.0%) that are admitted to inpatient rehabilitation, and an even higher proportion of outpatient clients (90.6%), are fitted with a prosthesis across prosthetic facilities in Canada. Other studies across the world have reported variable rates of prosthetic fitting, ranging from 37% (Nehler et al., 2003) to 92% (Webster et al., 2012). One of the reasons for this variability has been related to the patient population studied (Webster et al., 2012). Studies with the lower rates of prosthesis fitting mainly focus on older patient population with vascular origin and higher level amputations (Webster et al., 2012). Older age and higher level amputations have been associated with substantial decrease in prosthetic fitting and usage (Davies & Datta, 2003; Fletcher et al., 2002). Other reasons for such variability have been attributed to different definitions of prosthetic fitting and the time

at which prosthetic fitting is evaluated (Webster et al., 2012). For example, Webster et al. (2012) showed that prosthetic fitting at four months post-amputation was 53%, whereas at twelve months post-amputation was 92%. In our study, we asked for a general rate of prosthesis fitting for all the clients (all ranges and aetiologies) without specifying a time point.

The majority of the Canadian prosthetic facilities seem to provide a rehabilitation program that includes balance and coordination, range of motion, gait training, cardiovascular training, strengthening, and prosthetic fit education. One hundred percent of the facilities reported that their lower limb prosthetic rehabilitation program includes balance and coordination training as well as gait training. Balance and gait training are crucial because they are two aspects of physical function that are most deteriorated post-amputation and are most essential for restoration of walking ability, which is the main goal of prosthetic rehabilitation (Van Velzen et al., 2006). Balance is particularly important for regaining walking ability because it is reported to be associated with walking ability in individuals with LLA (Van Velzen et al., 2006). Flexibility, range of motion, and cardiovascular training were also reported to be part of prosthetic rehabilitation programs for more than 90% of the facilities in this study. Flexibility and range of motion exercises are critical for preparing the residual limb for prolonged periods of prosthetic use and reducing the chance of developing contractures, which are common in this population (Munin et al., 2001). Cardiovascular training is another important component of prosthetic rehabilitation because it helps improve the aerobic fitness of the clients and enables them to meet the increased energy demand of walking with a prosthesis (Goktepe, Cakir, Yilmaz, & Yazicioglu, 2010; Pinzur, Gold,

Schwartz, & Gross, 1992; Vllasolli et al., 2014). In terms of healthcare providers that comprise the prosthetic rehabilitation team, the majority of the facilities have a specialized team of healthcare professionals. Almost 100% of the facilities reported that they have a physical therapist as part of their team. About 90% reported that they have an occupational therapist and a prosthetist, and between 72%-80% reported to have a physiatrist, a social worker, and a nurse as part of their patient care team.

The finding that the majority of the facilities provide reasonably long inpatient and outpatient rehabilitation services and have specialized healthcare provider teams is encouraging. However, we know from the literature that resource-intensive rehabilitation services (particularly inpatient) are costly and may not be sustainable as the demand for prosthetic rehabilitation is growing (Lusardi & Nielsen, 2007; Meier & Heckman, 2014). Furthermore, in Chapter 3 we learned that only 18% of the individuals with LLA receive inpatient rehabilitation in Canada. This may further indicate that although the majority of the prosthetic facilities in Canada provide both inpatient and outpatient prosthetic rehabilitation, only a small fraction of the individuals with LLA is admitted for inpatient rehabilitation. Therefore, future research is required to explore alternative cost-effective approaches for providing prosthetic rehabilitation.

4.4.1 Limitations

This study had a number of limitations. Despite considerable effort to identify all public prosthetic facilities in Canada, we missed smaller and private amputee clinics. Although we sent the survey link to only one representative from each facility, the anonymity of the survey

limits our ability to ensure that all facilities had only one respondent. Because the survey asked facility-level questions, we endeavoured to select the most suitable respondent from each facility to fill out the survey. In addition, we collected data from only one respondent per facility in order to maintain data independence, and thus, avoid counting some facilities more than once. However, since only one respondent per facility provided data, the responses may not be representative of the facility. Another limitation could be the survey questions. The wording of some of the questions may have been confusing or misleading and affected the responses. We endeavoured, however, to minimize this issue through piloting the survey and refining it through multiple rounds of iterations before collecting data. Due to the small sample size, and the unequal representation of prosthetic facilities in Canadian provinces, we were not able to look at provincial differences. Future studies should aim to look at provincial as well as urban/rural differences. Another limitation is that we only looked at variability in the length of rehabilitation by level of amputation and not by client's age. Because we aimed to keep the survey short to increase the completion rate, the number and the level of the specificity of the questions that we could ask limited us. Future Canadian surveys are required to collect data on more specific questions about prosthetic rehabilitation. Reporting or recall bias might be another limitation (Fadnes, Taube, & Tylleskär, 2008). As with any self-report data, there is a possibility of reporting false or inaccurate information (Fadnes, Taube, & Tylleskär, 2008; Raphael, 1987).

4.5 Conclusions

This was the first Canadian survey describing the current practices and service provision for lower limb prosthetic rehabilitation. The majority of the prosthetic rehabilitation facilities

reported that they provide both inpatient and outpatient services and have specialized healthcare provider teams comprising of a physical therapist, an occupational therapist, a prosthetist, and a social worker. The length of prosthetic rehabilitation seems to be adequately high and is consistent with the literature. The provision of both inpatient and outpatient prosthetic rehabilitation services across most prosthetic facilities in Canada, and the long periods of prosthetic rehabilitation reported in this study, though encouraging and beneficial to the clients, has important cost implications for the Canadian healthcare system. With the high cost of prosthetic rehabilitation (particularly for inpatient rehabilitation), and the growing demand for rehabilitation, it is becoming increasingly difficult to sustain the provision of long periods of inpatient and outpatient prosthetic rehabilitation. As a result, future research is needed to explore alternative or augmentative cost-effective approaches to deliver LLA rehabilitation

5 Use of Commercial Games in Lower Limb Prosthetic Rehabilitation

5.1 Introduction

Recent technological advances have facilitated the development and use of robotic and gaming technologies as augmentative therapeutic tools in rehabilitation. These devices allow for interactive therapy with minimal help from the therapists. Due to the high cost and limited accessibility of these devices, commercial games have gained popularity within the past few years (Bonnechere, Jansen, Omelina, & Van Sint Jan, 2016). Commercial games are attractive because they are not only low cost and widely available but also provide an interactive and engaging form of exercise. Among the commercial games available in the market, the Nintendo Wii Fit is the most popular and prevalent (Chao, Scherer, & Montgomery, 2015; Ravenek, Wolfe, & Hitzig, 2015). The Wii Fit offers a variety of interactive physical activity and fitness oriented exercises that can be used in rehabilitation. Users stand on the Wii Fit balance board and interact with the games through weight shifting and/or using a remote controller. A recent scoping review on the use of commercial games in rehabilitation has reported that these devices are commonly used in practice by therapists, particularly physical and occupational therapists, across a variety of client populations (Ravenek, Wolfe, & Hitzig, 2015). At our local rehabilitation facility, the Wii Fit games are currently being used for prosthetic rehabilitation. Although we speculate that this is the trend in other facilities in Canada, we do not have concrete data to support this belief. Furthermore, despite the continued growth in adoption and use of commercial games in practice, data on therapists' experiences and attitudes about these games are currently lacking. Such data will provide knowledge on the acceptability and usability of the games

and can be insightful to therapists that are considering using these games for their clients' rehabilitation or would like to recommend the games to their clients for home training after discharge. A study that surveyed the use of the Wii Fit in rehabilitation of clients with burn injuries found that the majority of physical and occupational therapists viewed the games positively and as a useful adjunct to traditional therapy (Fung et al., 2010). In another qualitative study, physical therapists regarded the Wii Fit as a fun, self-motivating, and challenging balance training program for clients with multiple sclerosis (Forsberg, Nilsagård, & Boström, 2015).

To our knowledge, there are no published reports about the prevalence of use of commercial games in Canada or data on therapists' perspectives on the use of Wii Fit in lower limb prosthetic rehabilitation. Therefore, the overall objective of this study was to obtain an understanding about the use of commercial games, particularly the Wii Fit, in lower limb prosthetic rehabilitation in Canada. The specific objectives were to discover the prevalence of use and types of games used as well as the therapists' perspectives (i.e. preferences, perceived benefits and perceived challenges/barriers) about the use of these games in lower limb prosthetic rehabilitation.

5.2 Methods

5.2.1 Design and sample

This chapter presents data from sections 2 and 3 of the cross-sectional online survey described in Chapter 4. Data were collected from physical and occupational therapists across

the 65 Canadian public prosthetic rehabilitation facilities identified in Chapter 4. We chose to include only physical and occupational therapists because the literature suggests these games are mostly utilized by these groups (Ravenek, Wolfe, & Hitzig, 2015). The 65 facilities provided lower limb prosthetic rehabilitation, had a minimum of ten rehabilitation beds designated to any one diagnosis, and annually had a minimum of five clients with LLA.

The email addresses of potential respondents were obtained from the facilities' physical/occupational therapy clinical practice leaders. To be eligible for inclusion in the study, the potential respondents had to be physical therapists or occupational therapists with experience providing prosthetic lower limb rehabilitation or with knowledge of lower limb prosthetic rehabilitation services within their facility, and able to read, write and speak in English or French.

The potential respondents were contacted by email. Initially, we emailed the introductory study letter with the survey link. If participants opened the survey link, they were directed to the consent form, which had the option of "I agree" to indicate consent. Upon providing consent, participants were directed to the survey questions. Reminder emails were sent to all participants at two weeks, four weeks, and six weeks later (Dillman, 2000). The study was approved by the Clinical Research Ethics Board at the University of British Columbia.

5.2.2 Survey questions

The survey was first developed in English and piloted using five iterations which included a think aloud process (Fonteyn, Kuipers, & Grobe, 1993). The French version evolved from the English version and was back translated for refinement.

Sections 2 and 3 of the survey had a total of eighteen close-ended questions categorized as multiple choice questions, yes/no questions, and four- or five-level Likert questions. Comment boxes were provided for questions that required elaboration (Appendix A).

Prevalence of use and types of commercial games in clinical practice: we asked if facilities use commercial games in practice. If the answer was yes, we asked about the types of games used, the frequency of use and the timepoints (i.e. as soon as the client is able to have weight bearing for 30 minutes, 1-2 hours, or >2 hours; close to discharge; or after discharge) at which the games are used. Therapists that indicated they do not use commercial games in practice were presented with a list of possible reasons, with a "yes/no" response category, and asked to select the appropriate reason(s). A comment box was provided to allow respondents to enter any additional reasons.

Therapists' familiarity with the Wii Fit and recommendation for use as a home program: we asked how familiar the respondents were with the Wii Fit games. The response options were "not familiar at all", "a little familiar", "somewhat familiar", or "very familiar". Next, respondents were asked if they recommend the Wii Fit as a home program to their clients to maintain or improve their functional skills, with a "yes/no'" response option. If respondents

responded “no” to this question, they were asked to provide reasons in the comment box provided.

Therapists’ perceived benefits about the use of the Wii Fit in practice: respondents were asked to indicate their level of agreement (i.e. “strongly agree”, “agree”, “neutral”, “disagree”, “strongly disagree”, and “do not know”) related to: motivation and level of engagement, suitability for home and group therapies, and the achievement of therapy goals (e.g. balance, walking capacity, etc.). Respondents were asked to identify any other perceived benefits in the comment box provided.

Therapists’ perceived barriers/challenges about the use of the Wii Fit in practice: respondents were asked to indicate their level of agreement (response categories same as above) about potential barriers/challenges related to: the time and training requirements for the therapists, lack of familiarity with the games, the difficulty levels of the games for the clients, finding a training space, inability to individualize training, lack of time in clients’ training program, cost of the games, or the games not being viewed as clinically useful by therapists or clients. Respondents were asked to identify any other perceived barriers/challenges in the comment box provided.

Appropriate clients’ age for Wii Fit therapy: therapists’ opinion about the appropriate age categories for using the Wii Fit games in lower limb prosthetic rehabilitation was collected. The response categories were: “12 years of age and younger”, “13-19 years of age”, “20-49 years of age”, “50-64 years of age”, and “65+ years of age.”

Respondents' demographic information: we asked about years of experience and expertise, frequency of working with clients with LLA (i.e. "everyday", "a few times a week", "once a week", "a few times a month", "once a month", "a few times a year", and "once a year"), position (i.e. "clinical practice leader", "therapist", or "other"), province, age, and sex.

5.2.3 Data management and statistical analyses

Summary statistics including mean, standard deviation, frequency, percentage as well as graphs were used to describe the sample and address the study objectives. Because of small cell counts, the response options "strongly agree" and "agree" were collapsed together. Similarly, the response options "strongly disagree" and "disagree" were collapsed together.

5.3 Results

5.3.1 Demographics

The survey link was sent to 108 physical and occupational therapists that were identified. Of those, 82 responded (response rate=75.9%). The respondents were primarily English speaking (n=62/82, 75.6%) and physical therapists (n=61/82, 74.4%). The mean (SD) years of professional practice was 18.2 (9.8) years, and the mean (SD) years of practicing at the facility was 13.8 (9.1) (Table 5.1). Of the 82 respondents, 8 (9.8%) were from Atlantic, 36 (43.9%) were from Ontario, 20 (24.4%) were from Quebec, and 18 (22%) were from Western Canada.

Table 5.1. Demographic information and summary of descriptive variables (n=82)

Variables	**Total (n=82)**
Practice area	
Physical therapy	61 (74.4%)
Occupational therapy	21 (25.6%)
Position	
Clinical Practice Leader	13 (15.9%)
Therapist	66 (80.4%)
Years of professional practice	18.2 (9.8)
Years of working at the facility	13.8 (9.1)
Frequency of working with clients with LLA	
Everyday	27 (32.9%)
A few times a week	26 (31.7%)
Once a week/a few times a month	12 (14.7%)
Once a month/a few times a year	14 (17.1%)
Once a year	3 (3.6%)
Age (years)	43.1 (9.4)
Sex	
Females	73 (89.0%)
Males	9 (11.0%)

5.3.2 Study objectives

Prevalence of use and types of commercial games in clinical practice: overall, 38/82 (46.3%) of respondents reported that they use commercial games in prosthetic lower limb rehabilitation. Of all of the respondents, 36/82 (43.9%) indicated that they use Wii Fit in prosthetic rehabilitation, and 7/82 (8.5%) reported that they use Xbox Kinect. One respondent (1.2%) indicated that they use Play Station Eye Toy.

Of those that reported that they use commercial games in prosthetic rehabilitation, the majority (n=21/38, 55.2%) indicated that their clients typically spend <1 hour per week practicing these games. Seven (8.5%) reported that their clients spend between 1-3 hours per week using these games in the clinic, and the remaining respondents (n=11/38, 13.4%) indicated that the amount of use varies considerably depending on the client. In terms of the timepoints during clients' rehabilitation at which commercial games are used, the majority (n=29/38, 76.3%) reported that these games are used "close to discharge" (Figure 5.1).

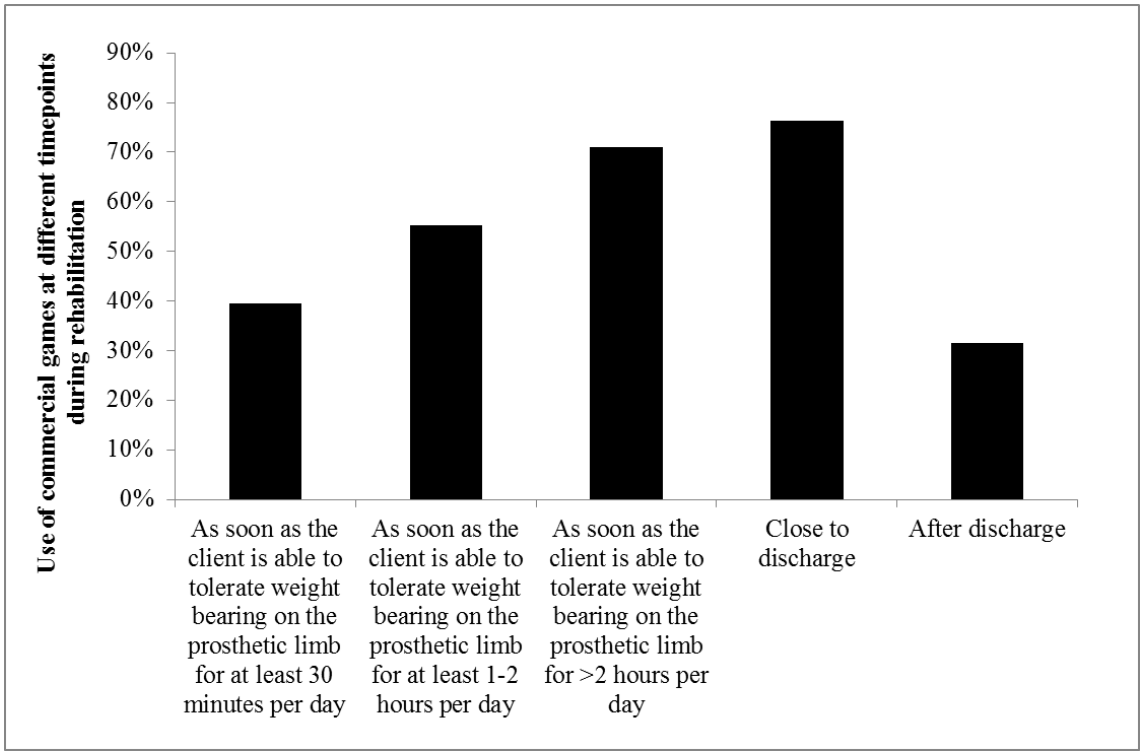

Figure 5.1. Summary of the responses for timepoints at which commercial games are used for prosthetic rehabilitation. ***Respondents were asked to check all that apply.***

For respondents that reported that they do not use commercial games in practice, the most selected reason (n=15/44, 34.0%) was that "they are not familiar with the games" (Figure

5.2). Of the 9/44 (20%) that selected “other” as the reason for not using the games, only one participant elaborated on this point and explained that their clients are too young to use the games.

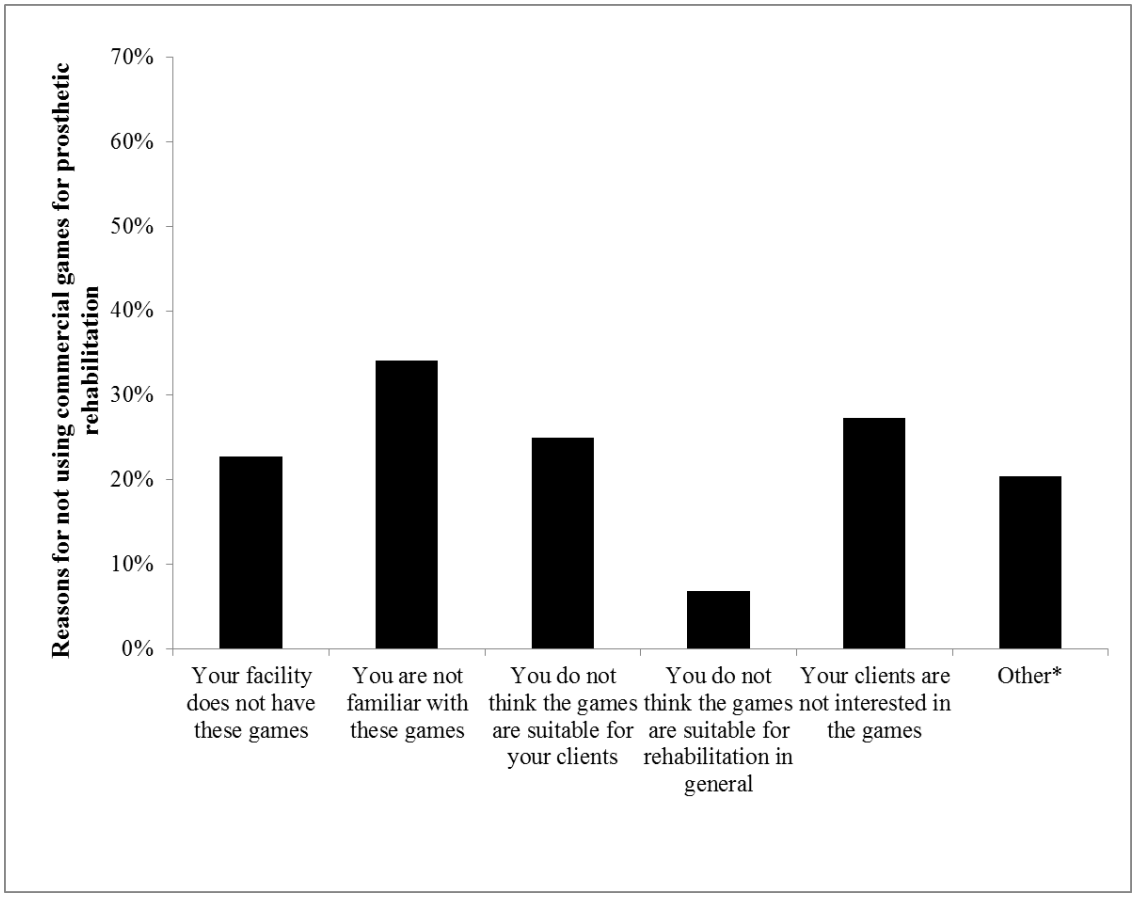

Figure 5.2. Summary of responses of reasons why respondents do not use commercial games for prosthetic rehabilitation. ***Respondents were asked to check all that apply.***

Therapists’ familiarity with the Wii Fit and recommendation for use as a home program:

when respondents were asked how familiar they were with the Wii Fit games, 41/82 (53.6%) responded that they were “somewhat familiar” or “very familiar”, while 38/82 (45.4%) were either “not familiar at all” or just “a little familiar”.

Overall, 47/82 (57.5%) of the respondents indicated that they "would recommend the Wii Fit games as a home program" to their clients to maintain or improve their functional skills; 12/82 (14.6%) reported that they would not recommend these games; and 23/82 (28%) were unsure. The 12/82 (14.2%) respondents who reported that they would not recommend the Wii Fit listed the following reasons: older age of clients and, thus, lack of interest and familiarity with technology and video games; uncertainty about how older clients would react to the games; clients' limited resources to purchase the games; safety concerns for older adults; clients' low energy state due to illness; and inability to correct posture.

Therapists' perceived benefits about the use of the Wii Fit in practice: the most common perceived benefits associated with using the Wii Fit games in practice (Table 5.2) were "making rehabilitation more motivating for clients" (n=75/82, 91.5%), "complementing traditional rehabilitation" (n=75/82, 91.5%), "increasing the clients' level of engagement" (n=69/82, 84.2%), "helping to improve balance" (n=75/82, 91.4%), "helping to improve proprioception" (n=69/82, 84.1%), and "helping to improve weight bearing" (n=76/82, 92.8%).

Seven respondents (8.5%) listed additional perceived benefits, such as improving self-confidence; enabling clients to participate in favoured recreations (e.g. tennis); increased acceptance of sport as an activity option; distraction from disability; and enhanced social support.

Table 5.2. Perceived benefits to using the Wii Fit games in routine lower limb prosthetic rehabilitation (n=82)

Perceived benefits	Strongly agree/agree	Neutral	Strongly disagree/disagree	Do not know
Making rehabilitation more motivating	75 (91.5%)	7 (8.5%)	.	.
Offering an option for home therapies close to or after discharge	62 (75.7%)	16 (19.5%)	4 (4.9%)	.
Complementing traditional rehabilitation	75 (91.5%)	6 (7.3%)	1 (1.2%)	.
Increasing clients' level of engagement in their rehabilitation	69 (84.2%)	10 (12.2%)	3 (3.7%)	.
Allowing for the training of multiple clients at a time (i.e. group training)	35 (42.7%)	27 (32.9%)	16 (19.5%)	4 (4.9%)
Enhancing the achievement of therapy goals	57 (69.5%)	19 (23.3%)	16 (19.5%)	2 (2.4%)
Providing a useful performance summary at the end of each activity	42 (51.2%)	25 (30.5%)	6 (7.3%)	9 (11.0%)
Helping to improve clients' walking capacity	38 (46.3%)	31 (37.8%)	5 (6.1%)	8 (9.8%)
Helping to improve clients' balance	75 (91.4%)	4 (4.9%)	.	3 (3.7%)
Helping to improve clients' proprioception	69 (84.1%)	10 (12.2%)	.	3 (3.7%)
Helping to improve clients' weight shifting	76 (92.7%)	3 (3.7%)	1 (1.2%)	2 (2.4%)

Therapists' perceived barriers/challenges about the use of the Wii Fit in practice: the most frequently reported perceived barriers/challenges (Table 5.3) to using the Wii Fit were "lack of familiarity of therapists with the games" (n=58/82, 70.7%), "lack of time to add the games to the clients' program" (n=58/82, 70.7%), "time/effort requirement to set up the games" (n=49/82, 59.8%), and "cost of the games" (n=48/82, 58.5%). The least reported perceived barriers/challenges were the "games not well received by clients" (n=12/82, 14.6%) and "the games not well received by therapists" (n=12/82, 14.6%).

Additional perceived barriers/challenges identified by the participants were difficulty to keep up with technology and new games, and safety and risk of falls.

Table 5.3. Perceived barriers/challenges to using the Wii Fit games in routine lower limb prosthetic rehabilitation (n=82)

Perceived barriers/challenges	Strongly agree/agree	Neutral	Strongly disagree/disagree	Do not know
Training requirements for therapists to learn the games/gaming system	41 (50%)	15 (18.3%)	25 (30.5%)	1 (1.2%)
Time/effort requirements for therapists to set up the system	49 (59.8%)	11 (13.4%)	22 (26.8%)	.
Time/effort requirement for maintaining the system	31 (37.8%)	20 (20.4%)	31 (37.8%)	.
Lack of familiarity of therapists with the games	58 (70.7%)	12 (14.6%)	11 (13.4%)	1 (1.2%)
The games being too physically challenging for clients	39 (47.6%)	22 (26.8%)	19 (23.2%)	2 (2.4%)
The games being too cognitively challenging for clients	34 (41.5%)	22 (26.8%)	24 (29.3%)	2 (2.4%)

Perceived barriers/challenges	Strongly agree/agree	Neutral	Strongly disagree/disagree	Do not know
Time/effort requirements to find an appropriate training location within facility	41 (50%)	13 (15.9%)	26 (31.7%)	2 (2.4%)
Limited options for individualizing the training parameters	44 (53.7%)	22 (26.8%)	12 (14.6%)	4 (4.9%)
Cost of purchasing the games	48 (58.5%)	19 (23.3%)	14 (17.1%)	1 (1.2%)
Therapists not having enough time available to add the games to the clients' program	58 (70.7%)	11 (13.4%)	12 (14.6%)	1 (1.2%)
Not having enough time available in clients' rehabilitation schedule. Clients' programs are already too busy	30 (36.6%)	14 (17.1%)	37 (45.1%)	1 (1.2%)
Not being well received by therapists. They do not view the games as being clinically useful	12 (14.6%)	19 (23.2%)	48 (58.5%)	3 (3.7%)
Not being well received by clients	12 (14.6%)	30 (36.6%)	37 (45.1%)	3 (3.7%)

Appropriate clients' age for Wii Fit training: when respondents were asked in which client age categories it would be appropriate to use the Wii Fit games for prosthetic rehabilitation, 78/82 (95.1%) reported ages 20-49 years, whereas 44/82 (53.7%) indicated 65+ years old (Figure 5.3).

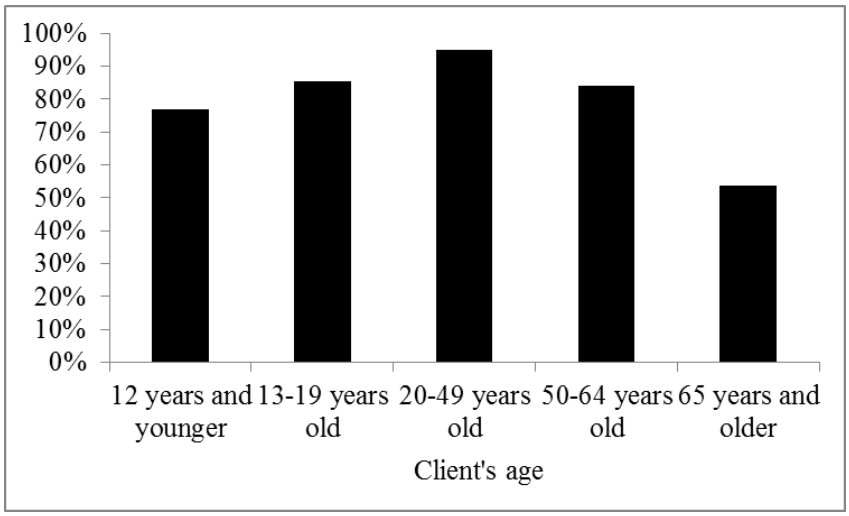

Figure 5.3. Summary of responses showing therapists' opinion about appropriateness of using the Wii Fit games for different age categories. ***Respondents were asked to select all that apply.***

5.4 Discussion

This was the first study that explored the use of commercial games across prosthetic rehabilitation facilities and therapists' perspectives about using commercial games in lower limb prosthetic rehabilitation. As the results of a scoping review of studies from 1990 to 2014 suggested, commercial games (particularly the Wii Fit) are increasingly being adopted by therapists (Ravenek, Wolfe, & Hitzig, 2015). Although commercial games offer great promise for lower limb prosthetic rehabilitation, there has been no previous research on the usage pattern across Canada and therapists' perspectives about these games in lower limb prosthetic rehabilitation.

In this study, we found that almost half of the respondents across Canada use commercial games in lower limb prosthetic practice. This finding provides evidence to support the claim by Ravenek et al. (2015) that commercial games are rapidly becoming popular and prevalent in rehabilitation. Our results showed that among different types of commercial games used by therapists, Wii Fit was the most prevalent. Almost 95% of those that reported using commercial games in practice indicated that they use Wii Fit games. This is consistent with Ravenek et al.'s (2015) scoping review of gaming use in rehabilitation. The higher popularity and prevalence of Wii Fit use compared to other commercial games may suggest that therapists view the Wii Fit exercises as more suitable for this population. Alternatively, the higher prevalence could be related to the fact that Wii Fit has been around for a longer time and there is more research on its use; and therefore, therapists are more familiar and comfortable with using it. When we asked about therapists' familiarity with the Wii Fit games, half of the sample responded that they are somewhat familiar with the games; whereas the other half indicated that they are either a little familiar with the games or not familiar at all. It is challenging for busy therapists to keep up with the pace of rapidly growing technologies. The Xbox Kinect, for example, is the latest commercial gaming technology in the market and may hold greater promise for use in rehabilitation because of the advanced motion tracking technology that it uses; however, compared to the Wii Fit, it is less commonly used in rehabilitation and the research evidence for its use in rehabilitation is still limited.

Most respondents in our study (76%) reported that they use commercial games to assist with clients' rehabilitation close to the time of their discharge. Thirty-two percent reported that

they use these games after discharge. When we asked if the therapists would ever recommend the Wii Fit games as a home program, the majority indicated that they would. Those that indicated that they would not recommend these games stated that this was because their clients did not have these games or were older and would not like video games. It is interesting that despite the concern that clients do not have these games, the Entertainment Software Association of Canada (2014) has shown that 62% of Canadians have at least one video gaming console in their home. Additionally, 54% of Canadians have played video games in the past four weeks. Specifically, among Canadians older than 55 years old, 34% play video games (Entertainment Software Association of Canada, 2014). Another report showed that the use of technology is growing quickly among the elderly in the US (Czaja et al., 2006). In fact, it has been shown that older adults generally have positive attitudes towards technology, particularly towards devices that can be used at home to improve their health and independence level (Mitzner et al., 2010). This suggests that, in contrast to the belief that older adults are unwilling or unable to use technology, recent advancements and widespread access have resulted in older adults becoming more familiar with, and willing to use, technology (Mitzner et al., 2010). There is an increasing number of studies in the literature that report favourably on the use and appropriateness of the Wii Fit in older adults. Bieryla and Dold (2013) reported that a three-week intervention with the Wii Fit improved balance in adults older than 70 years of age. In an RCT by Padala et al. (2017) in community-living adults older than 60 years of age, the Wii Fit group showed a statistically significant improvement in balance compared to the control group who played with cognitive video games. In another randomized controlled trial in older adults (>65 years old) living in a nursing home, the Wii Fit group showed a statistically significant decrease in incidence of

falls compared to the control group that received the conventional physical therapy (Fu et al., 2015). Similarly, Nicholson, McKean, Lowe, Fawcett, and Burkett (2015) determined the effect of a six-week unsupervised Wii Fit training in older adults aged 65 and older and reported statistically significant improvements in the Timed Up and Go, single leg balance, lateral reach and gait speed in the Wii Fit group compared to the control that received conventional training. In addition, the Wii Fit group participants reported an increased level of enjoyment during the training.

There are also reports on feasibility, safety, and acceptability of the Wii Fit in older adults. According to a systematic review by Chao, Scherer, and Montgomery (2013), the Wii Fit is safe and feasible for use in older adults aged 60 and older. In another study that used Wii Fit training in older adults, the participants reported enjoyment and improvements in balance and activities of daily living as well as the desire to continue playing with the games (Agmon, Perry, Phelan, Demiris, & Nguyen, 2011). In our study, the majority of the therapists reported that appropriate ages for the use of the Wii Fit are 20 to 49 years old, while about half of the therapists indicated that the Wii Fit is appropriate to be used with clients over the age of 65 years old. Although we are not aware of a study that has directly reported on age appropriateness of the Wii Fit, a study by Graves et al. (2010) showed that the Wii Fit training was found to be enjoyable by adolescents (11-17 years old), and young (21-38 years old) and older adults (45-70 years old). Nonetheless, not all older adults like technology and video games, nor are they all capable of using them. Our personal observation showed that older participants with severe functional limitations or with visual, auditory, or cognitive impairments are not able to use these games. Some of the games are just too challenging for

these older adults and may lead to lack of enjoyment and frustration. As a result, although the Wii Fit may hold a promise for use in older adults, the inherent limitations of its use in some older adults should be taken into account.

When we asked about the respondents' perceived benefits and barriers/challenges associated with using the Wii Fit games in lower limb prosthetic rehabilitation, respondents reported more benefits than barriers/challenges (mean percent agreement=74.6% versus 46.6%, respectively). This may suggest that therapists generally have positive experiences using these games in clinical practice. The most commonly reported perceived benefits (~92%) were "making rehabilitation more motivating for clients" and "complementing traditional rehabilitation." Numerous studies have reported similar findings associated with using Wii Fit in different patient populations (Forsberg, Nilsagård, & Boström, 2015; Goble, Cone, & Fling, 2014; Meldrum, Glennon, Herdman, Murray, & McConn-Walsh, 2012). In a focus group that was conducted to explore physical therapists' experiences with using the Wii Fit for balance training in individuals with multiple sclerosis, most physical therapists reported that exercising using the Wii Fit was fun and self-motivating for their clients (Forsberg, Nilsagård, & Boström, 2015). Additionally, the physical therapists indicated that the Wii Fit games complemented traditional therapy by providing training on important components of function such as balance (Forsberg, Nilsagård, & Boström, 2015).

Other commonly reported (>90%) perceived benefits in our study were "helping to improve balance" and "helping to improve weight bearing." This was not surprising because the Wii Fit is largely viewed as helpful for improving balance (Forsberg, Nilsagård, & Boström,

2015). Ravenek et al.'s (2015) scoping review showed that commercial games, especially the Wii Fit, have been primarily used by therapists for clients with balance impairments. Approximately 76% of respondents agreed that the Wii Fit "offers an option for home therapies close or after discharge." This is promising and may indicate that therapists view these games as clinically useful, with potential for use after discharge to help clients retain their functional skills. Although a valid concern of some therapists was clients' safety, there are emerging trials that report favourably on the feasibility and safety of using the Wii Fit for home therapy (Esculier, Vaudrin, Bériault, Gagnon, & Tremblay, 2012; Prosperini et al., 2013).

The most commonly reported barriers/challenges to using the Wii Fit in prosthetic rehabilitation were "lack of familiarity of therapists with the games" and "lack of time to add these games to the clients program." This finding corroborates earlier reports that stated therapists' reluctance in using video games partly stemmed from their unfamiliarity with the games and their concern about the associated training requirements (Schwartzman, Segal, & Drapeau, 2012). Similarly, Liu et al. (2015) reported that time constraints and training requirements were the main barriers for adopting new technologies by clinicians in rehabilitation. For therapists that often have heavy caseloads, it is challenging to find the time to learn about new technologies and rapidly evolving interventions. The results of this study showed that although therapists generally have positive attitudes toward using commercial games in clinical practice, they need more support in terms of reducing the time required for learning and adopting these games. Frequent knowledge translation efforts, including educational sessions, could be helpful in overcoming these barriers by familiarizing

clinicians with the latest findings about these games. Furthermore, developing standardized treatment protocols that provide detailed guidelines about the use of these games could help in minimizing the time required for therapists to learn the games (Schwartzman, Segal, & Drapeau, 2012).

5.4.1 Limitations

In this study, we included only physical and occupational therapists because among other healthcare professionals they utilize commercial games the most (Ravenek, Wolfe, & Hitzig, 2015). Therefore, we are missing data on other healthcare professionals, such as recreational therapists that may also use commercial games. However, the number of recreational therapists that use commercial games in practice is expected to be low as the Ravenek et al.'s (2015) scoping review reported that only 3% of recreational therapists use these games in rehabilitation. Another limitation is that despite considerable effort to identify the physical and occupational therapists who work with lower limb clients with LLA at prosthetic facilities in Canada, it is likely that we missed therapists from smaller and private amputee clinics. Another potential limitation is reporting or recall bias (Fadnes, Taube, & Tylleskär, 2008). As with any self-report data, there is the possibility of social desirability factors (Fadnes, Taube, & Tylleskär, 2008; Raphael, 1987). The phrasing of the questions and the response options could also affect the responses and lead to misinterpretation (Schwarz, 1999). For example, questions with fixed response options limit respondents' abilities to provide answers that are not included in the response options and subsequently may decrease data precision (Schwarz, 1999). We endeavoured to minimize biases associated with the survey questions by operationalizing the survey questions and providing comment boxes

throughout the survey so that participants could leave any additional information that was not in the response options. We also improved the wording, content, and formatting of the survey questions through five iterative cycles. Finally, since this was a Canadian survey, the results may not be generalizable outside of Canada. Future studies are required to explore and compare the use pattern of commercial games in other countries.

5.5 Conclusions

In conclusion, this was the first study that aimed to determine the use of commercial games in prosthetic rehabilitation and therapists' perspectives about the benefits and challenges associated with the use of these games. Our results showed that commercial games, particularly the Wii Fit, are used commonly in prosthetic rehabilitation and viewed positively by physical and occupational therapists in Canada. The majority of the therapists queried view these games as self-motivating, having the potential to complement traditional therapy, and beneficial for use as home therapies. The most commonly reported perceived barriers/challenges with the use of these games were lack of time, lack of familiarity with the games, and training requirements. Knowledge translation activities and developing standardized treatment protocols could be helpful in minimizing these barriers.

6 A Randomized Controlled Feasibility Trial to Evaluate the Use of the Nintendo Wii Fit for Rehabilitation in Older Adults with Lower Limb Amputation*

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*A version of this chapter has been published.
Imam, B., Miller, W.C., Finlayson, H., Eng, J.J., & Jarus, T. (2017). A randomized controlled trial to evaluate the feasibility of the Wii Fit for improving walking in older adults with lower limb amputation. *Clinical Rehabilitation, 31,* 82-92.

6.1 Introduction

In previous chapters we highlighted that there is a need for novel and cost-effective augmentative or alternative forms of LLA rehabilitation service delivery. Commercial games, mainly the Nintendo Wii Fit, have recently received attention by researchers and therapists as potential rehabilitation tools. The findings from Chapter 5 showed that the majority of the therapists queried across prosthetic facilities in Canada use the Wii Fit in their clients' lower limb amputation (LLA) rehabilitation. The therapists also expressed generally positive attitudes towards using the Wii Fit in practice.

Although Wii Fit is being used in clients' LLA rehabilitation across Canada, evidence for the efficacy of this approach is lacking. Recently, a number of studies that assessed the feasibility and efficacy of Wii Fit in rehabilitation for other client populations have been published. For example, Wii Fit training resulted in improvement in walking capacity in assisted-living older adults (Chao, Scherer, Wu, Lucke, & Montgomery, 2013), and improvement in balance in older adults with impaired balance (Agmon, Perry, Phelan, Demiris, & Nguyen, 2011) and post stroke (Bower, Clark, McGinley, Martin, & Miller, 2014). Table 6.1 summarizes the recent Wii Fit interventional studies conducted to improve

rehabilitation outcomes associated with lower limb in adult populations. This search was not a systematic review. These studies were identified by myself from Medline, Embase, and Cochrane Register of Controlled Trials using search terms related to video games, Wii Fit, or commercial games, and lower limb. Studies from January 2011 to December 2016 were included.

Table 6.1. Summary of recent Wii Fit interventional studies with lower limb related outcomes

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
Morone et al. (2016)	Randomized controlled trial	38 females, >65 years old with a bone loss condition and balance impairment	Wii Fit training for 1 hour sessions, 2x/week for 8 weeks	Conventional balance exercises	Berg Balance Scale, SF-36, Short Falls Efficacy Scale-International, Global Self-Esteem Scale of Morris Rosenberg	The Wii Fit group showed statistically higher improvements in Berg Balance ($p=0.027$) and physical activity score of the SF-36 ($p=0.031$)
Ibrahim, Mattar, & Elhafez (2016)	Randomized controlled trial	30 healthy adults, from 35 to 55 years old	Wii Fit balance training for 15 minute sessions, 3x/week for 4 weeks	Biodex Balance System	Overall balance tested using Biodex Balance System	No statistically significant difference in balance was found between the groups. Wii Fit was enjoyable by 82% of the participants.

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
Fu, Gao, Tung, Tsang, & Kwan (2015)	Randomized controlled trial	60 adults ≥65 years old	Wii Fit training for 1 hour sessions, 3x/week for 6 weeks	Conventional balance training	Physiological Profile Assessment scores and incidence of falls	Statistically greater improvement in both outcomes ($p=0.004$ $p<0.001$) in the Wii Fit group compared to control group.
Cone, Levy, & Goble (2015)	Controlled pre-post	40 healthy adults aged 18-35 years old	Wii Fit training for 30-45 minute sessions, 2-4x/week for 6 weeks	None	NeuroCom balance testing	Statistically significant difference between the groups for condition 5 of NeuroCom ($p<0.03$).
Chao, Scherer, Montgomery, Wu, Lucke (2015)	Quasi-experimental pre-post	32 residents in assisted living ≥ 65 years old	Wii Fit training for 60 minute sessions, 2x/week for 4 weeks	Health education program	Physical function, fear of falling, and quality of life	Statistically significant improvements in balance and mobility in the Wii Fit group ($p<0.05$).
Hakim, Salvo, Balent, Keyasko, & McGlynn (2015)	Case study	A 76 year old patient with bilateral peripheral neuropathy	Wii Fit training for 60 minute sessions, 2x/week for 6 weeks	None	Computerized Dynamic Posturography system, Limits of Stability, Adaptation Test and Motor Control Test and clinical testing with the Berg Balance Scale, Timed	Improvements in maximum excursion abilities, motor control test scores for amplitude with forward translations, adaptation test for downward platform rotations, Balance Berg Scale,

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
					Up and Go, Activities-specific Balance Confidence scale and 30-s Chair Stand.	Activities-specific Balance Confidence, and Timed Up and Go.
McPhail et al. (2015)	Pilot randomized controlled trial	18 outpatients following knee replacement	Physiotherapy followed by 15 minutes Wii Fit training for 6 sessions	Usual care physiotherapy	2 Minute Walk Test, Range of motion, timed standing, Activities-specific Balance Confidence, Lower Extremity Functional Scale	No statistically significant difference between the groups.
Nicholson, McKean, Lowe, Fawcett, & Burkett (2015)	Controlled pre-post	41 adults ≥65 years old	Wii Fit training for 30 minute sessions, 3x/week for 6 weeks	Usual exercise program	Timed Up and Go, functional reach test, lateral reach, single-leg balance, 30 second chair stand, usual gait speed, Iconographical Falls Efficacy Scale	The Wii Fit group showed a statistically greater improvement in Timed Up and Go, single-leg balance, lateral reach, and gait speed ($p<0.05$)
Omiyale, Crowell, & Madhavan (2015)	Pre-post	10 adults with ischemic stroke and residual hemiparesis; mean age=57 years old	Wii Fit training for 60 minute sessions, 3x/week for 3 weeks	None	Dual Time Up and Go Test, Activities-specific Balance Confidence	Participants showed statistically significant ($p<0.05$) improvements in the dual Timed Up and Go and balance

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
						confidence.
Roopchand-Martin, McLean, Gordon, & Nelson (2015)	Pre-post	36 community living Jamaicans ≥60 year old	Wii Fit training for 30 minute sessions, 2x/week for 6 weeks	None	Berg Balance Scale, Multi Directional Reach Test, Star Excursion Balance Test, Modified Clinical Test for Sensory Integration in Balance	Statistically significant improvement in the Berg Balance Scale score, Star Excursion Balance Test, and Multidirectional Reach Test ($p<0.05$).
Morone et al. (2014)	Randomized controlled trial	50 adults after stroke in subacute phase	Conventional physiotherapy followed by 20 minute Wii Fit training sessions, 3x/week for 4 weeks	Conventional physiotherapy and balance therapy	Berg Balance Scale, Barthel Index, Functional Ambulation Category, and 10-Meter Walk Test	Statistically significant difference in Berg Balance ($p=0.004$) and independency in activity of daily living ($p=0.021$).
Hung et al. (2014)	Randomized controlled trial	30 individuals with chronic stroke and balance deficits	Wii Fit training for 30 minute sessions, 2x/week for 12 weeks	Conventional weight-shifting training	Posturography to measure static balance, stability index, % of weight bearing, Timed Up and Go, forward reach test, Falls Efficacy Scale, Physical Activity Enjoyment Scale	The Wii Fit group showed a greater improvement in stability index and enjoyed the training more than the control group ($p=0.03$).

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
Bower, Clark, McGinley, Martin, & Miller (2014)	Pilot randomized controlled trial	30 adults with a mean age of 64 years old who were <3 months post stroke	Wii Fit balance exercises for 45 minute sessions 3x/week for 2 to 4 weeks	Wii Fit exercises in standing	Step Test, Functional Reach Test, Timed Up and Go, Wii Balance Board balance test, Short Falls Efficacy Scale	Statistically significant greater improvement in Step Test and balance in the Wii Fit group ($p<0.05$).
Bieryla & Dold (2013)	Pilot randomized controlled trial	12 health adults <70 years old	Wii Fit training 3x/week for 3 weeks	None	Berg Balance Scale, Fullerton Advanced Balance Scale, Functional Reach, and Timed Up and Go	Statistically significant improvement in Wii Fit group compared to control in Berg Balance Scale ($p<0.05$).
Chao, Scherer, Wu, Lucke, & Montgomery (2013)	Pre-post	7 adults aged 80-94 years old	Wii Fit training for 30 minute sessions 2x/week for 8 weeks	None	Berg Balance Scale, Timed Up and Go, 6 Minute Walk Test, Falls Efficacy Scale, Self-efficacy for Exercise Scale, Outcome Expectations for Exercise Scale	Significant improvement in balance ($p<0.05$).
Imam, Miller, McLaren, Chapman, & Finlayson (2013)	Single subject research design	6 adults with lower limb amputation and a median age of 49 years	Wii Fit training 30 minute sessions, 5x/ week for 2-6 weeks	None	2 Minute Walk Test, Short Physical Performance Battery, L test, Activities-specific	5 subjects showed statistical improvement on the 2 Minute Walk Test, 4 on the Short Physical

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
		old			Balance Confidence	Performance Battery, and 2 on Activities-specific Balance Confidence ($p<0.05$)
Nilsagård, Forsberg, & von Koch (2013)	Randomized controlled trial	84 adults with multiple sclerosis and a mean age of 50 years old	Wii Fit training for 30 minute sessions, 2x/week for 6-7 week	None	Timed Up and Go, 4 Step Square Test, 25 foot walk test, dynamic gait index, 12-item walking scale, Activities Balance Confidence, timed chair stand test	The Wii Fit group showed statistical improvement in all measures except walking speed and Activities Balance Confidence.
Bateni (2012)	Controlled pre-post	17 adults with a mean age of 76 years old	Wii Fit training 3x/week for 4 weeks	Conventional physical therapy	Berg Balance Scale, Bubble Test	Both groups improved in both outcomes. No statistically significant difference.
Daniel (2012)	Randomized controlled trial with 3 groups	21 pre-frail adults with a mean age 77 years old	Wii Fit training for 45 minute sessions, 3x/week for 15 weeks	Control 1: seated exercise Control 2: no treatment	2 Minute Walk Test, Timed Up and Go, chair stands, sit and reach, balance efficacy scale, Activities Balance Confidence	No statistically significant difference between the groups.
Orsega-Smith, Davis, Slavish,		25 older adults; mean age=72	Wii Fit training for 30 minute sessions,	Healthy community dwelling overweigh	8-foot Timed Up and Go, 30-second chair stands,	Statistically significant improvement in chair

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
& Gimbutas (2012)		years old	2x/week for either 4 or 8 weeks	t older adults	the Berg Balance Scale, Activities-specific Balance Confidence Scale, Falls Self-Efficacy Scale, and the Activities of Daily Living Scale	stands, Berg Balance, and Activities of Daily Living Scale for the 4-week participants. Statistically significant improvements in Berg Balance, Activities-specific Balance Confidence, and Activities of Daily Living Scale in the 8-week group.
Franco, Jacobs, Inzerillo, & Kluzik (2012)	Randomized controlled trial with 3 groups	32 older adults with a mean age of 78 years old	Wii Fit and home exercises for 10-15 minute sessions, 2x/week for 3 weeks	Control 1: Matter Balance program Control 2: no treatment	Berg Balance Board, Tinetti Gait and Balance Assessment, SF-36	No statistically significant improvement between the groups.
Fung, Ho, Shaffer, Chung, & Gomez (2012)	Pilot randomized controlled trial	50 adult outpatient following total knee replacement; mean age=68 years old	Wii training for 15 minute sessions throughout client's rehabilitation	Physiotherapy	2 Minute Walk Test, Timed Standing, Activities-specific Balance Confidence	No statistically significant difference was observed between the groups.
Padala et al. (2012)	Pilot randomized controlled trial	22 with mild Alzheimer's dementia and a mean	Wii Fit training for 30 minute sessions, 5x/week for	Walking	Berg Balance Scale, TUG, Tinetti Gait and Balance Assessment	Statistically greater improvement in Berg ($p<0.005$),

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
		age of 80 years old	8 weeks			and Tinetti test ($p<0.05$) in the Wii Fit group
Esculier, Vaudrin, Bériault, Gagnon, & Tremblay (2012)	Cohort	10 with Parkinson's disease, mean age of 62 years old 8 healthy elderly with a mean age of 64 years old	Home-based Wii Fit training for 40 minute sessions, 3x/week for 6 weeks	Healthy subjects	Sit to Stand, Timed Up and Go, Tinetti Gait and Balance Assessment, 10 Meter Walk Test, Community Balance and Mobility Assessment, Activities-specific Balance Confidence, Force platform	Both groups significantly ($p<0.05$) improved in Timed Up and Go, Sit to Stand, 10m Walk Test, Community Balance, and Force platform
Rendon et al. (2012)	Randomized controlled trial	40 older adults with a mean age of 85 years old	Wii Fit training for 35-45 minute sessions, 3x/week for 6 weeks	No treatment	Timed Up and Go, Activities Balance Confidence	The Wii Fit group showed statistically greater improvement on both outcomes ($p<0.05$).
Miller, Hayes, Dye, Johnson, & Meyers (2012)	Case study	2 older adults with lower limb amputation and a mean age of 60 years old	Wii Fit and body weight support for 40 minute sessions, 2x/week for 6 weeks	None	Dynamic balance, Activities-specific Balance Confidence, gait parameters	Both participants showed improvement in balance, balance confidence, and gait parameters.
Agmon, Perry,	Case studies	7 older adults with	Home-based Wii Fit	None	Berg Balance Scale, 4-m	Statistically significant

Study	Design	Population	Intervention	Control	Outcomes related to lower limb	Findings
Phelan, Demiris, & Nguyen (2011)		a mean age of 84 years old	training for at least 30 minute sessions, 3x/week for 3 months		Walk Test	improvement ($p<0.05$) on the Berg and walk test
Williams, Doherty, Bender, Mattox, & Tibbs (2011)	Pre-post	22 community living older adults; mean age=84 years old	Wii Fit training for at 20 minute sessions, 3x/week for 4 weeks	None	Berg Balance Scale	Statistically significant improvement in the scores in post intervention ($p<0.05$).

In individuals with LLA, a case study with two participants (Miller, Hayes, Dye, Johnson, Meyers, 2012) has shown improvements in balance confidence, gait (Miller, Hayes, Dye, Johnson, Meyers, 2012). In addition, we conducted a multiple baseline single subject research design study with six participants with LLA, in which the baseline period varied for each participant from three times a week, for a minimum of two weeks to three times a week for a maximum of six weeks. Wii Fit training was provided for thirty minutes, five times a week, for a minimum of two to a maximum of six weeks. The results indicated that walking capacity was improved in participants that had received longer than three weeks of training (Imam, Miller, McLaren, Chapman, & Finlayson, 2013). Although these studies provide useful foundational evidence for the use of Wii Fit in LLA rehabilitation, the best way to determine efficacy is to conduct a randomized controlled trial (RCT). Prior to that, it is important to obtain feasibility data and ensure that the trial design is robust. Therefore, the overall objective of this trial was to assess the feasibility of an RCT for evaluating the use of Wii Fit in LLA rehabilitation. Based on preliminary work (Imam, Miller, McLaren,

Chapman, & Finlayson, 2013), we developed Wii.n.Walk, a four-week training program using the Wii Fit, for improving walking capacity in older adults with LLA. The Wii.n.Walk program starts in the clinic with groups of three participants and graduates to unsupervised home training.

Our overall hypothesis was that Wii.n.Walk would be a feasible intervention with older adults with LLA with respect to trial process (i.e. recruitment, enrolment, retention, participants' perceived benefit); resources (i.e. treatment adherence), management (i.e. participant processing, masking); and treatment (i.e. adverse event, pain and fatigue levels, effect size and variance for sample size calculation).

Our primary clinical outcome hypothesis was that participants in the Wii.n.Walk group would experience an improvement in walking capacity compared to the control group. Walking capacity was selected as the primary outcome because it is the strongest determinant of health-related quality of life and prosthetic walking in individuals with LLA (van der Schans, Geertzen, Schoppen, & Dijkstra, 2002).

The secondary clinical hypotheses were that participants in the Wii.n.Walk group would experience an improvement in balance confidence, physical activity, prosthetic use measured by mean number of steps per day, walking while talking, lower limb functioning, and locomotor capabilities.

6.2 Methods

6.2.1 Design overview and randomization

This was a parallel, evaluator-blind RCT. Participants were block randomized, using a 1:1 ratio by a biostatistician, to either the Wii.n.Walk or cognition game control intervention using a computerized randomization process with undisclosed variable block sizes. Randomization occurred after the participant was screened and enrolled. Allocation was concealed from the participants until baseline measurements were completed. Throughout the trial, we attempted to keep the participants masked to the trial objectives by stating: "evidence suggests having good cognition improves physical outcomes and vice versa. In this study, we are trying to determine whether cognitive or physical activity training is better for improving both physical and cognitive outcomes." This was made clear in the consent form and when addressing participants' comments/questions. We masked participants to the study objectives because if one is aware of their assignment to the experimental or the control intervention it can impact their outcomes (Gaudiano & Herbert, 2005). We were unable to mask participants to the interventions, due to the transparent nature of them, so to minimize the potential impact of participants' biases and expectations on their own outcomes, we masked participants to the study objectives.

6.2.2 Setting and participants

The study was conducted at GF Strong Rehabilitation Centre in Vancouver, British Columbia, Canada. Participants were recruited through local hospital and prosthetic clinic

client databases from January 2013 to January 2014. The inclusion criteria were: community-living individuals who are ≥ 50 years of age, at least one year post a unilateral transtibial or transfemoral amputation; using a prosthesis for at least two hours per day for the past six months; and currently not participating in a formal exercise/training program (e.g. balance training). The exclusion criteria were: inability to provide consent or communicate in English; substantial medical conditions such as congestive heart failure that contraindicated participation in an exercise program (ACSM's guidelines, 2010); or prosthetic socket fit issues as indicated by scores <6 on the Prosthetic Socket Fit Comfort Scale (Hanspal, Fisher, & Nieveen, 2013).

6.2.3 Target sample size and justification

According to Moore et al. (2011), a trial's target sample size must align with its primary objective. In feasibility trials, because the primary objective is to assess feasibility rather than efficacy, a formal calculation is inappropriate. However, sample size *justification* is important (Billingham, Whitehead, & Julious, 2013; Stallard, 2012) and should be based on feasibility and precision about the mean and variance (Julious, 2005). As a rule of thumb for feasibility trials, a minimum of 12 participants per group is recommended to provide a sufficient balance between feasibility and mean and variance precision (Julious, 2005). Therefore, a target sample size of 24 participants (12 per research arm) was selected for this study to enable decision-making regarding the feasibility of a larger RCT.

6.2.4 Wii.n.Walk intervention

The Wii.n.Walk protocol consisted of Wii Fit activities for 40 minutes, three times a week (Mondays, Wednesdays, and Fridays), for four weeks. We selected a four-week duration because the results for the previous single subject research design study showed a statistical improvement in walking capacity in participants who had ≥ three weeks of the intervention (Imam, Miller, McLaren, Chapman, & Finlayson, 2013).

The Wii.n.Walk intervention started in the clinic and graduated to a home-based program. We purposely began the intervention in the clinic to introduce group participants and the trainer, initiate group dynamics, and teach the Wii.n.Walk program in a safe and monitored environment. In total, participants received twelve sessions with six supervised at the clinic and six unsupervised at their home (Figure 6.1). For the in-clinic sessions, the intervention was conducted in groups of three participants to encourage peer modeling, social interaction, and competition, and to provide an opportunity for vicarious learning (Bandura, 1997). Social Cognitive Theory defines vicarious experience as learning by watching others successfully accomplish activities. This social learning opportunity provides self-efficacy to the observer that they also have the ability to accomplish the task (Bandura, 1997). The increased self-efficacy enhances learning (Bandura, 1997). Group training has been shown to be important for increasing self-efficacy, learning, and adherence in older adults (Williams & Lord, 1995).

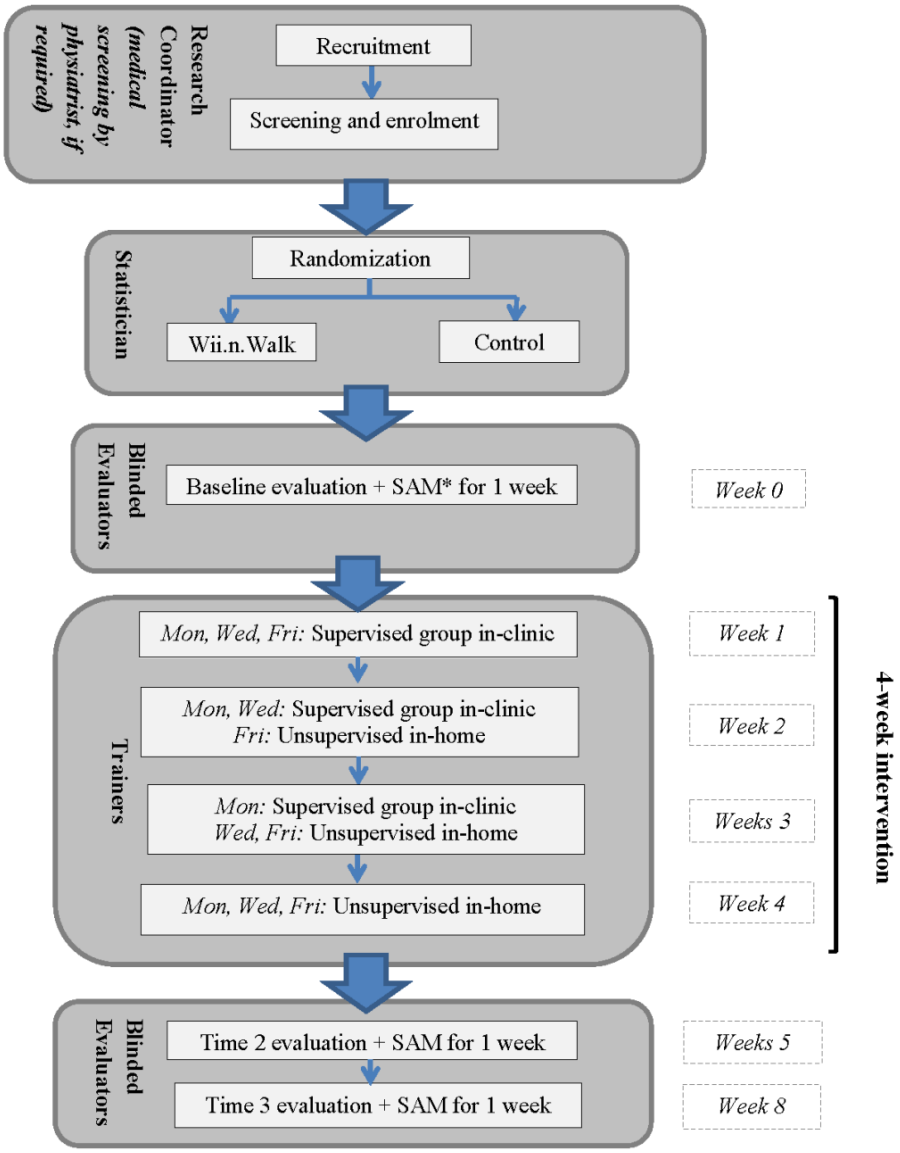

Figure 6.1. Trial procedures diagram

*** Stepwatch activity monitor™**

The Wii.n.Walk activities required participants to stand on the Wii Fit balance board and interact with the games through weight shifting or using the Wii remote control. The protocol included selected exercises such as yoga (i.e. static and dynamic single and double leg

poses), balance games (i.e. lateral, posterior, and anterior weight shifting exercises), strength training (i.e. dynamic single and double leg exercises), and aerobics (i.e. running on the spot and step class). The trainer corrected unsafe/incorrect postures according to the Wii.n.Walk manual developed by our clinical research team (Appendix B). For example, a common postural mistake for the balance games was incorrect weight shifting by bending or twisting the torso to the sides and forward. The trainer corrected this by instructing participants to weight shift using their ankles while keeping the torso straight and in line with the body. Depending on the participant's ability level and potential for safety issues, one or two high back chairs were placed at the side(s) of the participant to minimize chances of falls. The Wii Fit games were chosen according to our Wii Fit manual (Appendix B) and based on participants' functional level. In each session, we aimed to complete ten minutes of each of yoga, balance, strength training, and aerobics activities. If a particular game was unsafe to use for a participant, it was replaced by an easier game from the same category. Modifications were made if the participant had difficulties or was unable to do the activity. As an example, some activities were modified and others were eliminated for individuals with a transfemoral amputation if the prosthesis was not structurally capable of assuming the exercise position (e.g., exercises requiring stance phase prosthetic knee flexion). Participants started with the easier levels of the activities. By default, the advanced levels of the games were locked at the beginning and became automatically unlocked when the participant successfully completed easier precursor levels.

A few days before the home sessions started, the trainer travelled to participants' home to set up the Wii Fit and provide training on how to use the program at home. Participants were

also given a manual (Appendix C), which detailed all the steps on how to use the games (i.e. from turning on your TV to how to correctly do an exercise). Participants were instructed to continue following the same training schedule and do the same exercises they did during the in-clinic sessions, while progressing themselves to the advanced levels when these levels were unlocked. In an attempt to systematically control the dose of the intervention, as well as maintain equivalency between the two arms, participants were instructed to limit their non-scheduled usage for the in-home sessions.

6.2.5 Control intervention

Participants in the control group completed an identical protocol but were trained using the Wii Big Brain Academy Degree program, which is a low-cost commercial game to improve cognition. Participants sat on comfortable chairs and used the Wii remote to engage with the games through pointing and clicking on the screen. The Big Brain games required participants to identify, memorize, analyze, compute, and visualize. The trainer supervised the in-clinic sessions and provided instruction/feedback. Similar to the Wii.n.Walk group, the control group trainer set up the games at participants' home and provided training on how to use them. Participants were given a Big Brain manual (Appendix D) and instructed to continue playing the same games they did in the clinic and limit their usage to the scheduled sessions.

We chose cognitive video gaming for the control group because it enabled attention regulation and controlled for non-specific effects of the Wii.n.Walk intervention (e.g. the attention and care given to participants by the research team) in a similar fashion to how

placebo drugs work in pharmaceutical trials (Pagoto et al., 2012). Further, there was minimal concern that it would impact the primary clinical outcome because of its non-physical nature. For feasibility trials, it is recommended to use control groups that do not include the active ingredients of the intervention (in this case physical activity). The use of control groups that have active ingredients is inappropriate in small trials because they increase the chance of missing potential treatment effects due to insufficient power. Therefore, they may erroneously lead researchers to decide that it is not worth evaluating the treatment in a larger trial (Freedland, Mohr, Davidson, & Schwartz, 2011; Mohr et al., 2009). The Big Brain program uses similar technology to that of Wii.n.Walk, thus, minimizing placebo effects associated with the use of video games and technology. It is also potentially beneficial and ethically acceptable (Djulbegovic, Cantor, & Clarke, 2003).

6.2.6 Measurements

Demographic and clinical information: demographic (e.g. sex) and clinical information (e.g. amputation cause) were collected to describe the sample (Appendix E). Information on comorbidities was collected for a list of 37 chronic conditions (e.g. diabetes). The total scores ranged from 0 to 37, with higher scores representing a higher number of comorbidities. The Mini Mental State Examination (MMSE) was completed to assess cognitive function (Appendix F). The total scores ranged from 0 to 30, with higher scores indicating higher cognitive function (Argell & Dehlin, 2000; Folstein, Folstein, & McHugh, 1975). We assessed cognitive function because cognitive impairment is relatively common in individuals with LLA and negatively impacts their health outcomes (Coffey, O'Keeffe, Gallagher, Desmond, & Lombard-Vance, 2012). Participants' height and weight were

determined and Body Mass Index (BMI) was calculated (kg/cm^2). Participants were asked to rate their socket comfort score (SCS) on a scale from 0 (the most uncomfortable) to 10 (the most comfortable socket imaginable) (Hanspal, Fisher, & Nieveen, 2003).

Feasibility indicators: feasibility indicators included process, resource, management, and treatment parameters were collected throughout the intervention period and at the end of the trial.

The process parameters were recruitment, enrolment, retention, and Wii.n.Walk group participants' perceived benefit from the intervention. Perceived benefit to participants was explored using an exit questionnaire with questions regarding: if they found the Wii.n.Walk activities useful in improving their walking and/or ability to participate in day-to-day activities; if Wii.n.Walk was easy to use and/or safe; if they felt their walking would have improved more if they had continued using the program; if they would like to continue using the program at home on a regular basis; if the real-time tracking of their motion helped them improve their walking; if they found the feedback given by the software useful; and if the Wii.n.Walk activities made it easier to discuss progress with the trainer or their clinicians. The scores ranged from 0 to 45, with higher scores indicating a greater positive experience. Participants' written and verbal comments were also collected.

The resource indicators measured were in-clinic and in-home treatment adherence rates calculated by the number of sessions completed/the total number of sessions x100.

The management parameters were participant processing, measured by the mean (SD) days taken from enrolment to the start of intervention, and the number (%) of sessions to which the evaluators remained masked.

The treatment parameters were adverse events (e.g. injuries), mean (SD) post intervention self-reported pain and fatigue levels (from 0 to 10), and estimates of the treatment parameters: effect size (measured by Cohen's d) and variance.

Table 6.2 summarizes the feasibility indicators and their criteria for success. Operationally, the criteria for success were selected based on existing indicators when available, such as known standards for adherence and retention rates. For some indicators, we selected success criteria that were relevant to specific measures (e.g. cut-off points for fatigue and pain levels). In other instances where the criteria for success were not available, we subjectively selected the success levels based on what we considered would be feasible (e.g. enrolment rate).

Table 6.2. A detailed description of the feasibility indicators and criteria for success

Feasibility indicator	Evaluation	Success criteria
Process		
Recruitment rate	Mean # recruited per month	2/month
Enrolment rate	(# enrolled / # recruited)*100	≥40%
Retention rate	% with complete data (T_1 to T_3)	≥ 80%
Perceived benefit from Wii.n.Walk intervention	Mean (SD) scores on exit questionnaire (0 to 45)	≥ 35
Resources		
Overall Wii.n.Walk adherence	(#completed sessions/12)*100	≥ 80%
In-clinic Wii.n.Walk adherence	(#completed sessions/6)*100	≥ 80%
In-home Wii.n.Walk adherence	(#completed sessions/6)*100	≥ 80%
Overall control adherence	(#completed sessions/12)*100	≥ 80%
In-clinic control adherence	(#completed sessions/6)*100	≥ 80%
In-home control adherence	(#completed sessions/6)*100	≥ 80%
Management		
Participant processing	Mean (SD) from enrolment to the start of intervention	< 14 days
Evaluator masked	% of evaluations masked	≥80.0%
Treatment		
Intervention adverse events	# adverse events during intervention	
Wii.n.Walk in-clinic		No injuries
Wii.n.Walk in-home		No injuries
Control in-clinic		No injuries
Control in-home		No injuries
Evaluation adverse events		
Wii.n.Walk	# adverse events during evaluation	No injuries
Control		No injuries
Post intervention pain	Mean (SD) score on one-item self-report scale (0 to 10)	
Wii.n.Walk		≤ 5
Control		
Post intervention fatigue	Mean (SD) score on one-item self-report scale (0 to 10)	≤ 5
Wii.n.Walk		
Control		
2MWT treatment effect at T2	Estimate of Cohen's d and variance for sample size calculation	n/a

Clinical outcome measures: outcomes were evaluated at baseline (T1), end of treatment (T2), and three-week retention (T3). A three-week retention was chosen because it was deemed practical for this feasibility trial. Three masked evaluators collected the data. Efforts were made so that the same evaluator collected data for all three timepoints of a participant. If the evaluator became unmasked to the participant's group assignment, the other two masked evaluators completed the data collection for the subsequent sessions. The evaluators were undergraduate students at the University of British Columbia and were trained by myself and using an evaluation manual developed by the study team (Appendix G).

i. Primary

The Two Minute Walk Test (2MWT) was used to measure walking capacity (Appendix H). Starting from a standing position, participants were asked to walk as far as they could for two minutes in an indoor 80-meter flat course. The distance travelled to the nearest meter was recorded. Reliability (Brooks et al., 2002), validity, and responsiveness to change (Mean (SD) =13.6 (19.9) metres) were shown in individuals with LLA (Brooks, Parsons, Hunter, Devlin, & Walker, 2001). Walking capacity was selected as the primary outcome because it is the strongest determinant of health-related quality of life and prosthetic walking in individuals with LLA (van der Schans, Geertzen, Schoppen, & Dijkstra, 2002). The ability to walk longer distances allows the individual to explore independently their environment, which influences their choice of activities and participation (Munin et al., 2001). Walking capacity also determines whether the client is going to maintain wearing their prosthesis or they are going to abandon it (Geertzen, Bosmans, van der Schans, & Dijkstra, 2005). Poor

walking capacity limits the individual's ability to walk with the prosthesis and may eventually lead to prosthetic abandonment (Geertzen, Bosmans, van der Schans, & Dijkstra, 2005). The 2MWT was selected because the Canadian Physical Medicine and Rehabilitation Association's Amputee Special Interest Group (Dudek, Deathe, Devlin, Hebert, & Payne, 2010) and others (Deathe et al., 2009; Stevens, 2009) recommended it as the preferred measure of walking capacity. Moreover, it is used in more trials of individuals with LLA (Bhangu, Devlin, & Pauley, 2009; Gremeaux et al., 2012; Parker, Kirby, & Adderson, 2010) than any other measure, which enables us to compare the effect of our results with previous studies.

ii. Secondary

The Short Physical Performance Battery (SPPB) was used to measure lower limb functioning by capturing timed standing balance (parallel foot stance, semi-tandem, or tandem at 10 seconds each), time taken to complete five sit-to-stand chair transfers, and gait speed over four meters (Appendix I). The total score ranges from 0 to 12, with higher scores indicating higher functions (Guralnik et al., 1994). There is support for reliability and validity in older adults with disability (Freiberger et al., 2012; Ostir, Volpato, Fried, Chaves, & Guralnik, 2002).

The Physical Activity Scale for the Elderly (PASE) is a self-report that captures information on the frequency, duration, and intensity of various physical activities (Appendix J). The total score ranges from 0 to 500, with higher scores representing higher physical activity levels.

Evidence of reliability and validity has been reported for older adults (Washburn, McAuley, Katula, Mihalko, & Boileau, 1999).

The Activities-specific Balance Confidence (ABC) is a self-report to assess perceived balance confidence (Appendix K). The total score ranges from 0 to 100, with higher scores indicating more confidence. Evidence of validity and reliability has been shown for this population (Miller, Deathe, & Speechley, 2003).

Modus Health Stepwatch ^{TM} Activity Monitor (SAM) was mounted on the prosthetic ankle to record number of steps taken per day. It has 99.4% accuracy in individuals with LLA (Coleman, Boone, Smith, Mathews, & Laing, 1998; Modus Health). The SAM data were collected for one week at each evaluation time point.

The Walking While Talking Test (WWT) is a test of cognitive-motor interaction (de Hoon et al., 2003). Participants were timed walking six meters on an indoor flat course, turning around, and walking six meters back to the start. The first time, the participant completed this while reciting the letters of the alphabet (a, b, c, ...) aloud (WWT-simple), and the second time, while reciting alternate letters of the alphabet (a, c, e, …) aloud (WWT-complex). Evidence of reliability and validity has been reported for older adults (Verghese et al., 2002). The WWT was collected with the goal of 'misdirecting' participants and potentially masking the trial objectives (Appendix L).

The Locomotor Capabilities Index in Amputees (LCI-5) is a self-report scale that asks about the participant's abilities to perform different locomotor activities (Appendix M). The total score ranges from 0 to 56, with higher scores indicating greater locomotor capabilities. The LCI-5 has evidence of reliability and validity in individuals with LLA (Franchignoni, Orlandini, Ferriero, & Moscato, 2004).

This trial received approval by the University of British Columbia's ethics board and was registered at clinicaltrial.gov (NCT01715662) on October 15, 2012 (last update on November 27, 2014). The CONSORT (Consolidated Standards of Reporting Trials) 2010 statement with updated guidelines was used for the reporting of this RCT (Schulz, Altman, Moher, & CONSORT Group, 2010).

6.2.7 Statistical analyses

The feasibility indicators for process, resource, management, and treatment were classified as binary (successful/unsuccessful) based on the a priori selected criteria for their success. Successful indicated that the protocol was sufficiently robust (with minimal or no changes required) to proceed with the larger RCT. Unsuccessful indicated that protocol modifications were required before moving forward.

Mean and standard deviation (SD), or frequency and percentage (%), were used to describe the sample and the scores. Post-treatment scores for T2 and T3 in the Wii.n.Walk group were compared against those of the control group using analysis of covariance (ANCOVA), controlling for baseline scores and comorbidities. The number of comorbidities was selected

as a covariate because it is a strong predictor for rehabilitation success in older adults with LLA (Hamamura et al., 2009). The assumptions of ANCOVA (e.g. linearity) were tested. If the assumptions of ANCOVA were not met, transformations (e.g. Log10) were conducted. If transformation did not help, the scores were changed to binary variables and logistic regression was used instead and odds ratios were calculated.

Significance testing (*p*) and descriptive means with 95% confidence intervals were determined. Effect size (Cohen's d) was calculated using standardized marginal mean differences. For transformed data, back transformations were done to estimate the marginal mean values (Howell, 2007). Cohen's d effect size values are defined as: <0.2= trivial effect; 0.2-0.5 = small effect; 0.5-0.8 = medium effect; > 0.8= large effect (Cohen, 1998). The required sample size for a future powered trial was calculated using the sample size calculation formula for ANCOVA in RCTs (α=0.05; β=0.1; ρ=correlation between baseline and end of treatment scores). The calculated sample size was inflated to account for 25% potential dropout rate (Borm, Fransen, & Lemmens, 2007).

Primary analysis of clinical outcomes was based on intention to treat to include all randomized participants in their assigned groups, regardless of whether they received the allocated intervention or not. Missing data were handled using multiple imputation with ten imputations and were reported according to the guidelines of reporting missing data for RCTs (Groenwold, Moons, & Vandenbroucke, 2014). Statistical inferences were based on the pooled effects of the ten imputations (Rubin, 1987). Secondary per protocol analyses were conducted to include those who received and completed the allocated intervention

(Groenwold, Moons, & Vandenbroucke, 2014).

6.3 Results

6.3.1 Demographic and clinical information

Figure 6.2 shows the CONSORT flow diagram for trial participants. Out of the 61 participants approached, 28 (14 per arm) were enrolled and randomized. Two participants from each arm withdrew after randomization but before receiving any intervention. These four participants were all males with mean age of 60.5 (13.0) years old and (n=1 transtibial; n=3 transfemoral). The remaining 24 participants completed their allocated interventions (12 per arm). One participant (66 year old male with transfemoral amputation) in the Wii.n.Walk group missed T3 outcome evaluation due to a pre-existing lung disease that required hospitalization. The mean (SD) age of all randomized participants was 62.1 (1.7) years; 64.3% were male and 53.6% had a transtibial amputation (Table 6.3).

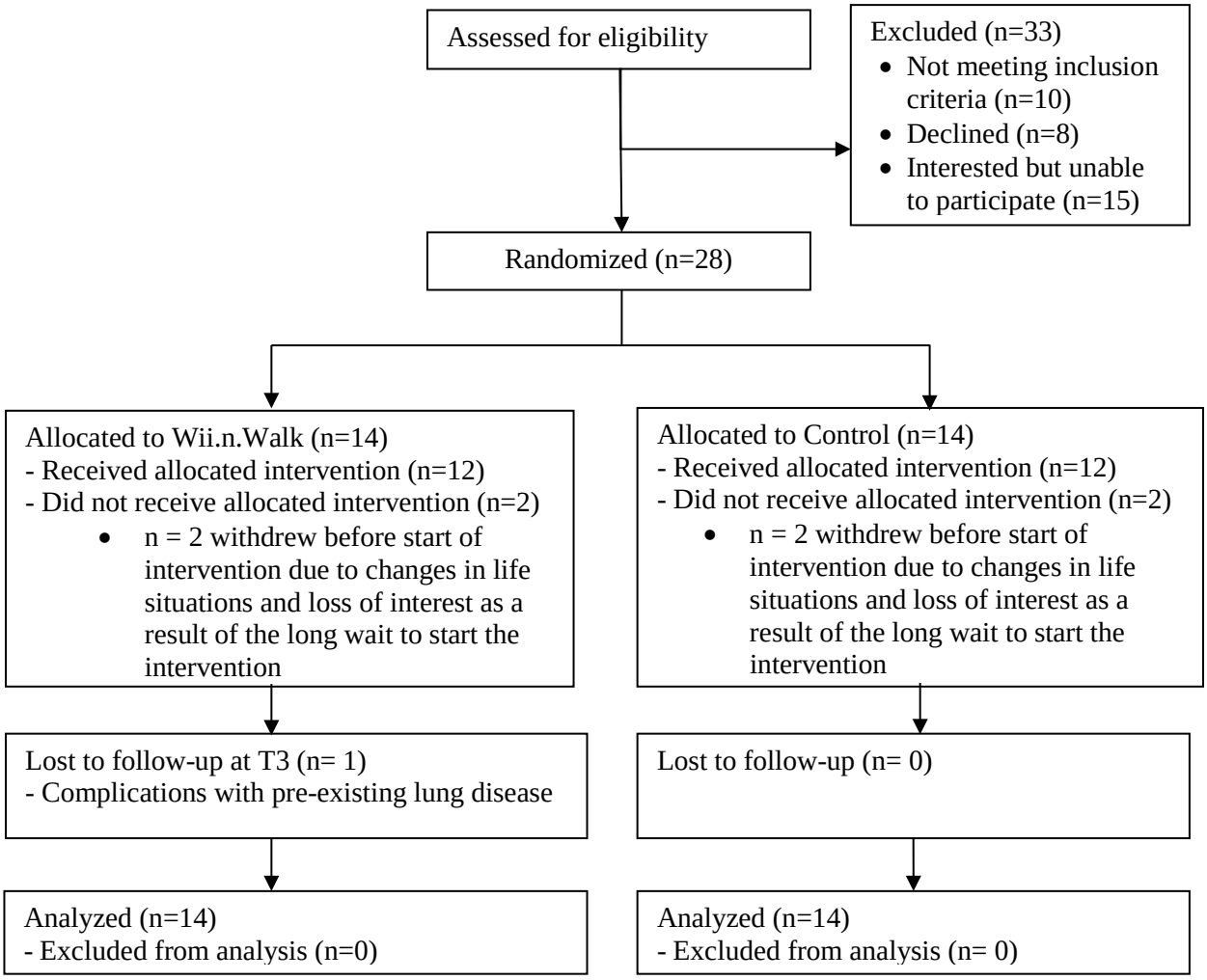

Figure 6.2. CONSORT flow diagram of the trial

Table 6.3. Baseline demographic and clinical information of the participants (n=28)

Participant Characteristics	Wii.n.Walk (n=14)	Control (n=14)	Total (n=28)
Demographic and personal information			
Age, y, mean (SD); range	61.9 (10.2); 50-78	62.3 (8.6); 50-78	62.1 (1.7); 50-78
Sex, no. (%) • Male	12 (85.7)	6 (42.9)	18 (64.3)
Living situation • With someone	12 (85.7)	7 (50.0)	19 (67.8)
Marital status, no. (%) • Married or common law	8 (57.1)	6 (42.9)	14 (50.0)
Education level, no. (%) • HS and lower • Some college • Bachelor's and higher	 5 (35.7) 6 (42.9) 3 (21.4)	 4 (28.6) 6 (42.9) 4 (28.6)	 9 (32.1) 12 (42.9) 7 (25.0)
Employment status, no. (%) • Unemployed or retired or student or volunteer • Employed	 10 (71.4) 4 (28.6)	 9 (64.3) 5 (35.7)	 19 (67.9) 9 (32.1)
Clinical variables			
Years since amputation, mean (SD); range	14.8 (4.6); 1.0-56.4	16.5 (3.8); 2.0-40.7	15.7 (2.9); 1.0-56.0
Amputation level, no. (%) • Transtibial • Transfemoral or knee disarticulation	 7 (50.0) 7 (50.0)	 8 (57.1) 6 (42.9)	 15 (53.6) 13 (46.4)
Cause of amputation, no. (%) • Vascular • Trauma • Cancer	 6 (42.8) 7 (50.0) 1 (7.1)	 6 (32.9) 8 (57.1) 0	 12 (42.8) 15 (53.6) 1 (3.6)
Type of prosthesis, no. (%) • Mechanical • Microprocessor	 12 (85.7) 2 (14.3)	 10 (71.4) 4 (28.6)	 22 (78.6) 6 (21.4)
Socket comfort scale (0-10), mean (SD); range	7.7 (1.6); 4-10	8.1 (1.5); 5-10	7.9 (1.5); 4-10

Participant Characteristics	Wii.n.Walk (n=14)	Control (n=14)	Total (n=28)
Comorbidities (0-37), mean (SD); range	2.9 (2.1); 0-7	4.5 (3.8); 1-12	3.8 (3.2); 0-12
BMI, mean (SD); range	26.8 (4.8); 18.5-33	27.5 (6.7); 20.5-41.1	27.2 (5.8); 18.5-41.1
MMSE (0-30), mean (SD); range	27.8 (2.3); 23-30	28.0 (1.9); 25-30	27.9 (2.1); 23-30

6.3.2 Feasibility indicators

The results for the feasibility indicators are presented in Table 6.4. Mean recruitment was 5 participants per month with 46% of those enrolled. Mean score for the exit questionnaire was 38.9/45 (6.8). Mean wait time from enrolment to the start of the intervention was 33.3 (44.9) days. Overall, Wii.n.Walk intervention adherence was 83.4% (89% for in-clinic and 77.8% for in-home). There were no adverse events. Two participants reported a loss of balance with no fall or resultant injuries during the in-home sessions.

Table 6.4. Results for the feasibility indicators

Feasibility indicator	Success criteria	Result	Success (Yes/No)
Process			
Recruitment rate	2/month	5/month	Yes
Enrolment rate	≥40%	46% (mean 2/month)	Yes
Retention rate	≥ 80%	82%	Yes
Perceived benefit from Wii.n.Walk intervention	≥ 35	38.9 (6.8)	Yes
Resources			
Overall Wii.n.Walk adherence	≥ 80%	83.4%	Yes
In-clinic Wii.n.Walk adherence	≥ 80%	89.0%	Yes
In-home Wii.n.Walk adherence	≥ 80%	77.8%	No
Overall control adherence	≥ 80%	81.3%	Yes
In-clinic control adherence	≥ 80%	95.8%	Yes
In-home control adherence	≥ 80%	76.4%	No
Management			
Participant processing	< 14 days	33.3 (44.9)	No
Evaluator masked	≥80.0%	82.2%	Yes
Treatment			
Intervention adverse events	No		
Wii.n.Walk in-clinic	injuries	None.	Yes
Wii.n.Walk in-home		2 lost balance but no injuries.	Yes
Control in-clinic		None.	
Control in-home		None.	Yes
Evaluation adverse events			Yes
Wii.n.Walk	No	None.	Yes
Control	injuries	None.	Yes
Post intervention pain			
Wii.n.Walk	≤ 5	1.9 (2.3)	Yes
Control		2.4 (2.8)	Yes
Post intervention fatigue			
Wii.n.Walk	≤ 5	3.8 (2.5)	Yes
Control		1.6 (2.5)	Yes
2MWT treatment effect at T2	n/a	Cohen's d = 0.5* or 0.9† Pooled variance = 265.7* or 237.2†	n/a

*** based on intention-to-treat analysis with imputed data; † based on per protocol analysis**

6.3.3 Clinical outcome measures

i. Primary

The ANCOVA results based on intention to treat analyses with imputed data (n=28) are presented in Table 6.5, and the results for per protocol analyses (n=24) are shown in Table 6.6. The mean change scores between the groups, based on intention to treat with imputed data, were 6.5 (baseline to T2), and 7.4 meters (baseline to T3); and change scores, based on per protocol analysis, were 11.3 meters (baseline to T2), and 12.1 meters (baseline to T3). The Cohen's d effect sizes were 0.5 for T2 and 0.6 for T3, based on intention to treat with imputed data; and effect sizes of 0.9 and 1.2, based on per protocol analyses ($p<0.05$). The required sample size ($\rho=0.9$) for a future larger RCT was calculated to be 72 (36 per arm).

ii. Secondary

LCI-5, ABC, PASE, and WWT did not meet the ANCOVA assumptions. LCI-5 and ABC showed ceiling effects, and transformation did not help. As a result, they were collapsed into binary variables, and logistic regression was used instead. The cut-off point for collapsing was chosen so that there were approximately equal distributions below and above the cut-off (≥ 80 and <80 for ABC; ≥ 51 and <51 for LCI-5). For the PASE and WWT tasks, transformation helped the data to meet the assumptions; and, therefore, ANCOVA was used on the transformed data.

Of the secondary outcomes, only the Wii.n.Walk group showed improvement ($p<0.05$ for the WWT tasks based on per protocol) on the walking measures (number of steps per day and WWT tasks) (Tables 6.5 and 6.6).

Table 6.5. Mean (SD) and effect sizes for primary and secondary clinical outcomes, based on intention-to-treat analyses with imputed data (n=28)

Outcome	**Wii.n.Walk group**			**Control group**			**F statistic** (1,24)		**Cohen's d** ***(standardized marginal mean difference)***	
Primary	T1 Mean (SD)	T2 Mean (SD); *95% CI*	T3 Mean (SD); *95% CI*	T1 Mean (SD)	T2 Mean (SD); *95% CI*	T3 Mean (SD); *95% CI*	T2-T1	T3-T1	T2-T1	T3-T1
2MWT (meters)	141.1 (44.0)	146.3 (44.5); *(121.1,171.5)*	148.5 (47.4); *(120.5, 176.5)*	133.3 (43.5)	131.9 (41.5); *(108.4,155.4)*	133.3 (42.0); *(109.5, 157.1)*	1.8	2.5	0.5	0.6
Secondary										
PASE (0-500)	129.1 (107.6)	167.3 (114.7); *(102.4, 232.2)*	150.0 (117.3); *(80.1, 219.3)*	148.5 (108.4)	169.9 (117.2); *(103.6, 236.2)*	155.9 (103.8); *(97.2, 214.6)*	0.004	0.02	0.01	0.02
SAM (mean #steps/ day)	2208 (1045)	2576.7(1246.7); *(1871.2,3282.1)*	2261.0 (1194.4); *(1555.2, 2966.8)*	1730.5 (942.0)	1988.8 (1182.2); *(1319.9, 2657.7)*	1445.2 (940.3); *(913.2, 1977.2)*	0.2	2.3	0.2	0.6
WWT-simple (sec)	14.1 (4.5)	14.0 (5.0); *(11.2, 16.8)*	13.9 (6.0); *(10.4, 17.5)*	15.5 (7.0)	16.3 (7.2); *(12.2, 20.4)*	16.4 (7.2); *(12.3, 20.5)*	2.5	1.5	0.5	0.4
WWT-complex (sec)	16.2 (5.5)	15.2 (4.8); *(12.5, 17.9)*	15.8 (5.1); *(12.8, 18.8)*	16.9 (7.7)	18.4 (8.7); *(13.5, 23.3)*	18.3 (7.3); *(14.2, 22.4)*	4.2	1.8	0.7	0.5

Outcome	**Wii.n.Walk group**			**Control group**			**F statistic** $_{(1,24)}$		**Cohen's d** ***(standardized marginal mean difference)***	
SPPB (0-12)	7.9 (2.7)	7.8 (2.3); *(6.5, 9.1)*	7.7 (2.6); *(6.2, 9.2)*	5.7 (2.5)	7.2 (2.5); *(5.8, 8.6)*	6.7 (2.6); *(5.2, 8.2)*	2.6	0.8	-0.5	-0.3
ABC (0-100)	78.9 (13.0)	80.5 (12.2); *(73.6, 87.4)*	81.4 (16.8); *(71.5, 91.3)*	76.7 (19.6)	77.6 (23.8); *(64.1, 91.1)*	82.1 (20.1); *(70.7, 93.5)*	0.9	1.3	*OR:* *1.0	*OR:* 1.0
LCI-5 (0-56)	49.8 (6.4)	49.9 (7.1); *(45.9, 53.9)*	50.7 (7.7); *(46.2, 55.3)*	48.7 (8.7)	50.8 (7.5); *(46.6, 55.0)*	50.1 (7.6); *(45.8, 54.4)*	1.0	1.0	*OR:* 1.0	*OR:* 1.0

***OR=Odds ratio**

PASE, WWT-simple, and WWT-complex data were transformed for analyses and then back transformed for results.

Table 6.6. Mean (SD) and effect sizes for primary and secondary clinical outcomes, based on per-protocol analysis (n=24)

Outcome	**Wii.n.Walk group**			**Control group**			**F statistic** (1,20)		**Cohen's d** ***(standardized marginal mean difference)***	
Primary	T1 Mean (SD)	T2 Mean (SD); *95% CI*	T3 Mean (SD); *95% CI*	T1 Mean (SD)	T2 Mean (SD); *95% CI*	T3 Mean (SD); *95% CI*	T2-T1	T3-T1	T2-T1	T3-T1
2MWT (meter)	139.5 (47.1)	147.6 (48.2); *(120.3, 174.9)*	149.9 (53.7); *(118.2,181.6)*	133.9 (47.2)	130.7 (44.9); *(105.3, 156.1)*	132.2 (45.3); *(106.6, 157.8)*	4.4*	7.1*	0.9	1.2
Secondary										
PASE (0-500)	120.7 (113.5)	167.1 (124.5); *(96.7, 237.5)*	148.1 (133.7); *(69.1, 227.1)*	155.2 (115.8)	170.8 (127.3); *(98.8, 242.8)*	156.4 (112.7); *(92.6, 220.2)*	0.02	0.05	0.1	0.1
SAM (mean # steps/ day)	2128 (1072)	2623.5 (1348.4); *(1860.6, 3386.4)*	2373.3 (1337.0); *(1583.2, 3163.4)*	1681.7 (1015.0)	1939.8 (1278.4); *(1216.5, 2663.1)*	1378.3 (1005.2); *(809.6, 1947.0)*	0.5	1.9	0.3	0.6
WWT-simple (sec)	14.3 (4.7)	13.9 (5.3); *(10.9, 16.9)*	13.4 (7.1); *(9.2, 17.6)*	15.6 (7.5)	16.5 (7.7); *(12.1, 20.9)*	16.6 (7.7); *(12.2, 21.0)*	5.3*	3.5†	1.0	0.8
WWT-complex (sec)	16.7 (5.7)	15.1 (5.1); *(12.2, 18.0)*	15.5 (5.6); *(12.2, 18.8)*	16.7 (8.3)	18.4 (9.3); *(13.1, 23.7)*	18.4 (7.8); *(14.0, 22.8)*	6.2*	4.6*	1.1	1.0

Outcome	**Wii.n.Walk group**			**Control group**			**F statistic** (1,20)		**Cohen's d** ***(standardized marginal mean difference)***	
SPPB (0-12)	7.8 (2.8)	7.8 (2.5); *(6.4, 9.2)*	7.8 (2.9); *(6.1, 9.5)*	5.8 (2.6)	7.2 (2.6); *(5.7, 8.7)*	6.5 (2.7); *(5.0, 8.0)*	2.6	0.5	-0.7	-0.3
ABC (0-100)	78.8 (14.0)	80.5 (13.1); *(73.1, 87.9)*	81.2 (19.0); *(70.0, 92.4)*	76.8 (21.2)	77.6 (25.5); *(63.2, 92.0)*	82.1 (21.8); *(69.8, 94.4)*	0.18	1.0	*OR:* ‡ 0.7	*OR:* 1.3
LCI-5 (0-56)	49.2 (6.6)	49.8 (8.2); *(45.2, 54.4)*	50.8 (6.5); *(47.0, 54.6)*	48.7 (9.4)	50.7 (8.0); *(46.2, 55.2)*	49.8 (8.2); *(45.2, 54.4)*	0	0.07	*OR:* 1.0	*OR:* 1.3

*** p<0.05; † approached significance**

‡ OR=Odds ratio

PASE, WWT-simple, and WWT-complex data were transformed for analyses and then back transformed for results.

6.4 Discussion

6.4.1 Feasibility indicators

Success was achieved on 17 of 20 feasibility indicators, demonstrating that with minor modifications the protocol is sufficiently robust to proceed with the larger RCT. Participants that received at least one session of their allocated intervention remained in the trial and completed the intervention. Four participants withdrew before the start of their allocated intervention because of the long wait time between enrolment and the start of intervention. The wait time was the consequence of randomizing individually and sometimes it took a long time to enrol and randomize three participants to the same arm. Therefore, some participants lost interest in participating, or their life situations changed during the wait time. One solution to this problem is to randomize participants in triplets. Although this might alleviate the problem, group training can still be challenging because of the efforts required to schedule three participants to the same training time. Our experience showed that participants preferred different time slots depending on their family/work/transportation situations, which further complicated scheduling the group sessions. This issue begs the question of whether or not group training is worth the effort. From the healthcare perspective, group training offers numerous benefits including lower costs, peer-based learning, and social interaction. However, there is an inevitable trade-off between these added benefits and the associated feasibility issues that should be taken into consideration.

The results of the exit questionnaire suggested that the majority of participants perceived the Wii.n.Walk intervention useful in improving their walking, and they would have liked to

continue using the equipment at home on a regular basis. This finding provides support for our discussion in Chapter 5 that, in contrast to the stereotype that older adults do not like or are unable to use video games, they do actually show an interest and are capable of learning the games if enough training is provided. In another study, more than 80% of older adults wished to continue Wii Fit training at home (Chan et al., 2012). In a study of individuals with neurological disorders, 90% desired the Wii Fit to be included in their rehabilitation (Meldrum, Glennon, Herdman, Murray, & McConn-Walsh, 2012). Similarly, individuals with multiple sclerosis perceived the Wii Fit activities as having positive effects on their walking (Forsberg, Nilsagård, & Boström, 2014). Satisfaction and positive perception are linked to adherence (Hagberg, Lindahl, Nyberg, & Hellénius, 2009; Lewis, Woods, Rosie, & McPherson, 2011). The overall adherence was high in our trial (≥80%), supporting this notion. The in-home adherence was slightly lower than the in-clinic adherence. Participants' feedback revealed that they preferred the group and supervision elements of training in-clinic, but they liked the convenience and accessibility of the in-home training. It seems plausible that a form of tele-rehabilitation that enables in-home training of groups of participants might present a suitable solution. Ideally, this solution might offer remote supervision in order to provide participants with instruction and feedback about their posture/technique.

The calculated required sample size of 72 seems feasible for the next efficacy RCT. According to the recruitment/enrolment rates observed in this study, it should take about 2.6 years to recruit and enrol 72 participants. This estimated enrolment time may be reduced through the modifications that we suggested earlier about randomizing in triplets.

Furthermore, the recruitment/enrolment rates can be improved through conducting a multi-site trial.

6.4.2 Clinical outcome measures

i. Primary

The results of our study showed improvement in walking capacity for both T2 and T3 end points in the Wii.n.Walk group, whereas the control group performance declined. The intention to treat analysis with imputed data showed medium effect sizes for both T2 and T3 walking capacity scores, while the per protocol analysis showed large and statistically significant effect sizes ($p<0.05$). The improvement in walking capacity was consistent with preliminary findings (Imam, Miller, McLaren, Chapman, & Finlayson, 2013). In a trial with older adults with LLA being discharged from rehabilitation (Brooks, Parsons, Hunter, Devlin, & Walker, 2001), the responsiveness of the 2MWT was 13.6 meters (SD=19.9). In another RCT with younger community-living individuals with LLA (Rau, Bonvin, & de Bie, 2007), the mean difference between the groups after an exercise program was 11.2 meters (SD=18.4). In our trial, as our population was older and community-living, a smaller room for improvement was expected compared to studies that included young inpatient/outpatient individuals with LLA. Nonetheless, our mean change scores based on per protocol analyses (11.3 meters for T2 and 12.1 for T3) were comparable to these published change score values. The intention to treat analyses with imputed data, however, showed smaller magnitudes (6.5 meters for T2 and 7.4 for T3).

As this was a feasibility trial, and our sample size was small, the imputation of the missing data for the four individuals who did not receive any intervention was stringent and perhaps increased susceptibility to type II error (Armijo-Olivo, Warren, & Magee, 2009). Some might argue that, given the nature of this trial, imputing data for these four individuals is inappropriate because this approach would then analyze the effect of "treatment assigned" rather than the "treatment received" (Armijo-Olivo, Warren, & Magee, 2009). Since the purpose of this trial was to explore feasibility and the "potential" treatment effect under ideal conditions (rather than if the treatment actually works), it may be more appropriate to only analyze the data based on individuals who actually received the intervention (i.e. per protocol analysis) (Armijo-Olivo, Warren, & Magee, 2009). Moreover, since the rates and reasons for dropouts were similar for both groups and not related to the treatment (e.g. adverse event), the missing data is unlikely to have biased the estimate of the treatment effect. However, in this trial, we decided to present the results based on both intention to treat with imputed data and per protocol analyses for the purpose of completeness and also because it is recommended by the CONSORT 2010 statement for reporting of RCTs (Schulz, Altman, Moher, & CONSORT Group, 2010). Regardless of the analysis method, the observed improvement in walking capacity in the Wii.n.Walk group is promising. Since the ideal goal of prosthetic rehabilitation is independent prosthetic ambulation (Munin et al., 2001), the augmentation of Wii.n.Walk into participants' rehabilitation or prescription for use after discharge may help clients reach this goal.

ii. Secondary

Consistent with improvement in walking capacity, the rest of our walking outcomes (number of steps per day and WWT) showed improvement in favour of the Wii.n.Walk group. Although the difference was small, the Wii.n.Walk participants clearly took more steps.

It is interesting that the differences in WWT tasks were also in favour of the Wii.n.Walk group (large statistically significant effect sizes), despite the fact that it was the control group that received cognitive training. It may be plausible to suggest that Wii Fit improved cognitive-motor interactions, as it required participants to follow visual and auditory instructions and perform the required exercises simultaneously.

Although LCI-5 has been recommended for use in individuals with LLA (Dudek, Deathe, Devlin, Hebert, & Payne, 2010), it showed a ceiling effect with the mean of 49+/ 56, which suggests that it may not be sensitive enough to detect change for community-living ambulators. No change or small improvement was observed in the rest of secondary outcomes. Since walking capacity was improved in this study and because of the evidence that balance and walking capacity are highly correlated (Van Velzen et al., 2006), it was expected to see improvements in balance as well. The lack of improvement in balance could be because the intervention did not have any effect. It may also be due to the possible lack of responsiveness to change of our balance outcome measurements in this population. Due to the paucity of validated outcome measures for community living amputees, it is challenging to select appropriate outcome measures for this population. Prior to this study, we trialed

different validated balance measures such as the Berg Balance Scale in order to find the most suitable outcome measure for this population; however a responsive balance outcome measure was not found as all measures showed ceiling effects. As a result, we highlight the importance of future studies to develop and validate measures that are responsive to change and are specific to community living older adults with LLA.

6.4.3 Limitations

This trial had a number of limitations. As this was a feasibility trial, a practical volunteer sample size was selected. The primary goal of this trial was to assess the feasibility of Wii.n.Walk to inform the design of a larger RCT as opposed to drawing conclusions about its efficacy. Our sample included only older adults with unilateral LLA. Masking was a challenge as participants liked to talk about their training with the evaluators, despite having been told not to reveal their group status. We randomized participants individually to minimize between-cluster variations, which occurs with group randomizations. However, this resulted in a longer time to randomize three participants to the same arm that could also attend the same training time. In a future trial, randomization should be conducted in triplets, and between-cluster variations should be adjusted for at analyses. Nonetheless, the challenges of group training should be taken into consideration. Since the retention follow up was short in this study, we cannot comment if the usage of Wii.n.Walk continues long term. Future work should consider longer retention follow-up and, perhaps, leaving the Wii units at the participants' home for a longer period to see if usage changes. One missed opportunity in this clinical trial was the implementation of a mixed-method design. The collecting of qualitative data would have contributed to our understanding about clients' perception about

their outcome improvement, satisfaction with and acceptability of the intervention, and other feasibility parameters from the clients' perspectives. Although in this study we collected quantitative data on clients' opinions about the Wii Fit intervention, future qualitative studies are required to further explore the feasibility of the use of the Wii Fit from clients' perspectives.

6.5 Conclusions

Wii.n.Walk appeared to be a feasible approach with a medium effect size for improving walking capacity in older adults with LLA. Given this finding, 72 (36 per arm) participants are required for a future powered RCT to evaluate efficacy. Participants' feedback revealed that they enjoyed the intervention and found it useful for improving their walking capacity. Participants preferred supervised group training but also liked the convenience and accessibility of training at home. A future powered RCT focused on efficacy and cost-effectiveness is warranted.

7 Overall Discussion, Synthesis and Future Directions

7.1 Overview

Lower limb amputation (LLA) is a disabling condition affecting the functional independence and quality of life of the individuals (Horgan & MacLachlan, 2004). LLA is costly to the healthcare system due to the loss of mobility and independence of the individuals as well as the number of in-hospital stay days required for recovery and rehabilitation (Dawes, Iqbal, Steinmetz, & Mayo, 2010). In Western countries, LLA is primarily the consequence of complications associated with diabetes and vascular disease (Lusardi & Nielsen, 2007). With the aging population and the exponential growth in the rate of diabetes, the number of individuals living with LLA is expected to increase in Western countries (Lusardi & Nielsen, 2007; Ziegler-Graham, Mackenzie, Ephraim, Travison, & Brookmeyer, 2008). LLA is recognized globally as a public health issue and efforts have been directed to understand its incidence and etiology around the world in order to optimize preventive, health, and rehabilitative services (Ephraim, Dillingham, Sector, Pezzin, & Mackenzie, 2003). In Canada, there is a dearth of evidence-based data about LLA, particularly around incidence, current practices, and rehabilitation. Without having accurate incidence and rehabilitation data, we are not able to determine the burden of LLA on the Canadian healthcare system and nor can we make any informed healthcare decisions about preventive and rehabilitative services (Johannesson et al., 2009). With the aging population, limited resources, and the increasing demand for rehabilitation, it is important to understand the current services that are being provided across the country so we can promote best practices while trying to minimize the healthcare costs. The purpose of this dissertation was to fill in the gaps in the

literature about the incidence, current practices, and rehabilitation of LLA in Canada as well as to design and evaluate an augmentative intervention that can be delivered in groups of three in the clinic and at clients' home at a low cost. In this Chapter, I will provide the strengths of this dissertation, synthesis and discussion of key findings, implications, limitations, and potential future directions.

7.2 Strengths of this research

This dissertation is the first study to determine:

The incidence of LLA in Canada and the ten provinces: in this population-based study we used the most recent 6-year record-level hospital admission data from the Canadian Institute of Health Information (CIHI) to accurately count the new cases of LLA in Canada. We reported the incidence level by age, sex, level, and cause of LLA which are important variables associated with LLA. We also looked at regional differences across Canada as well as temporal changes in the incidence rates. We reported incidence data on all levels of LLA including from hip and pelvis to foot and toe amputations. The majority of the previously published studies for other countries only reported on the incidence of LLA from above the ankle with excluding foot and toe amputations. Because foot and toe amputations comprise more than 40% of the LLAs, their exclusion results in an inadequate estimate of the incidence of LLA (Dawes, Iqbal, Steinmetz, & Mayo, 2010; Dillon, Kohler, & Peeva, 2014; Jeffcoate, 2005). Our results on the incidence of LLA for all levels and causes provide accurate foundational knowledge for determining the size of the problem in Canada.

The provision of inpatient rehabilitation services in Canada: we calculated the percentage of individuals with major LLA who receive inpatient rehabilitation services in Canada as well as the length of their stay and their functional status at the time of discharge. We used the most recent 6-year population-based data from the CIHI to determine the temporal change in admission of clients to inpatient rehabilitation services. This allowed us to understand LLA rehabilitation services from the inpatient side, which is the most costly and resource-intensive form of rehabilitation delivery. The temporal change data helped us determine whether there have been any changes in admission of clients to inpatient rehabilitation services in response to the increase in the healthcare costs and the aging population.

The state-of-the-art of lower limb prosthetic rehabilitation practices in Canada: we used a nation-wide online survey to learn about the current prosthetic rehabilitation practices and rehabilitation delivery services in Canada. Survey studies are powerful tools for understanding service provision from a national perspective. With the current contextual shift from hospital-based to community-based rehabilitation in an effort to reduce the healthcare costs, it is important to understand how prosthetic rehabilitation is being done in Canada. Having a conceptual understanding of current rehabilitation service delivery and practices is imperative to the use and adoption of sustainable evidence-based practices.

The use of commercial games for lower limb prosthetic rehabilitation: we used a national survey to explore how widely commercial games are currently being used in lower limb prosthetic rehabilitation in Canada. This dissertation is also the first that has elicited therapists' opinions about the use of these games in lower limb prosthetic rehabilitation.

The feasibility of an RCT to evaluate the Wii Fit for prosthetic rehabilitation: despite the popularity and the use of the Wii Fit in prosthetic rehabilitation, evidence for feasibility and efficacy was lacking. This study generated some evidence for the use of the Wii Fit as a potential augmentative intervention for lower limb prosthetic rehabilitation.

7.3 What are the key findings, synthesis, and implications?

In Chapter 2 we showed that the overall age-adjusted rate of LLA in Canada is 22.9 per 100,000 individuals. This indicated that the incidence of LLA in Canada is larger than some of the Western countries such as Netherlands that has an incidence of 8.8 per 100,000 (Fortington et al., 2013) and smaller than others such as Ireland that has an incidence of 92.5 per 100,000 (Buckley et al., 2012). The difference in LLA incidence rates across the globe may reflect differences in health, obesity and smoking rates, and diabetes prevention and management strategies (Buckley et al., 2013; Nielsen & Lusardi, 2007). However, the results should be interpreted with caution because different methodologies (e.g. crude versus age-adjusted) and denominator (e.g. total population versus population at risk) have been used across the studies for calculating the incidence rates (Fortington et al., 2013). In this study, since the aim was to primarily determine the burden of the disability on the healthcare system we calculated the incidence rates based on 'total population'. We also derived the incidence rates for 'population at risk' by calculating the incidence rate in individuals with diabetes in order to understand the role of diabetes in the incidence of LLA in Canada and to compare our results with the studies that have presented the incidence rates for diabetic populations.

The results for temporal changes in the incidence rates showed that despite the fact that both crude and age-adjusted rates of LLA have declined in Canada over the six study years, the number of LLAs has actually increased. A likely explanation for this finding as stated in Chapter 2 is the difference between ‘absolute number’ and ‘rate’. Absolute numbers only count the number of LLAs; however rates involve dividing the absolute number by the population size. As a result, although there has been a growth in the absolute number of LLAs in Canada over the study years, since the Canadian population particularly for older age categories has grown much faster than the number of LLAs, the rate of LLA has declined. The finding that the slope of the increase in the number of LLA is not as steep as that for the aging Canadian population is encouraging and perhaps is attributable to early diabetes detection, awareness efforts, and chronic disease management. Nonetheless, the increase in the number of LLAs has important implications for the rehabilitative and health services that are required for this growing population. Our results showed that diabetes and vascular disease remain to account for about 60% of the LLA cases in Canada as well as conferring a relative risk of 28.9. Hence, efforts on diabetes and chronic disease prevention, health education, screening and early diagnosis, treatment and foot care management should increase (Dillon, Kohler, & Peeva, 2014; Gamba, Gotlieb, Bergamaschi, & Vianna, 2004; Johannesson et al., 2009). These programs should become integrated into public health services and be available to the individuals at risk (Dillon, Kohler, & Peeva, 2014; Gamba, Gotlieb, Bergamaschi, & Vianna, 2004).

Implications: Healthcare policy makers, clinicians, researchers, and the government need to be informed about the continued growth in the number of LLAs in Canada and the resultant increase in the demand for rehabilitative and health services. These services should be evidence-based, cost-effective, and accessible to individuals with LLA. Efforts on diabetes prevention, early detection, and management should also be optimized in order to decrease the number of future LLAs.

Chapters 3 and 4 shed light on LLA service provision and current practices across Canada. The results for the national survey in Chapter 4 indicated that the majority of prosthetic rehabilitation facilities in Canada provide both inpatient and outpatient prosthetic rehabilitation to clients with LLA; however the findings for the population-based study in Chapter 3 showed that inpatient rehabilitation services are only received by 18% of individuals with major LLA in Canada. The provision of inpatient rehabilitation services found in this study is slightly higher than other published studies in other countries. In the United States (US), the LLA inpatient rehabilitation provision is reported to be 15% for trauma-related cases and 9.6% for vascular cases (Dillingham, Pezzin, & Mackenzie, 1998; Dillingham, Pezzin, & Mackenzie, 2002). Our finding that only a small proportion of individuals with LLA receive inpatient rehabilitation may be because of the cost and resource constraints associated with inpatient rehabilitation. We discussed in Chapter 1 that there has been a contextual shift in rehabilitation service delivery from inpatient to community-based rehabilitation in order to reduce the healthcare costs. In fact, a study conducted in the US reported that the period of inpatient rehabilitation for LLA has been mostly eliminated because of the costs (Meier, & Heckman, 2014). As a result, our finding of low inpatient

provision highlights the need for cost-effective and accessible models of rehabilitation delivery for this population.

Implications: Less than a quarter of individuals with major LLA receive inpatient rehabilitation in Canada. The low provision of inpatient rehabilitation services may be because of the associated high costs and resource demand. Novel, cost-effective and community-based rehabilitation strategies that require less reliance on therapists may help improve access and provision of rehabilitation services. These strategies may augment existing rehabilitation services to ensure optimal rehabilitation is provided to the individuals for improving or sustaining their functional independence and quality of life.

As discussed earlier, with the increasing healthcare costs, the shift from hospital-based to community-based rehabilitation, and the low provision of inpatient rehabilitation services in Canada, the solution may lie in developing home-based interventions using commercial games that allow clients to transition quicker from dependent acute settings to independent home settings. Home-based interventions have numerous benefits, including empowering clients, requiring less reliance on therapists, and being more cost-effective and accessible (Dalal, Zawada, Jolly, Moxham, & Taylor, 2010; Mahomed et al., 2008).

Commercial games, particularly the Wii Fit, hold a great promise for use as a rehabilitation tool (Ravenek, Wolfe, & Hitzig, 2015). Commercial games are prevalent and popular, and therefore are more likely to be adopted as a form of physical activity. In the US alone, 150 million people play video games; of which 42% play regularly (Entertainment Software

Association, 2015). In Canada, 62% have at least one video gaming console at home (Entertainment Software Association of Canada, 2014). Even among older adults (>55 years old) who are traditionally viewed as disinterested or unwilling to play video games, 34% play video games in Canada (Entertainment Software Association of Canada, 2014). Thus, integrating video games into clients' rehabilitation may be a viable option for improvement or retention of function in both younger and older adults with LLA.

The results of the survey study in Chapter 5 showed that therapists in Canada commonly use commercial games, especially the Wii Fit, as a means of providing LLA rehabilitation in clinic or at participants' home. This confirms the findings from a recent scoping review that showed Wii Fit is widely used by therapists for rehabilitation across several different client populations (Ravenek, Wolfe, & Hitzig, 2015). Therapists in our study expressed generally positive attitudes towards using the Wii Fit in practice as well as recommending it to their clients as an in-home rehabilitation. Therapists indicated that they view the Wii Fit games as self-motivating and having the potential to complement existing therapy. Previous reports corroborate our findings. In a study that used the Wii Fit for rehabilitation in individuals with multiple sclerosis, therapists reported that using the Wii Fit was fun and self-motivating for their clients and viewed as a useful addition to existing therapy (Forsberg, Nilsagård, & Boström, 2015).

Implications: Wii Fit has been adopted and is currently being used by therapists in Canada for providing prosthetic rehabilitation to clients with LLA. Therapists generally view these games positively with having potential to become an integral part of clients' rehabilitation in clinic or at home to improve their functional outcomes. Despite the widespread use of Wii Fit in LLA rehabilitation, robust evidence for its efficacy is still lacking. Randomized controlled trials should be conducted to evaluate the efficacy of the Wii Fit in LLA rehabilitation.

In Chapter 6, we developed, Wii.n.Walk, a Wii Fit based rehabilitation program guided by Social Cognitive Theory. Social Cognitive Theory is a useful theory for understanding behaviour changes and has provided the foundation of several effective interventions for improving health-related outcomes and chronic disease managements (Basen-Engquist et al., 2011; Brassington, Atienza, Perczek, DiLorenzo, & King, 2002; Stacey, James, Chapman, Courneya, & Lubans, 2015). The first half of the training was supervised in the clinic and conducted in groups of three with the goal of peer modeling, social interaction and social support, and improving learning via vicarious learning and enhancing self-efficacy (Bandura, 1997). The training was initiated in the clinic so that participants could learn the activities in a safe and monitored environment, and meet the trainer and the group participants. The second half of the training occurred at participants' home with minimal supervision from the trainer.

Implications: Wii.n.Walk uses the principles of Social Cognitive Theory and may improve outcomes via enhancing self-efficacy. The use of group training for LLA rehabilitation may not only add the elements of vicarious learning and social interaction but also be more cost-effective and less resource intensive than the traditional 1:1 training model.

We conducted a feasibility RCT to evaluate the use of Wii.n.Walk for rehabilitation in older adults with LLA. Additionally, we evaluated the potential treatment effect of Wii.n.Walk compared with a cognitive-training control group. Our results showed that Wii.n.Walk is a feasible approach and has potential for improving walking capacity. Our high retention and adherence rates indicated potential for successful uptake of the Wii.n.Walk program by clients. Every participant who at least received one session of the intervention remained in the study and completed the intervention. The four participants that did not complete the study, withdrew prior to the start of the intervention. The reason for these participants' withdrawal was not related to the intervention, but rather related to the pragmatics of group training. Because we randomized each participant individually as they enrolled in the study, sometimes depending on our recruitment success, it took us many weeks before we enrolled and randomized three participants to the same arm. This wait time resulted in frustration and loss of interest for some participants as their eligibility and availability (e.g. socket fit, family situations) changed over the period of waiting time. The lesson learned for future study is to randomize in triplets so that all three participants are randomized to one arm. Although this will alleviate the problem, it will not entirely solve it as group training requires all three participants to attend the same training time which may be hard to coordinate due to participants' different availabilities. As a result, although group training has numerous health

benefits it is associated with inevitable feasibility issues that need to be taken into consideration.

Implications: Future RCTs with group-based interventions should consider randomizing participants in clusters to decrease the wait time from randomization to the start of intervention. Although group training has numerous benefits for the individuals and the healthcare system, the associated feasibility issues should be taken into consideration when designing such interventions.

The 100% retention rate for participants who received the intervention as well as the results for the exit questionnaire suggested that participants enjoyed the intervention. In fact, once the study was completed, many participants approached us to find out how they can purchase the games in order to continue training at home. This finding may indicate that in contrast to the stereotype that older adults do not enjoy or incapable of using video games, they do express an interest and are able to learn the games once enough training is provided (Entertainment Software Association, 2014). Previous studies reported similar results. In a study that used the Wii Fit for providing rehabilitation in older adults, more than 80% of participants wished to continue training at home (Chan et al., 2012). Similarly, a scoping review on usability and acceptability of exercise video games, including the Wii Fit, in older adults' rehabilitation indicated that the games are generally well perceived by older adults (Nawaz et al., 2015). Our experience showed that although there was an initial reluctance and perceived lack of confidence by participants in their ability to learn the games, almost all learned how to use the games and became comfortable with using it after two-three training

sessions. We learned that it is imperative to provide enough training with clear and simplified instructions in order to avoid potential frustration and loss of interest associated with technology use. In our study although the overall adherence was high, adherence for home sessions was slightly lower than that for the clinic sessions. Participants' feedback revealed that they preferred the group training aspect of the in-clinic sessions because exercising with peers increased their motivation and interest to participate in physical activity. On the other hand, they enjoyed the convenience of doing their training at home and avoiding commuting to the rehabilitation centre. This suggests that telehealth solutions that allow home-based training and remote supervision and group training might be ideal.

Implications: Adequate training with streamlined and clear instructions is important when teaching older clients how to use technology. This will help minimize fear of technology that may exist among older adults. Unlike the common belief that older adults dislike video games or are unable to learn how to use them, with proper training they learn and enjoy the games. Participants reported positive experiences with the Wii.n.Walk program and perceived it as an enjoyable and useful approach for improving their outcomes. Our results showed that participants prefer group training over individualized training while they enjoy the convenience of training at their home. Future studies should explore telehealth options for home-based programs that allow group training and remote supervision.

Although the primary objective of this RCT was to look at feasibility, we also explored the treatment effect and preliminary efficacy in this study. Investigating treatment effect would be essential for future trials' sample size determination. Our intention to treat analysis with

the inclusion of all randomized participants showed a medium effect size for Wii.n.Walk for improving walking capacity. On the other hand, the per protocol analysis showed a large and a statistically significant treatment effect. This is perhaps attributable to the fact that in intention to treat analysis we needed to include the four participants who withdrew prior to the start of the intervention and use statistical software to impute the missing data. Although we used Multiple Imputation, which is the most robust form of missing data imputation, imputing data can never replace the real data values. Nonetheless, analyses by both per protocol and intention to treat showed improvement in walking capacity in the Wii.n.Walk group compared with the control. Therefore, this study showed preliminary evidence for the efficacy of Wii.n.Walk for improving walking capacity in older adults with LLA. This finding is encouraging as walking capacity is the strongest determinant of quality of life and the best predictor of prosthetic mobility in this population (van der Schans, Geertzen, Schoppen, & Dijkstra, 2002). Interventions that can improve clients' walking capacity may not only improve the clients' quality of life and prosthetic walking but also improve activities and participation levels (Munin et al., 2001; van der Schans, Geertzen, Schoppen, & Dijkstra, 2002). Future research is required to evaluate the long-term use of the Wii.n.Walk and the impact on walking capacity. Since this was a feasibility trial, our retention follow up was only three weeks long. Future studies should explore if usage and outcome are sustainable over a long period of time. Out of our secondary outcomes, only prosthetic use (i.e. the number of steps per day) and walking while talking tests showed improvement (though not statistically significant) in favour of the Wii.n.Walk group. The lack of statistical improvement in the secondary outcomes could be due to the lack of power to detect

difference or suggests that the intervention did not have an effect on these outcomes. Future larger studies are required to adequately evaluate the efficacy of the Wii.n.Walk.

Implications: Wii.n.Walk is feasible with a medium effect size and potential for improving walking capacity in older adults with LLA. Seventy two (36 per arm) participants are required for the future powered RCT for evaluating efficacy. More research is needed to understand the long-term use of Wii.n.Walk in the community.

7.4 Limitations of this research

There were limitations associated with this research. The population-based epidemiological and survey studies presented in this dissertation are Canadian based and therefore the results are not generalizable to other countries. Nonetheless, these national studies are helpful to inform LLA rehabilitation practices in Canada.

Chapter 2 provided some evidence for the epidemiology of LLA in Canada. Although we were able to determine the incidence of LLA, we were not able to comment on prevalence. Determining prevalence requires an entirely different methodological study which involves surveying the population. Despite the fact that it is essential to determine prevalence, prevalence data may not give a clear picture of the burden of LLA in Canada as the mortality rate in this population is high. Incidence is a better indicator of the burden of a disease/disability. Another limitation is that we presented the incidence data for LLA, and not for amputees. Presenting the incidence data only for LLA is consistent with previous

studies and allowed comparing our rates with other countries. Additionally, a close look at our data showed that counting the number of LLA was more accurate than counting the number of amputees because the patient identification codes were missing for some of the amputation cases, making it difficult to decide if the amputation was on an existing amputee or a new amputee. Selection of the appropriate population for age-adjustment was another issue. The standard population that we used was the final post censual Canadian population 2011, which is the most recent Canadian standardized population and it is recommended by Statistics Canada to be used for all age-adjustment statistics. This age-adjustment allowed us to compare the rates across the study years with removing the confounding effect of age. However, when comparing our rates with the rates from other countries, because different standard populations are used across studies, the comparison is difficult and perhaps biased. This raises an important issue that a single standard population should be used across the studies so that valid and unbiased comparisons can be made (Vital and Health Statistics, 1998).

Chapter 3 was a population-based study that reported on inpatient rehabilitation in Canada. We reported only on inpatient data because outpatient and prosthetic rehabilitation data are not collected by CIHI. Therefore, this limited our ability to fully understand the rehabilitation service provision in Canada. In addition, Quebec inpatient rehabilitation data are not submitted to CIHI and therefore were not available. We endeavoured to overcome this limitation by collecting data on outpatient and prosthetic rehabilitation in Canada through conducting a national survey in Chapter 4. However, although survey studies are great tools for obtaining national data, they are associated with limitations. First off, despite our effort to

send the survey to one representative from each facility, the anonymity of the survey limits our confidence that all facilities had only one respondent. Even if we assume each facility only had one respondent, because one respondent was answering on behalf of a facility, the results may not be the accurate reflection of how prosthetic rehabilitation is done in Canada. The survey questions also impose additional limitation. The word choice or the structure of the questions may have been misleading and affected the responses. We, however, tried to minimize this limitation by revising the survey through multiple rounds of iteration. The second part of the survey which collected information about commercial games in practice was completed by physical and occupational therapists, which among healthcare professionals use these games the most (Ravenek, Wolfe, & Hitzig, 2015). Future studies should include other healthcare professionals, such as recreational therapists who are also involved in providing clients' LLA rehabilitation and may use commercial games in practice.

Chapter 6 presented data for a feasibility RCT. As a result, the primary goal was to assess feasibility rather than efficacy. A feasible and convenience sample was selected to find out about the pragmatics of the trial including randomization design, recruitment strategies and success, adverse events, acceptability of the intervention, etc. The other goal of the feasibility trial is to establish a treatment effect so that sample size can be calculated for a future trial. The calculation of treatment effect provides some evidence for the preliminary efficacy of the intervention. However, in order to fully establish efficacy, a powered trial needs to be conducted. The other limitation is that our results are not applicable to younger individuals with LLA. Additionally, we cannot comment on the long term usage of the Wii.n.Walk and

the impact on the participants' outcomes because of our short retention follow up. Future studies should evaluate the long term usage through longer periods of retention follow-up.

7.5 Future directions

The prevalence of LLA needs to be determined in a future study in order to fully understand the epidemiology of LLA in Canada. Additionally, the incidence of LLA should continue to be determined in the future to facilitate tracking changes in the burden of the disability. In terms of rehabilitation data, additional research is required to investigate the reasons for the low provision of inpatient rehabilitation services in Canada. Furthermore, data on long-term functional outcomes of clients that receive inpatient rehabilitation versus those that do not will be essential for understanding the impact of the low provision of inpatient LLA rehabilitation in Canada. In our survey studies, because we aimed to keep the survey short and therefore increase the response rate, we were limited by the number of questions and the level of the specificity that we could ask. Future additional surveys are required to collect data on more specific questions about prosthetic rehabilitation such as length of LLA rehabilitation by clients' age. Additionally, future studies should explore provincial as well as urban/rural differences in rehabilitation service provision in Canada.

As the use of video games and technology in rehabilitation is growing, knowledge translation activities and developing standardized treatment protocols will be helpful to reduce therapists' perceived barriers of time and training requirement. It is worthwhile to explore and evaluate knowledge translation strategies in order to enhance uptake.

Future powered RCTs are required to evaluate the efficacy of Wii.n.Walk for rehabilitation in older adults with LLA. Such trials could also explore evaluating tablet-enabled telehealth options where Wii.n.Walk can still be conducted at participants' home while allowing remote group training and supervision via videoconferencing. The tablet-enabled intervention could be a promising cost and time effective delivery model which could be used in remote areas and for those that do not have access to the rehabilitation resources.

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Appendices

Appendix A: National Lower Limb Prosthetic Survey

Section 1. Lower Limb Prosthetic Rehabilitation Services Provided in Your Facility

For this survey, we have defined prosthetic rehabilitation as training someone to use a prosthesis.

1. Does your facility provide **inpatient** rehabilitation services to clients with lower limb amputation?
   □ Yes □ No if no → Skip questions 2-6

2. Does your facility have a dedicated **inpatient** prosthetic rehabilitation program (i.e., beds allocated for clients with amputations) or are these clients admitted under another program?
   □ Dedicated inpatient program
   □ Clients admitted under a specific inpatient rehabilitation program (e.g., Musculoskeletal)
   □ Clients admitted under a general inpatient rehabilitation program

3. To the best of your knowledge, how long is **inpatient** prosthetic rehabilitation (from being fitted to discharge) at your facility for the following types of clients with lower limb amputation?

	Unilateral transtibial	Unilateral transfemoral	Bilateral transtibial	Bilateral transfemoral
1-3 weeks				
4-6 weeks				
7-9 weeks				
10-12 weeks				
>12 weeks				

4. To the best of your knowledge, how many clients with lower limb amputation are admitted annually as **inpatients** to your facility?

   [ ]

5. To the best of your knowledge, how many of the clients you mentioned in question 4 are fitted with a prosthesis?

   [ ]

6. To the best of your knowledge, how many clinicians (full time or part time) in your facility provide **inpatient** lower limb prosthetic rehabilitation?

   [ ]

7. Does your facility provide **outpatient** rehabilitation services to the clients with lower limb amputation?
   □ Yes □ No if no → Skip questions 8-12

8. Does your facility have a dedicated **outpatient** prosthetic rehabilitation program or are these clients serviced under another program?
   □ Dedicated outpatient program
   □ Clients serviced under a specific outpatient rehabilitation program (e.g., Musculoskeletal)
   □ Clients serviced under a general outpatient rehabilitation program

9. To the best of your knowledge, how long is **outpatient** prosthetic rehabilitation (from being fitted to discharge) at your facility for the following types of clients with lower limb amputation?

	Unilateral transtibial	Unilateral transfemoral	Bilateral transtibial	Bilateral transfemoral
1-3 weeks				
4-6 weeks				
7-9 weeks				
10-12 weeks				
>12 weeks				

10. To the best of your knowledge, how many clients with lower limb amputation are serviced annually as **outpatients** in your facility?

    [ ]

11. To the best of your knowledge, how many of the clients you mentioned in question 10 are fitted with a prosthesis?

    [ ]

12. To the best of your knowledge, how many clinicians (full time or part time) in your facility provide **outpatient** lower limb prosthetic rehabilitation?

    [ ]

13. Are the following typically provided in the lower limb prosthetic rehabilitation program in your facility?

Flexibility/range of motion (muscle stretching)	Yes	No
Muscle strengthening	Yes	No
Cardiovascular training (aerobic fitness training)	Yes	No
Balance and coordination	Yes	No
Gait training	Yes	No
Support groups	Yes	No
Prosthetic fit education (skin care, bandaging)	Yes	No
Graduated return to work program	Yes	No
Recreational program (example: learning how to ride a bike)	Yes	No
Other → please specify	Yes	No

14. Are clients of these age ranges serviced/admitted to the lower limb prosthetic rehabilitation in your facility?

12 years of age and younger	Yes	No
13-19 years of age	Yes	No
20-49 years of age	Yes	No
50-64 years of age	Yes	No
65+ years of age	Yes	No

15. Are the following health care providers part of your prosthetic rehabilitation team?

Physical therapist	Yes	No
Occupational therapist	Yes	No
Physiatrist	Yes	No
Prosthetist	Yes	No
Nurse	Yes	No
Social worker	Yes	No
Psychologist	Yes	No
Recreational therapist	Yes	No
Vocational therapist	Yes	No
Dietician	Yes	No
Pharmacist	Yes	No
Other → please specify	Yes	No

Section 2. Use of Commercial Games in Lower Limb Prosthetic Rehabilitation and Clinicians' Perception of the Benefits and Barriers/Challenges

The following questions ask about the use of commercial games such as Nintendo Wii/Wii Fit™, Xbox Kinect™, and PlayStation EyeToy® as part of the lower limb prosthetic rehabilitation practice within your facility, as well as your perception of the benefits and barriers/challenges associated with implementing these games in clinical practice.

16. Are commercial games used for lower limb prosthetic rehabilitation in your facility?
    □ Yes → Continue to 17 (but skip 20)
    □ No → Skip questions 17-19
    □ Not sure → Continue to 21

17. Which of the following commercial games are used in your facility to assist with lower limb prosthetic rehabilitation? [Check all that apply]
    □ Nintendo Wii/Wii Fit
    □ Xbox Kinect
    □ Sony PlayStation EyeToy
    □ Other → please specify: _____

18. To the best of your knowledge, how many hours per week do clients typically spend using commercial games for lower limb prosthetic rehabilitation?
    □ <1 hour per week
    □ 1-3 hours per week
    □ 4-6 hours per week
    □ 6+ hours per week
    □ Varies considerably depending on client

19. Do you use commercial games to assist with the prosthetic rehabilitation of your clients at the following time-points?

As soon as the client is fitted with a prosthesis	Yes	No
As soon as the client is able to tolerate weight bearing on the prosthetic limb for at least 30 minutes per day	Yes	No
As soon as the client is able to tolerate weight bearing on the prosthetic limb for at least 1-2 hours per day	Yes	No
As soon as the client is able to tolerate weight bearing on the prosthetic limb for >2 hours per day	Yes	No
Close to discharge	Yes	No
After discharge	Yes	No

20. Why does your facility or you do not use commercial games for lower limb prosthetic rehabilitation?

Your facility does not have these games	Yes	No
You are not familiar with these games	Yes	No

You do not think the games are suitable for your clients	Yes	No
You do not think the games are suitable for rehabilitation in general	Yes	No
Your clients are not interested in the games	Yes	No
Other → please specify	Yes	No

Nintendo Wii/Wii Fit is currently the primary commercial gaming technology being used in clinical research. The following questions are specifically about the Nintendo Wii/Wii Fit games.

21. How familiar are you with the Nintendo Wii/Wii Fit games and its use in rehabilitation?
    □ Not familiar at all
    □ A little familiar
    □ Somewhat familiar
    □ Very familiar

22. Would you ever recommend the Nintendo Wii/Wii Fit as a home program to your clients to maintain or improve their functional skills?
    □ Yes
    □ No → Why? _____

23. How strongly do you agree or disagree that the following are or could be **benefits** to using Nintendo Wii/Wii Fit games in routine lower limb prosthetic rehabilitation?

Making rehabilitation more motivating for clients
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Offering an option for home therapies close to or after discharge
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Complementing traditional rehabilitation
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Increasing clients' level of engagement in their rehabilitation
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Allowing for the training of multiple clients at a time (i.e. group training)
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Enhancing the achievement of therapy goals

□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Providing a useful performance summary at the end of each activity
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Helping to improve clients' walking capacity
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Helping to improve clients' balance
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Helping to improve clients' proprioception
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Helping to improve clients' weight shifting
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Please list additional perceived benefits:

_____

24. How strongly do you agree or disagree that the following are or could be **barriers/challenges** to using Nintendo Wii/Wii Fit games in routine lower limb prosthetic rehabilitation?

Training requirements for therapists to learn the games/gaming system
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Time/effort requirements for therapists to set up the system
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Time/effort requirement for maintaining the system (e.g. replacing batteries)
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Lack of familiarity of therapists with the games
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

The games being too physically challenging for your clients
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

The games being too cognitively challenging for your clients
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Effort/time requirements to find an appropriate training location within your facility
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Limited options for individualizing the training parameters (e.g. the speed of the games, delay between the activities)
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Cost of purchasing the games
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Therapists not having enough time available to add the games to the clients' program
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Not having enough time available in clients' rehabilitation schedule. Clients' rehabilitation programs are already too busy
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Not being well received by therapists. They do not view the games as being clinically useful

□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Not being well received by clients
□ Strongly agree □ Agree □Neutral □ Disagree □ Strongly disagree □ Do not know

Please list additional perceived barriers/challenges:
_____

25. In your opinion, what are the appropriate age categories for using Nintendo Wii / Wii Fit games in lower limb prosthetic rehabilitation? [Check all the apply]

□ 12 years of age and younger
□ 13-19 years of age
□ 20-49 years of age
□ 50-64 years of age
□ 65+ years of age

Section 3. Demographics

This section collects demographic information. This information will be used only to describe the study respondents. Individual responses will not be identifiable.

26. Please identify your professional practice:
□ Physical Therapy
□ Occupational Therapy
□ Other
If other, please specify _____

27. In which province or territory is your facility located?
□ BC □ AB □ MB □ SK □ ON □ QC □ NS □ NB □ NL □ PEI □ Northwest Territories/Nunavut/Yukon

28. What is your current position at your facility?
□ Department Head or Clinical Practice Leader
□ Therapist
□ Other (please specify) _____

29. How many years in total have you been practicing your profession?

30. How many years have you been practicing at your rehabilitation facility?

31. How often do you work with clients with lower limb amputation?
□ Everyday
□ A few times a week
□ Once a week
□ A few times a month
□ Once a month
□ A few times a year
□ Once a year
□ Never

32. Please select your sex:
□ Male □ Female

33. Please indicate your age: _____

Additional comments:
_____

Thank you for taking the time to complete this survey.

We would like to offer you a $10 Starbucks card as a token of our appreciation. If you are interested in receiving the Starbucks card, please provide your name and mailing address in the space below. This information will ONLY be used for this purpose. Your name and mailing address will NOT be associated with the information that you provided in the survey.

Name: _____

Mailing address: _____

Appendix B: Use of Nintendo Wii Fit™ for Individuals with a Unilateral Transtibial or Transfemoral Amputation

-Manual-

Bita Imam, BSc
Linda McLaren, PT
William C Miller, FCAOT, PhD

This manual and related materials can be downloaded from:
http://millerresearch.osot.ubc.ca/resources

ACKNOWLEDGEMENTS

The development of the Wii Fit Intervention was made possible by the contributions of the Amputee Coalition of Canada; the University of Alberta-Franklin Fund; Canadian Institutes of Health Research; and the Vanier Canada Graduate Scholarship.

Executive Summary

This manual provides therapists with guidelines for using the Nintendo Wii Fit for rehabilitation with older adults with lower limb amputations. The Wii Fit can be used as an in-clinic or at-home rehabilitation tool to improve the functional skills of older adults living with a unilateral transtibial or transfemoral amputation.

Introduction

The Wii Fit Intervention consists of performing Nintendo Wii Fit activities. Clients stand on the Wii Fit balance board and interact with the Wii games displayed on their TV screen through weight shifting or using the Wii handheld remote control. The Wii Fit Intervention was developed by core members of our research team, including Bita Imam, Linda McLaren, and Dr. William C. Miller. Bita Imam is a PhD Candidate in Rehabilitation Sciences at the University of British Columbia and a Vanier Scholar working with Dr. William C. Miller. Linda McLaren is a physical therapist for individuals with lower limb amputation who has been instrumental in developing this manual. Dr. William C. Miller is trained as an occupational therapist and epidemiologist. He is one of the leading clinical investigators in amputee research in Canada.

This manual originated from Ms. Linda McLaren's preliminary clinical application of the Wii Fit with her clients with transfemoral amputations (CTF) and clients with transtibial amputations (CTT). Our research team subsequently evaluated the Wii Fit for improving walking capacity in a pilot study with six outpatient participants with lower limb amputations, using a single subject research design (Imam et al. 2013). The promising results from this pilot led to a randomized controlled trial evaluating the feasibility of Wii Fit with twenty-eight individuals discharged from prosthetic rehabilitation for greater than one year (Imam et al. 2017). Wii Fit was found to be feasible with having potential to improve walking capacity in individuals with lower limb amputation (Imam et al. 2017).

The Wii Fit intervention was refined based on our findings and the feedback received from the participants during these trials. Modifications for trainer instructions were made to Wii Fit postures and activities to prevent incorrect posture and promote function and safety.

To participate in the Wii Fit Intervention, clients must have:

1. a comfortable fitting socket
2. a safe standing alignment
3. the ability to stand on either leg (with support if required)

The Wii Fit Intervention tests one's:

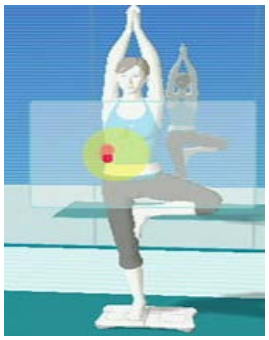
1. ability to stand in one place
2. centre of balance
3. ability to shift weight side-to-side and front-to-back
4. ability to copy postures and movement

The Wii Fit Intervention includes the following targeted exercises:

1. Yoga (static and dynamic single and double leg poses)
2. Balance tasks (lateral, posterior and anterior weight shifting exercises)
3. Strength training (dynamic single and double leg exercises)
4. Aerobics (running on the spot and step class)

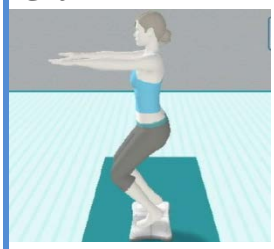
Exercises

Yoga

Activity	**Degree of Difficulty**	**Common Mistakes/ Correct Posture**	**Modifications / Safety**
Half Moon 	Easy	Mistakes: Reaching forward; twisting torso. CORRECT POSTURE: Bending to one side, arms stretched out, feet together.	Modifications: Use hand support for balance; copy movement with one arm instead of two.
Warrior 	Difficult	Mistakes: Twisted hips, leaning forward. CORRECT POSTURE: Hips aligned with body, arms stretched out, distribute weight between front and back leg.	Modifications: Shorten distance between feet. SAFETY: Clients with transfemoral amputations (CTF) cannot put the prosthetic leg forward. Repeat the exercise with non-amputated leg forward.
Tree 	Difficult	Mistakes: Not standing in centre of board; bent knee not in line with body. CORRECT POSTURE: Standing in centre of board, arms stretched out, bent knee in line with body.	Modifications: Use hand support for balance; copy movement with one arm instead of two. If the balance board does not respond to the prosthesis, instruct the client to step on with the opposite leg first until the pose activates and then step back on and continue with the prosthetic leg. SAFETY: CTF should hold prosthetic leg out to side.

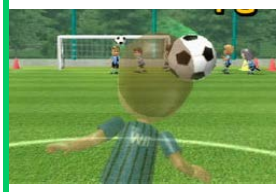
Activity	Degree of Difficulty	Common Mistakes/ Correct Posture	Modifications / Safety
Palm Tree 	Difficult	Mistakes: Bending torso forward. CORRECT POSTURE: Weight shifting with ankles, arms stretched to the back with palms up.	Modifications: Use of hand support for balance. SAFETY: For CTF, knee may collapse.
Standing Knee 	Difficult	Mistakes: Foot not in centre of board; bending forward; pinching of hands while holding prosthetic. CORRECT POSTURE: Foot in the centre of board, back straight.	Modifications: Use of hand support for balance; copy movement with one arm instead of two. If the balance board does not respond to the prosthesis, instruct the client to step on with the opposite leg first until the pose activates. Then step back on and continue with the prosthetic leg. SAFETY: For CTF, knee may collapse.
Triangle 	Difficult	Mistakes: Bent knees; not enough flexibility to bend over. CORRECT POSTURE: Keep knees straight, arms stretched out, back straight.	Modifications: Use of hand support for balance; Shorten distance between feet. SAFETY: For CTF, when the prosthesis is forward, there will be no forefoot contact with board.
Downward Facing Dog 	Difficult	Mistakes: Bent knees; too much weight on hands. CORRECT POSTURE: Back straight, knees straight, distribute weight between hands and feet.	Modifications: Match angle of prosthetic foot with good foot. SAFETY: Getting dizzy from bending over.

Activity	Degree of Difficulty	Common Mistakes/ Correct Posture	Modifications / Safety
Bridge 	Difficult	Mistakes: Unable to lift hips high enough. CORRECT POSTURE: No additional notes.	Modifications: None SAFETY: For CTF, prosthetic foot needs positioning with hands. Be careful of lower back strain; lift only as high as comfortable; be careful when standing up (potential dizziness or loss of balance).
Spinal Twist 	Difficult	Mistakes: Not lying straight on the floor before starting exercise; shoulders come off the mat. CORRECT POSTURE: No additional notes	Modifications: Use hands to place above knee prosthesis; reduce amount of twisting. SAFETY: Watch for back pain.
Cobra 	Difficult	Mistakes: Back arched too much, which lifts front of hips off the mat. CORRECT POSTURE: No additional notes.	Modifications: If back hurts or is feeling strained, hold position on elbows versus hands. SAFETY: No additional notes.
Shoulder Stand 	Difficult	Mistakes: None. CORRECT POSTURE: No additional notes.	Modifications: None SAFETY: Prosthetic knee should be locked if possible, as knee may bend; monitor for neck strain.
Sun Salutation 	Difficult	Mistakes: None. CORRECT POSTURE: No additional notes.	Modifications: None SAFETY: Transfemoral unable to bend knees.

Activity	Degree of Difficulty	Common Mistakes/ Correct Posture	Modifications / Safety
Chair 	Difficult	Mistakes: Loss of balance when forward. CORRECT POSTURE: No additional notes.	Modifications: Use of hand support for balance; for clients with transtibial amputations (CTT), reduce amount of knee bend. SAFETY: CTF may be unable to do this exercise.
Dance 	Very difficult	Mistakes: Loss of balance; trying to lift leg higher than able and bending forward at waist. CORRECT POSTURE: No additional notes.	Modifications: CTT may need to reduce height of leg. SAFETY: CTF must hold prosthetic foot to support prosthesis.

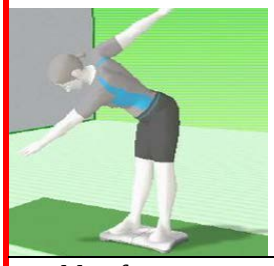
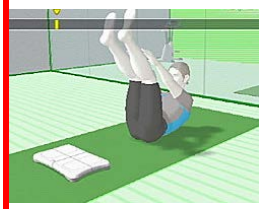
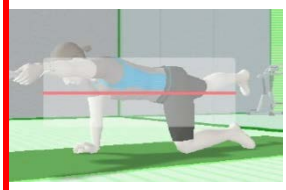
Balance Games

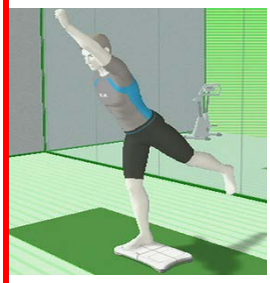
Activity	Degree of Difficulty	Common Mistakes /Correct Posture	Modifications / Safety
Penguin Slide 	Moderate	Mistakes: Bending sideways with trunk; weight shifts that are too slow. CORRECT POSTURE: Shift weight with ankles.	Modifications: Use of hand support for balance. SAFETY: No additional notes.
Bubble 	Moderate	Mistakes: Too fast of a weight shift CORRECT POSTURE: Shift weight with ankles.	Modifications: Use of hand support for balance SAFETY: Watch for risk of falls when shifting weight forward.
Tilt Table 	Moderate	Mistakes: Bending sideways with trunk. Rapid weight shift causing the board to oscillate versus subtle weight shift to start ball rolling and sustaining	Modifications: Use of hand support for balance. SAFETY: Watch for risk of falls when shifting weight forward.

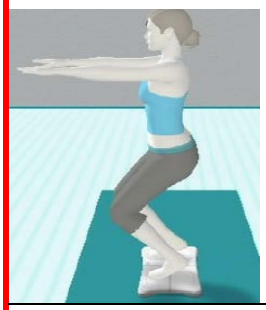
Activity	Degree of Difficulty	Common Mistakes /Correct Posture	Modifications / Safety
		the roll. CORRECT POSTURE: Shift weight with ankles.	
Soccer Ball 	Difficult	<u>Mistakes:</u> Reaching with head versus rapid weight shift side-to-side at feet. CORRECT POSTURE: Shift weight with ankles; keep back straight.	<u>Modifications:</u> Use of hand support for balance. SAFETY: No additional notes.
Ski Slalom 	Difficult	<u>Mistakes:</u> Too large of weight shift; poking and twisting hips backwards 'to steer' CORRECT POSTURE: Shift weight with ankles.	<u>Modifications:</u> Use of hand support for balance. SAFETY: Watch for risk of falls when shifting weight forward.
Ski Jump 	Difficult	<u>Mistakes:</u> Not straightening knees fast enough; jumping off board; not maintaining equal weight between feet. CORRECT POSTURE: No additional notes.	<u>Modifications:</u> Use of hand support for balance. SAFETY: CTF bent knee requires a stance phase flexion prosthetic knee.
Walking the Wire 	Difficult	<u>Mistakes:</u> Timing of stepping and unequal weight shifting leads to falling off the wire. CORRECT POSTURE: No additional notes.	<u>Modifications:</u> Use of hand support for balance. SAFETY: CTF will be unable to do this exercise, as jumps are required.

Activity	Degree of Difficulty	Common Mistakes /Correct Posture	Modifications / Safety
Snowboard 	Difficult	Mistakes: Weight shifting in opposite direction of what is required. CORRECT POSTURE: Shift weight with ankles in the right direction.	Modifications: Use of hand support for balance. SAFETY: No additional notes.

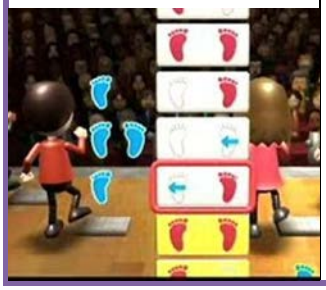
Strength

Activity	Degree of Difficulty	Common Mistakes/ Correct Posture	Modifications / Safety
Triceps Extension 	Easy	Mistakes: Bringing elbow forward toward nose. CORRECT POSTURE: No additional notes.	Modifications: none SAFETY: No additional notes.
Torso Twist 	Easy	Mistakes: Twisting with trunk rather than from hips; bending of knees. CORRECT POSTURE: No additional notes.	Modifications: Reduce distance of reach. SAFETY: Watch for risk of fall when reaching forward; for CTF, prosthetic toes will lift off the board.
Jackknife 	Easy-moderate for CTT Moderate-difficult for CTF	Mistakes: Leading with neck causing neck strain; unable to lift legs high enough. CORRECT POSTURE: No additional notes.	SAFTEY: For CTF, prosthetic knee will bend into a lot of flexion. SAFETY: No additional notes.
Arm and Leg Lift 	Moderate / Difficult	Mistakes: Not lifting back leg high enough. CORRECT POSTURE: No additional notes.	Modifications: Lift arm not the leg (remain kneeling on both legs); place towel under knee for stability. SAFETY: Watch for pain on kneeling on prosthesis with loss stability and fall.

Activity	Degree of Difficulty	Common Mistakes/ Correct Posture	Modifications / Safety
Single Leg Extension 	Difficult	Mistakes: Bending back, not fully extending the moving leg. CORRECT POSTURE: No additional notes.	Modifications: Use of hand support for balance. If the balance board does not respond to the prosthesis, instruct the client to step on with the opposite leg first until the pose activates, and then step back on and continue with the prosthetic leg. SAFETY: Prosthetic knee may be unstable.
Plank 	Difficult	Mistakes: Hips too high; pelvis not leveled. CORRECT POSTURE: No additional notes.	Modifications: Try on knees, but discontinue if there is a complaint of back pain. SAFETY: Watch for back strain.
Sideway Leg Extension 	Difficult	Mistakes: Unable to weight bear on prosthetic limb for duration of exercise. CORRECT POSTURE: No additional notes.	Modifications: When standing on non-amputated limb, reduce distance of prosthetic limb extension, or use two hands for support. If the balance board does not respond to the prosthesis, instruct the client to step on with the opposite leg first until the pose activates and then step back on and continue with the prosthetic leg. SAFETY: No additional notes.

Activity	Degree of Difficulty	Common Mistakes/ Correct Posture	Modifications / Safety
Single Leg Twist 	Difficult	Mistakes: Bending forward of the trunk; unable to hold prosthetic limb forward in correct position (femoral pain). CORRECT POSTURE: No additional notes.	Modifications: Reduce lift of forward leg, may require two-handed support when standing on prosthetic limb. If the balance board does not respond to the prosthesis, instruct the client to step on with the opposite leg first until the pose activates and then step back on and continue with the prosthetic leg. SAFETY: Watch for femoral pain.
Rowing Squat 	Difficult	Mistakes: Unable to raise heels due to balance difficulty. CORRECT POSTURE: No additional notes.	Modifications: none SAFETY: CTF should avoid this exercise.
Pushup 	Difficult	Mistakes: None. CORRECT POSTURE: No additional notes.	Modifications: Hold the position from knees. SAFETY: Watch for back pain.
Lunge 	Very difficult	Mistakes: Unable to lower to correct position. CORRECT POSTURE: No additional notes.	Modifications: Use two arms for support. SAFETY: For CTF, prosthetic leg cannot ever be forward.

Aerobics

Activity	**Degree of Difficulty**	**Common Mistakes/ Correct Posture**	**Modifications / Safety**
Basic run 	Difficult	<u>Mistakes:</u> None. CORRECT POSTURE: No additional notes.	<u>Modifications:</u> Use both hands for support if needed. SAFETY: Balance board is NOT used for this exercise. CTT will need to have good single limb standing time on prosthetic side. CTF, the prosthesis needs to be held directly beneath, with the knee held straight or locked.
Basic step 	Difficult	<u>Mistakes:</u> None. CORRECT POSTURE: No additional notes.	<u>Modifications:</u> None. SAFETY: Watch for risk of fall when stepping on and off the board.

Limitations/Considerations

Clients must bear a minimum amount of weight on their lower limbs for the balance board to register their movements. For clients with transfemoral amputations, it may be difficult to maintain this minimum weight requirement. In these cases, clinicians should discourage the use of exercises that require a single leg stance and instead encourage the use of two-legged exercises. The other limitation is that these games may not be suitable for clients who have visual or cognitive impairments.

References

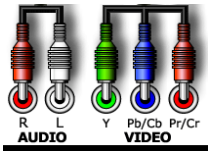
Imam, B., Miller, W.C., Finlayson, H., Eng, J.J., & Jarus T. 2017. A randomized controlled trial to evaluate the feasibility of the Wii Fit for improving walking in older adults with lower limb amputation. *Clinical Rehabilitation, 31*, 82-92.

Imam, B., Miller, W.C., McLaren, L., Chapman, P., & Finlayson, H. (2013). Feasibility of the Nintendo WiiFit™ for improving walking in individuals with a lower limb amputation. *SAGE Open Medicine, 1*, 2050312113497942.

Equipment Requirements

Television

**Must have either an AV composite or component input. Check the back or the sides of the TV to find the appropriate input)*

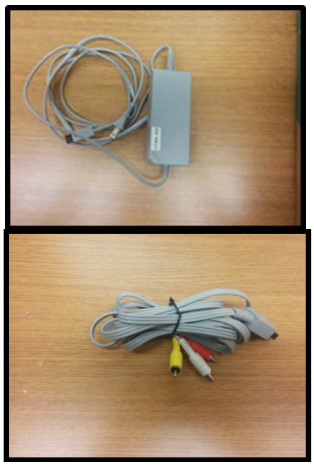


Wii Console

Wii Fit CD

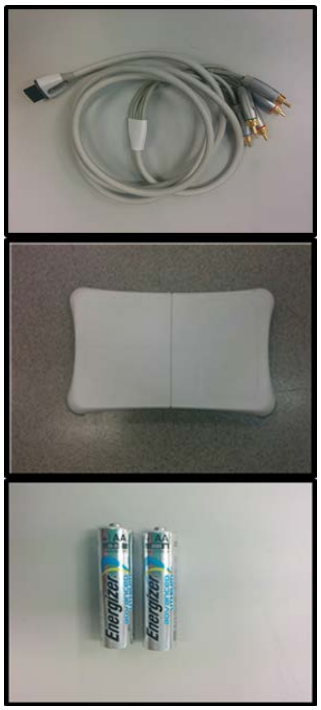
Wii Remote

Wii Sensor Bar



Wii Charger

Wii AV composite cord (newer TVs may require component cable instead. Please see below)



Wii Component Cable (only for TVs that the AV composite cord is not compatible with)

Wii Fit Balance Board

6 AA Batteries (2 for remote; 4 for balance board)

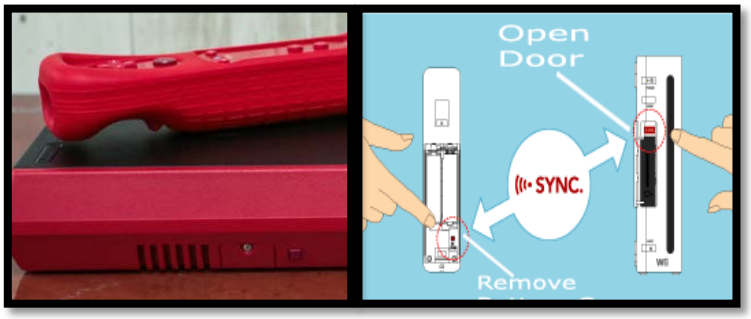
Wii Fit Set Up Manual

❶ Start by connecting the Wii console to the television.

- Plug outlet cord into Wii Console and then into wall outlet.
- Connect AV Cord (three-prong cord) to the Wii console and then place three coloured prongs into corresponding coloured inserts on television (white, yellow and red). Some TVs are only compatible with component cables (five-prong cord).

- Turn on the Wii Console and insert the CD (the CD should be inside the balance board box).

- Using the TV's remote control, switch the *input* (HDMI1, HDMI2, AV, Component, etc) until you can see the Wii page on the TV screen. You may have to test different inputs, as it varies from TV to TV.
- If you cannot get the Wii game to show up on the television, or there is something wrong with the picture (e.g., it is in black and white) check that the prongs are in the corresponding colours and/or try taking them out and placing them back in. Sometimes if they are plugged in too tight or too loose it can affect the picture on the screen.
- Plug the remote sensor into the Wii console and place directly below the TV.



- Sync the Wii remote control with the Wii console. To sync, you hold the red button on the Wii console (located on the inside of the SD Card compartment) and the red button on the remote (located under the battery cover). Hold both at the same time for a few seconds.
- Follow the instructions on the screen to create a Mii character for the client and set-up the Wii Fit game with the client (have them do the body test). Before doing the body test you will need to sync the balance board with the Wii console (the game indicates when to do it). To sync, turn the Wii Balance Board upside down and remove the battery cover. Hold the red button on the Wii and the red button on the Balance Board (located under the battery cover) simultaneously. Holding both at the same time, the screen will indicate when they are synced.
- Make sure clients will have hand support at both sides for the sessions; chairs, tables, or a walker can be used.

Appendix C: Wii Fit Instructions for Participants

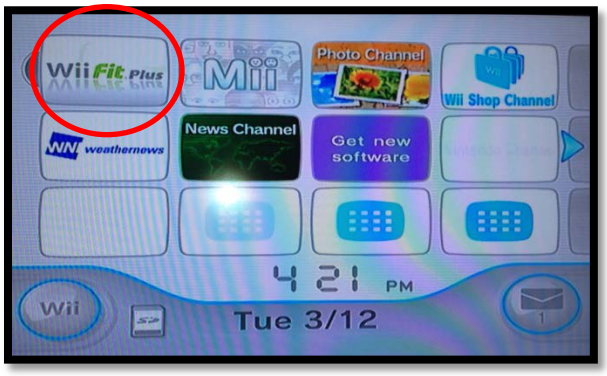
I. Getting Started

1. Turn on the TV

2. Turn on the Wii console

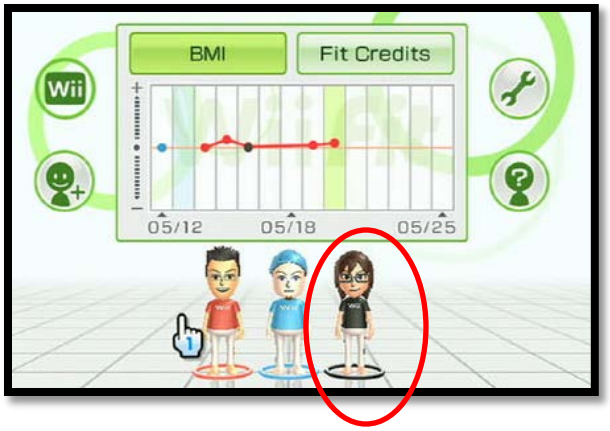
3. Point the remote controller to the TV screen and press A when you get the message “press A to continue”

4. Press A to click on the Wii Fit plus icon on the left hand corner on the top row.



5. Click on Start by pressing A.

6. When you see your own avatar, click on it and then press start



7. Keep pressing A to skip the talk

8. Once you are on the page with a calendar on, click on training

9. Try to complete *40 minutes of total training* (10 min Yoga, 10 min balance games, 10 min strength training, and 10 min aerobics) at each session. Your total time is displayed on the screen.

10. Start the training with **Yoga**. End it when your total time on the screen shows 10 minutes.
10. Next go to **Balance Games**. End it when your total time on the screen shows 20 minutes.
11. Next go to **Strength Training**. End it when your total time on the screen shows 30 minutes.
12. At the end, go to **Aerobics**. End it when your total time on the screen shows 40 minutes.

** Take a break between exercises if you need to. Try to complete the 40 minute exercise within maximum of an hour and half. Please keep the exercise frequency to 3 times a week (Monday, Wednesday, and Friday). Do NOT exercise for more than 40 minutes per session.

General information:

-Press back if you want to go back

-Press home if you want to go back to the Wii Fit main page. Do NOT press reset.

-If you want to pause or quit any activity, press the + sign on the remote controller. You can resume the exercise by clicking continue, or you can retry or quit it.

Frequently Asked Questions

1. *What exercises should I do?*

Exercises or games selected from Yoga, Balance Games, Strength Training, and Aerobics

2. *How long exercise should I do in each session?*

For each session you should try a total of 40 minutes exercises. This means 10 minutes of each of Yoga, Balance Games, Strength Training, and Aerobics.

3. *How can I unlock exercises/games?*

You need to either collect enough total exercise minutes or obtain 3 or 4 stars on certain games in order to start unlocking the locked games. For balance games, once you successfully complete the beginner level of the games the higher levels become unlocked.

4. *How can I increase the difficulty level of the exercises/games?*

You can increase the difficulty level when you select the activity.

5. *Can I pause an activity?*

Yes, you can pause an activity by pressing the + sign on the remote controller. You can resume the activity by pressing continue.

Appendix D: Wii Big Brain Academy Instructions for Participants

Getting Started

1. Insert the Big Brain Academy: Wii Degree Game Disc in the Game Disc slot of the Wii console. The power on the Wii console will turn ON. You should then see the following screen. After you read it carefully, press A to continue.

2. Select the Disc Channel (the orange square in the top left hand corner of the screen) from the Wii Menu.

3. When you see the Channel Preview Screen, select Start to make the game start.

4. You will then see the Wrist Strap Reminder Screen. Also, the first time you play the game, you'll be asked whether you want to create a save file for your game progress. Remember to click OK.

5. Once the title screen appears, select Start to begin game play. If this is your first time playing, you'll go automatically to the Enrol screen to enrol yourself. This will be recorded in your saved file. If you already have saved data, you'll instead go directly to the Academy Hallway.

How to Enrol

1. When you first play the game, you must enrol in the academy, selecting one of your "Miis" as a student-record "photo" and creating a student name. You will then be registered as a student and be given your own student record book where grades and other measurements of your progress will be recorded.

2. First select your student photo by picking a Mii. Big Brain Academy includes 6 premade academy Miis.

3. When you choose a Mii, you can give your character a student name. Select the student name field, then create a name, selecting one character at a time on the keyboard. Select OK to confirm.

What to Do

Please keep each session to a total of 60 minutes.

1. Once you have enrolled, you will be sent back to the Academy Hallway. Hover your cursor over the sign that says “Solo” to bring you to the Solo room. Then click on Practice.
2. Select a mental category, starting with **Identify**. Then, select the specific activity you would like to play, moving from A through C. For example, in Identify, you would start with **Whack Match**, then move to **Fast Focus**, and finally **Species Spotlight**. Play each of these games **once** through, beginning with the Easy level. *Do not advance to higher levels until you have scored at least 300 grams (Gold medal) at the Easy level.*

3. Once you have completed each one of the three games in the Identify category at the Easy level, move clockwise to the next category, **Memorize**. Again, play through each of the games (**Covered Cages, Face Case, Reverse Retention**) once through.
4. Repeat steps 2 and 3 with the rest of the categories (Analyze, Compute and Visualize). This should take about 30 minutes in total. If not, repeat steps 3 and 4 until you reach 30 mins.
5. You are now ready to take a "Test". Go back to the Academy Hallway, and select the Test room. Select a student to take the rest and choose OK. Then select Start Test on the Brain Graph screen. Select OK on the next screen to begin. Every time you take the test, the order of mental categories may change.
6. Play through Test once, and then repeat again for about 30 minutes.
7. This should equal approximately a 60-minute session. If there is some time left over, you may go back to Practice and play through a few more games for the remainder of the session.
8. For subsequent sessions, repeat from Step 2, playing through each of the 5 categories and 15 games in the same order (Identify, Memorize, Analyze, Compute and Visualize; and games A, B and C) at the Easy level and then following with approximately 2 tests.
9. Eventually, you may wish to play only in Test mode, once you are completely familiar with the games.

Wii Big Brain Academy Game Descriptions

Solo Modes

Identify

Whack Match

Whack moles that hold key objects. Select a mole, then press the A button.

Fast Focus

Watch the image as it comes into focus, and select what it is when you know.

Species Spotlight

Shine your light to see the creatures, and choose the type there is more of.

Memorize

Covered Cages

Keep track of the birds while their cages shuffle, then point out where they've ended up.

Face Case

Watch the children speed past, then recall which faces you saw.

Reverse Retention
Memorize the order of the images, then repeat in reverse order.

Analyze

Match Blast

Shoot the blocks below, so the pile matches the top picture.

Speed Sorting

Which photos fit in the category? Zap every one that fits the bill.

Block Spot

Study the cluster above, then select the match from the four down below.

Compute

Balloon Burst

Pop the numbered balloons in order from lowest value to highest.

Mallet Math

Study the total on the right, then knock out the blocks that don't belong.

Color Count

Keep track of the balls that make it in the basket, and identify which there are more of.

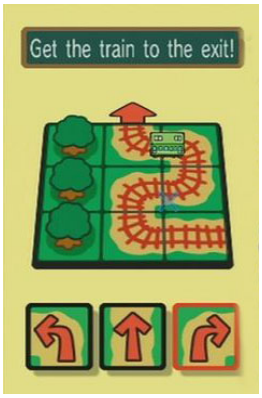
Visualize

Art Parts

What's missing from the painting? Put missing bits in the right places according to the example picture.

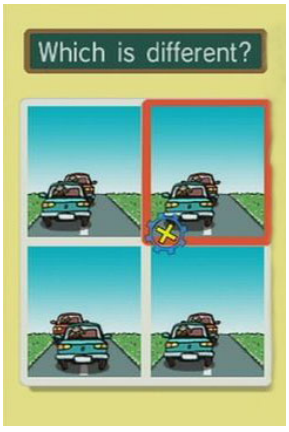
Train Turns

Guide the train to the exit by giving it orders to turn or go straight.



Odd One Out

Three animations are the same, but one isn't. Choose the odd one out.



Frequently Asked Questions

1. *I'm in the Wii Menu. How do I start playing the game?*
   Locate the Big Brain icon and select the Disc Channel from the Wii Menu. When you see the Channel Preview Screen, select Start to make the game start. Once the title screen appears, select Start to begin game play. If this is your first time playing you will automatically go to the Enrol screen to enrol your first student, who will be recorded in your save file. If you have already played/enrolled, you will go directly to the Academy Hallway.

2. *Is it possible to skip past the "teacher" talking?*
   Unfortunately, the only way to skip past the "teacher" is to press the A button (located on the Wii remote) for each bubble. It is important to listen to the teacher the first time through, but feel free to skip ahead if you're feeling confident.

3. *How do I turn off the sound on the Wii remote?*
   To turn off the "Remote Coach", click on Home, and then Wii Remote Setting and adjust the remote volume to your desired setting. Click the Home button again to close.

4. *How can I adjust the sensitivity of the remote?*
   Select the Wii icon on the bottom left of the Main Menu. Select Wii Settings, and flip to Page 2 of the settings. Select Sensor Bar, and then Sensitivity. You can select a sensitivity setting from 1 to 5. Also, ensure that you are a good distance away from the TV/Sensor Bar (at least 7-8 feet).

5. *How do I save my game?*
   If you create a save file, the game will automatically save your progress to your student record book every time you complete a session in one of the solo or group classrooms. The Save icon will appear whenever the game is automatically saving, so when you see this, do not turn the power OFF or press RESET.

6. *How do I view my "student records"? What can I find out?*
   To view your records, select View Records in the Office Menu, and select a student record to read it. Student records track student progress, including brain weight, grade, and practice medals earned. In the graph, the blue shape shows your recent performance in all activities. You can also change a student photo or student name at any time by selecting it in the student record.

7. *What is "Solo" mode?*
   In Solo mode, you are challenged with each of the five categories in random order. There are 12 questions per category (four for each minigame), resulting in 60 questions in total. You are scored based on speed and accuracy; the faster you answer a question, the more "grams" you earn (which represents your score), but an incorrect

answer scores no grams. Each mini-game can be played separately, and depending on your results, you can be awarded with a medal (bronze, silver or gold) according to your score. There are three levels of difficult: Easy, Medium, and Hard.

8. *What are the different activities called? What are they testing?*
   The 5 categories of activities are: Identify, Memories, Analyze, Compute and Visualize.
   Identify (identification-themed questions)
   Memorize (memory-themed questions)
   Analyze (reason-based questions)
   Compute (math-themed questions)
   Visualize (visual-themed questions)

9. *What is "Test" mode?*
   Test mode checks how "big" your brain is by measuring you in 15 activities that span five mental categories. You'll not only see your brain "size", but you'll also receive a grade based on your performance, and see what kind of mind you might have based on your test results. To take a "test", select a student to take the test and click OK. Then select Start Test on the Brain Graph screen. Select OK on the next screen to begin. Every time you take a Test, the order of the mental categories may change. Once you have answered all of the problems in the five mental categories, you'll learn how big your brain is. Press A to read through all the results. Then you'll learn your overall test grade.

10. *What is "Practice" mode?*
    Practice sessions are a great way to improve your skills in specific mental categories or with specific activities. To enter a "practice", select a student to enter a practice session. Select the mental category (e.g. Identify), then the specific activity (e.g. Whack Match), and then the difficulty level (Easy, Medium or Hard). Select OK on the confirmation screen to start the practice session.
    Your brain weight for the specific activity will be revealed once you have answered 10 practice problems. Press A to read through all the practice session results.

11. *Is there any way to go back if I click on the wrong activity in Practice mode?*
    Yes. You can press the "+" sign on the remote controller and that will give you the option to quit the activity ☺.

Appendix E: Demographic Information Sheet

<table>
<tr><td>Age: _____</td><td>Sex:

☐ Male (0) ☐ Female (1)</td><td colspan="2">Living arrangement:

☐ Single (0) ☐With someone (1)</td></tr>
<tr><td colspan="4">Marital status:
☐ Married (0) ☐ Single (1) ☐ Separated (2) ☐ Divorced (3) ☐ Common Law (4)
☐ Widowed (5)</td></tr>
<tr><td colspan="4">Education level (Highest grade or degree completed):
☐ Less than high school (0) What grade level? _____
☐ High school (1) What grade level? _____
☐ Some college (2) Please specify_____
☐ Bachelor's (3)
☐ Professional (4) (e.g. medicine, dentistry, veterinary)
☐ Masters (5) ☐ PhD (6)</td></tr>
<tr><td colspan="4">Employment status (Check all that apply)
☐ Retired
☐ Unemployed
☐ Employed ☐ Part-time ☐ Full-time
☐ Student ☐ Part-time ☐ Full-time
☐ Volunteer</td></tr>
<tr><td colspan="2">Date of amputation_____
(mm/yyyy)

Time since amputation in months _____</td><td colspan="2">Amputation Level:

☐ Transtibial or below knee (0)
☐ Transfemoral or above knee (1)
☐ Knee disarticulation or at knee joint (2)</td></tr>
<tr><td colspan="2">Amputation Side:

☐ Right (0) ☐ Left (1)</td><td colspan="2">Cause of Amputation:
☐ Vascular (0) ☐ Trauma (1) ☐ Cancer (2)
☐ Infection (3) ☐ Other (4) _____</td></tr>
<tr><td>Socket comfort score at enrolment: ____/10

Ask subject to rate their socket comfort on a scale of 0 - 10 (0 = the most uncomfortable, 10 = the most comfortable socket imaginable).</td><td>Type of prosthesis:
☐ Mechanical or manual (0)
☐ Microprocessor or C-leg (1)
Specify _____</td><td>Assistive device:
(Check all that apply)
☐ None
☐ One cane
☐ Two canes
☐ Two crutches
☐ Walker
☐ Wheelchair</td><td>Time since previous rehabilitation in months
_____</td></tr>
</table>

Additional notes:

_____

_____

Appendix F: The Folstein Mini-Mental Status Examination (MMSE)

Score 1 for every correct answer:

1. What year is it? _____

2. What season are we in? _____

3. What month are we in? _____

4. What is today's date? _____

5. What day of the week is it? _____

6. What country are we in? _____

7. What province are we in? _____

8. What city are we in? _____

9. What hospital are we in? _____

10. What floor of the hospital are we on? _____

Name three objects ("Ball," "Car," "Man"). Take a second to pronounce each word. Then ask the patient to repeat all 3 words. Take into account only correct answers given on the first try. Repeat these steps until the subject learns all the words.

11. Ball? _____

12. Car? _____

13. Man? _____

Either "please spell the word WORLD and now spell it backwards" or "Please count from 100 subtracting 7 every time"

14. “D” or 93 _____

15. “L” or 86 _____

16. “R” or 79 _____

17. “O” or 72 _____

18. “W” or 65 _____

What were the 3 words I asked you to remember earlier?

19. Ball? _____

20. Car? _____

21. Man? _____

Show the subject a pen and ask: “Could you name this object?”

22. Pen. _____

Show the subject your watch and ask: “Could you name this object?”

23. Watch _____

Listen and repeat after me:

24. “No ifs, ands, or buts.” _____

Put a sheet of paper on the desk and show it while saying: “Listen carefully and do as I say.”

25. Take the sheet with your left/right (unaffected) hand. _____

26. Fold it in half. _____

27. Put in on the floor. _____

Show the patient the visual instruction page directing him/her to “CLOSE YOUR EYES” and say:

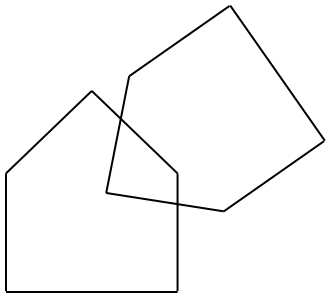
28. Do what is written on this page. _____

Give the subject a blank sheet and a pen and ask:

29. Write or say a complete sentence of your choice. _____

Give the patient the geometric design page and ask:

30. Could you please copy drawing on the next page? _____



Total Score: (/30) _____

Appendix G: Outcome evaluation manual

The following outcomes will be evaluated at **baseline**, **end of treatment**, and **three weeks post end of treatment**.

-The evaluator has to be masked to subject's group allocation. Please record on the data collection form if you are not masked to the allocation.

-Please note that subjects are masked to the study objectives/main outcome.

Assessment Booklet (arranged in random order):

1. **Demographic Information Form**
2. **The Mini Mental State Examination (MMSE)**
3. **2 Minute Walk Test (2MWT)**
4. **Short Physical Performance Battery (SPPB)**
5. **Walking While Talking Test (WWT)**
6. **The Activities-specific Balance Confidence (ABC) scale**
7. **The Physical Activity Scale for the Elderly (PASE)**
8. **The Locomotor Capabilities Index in Amputees (LCI-5)**
9. **The Modus Health Stepwatch^{TM} Activity Monitor (SAM)**

Demographic Information Form	**Interview**
The Mini Mental State Examination (MMSE)	**Interview**
Fall Calendar	**Interview**
2 Minute Walk Test (2MWT)	**Performance-based**
Short Physical Performance Battery (SPPB)	**Performance-based**
Walking While Talking Test (WWT)	**Performance-based**
The Activities-specific Balance Confidence (ABC) scale	**Self-report**
The Physical Activity Scale for the Elderly (PASE)	**Self-report**
The Locomotor Capabilities Index in Amputees (LCI-5)	**Self-report**
The Modus Health Stepwatch^{TM} Activity Monitor (SAM)	**Performance-based (one-week intervals)**

INTRODUCTION

Briefly introduce the study again and identify the data collection process:

"Previous research suggests that there is a relationship between physical and brain functioning in older adults. Regular physical activity may not only improve physical function, but also reduce age-related decline in brain function, including memory, thinking, etc. Likewise, improvement in brain function positively affects physical function, such as the general function of lower and upper limbs. In this study we evaluate the effects

of a brain and a physical activity video gaming program on the functions of individuals with a single-leg below knee or above knee amputation.
Over the next couple of hours, you will complete several questionnaires and performance-based measures. If you need a break during testing, please feel free to let me know. Your information will be kept strictly confidential.
Before we begin, do you have any questions?"

DATA COLLECTION

The Demographic Information Form will be administered first, followed by the other 9 measures.

1. **Demographic Form:** Interview
2. **Mini Mental State Examination:** Interview, need a pen, watch, blank sheet of paper.
    a. Advise the subject that you are going to ask a series of questions and ask them to perform a few tasks.
    b. Ask them to answer each of the questions and perform the tasks.
    c. Read the questions out loud.
    d. Provide a score for each item (1 for correct items, 0 for incorrect)
    e. Calculate the summary score by summing the scores from individual items

3. **2 Minute Walk Test:** Performance-based, need a timer, 3 chairs, 2 cones placed 80-meters apart
    a) The 2MWT will be outside of the lab in the hallway over an 80-meter course
    b) Place 1 cone at the beginning of the walking course and 1 at the end of the course
    c) Put 3 chairs along the course if subject needs to take a break
    d) Instruct the subject: ***"I would like you to walk as far as you can in 2 minutes, if you feel tired, you can take a short break at any time."***
    e) Start the timer when subject takes the first step and stop it at the end of 2 minutes
    f) Count the number of meters subject has walked and record it down. Record if subject took a break.

4. **Short Physical Performance Battery:** Performance-based, need a timer, 2 cones placed 4 meters apart, a standard chair with arm rests.
    a) The test needs to be performed close to a wall so that subject can use it as a support in case of falls.
    b) For balance tests and 5x times chair stands, the subject should NOT use their assistive devices. Carefully watch the subject during the test to prevent subject from falling. Subject may use their assistive device for the gait speed test.
    c) Follow the SPPB protocol and provide instructions as provided in the protocol.

5. **Walking While Talking Test (WWT)**: performance-based, need timer, 2 cones placed 6 meters apart
    a) Place a cone at a start and stop lines.
    b) Ask subject to stand behind the start line.
    c) Instruct the subject: ***"I would like you to walk as fast as you can to the other cone, turn around the cone, and walk back to the starting point while reciting the letters of the alphabet (a,b,c,…). Please start when I say go. Ready, go"***
    d) Begin timing as the subject takes the first step and stop timing when one of the participant's feet is completely across the end line. Record down the time taken to complete the course. Also, record the number of errors.
    e) Instruct the subject to repeat the test: ***"Now, I would like you to walk as fast as you can to the other cone, turn around the cone, and walk back to the starting point while reciting the alternate letters of the alphabet (a,c,e,...). Please start when I say go. Ready, go"***
    f) Record down the time taken to complete the course. Also, record the number of errors.

6. **Activities specific Balance Confidence (ABC):** self-report
    a) Give the ABC scale to the subject
    b) Instruct the subject: ***"For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale. Answer all items even if they are activities you would not do or are unsure about."***
    c) Ensure all items have a response after completion
    d) Calculate the mean score and record it down

7. The Physical Activity Scale for the Elderly (PASE)
    a) Give the PASE questionnaire to the subject
    b) Instruct the subject: ***"Please complete this questionnaire by either circling the correct response or filling in the blank. Here is an example:***

During the past 7 days, how often have you seen the sun?

[0.] NEVER [1.] SELDOM (1-2 DAYS) [2.] SOMETIMES (3-4 DAYS) [3.] OFTEN (5-7 DAYS)

Answer all items as accurately as possible."

c) Ensure all items have a response after completion

8. The Locomotor Capabilities Index in Amputees (LCI-5)
a) Give the LCI-5 questionnaire to the subject

b) Instruct the subject "***Would you say that you are "able" to do the following activities <u>WITH YOUR PROSTHESIS ON?</u> Please circle the number that best describes your capability."***

c) Ensure all items have a response after completion

d) Calculate the sum score and record it down

9. The Modus Health Stepwatch™ Activity Monitor (SAM)

a) Explain to the subject that you will be attaching a step counter device to their prosthetic ankle to record their step count in 1 week.

b) Connect the dock to the laptop. Place the SAM onto the dock

c) Click on the Stepwatch – Shortcut icon on the desktop to open the program. Enter subject's information. Adjust appropriate settings. If the subject has shuffling walking characteristics, you need to adjust the setting:
go to <u>advanced programing</u> and from there change the sensitivity to 8 and cadence to 40.
The default setting is sensitivity at 11 and cadence at 74.

d) Set the SAM to collect data for 1 week. When done, save the settings.

e) Attach the SAM securely to the outside of the subject's prosthetic ankle. <u>The SAM must to be worn with the rounded end UP.</u>

f) Subject will wear the SAM for 1 week. At the end of 1 week, arrange to retrieve the SAM. For the baseline timepoint, the SAM can be retrieved at subject's first intervention session at GF Strong (1 week after baseline assessment). For all other timepoints, the evaluator has to arrange to retrieve the SAM from the subject's home.

END OF DATA COLLECTION

At the completion of the data collection, ensure:

1) All measures have been administered
2) All items on all measures have been responded to.
3) All measures have the participant ID and date
4) Thank the participant for their participation ☺.

Appendix H: 2 Minute Walk Test (2MWT)

Protocol:

Set up a course of known distance within the research facility. Instruct subjects to walk along the specifically defined course.

Read the following instructions to the subject before the start of the test:

"*I would like you to walk **as far as** you can in 2 minutes. If you feel tired, you can take a short break at any time."*

Assistive device used during this test:

0 = None
1 = Cane (❑ quadric cane (a); ❑ regular cane (b))
2 = Crutch (❑ one side (a);❑ both side (b))
3 = Walker (❑ wheeled (a); ❑ regular (b))
4 = Brace (AFO or others: _____)

- Completed without a break : 0 = No; 1 = Yes

2 Minute Walk Test: _____ meters

Appendix I: Short Physical Performance Battery (SPPB)

All of the tests should be performed in the same order as they are presented in this protocol. Instructions to the participants are shown in bold italic and should be given exactly as they are written in this script.

1. BALANCE TESTS

The participant must be able to stand unassisted without the use of a cane or walker. This test needs to be done close to a wall so that subject can use the wall for support in case of falls.

"Now let's begin the evaluation. I would now like you to try to move your body in different movements. I will first describe and show each movement to you. Then I'd like you to try to do it. If you cannot do a particular movement, or if you feel it would be unsafe to try to do it, tell me and we'll move on to the next one. Let me emphasize that I do not want you to try to do any exercise that you feel might be unsafe.
Do you have any questions before we begin?"

A. Side-by-Side Stand (subjects should NOT use their assistive device for this movement)

1. "***I will show you the first movement***."
2. (Demonstrate) "***I want you to try to stand with your feet together, side-by-side, for about 10 seconds.***
You may use your arms, bend your knees, or move your body to get into the position, but try not to move your feet or use your arms for support when I begin timing. Try to hold this position until I tell you to stop".
4. Stand next to the participant to help him/her into the side-by-side position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the *gait speed test*.

B. Semi-Tandem Stand (subjects should NOT use their assistive device for this movement)

1. "***I will show you the second movement***."
2. (Demonstrate) "***Now I want you to try to stand with the side of the heel of one foot touching the big toe of the other foot for about 10 seconds. We will do this twice, once with***

the left foot in front and once with the right foot in the front. You can start with whichever foot you are comfortable with.
Again you may use your arms, bend your knees, or move your body to get into the position, but try not to move your feet or use your arms for support when I begin timing. Try to hold this position until I tell you to stop."
4. Stand next to the participant to help him/her into the semi-tandem position
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.
9. If participant is unable to hold the position for 10 seconds, record result and go to the gait speed test.

** Ask subject to repeat this movement with the other foot in the front.*

C. Tandem Stand (subjects should NOT use their assistive device for this movement)

1. "***I will show you the third movement***."
2. (Demonstrate) "***Now I want you to try to stand with the heel of one foot in front of and touching the toes of the other foot for about 10 seconds. We will do this twice, once with the left foot in front and once with the right foot in the front. You can start with whichever foot you are comfortable with. You may use your arms, bend your knees, or move your body to get into the position, but try not to move your feet or use your arms for support when I begin timing. Try to hold this position until I tell you to stop."***
4. Stand next to the participant to help him/her into the tandem position.
5. Supply just enough support to the participant's arm to prevent loss of balance.
6. When the participant has his/her feet together, ask ***"Are you ready?"***
7. Then let go and begin timing as you say, ***"Ready, begin."***
8. Stop the stopwatch and say ***"Stop"*** after 10 seconds or when the participant steps out of position or grabs your arm.

** Ask subject to repeat this movement with the other foot in the front.*

SCORING:

Right leg in front:

Score	**Description**
0	Unable or did not attempt the test
1	Could hold a side-by-side standing position for 10 seconds but unable to hold a semi-tandem stance for 10 sec.
2	Can hold a semi-tandem position for 10 sec but unable to hold a full tandem position for more than 2 seconds
3	Can stand in the full tandem position for 3 to 9 sec.
4	Can stand in full tandem position for 10 sec.

Left leg in front:

Score	Description
0	Unable or did not attempt the test
1	Could hold a side-by-side standing position for 10 seconds but unable to hold a semi-tandem stance for 10 sec.
2	Can hold a semi-tandem position for 10 sec but unable to hold a full tandem position for more than 2 seconds
3	Can stand in the full tandem position for 3 to 9 sec.
4	Can stand in full tandem position for 10 sec.

D. Total Balance Tests score (Take the average of left and right): _____
Comments:
_____
_____
_____
_____

2. GAIT SPEED TEST (subjects may use their assistive device this test, if they wish)

Use 2 cones 4 meters apart to identify the start and end points.

A. First Gait Speed Test
1. "***I want you to walk to the other end of the course at your usual speed, just as if you were walking down the street to go to the store."***
2. Demonstrate the walk for the participant.
3. "***Walk all the way past the other end of the tape before you stop. I will walk with you. Do you feel this would be safe?"***
4. Have the participant stand with both feet touching the starting line.
5. "***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
6. Press the start/stop button to start the stopwatch as the participant begins walking.
7. Walk behind and to the side of the participant.
8. Stop timing when one of the participant's feet is completely across the end line.

B. Second Gait Speed Test
1. ***Now I want you to repeat the walk. Remember to walk at your usual pace, and go all the way past the other end of the course.***
2. Have the participant stand with both feet touching the starting line.
3. ***When I want you to start, I will say: "Ready, begin."*** When the participant acknowledges this instruction say: ***"Ready, begin."***
4. Press the start/stop button to start the stopwatch as the participant begins walking.
5. Walk behind and to the side of the participant.
6. Stop timing when one of the participant's feet is completely across the end line.

GAIT SPEED TEST SCORING:
Walking:
Instructed to walk 4.0 m at normal walking pace. Best of the two times is recorded
Time for trial 1: _____sec
Time for trial 2: _____sec

Score	Description
0	Unable or did not attempt the test
1	Greater/equal to 5.7 seconds(less/equal to 0.42 m/sec)
2	4.1 - 5.6 seconds (0.44-0.60 m/sec)
3	3.2 – 4.0 seconds (0.61-0.77 m/sec)
4	Less than/equal to 3.1 seconds (greater/equal to 0.78 m/sec)

Aids for first walk: □ None (0) □ Cane (1) □ Crutches (2) □ Walker (3) □ Other (4)
Comments:
_____
_____
_____

3. CHAIR STAND TEST (subjects should NOT use their assistive device for this movement)

Single Chair Stand
1. "***Let's do the last movement test. Do you think it would be safe for you to try to stand up from a chair without using your arms?"***
2. "***The next test measures the strength in your legs.***
3. (Demonstrate and explain the procedure.) "***First, fold your arms across your chest and sit so that your feet are on the floor; then stand up straight keeping your arms folded across your chest."***
4. ***Please stand up keeping your arms folded across your chest*** (Record result).
5. If participant cannot rise without using arms, say ***"Okay, try to stand up using your arms."*** This is the end of their test. Record result and go to the scoring page.

Repeated Chair Stands
1. If subject is able to successfully rise one time without using arms, ask the following: "***Do you think it would be safe for you to try to stand up from a chair five times without using your arms?"***
2. (Demonstrate and explain the procedure): "***Please stand up straight as QUICKLY as you can five times, without stopping in between. After standing up each time, sit down with your back and buttocks touching the backrest, and then stand up straight again. Keep your arms folded across your chest. I'll be timing you with a stopwatch."***
3. When the participant is properly seated, say: ***"Ready? Stand"*** and begin timing.
4. **Count out loud** as the participant arises each time, up to five times.

5. Stop if participant becomes tired or short of breath during repeated chair stands.
6. Stop the stopwatch when he/she has straightened up completely for the fifth time.
7. Also stop:
• If participant uses his/her arms
• After 1 minute, if participant has not completed rises
• At your discretion, if concerned for participant's safety
8. If the participant stops and appears to be fatigued before completing the five stands, confirm this by asking ***"Can you continue?"***
9. If participant says "Yes," continue timing. If participant says "No," stop and reset the stopwatch.

SCORING
Single Chair Stand Test

A. Safe to stand **one time** without help or using arms? □**YES (1)** □ **NO (0)**

B. Results:
Participant stood without using arms Go to Repeated Chair Stand Test
Participant used arms to stand End test; score as (0) points
Test not completed End test; score as (0) points

C. If participant did not attempt test or failed, circle why:
Tried but unable (1)
Participant could not stand unassisted (2)
Not attempted, you felt unsafe (3)
Not attempted, participant felt unsafe (4)
Participant unable to understand instructions (5)
Participant refused (6)
Other (Specify) _____ (7)

Repeated Chair Stand Test
A. Safe to stand **five times** without help or using arms**?** □**YES (1)** □ **NO (0)**

B. If participant did not attempt test or failed, circle why:
Tried but unable (1)
Participant could not stand unassisted (2)
Not attempted, you felt unsafe (3)
Not attempted, participant felt unsafe (4)
Participant unable to understand instructions (5)
Participant refused (6)
Other (Specify) (7)

C. If five stands done successfully, record time in seconds.
Time to complete five stands _____ sec

Scoring the Repeated Chair Test

Score	Description
0	Unable or did not attempt the test
1	Greater/equal to 16.7 seconds
2	13.7 – 16.6 seconds
3	11.2-13.6 seconds
4	Less/equal to 11.1 seconds

Scoring for Complete Short Physical Performance Battery (only include the scores in the 4 boxes above)

Total Balance Test score _____ points

Gait Speed Test score _____ points

Chair Stand Test score _____ points

Total Score _____ points (sum of points above)

Appendix J: Physical Activity Scale For The Elderly (PASE)

INSTRUCTIONS:

Please complete this questionnaire by either circling the correct response or filling in the blank. Here is an example:

During the past 7 days, how often have you seen the sun?

[0.] NEVER [1.] SELDOM (1-2 DAYS) [2.] SOMETIMES (3-4 DAYS) [3.] OFTEN (5-7 DAYS)

Answer all items as accurately as possible. All information is strictly confidential.

LEISURE TIME ACTIVITY

1. Over the past 7 days, how often did you participate in sitting activities such as reading, watching TV or doing handcrafts?

[0.] NEVER [1.] SELDOM (1-2 DAYS) [2.] SOMETIMES (3-4 DAYS) [3.] OFTEN (5-7 DAYS)

GO TO Q.#2

1a. What were these activities?

_____

1b. On average, how many hours per day did you engage in these sitting activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

2. Over the past 7 days, how often did you take a walk outside your home or yard for any reason? For example, for fun or exercise, walking to work, walking the dog, etc.?

[0.] NEVER [1.] SELDOM (1-2 DAYS) [2.] SOMETIMES (3-4 DAYS) [3.] OFTEN (5-7 DAYS)

GO TO Q.#3

2a. On average, how many hours per day did you spend walking?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

3. Over the past 7 days, how often did you engage in light sport or recreational activities such as bowling, golf with a cart, shuffleboard, fishing from a boat or pier or other similar activities?

[0.] NEVER [1.] SELDOM (1-2 DAYS) [2.] SOMETIMES (3-4 DAYS) [3.] OFTEN (5-7 DAYS)

GO TO Q.#4

3a. What were these activities?

_____

3b. On average, how many hours per day did you engage in these light sport or recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

4. Over the past 7 days, how often did you engage in moderate sport and recreational activities such as doubles tennis, ballroom dancing, hunting, ice skating, golf without a cart, softball or other similar activities?

[0.] NEVER [1.] SELDOM [2.] SOMETIMES [3.] OFTEN
(1-2 DAYS) (3-4 DAYS) (5-7 DAYS)
GO TO Q.#5

4a. What were these activities?
_____

4b. On average, how many hours per day did you engage in these moderate sport and recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

5. Over the past 7 days, how often did you engage in strenuous sport and recreational activities such as jogging, swimming, cycling, singles tennis, aerobic dance, skiing (downhill or cross-country) or other similar activities?

[0.] NEVER [1.] SELDOM [2.] SOMETIMES [3.] OFTEN
(1-2 DAYS) (3-4 DAYS) (5-7 DAYS)
GO TO Q.#6

5a. What were these activities?
_____

5b. On average, how many hours per day did you engage in these strenuous sport and recreational activities?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

6. Over the past 7 days, how often did you do any exercises specifically to increase muscle strength and endurance, such as lifting weights or pushups, etc.?

[0.] NEVER [1.] SELDOM [2.] SOMETIMES [3.] OFTEN

(1-2 DAYS) (3-4 DAYS) (5-7 DAYS)

GO TO Q.#7

6a. What were these activities?

_____

6b. On average, how many hours per day did you engage in exercises to increase muscle strength and endurance?

[1.] LESS THAN 1 HOUR [2.] 1 BUT LESS THAN 2 HOURS

[3.] 2-4 HOURS [4.] MORE THAN 4 HOURS

HOUSEHOLD ACTIVITY

7. During the past 7 days, have you done any light housework, such as dusting or washing dishes?

[1.] NO [2.] YES

8. During the past 7 days, have you done any heavy housework or chores, such as vacuuming, scrubbing floors, washing windows, or carrying wood?

[1.] NO [2.] YES

9. During the past 7 days, did you engage in any of the following activities?

Please answer YES or NO for each item.

		NO	YES
a.	Home repairs like painting, wallpapering, electrical work, etc.	1	2

b.	Lawn work or yard care, including snow or leaf removal, wood chopping, etc.	1	2
c.	Outdoor gardening	1	2
d.	Caring for an other person, such as children, dependent spouse, or an other adult	1	2

WORK-RELATED ACTIVITY

10. During the past 7 days, did you work for pay or as a volunteer?

[1.] NO [2.] YES

10a. How many hours per week did you work for pay and/or as a volunteer?

_____ HOURS

10b. Which of the following categories best describes the amount of physical activity required on your job and/or volunteer work?

[1] Mainly sitting with slight arm movements. [**Examples:** office worker, watchmaker, seated assembly line worker, bus driver, etc.]

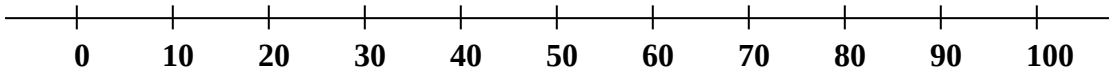
[2] Sitting or standing with some walking. [**Examples:** cashier, general office worker, light tool and machinery worker.]

[3] Walking, with some handling of materials generally weighing less than 50 pounds. [**Examples:** mailman, waiter/waitress, construction worker, heavy tool and machinery worker.]

[4] Walking and heavy manual work often requiring handling of materials weighing over 50 pounds. [**Examples:** lumberjack, stone mason, farm or general laborer

Appendix K: Activities-Specific Balance Confidence Rating Score (ABC Scale)

For each of the following activities, please indicate your level of self-confidence by choosing a corresponding number from the following rating scale. Answer all items even if they are activities you would not do or are unsure about.



Not confident **Completely confident**

How confident are you that you will not lose your balance or become unsteady when you.....

1) .....walk around the house? _____%
2) .....walk up and down stairs?_____%
3) .....pick up a slipper from the floor?_____%
4) .....reach at eye level?_____%
5) .....reach while standing on your tiptoes?_____%
6) .....stand on a chair to reach?_____%
7) .....sweep the floor?_____%
8) .....walk outside to nearby car?_____%
9) .....get in and out of a car?_____%
10) .....walk across a parking lot?_____%
11) .....walk up and down a ramp?_____%
12) .....walk in a crowded mall?_____%
13) .....walk in a crowd or get bumped?_____%
14) .....ride an escalator holding the rail?_____%
15) .....ride an escalator not holding the rail?_____%
16) ....walk on icy sidewalks?_____%

Total score / 16 = _____

Appendix L: Walking While Talking Test (WWT)

Have the participant stand with both feet touching the starting line:

A. Instruct the subject: ***"I would like you to walk as fast as you can to the other cone at the end of the line, turn around and walk back to the starting point while reciting the letters of the alphabet (a,b,c,…). Please start when I say go. Ready, go"***

Total time: _____
Total errors: _____

B. Instruct the subject: ***"Now, I would like you to walk as fast as you can to the other cone at the end of the line, turn around and walk back to the starting point while reciting the alternate letters of the alphabet (a,c,e,...). Please start when I say go. Ready, go"***

Total time: _____
Total errors: _____

Walking While Talking Test (WWT) – Trial A Recording Sheet

A. Instruct the subject: *"I would like you to walk as fast as you can to the other cone at the end of the line, turn around and walk back to the starting point while reciting the letters of the alphabet (a,b,c,…). Please start when I say go. Ready, go"*

A B C D E F G

H I J K L M N

O P Q R S T U

V W X Y Z

A B C D E F G

H I J K L M N

O P Q R S T U

V W X Y Z

Walking While Talking Test (WWT) – Trial B Recording Sheet

Ask participants to recite every alternate letters of the alphabet starting from A at baseline; starting from C at T2 and starting from B at T3. Circle the letters recited in the alphabet below.

A B C D E F G

H I J K L M N

O P Q R S T U

V W X Y Z

A B C D E F G

H I J K L M N

O P Q R S T U

V W X Y Z

Appendix M: Locomotor Capabilities Index in Amputees (LCI-5)

Would you say that you are "able" to do the following activities WITH YOUR PROSTHESIS ON? Please **circle the number** that best describes your capability.

ITEM	NO	YES, if someone helps me	YES, if someone is near me	YES, alone, with ambulation aids	YES, alone, without ambulation aids
1. Get up from a chair	0	1	2	3	4
2. Walk in the house	0	1	2	3	4
3. Walk outside on even ground	0	1	2	3	4
4. Go up the stairs with a handrail	0	1	2	3	4
5. Go down the stairs with a handrail	0	1	2	3	4
6. Step up a sidewalk curb	0	1	2	3	4
7. Step down a sidewalk curb	0	1	2	3	4
Basic Activities Score					
1. Pick up an object from the floor (when you are standing up with your prosthesis)	0	1	2	3	4
2. Get up from the floor (e.g. if you fall)	0	1	2	3	4
3. Walk outside on uneven ground (e.g. grass, gravel, slope)	0	1	2	3	4
4. Walk outside in inclement weather (e.g. snow, rain, ice)	0	1	2	3	4
5. Go up a few steps (stairs) without a handrail	0	1	2	3	4
6. Go down a few steps (stairs) without a handrail	0	1	2	3	4
7. Walk while carrying an object.	0	1	2	3	4
Advanced Activities Score					
Total Score					