

Technologies Targeting Walking Capacity and Performance in People with Gait Vulnerabilities:
Time for a Business Model

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DEDICATION

I dedicate this thesis to my family and friends especially my beloved father (Omar), mother (Donya) and my wife (Bisan). Without their patience, understanding, support, and most of all their unconditional love, the completion of this work would not have been possible. I would also like to dedicate this thesis to my lifelong mentors Dr. Nancy E. Mayo and Dr. Kedar K.V. Mate.

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ABBREVIATIONS

AV	Angular Velocity
APA	American Psychological Association
%ile	Percentile
°/s	Degrees per second
2MWT	2-Minute Walk Test
6-MWT	6-Minute Walk Test
ACSI	American Customer Satisfaction Index
ADL	Activities of Daily Living
AIC	Akaike Information Criteria
APAO	Adopter, Product, Advantage, Outcome, Client
ASQ	After-Scenario Questionnaire
AT	Attitude Towards Use
BIC	Bayesian Information Criteria
BOS	Base of Support
c	Continuous Feedback
CI	Confidence Intervals
COM	Center of Mass
COM-B Model	Capability, Opportunity, Motivation and Behavior Model
COP	Center of Pressure
COPD	Chronic Obstructive Pulmonary Disease
D & I	Dissemination & Implementation
DOI	Diffusion of Innovation Theory
FES-I	Falls Efficacy Scale - International
FOG	Freezing of Gait
Fr χ^2	Friedman's χ^2
FSST	Four Square Step Test
GBTA	Group-Based Trajectory Analysis
HR	Hazard Ratio
HRQoL	Health-Related Quality of Life

ICF	International Classification of Functioning, Disability and Health
IMU	Inertial Measurement Unit
IMU	Igarria's Model
IP	Intellectual Property
KT	Knowledge Translation
KTa	Knowledge to Action
LEFS	Lower Extremity Function Scale
m/s	Meters/seconds
MDS-UPDRS	Movement Disorder Society- Unified Parkinson's Disease Rating Scale
m-health	Mobile-Health
MM	Motivational Model
MOCA	Montreal Cognitive Assessment
MPCU	The Model of PC Utilization
ms	Milliseconds
NPS	Net Promoter Score
OLS	Ordinary Least Squares Regression
OR	Odds Ratio
PAFS	Pilot and Feasibility Studies
PCT	Prospective Controlled Trial
PD	Parkinson's Disease
PDQ-8	Parkinson Disease Questionnaire - 8
PEOU	Perceived Ease of Use
PerfO	Performance Outcomes
PICOT	Population, Intervention, Control, Outcomes, Time
POR	Proportional Odds Ratio
PRO	Patient-Reported Outcomes
PT	Physiotherapist
PU	Perceived Usefulness
QoL	Quality of Life
RCT	Randomized Controlled Trial

ROI	Registration of Invention
RR	Relative Risk
SAS	Statistical Analysis Software
SCT	Social Cognitive Theory
SD	Standard Deviation
SES	Socio-Economic Status
STAM	Senior Technology Acceptance Model
SUS	System Usability Scale
TAM	Technologt Acceptance Model
TechO	Technologically Assessed Outcomes
TIB	Theory of Interpersonal Behaviour
TPB	Theory of Planned Behavior
TR	Technology Readiness
TRA	Theory of Reasoned Action
U&G	Uses and Gratification Theory
UB	Usage Behavior
UPDRS	Unified Parkinson's Disease Rating Scale
UTAUT	Unified Theory of Acceptance and Use of Technology
VAHS	Visual Analogue Health States
Walk- BEST	Walk <u>B</u> etter, Faster, Longer, <u>S</u> tronger

ABSTRACT

The prevalence of disabling health conditions and mobility-related disability are increasing worldwide owing to aging and increased longevity for people with chronic diseases. Effective and accessible treatments for gait impairments will increasingly be needed with the aging of the population and as people with health conditions live longer. Increasingly people with gait vulnerabilities and family members will turn to technological solutions to supplement and extend rehabilitation services. This growth in technological health interventions developed in academic-research institutions, evaluated for efficacy and effectiveness, appear in peer-reviewed papers and are not disseminated to patients in need. The full potential of health research will go unrealized without the design of appropriate organizational, managerial and business models. This thesis applies a business lens to the development and marketing of technologies to improve gait and walking behaviours in gait vulnerable populations. It demonstrates how business thinking applies to getting products to people. The first manuscript identified, through a cross-sectional survey of 649 older Canadians, perceptions of walking quality and identified contributors to and consequences of perceived walking. The most important elements of walking quality were foot, ankle, hip, and knee mobility with little difference in ranks across walking perception (Fr $\chi^2 = 5.0$, df 12, $p > 0.05$). Lung disease showed the highest association with a perception of not walking well (POR: 7.2; 95% CI: 3.7, 14.2). The odds of being willing to pay more for a technology to improve walking were always greater for those with a lower perception of their walking quality. The second manuscript estimated the extent to which the distribution of step count data over a period of weeks to months identifies different subgroups of people which could be used to indicate walking reserve. I considered the difference between the 90th percentile and the 50th percentile (median) to indicate reserve. The percentile distribution (10th to 90th) was used in a cluster analysis. 44 community dwelling seniors contributed 4180 persons-day of data. Four clusters were identified: (1) sedentary, low reserve; (2) limited activity, low reserve; (3) active, high reserve; and (4) very active, very high reserve. Low mood was associated with being in a lower activating cluster suggesting that people with low levels of activity post-fracture should be assessed for and treated for these factors before focusing only on increased physical capacity and activity. The third manuscript identified challenges of implementing a novel technology to improve walking in people with Parkinson's Disease where challenges arise from the device, engagement, usability perception of the client, and need for informational/technological support. A two-group,

randomized feasibility trial with 2:1 intervention to control randomization was carried out. This paper reports on the usability of the Heel2Toe sensor in a real-world setting. The system usability scale, administered only to those completing the intervention (n=14), yielded 182 person-responses. Overall, the rate of positive, neutral and negative endorsements was 0.41, 0.34, 0.25, respectively. The total number of calls among the 18 participants in the Heel2Toe group over the whole intervention period was 117, ranging from 1 to 29 calls, averaging 7 per person and the total time was 344 minutes, ranging from 2 to 70 minutes for an average of 22 minutes per person. All but one-person experienced challenges. The device tested in this pilot study was classified as the second revision, REV-B. By the end of the study, the device was in REV-D and now REV-E. Despite the challenges with the usability of the Heel2Toe, there was positive feedback related to the benefits of the Heel2Toe sensor. This thesis contributed methods and insights needed to develop a viable business plan to promote the adoption of technologies.

ABRÉGÉ

La prévalence des problèmes de santé invalidants et les incapacités liés à la mobilité augmentent dans le monde entier. Ceci est dû au vieillissement et de l'augmentation de la longévité des personnes atteintes de maladies chroniques. Des traitements efficaces et accessibles pour les troubles de la marche seront de plus en plus nécessaires. Beaucoup de personnes vulnérables à la démarche se tourneront vers des solutions technologiques. La croissance des interventions technologiques en santé, développées dans les établissements de recherche universitaire apparaît dans les articles scientifiques et ne sont pas diffusée aux patients qui en ont besoin. La conception de modèles organisationnels de gestion et d'affaires serait nécessaire. Cette thèse applique une perspective entrepreneuriale au développement et à la commercialisation de technologies visant à améliorer la qualité de la marche. Elle démontrera comment une réflexion entrepreneuriale s'applique à l'acheminement des produits aux gens. Le premier manuscrit a identifié, via un sondage transversale menée auprès de 649 Canadiens âgés, les perceptions de la qualité de la marche et les contributeurs et conséquences à la qualité de la marche perçue. Les éléments les plus importants de la qualité de la marche étaient la mobilité du pied, de la cheville, de la hanche et du genou avec peu de différence dans les rangs selon la perception de la marche (Fr $\chi^2 = 5,0$, df 12, $p > 0,05$). La maladie pulmonaire a montré l'association la plus élevée avec une perception de ne pas bien marcher (POR:7.2; 95%CI: 3.7, 14.2). Les chances d'être prêt à payer plus pour une technologie permettant d'améliorer la marche étaient toujours plus grandes pour ceux qui avaient une perception inférieure de leur capacité à marcher. Le deuxième manuscrit a estimé dans quelle mesure la distribution des données sur le nombre de pas sur une période de semaines à mois identifie différents sous-groupes de personnes. Ceci pourrait être utilisés pour indiquer la réserve de marche. J'ai examiné la différence entre le 90e centile et le 50e centile (médiane) pour indiquer la réserve. La distribution du centile (10e à 90e) a été analysée en grappes. 44 aînés vivant dans la communauté ont fourni 4180 personnes par jour de données. Quatre grappes ont été identifiées : (1) sédentaire, réserve faible; (2) activité limitée, réserve faible; (3) actif, réserve élevée; et (4) très actif, réserve très élevée. La mauvaise humeur était associée dans un groupe de faible actif. Le troisième manuscrit a identifié les défis liés à la mise en œuvre d'une nouvelle technologie pour améliorer la marche chez les personnes atteintes de la maladie de Parkinson où les défis découlent de l'appareil, de l'engagement, de la perception de la convivialité du client et du besoin de soutien informationnel/technologique. Celle-ci rend compte de la facilité d'utilisation du capteur

Heel2Toe. L'échelle d'utilisabilité du système, administrée uniquement aux personnes ayant terminé l'intervention ($n = 14$), a donné 182 réponses-personnes. Le taux d'approbations positives, neutres et négatives était de 0,41, 0,34, 0,25, respectivement. Le nombre total d'appels parmi les 18 participants du groupe Heel2Toe sur l'ensemble de la période d'intervention était de 117, allant de 1 à 29 appels, soit une moyenne de 7 par personne et le temps total était de 344 minutes, allant de 2 à 70 minutes pour une moyenne de 22 minutes par personne. Toutes les personnes sauf une ont eu des défis avec le Heel2Toe. L'appareil testé dans cette étude pilote a été classé comme la deuxième révision, REV-B. À la fin de l'étude, l'appareil était en REV-D et maintenant en REV-E. Malgré les défis liés à la convivialité du Heel2Toe, il y a eu des commentaires positifs liés aux avantages du capteur Heel2Toe. Cette thèse a fourni les méthodes et les connaissances nécessaires à l'élaboration d'un plan d'affaires viable pour promouvoir l'adoption de technologies.

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I would like to start by saying the following:

“O my Lord! Open for me my chest (grant me self-confidence, contentment, and boldness); Ease my task for me; And remove the impediment from my speech, so they may understand what I say.”

First and foremost, my faith in the Almighty God has made it easier for me to get through the PhD journey. My faith helped me see the invisible, believing in the impossible, and trusting in the unknown.

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assessing and overall conducting proper research. Her expertise was invaluable, and I thank you sincerely for all that you have done for me.

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Finally, a big thank you to all the participants and collaborators who took part in this thesis and who made this work possible.

To this day, I believe I am starting to know what I do not know.

PREFACE

Statement of Originality

As a physiotherapist, I was keen in developing, testing and implementing research innovations to people with walking challenges. As part of my PhD studies in rehabilitation science, I had been selected to participate in two entrepreneurial programs: (1) a 13-week intensive Entrepreneurial Acceleration Program offered by CenTech MedTech in collaboration with École de Technologie Supérieure and (2) McGill Dobson Entrepreneurship Program. These programs opened my eyes to a new world of opportunity in health research through a business perspective. It provided me with insights, tools and strategies necessary to commercialize viable health technologies. It struck me how similar knowledge translation and business models were, in that ultimately both models want to solve something in the world to make a populational and societal impact. The complementarity of both fields throughout the inception of an idea all the way to development, testing, licensing, marketing can be interchanged for commercialization of viable products, as funding is limited for academic researchers and does not guarantee a population health impact.

From these Acceleration Programs, I co-founded PhysioBiometrics Inc., a McGill spin-off enterprise dedicated to developing and marketing accessible therapeutic wearables to those who need them most, this places me in a conflict of interest. The technology presented in my thesis is being marketed through this company and experience with using this technology is part of my thesis work. I have no intention of letting my work with the company interfere with completing my doctoral thesis in a timely fashion. I must declare this conflict of interest as per rules and regulations of McGill.

The principal product line of PhysioBiometrics (www.physiobiometrics.com) Inc. targets gait quality through the Walk-BESTTM[1] toolkit developed by physiotherapists, researchers, and engineers to aid people with mobility challenges to walk Better Faster, Longer, Stronger, which is an achievable goal for people with gait vulnerabilities. The pivotal tool in the toolkit is the Heel2Toe sensor which is a new generation of SMART, (auditory) feedback-enhanced, wearables that provides accurate assessment of walking pattern, and real-time auditory feedback for efforts to optimize walking pattern [2-6]. The Heel2Toe sensor is registered as an invention with McGill University (ROI: 2021:007). The Intellectual Property in the Heel2Toe sensor is licensed to PhysioBiometrics Inc. by McGill University. The sensor is classified as a Class I Medical Device

by Health Canada and PhysioBiometrics Inc. holds a Medical Device Establishment License for sales and distribution in Canada.

While experience with forming a company and training clients to use the Heel2Toe sensor was the motivation to think of the practice of physiotherapy as a business model, the thesis is more general with respect to use of technology. Three papers make up the research activities I conducted which will be briefly described below.

Contributions of Authors

The manuscripts in this thesis are the work of Ahmed Abou-Sharkh with guidance from Dr. Nancy Mayo and Dr. Suzanne Morin.

The first manuscript relates to the size of the market and identified older Canadians' perception about the importance of expert generated walking elements and identified contributors and consequences of perceived walking quality. Mr. Inceer contributed to the expert-generated elements of walking well. Dr. Mate contributed to the development of the survey. Drs. Morais and Morin are co-authors on this manuscript and provided feedback on the manuscript. The manuscript is published in Physiotherapy Canada.

The second manuscript used the data from a Canadian Institutes of Health Research (CIHR) funded Randomized Controlled Trial (RCT) on A Community-based Monitoring, Rehabilitation and Learning e-System for Patients following a Fracture (Hip Mobile; PI: SN. Morin, NE Mayo, NCT03153943). This manuscript relates to repurposing existing technologies for innovating applications. Daily step count data on people with fracture were available for analysis. This manuscript identifies different subgroups of people which could be used to indicate walking capacity and reserve. I was responsible of recruiting and assessing the participants and my observations led me to derive methods and insights about an important gait vulnerability, low walking reserve. This project was supervised by Dr. Nancy Mayo and Dr. Suzanne Morin. The list of authors has not yet been finalized as the manuscript is not final.

The data for the last manuscript was obtained from a feasibility study on the Heel2Toe sensor on 27 people with Parkinson' Disease. I designed the protocol, selected the outcomes, conducted baseline and post-training evaluation, trained the participants at their homes in using the Heel2Toe sensor, and processed the usability and user experience data from the Heel2Toe. This project was

supervised by Dr. Nancy Mayo. The list of authors has not yet been finalized as the manuscript is not final.

The idea for this thesis came from my participation in entrepreneurial school during my PhD journey. It applies a business lens to the development and marketing of technologies to improve gait and walking behaviours in gait vulnerable populations. I contributed original thought and work on all of the projects that went into this thesis. Dr. Mayo oversaw all aspects of this thesis work and provided expert feedback on methodology and statistical analysis. Dr. Morin was a co-supervisor participating mainly in manuscript two and as a valuable mentor.

Thesis Organization and Overview

This thesis consists of three manuscripts of which the first has been published. The two last manuscripts are completed will be submitted to scientific journal to under-go peer review. This thesis is organized based on guidelines from Graduate and Postdoctoral Studies (GPS) and requirements of Library and Archives Canada: the work therein is organized as per below:

Chapters 1 through 4 set out background information that framed the research components.

Chapter 1 outlines the business need, the size of the market, and provides details on three gait vulnerable populations that were under study for this project.

Chapter 2 presents a review of existing technologies targeting gait. Here I take the customer's point of view when searching for technologies that are commercially available.

Chapter 3 presents the similarities and differences between knowledge translation and business models.

Chapter 4 presents the background on the challenges related to user experience metrics.

Chapter 5 presents the rationale and objectives of this thesis.

Chapters 6, 8 and 10 present the research components set out in three manuscripts.

Chapter 6 is Manuscript 1, titled: "What Do Older Canadians Think They Need to Walk-Well?"

Chapter 8 is Manuscript 2, titled, "Step-Count Distribution as an Indicator of Walking Reserve in People with Gait Vulnerabilities".

Chapter 10 is Manuscript 3, titled, “User Experience with the Heel2toe Sensor: A Novel Technology to Improve Walking in People with Parkinson’s Disease”.

Chapters 7 and 9 show the links between manuscript 1 and 2 and between 2 to 3, respectively.

Chapter 11 presents overall discussion of the findings, ideas for future direction, and conclusion.

References, Figures, and Tables are presented at the end of Chapter 8 (Manuscript 2) and Chapter 10 (Manuscript 3). As for Chapter 6 (Manuscript 1) the Tables and Figures are presented within the text. Referencing style reflects the journal guidelines. Referencing for Chapter 1 to 4 and Chapter 11 will be presented at the end of the thesis. Tables and Figures for these chapters are integrated within the text. All projects were approved by the Research Ethics Board of the McGill University Health Centre and all the participants signed an informed consent form.

CHAPTER 1: BACKGROUND

Problem and Impact

The prevalence of disabling health conditions is increasing worldwide owing to aging and increased longevity for people with chronic diseases[7, 8]. For example, the aging Canadian population is expected to increase over the next 15 years from some 7 million to over 9.5 million[9]. Complicating the aging process is that the occurrence of neurological conditions such as stroke and Parkinson's Disease (PD) rise with age[10] and 50% of seniors report some form of arthritis[11], many of whom undergo surgery for damaged joints. Canadian seniors wish to age well and remain active even with an increasing burden of morbidity and disability. The most prevalent disabilities for the aging population are pain (22%), decreased flexibility (19%) and mobility limitations (21%)[11]. Mobility limitations stem directly from impairments in strength, range of motion, balance, and endurance[12-14]. Mobility-related disabilities are the most prevalent in people aged over 45 years in the United States (US) and Canada with gait abnormalities as the leading reason of reduced mobility and independence[11, 15]. Some 8% of adults in the US are unable or find it very difficult to walk a quarter mile (400 m.)[16].

The gait pattern that characterizes optimal bipedal gait has evolved in order for man to be able to walk long distances efficiently and safely[17, 18]. In addition to descriptions of normal gait[19], a considerable amount of normative data has been accumulated[20-23].

Figure 1 shows the phases of normal gait and the values of angular velocity (AV) at ankle joint during the gait cycle.

Figure 1A shows a typical gait cycle. The cycle starts with heel strike (yellow foot) as the initial contact followed by foot flat where the body weight is transferred to the leading leg while the other leg is in toe-off phase (blue foot). The next part of the cycle is the pre-swing phase that starts with heel off. The swing phase starts with toe-off and terminates in preparation for heel strike (yellow foot).

Figure 1B shows the gait cycle from the perspective of ankle angular velocity. The cycle is characterized by two troughs (heel strike and toe-off) and one peak (swing). The values of AV are negative when the ankle joint moves in a clockwise direction and positive for counter clockwise movements. The first trough is a result of heel strike while the second trough is due to toe off, both

around the ankle joint resulting in negative values. The peak (positive value) is for swing phase when the ankle rotates counter clockwise to allow for foot clearance.

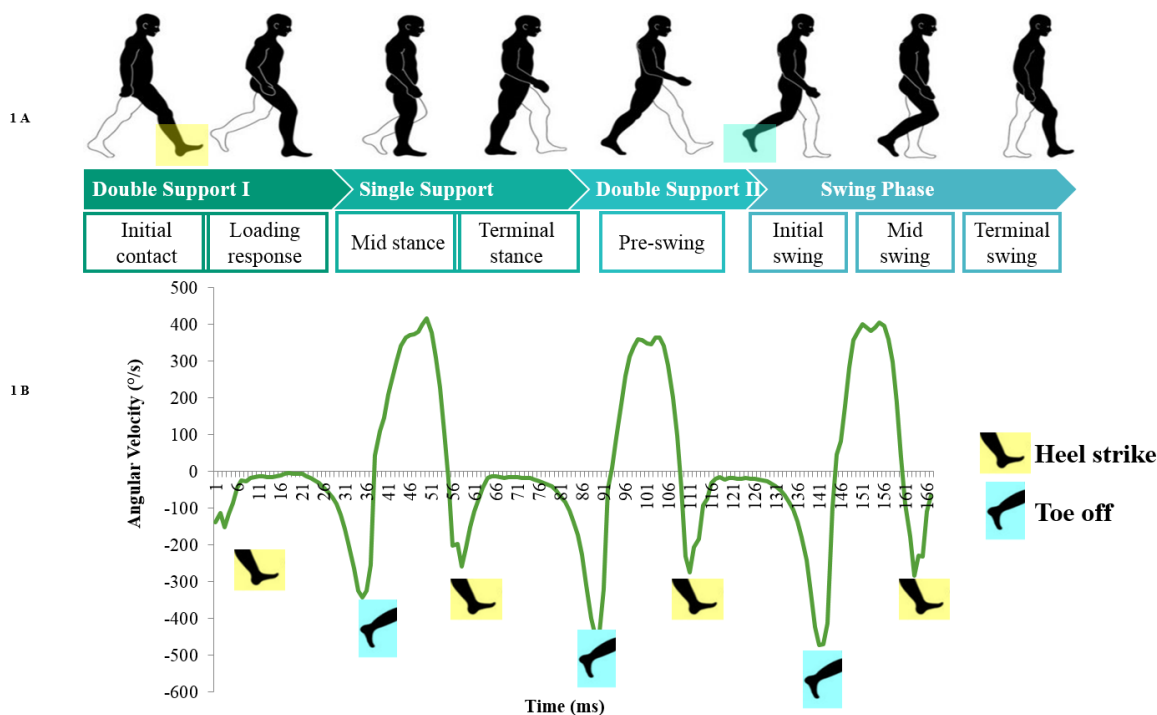


Figure 1 The Gait Cycle.

With aging, this optimal gait pattern can deteriorate to one that is slow, inefficient, fatiguing and unsafe and, as a result, is ill-suited to respond to demands of community walking and to meeting physical activity guidelines for health promotion[24-26]. Physical activity guidelines recommend 150 minutes of moderate to vigorous intensity physical activity over a week in bouts of 10 minutes (<http://www.csep.ca/en/guidelines/get-the-guidelines>)[27]. This translates walking at a pace of a 100 steps per minute in bouts of 10 minutes, twice a day for 150 minutes a week, every week[27, 28]. A survey from Statistics Canada indicated that only 12% of Canadian seniors above the age of 65 meet the current Physical Activity Guidelines (minimum 150 minutes per week), accumulating less than half the recommended physical activity time (~56 min/week)[29]. One of the most accessible and effective physical activities is walking[30] and it is recommended for older persons to accumulate at least 15,000 steps per week (Figure 2)[28, 31]. However, many people with gait impairments do not walk well enough to sustain walking at an intensity and duration to achieve these health promoting targets[32]. Walking at a brisk pace for 3000 steps could take upwards of 30 minutes.

Figure 2, from Tudor-Locke[31, 33], provides step-count targets for different populations. In 2004 Tudor-Locke[33] critiqued the “10,000 steps a day” value as being unrealistic and too much for some (older persons and those with chronic conditions) and not enough for younger populations. For older adults and people with disabilities, the recommendation is to accumulate at least 15,000 steps per week at a brisk pace. This “3000 steps per day” value through targeted walking accumulated over and above usual activities was suggested as a public health approach for health promotion[34].

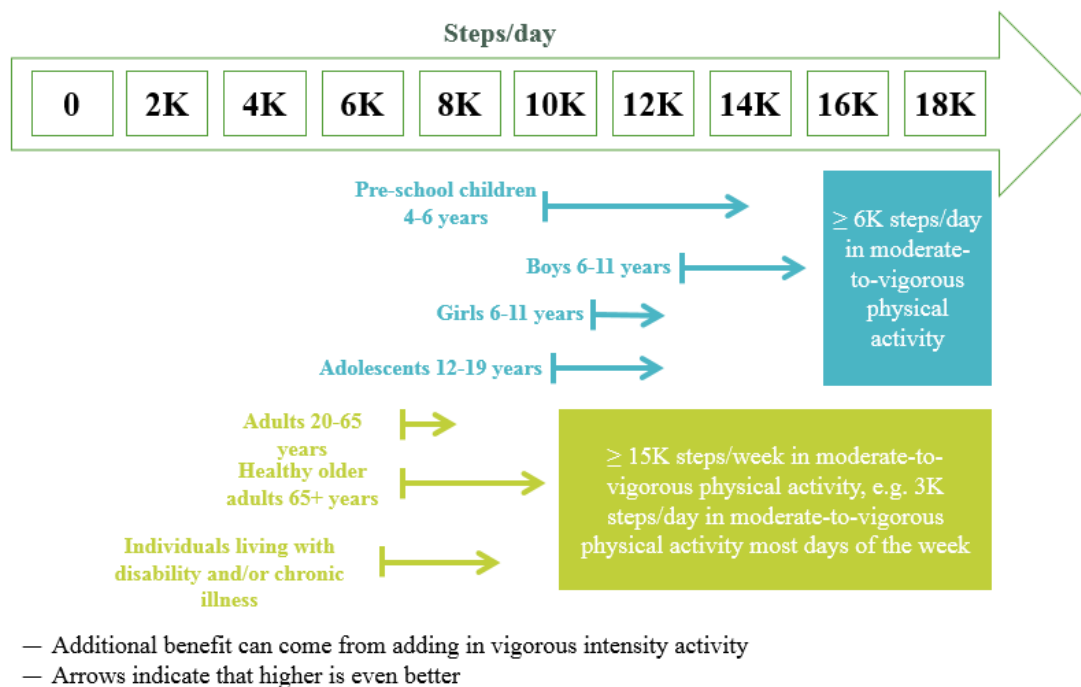


Figure 2 Recommended Step Counts for Different Populations (Adapted from Tudor-Locke et al. (2011))

Promoting healthful walking is not only good for the body, it is good for the brain[35]. Despite capacity to walk at a health promoting pace when tested clinically, it is rare for the North American senior to do this in the real world for more than a few minutes a day[32].

Tudor-Locke has defined different cadence bands as shown in Figure 3 below[36]. Healthy older persons typically walk at a pace between brisk and fast over a short distance[37] but may not sustain this over a longer distance.



Figure 3 Cadence Bands (Adapted from Tudor-Locke et al. (2018))

There is considerable evidence that sustained engagement in physical activity is important for the prevention of health conditions including osteoporosis[38, 39], obesity[40, 41], cardiovascular disease[42, 43], stroke[44-46], arthritis[47], and falls[48, 49]. Fear of falling and age or illness-related changes co-occur in the majority of gait vulnerable people and can induce an inefficient and dangerous gait pattern[24-26].

The Clinical Solution: Rehabilitation and Physiotherapy

The health professionals most engaged in improving walking capacity are physiotherapists (PTs), alone, or as part of a multi-disciplinary health team comprising medical, surgical, and rehabilitative disciplines. Rehabilitation services currently support seniors only in cases of health crises such as after a fall resulting in an injury. However, the physical changes leading to falls occur long before the event. The at-risk population rarely enters the health care system for fall prevention. This is a gap that needs to be bridged.

The practice of physiotherapy is evolving. Historically, focused on providing therapy in response to health crisis, PTs now have an important role to play in prevention and health promotion[50-52] as the global burden of disease and mobility-related disabilities is rising[7, 15].

There is Level 1A evidence as per the Centre for Evidence-Based Medicine (Oxford) classification[53] (from systematic reviews) that gait training is effective in improving gait pattern following acute events[54-58]. In the case of chronic health conditions, gait training is only

partially effective[59-62], and effects abate without continued instructions and feedback[61, 63, 64].

Typically, during clinical gait training, PTs use several verbal and visual cues to place the heel first when stepping[65-67]. This is a key target as heel strike initiates the gait cycle and sets up the other phases. This simple strategy changes posture from stooped to upright and lengthens the stride[65-67]. But once verbal cueing ceases, patients revert to an inefficient foot-flat gait [65-67]. Hence alone, gait training will not translate into the sustained behavioural change needed for promoting healthful walking.

The recent literature has now moved to developing and evaluating technological innovations such as robot assisted gait training, treadmill, wearable technologies and virtual reality[68-73] to enhance the effectiveness of gait training.

What is Walking?

Walking is a natural way to get about[30] but with age, gait deviations emerge making walking inefficient and potentially dangerous. A variety of terms are used to describe different aspects of walking (Table 1).

Table 1 Definitions of Walking, Gait, Stepping, Ambulation, Capacity and Performance

Walking	A rhythmic, dynamic, aerobic activity involving large skeletal muscles usually done for recreational purpose or as an exercise[30].
Gait	The manner of walking.
Stepping	The action of the lifting one foot off the ground and placing it elsewhere, producing a locomotor displacement for centre of mass and is a feature of very slow walking speed.
Ambulation	The action of walking about with no stipulation as to how (http://medical-dictionary.thefreedictionary.com/ambulation)
Capacity	What an individual can do in a 'standardized' environment[74].
Performance	What an individual actually does in his or her 'current' (usual) environment[74].

In the field of rehabilitation, gait and walking are described by the International Classification of Functioning, Disability, and Health (ICF). Gait is the manner of walking and is classified in the ICF as functions of movement patterns associated with walking, running or other whole body movements (b770)[74]. Walking classified in ICF as moving along a surface on foot, step by step, so that one foot is always on the ground, such as when strolling, sauntering, walking forwards, backwards, or sideways. (d450)[74].

Gait-related impairment is a part of functioning covering body functions (physiological functions of body systems) and structures (anatomical parts of the body), activity (execution of a task or activity) limitations and participation (involvement in life situations) restriction[74](Figure 4). The ICF also defines two other aspects of function: “capacity” is what an individual can do in a ‘standardized’ environment; and “performance” is what the person actually does in his or her ‘current’ (usual) environment[74]. In other words, capacity is “can do” and performance is “does do”[75]. In the context of walking, performance is the ability to use the person’s existing capacity to achieve goals such as walking for activities of daily living, work, recreation, leisure, and health promotion.

The ICF provides a biopsychosocial framework to understand systematically phenomena related to function specifically to gait-related impairment as per the aim of this thesis. A literature review revealed that older people’s participation in out-of-home activities are indicators of well-being and are critical to ageing well and to fulfill basic, social, and emotional needs[76-78]. Thus, the importance of walking.

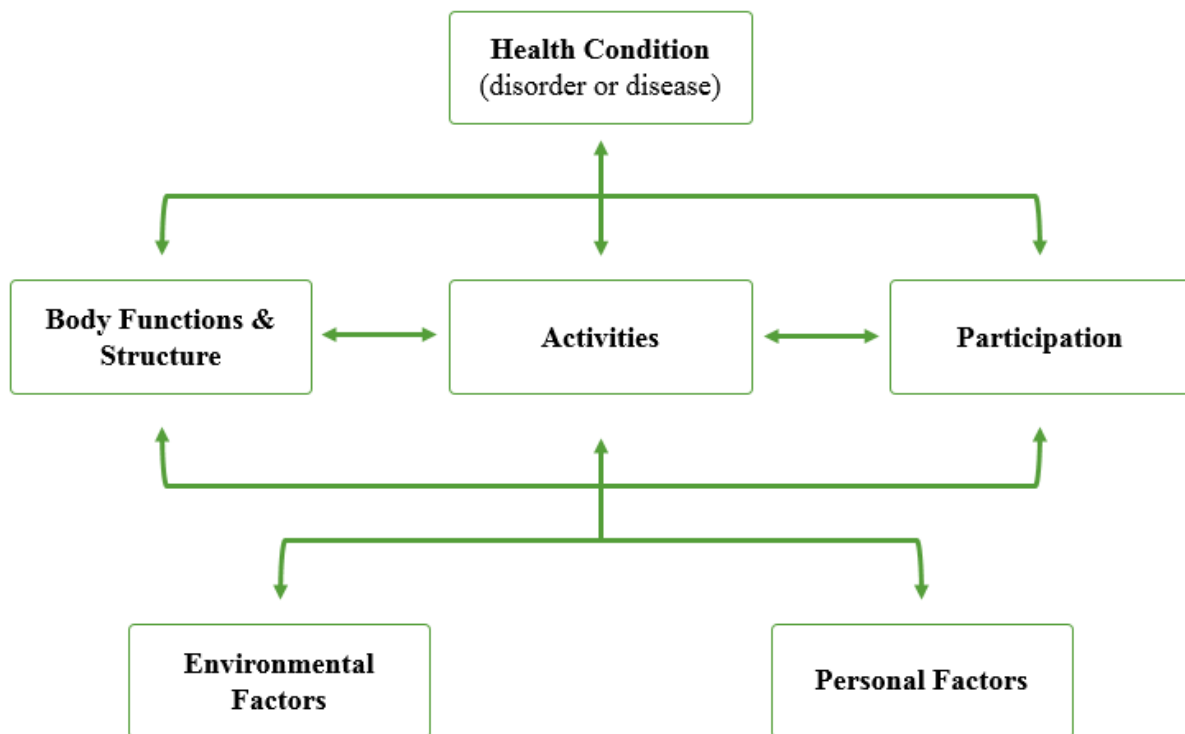


Figure 4 International Classification of Functioning, Disability, and Health (ICF) Model

Behaviour Change Wheel: The COM-B Model

Performance under the ICF could also be considered a behaviour optimized through applying a behaviour change model[79]. Most behaviour change models are not specifically operationalized with respect to changing behaviours in people with physical disabilities limiting the behaviour.

A model that is compatible with the ICF framework is the Behavior Change Wheel model[80], known as the COM-B model[79]. In this model, **C**apability is defined as “*the individual’s psychological and physical capacity to engage in the activity concerned. It includes having the necessary knowledge and skills.*” **M**otivation is defined as “*all those brain processes that energize and direct behaviour, not just goals and conscious decision-making. It includes habitual processes, emotional responding, as well as analytical decision-making*”. **O**ppportunity is defined as “*all the factors that lie outside the individual that make the behaviour possible or prompt it*”. The relationships between these concepts are dependent as both capability and opportunity can influence motivation. The American Psychological Association (APA) Dictionary of Psychology[81] refers to behavior as observable, introspective, or non-conscious activities that occur in response to external or internal stimuli. Observable behaviors are those that can be directly measured. **C**apability, **O**ppportunity and **M**otivation are necessary contributors to **B**ehaviour, which in my context is walking (Figure 5).

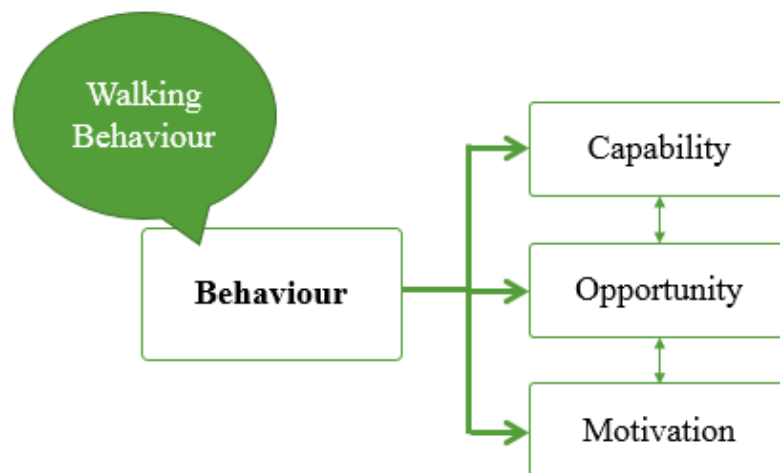


Figure 5 COM-B Model

Figure 6 operationalizes the COM part of the COM-B model. In this context, people need sufficient physical capacity to walk which includes optimal gait pattern, strength, joint mobility, joint stability, balance, endurance, speed, co-ordination and it is pain-free. Opportunity includes time,

built environment, social support, independence. Motivation includes cognition, energy, optimism, and low stress[82].

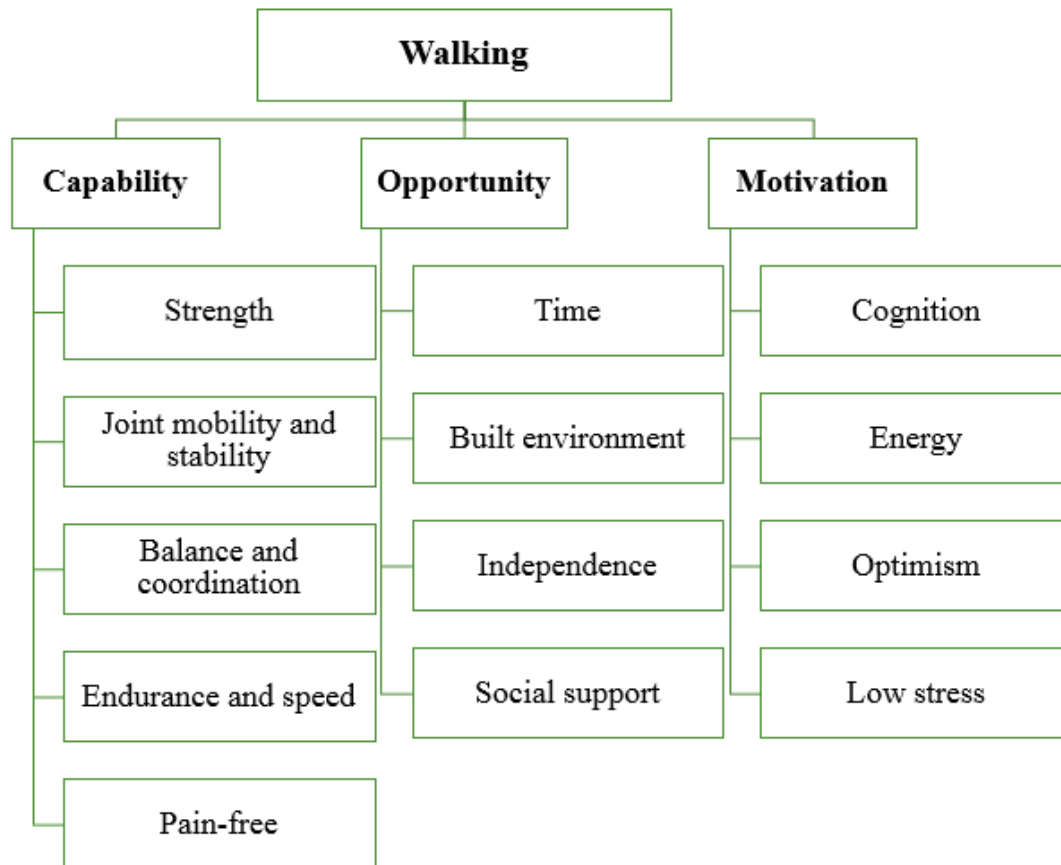


Figure 6 Components of COM-B Model in Older Persons with Gait-Vulnerability

Gait Vulnerable Populations

Three populations with gait vulnerability are under study in this thesis and are briefly described below.

Older Adults

Normal physiological changes occur with aging, resulting in decreased ability of the musculoskeletal, nervous, and cardiovascular systems to interact with one another[83]. These changes may affect movement production and control, leading to mobility limitations such as gait abnormalities and modifications in posture[12-14]. After a serious health event affecting mobility such as hip fracture, the return to a normal gait pattern, let alone a gait pattern that permits health promoting walking is jeopardized[14]. Evidence shows that gait training is effective in improving gait pattern[54-58], but effects abate with cessation of training[61, 63, 64].

Natural aging and disabling health conditions affect balance, strength, flexibility, endurance, and attention paid to walking pattern[84, 85]. These result in a walking pattern that deviates from optimal, is slower, and requires more effort. Eventually gait vulnerable people choose to walk less. Illness or injury can accelerate this downward cascade and lead to permanent disability and premature mortality.

Every person at one point in their lives will experience, or witness in a loved one, a deterioration in mobility, notably walking. Walking is the most valued life activity[86] and 2 of 3 seniors self-identify that they do not walk well[87]. People who do not walk well are at high risk of falls as most falls occur while walking[88]. Given that 10% of people 70+ years will fall annually, generating some 2 billion \$CAD in health care costs, reducing fall risk is a personal and public health priority[88, 89]. It is important to promote better and safer walking.

Fractures

Among the common health events that occur as people age, lower limb fractures are one of the most debilitating and threatening to an older person's ability to live independently[90]. Older people who sustain lower limb fractures or injuries often already have co-morbidities or mobility challenges at time of injury[91]. After injury and treatment many do not regain previous function[92, 93] and even show deterioration in general health and self-efficacy leading to restricted social activities and isolation[94].

Fall-related injuries in older people lead to hospitalisation, loss of autonomy, persistent morbidity, and premature death[95]. Some 30% of older people fall each year and, in many cases, falls are recurrent. Falls in this population are associated with increased risk of fractures and this increases with age[96, 97]. Treatment costs associated to these injuries were estimated to be 1.3 billion dollars attributed to acute care hospitalization and rehabilitation[98]. This makes fall prevention a public health priority. The rehabilitation process after hip fracture is centered on retraining gait but many do not recover fully their capacity to walk for exercise, recreation, or health[99].

Parkinson's Disease (PD)

Parkinson's Disease affects 1 in every 500 people in Canada and >100,000 are living with PD today and this will increase by 65% by 2031[100]. Of the neurological conditions, PD has the 3rd highest level of direct health care costs and the highest use of prescription medications[101].

Approximately four million people worldwide are living with the condition. Even within 5 years of diagnosis, 60% will experience difficulty walking and postural instability leading to a fall[102]. One of the most serious consequence of PD is falls and fractures, most of which occur during walking[103]. People with PD are more >2.5 times more likely than a peer group to sustain a hip fracture[104, 105]. The cost of treating hip fractures alone for people with PD in Canada would be estimated at \$3.6 million[104, 106-108].

People with PD have a distinguishing gait pattern, one that is characterized by stooped posture, and small shuffling steps with the center of mass too far forward to be safe. This pattern is disabling and dangerous and diminishes quality of life[109]. In Canada, people with PD are not routinely offered public sector rehabilitation services unless after a health crisis. The recent Canadian Guideline for Parkinson Disease[110] states that “*Physiotherapy specific to PD should be offered to people who are experiencing balance or motor function problems*”. There is a huge gap between should and are: only 1.5% of home care visits in Canada are attributed to PD[111]. At best, they may see a therapist at a regular medical visit for an assessment. People can access private physiotherapy but costs approach \$100 per visit unless the person has private insurance and few private practices specialize in neurological conditions.

Summary

Gait is one of the most frequently assessed attributes in clinical settings as gait impairments are hallmark of different health conditions[112, 113]. Prevalence of poor gait and gait associated consequences are on the rise as people are living longer, with multi-morbidities such as obesity, and diabetes and a global increase in the proportion of neurological conditions[26, 114]. Gait impairments and walking limitations from aging, disease, or injury, increase the risk for falls, joint damage, and a sedentary lifestyle leading to a vicious cycle towards further deterioration[115].

Practical treatments for gait impairments will increasingly be needed as rehabilitation services will not be able to keep up with the demand for treatment, let alone prevention and health promotion. Technological innovations are poised to close the gap between demand and supply. The research in this thesis focuses on the use of technology to fill this access gap illustrated for three populations: older persons, people with lower limb fractures and people with PD.

CHAPTER 2: TECHNOLOGY TO SUPPORT REHABILITATION FOR GAIT AND WALKING

Effective and accessible treatments for gait impairments will increasingly be needed with the aging of the population and as people with health conditions live longer. Increasingly people with gait vulnerabilities and family members will turn to technological solutions to supplement and extend rehabilitation services. Technological innovations are poised to close the gap between demand and supply. There no doubt that older adults and people living with health conditions would benefit focused gait training beyond what is offered during a clinical visit. Technologies can provide people with opportunities to practice gait-related skills outside the clinical environment and gain ‘ownership’ over their therapy[116]. There is evidence that simply using technology can influence positive behaviour change; interactive smartphone applications can reduce sedentary time by 41 minutes per day[117, 118]. These effects are thought to be a result of the user’s ability to self-monitor and self-correct, thus providing more control and responsibility for their own therapy[118]. Given the unmet need for access to rehabilitation services and the need to continue therapy outside clinical settings, commercialization of technology is timely and necessary.

Available devices range in sophistication, from non-electronic shoe insoles and walking aids to inertial or pressure sensors. Most technologies have gait assessment functionality but there is now increasing interest in harnessing the capacity of wearable sensors to provide biofeedback. The literature is rich in supporting the effectiveness of biofeedback in improving gait patterns in healthy and clinical populations[62, 119-121].

There is an increasing number of devices that claim to improve gait impairments through biofeedback. However, it is still rare that these devices are available to the consumer, most are still tied to a laboratory setting. There is an urgent need to move technological innovations from research laboratories to the people who would benefit the most, those with gait impairments.

The market of people needing gait training technologies is huge. As a result of direct access to several technologies to the general public, the impact of evidence presented on the websites could affect purchasing behaviour. A study on buying intention of online consumers found that “high involvement” consumers, meaning they were intently looking to purchase something specific, were more likely to purchase a product if the number of quality reviews was high[122]. Individuals with gait impairments may be considered “high-involvement” consumers, and therefore may

purchase related products based solely on available reviews which may or may not have research quality.

Gait training technologies must be appealing with features such as product attractiveness, functionality, and price as well as being supported by robust research demonstrating efficacy and effectiveness. All these features are equally important, an attractive product that does not work or an expensive product that does work would not be appealing. While the attractiveness of technologies is often featured on the websites, the evidence could be hard to locate. Furthermore, public is not likely to have the time or training to critically appraise the literature to guide their willingness to purchase.

This chapter presents a review of existing technologies targeting gait. Here I take the customer's point of view when searching for technologies that are commercially available.

Searching for Technologies

There is no systematic way of identifying technologies that are available to the public to help improve gait. Several systematic reviews provide evidence to support the efficacy and effectiveness of biofeedback technology to improve gait among people with and without health conditions[123-127]. These systematic reviews led to technologies such as smart soles, smart socks, and others. This preliminary set of devices acted as a seed to identify other technologies thus simulating a snowball sampling strategy. The technologies identified through this process were combined with those that were identified using search terms such as 'biofeedback devices walking', 'wearable sensors' on public search engines such as Google and medical database such as PubMed.

The terms were selected from a consumers' perspective of what they are most likely to use. A findable list of technological devices targeted to health conditions was extracted separately by three authors and compared for completeness. Information on the target population, mechanism of feedback, evidence for efficacy/effectiveness, and commercial availability were obtained from the published material or websites. Only devices that claimed gait rehabilitation or gait quality improvement through any mode of sensory feedback such as visual, auditory, haptic (tactile or kinesthetic), or vibration were included. The devices were excluded if the technology was not targeted to any health conditions or targeted high functioning populations such as athletes or

healthy individuals. The term ‘feedback’ is defined as physiological signal arising as a result of human movement that in turn generates an output (error or correct performance) which is relayed back to the user that has the potential to modulate (enhances or diminishes) subsequent movement.

For each device identified, the evidence for efficacy or effectiveness was extracted from material displayed on the websites and full-text articles were obtained from the scientific databases, PubMed, Ovid Medline, Scopus, or Google Scholar. A level of evidence was assigned to each study involving the device using the *Oxford Centre for Evidence-based Medicine Levels of Evidence*[53, 128] (Appendix 1).

Findings

The search yielded a total of 17 devices that claim to target improvement in gait quality through various types of feedback: 11 commercially available, and 6 at various stages of research and development. The inclusion of these devices was appraised by me and one other reviewer. Table 1 shows all the technological devices extracted from the search and are divided into those that are commercially available to the users and those that are in various stages of research and development. For each device (alphabetically), Table 1 presents a brief description of the device, feedback type, target condition, level of evidence, components, and website link available at the time. Overall, five of 10 these devices are targeted to gait training in people with Parkinson’s. Table 2 presents information on population, intervention, control, outcomes, time, training, results, usability, and level of evidence with study design. All the 11 studies covering three devices had small sizes ranging from 6 to 40. This calls into question the strength of the evidence and the generalizability of the findings outside the study population.

To illustrate an example, the BalancePro insoles are plastic insoles with a raised ridge around the perimeter that provides continuous haptic feedback, targeted to people with Parkinson’s and older adults. The insoles are available for direct purchase on the company website, and the design patent application is under review. The evidence supporting the BalancePro technology comes from two cross-over study designs and one randomized controlled trial at level 2b[53, 128].

Discussion

There is a challenge in searching for information on technology. In a paper on aqua-therapy for people with Parkinson's Disease, the authors used a commercial "social listening" service, Awario©, which searches a variety of social media platforms (i.e. Twitter, Instagram) and the web for investigator selected key words[129]. The strategy used here was a form of "snowball" sampling where systematic reviews served as the source and the web was searched for any devices named in these reviews.

Eleven of 17 technological devices are commercially available to the public and have a dedicated website for direct purchase. Four of these 11 devices had published evidence on effectiveness at level 2b of evidence (see Table 2). There was no searchable evidence available for efficacy or effectiveness of the feedback from the remaining seven gait training technologies.

Most of the technologies used a variety of biofeedback (positive, negative, and continuous) and had options for choosing or providing a single pre-set sensory stimulus - auditory, haptic, visual, or vibration. A few devices offered practitioners and consumers with a choice to select the feedback frequency and type stimuli. When it comes to choosing the type of sensory stimuli, there is no information available on the efficacy of one sensory stimulus over the other.

Most devices target gait improvement for people with neurological conditions. Evidence is primarily generated for one health condition, but the claims are generalized to other health conditions with similar impairments. There was limited to no data available on usability and safety. Almost all websites stated some user review or testimonials from the user, which are likely to be selective in favor of supporting the technology. It is important for clinicians to be aware that some scientific evidence supporting the technology may exist, but a consumer is mostly likely unable to access the published material. A consumer may be driven to purchase a device merely by reading reviews or testimonials.

Most technology producing companies reported one or more clinical trials that are underway, yet there is lack of any trial specific information. A potential consumer is unlikely to track these details. It is important to consider the transparency and accessibility of scientific evidence when educating and making evidence-based recommendations to patients.

One of the technologies reviewed was developed by PhysioBiometrics Inc., which is a McGill spin-off company. It provides, real-time positive auditory feedback for a “good” step. It has level 2a evidence for effectiveness (see Table 1).

As newer technologies for gait training are continuously developed it is important that the evidence supporting efficacy and effectiveness are available to people to make an informed choice. Often the published literature is unavailable to the general population because of the journal firewalls. There was also a lack of consistency in reporting information related to usability, safety, or user-feedback. Standards for reporting on research involving technological devices, in the form of reporting guidelines appears to be needed to ensure that the data needed for the potential consumer is communicated.

This review provides a summary of commercial wearable gait training technology that are currently available in market or in development phase. A unique feature of this review is that it was conducted from the perspective of a consumer and then augmented by summarizing the evidence from scientific publications. While the strength of evidence supporting the effectiveness of technology is low or moderate at best, the claims on website often surpass the evidence. The results can also be used by professionals involved gait rehabilitation to direct their clients to promising technologies based on available evidence. These technologies can also be incorporated into treatment plans.

While there is strong interest from academic institutions and government agencies to transfer technologies from laboratories to clients, there is a need for due diligence, both on the part of the institutions and industries, to accurately report the findings that not only support the science but will influence a client’s or an organization’s decision to purchase the technology.

Strengths and limitations

The approach taken here may not yield complete results and, as new technologies are continuously developed and added to or removed from the market, the results can quickly become out of date. The findings of this review are therefore only valid based on the search conducted at the time. Given the difficulty in searching for technologies, the search method reported here may be difficult to reproduce.

Conclusion

This systematized review provides the public and healthcare practitioners a summary of information that can be used to choose or not to adopt technologies. The review covers 17 wearable devices and outlines the mechanisms claimed to underlie gait improvement. There was no predominance for biofeedback type (positive, negative, or continuous). A variety of biofeedback modes are used (auditory, visual, or haptic), with auditory and vibratory haptic being the most common. The strength of the evidence supporting these devices from scientific sources was at a 2a or 2b level.

Tables

Table 1 Description of Gait Training Devices Available to Consumers and for Research Only

Gait Rehabilitation Devices	Feedback Type	Condition	Evidence for Efficacy or Effectiveness (number of studies)	Interface	Website
Targeted: Directly available to clients					
BalancePro: Insole with raised edges that provides passive sensory feedback on soles to enhance proprioception	Haptic c	Older adults, impaired circulation, neuropathy	Level 2b (3)	None	https://balancepro.ca
FeetMe Stimulate/Insole/Rehab: Insoles with embedded sensors that collect gait and balance data and provides electrical stimulation at the foot or ankle to correct gait pattern	Auditory +, haptic +, Visual +	Neurological conditions, obesity, COPD, older adults	---	Pressure and IMU sensors in insole, electrodes, Android app,	https://feetmehealth.com
Heel2Toe: Sensor worn over the shoe that provides real-time auditory feedback on making 'good steps' heel strike	Auditory +	Parkinsons, older adults	Level 2b (1)	IMU, Android app	http://physiobiometrics.com
Isowalk: Self-propulsive cane that guides user's step forwards	Haptic c	Fall risk	---	None	http://isowalk.com
MEDRhythms: Two wearable sensors attached to each shoe, that provide rhythmic auditory feedback based on gait parameters to improve gait.	Auditory +	Neurological conditions	---	Headphones, IMUs, smartphone app	https://www.medrhythms.com
WalkWithPath (Pathfeel): Insoles with embedded pressure sensors that provide vibration corresponding to the pressure detected to enhance sensory information coming from the foot.	Haptic vibration c	Parkinsons, peripheral neuropathy	---	Pressure sensors, Bluetooth connection to smartphone app	https://walkwithpath.com

WalkWithPath (Path Finder Laser Shoes): Lasers attached to shoes bilaterally activated by body weight on the stance foot and emits a horizontal light line on the floor on the opposite side for user to step on or over	Visual c	Parkinsons	Level 2b (3)	None	https://walkwithpath.com
ReMoD V5.0 Type I: Vest with attached sensors that detect postural deviations and provides electrical stimulation at the anterior shoulders to correct trunk position when the user deviates past the set threshold.	Electrical -	Stroke, scoliosis, poor posture, sensory or vestibular dysfunction	---	None	https://www.hemiparesis-therapy.com
Vibrating Insoles (Wyss Institute): Insoles that provide subthreshold vibration continuously to enhance natural sensory information coming from the foot to improve balance and step consistency	Vibration c	Recreational athletes, older adults, neurological conditions	---	None	https://wyss.harvard.edu/technology/vibrating-insoles-for-better-balance/
VOXX HPT Socks & Insoles: Socks or insoles with embedded tactile pattern under the ball of the foot that stimulates neural system to encourage the brain into a state of homeostasis	Tactile c	Poor balance, fall risk	---	None	https://voxxlife.com/shop/
Walkasins: Insoles attached to ankle unit that detect pressure under the foot and provides vibration just above the ankles to improve balance and gait	Haptic vibration +	Asymmetric gait (stroke), Neuropathy	---	None	https://rxfunction.com
CuPiD/Gait Tutor: Three wireless sensors that evaluates real-time quality of gait and provided vocal message to walk safely, effectively, and smoothly.	Auditory and visual -	Parkinsons	2b (2)	Smartphone, IMUs, docking station	https://mhealthtechnologies.it
Research only, not commercially available					
AmbuloSono: Wearable sensor worn on the leg and provides auditory feedback (music) once a pre-set threshold is reached. If steps are too small, the music will stop.	Auditory +	Parkinsons	---	IMU, audio speaker, iPod touch, Bluetooth	none

Artistic 2.0: Insoles that detect asymmetries and uses a smartphone app display, high/low tone beeps, or long/short vibrations at the ankle to encourage symmetry	Auditory, visual, vibration -	Neurological conditions, amputations	---	Silicon insoles with force sensors, a microcontroller, Bluetooth, Android app	none
CueStim: Electrical stimulation unit with electrodes on the quadriceps or hamstrings that continuously ramp up and down to overcome shuffling and freezing of gait	Electrical c	Parkinsons	---	Electrostimulation device, Bluetooth, smartphone app, electrodes	none
VibeForward: Two vibratory tactors placed inside the user's personal shoes, a small electronics box containing a battery and an IMU strapped around the ankle, and Bluetooth connection to a smartphone app. When activated by a switch on the device or a remote, the tactors provide vibration cycling from the hind to forefoot in synchrony with the user's step. The smartphone app acts as a remote control for the vibration	Vibration -	Parkinsons	---	Tactors, IMUs, Bluetooth connection, smartphone app.	none
Walk-Even: Insoles detects uneven weight distribution signals a speaker on the waist band to change weight distribution (auditory cue) or nociceptive electric stimulation is given on the thigh of the unaffected leg to encourages faster movement of the paretic limb.	Auditory -, Nociceptive -	Asymmetric gait (stroke)	---	Hard wired	none
Walk-Mate: Wearable sensor, auditory feedback on foot-ground contact. Used as a gait compensation device to promote consistent cadence and gait symmetry	Auditory -	Neurological conditions	---	IMU, computer, headphones, hard wired	none

+: positive feedback, -: negative feedback, c: continuous feedback

IMU: Inertial Measurement Unit; COPD: Chronic Obstructive Pulmonary Disease

Table 2 Evidence Supporting Effectiveness of Gait Training Devices

BalancePro	
Author, Year	Jenkins, 2009 [130]
Population	Parkinsons, n=40: 16 women / 24 men; age-matched controls n=40: 25 women / 15 men
Intervention	Facilitatory shoe insole
Control	Conventional flat insole
Outcome	Spatio-temporal gait parameters using GAITRite mat, and muscle activity using EMG (in 20 people with Parkinsons and 20 controls)
Time	Concurrent trials
Training	10 walking trials: 5 with facilitatory and 5 with conventional insoles
Results	Group effect on velocity, step length, and step length variability
Usability	Not reported
Level of evidence, study design	2b, cross-over (Website and PubMed)
Author, Year	Maki, 1999 [131]
Population	Older adults, n=14: 6 women / 8 men; 7 healthy controls
Intervention	Modified insoles
Control	None
Outcome	Center of mass displacement and stepping reactions using force plates
Time	Concurrent trials
Experimental condition	multiple transient and continuous perturbations, 40 and 16 for older adults; 56 and 24 for controls
Results	facilitation reduced the number of forward step reactions to perturbations
Usability	Not reported
Level of evidence, study design	2b, cross-over (Website and PubMed)
Author, Year	Perry, 2008 [132]
Population	Older adults, n=40: 19 women / 21 men; age 65-75 years
Intervention	Facilitatory insole
Control	Conventional insole
Outcome	Lateral displacement of COM in relation to BOS during single-support phase
Time	12 weeks
Training	12 trials on 4 uneven surfaces wearing each sole
Experimental	12 weeks of wearing randomly assigned sole
Results	Outcome effect for 2/4 uneven surface conditions
Usability	Lower fall rate in intervention (25% vs. 45%); mild discomfort occurrences reported for 17/240 wear-weeks; 17/20 would continue wearing
Level of evidence, study design	2b, randomized trial (Website and PubMed)

<u>Heel2Toe</u>	
Author, Year	Mate, 2020[6]
Population	Older frail and pre-frail person, n=6: 4 women / 2 men
Intervention	Supervised training with the Heel2Toe sensor, 5 sessions over 2 weeks
Control	None
Outcome	Spatio-temporal gait parameters, system usability.
Time	Immediate pre-post feedback; end of training without and with feedback
Training	Supervised gait training and walking practice with the Heel2Toe sensor providing feedback for good steps. Prescription of 5 exercises, 1 per walking component.
Results	Immediate and post-training response: 5/6 made meaningful change on good steps, angular velocity, and coefficient of variation. 1/6 high functioning person showed no change.
Usability	38 item responses: 25/38 (66%) at optimal levels and 9/38 (24%) were at poorest levels
Level of evidence, study design	2b (Website and PubMed)
<u>Walk With Path</u>	
Author, Year	McCandless 2016[133]
Population	Parkinsons, n=20: 14 men/6 women; mean age 68 years; independently ambulatory indoors; with freezing of gait (FOG)
Intervention	laser cane, sound metronome, vibrating metronome, vibrating walking stick
Control	No cueing
Outcome	Frequency of FOG episodes over 3 m. walk, first step length, second step length, forward COM velocity, sideways COM velocity, number of forward/backward sways, and the number of sideways sways, Forward COP velocity (m/s) side to side COP velocity.
Time	Concurrent trials, 3 per device and 3 control (total 15 trials per participant)
Training	None
Results	12/20 participants contributed 100 freezing and 91 non-freezing trials laser cane was most effective for FOG and for movement strategies to reinitiate movement. vibrating walking stick second most effective, vibration metronome disrupt movement compared to the sound metronome at the same beat frequency.
Usability	Not reported
Level of evidence, study design	2b, cross-over (Website and PubMed)
Author, Year	Barthel, 2018[134]
Population	Parkinsons with FOG, n=21: 5 women / 15 men
Intervention	Visual cueing using laser shoes
Control	No cueing
Outcome	Duration and number of FOG
Time	Concurrent trials, 5 trials each during 'on' and 'off' period

Training	(1) walking back and forth over 10 meters; (2) task 1 plus counting down from 100 in steps of 7 or 3; (3) turning on command while walking, including 180° and 360° right and left turns; (4) walking to pick up a cone at 7 meters and then back carrying the cone; (5) walking around obstacles placed on the walkway.
Results	Cueing reduced the number of FOG episodes, both “off” (45.9%) and “on” (37.7%) medication, reduced the % time frozen while 'off' period by 56.5% (95% confidence interval 32.5 to 85.8), reduced % time frozen while 'on' by 51.4% (95% CI -41.8 to 91.5)
Usability	Not reported
Level of evidence, study design	2b, cross-over (Website and PubMed)

Author, Year	Velik, 2012[135]
Population	Parkinsons with FOG, n=7: 1 women / 6 men
Intervention	3 cueing conditions: no cue, visual cue on for 10s whenever freezing occurred, and continuous visual cue
Control	No cue condition
Outcome	Average duration and number of freezing episodes under three conditions
Time	Concurrent trials
Training	6 task performance and also in reverse: (1) standing up from a chair and getting a glass of water from the kitchen; (2) going with the glass to the bathroom and leaving the glass on the washbasin; (3) Walking to the bedroom and picking up a clothes hanger from the cupboard; (4) Carrying a clothes hanger to the washing room and leaving it there; (5) Going back to the chair
Results	Continuous cueing: mean duration of freezing reduced by 51% with 43% less FOG episodes On-demand cueing: mean duration of freezing reduced by 69% with 9% less FOG episodes
Usability	Not reported
Level of evidence, study design	2b, cross-over (Website and PubMed)

CuPiD/Gait Tutor

Author, Year	Ginis 2016[136]
Population	Parkinsons, n=40: 8 women / 30 men independently ambulatory for at least 10 mins; with freezing of gait (FOG)
Intervention	Supervised weekly visits for 6 weeks plus recommendation to walk at least 3 times per week for 30 mins with feedback and cue separately
Control	Walking training with no feedback
Outcome	Gait speed, stride length, and dual support time for comfortable gait and dual gait task, balance using miniBEST, FSST, FES-1, 2-minute walk test (2MWT), freezing of gait, UPDRS III, cognition, quality of life.
Time	Pre, post-training (6 weeks), retention (4 weeks).
Training	Weekly home visits for 6 weeks

Results	Single and dual task gait speeds improved within group at post-test and follow-up. Intervention group improved on balance at post-training.
Usability	Reported
Level of evidence, study design	2b, randomized clinical trial (Website and PubMed)
Author, Year	Ginis 2017[137]
Population	Parkinsons, n=28: 5 women/23 men; 14 age-matched
Intervention	Four walks (continuous and intelligent cue, intelligent feedback, no information) over 6 weeks with atleast 1 week between the walks:
Control	No information
Outcome	Cadence, stride length, fatigue
Time	Concurrent trials
Training	1 min comfortable reference walk prior to testing
Results	Decrease in cadence in people with PD without cue or feedback. People with PD reported more fatigue when continuous cueing and intelligent feedback. Increase in coefficient of variation in cadence in people with PD. Less variation in cadence with continuous and intelligent cueing in people with PD.
Usability	Not reported
Level of evidence, study design	2b, cross-over (Website and PubMed)

CHAPTER 3: FROM KNOWLEDGE TRANSLATION TO A BUSINESS MODEL

Advances in technological health interventions have increased in the past decades in response to the continuous increase of the global burden of disease[138] and mobility-related disability[11, 15]. One-on-one physiotherapy for people with gait-related impairments is not a viable solution for a public and population health problem that affects 10% of the Canadian population[139]. Technology is poised to extend the reach of physiotherapists beyond the clinic into prevention and health promotion. Despite this growth in e-health, inventions developed in academic-research institutions, although evaluated for safety, efficacy and effectiveness, appear mostly in peer-reviewed papers and are often not disseminated to patients in need[140-142]. Business has the tools and resources to market digital and technological health innovations to the people that in need[143].

The chapter describes the similarities and differences between knowledge translation models and business models as they apply to research and development of technological interventions related to mobility in general and improving walking capacity and behaviours, specifically.

Research: Definitions & Concepts

One key similarity is that all innovations and advances in health care starts with research. Research is the process of discovering new knowledge given a need to address existing uncertainties. It is the search for knowledge through the accumulation of different types of evidence (e.g. observation, experimentation, appraising existing evidence)[144-146].

As outlined by Daniel Sokol[147] the three key features of research are: (i) sceptical thinking and critically reviewing of existing knowledge; (ii) following a systematic and well defined process; and (iii) behaving ethically, first “do no harm”. This research process leads to research that is honest and transparent and making the results more reliable, replicable and trustworthy[148].

Research uses a systematic process called the scientific method to create knowledge. The scientific method is an iterative process consisting of observation and experimentation that leads to the creation of a hypothesis[148, 149]. A hypothesis is an informed and educated prediction or explanation about a phenomenon. Part of the research process involves testing a hypothesis, and then appraising the results to make a sound and balanced conclusion[150-152]. Research studies are designed in a way to increase the chances of collecting the information needed to answer a

question without bias and with precision[153-155]. Research is dependent upon a clear and operational question, on the quality of the research method and on its guiding design and measurement approach[150, 152]. A design is used to structure the research, to show how all the major parts of the research project work together to try to address the central research questions. A research design provides the glue that holds the research project together[156]. Also, the question needs to be clear, concise and operational: (i) who is being studied (Population), (ii) what the intervention is; (iii) what the comparator is; (iv) what the outcomes are; (v) and what is the time frame (PICOT)[156]. Perhaps the gap between research and knowledge translation could be bridged by an important, clear, complete, operational and informative research question[157]. In this chapter, I will show that the research process is closely similar to the business process of making a product available to those who need it.

Dissemination and Implementation Models in Health Practice

There are many models describing the process from research to implementation. A literature review of models specifically used in “Dissemination & Implementation” (D&I) research yielded 89 models that the authors of this review categorized according to socio-ecological level of inquiry which is essentially the stakeholders targeted (individual, organization, community, health system, and policy), the field of origin (clinical or public health context), construct (information gathered), and number of cited articles up to 2011[158]. They presented the model descriptions in Table 2 in their publication which is reproduced and adapted in Appendix 2.

The models predominantly covered either dissemination or implementation strategies and spanned a variety of field of research, such as health promotion, improving health services research dissemination, coordinating implementation, policy process, knowledge infrastructure, social marketing, patient safety, technology transfer, and evidence-based practice in public services[158].

An interesting observation from the review of these models is that, although multiple stakeholders are identified (individual, community, organization, system, policy) very few (6/89) targeted all stakeholders: most targeted the organization (n=83) and the individual (n=53). As will be presented later on, any model for business has to act at all levels.

The ultimate use of models is said to describe and guide the process of translating research into practice[159, 160].

In Appendix 2, there are clear similarities in terms of information that is essential to the model, meaning that many models are generalizable to other contexts. One of the most widely used models in health research is the Knowledge to Action (KTA) model to guide the implementation of an intervention (i.e. technological innovation).

Knowledge to Action Model

The knowledge to action framework, presented in Figure 1, recognizes two interrelated components for taking research to action: (i) Knowledge Creation and (ii) the Action Cycle. Both phases are dynamic and can be conducted simultaneously[140]

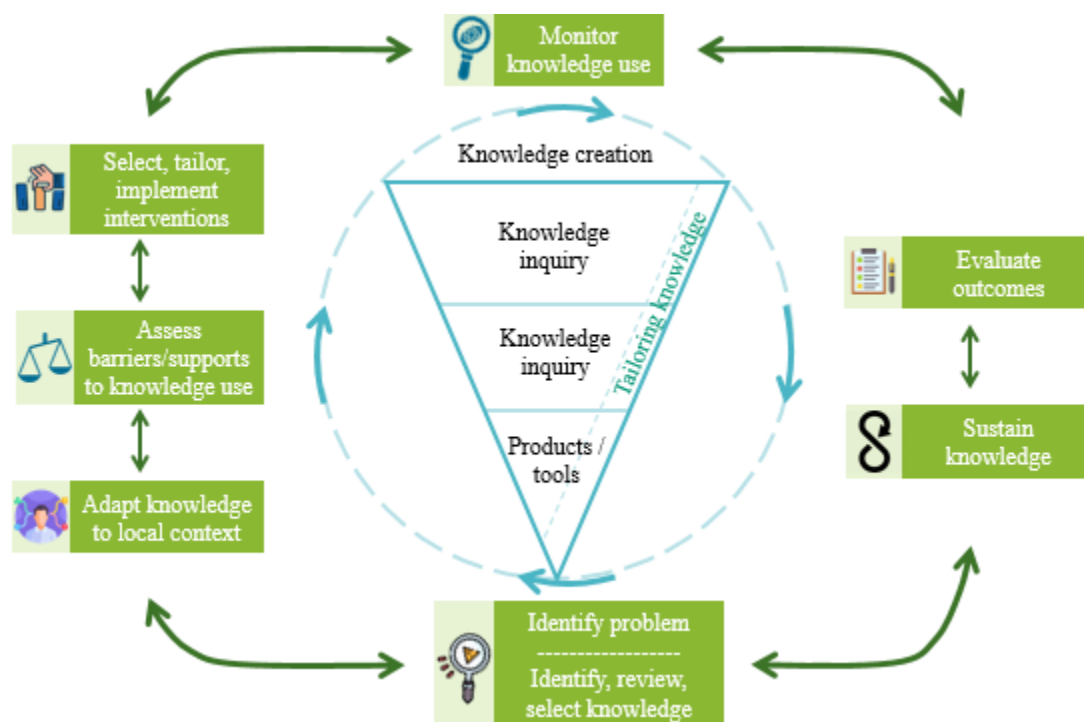


Figure 1 Knowledge to Action Cycle

The knowledge creation component, represented by a funnel, starts with inquiry about the research that is available to inform the other components of the cycle. In the context of a technological innovation for gait-related impairments, the funnel part of the KTA cycle is related to the literature review on a topic. The action cycle outlines a process, representing the activities needed for knowledge to be applied in practice such as through a Knowledge Translation (KT) intervention.

Technology Transfer Model

Among the models described in Appendix 2, the technology transfer model relates most closely to the world of business rather than clinical care. Technology transfer is the process of changing ownership and control over an invention from the inventor to entities that can commercialize a product or service.

A simple description of this process is depicted below in Figure 2 and a description of each term is presented in Table 1[161, 162].

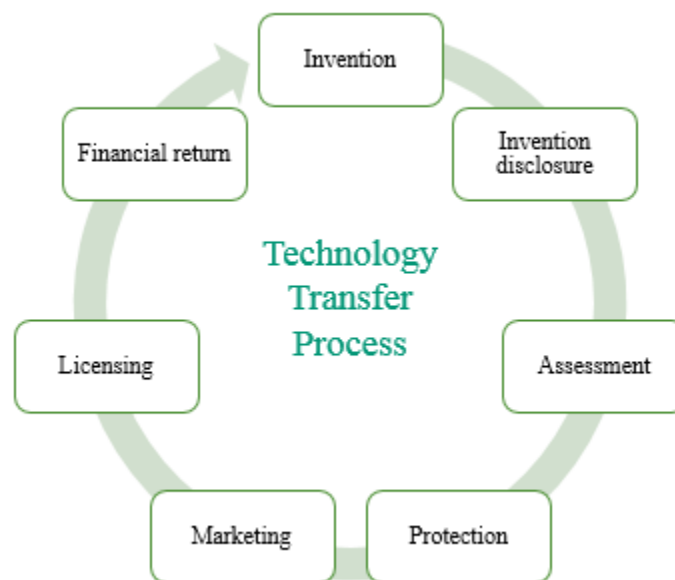


Figure 2 Technology Transfer Process

Table 1 Technology Transfer Process Definitions

Terms	Description
Invention	Start of technology transfer process. A new idea or a technology being developed to be ultimately commercialized.
Invention Disclosure	Disclosure of the innovation to the Technology Transfer Officer (TTO). The registration of an invention form is completed, and it serves as the initial documentation of the invention. It allows the inventor to clearly describe the innovation, its commercial applications, and details on who was involved in the invention process.
Assessment	Evaluation of the registered invention to ensure the marketability and patentability of the technology.
Protection	If the invention becomes a commercial product, protection of the invention is necessary. This protection is typically in the form of a

	trademark, Intellectual Property and patent[163]. This protection allows inventors to gain financial investments made to commercialize the product.
Marketing	Marketing of the product is to attract customers to purchase the innovation.
Licensing	When a company is interested in securing rights to a researcher's product, a license is usually required. A license is an agreement where the owners (i.e. researchers) of the invention give another party right to the technology allowing them to produce, use, or sell it.
Financial Return	After a license is negotiated, post-license compliance must be maintained to ensure the development of the technology and payment of royalties.

This process usually involves placing a person with business acumen into the company in order that the invention is properly managed. This is often at the marketing stage. This is somewhat similar to what happens in a KT framework where the “inventor” is the researchers and the “invention”, the intervention or program, is placed into the hands of a KT expert to implement.

Most academic researchers shy away from research commercialization because business is a black box to them. Entrepreneurship and business awareness need to be introduced into science training programs in order to end the cycle of failed knowledge translation[141, 142]. Business models have become a relevant topic in the world of academia owing the need for innovative products being made available to improve effectiveness and efficiency of care. The field of digital health innovation is exploding as health care practitioners, patients, organizations, and government is realizing the demand for health management is greater than what can be met through traditional clinical channels. There are over 600 systematic reviews of digital health technologies indexed in PUBMED in almost every clinical context in the past 5 years, compared with less than 60 in the previous 5 years.

Business Models

An important element of the business¹[164] model concept is the word “model”, models play several important roles: they help to describe different business activities, and to establish taxonomies allowing for the classification and comparison of business models[165, 166]. They also provide businesses with recipes and show lessons of success in different contexts, as models can be manipulated, adapted and experimented depending on the context.

¹ Operationally, a business is any form of business-related activities in which a product or service is sold in exchange of money. Whereas, a company is the place in which business takes place.

There is not a single way to define a business model, but most studies seem to have adopted that a business model is a high-level conceptual description of the activities of value creation (the creation of a product that meets customers' needs), value capture (the marketing, support, and sale of the product), and value architecture (the chain of activities that link customers to the suppliers of a product)[166-170] (Figure 3). As opposed to research models, that searches for the truth in something, business models focus on monetizing innovative products.

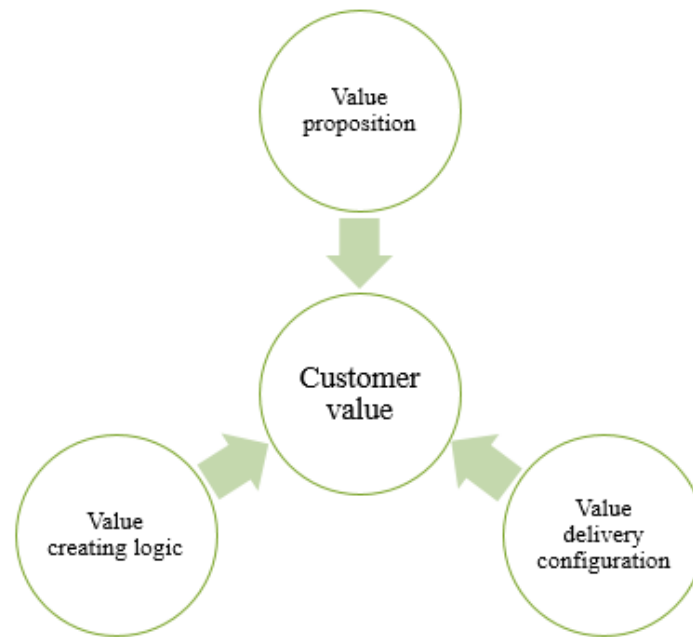


Figure 3 Strategic Elements of a Business Model

Business models emerged with the growing popularity of electronic-businesses in the mid-20th century[171]. More recently, the concept has broadened and is now discussed in relations to innovation and technology-driven enterprises[171]. For technological interventions to provide benefit for consumers, as well as business entities, business models need to adapt and be refined throughout the development process of a technological device[172]. As such, a business model employs an iterative process like research models.

Technological advancement leads to new ways of doing business. Technological innovation in business as, in academic research institutions, requires complementarity from different fields depending on the product being developed. In the context of health, partnerships from healthcare professionals, researchers, engineers and industry partners is important for a successful profitable business[173, 174]. Health technology provides a new way of delivering health care. Using a

business lens, it is like a new way of serving customers. This requires a distribution strategy and a monetary value creation strategy in order to produce a competitive business[173]. Technological innovations act to prevent, treat, rehabilitate, and promote health through translating these types of interventions to real-world situations outside the clinic and laboratory.

Research and Business: Similarities and Differences

Having provided the background, motivation and overview of health research and business models as applied to technological intervention, the similarities and differences of health research and business models will be addressed.

Developing a business requires many of the components of the research-based scientific method. First there needs to be a hypothesis, that is then tested and revised if necessary[175]. A business model comprises hypotheses about what customers want, how they want it and what they will pay for, and how an enterprise can organize to best meet customer needs and be profitable[176]. As for research, a hypothesis is also formulated about the impact of an intervention. Researchers use a controlled laboratory environment to test a hypothesis through observation and experimentation, whereas entrepreneurs build business model experiments to test their business ideas instantly in the real world[175]. Thus, designing, executing and implementing business models for an entrepreneur is like designing a study and testing its efficacy through experiments for researchers. Researchers and business entities follow a detailed proposal to test the feasibility and effectiveness of a health intervention or a technological innovation through, for example measuring a user experience or a patient's health outcomes. The main difference between both models, is that business focuses on selling a product or a service to users in exchange for money, whereas research focuses on estimating the effectiveness of something or a product without implementing it directly to people in need but by disseminating it through conference presentations and peer-reviewed published papers which may not guarantee population health impact[148, 175, 177]

Business and research both focus on identifying a societal need or a problem that needs to be addressed in which a specified target population or customer segment is the focus. In business, however, it does not stop there as the product will be marketed and sold to people in need to generate revenue[148, 177]. In research, KT experts are needed to get the product into the hands of the clinicians who will use it.

Knowledge Translation and Business Models

The process of taking research from laboratory to people in need is known under many names such as translational research, dissemination and implementation (D & I) research, and knowledge translation and transfer[178]. These terms are often used interchangeably in the scientific literature. Even with a growing “implementation science” community and methods, only 14% of original research findings are translated into practice and it takes some 17 years for research evidence about interventions that are safe and efficacious to reach clinical practice[142, 178]. Part of this gap and delay is that researchers are not in the best position to do the translation and do not have the infrastructure (marketing, sales, supply and demand etc.) to develop the processes that need to be put into place to successfully take the innovation to the community.

Similar to changing behaviours, some knowledge is more difficult to translate than others[179]. Knowledge about changing ingrained practices that don’t produce tangible immediate results are harder to translate. Health technologies that have the advantage of increased efficiency and immediacy should be easier to translate, yet they too are often not integrated into health practices at all or only after a very long time[180]. It seems the health world is not well equipped for streamlining the pipeline from invention to adoption.

The business world on the other hand is expert in convincing the community of the value and need of their products and have developed very successful marketing strategies to reach their target markets. In fact, they are expert in selling products that people don’t even need or want. A major part of their success is the understanding of the market drivers and how to respond to these drivers rapidly.

In the context of this thesis, the challenge under study is the translation of technology targeting gait and walking quality to two consumer groups, people with gait vulnerabilities for whom the technology was developed and therapists who treat them.

I am proposing that reaching these two consumer groups requires borrowing methods from business models. I am proposing a “business model approach” as a complement to a “knowledge translation approach” for stimulating uptake of technology.

The main aim of business is to make money. This will not happen unless the product reaches the target market and is purchased. To make money first and foremost, the need is for a viable product. For a product to be viable it must be a “living” entity that not only meets current market needs but

also is rapidly adaptable to changing needs. The business also needs to develop strategies to optimize how they interact with their suppliers and how to be continuously responsive to customers[141, 167-170] . This is depicted graphically in Figure 4.



Figure 4 Simplified Business Model

A key feature of this simplified business model is that there is a feedback loop between the customers and the business (who comprise entrepreneurs, researchers, and marketers) to continuously improve the product. The business also has to keep a close eye on competitors in order to learn from them and improve their product. The business is also sensitive to suppliers. This reliance on suppliers was very much in evidence with the COVID pandemic when the supply of computer chips was greatly reduced.

In contrast, Figure 5 shows a simplified version of a KT model from research evidence to implementations. The KT team can only translate the product it has; they have no control over the product, and they do not interact with the people who provide the evidence. As in the business model, the KT team are experts in developing a strong relationship with their clients (systems, clinicians and sometime patients) in terms of adapting the marketing of the product to their needs. Although in an ideal world there would be a feedback loop from clinicians working with the patients to researchers developing and testing interventions, this loop is either non-existent or very weak.

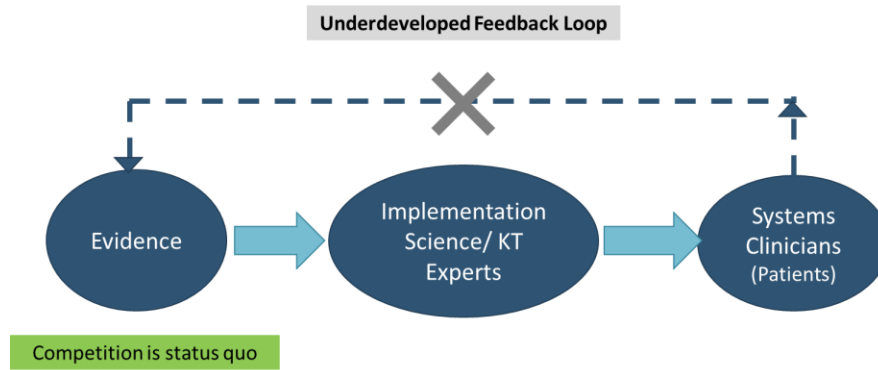


Figure 5 Simplified Knowledge Translation

Summary

The following Table 2 summarizes the similarities and differences among the three areas presented here: research, KT, business.

Table 2 Similarities and Differences Between Research and Business

Research	Business
Problem	Problem
<u>Question</u> : Efficacy or Effectiveness	Viability of the solution/product
Population	Market / Competitors
Methods	How: Marketing, attracting investors, sales venues, finances
Results	Market shares, New users, Return on Investment
Knowledge Translation Models	Business Model

Perhaps the most striking difference between research and business is how the underlying question about the product is posed. Research into efficacy or effectiveness uses the PICOT format: among POPULATION, to what extent does INTERVENTION in comparison to the CONTROL, change OUTCOMES, at TIME t. In business, the wise entrepreneur will pose the following question: *To what extent does adopting this product produce advantages to the adopter and generate better outcomes for their clients?* This format could be shortened to APAOC for ADOPTER, PRODUCT, ADVANTAGE. OUTCOME, CLIENT.

The products to be marketed that are the topics presented in this thesis relate to improving walking quality among people with gait vulnerabilities: Walk BEST (Better, Faster, Longer, Stronger) to

walk more. Here, the results are measured in sales to ultimately generate money as shown in Table 3.

Table 3 Business Requirements to the Application of Technology for Gait Vulnerability

Business requirements	Application of technology for gait vulnerability
Viability of the solution/product	Viability of technologies to improve walking
Important problem	Gait-Vulnerability
Market / Competitors	Market Research
Marketing, attracting investors, sales venues, finances	Research to support the product and business plan
Results	Money
Plan	Business model canvas

Finally, an overview of how KT is different from business is shown in Table 4. Here, the challenge of KT is shown in that often the target users are happy with the status quo and do not want to change; this affects uptake. In business, the technology to be marketed must be valued and shown to improve how things are done or there will not be any sales.

Table 4 Commercialization of Technology is a Special Case of Knowledge Translation

Evidence needs KT	Technology needs Business
About what needs to be done	About how something can be done better
About changing practice	About adding to practice
Often not valued by the users	Often valued by users because of the technology trend or “bandwagon”
Necessary for KT, but not sufficient	Evidence is neither necessary nor sufficient
CAN be inconvenient	CANNOT be inconvenient

Physiotherapists will need to embrace accessible technologies to have a wider population, societal and economic health impact. This chapter provides an overview about how the future of clinical practice could be through the integration of business-research models to increase the uptake of technological devices that promotes quality of life [181]. Designing and developing safe and effective health technologies requires sustained and intensive interdisciplinary teamwork involving all types of clinicians involved in the care continuum, as well as engineers (software,

mechanic), methodologists (measurement experts) and, most importantly, the active involvement of the person with the targeted disability or health situation.

A key component of the business plan is to accurately measure how clients are reacting to and engaging with the product in addition to how they are benefiting from it. The next chapter will present methods of measuring technology adoption and user experience.

CHAPTER 4: MEASUREMENT OF TECHNOLOGY SUCCESS

For a business to succeed, the technology being marketed must be adopted by the person. Understanding how a person chooses to adopt or reject a technology is necessary for the dissemination of health technology products as this leads to sales, the business outcome. This chapter will review models and measures of technology adoption and identify the challenges in measuring this construct. In the context of this thesis, the end-users are people with gait-vulnerabilities and the technology is a sensor, Heel2Toe, that promotes healthful walking.

Technology Adoption

Technology adoption was first introduced in the 1920s by anthropologists and sociologists with a view to understand social change[182]. Technology adoption includes being aware of the technology, embracing the technology and using it. There are three stages in the technology adoption process: preadoption, adoption, and postadoption[183]. Preadoption is the intention to adopt or reject a new technology. Adoption is the use of a technology, whereas postadoption refers to users' decisions to continue or discontinue using new technology[183].

Figure 1 presents an overview of models for health technology adoption[184]. Qualitative data from a study by Anderson et al. (2016) endorsed the relevance of these models for adopting mobile health apps[185, 186]: indicators related to adoption were engagement, functionality, information management and ease of use.

The following section will describe two most widely used adoption/acceptance model: Technology Acceptance Model (TAM) and Diffusion of Innovation (DOI) theory[187]. These models have been developed to explain people's adoption of new technologies and these models introduce factors that can affect the person's acceptance. These models are relevant in the context of marketing health technologies specifically for gait improvement.

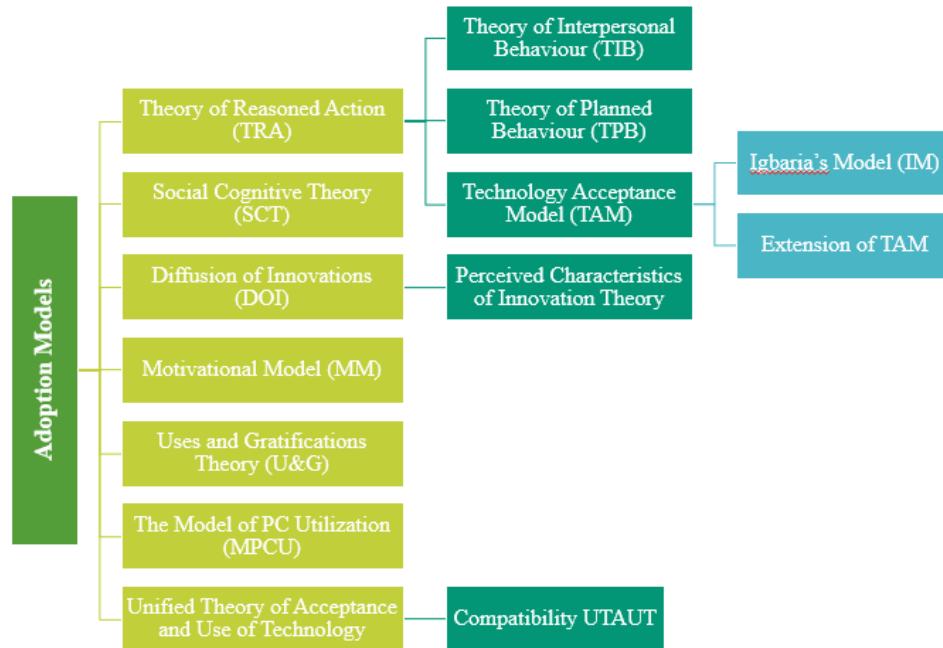


Figure 1 Adoption Models

Technology Acceptance Model (1986, updated 1989)

Technology Acceptance Model (TAM) is one of the most widely cited models in the field of technology acceptance[187-190]. Figure 2 show the components of the TAM model and Table 1 defines the specific terms relevant to this model. As illustrated, motivation for using a technology is based on perceived usefulness, perceived ease of use, and having a positive attitude toward use[188, 191]. External variables such as user training, system characteristics, user participation in the design and the implementation process, also factor into the TAM model[188, 191]. The limitation of this model is that it does not consider the social influence (i.e. social pressure) on adoption of technology[188].

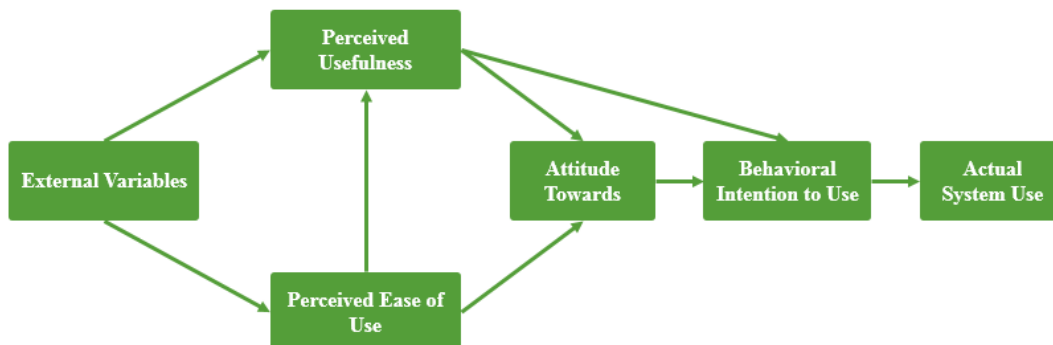


Figure 2 Technology Acceptance Model [188, 192]

Table 1 Technology Acceptance Model: Definitions[193]

Latent Variables	Definitions
Perceived usefulness	“The degree to which a person believes that using a particular system would enhance his or her job performance”
Perceived ease of use	“The degree to which a person believes that using a particular system would be free of effort”

Diffusion of Innovations Theory (1962, updated 1995)

An older model, the Diffusion of Innovation (DOI) theory, outlines factors that generally impact the spread or diffusion of a new idea[194]. Adoption under this model is considered at a global level and is affected by time (current need, rate of adoption), communication channels (how the information about the innovation is spread), features of the innovation, and the social system. In today’s health context, the social system would encompass access to health services, health literacy and e-health literacy[195-198]. The characteristics of an innovation (e.g. technology) that favour adoption are: relative advantage over what else is available, compatibility with values and needs of the potential adopters, complexity, research underlying the innovation, and observability of benefits to the end-use[194, 199]

The DOI is illustrated in a bell-shaped adoption curve that is shown in Figure 3 to characterizes who adopts when. This information would be useful in marketing a new product. For example, the first people to adopt technology are innovators and early adopters; they will adopt if they are made aware of the technology. Many people need convincing before adopting technologies and marketing strategies would need to be tailored specifically to middle and late adopters. Table 2 defines these adopter types.



Figure 3 Innovation Adoption Curve[200].

Table 2 Description of Innovation Adoption Curve Elements and their Marketing Strategy[200].

Elements	Description	Marketing Strategy
Innovators	People are considered “techies” who love to play with new technologies	Provide demonstration models and prototypes. Invite as advisors
Early adopters	People are considered visionaries. They would like to see how this technology may make life better. Early adopters are people that may have a disability that is limiting Activities of Daily Living (ADL) and would like to try this new technology	Market to people with specific health conditions accessible through organizations
Early majority	People are considered pragmatic. They see a practical application of that technology that is efficient and effective.	Market more widely for prevention and health promotion
Late majority	People are considered conservative. They would wait until someone else has adopted and that it works before adopting the technology	Market by providing data on numbers of people who have adopted and benefited from the technology (testimonials)
Laggards	People are sceptical. They do not want to change behavior and do not want to adopt new technology. Things are fine the way they are.	Often termed the latent market. People need to be shown that things are not fine the way they are and that there is advantage to doing something better. Provide opportunities for self-assessment.

There is no one-size-fits-all technology adoption model as they need to be context-specific[172]. However, most adoption theories and models share three characteristics that affect adoption of an innovation: (i) Individual characteristics that predispose a person to use or reject a product; (ii) Innovation characteristics are specific to the technology - how easy an innovation is to use, how the use of an innovation relates to the lifestyle of an individual; and (iii) Contextual characteristics make up the environment and surroundings of an individual during the adoption process as facilitators of change[201, 202].

Electronic Health Technology Adoption in Older People

Adoption of mobile-health² (m-health) technology is rising rapidly among older people in Canada[203]. In 2016, a Canadian survey on technology adoption showed that internet use rose

² Mobile-health: Subset of electronic -health (e-Health) that covers areas of networking, mobile computing, medical sensors, and other communication technologies within healthcare⁶⁹.

from 65% to 81% among people aged 65 to 74 years and from 35% to 50% among adults aged ≥ 75 years[203]. Smartphone adoption in people above 65 years was estimated at 69%[203]. There's no consensus on whether older adults share similar opinions of technology given that there's many factors that can impact behavior towards use of technology including factors associated with person's health, socio-demographic variables, and prior experience along with environmental factors[204, 205]. Studies have shown that older adults are accepting of technologies[206-208], whereas other studies have indicated the presence of resistance and apprehension related to technology adoption[209]. Rejection of technologies among older adults can be attributed to: physical limitations, scepticism toward technology, lack of perceived usefulness, availability, access, lifestyle, privacy, hardware and software issues, and difficulty in learning how to use technological products[210-214].

Senior Technology Acceptance Model

The Senior Technology Acceptance Model (STAM) is a conceptual model, illustrated in Figure 4, focusing on the factors that lead to the use of gerotechnology, operationally defined as electronic-health products that can increase independent living and social participation of older persons with gait-related impairments by improving health, comfort and safety[215]. It is based on an extension of the TAM. In this model, acceptance is defined as positive attitudes and usage behavior towards technology[215]. The predictive factors include perceived usefulness, perceived ease of use, attitude towards use, facilitating conditions, gerotechnology self-efficacy, and gerotechnology anxiety. Age-related variables are a part of this model and may be predictive of technology use as ageing affects physical functioning and psycho-social aspects of life[216]. This includes self-reported health conditions, cognitive abilities, attitudes towards ageing and life satisfaction, social relationships and physical functioning[215]. The STAM also identifies four person-related variables, age, gender, education level, and economic status, which may impact technology acceptance[215] (Figure 4).

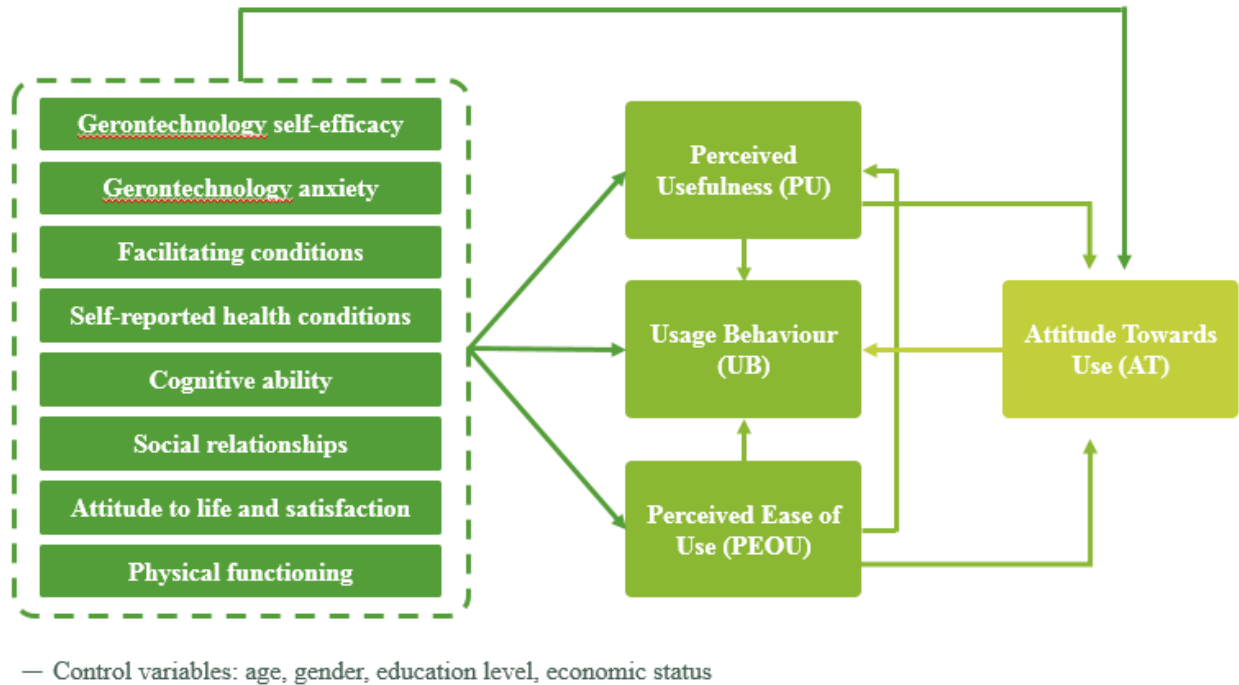


Figure 4 Senior Technology Acceptance Model[215].

Conceptual Model of use of Gerontechnology integrating Lifespan Theory of Control and Congruence Model of Person-Environment interaction

This model, shown in Figure 5, focuses on the factors influencing the use of gerontechnology by older people with disabilities[217] (i.e. decline in physical functioning). Motivation is a powerful factor influencing attitudes toward the use of gerontechnology[217, 218]. Age, socioeconomic status, personal history, perception of gerontechnology, and health are internal factors that could impact the decision to use gerontechnology[217]. External factors considered in the model are cultural factors and interactions with caregivers[217]. This model integrates the lifespan theory of control and congruence model of person environment interaction and illustrates the role of gerontechnology for improving quality of life in the aging population. The life span theory of control, shown in Figure 6, suggests that older people are motivated to achieve a specific goal[218]. The congruence model, Figure 7, highlights the persons interaction with the environment which is based on the needs, perceptions, and preferences. This interaction determines the level of congruence between the environment and the individual needs[219].

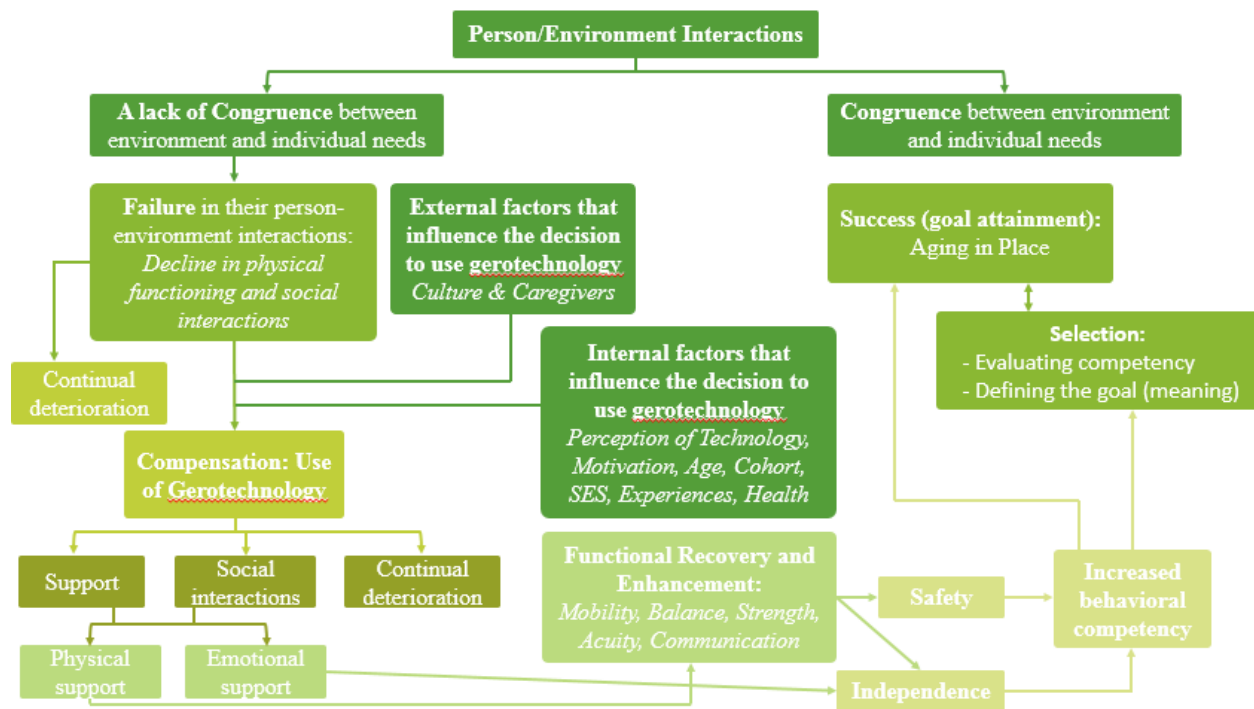


Figure 5 Conceptual Model of use of Gerotechnology integrating Lifespan Theory of Control and Congruence Model of Person-Environment Interaction[217].

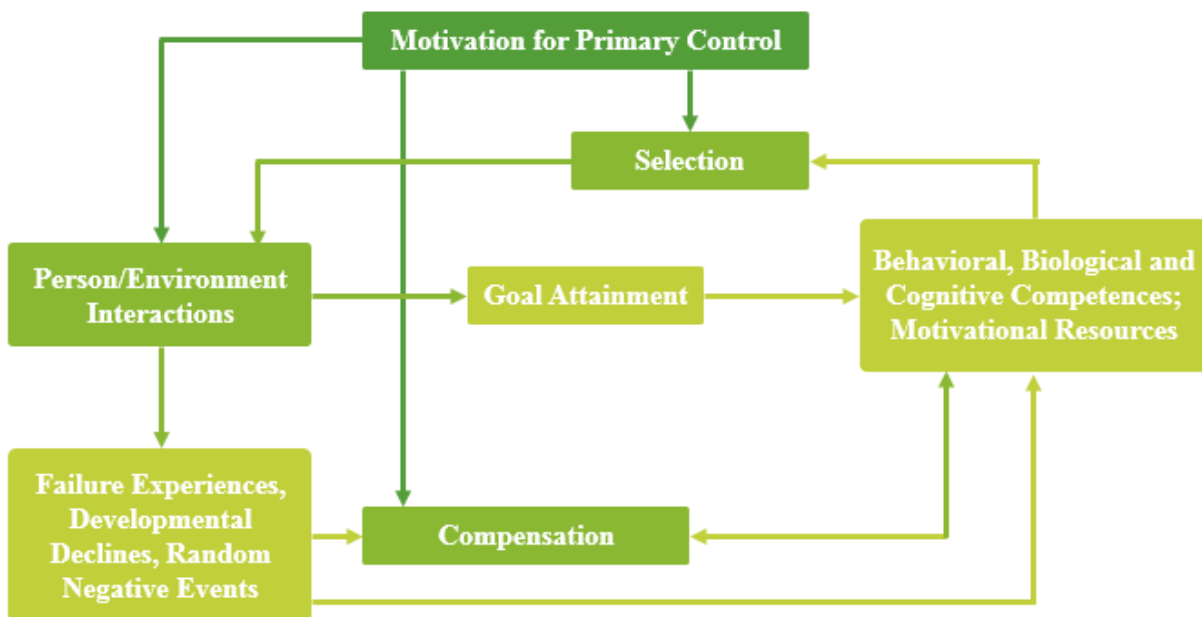


Figure 6 Lifespan Theory of Control[218].

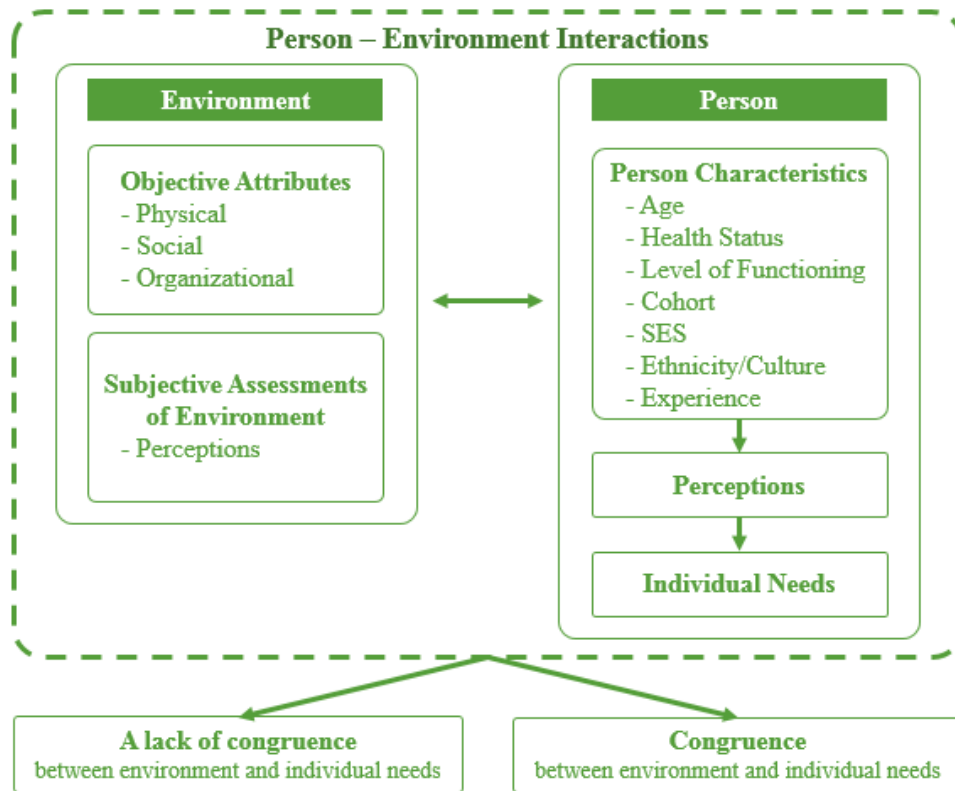


Figure 7 Congruence Model of Person-Environment Interaction[219].

These models suggest that older people’s technology acceptance is not mainly impacted by usability, ease of use, cultural and social contexts for use, age-related changes in capabilities, perceived self-efficacy, and the costs of such technology[220, 221] but strongly on perceived benefits[222]. Therefore, older adults make decisions to use or not to use a technology based on motivation and goals that support their independence and improves their quality of life.

Usability and Technology Readiness

Advances in technologies does not necessarily mean that technologies are being used and that they are safe for people. Hence, user experience metrics are critical as to identify and estimate that technologies are safe, effective, efficient, easy to use and engaging to people[223]. User experience can be characterized as the person’s entire interaction with the technology. Usability is the functionality, design, and learnability of the technology that leads to the ability of the person to a carry out a task successfully[223, 224].

Technology Readiness (TR) is defined as “people’s propensity to embrace and use new technologies for accomplishing goals in home life and at work” [225]. It is a state of mind, resulting

from “mental enablers and inhibitors that collectively determine a person’s predisposition to use new technologies.” Four areas of TR have been identified, discomfort, insecurity, optimism, and innovativeness[225]. These indicators should be considered when measuring the user experience.

User Experience Metrics

A user experience metric reveals something about the interaction between the person and the technology around factors related to effectiveness (being able to complete a task), efficiency (the amount of effort required to complete a task), and satisfaction[223]. Measuring people as thinking subjects with certain skills, attitudes, beliefs, knowledge which may impact behavior of adopting a technology is a challenge as we need to have reliable, valid measures with a clear identification of the measurement scale. There are several user experience metrics. Table 3 describes comprehensively the different use experience metrics which has been reproduced from Albert and Thomas (2013) and adapted in this chapter. I will elaborate on two user experience metrics in the following sections. Understanding the user experience metrics will inform the statistical analysis and will help evaluate, estimate effectiveness and predict the factors contributing to technology adoption leading to an informed decision to reject or adopt a technology.

Table 3 Description of User Experience Metrics[223] (reproduced and adapted from Albert and Thomas. (2013))

User Experience Metrics	Description
User Experience Performance Metrics	
Task Success	The most widely used performance metric. It measures how effectively users are able to complete a given set of tasks. Success of completion can be either binary (pass/fail, completed task or not) or by levels of success.
Time on Task	It measures how much time it is required to complete a task
Errors	It reflects the mistake made during a task. Errors can be useful in pointing out confusing or misleading parts of an interface
Efficiency	Assesses the amount of effort a user expends to complete a task, such as the number of clicks in a website or the number of buttons presses on a mobile phone.
Learnability	Measures how performance improves or fails to improve over time
User Experience Self-Reported Metrics	

Rating Scales	Likert Scale	A typical item is a statement about the level of agreement. The statement may be positive (e.g., “The terminology used in this interface is clear”) or negative (e.g., “I found the navigation options “confusing”). Usually a five-point scale of agreement from strongly agree to strongly disagree)
	Semantic Differential Scales	It involves presenting pairs of bipolar, or opposite, adjectives at either end of a series of scales.
Post-Task Ratings	Ease of Use	The most common rating scale involving simply asking users to rate how easy or how difficult each task was from: Very Difficult to Very Easy.
	After-Scenario Questionnaire (ASQ)	Three rating scales designed to be used after the user completes a set of related tasks. The statements are rated on a 7-point scale from strongly agree to strongly disagree and eludes to the fundamental of usability (effectiveness, efficiency, satisfaction). For example: 1. “I am satisfied with the ease of completing the tasks in this scenario.”
	Expectation Measure	The most important thing about each task is how easy or difficult it was <i>in comparison to</i> how easy or difficult the user <i>thought</i> it was going to be. Before the users actually did any of the tasks, they asked them to rate how easy/difficult they <i>expect</i> each of the tasks to be, based simply on their understanding of the tasks and the type of product.
Post-Session Ratings	System Usability Scale (SUS)	One of the most widely used tools for assessing the perceived usability of a system or product. it consists of 10 statements to which users rate their level of agreement. Half the statements are worded positively, and half are worded negatively.
	Computer System Usability Questionnaire	It consists of 19 statements to which the user rates agreement on a seven-point scale of “Strongly Disagree” to “Strongly Agree,” plus N/A. For example: 1. Overall, I am satisfied with how easy it is to use this system. 2. It was simple to use this system. 3. I could effectively complete the tasks and scenarios using this system.

		4.I was able to complete the tasks and scenarios quickly using this system. 5.I was able to efficiently complete the tasks and scenarios using this system.
	Questionnaire for User Interface Satisfaction	It consists of 27 rating scales divided into five categories: Reaction, Screen, Terminology/System Information, Learning, and System Capabilities. The ratings are on 10-point scales whose anchors change depending on the statement. The first 6 scales (assessing Overall Reaction) are opposites with no statements (e.g., Terrible/Wonderful, Difficult/Easy, Frustrating/Satisfying).
	Usefulness, Satisfaction and Ease of-Use Questionnaire	It consists of 30 rating scales divided into four categories: Usefulness, Satisfaction, Ease of Use, and Ease of Learning. Each is a positive statement (e.g., “I would recommend it to a friend”), to which the user rates level of agreement on a seven-point Likert scale.
	Product Reaction Cards	It consists of a set of 118 cards, each containing adjectives (e.g., Fresh, Slow, Sophisticated, Inviting, Entertaining, Incomprehensible). The users would then simply choose the cards they felt described the system.
	Net Promoter Score (NPS)	It’s intended to be a measure of customer loyalty. NPS uses only one question: “How likely is it that you would recommend [this company, product, website, etc] to a friend or colleague?”
Online Services	Website Analysis and Measurement Inventory	It is composed of 20 statements with associated five-point Likert scales of agreement. Like SUS, some of the statements are positive and some are negative.
	American Customer Satisfaction Index (ACSI)	The ACSI questionnaire for websites is composed of a core set of 14 questions. Each asks for a rating on a 10-point scale of different attributes, such as the quality of information, freshness of content, clarity of site organization, overall satisfaction, and likelihood to return.
Other types of Self-Reported Metrics	Assessing Specific Attributes	Some of the attributes of a product or website that would be good in assessing: •Visual appeal •Perceived efficiency •Confidence •Usefulness •Enjoyment

Performance Metric: Task Success

Task success is the most widely used performance metric[223]. It measures how effectively people can complete a given set of tasks. Success of completion can be either binary (completed or not) or by levels of success (poor, moderate, good, excellent). To measure task success, each task that people are asked to perform must have a clear end state or be goal-oriented, such as evaluating tasks related a health technology platform[223]. To measure task success, it is important to operationally define what constitutes success for a specific context, where not having a clear definition may lead to poor measurement and thus, poor statistical analysis[226].

Self-Report Metric: Ease of Use and System Usability Scale

Ease of Use involves asking users to rate how easy or how difficult each task was[223]. For instance, testing all the content of a newly developed health technological platform and rating the ease of use of each element of the platform separately. On the other hand, System Usability Scale (SUS) is one of the most widely used tools for assessing the perceived usability of a product or a system after having used it. For instance, testing all the content of a newly developed mobile health application and rating its usability after having used it. It consists of 10 items that estimates the unobserved latent variable, usability, to which users rate their level of agreement on a five-point scale[223, 227] (Figure 8).

	Strongly disagree				Strongly agree	
1. I think that I would like to use this system frequently	1	2	3	4	5	4
2. I found the system unnecessarily complex	1	2	3	4	5	1
3. I thought the system was easy to use	1	2	3	4	5	1
4. I think that I would need the support of a technical person to be able to use this system	1	2	3	4	5	4
5. I found the various functions in this system were well integrated	1	2	3	4	5	1
6. I thought there was too much inconsistency in this system	1	2	3	4	5	2
7. I would imagine that most people would learn to use this system very quickly	1	2	3	4	5	1
8. I found the system very cumbersome to use	1	2	3	4	5	1
9. I felt very confident using the system	1	2	3	4	5	4
10. I needed to learn a lot of things before I could get going with this system	1	2	3	4	5	3
Total = 22						SUS Score = 22 * 2.5 = 55

Figure 8 System Usability Scale[227].

Summary

Measuring technology adoption is challenging. Technology adoption is a latent construct that cannot be directly measured. Depending on specific research question (the population studied), objectives and conceptual theoretical models or frameworks of technology acceptance-adoption, technology adoption can be indirectly measured by its indicators. In the context of gerotechnology, the usability (functionality, design, complexity, features), the person's attributes (skills, attitudes, knowledge, perceived usefulness and perceived ease of use) and the user experience or technology-person interaction (satisfaction, effectiveness, efficiency) are latent variables that can potentially predict technology adoption. There are many measures of usability and user experience that evaluate safety, efficacy and effectiveness of health technologies as seen in Table 3. Technology adoption is a complex process. However, as per Lord Kelvin:

“When you can measure what you are speaking about and express it in numbers, you know something about it. When you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind.” Therefore, “To measure is to know” and “if you cannot measure it you cannot improve it[228].”

CHAPTER 5: RATIONALE AND OBJECTIVES

Rationale

The context of applying a business lens to the development and marketing of technologies to improve gait and walking behaviours in gait vulnerable populations. The topics covered will relate to:

The size of the market;

Repurposing existing technologies for innovating applications and;

Identifying challenges of implementing a novel technology

These areas will demonstrate how business thinking applies to getting products to people.

Objectives

The objective of this thesis is to contribute methods and insights needed to develop a viable business plan to promote the adoption of technologies targeting walking capacity and performance in people with gait vulnerabilities. The data for these three projects came from primary data collection that I carried out independently. This thesis is built around manuscripts which is typical for theses in the Faculties of Medicine and Science.

The objective of the first manuscript is to identify from older Canadians perceptions of their walking quality and to identify contributors to and consequences of perceived walking quality (The Market). This information will be used to identify the extent to which seniors who are the most vulnerable to falls and injuries are aware of their walking quality and willing to adopt technology to improve their walking.

The objective of the second manuscript is to estimate the extent to which the distribution of step count data over a period of weeks to months identifies different subgroups of people which could be used to indicate walking reserve.

The objective of the third manuscript is to identify the challenges of implementing a novel technology to improve walking in people with Parkinson's where challenges could arise from the device itself, engagement, and usability perception of the client, and need for informational/technological support.

CHAPTER 6: MANUSCRIPT 1

What Do Older Canadians Think They Need to Walk Well?

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What Do Older Canadians Think They Need to Walk Well?

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ABSTRACT

Purpose: To identify older Canadians' perception of the importance of expert-generated elements of walking quality, and the contributors to and consequences of perceived walking quality. **Method:** Cross-sectional survey of 649 adults was conducted through a commercial participant panel, Hosted in Canada Surveys. **Results:** Of the 649 respondents, 75% were between 65 and 74 years old (25% ≥ 75) and 49% were women. The most important elements were foot, ankle, hip, and knee mobility with little difference in ranks across walking perception (Fr $\chi^2 = 5.0$, df 12, $p > 0.05$). People who were older by a decade were more likely to report poorer walking (POR: 1.4; 95% CI: 1.0–1.7), as were women compared to men, and people who used a walking aid compared to none. Lung disease showed the highest association with a perception of not walking well (POR: 7.2; 95% CI: 3.7, 14.2). The odds of being willing to pay more for a technology to improve walking were always greater for those with a lower perception of their walking quality. **Conclusions:** People who perceived their walking quality as poor were more likely to report poorer health and were willing to pay more for a technology to improve walking. This supports the opportunity of leveraging wearable technologies to improve walking.

Key Words: gait; health technology; physical activity; self-management; walking capacity.

Objectif : déterminer la perception des Canadiens âgés à l'égard de l'importance des éléments relatifs à la qualité de la marche produits par des experts et établir les incitatifs à la perception de la qualité de la marche, de même que les conséquences s'y rapportant. **Méthodologie :** sondage transversal auprès de 649 adultes au moyen de Hosted in Canada Surveys, un groupe commercial de participants. **Résultats :** sur les 649 répondants, 75 % étaient âgés de 65 à 74 ans (25 % ≥ 75 ans), et 49 % étaient des femmes. La mobilité du pied, de la cheville, de la hanche et du genou constituait les éléments les plus importants, et le niveau hiérarchique de chacun différait peu en matière de perceptions de la marche (test de Friedman [F.] $\chi^2 = 5,0$, degré de liberté [ddl] 12, $p > 0,05$). Les personnes âgées d'une décennie de plus risquaient davantage de déclarer moins bien marcher (rapport de cotes proportionnel [RCP] : 1,4; IC à 95 % : 1,0 à 1,7), tout comme les femmes et les personnes qui utilisaient une aide à la marche. La maladie pulmonaire était la plus liée à la perception de moins bien marcher (RCP : 7,2; IC à 95 % : 3,7, 14,2). La probabilité d'être prêt à payer plus cher pour disposer d'une technologie destinée à améliorer la marche était toujours plus forte chez les personnes qui avaient une moins bonne perception de leur qualité de marche. **Conclusion :** les personnes qui avaient une moins bonne perception de leur qualité de marche étaient plus susceptibles de se déclarer en moins bonne santé et étaient prêtes à payer plus cher pour disposer d'une technologie destinée à améliorer la marche. Cette constatation confirme la possibilité de mettre à profit des technologies portables pour améliorer la marche.

Mots-clés : activité physique, autogestion, capacité à la marche, démarche, technologie de la santé

The world population is ageing.¹ The number of seniors in Canada is expected to double by 2036 going from 4.7 million seniors in 2009 to more than 10 million.² Although age does not imply ill health or disability, the risk of both does increase as people age. In 2006, 33% of Canadians aged 65 or older had a disability and the proportion was larger (44%) for people aged 75 or older.³ Among seniors, the most prevalent disabilities are pain (22%), decreased

flexibility (19%), and mobility limitations (20.5%).³ Mobility limitations stem directly from impairments in strength, range of motion, balance, and endurance.⁴⁻⁶

In addition to developing age-related mobility limitations, chronic diseases that affect mobility also emerge with ageing. Conditions such as arthritis,⁷ diabetes,⁸ foot deformities,⁹ Parkinson's disease,¹⁰ mild cognitive impairment,¹¹ and stroke¹² render seniors' gait vulnerable. This

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Contributors: All authors designed the study; or collected, analyzed, or interpreted the data; and drafted or critically revised the article and approved the final draft.

Competing Interests: AA-S, KVM, and NEM are each 20% shareholders in PhysioBiometrics Inc., a company that is dedicated to the development of accessible innovations to support people with movement and posture vulnerabilities so they may maintain independence and achieve life goals. This article supports the need for technology to improve walking by seniors and the company is developing and marketing such a technology. The other authors have nothing to disclose. The study was funded by the Edith Strauss Foundation in Knowledge Translation.

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term, *gait vulnerability*, is used to describe a physiological health state that results in the person being at increased risk of developing deviations in gait parameters, limitations in walking capacity, and/or difficulty sustaining walking for purposes of participation and health promotion (i.e., poor walking performance).¹³

Older people have expectations for active ageing,¹⁴ that is, maintaining an active lifestyle even with a health condition. A literature review revealed that older people's participation in out-of-home activities is an indicator of well-being and is critical to ageing well and to fulfilling basic, social, and emotional needs.¹⁵⁻¹⁷ Walking is the most common method of maintaining an active lifestyle: it requires, no specialized environment, and can be physically and cognitively beneficial particularly when walking outdoors. The recently updated Guidelines on Physical Activity and Sedentary Behavior from the World Health Organization indicate that older adults should accumulate a minimum of 150 minutes of moderate intensity activity, or a minimum of 75 minutes of vigorous-intensity activity, per week in addition to focused exercises for balance and strengthening.¹⁸ Walking at a pace of 100 steps a minute for 10 minutes twice a day would meet this guideline.¹⁹ Despite the capacity to walk at this pace when tested clinically, it is rare for the North American senior to do this in the real world for more than a few minutes a day.²⁰ For many seniors, walking is a means of accomplishing activities of daily living and not for meeting health-related goals or recommendations.

Even for people who wish to be active, reasons for failing to meet guidelines include fear of falling or age-related gait abnormalities.^{21,22} These cascade into a slow, unstable, shuffling gait pattern that increases the work of walking and fatigue, as well as the risk of falls, hip fracture, and even death.²³⁻²⁶ Evidence shows that gait training is an effective intervention to improve gait pattern^{23,27-29} but effects abate with cessation of training,²⁸ as motor learning takes time, practice, and feedback.^{30,31} Hence, short-term gait training alone will not translate into the improved walking performance needed to meet the recommendations from the physical activity guidelines.

There are physical therapy services that target improvement in walking capacity and walking performance. The senior population would benefit from these services,³² but they are scarce in the public sector and expensive in private.³³ Many seniors may not be aware that they have gait deficits that place them at risk for falls and injuries. The advances in technologies and wearables would allow gait-vulnerable people to identify and self-manage walking challenges.^{16,34}

The aim of this study was to identify from older Canadians their perceptions of their walking quality and to identify contributors to and consequences of perceived walking quality. This information will be used to identify the extent to which seniors who are the most vulnerable

to falls and injuries are aware of their walking quality and willing to adopt technology to improve their walking.

METHODS

We conducted a cross-sectional survey through a deidentified confidential online commercial participant panel, Hosted in Canada Surveys (Hosted in Canada Surveys, Ottawa, ON). Participants are drawn from a data bank of people across Canada who have agreed to answer surveys for which they are paid a small amount to complete these surveys. Hosted in Canada Surveys manages the recruitment, validates the inclusion/exclusion criteria set by the researchers, scrutinizes the data for completeness, and charges the clients (researchers) only for valid responses. This is a non-probabilistic sample often used for marketing research. We requested a minimum of 600 people over the age of 65 from across Canada to have a sufficient sample size for subgroup analyses. The project was approved by McGill Ethics IRB (A00-B04-19B).

Survey instrument

The survey focused on the extent to which seniors endorsed the importance of expert-generated elements related to walking quality as well as their perception of their own walking quality. The elements were generated in our previous work: a participatory design approach engaging clinicians, researchers, and end-users to develop a walking self-management *Walk-Well Workbook*. Retitled now as the *Walk-BEST Workbook*, it is freely available on the PhysioBiometrics Inc. website (www.physiobiometrics.com).

Briefly, snowball sampling was used to query 34 national and international gait experts on the elements necessary to walk well. Sixteen of these experts were subsequently involved in two rounds of a Delphi consensus to rate the importance of each element and suggest exercises to improve each element.³⁵ In a parallel activity, 22 community-dwelling seniors endorsed very similar elements. A total of 15 elements were compiled into the *Walk-BEST Workbook*, that includes an assessment technique for each element as well as a suggested exercise to improve each element. An independent group of experts then reviewed the workbook and completed the Patient Educational Materials Assessment tool to evaluate the understandability and actionability of the workbook. The workbook was judged by clinicians, researchers, and seniors to be relevant, useful, and user-friendly, with the potential to benefit seniors with walking impairments. The walk-well elements in the *Walk-BEST Workbook* and included in the current study are: (i) knee mobility, (ii) hip mobility, (iii) upright posture, (iv) foot mobility, (v) ankle mobility, (vi) change direction easily, (vii) walk and look around, (viii) heel-to-toe gait, (ix) walk smoothly, (x) arm swing, (xi) walk without tiring, (xii) walk long distances, and (xiii) walk fast. For people to take advantage of these tools they must be made aware of their

walking status, hence the need to survey the general older public on their awareness.

Each element was rated for its importance for walking well using a 7-point Likert scale ranging from “strongly agree” to “strongly disagree.” We asked about their global perception of their own walking quality (“Do you think you walk well?” rated on a 3-point ordinal scale from “yes, definitely” to “no”) and whether they would be willing to pay for a technological device to improve walking, if available (on a 6-point nominal scale).

We also asked participants about their age, sex, health conditions, and self-reported health, variables used to assess the degree to which the Hosted in Canada Surveys sample was representative of the general Canadian population of this age group. We also collected data on physical function using 8 items from the lower extremity function scale (LEFS)^{36,37} (online Appendix 1). These 8 items were chosen for their relevance to this more vulnerable population but may reduce the precision of the total score.

Statistical analysis

We calculated distributional parameters for all study variables using SAS, version 9.4 (SAS Institute Inc., Cary, NC), and calculated and ranked the proportion of people strongly agreeing or agreeing on the importance of each element stratified by the perception of walking quality. When two or more elements had the same rank, each was assigned the average rank. Friedman's χ^2 test (Fr χ^2) was used to determine whether the ranks differed across perception categories. A non-significant χ^2 ($p > 0.05$) indicated failure to reject the null hypothesis of no difference in ranks.

The modelling approaches used to identify contributors to and consequences of perceived walking quality are summarized in online Appendix 2. The first model estimated the effect of personal characteristics on perception of walking quality (ordinal outcome variable with three categories) using the proportional odds model. The parameter estimated is the proportional odds ratio (POR), interpreted as the effect of each level of the variable on the odds of perceiving a poorer walking quality (no matter how *poorer* is defined). The assumption of the POR model (i.e., homogeneity of cut-point specific odds ratios) was met, as evaluated by the score test of homogeneity.³⁸

We hypothesized that the perception of walking quality would have consequences for physical function, health perception, and willingness to pay for improvement. For these models, “Yes, definitely” is the referent category for perception of walking quality. For physical function, measured by the LEFS, ordinary least squares regression (OLS) was used with adjustment for age, sex, and health condition. The assumptions of OLS were met. For self-reported health and willingness to pay (both of which are ordinal variables), POR models were used, with adjustment for age, sex, health condition, and LEFS.

We estimated sample size based on a 95% confidence interval of $\pm 10\%$ around a mid-range (40-60%) prevalence estimate³⁹ of endorsing the importance of a walking element. To account for sex (2 categories) and a distribution across levels of walking quality (3 categories), our minimum sample size was 600.

RESULTS

Table 1 presents the proportion of participants who strongly agreed or agreed on the importance of each walking element. For example, among people who perceived that they definitely walked well, three of the top four items were related to mobility (foot, ankle, knee) and the fourth was the ability to change direction easily; the ranking for people who perceived that they somewhat walked well was similar. For people who perceived that they did not walk well, the top-ranked item was upright posture; this item was ranked sixth for the other groups. Overall, there was little difference in ranks across walking perception (Fr $\chi^2 = 5.0$, df 12, $p > 0.05$)

Table 2 presents characteristics of participants according to their perception of walking quality. Of the 649 respondents, 75% were between 65 and 74 years old and 49% were women. Most participants (80%) reported that they definitely or somewhat walked well. The distribution of walking perception differed by age. People who were older by a decade were more likely to report poorer walking (POR: 1.4; 95% CI: 1.0, 1.7) as were women and people who walked with a cane or walker. Lung disease showed the highest association with a perception of not walking well (POR: 7.2; 95% CI: 3.7, 14.2).

Table 1 Endorsement and Ranking of Walk-Well Elements, Overall, and According to Perception of Walking Pattern

Walk-well elements	Strongly agree/Agree Overall %	Do you think you walk well? Rank		
		Yes, definitely	Somewhat	No
Foot mobility	85.8	1	2	2
Ankle mobility	85.3	2	1	3.5
Hip mobility	84.4	5	3	5.5
Knee mobility	83.3	3.5	7	7
Change direction easily	82.7	3.5	4.5	5.5
Walk and look around	80.3	7	4.5	3.5
Upright posture	77.5	6	6	1
Heel-to-toe gait	74.4	9	8	8
Walk smoothly	71.5	8	10	9
Arm swing	65.5	11	9	10
Walk without tiring	56.2	11	11	11
Walk long distances	50.0	13	13	12
Walk fast	49.6	11	12	13

Note: Analysis of variance of ranks indicates no statistical variation (Fr $\chi^2 = 5.0$, df 12, $p > 0.05$).

Table 2 Variables Contributing to Perception of Walking Quality

Explanatory variables	Outcome variable: Do you think you walk well?			
	Yes, definitely	Somewhat	No	Mean
	Mean (SD) or N [%]	Mean (SD) or N (%)	(SD) or N [%]	POR* (95% CI)
Participants	266 [41]	253 [39]	130 [20]	
Age (decade)	71.6 (4.3)	72.1 (5.1)	72.8 (5.2)	1.4 (1.0, 1.7)
Sex				
Women	117 [36.6]	124 [38.8]	79 [24.7]	1.6 (1.1, 2.1)
Men	149 [45.3]	129 [39.2]	51 [15.5]	Referent
Walking aids				
None	222 [49.6]	165 [37.1]	59 [13.3]	Referent
Cane	12 [4.5]	63 [24.9]	62 [47.7]	6.6 (4.5, 9.6)
Walker	1 [0.4]	21 [8.3]	44 [33.8]	12.9 (7.4, 22.4)
Health conditions				
None	167 [54.2]	107 [34.7]	34 [11.0]	Referent
Heart disease	9 [40.9]	7 [31.8]	6 [27.3]	3.0 (1.3, 6.7)
Diabetes	34 [35.8]	39 [41.1]	22 [23.2]	3.1 (2.0, 4.9)
Arthritis	51 [28.2]	78 [43.1]	52 [28.7]	4.4 (3.0, 6.4)
Lung disease	4 [11.1]	20 [55.6]	12 [33.3]	7.2 (3.7, 14.2)

* Proportional Odds Ratio (POR); 95% confidence interval (95% CI).

Table 3 presents the consequences of walking quality to physical function (LEFS). For the LEFS, the total score was regressed on the perception of walking quality (with adjustments for age, sex, and health condition). There were 6- to 8-point differences between the three categories ("Yes, definitely", "Somewhat", and "No"), clinically meaningful

Table 3 Consequences of Walking Quality to Physical Function (LEFS)

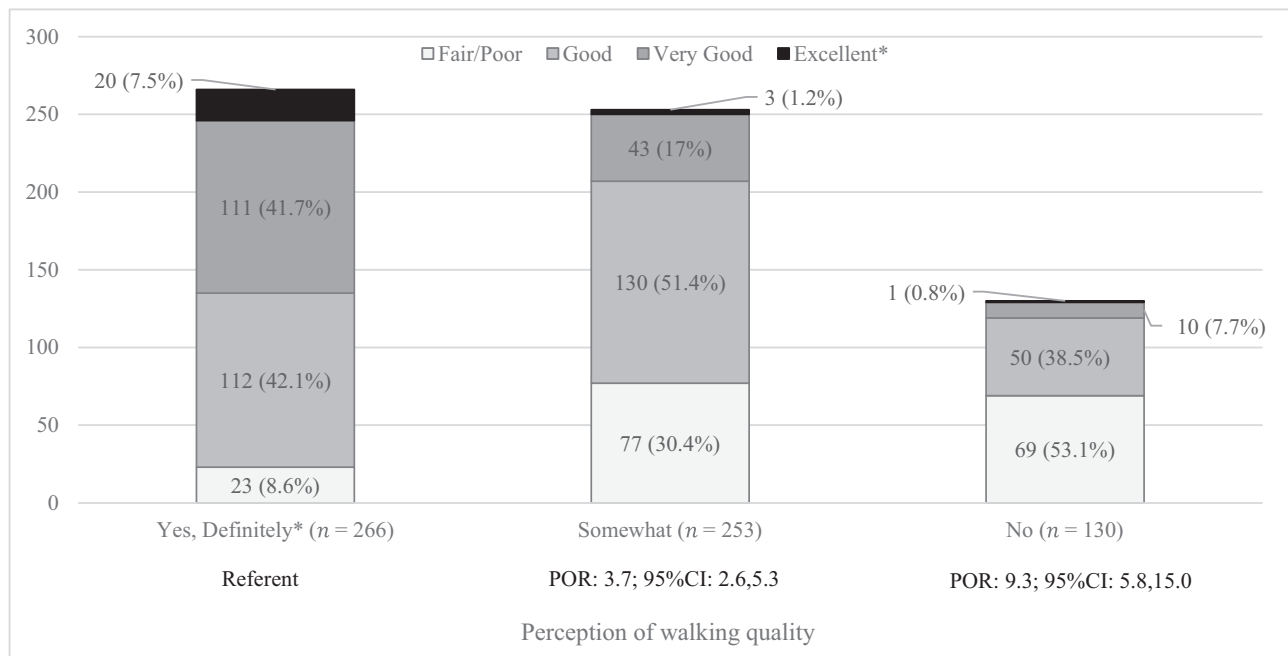
Explanatory variables	Outcome variable: LEFS Mean (SD)		
	Yes, definitely	Somewhat	No
	Mean (SD)	Mean (SD)	Mean (SD)
LEFS Score†	27.6 (4.6)	19.8 (6.5)	11.0 (7.3)
β (SE)	Referent	-6.7 (0.52)	-14.6 (0.65)

† Lower Extremity Functional Scale (LEFS) Score: 0–32; higher is better.

and statistically significant ($p < 0.001$). A key indicator of walking for health promotion is the LEFS item querying difficulty walking a mile: 75% of those who endorsed they definitely walked well reported no difficulty, in contrast to 18% of those who endorsed they somewhat walked well, and 5% of those who endorsed they did not walk well.

Figure 1 presents the perception of health according to participants' perception of walking quality. The odds of reporting poorer health (no matter how poorer health is defined), adjusted for age, sex and health condition, was 9.3 times greater for people who perceived they do not walk well than the odds for those who perceived that they walk well (POR: 9.3; 95% CI: 5.8, 15.0).

Figure 2 presents the distribution of willingness to pay for a device to improve walking across perception of walking quality. In comparison to the distribution of the amount willing to be paid among those who perceived they walk well, the odds of being willing to pay more, adjusted for age, sex, and health condition, were always greater for those with a lower perception of their walking quality.

**Figure 1** Self-reported health according to the perception of walking quality

* Referent

Note: POR (proportional odds ratio) adjusted for age, sex, health condition, and LEFS.

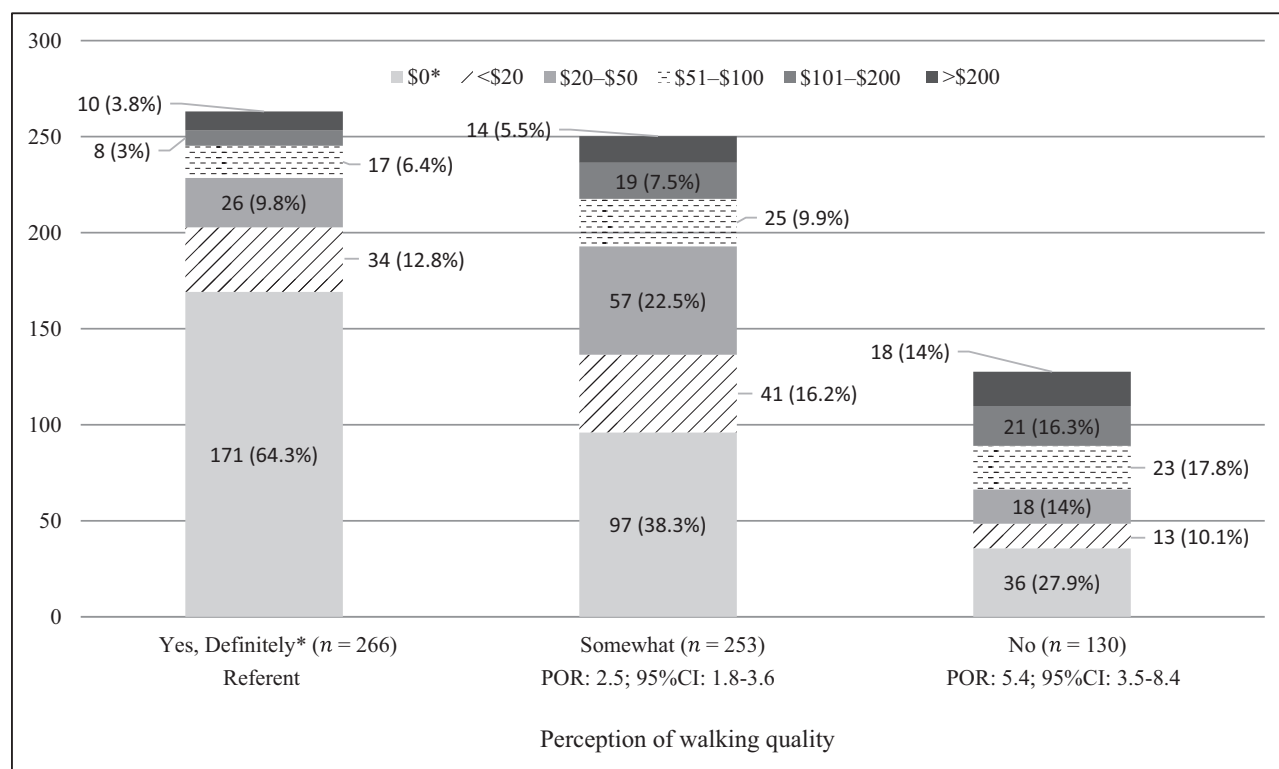


Figure 2 Willingness to pay for a device to improve walking according to the perception of walking quality

* Referent

Note: POR (proportional odds ratio) adjusted for age, sex, health condition, and LEFS.

DISCUSSION

Most seniors who participated in our study agreed or strongly agreed that the elements identified by gait experts were important for walking in older persons (Table 1). This degree of agreement would suggest that an expert-generated plan for a walking intervention would have face validity for an older population. In fact, this information was used to create a self-management workbook to improve walking in older persons and persons with disabilities. The Walk-BEST (BEtter, faster, longer, STronger) workbook was developed for this purpose and is available for download at no cost at www.physiobiometrics.com along with an accompanying app available in the Apple and Google stores.

Twenty percent of the sample reported they did not walk well (Table 2). This is in accordance with data from Statistics Canada on the proportion of people 65 years and older reporting mobility issues (24%).⁴⁰ The slight difference in proportions is likely due to the slight difference in age distributions: 25% ≥ 75 years vs. 38% for our sample and Statistics Canada, respectively. In addition, we also found that the perception of walking quality differed by known variables such as use of walking aids and health condition (Table 2). While walking quality may be closely linked to musculoskeletal health conditions such as arthritis,⁷ it was noteworthy that people with lung disease also reported not walking well as did those with heart disease and diabetes. These findings

reinforce the importance of assessing gait even among people without a primary musculoskeletal impairment, as poor gait can reduce physical activity and lead to falls.

Similar to what Bohannon found with people with stroke, walking fast was the least important walking element (Table 1).⁴¹ People with stroke were not concerned about gait speed but rather about the aesthetics of their gait.⁴¹ This is interesting given the emphasis on gait speed.²⁵ While gait speed has been shown to be associated with mortality, for people with a functional gait speed (> 0.8 m/sec), greater emphasis and physiotherapists' focus should be on those walking elements that would improve gait quality rather than speed.²⁵

The observation that, compared to men, women were more likely to report poorer walking quality (POR: 1.6; 95% CI: 1.1, 2.1) could be explained by both a sex and a gender effect. With ageing, changes in the structures and functions needed for safe, effortless, and health-promoting walking may differ across sexes. In their senior years, mobility issues, decreased functional capacity, and loss of independence are more prevalent in women than men.⁴² This is mainly due to differences in muscle mass and heart and lung capacity.^{43,44} With ageing, women experience greater changes in body composition (muscle mass decrease and increased visceral fat mass)^{43,44} resulting in a decrease in strength and muscle quality (muscle strength

relative to muscle mass).⁴⁵ The impact of sex differences in body composition has implications for physiological reserve, defined as resources an individual has at their disposal to combat stressors such as those arising from ageing, injury, or illness.⁴⁶ Thus, women may experience greater functional impact from stressors than men owing to a lower physiological reserve. Table 2 shows that 25% of women reported they did not walk well, as compared to 15% of men (POR: 0.6; 95% CI: 0.5, 0.9), and this sex differential remained even after adjusting for age and health condition. It is important for physiotherapists to consider physiological reserve in tailoring their therapies, as pushing a person past their physiological reserve capacity could do more harm than good. For certain conditions, a gradual increase in time spent in physical activity rather than increased intensity may be the solution.⁴⁷ It is also well known that women are less reluctant to report physical limitations than men for reasons related to gender role; men may feel stigmatized for reporting limitations.⁴⁸

The link between perceived walking quality and health shown in Figure 1 is an important finding because self-reported health is a strong predictor of mortality.⁴⁹ In a meta-analysis of 14 studies, people reporting their health as poor was associated with a greater 5+year mortality risk (RR:1.92; 95% CI, 1.64, 2.25) than people reporting their health as excellent or very good.⁵⁰ The relative risks of death associated with fair and good health were also elevated (RR:1.44 and 1.23, respectively). In our sample, the distribution of self-rated health was 3.7% (excellent), 25.3% (very good), 45% (good), 23% (fair), and 3.1% (poor). This distribution was somewhat different from the general population, who more often report excellent/very good health (45%), a smaller proportion of good health (34%), but a similar proportion of fair/poor health (21%).⁵⁰ The observation that walking quality is closely linked to perceived health underscores the importance of maintaining walking as it is linked to health. In a 2019 study published in *JAMA Internal Medicine* involving some 16,000 women from the Women's Health Study (mean age: 72 years) there was a dose-response relationship between median steps per day and mortality.⁵¹ Those taking over 8,000 steps per day had a much lower mortality risk (fully adjusted Hazard Ratio 0.34 (0.24-0.48)) than those taking 3,000 steps a day. As we found that walking quality affects walking quality (see Table 3), particularly the quality to walk a long distance (e.g. walking a mile, approximately 2000 steps)⁵², it is important for physiotherapists treating older people with any health condition to target walking quality as a treatment outcome.

There is a price to pay for good health. Physiotherapy services outside of a publicly funded institution are not free. A typical private clinic visit is approximately \$100, of which a proportion will be reimbursed for those holding private insurance. While people are willing to pay for treatment of an acute episode or injury, the amount they are willing to pay for prevention depends on their perceived risk of an adverse health event, which is widely underestimated.⁵³ Technology is poised not only for use in

rehabilitative treatment, but also in preventing gait deterioration in advance of an accident. We found that people with poorer walking quality would pay a higher amount for a technology to improve their walking.

CONCLUSION

Canadian seniors and experts agreed on what is important for walking well. The importance of joint mobility (foot, ankle, hip, knee) was strongly endorsed. Walking fast was the least important walking element, suggesting that physiotherapists should focus not only on gait speed but also on gait quality. Men and women differed in their perception of walking quality, with women reporting poorer walking quality than men, suggesting a sex and gender effect. Seniors surveyed had various health conditions which reinforces the importance of targeting walking quality as a treatment outcome, not only for people with musculoskeletal conditions, but also for people with lung and heart disease and diabetes. Canadian seniors with poorer perception of walking quality would pay more for a technology to improve their walking as compared to seniors who report they walk well. This supports the opportunity of leveraging wearable technologies to improve walking.

The main limitation of this study was the use of a participant panel, Hosted in Canada Surveys. This service recruits a non-probabilistic sample and therefore results may not be generalizable to the general Canadian population. To understand the biases inherent in the use of this sampling frame, we compared prevalence of walking disability and self-rated health in the Hosted in Canada sample to those of the Canadian general population of similar age. In our sample, the proportion that reported not walking well was 20% (see Table 2), closely similar to the proportion reporting mobility limitations for the general population of comparable age.^{3,40} The distribution of health perception in our sample was somewhat different from the general population, a greater proportion of whom reported excellent/very good health.⁵⁰

KEY MESSAGES

What is already known on this topic

The importance of gait pattern for function and fall prevention as well as the effectiveness of interventions for gait have been demonstrated.^{21,23,26-29} The current physical activity guidelines for older adults emphasize accumulating several hours of physical activity over a week.¹⁸ Walking is the most accessible and cost-effective means of achieving this activity target as it requires no equipment and no specialized environment. For many older people, walking is a means of accomplishing activities of daily living, but not in a goal-directed manner as exercise. Poor walking quality and walking capacity are barriers to achieving health-promoting physical activity.

What this study adds

One-on-one physical therapy for seniors who find themselves with mobility limitations (i.e., 20% of older

Canadians) is not a practical. The results from this project provided insight, from the perspective of seniors, on important elements needed to walk well as well as contributors to walking quality (including sex and lung condition) and consequences of walking quality (self-rated health and willingness to pay for help). There is great interest in using technology to promote health and seniors who do not walk well are willing to pay for this technology. This information guided the development of a self-management workbook and an app to assist seniors to self-assess their walking pattern, set goals, identify activities to improve walking, and track their progress towards healthful walking.

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CHAPTER 7: INTEGRATION OF MANUSCRIPT 1 AND 2

The first manuscript established that older people who self-identify having gait vulnerabilities reported having poorer health and were willing to pay more for any technology to help them improve walking.

The odds of willing to pay more for a technology to improve walking were greater for those with a lower perception of their walking quality. This gap could be filled by developing and leveraging technologies such as wearable devices targeted to walking. There are only a handful devices that commercially available and as this population is expected to grow there is need for major investment and research in bridging this gap.

While the focus of this thesis is on a novel technology developed by myself and the co-founders of PhysioBiometrics Inc there are commercially available technologies that provide data on daily activity. The most widely used technology captures step count continuously. Very little is done with these technologically derived data apart from reporting the mean and standard deviation. In the second manuscript, I present a novel way of considering these data to inform mobility outcomes.

The second manuscript links step count data with walking capacity, and walking reserve. For older people who have sustained a fracture, for whom walking is the most practical and accessible physical activity, the number of steps taken per day could be an indicator for walking capacity and reserve. While typical suggestions are to ‘walk more’, often walking is done to accomplish activities of daily living not as purposeful goal directed physical activity to improve capacity and reserve. The next manuscript will show how data collected from a simple pedometer could be used to establish a link between step count data with walking capacity, and walking reserve.

The next chapter presents the second manuscript, ‘Step-Count Distribution as an Indicator of Walking Reserve in People with Gait Vulnerabilities’. The global aim of this manuscript is to estimate the extent to which the distribution of step count data over a period of weeks to months identifies different subgroups of people which could be used to indicate walking reserve. The specific hypothesis is that the difference between the 90th percentile and the 50th percentile (median) will distinguish different clusters of people and that people in the lowest reserve cluster will differ from people in the higher reserve clusters on variables with the potential to influence step count distribution.

CHAPTER 8: MANUSCRIPT 2

Step-Count Distribution as an Indicator of Walking Reserve in People with Gait Vulnerabilities

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Contributors: All authors designed the study; or collected, analyzed, or interpreted the data; and drafted or critically revised the article and approved the final draft.

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ABSTRACT

Purpose. Steps-per-day a widely used physical activity indicator can provide a lot about the activity of the average person whose main source of activity is derived from walking. The purpose of this study is to estimate the extent to which the distribution of step count data over a period of weeks to months identifies different subgroups of people which could be used to indicate walking reserve. The specific hypothesis is that the difference between the 90th percentile and the 50th percentile (median) will distinguish different clusters of people and that people in the lowest reserve cluster will differ from people in the higher reserve clusters on variables with the potential to influence step count distribution.

Method. A time series design of a secondary data analysis was conducted to track the variability of daily step count in community dwelling men and women ≥ 60 years post fracture during an average period of 95 days. The full percentile (10th to 90th) distribution was used in a cluster analysis and group-based trajectory analysis was used for the longitudinal data. Ordinal regression was used to identify factors associated with cluster membership.

Results. Data were available on 44 people, 16 men (36%) and 8 women (64%); all but 3 (upper extremity) sustained a lower extremity fracture. The mean age of the participants was 75.8 years (SD: 9.75). Four clusters were identified: Cluster 1 would be classified as seniors who are sedentary with the fewest steps (mean 1678) and the difference between the median (50th percentile) and the 90th was 1314 steps, which kept them in the sedentary class. Cluster 2 would be classified as limited activity with a mean of 4297 steps/day, but still with low “reserve” as the 90th percentile still keeps them in the limited activity class; Cluster 3 would be classified in the active cluster (mean 7197) with high reserve moving them into the active cluster 10% of the time; Cluster 4 would be classified as very active (mean 9202) with the highest reserve (6964 steps). The factors associated with cluster membership were gait speed, sit-to-stand and depression.

Conclusion. The vast amount of data collected from a pedometer over time can be used to describe the activity pattern of seniors. Rather than focusing on the average over a restricted time period, the median and 90th percentile over a longer period of time indicates, not only typical patterns but also, the potential “reserve” the person could tap into for participating in special events that demand additional walking. Slow gait, muscle weakness, and low mood were identified as limiting walking reserve and would guide how to build up this reserve.

INTRODUCTION

Steps-per-day a widely used physical activity indicator can provide a lot about the activity of the average person whose main source of activity is derived from walking. According to the International Classification of Functioning, Disability and Health (ICF) walking is moving along a surface on foot, step by step, so that one foot is always on the ground, such as when strolling, sauntering, walking forwards, backwards, or sideways[1].

For the average person, for whom walking is the most practical and accessible physical activity, the pattern of steps taken per day over a time period can indicate not only what they typically do but also what they are capable of doing if they need or want to do more, termed reserve[2]. The concept of walking reserve is compatible with the concept of physical reserve which are the physiological and functional resources an individual has to call upon to meet health challenges and represents the latent or dormant abilities that can be called upon in times of perceived need[3]. In other words, what the person has in their “tank”.

For older persons, walking is the most common and safest form of physical activity. Walking for exercise requires a normal gait pattern otherwise, with gait deviations, there is a risk of exacerbating existing muscle and/or joint impairments. Age-related decline in physiological functions renders older people vulnerable for gait deviations. Gait vulnerability is defined as a physiological health state or disease that results in the person being at an increased risk of developing deviation in gait parameters, limitation in walking capacity, and/or sustaining walking for purposes of health promotion.

C. Tudor-Locke,[4, 5] a leader in step count analytics has provided targets for different populations. She has critiqued the “10,000 steps a day” value as being unrealistic and too high for some (older persons and those with chronic conditions) and not enough for younger populations.[4] Her work has led to defining these activity categories: (i) < 2,500 steps/day (basal or sedentary activity) ; (ii) 2,500- 4,999 steps/day (limited activity); (iii) 5000 to 7499 typically active, typical of daily activity without steps from exercise or sports; (iv) 7500 to 8999, very active, reflecting steps accumulated from exercise/sports or high occupational demands; and (v) ≥ 9000 highly active steps/day. Another way of thinking about these values is “3”, “5”, “7” and “9” (000) defining activity levels as sedentary, limited activity, active, and very active, respectively. Typically, active seniors would fall between the “5” and “7” values.

In a 2011 update of literature on “how many steps per day are enough”, she concluded that 3000 steps at a cadence 100 steps per minute over and above steps for usual daily activities would be a target[5]. This translates to around 7000 to 8000 steps per day. This “3000 steps per day” value accumulated over and above usual activities through targeted exercise was suggested as a public health approach for health promotion[6]. This value would also apply to older populations[5] as they take fewer steps for daily activities.

Most studies on step counts report median and mean values over a short period of time (days). For example, a 2019 study published in *JAMA Internal Medicine*[7] the some 16000 older women who participated in the Women’s Health Study (mean age 72 years) wore an accelerometer for 7 days. Mean (median) step count was 5499 (5094) per day with high degree of variability (interquartile range of 2128 for 25th percentile to 9954 for 75th percentile). The full distribution would be more informative especially with if longer term data (weeks or months) on step counts was available.

In another paper, Tudor-Locke et al. showed the full distribution of step-count data for men and women by age (see Appendix 1)[8]. The steepest decline over age was observed at the 95thile of the distribution, particularly for women where the value at age 60 was $\approx$ 10,000 steps (median $\approx$ 4,500) while the 95thile value at age 85 was 4,000 steps[8]. The corresponding values for men were 13,000 steps and 6,000, steps respectively[8]. Over all age categories, the greatest difference between men and women was between the 50th and 95th percentile[8]. This suggests that men and those of younger years have greater capacity to tap into resources to accomplish high step counts on some days. This capacity could be considered to measure walking reserve.

Most of the studies on step-counts are done while participants wear an accelerometer for a short time of some days (cite the studies), usually maximum of 7 days. For longer periods of time, taking a simple average does not do justice to the richness of the data and a different approach is needed to summarize these longitudinal data. We propose here that the full distribution of step counts over weeks to months can be used to identify subgroups of the population that differ not only on habitual physical activity for also on the amount of reserve they have at their disposal for augmenting typical activity days with more intensive exercise days.

OBJECTIVE

The purpose of this study is to estimate the extent to which the distribution of step count data over a period of weeks to months identifies different subgroups of people which could be used to

indicate walking reserve. The specific hypothesis is that the difference between the 90th percentile and the 50th percentile (median) will distinguish different clusters of people and that people in the lowest reserve cluster will differ from people in the higher reserve clusters on variables with the potential to influence step count distribution.

METHODS

One data source was used for this study which incorporated a pedometer that tracked the variability of daily step count. The data source is from a completed pragmatic randomized trial: *Hip Mobile: A Community-based Monitoring, Rehabilitation and Learning e-System for Patients following a Fracture* (SN. Morin, NE Mayo et al; NCT03153943). The global aim of the Hip Mobile project was to test the value of using technology to enable recovery and improve quality of life following a fracture through the implementation of the Hip Mobile technology 8 weeks post-fracture repair. The study obtained ethical approval from the Institutional Review Boards of the McGill University Health Center (MUHC).

The study sample comprised community dwelling men and women ≥ 60 years, treated for any fracture excluding hands, feet, patella, cervical spine, skull, ribs, or clavicle, at three Montreal affiliated hospitals with McGill University. Excluded were people living in or were discharge to a long-term care institution, or who had sustained multiple traumas, an open fracture, or a cancer-related fracture.

A time series design of a secondary data analysis was conducted to track the variability of daily step count. Each participant was provided with a Piezo[®] SC-StepX pedometer and was asked to record the number steps at the end of each day for the duration of the study intervention period (3-months post-intervention) which ranged from 5 to 12 weeks.

The measures for this analysis included patient reported outcomes (PRO), performance outcomes (PerfO) tests, administered at baseline (Time 0) only and technologically assessed outcomes (TechO)[9] providing data on step count over the entire study period (3-months). The primary outcome, daily step count, was obtained from records kept by participants of the steps from the pedometer. For each participant, the distributional parameters for the daily step count data were extracted: mean, standard deviation (SD), median, minimum, maximum, and percentiles.

PROs potentially affecting reserve were general health perception, pain, and depression measured on a visual analogue health scale (VAHS)[10] from 0-10 with higher values indicating better general health but greater pain and depression. Also measured were PerfOs of comfortable gait speed (meters per seconds), sit-stand (count in 30-seconds), and tandem stance (5 level ordinal scale).

STATISTICAL ANALYSIS

K means cluster analysis on the percentile distribution of step count over all recorded days was used (proc fastclus) to identify groups of people with similar step count distributions. The sample was described according to cluster membership and overall.

The longitudinal pattern of step count was also described using Group-based trajectory analysis (GBTa). This analysis identifies the number of unique longitudinal trajectories in the data. Different models were compared, including models with different number of trajectories as well as with different shapes of the same trajectory (intercept only, linear, and quadratic shape). Bayesian Information Criteria (BIC), Akaike's Information Criteria (AIC) and posterior probability were used to assess model fit and best model selection. Crude agreement between the cluster and trajectory groups was calculated.

Ordinal regression, the proportional odds model, was used to identify factors associated with being in a cluster with a higher step distribution. A multivariable model was used to identify the strongest predictors and the final model was the most parsimonious. This model estimates the odds of being in a higher cluster for each level of each variable compared to the odds associated with the lowest level of that variable, for each cut-point. An odds ratio (OR) and 95% confidence intervals (CI) across all cut-points is derived from the model. Homogeneity of the cut-point specific ORs is assessed using a score test. All analyses were done using Statistical Analysis Software (SAS 9.4TM).

RESULTS

Data were available on 44 people, 16 men (36%) and 8 women (64%); all but 3 (upper extremity) sustained a fracture. The mean age of the participants was 75.8 years (SD: 9.75); step count data was available for an average of 95 days (SD: 21.5), ranging from 47 to 123 days.

The 44 people contributed 4180 person-days of step counts. The percentile distribution for each person was calculated and the 50th and 90th percentile is displayed in Figure 1 which is sorted according to the 50th percentile. The difference between the 90th and 50th percentile is smallest for people with the lowest step count and increases with increasing median number of steps. The full percentile (10th to 90th) distribution was used in a cluster analysis.

Four clusters were identified and the distribution of step-counts over the study period are presented in Table 1. Cluster 1 comprises 8 people who would be classified as sedentary, mean <5000 steps per day. They had the fewest steps (mean 1678) and the difference between the median (50th percentile) and the 90th was 1314 steps, which kept them in the sedentary class. Cluster 2 comprises 21 people with a higher step count, mean 4297, considered limited activity, with low “reserve” as the 90th percentile still keeps them in the limited activity. Cluster 3 comprises 10 people classified in an active cluster (mean 7197). Cluster 4 would be classified as a very active cluster (mean 9202) comprising 5 people was identified: they had the highest reserve (6964 steps) and their 90th percentile placed them in the very active class for at least 10% of the time. The first two clusters differ by median step count (4081-1555) but cluster 2 has the capacity, on some days, to be active. Whereas the people in the limited active cluster did not have enough reserve to have days in the active range.

Figure 2 shows the variability of step counts over time. Four groups of people were identified with distinct longitudinal trajectories. The trajectory groups corresponded with the cluster groups as shown in Table 2. Overall, 36 of 44 (81.1%) people were classified in the same step count pattern using the cumulative clustering approach and the longitudinal trajectory approach. Thus, the cumulative approach was used to identify factors associated with cluster membership.

The characteristics of participants in each cluster are presented in Table 3. These factors were used in regression model to identify the extent to which they were associated to cluster membership. Table 4 shows that only gait speed, sit-to-stand and depression were associated with cluster membership.

DISCUSSION

While it is possible to measure the physical capacity after sustaining a fracture, there is no direct measure of reserve, which is defined as the resources that a person has to combat an incoming stressor[11]. Reserve is important as it can be used to reduce the impact of injuries or illnesses and hasten recovery from these stressors. Reserve can also allow older people to participate in special

activities that demand more walking than they typically do. We proposed a new method of characterizing walking activity and walking reserve from data provided by a simple technology, the pedometer.

The concept of walking reserve has not been studied and would be very relevant for the fracture population as this concept may provide important insight into the recovery process post hip-fracture. Typical walking activity, walking reserve, and associated factors would provide information for developing a more personalized rehabilitation program based on data collected from a simple, widely used, technology, the pedometer.

We defined walking reserve as the difference between the long-term 90th percentile value and the long-term median value, where long-term would be defined as 30 days or more. Tudor-Locke et al. (2013) described how percentile distribution of daily step counts differed by age group. While the median declined over age, the sharpest decline was at the 95th percentile. This difference between the median and the 95th percentile diminished with age supporting this metric as an indicator of reserve[8].

Little is known about recommended steps per day for older people following fractures. Studies have reported steps per day but for shorter time periods. A 2019 study published in *JAMA Internal Medicine* involving some 16000 women from the Women's Health Study (mean age 72 years) wore an accelerometer for only 7 days[7].

As we had the hypothesis *a priori* that people would differ on our “reserve” metric, the difference between the 90th percentile and the 50th percentile, we used a cluster analysis. The four clusters supported this hypothesis as two had low reserve (despite differences in median step count) and two had high and very high reserve. We classified reserve as low or high based on whether the people in the cluster had enough reserve to move into a higher activity group (Table 1).

It is interesting to note that neither age nor sex was associated with cluster membership in our study. In addition, there was a wide range of step counts across this sample with several people in cluster 3 and 4 having days where they walked more than 10,000 steps. The often-reported value of 10,000 steps per day does not have strong scientific rationale particularly for older people and no information is available after fractures. In 2004[4] Tudor-Locke critiqued the “10,000 steps a day” value as being unrealistic and too much for some (older persons and those with chronic

conditions) and not enough for younger populations; thus, the importance of having goal-oriented step count targets based on individual walking reserve and capacity.

To build reserve, gradual increase in time spent in activity rather than increased intensity has been suggested and tested[12]. Walking is an accessible form of exercise, but for many people post fracture, walking is done to accomplish activities of daily living not in a goal directed manner to improve capacity and reserve. A systematic review and meta-analysis showed that step-count monitoring interventions can lead to sustained increases in people's walking[13].

The observation that the cumulative approach to creating groups concurred with the longitudinal approach supported our decision to identify reserve factors using the cluster analysis groupings. Of the factors from Table 3 that we used in the ordinal model only gait speed, sit-to-stand, and low mood had an important association with cluster membership (Table 4). Here inference was made on the magnitude of the estimate of effect and the confidence interval rather than solely on the p-value as the sample size was small. All of the estimates of effect in Table 4 were closely similar, ranging from 0.22 to 0.29 (absolute values) for each meaningful difference in the explanatory variables with low mood (depression VAHS) having the largest effect (-0.29) although the upper limit of the confidence interval was 1.1.

It has been reported by Tuka et al. (2017)[14] that targeted physical activity is the holy grail of modern medicine which has the potential to reduce depressive symptoms and improve overall physical function and capacity. Targeted steps per day as per the walking capacity and reserve would give recommendations to improve walking capacity and health promotion walking.

Interestingly, a study by Costa et al. (2021)[15] proposed that walking speed reserve in people with chronic stroke could be measured by taking the difference between maximal and self-selected speed over a 10 meter course[15]. Arbitrarily, a difference of walking speed of 0.2 m/s between self-selected and the maximal speed[15] was set as an indicator of walking speed reserve. This, however, is a clinical test, and may not be reproduced in the real world if people have to rely on this reserve to avoid accidents such as when crossing the street. Mate and Mayo (2020) showed that in people with Multiple Sclerosis, the most able did not reproduce clinically assessed walking speed tests in the real world[16]. This would suggest that our approach using real world data would provide a better indication of walking reserve than a clinical test.

One challenge with interpreting step count data is that there are different labeling conventions depending on age[4, 5]. We have adopted a “3”, “5”, “7”, “9” (000) system to simplify setting personalized step count targets. Interestingly, Tudor-Locke identified that older persons typically take between “5” and “7” (000) steps supporting these values as targets: below typical, typical, or above typical.

LIMITATIONS

The main limitation in this study was the small sample size although there were 4180 person-days of walking. Some participants failed to record their number of steps for all days, leading to smaller days of recorded steps. No data was available on cadence or duration of walking bouts. Not all persons provided health outcome data. Replication in a large sample size is warranted.

CONCLUSION

The vast amount of data collected from a pedometer over time can be used to describe the activity pattern of seniors who have sustained a fracture. Rather than focusing on the average over a restricted time period, the median and 90thile over a longer period of time indicates, not only typical patterns but also, the potential “reserve” the person could tap into for participating in special events that demand additional walking. Slow gait, muscle weakness, and low mood were identified as limiting walking reserve and would guide how to build up this reserve.

TABLES & FIGURES

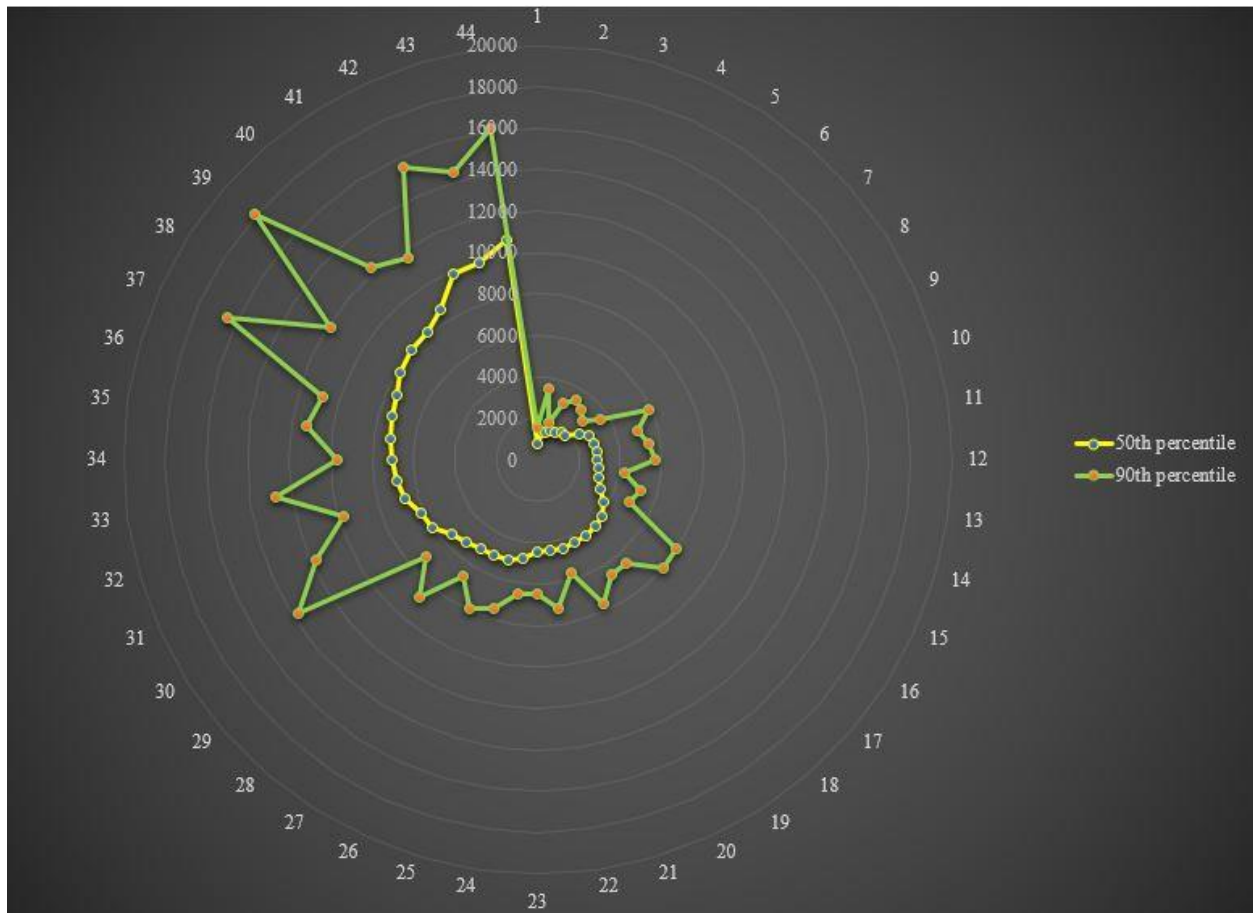
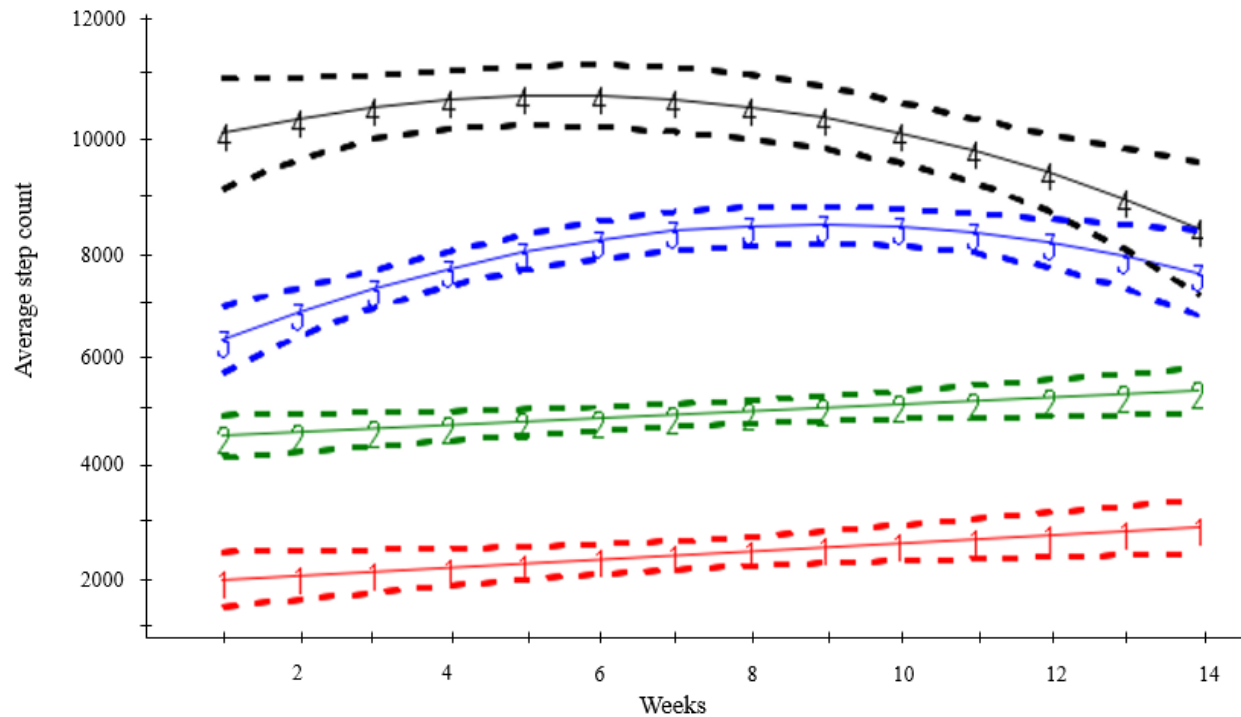


Figure 1. Radar Graph of the Distribution of Step Count (50th and 90th percentile) for all Participants (n=44)

Table 1 Step Count Distribution by Clusters.

Step count percentiles & mean	Sedentary, low reserve Cluster 1 (N=8)	Limited activity, low reserve Cluster 2 (N=21)	Active, high reserve Cluster 3 (N=10)	Very active, very high reserve Cluster 4 (N=5)
10th	725	2351	3820	4293
20th	931	2847	4795	5776
30th	1078	3205	5566	7112
40th	1301	3641	6293	8192
Mean $\pm$ SD	1678 $\pm$ 448	4297 $\pm$ 877	7408 $\pm$ 593	9633 $\pm$ 906
50th	1555	4081	7197	9202
60th	1741	4568	7923	10183
70th	1941	5045	8723	11329

80th	2356	5675	9692	13080
90th	2870	6520	11566	16166
Maximum	4779	9508	16325	20372
90th- 50th	1314.3	2439	4370.1	6964.2



	Group based trajectory analysis group membership n=44 n [%]			
	Group 1 15 [34.05]	Group 2 14 [31.85]	Group 3 11 [24.97]	Group 4 4 [9.11]
Mean Step Count (SD)	1833.6 (207.3)	4421.2 (212.8)	5647.3 (400.6)	9507.9 (668.4)

Figure 2 Average Step Count over 14 Weeks for Different Groups of Participants.

Table 2 Concordance of Cluster Groupings with Trajectory Groupings.

		Cluster				Total
		1	2	3	4	
GBTA	1	8	7			15
	2		14			14
	3			10	1	11
	4				4	4
Total		8	21	10	5	44

Crude Agreement = 36/44 (81.8%)

Table 3 Characteristics of Study Participants at Study Entry According to Step Count Cluster (n=44)

Variables	Sedentary, low reserve Cluster 1 (N=8)	Limited activity, low reserve Cluster 2 (N=21)	Active, high reserve Cluster 3 (N=10)	Very Active, very high reserve Cluster 4 (N=5)
	Mean $\pm$ SD or n [%]			
Age	80 $\pm$ 9.2	77 $\pm$ 11.4	73 $\pm$ 8.3	68 $\pm$ 5.4
Sex				
Men	3 [37]	5 [24]	4 [40]	4 [80]
Women	5 [63]	16 [76]	6 [60]	1 [20]
Fracture Site				
Lower Extremity proximal (hip, sacrum, pelvis)	6 [75]	15 [71]	4 [40]	1 [20]
Lower Extremity distal (tibia, ankle)	2 [25]	4 [19]	5 [50]	4 [80]
Upper Extremity (humerus, wrist)	0 [0]	2 [10]	1 [10]	0 [0]
Gait speed	0.6 $\pm$ 0.15	0.81 $\pm$ 0.3	1.1 $\pm$ 0.3	1.1 $\pm$ 0.13
Tandem* N [%]	2 [25]	9 [43]	7 [70]	4 [80]
Sit-to-stand	5 $\pm$ 5.7	9 $\pm$ 3.8	11 $\pm$ 4.4	14 $\pm$ 2.6
General health perception	5.1 $\pm$ 1.9	2.9 $\pm$ 2.3	2.6 $\pm$ 2.4	4.2 $\pm$ 1.1
Depression	3 $\pm$ 3.5	0.9 $\pm$ 1.7	0.9 $\pm$ 1.4	0.6 $\pm$ 0.9
Pain	3.4 $\pm$ 2.8	2 $\pm$ 2.1	3.2 $\pm$ 2.5	3 $\pm$ 1.4

* Percentage with score of 4 on Tandem

Table 4 Important Predictors of High Step Count

Variables	B	Standard Error	OR (95% CI)
Gait Speed (per 0.1m/sec)	0.27	0.13	1.31 (1.02, 1.69)
Sit-to-Stand	0.22	0.08	1.24 (1.06, 1.46)
Depression	-0.29	0.18	0.75 (0.53, 1.1)

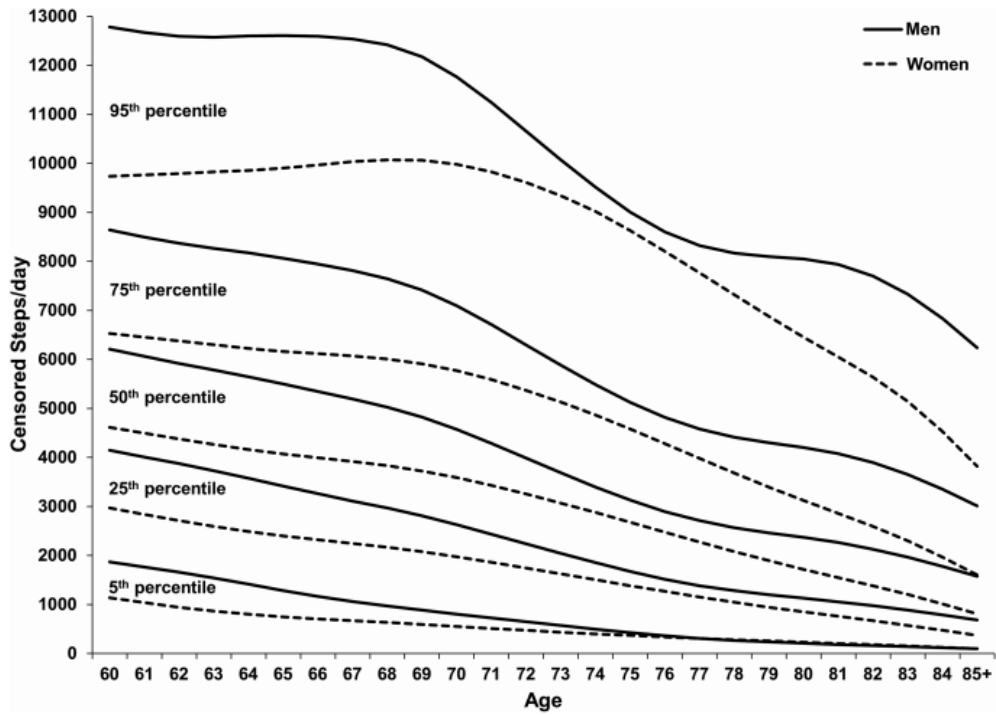
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APPENDIX

Appendix 1. Distribution of Steps per Day by Age Stratified by Sex (Tudor-Locke et al. 2013 [8])



CHAPTER 9: INTEGRATION OF MANUSCRIPT 2 AND 3

The second manuscript estimated the extent to which the distribution of step count data over a period of weeks to months identified different subgroups of people which could be used to indicate walking reserve. It showed how a simple technology, the pedometer, can be used to promote walking capacity and reserve in people who have sustained a fracture.

In the last manuscript, I demonstrate the user experience with a more complex technology that focuses on walking capacity and gait quality. Manuscript 2 and 3 relate to technology. The first, relates to a well-established technology, pedometer, that is not used to its maximum in terms of data exploration. The second relates to an emerging technology, Heel2Toe sensor, that is being developed for maximum use and optimal data mining.

The next chapter presents the third manuscript, ‘User Experience with the Heel2toe Sensor: A Novel Technology to Improve Walking in People with Parkinson’s Disease. The global aim of this manuscript is to identify the challenges in implementing a novel technology to improve walking in people with Parkinson where challenges arise from the device, usability perception of the client, need for informational/technological support, engagement with the device, and overall user experience.

CHAPTER 10: MANUSCRIPT 3

User Experience with the Heel2toe Sensor: A Novel Technology to Improve Walking in People with Parkinson's Disease

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Contributors: All authors designed the study; or collected, analyzed, or interpreted the data; and drafted or critically revised the article; and approved the final draft.

Competing Interests: The authors of this article are co-founders and owners of PhysioBiometrics Inc. an enterprise dedicated to the development of practical and accessible technologies for people with posture and movement vulnerabilities. One of the products presented in this article, the Heel2Toe sensor, is a product of PhysioBiometrics Inc.

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ABSTRACT

Purpose. The purpose of this study is to identify the challenges in implementing a novel technology, the Heel2Toe sensor, to improve walking in people with Parkinson

Method. A two-group, randomized feasibility trial with 2:1 intervention to control randomization was carried out. The intervention period lasted 3 months with an additional 3-months of follow-up. This paper reports on the usability of the Heel2Toe sensor in a real-world setting.

Results. Twenty-seven people with Parkinson were in the study separated into two groups: The Heel-to-Toe group (n=18) and the Workbook group (n=9). The average age of participants was 70 years of age with twice as many men as women. The results on the System Usability Scale (SUS) was reported on participants who completed the intervention (n=14). The 10-items were separated into those referring to positive experiences and those referring to negative experiences. To summarize all the items from the SUS, the number of person-responses was calculated as the product of people and items. The rate of positive, neutral and negative endorsements was 0.41, 0.34, 0.25, respectively. Some challenges were reported by the participants which were related to the connection, battery, device attachment, the sound, and the app. The total number of calls among the participants in the Heel2toe group over the whole intervention period was 117, ranging from 1 to 29 calls. These challenges and troubleshooting calls helped the development team to refine and optimize the Heel2Toe device going from version REV-B to REV-E. Despite that, there was some positive feedback after using the Heel2Toe sensor: “Walking quality improved”.

Conclusion. Usability is important to measure as it impacts implementation. In people with PD, the usability (functionality, design, complexity, features), the person’s attributes (skills, attitudes, perceived usefulness and perceived ease of use) and the user experience or technology-person interaction (satisfaction, effectiveness, efficiency) can potentially predict technology adoption. Technology adoption is a complex process. It is important to understand the drivers of technology adoption among people with PD to make an evidence-informed decision on how to improve the user experience around the technology.

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INTRODUCTION

Parkinson Disease (PD) affects 1 in every 500 people in Canada and >100,000 people are living with PD today and this proportion will increase by 65% by 2031[1]. Of the neurological conditions, PD has the 3rd highest level of direct health care costs and the highest use of prescription medications[2].

Typically, people with PD show a deteriorating gait pattern characterised by quick, short, shuffling steps, on a narrow base of support, with stooped posture, rigid trunk, and reduced arm swing. The lack of heel strike during gait, a feature of shuffling gait, shortens the stride often causing the shoes to scuff the ground, making people with PD more likely to trip and fall[3-5]. Starting, stopping, and changing direction is more difficult; gait pattern is inconsistent[6] and freezing is common[7]. As gait impairments progress, asymmetries develop, and people have difficulty adapting their walking to new environments or to increased task burden[8, 9]. Eventually, walking for enjoyment and health promotion abates and ultimately ceases.

In Canada, people with PD are not routinely offered public health sector rehabilitation services unless after a health crisis. The recent Canadian Guideline for Parkinson Disease[10] states that “*Physiotherapy specific to PD should be offered to people who are experiencing balance or motor function problems*”. There is a gap between should and is: only 1.5% of home care visits in Canada are attributed to PD[11]. At best, they may see a therapist at a regular medical visit for an assessment. People can access private physical therapy but costs approach \$100 per visit unless the person has private insurance and few private practices specialize in neurological conditions. Some community organizations offer fall prevention classes or exercise classes for people with disabilities which may be free, if part of public health, or with a registration fee. Some of these have moved on-line during COVID. Technology is poised to change the way people with health conditions manage their disabilities, but barriers exist particularly for older persons.

A recent systematic review (2020) reported barriers to technology adoption among older persons[12]. It showed that lack of perceived usefulness, difficulty in learning how to use technological products, physical limitations, scepticism toward technology, availability, access, lifestyle, privacy, hardware and software were barrier in adopting a technology[12].

Nonetheless, Adoption of mobile-health¹ (m-health) technology is rising rapidly among older people in Canada[13]. In 2016, a Canadian survey on technology adoption showed that internet use rose from 65% to 81% among people aged 65 to 74 years and from 35% to 50% among adults aged ≥ 75 years[13]. Smartphone adoption in people above 65 years was noted to be 69%[13].

The Technology

The principal product line of PhysioBiometrics Inc. targets gait quality through the Walk-BEST[14] toolkit developed by physiotherapists, researchers, and engineers to aid people with mobility challenges to walk BEtter Faster, Longer, STronger, which is a realist and achievable goal for people living with PD. The pivotal tool in the toolkit is the Heel2ToeTM sensor which is a new generation of SMART, (auditory) feedback-enhanced, wearables that provides accurate assessment of walking pattern, and real-time auditory feedback for efforts to optimize walking pattern [15-19]. The Heel2Toe sensor is registered as an invention with McGill University (ROI: 2021:007). The Intellectual Property (IP) in the Heel2Toe sensor is licensed to PhysioBiometrics Inc. by McGill University. The sensor is classified as a Class I Medical Device by Health Canada and PhysioBiometrics Inc. holds a Medical Device Establishment License for sales and distribution in Canada.

The Heel2Toe device automates a strategy that Physiotherapists use during gait training, instructing the patient to place the heel first when walking. This simple strategy lengthens the stride and changes a stooped, shuffling gait to one that is upright and striding[5]. If the person could walk in this manner they would and so something beyond giving instruction is needed. The Heel2ToeTM sensor detects the speed at which the foot pivots around the ankle joint during gait. When the speed of this rotation exceeds a pre-determined threshold for a “good” step, one in which the heel is the first point of contact with the floor during stepping, a signal is sent via Bluetooth to a smartphone that then emits a congratulatory “beep” each time the person makes a “good” step. This type of positive auditory feedback has been shown to stimulate neural connections, and through the process of neuroplasticity, imprints this desirable gait pattern through mechanisms related to motor learning[20-25], essentially harnessing the power of the brain to automate a more optimal gait pattern. It is small enough to clip to the side of the shoe.

¹ Mobile-health: Subset of electronic -health (e-Health) that covers areas of networking, mobile computing, medical sensors, and other communication technologies within healthcare⁶⁹.

The Heel2Toe sensor shown on Figure 1 , provides real-time data on step quality to inform therapy and help people track their own progress. Positive auditory feedback also has been shown to increase motivation because when the brain anticipates a reward for a good step the dopamine cycle is activated. The auditory reward is one thing but a greater reward is in achieving good walking and this increases the dopamine signalling[26-29].



Figure 1. Heel2Toe Sensor Attached to the Shoe

The Evidence to Date

To normalize walking, people with PD must relearn motor sequences and develop needed adjuncts to efficient walking; strength, power, core stability, balance, etc. Physiotherapy targets adjuncts, but motor learning requires instruction, practice and feedback[30]. At least some of the neural mechanisms underlying this learning are likely aberrant in PD; in particular, the brain's ability to signal feedback. Feedback signals are critical for modulating neuroplasticity.

The Heel2Toe sensor has been shown to detect a strong heel strike with over 90% accuracy which is a gait parameter important for healthful walking, particularly in people with PD as it is associated with foot clearance and cadence[31, 32]. The device has been tested in 2 clinical populations, seniors and people with PD and data showed that those with gait deficits were able to improve walking pattern over 5 training sessions with total time ranging from 30 to 70 minutes[19, 33].

In research, when new interventions (i.e. Heel2Toe sensor in this context) are developed the uptake into clinical practice is driven by implementation science using methods for knowledge translation. In the clinical context, the users are usually clinicians who have no input into the product (intervention) to be implemented. In the context of technology, it is the business world that carries out the implementation. The focus is to have a successful product that is usable, operationally defined as being functional, learnable, and leading to the ability of the person to carry out a task successfully by using the product.

Therefore, it is important to understand the challenges and contributors to usability of a newly developed product. In a recent systematic review of technologies to improve walking that was presented in Chapter 2, only 3 publications relating to gait-related technologies tested usability. The technologies that reported usability were CuPiD/Gait Tutor[34], BalancePro[35] and Heel2Toe[18]. The usability of the Heel2Toe sensor has been previously studied on 6 people with PD over 5-days of supervised training period by Carvalho et al. (2020)[36]. People with PD reported that their experience was enjoyable, stimulating gratifying and beneficial[36]. Thus, the need to understand the longer-term of unsupervised user experience of the Heel2Toe device.

OBJECTIVES

The purpose of this study is to identify the challenges in implementing a novel technology to improve walking in people with Parkinson where challenges arise from the device, usability perception of the client, need for informational/technological support, engagement with the device, and overall user experience.

METHODS

A two-group, randomized feasibility trial with 2:1 intervention to control randomization was carried out. The intervention period lasted 3 months with an additional 3-months of follow-up. The feasibility phase followed the recommendations from the new CONSORT extension to randomized pilot and feasibility study (PAFS) trials[37, 38]. The emphasis of PAFS is on testing all aspects of data collection and processes of administering the intervention and measures. This paper reports on the usability of the Heel2Toe sensor in a real-world setting. Time spent on the phone with participants for troubleshooting with the Heel2Toe sensor was collected. The trial is registered on ClinicalTrials.gov Identifier: NCT04300348.

POPULATION

People with PD manifesting gait impairments or limitations in walking capacity meeting the criterion that usual walking is without a walking aid (Self-Rated Walking and Balance item on the Movement Disorder Society- Unified Parkinson's Disease Rating Scale (MDS-UPDRS)[39] were eligible. This criterion would correspond to Hoehn and Yahr Scale of 2 to 3[40]. Use of a walking aid prohibits an optimal walking pattern so people requiring a walking aid for usual walking were excluded. Patients with cognitive impairment were also excluded based on a score of <21/30 on

the Montreal Cognitive Assessment (MOCA)[41]. All patients were taking their usual dopaminergic medications throughout the study. Recruitment was through the Quebec Parkinson Network and the Movement Disorders Clinics at McGill sites.

INTERVENTION

The technology tested here are components from the Walk-BEST program (**BE**tter, Faster, Longer, **ST**ronger; www.physiobiometrics.com).

Both the Heel2Toe group and the Workbook group received the Walk-BEST workbook that has instructions on how to identify gait deficits and received instructions for 5 body-weight exercises, to be performed each day, to facilitate a better walking pattern. Both groups received 5 virtual or in-person training sessions with a physical therapist to practice walking BEST, followed by home practice over 3 months.

The Heel2Toe group was trained to walk with the Heel2Toe sensor in feedback mode during the 5 therapy sessions and practiced with the sensor at home for 3 months. During the home practice, participants were instructed to walk with the device for a minimum of two 5-minutes walk per day in feedback mode.

MEASUREMENT

The sample was characterized on symptoms, function, health-related quality of life, and user experience. Symptoms included were pain, energy, mood, and anxiety measured on a 0-100 scale (higher is better) using the Visual Analogue Health States (VAHS)[42] and a single item on concentration from the Parkinson Disease Questionnaire-8 (PDQ-8)[43]. Function was measured using indicators of walking capacity: the 6-minute walk test (6MWT: distance in meters); items from the Neuro-Qol Lower Extremity Function –Short Form[44]; a single item on community mobility from the PDQ-8; and motivation for daily activities. Health-related quality of life (HRQoL) was measured using the EuroQol EQ-5D-3L[45], and a single item for Quality of Life (QoL) on a 0-100 scale .

Information on user experience was gathered using exit interviews. Contributors to user experience were also measured and informed by the model in Figure 2. Technology readiness was not apart of this study but the information on the user experience will guide future work.

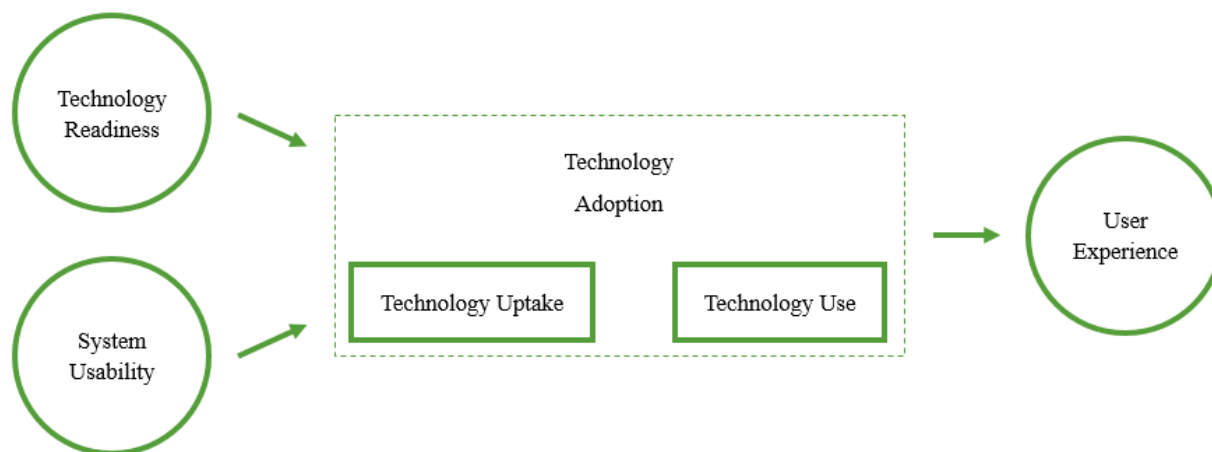


Figure 2. User Experience Model

The System Usability Scale (SUS), comprising 10-items measured on a five-point Likert scale, was used for assessing the perceived usability of a product or a system after having used it[46]. Technology uptake was measured over the first two training weeks during which training was provided. It was quantified by the proportion of days (n=14) when the person had one or more Heel2Toe sessions. Technology use was measured over the home use period (n=76 days) when the person was not coached.

RESULTS

Table 1 shows demographic characteristics of the study participants separately for the Heel-to-Toe group (n=18) and the Workbook group (n=9). The average age of participants was approximately 70 years of age with more than twice as many men as women and twice as many participants living accompanied as alone. There was no strong tendency for one group to report more positive or negative values on the selected health outcome indicators. As this is a feasibility study, no between group comparisons are made.

The results on the System Usability Scale (SUS), administered only to those completing the intervention (n=14), are presented in Table 2. The 10-items were separated into those referring to positive experiences and those referring to negative experiences. The proportions of people selecting strongly agree or agree (responses 5 or 4) and strongly disagree or disagree (responses 1 or 2) are presented. For example, for the positive item “Would you recommend the Heel2Toe device to someone else”, 9/14 endorsed this positive response and 1/14 this positive response. As for the negative item, “I needed to learn a lot of things before I could get going with this Heel2Toe

device” 2/14 endorsed this negative response and 7/14 denied this negative response. To summarize all the items, the number of person-responses was calculated as the product of people and items. For example, for positive items we divided the number of positive person-response (55+20) by the total rate response-items (182) which gives 0.42. There was a higher rate of positive endorsements (0.42) than negative endorsements (0.23). As for the negative items, there was a lower rate of per person-response negativity (0.21 vs. 0.36). Overall, the rate of positive, neutral and negative endorsements was 0.41, 0.34, 0.25, respectively.

Figure 3 presents the distribution of Heel2Toe use for each participant in the intervention group over the 2-week training period (blue bars) and over the 3-month home practice (orange bars). All participants were instructed to use the Heel2Toe sensor twice daily for 5 minutes. The proportion of days of use during the training period ranged from 0% (person A) to >180% (person P). The median usage value was 54%, located between person H and I. The orange bars show the usage for the period of home practice. Usage in the training period was not carried over into the home training period: the range was from 0% to >100% and the median value was 37%, located at person M.

Table 3 lists the usability challenges experienced by the participants and the changes made to the Heel2Toe sensor addressing the challenges. The challenges were related to the connection, battery, device attachment, the sound, the app, the flashing lights on the sensor and the comfort. The device tested in this study was classified as the second revision, REV-B. By the end of the study, the device was in REV-D and now REV-E. The changes made from REV-B to REV-E are listed in the table. Table 4 lists the positive feedback related to the Heel2Toe sensor.

The total number of calls among the 18 participants in the Heel2toe group over the whole intervention period was 117, ranging from 1 to 29 calls, averaging 7 per person and the total time was 344 minutes, ranging from 2 to 70 minutes for an average of 22 per person.

DISCUSSION

Accepting and adopting a new technological innovation presented itself with some usability concerns among people with PD. These concerns were related to Bluetooth connection between the Heel2Toe sensor and the application, the device attachment and the comfort (Table 3).

A systematic review by Gordt et al. (2018) on the ‘Effects of Wearable Sensor-Based Balance and Gait Training on Balance, Gait, and Functional Performance’ looked at the usability of wearable sensor in people with PD[47]. The wearable sensor (WS) was defined in this review as a sensor that goes on the individuals body measuring kinetic and kinematic motion data[47]. The WS was generally accepted and that people with PD enjoyed it very much[47]. The main contributors for not adopting a technology in this review were related to physical limitations due to tremors (touchscreen), lack of perceived usefulness, access, hardware and software issues, and difficulty in learning how to use technological products. Another systematic review on the usability of upper body wearable rehabilitation technologies have identified the following concerns among people with musculoskeletal disorders: comfort of the technology, engagement with the technology and ease of use[48].

We found that there was more positive endorsement on the SUS as compared to negative, 41% and 25% respectively. This suggests that our early iteration of the Heel2Toe sensor has potential to improve walking quality in people with PD. In fact, a study by Carvalho et al. have showed benefits of improving gait parameters (i.e. heel strike) during a two-three week of supervised training period[36]. Five out six people in this study reported that they were satisfied and especially happy that the sensor helped them walk better to walk more. This suggests an improvement in walking capacity over a short-term period of time[36].

Interestingly, we have found that during the 2-week training period, participants used the device proportionally more often than when they used it by themselves during the 3-month home practice period. A reason for that was that during the 2 weeks training period the participants had a physiotherapist instructing them what to do which was likely more stimulating than using the Heel2Toe sensor alone for 3-month. As people with PD present with a lack of motivation, meaningful engagement and positive reinforcement (i.e. positive feedback) should not be underestimated[49].

There’s no consensus on whether people with PD share similar opinions of technology given that there’s many factors that could impact behavior towards use of technology including factors associated with patient health, socio-demographic variables, and prior experience along with environmental factors.

In business, for a newly product to be viable it must be a “living” entity that not only meets current market needs but also is rapidly adaptable to changing needs of the customers. Troubleshoot calls were necessary to solve issues related to the sensor and to get recommendations to make the sensor more user-friendly. With that being said, the Heel2Toe sensor has been refined and optimized to a newer version in response to the usability concerns by the customers going from version REV-B to REV-E. Usability is an important factor for successfully implementing a product in the market[47].

Given that people with PD have impaired automatic movement resulting in a shuffling gait pattern, the Heel2Toe sensor is beneficial through positive reinforcement, in real time, which stimulates motor learning of correct gait[36]. Also, this sensor can help identify if an individual is at risk for a fall or other instability and as a means of prevention for people that may not be aware of gait deficiency. Encouraging a behavior change for an individual is complex and has many steps before success. However, by working to build physical capacity, make opportunities, and encourage change by motivation and positive reinforcement, the Heel2Toe sensor can help encourage neural networks to function more accurately with respect to gait movements in people with PD.

In fact, despite the challenges with the usability of the Heel2Toe, there was positive feedback related to the benefits of the Heel2Toe sensor (Table 4). Some of the comments from the users were: “It really helped me concentrate on walking properly”, “ I really liked the device and that I saw how it helped me walk better” and “It motivated me to walk at a better pace every time I heard the beep”.

There is great potential for this type of therapeutic wearable of gait dynamics for those with known gait issues such as people who have sustained a fracture and people with neurological conditions. The focused practice monitoring of gait with this device also generates a tremendous amount of data for each individual that can be mined to develop predictive algorithms for falls and other gait related events, positive or negative.

LIMITATIONS

This pilot study was small by design, but it is important to underscore that usability metrics must be part of all research on technologies.

CONCLUSION

Usability is important to measure as it impacts implementation. In people with PD, the usability (functionality, design, complexity, features), the person's attributes (skills, attitudes, perceived usefulness and perceived ease of use) and the user experience or technology-person interaction (satisfaction, effectiveness, efficiency) can potentially predict technology adoption. There are many measures of usability and user experience that evaluate safety, efficacy and effectiveness of health technologies (as seen in Chapter 4 of this thesis).

Technology adoption is a complex process. It is important to understand the drivers of technology adoption among people with PD to make an evidence-informed decision on how to improve the user experience around the technology. It is essential to identify and remedy the challenges in adopting technology among people with gait related impairments which is the most prevalent disability among the aging population[50, 51]. For this to happen, the measures of technology adoption need to be fit for purpose and implemented consistently in all research on new technologies.

As per Lord Kelvin

“When you can measure what you are speaking about and express it in numbers, you know something about it. When you cannot express it in numbers, your knowledge is of a meagre and unsatisfactory kind.” Therefore, “To measure is to know” and “if you cannot measure it you cannot improve it[52]”

TABLES & FIGURES

Table 1 Demographic Characteristics of the Study Participants (n=27) and Proportions Reporting Challenges with Selected Health Outcome Indicators

Variables	Heel-to-Toe (n=18)	Workbook (n=9)
	Mean ± SD or n [%]	Mean ± SD or n [%]
Age (years)	70.2 ± 8.5	70.7 ± 8.8
Min – Max: is it hyphen or dash?	51 – 84	53 – 82
Gender		
Women	5 [28]	3 [33]
Men	13 [72]	6 [67]
Living Arrangement ¹		
Alone	6 [33]	2 [22]
With someone	11 [61]	7 [78]
Employment ¹		
Working	3 [11]	---
Retired	9 [50]	8 [89]
Disabled	5 [28]	1 [11]
Visual Analogue Scale (0 – 100, higher is better)		
Pain	55.2 ± 32.5	39.9 ± 28.3
Energy	57.8 ± 20.2	36.6 ± 28.5
Mood	62.6 ± 29.2	47.1 ± 34.0
Anxiety	57.5 ± 28.1	53.6 ± 27.8
<u>Parkinson Disease Questionnaire¹ (ordinal scale of 0 to 5: higher is no impairment)</u>		
Had problems with your concentration? ²	9 [53]	5 [56]
<u>Walking Capacity</u>		
6 MWT in meters	381 ± 140.1	409.3 ± 183.4
<u>Neuro-QOL items, Ability to ^{1,3}:</u>		
Get in and out of a car?	3 [18]	3 [33]
Get up off the floor without help?	6 [35]	3 [33]
Walk for at least 15 minutes?	3 [18]	2 [22]
<u>Parkinson Disease Questionnaire¹</u>		
Had difficulty getting around in public places ⁴ ?	4 [24]	5 [56]

Apathy¹

Are you interested in learning new things ⁵ ?	1 [11]	0 [0]
Do you have motivation ⁵ ?	3 [18]	1 [11]

Motivation^{1,6}

Learning new things for pleasure or recreation	5 [29]	0 [0]
Learning new things for work or necessity	8 [47]	3 [33]
Walking for exercise	2 [12]	3 [33]
Exercising regularly	6 [35]	3 [33]

Effort^{1,7}

Learning new things for pleasure or recreation	6 [35]	5 [56]
Learning new things for work or necessity	7 [41]	3 [33]
Walking for exercise	12 [71]	3 [33]
Exercising regularly	8 [47]	4 [11]

Enjoyment^{1,8}

Learning new things for pleasure or recreation	4 [24]	1 [11]
Learning new things for work or necessity	8 [47]	5 [56]
Walking for exercise	4 [24]	1 [11]
Exercising regularly	5 [29]	3 [33]

EQ-5D-3L^{1,9}

Mobility	7 [41]	4 [44]
Self-care	3 [18]	2 [22]
Usual Activities	8 [47]	6 [67]
Pain/Discomfort	10 [59]	5 [56]
Anxiety/Depression	9 [53]	5 [56]
Utility Score ¹⁰ (Mean $\pm$ SD)	0.77 $\pm$ 0.11	0.76 $\pm$ 0.11
VAS ¹⁰ (Mean $\pm$ SD)	64.4 $\pm$ 18.2	77.5 $\pm$ 14.2
Quality of life ¹⁰	63.6 $\pm$ 21.4	71.0 $\pm$ 17.5

-
- 1 Missing data from 1 person in Heel2Toe group (n=17)
 - 2 Always/Often/Sometimes vs. Occasionally/Never
 - 3 Unable/Much Difficulty/Some Difficulty vs. Little Difficulty/Without any difficulty
 - 4 Always/Often/Sometimes vs. Occasionally/Never
 - 5 Slightly/Not at all vs. some/a lot
 - 6 Do not care/Need a push vs. on my own
 - 7 A little vs. A lot/some
 - 8 No/Neutral vs. Yes
 - 9 EuroQol-5 Dimensions: some/ extreme problems vs. no problems
 - 10 Higher is better: 1.0 for utility and 100 for VAS and quality of life

Table 2 Proportion of Participants who Reported Positively and Negatively on Usability of the Heel-to-Toe Sensor. Only Participants from the Heel-to-Toe (Intervention) Group are Reported.

	Strongly agree/ Agree	Strongly Disagree/ Disagree
	n=14 in percentage [%]	
<u>Positive items</u>		
Would you recommend the Heel2Toe device to someone else	9 [64]	1 [7]
What is your overall satisfaction with this Heel2Toe device**	8 [57]	4 [29]
I felt very confident using the Heel2Toe device	6 [43]	4 [29]
Does the Heel2Toe device meet your expectations	7 [50]	1 [7]
I found the various functions in this Heel2Toe device to be well integrated	7 [50]	2 [14]
I thought the Heel2Toe device was easy to use	2 [14]	6 [43]
Does the Heel2Toe device compared to your idea of an ideal Heel2Toe device for walking	6 [43]	4 [29]
I think that I would like to use the Heel2Toe device frequently	4 [29]	3 [21]
I would imagine that most people would learn to use this Heel2Toe device very quickly	4 [29]	4 [29]
Rate over 126 person-responses	55	34
Rate per person-response	0.42	0.23
<u>Negative items</u>		
I needed to learn a lot of things before I could get going with this Heel2Toe device	2 [14]	7 [50]
I found the Heel2Toe device unnecessarily complex	4 [29]	4 [29]
I think that I would need the support of a technical person to be able to use this Heel2Toe device	4 [29]	4 [29]
I found the Heel2Toe device very cumbersome to use	2 [14]	5 [36]
Rate over 56 person-responses	12	20
Rate per person-response	0.21	0.36
Rate over 182 person-responses	75 + 61*	46 -
Rate per person-response	0.41 + 0.34*	0.25 -

+ positive endorsement of usability

- negative endorsement of usability

* neutral endorsement of usability

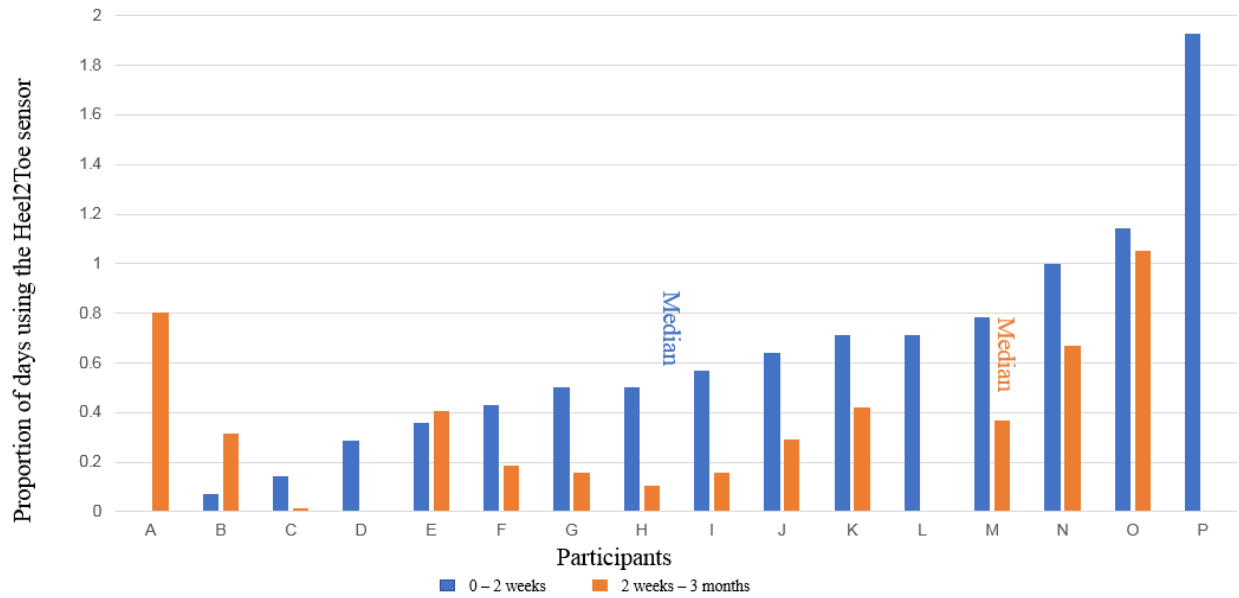


Figure 3 Distribution of Heel2Toe use for Each Participant over a 2-Weeks Training Period Followed by a 3-Month Home Practice

Table 3 Usability Challenges Experienced by the Users of the Heel2Toe Sensor as Reported over the 3 Month of Home Use and the Respective Changes Made to the Sensor.

Usability Concerns	Changes Made
Connection	Revisions were made to the circuit board
Battery	Changed for longer life and indicator of charging status integrated
Device attachment	A new attachment has been designed
App	Improvements made, still under revision
Lights flashing	Instruction manual explains the lights
Sound	Improved with new version
Comfort	Improved with new attachment

Table 4 Positive Feedback Received from the Users of the Heel2Toe Sensor (n=14) after 3 Months of Home Use

Positive Feedback
Ma satisfaction est positive lorsque sa fonctionne bien. c'est encourageant d'entendre le bip
Me signaler que j'ai bien déposer le pied avec le beep. sa me motive à accélérer mon rythme de marche.
I really liked the device and that I saw how it helped me walk better
My walking is great!
Once I was in athletic mode, it made it easier for me to stretch my left leg forward and rebalance the left leg with the right that isn't affected by Parkinson's yet. The arm swing also improved significantly after that, from a trembling when I swung my arms strongly to now no trembling.
The concept is very interesting, and the assistance of physiotherapists was most useful . Thank you
It did his job as it was
It really helped me concentrate on walking properly
It's good

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CHAPTER 11: GLOBAL DISCUSSION

The overall objective of this thesis is to contribute methods and insights needed to develop a viable business plan to promote the adoption of technologies targeting walking capacity and performance in people with gait vulnerabilities. The global aim was to use the knowledge gained in this specific context to postulate how adopting a business model could benefit the practice of physiotherapy in general. This overall objective was achieved through one literature review paper (Chapter 2) and three linked manuscripts, two of which will be submitted for publication at a later date and one already published in *Physiotherapy Canada*.

A systematic review on technologies that provide feedback for gait rehabilitation showed that there is weak evidence for technologies targeting walking (Chapter 2). Most devices presented targeted gait improvement for people with neurological conditions with claims that are generalized to other health conditions. Consumers are unable to access the published material that shows if the device is effective or not. There were no data available on usability. There were some selected user reviews or testimonials, most providing favorable comments. A consumer may be driven to purchase a device only by reading reviews or testimonials even though these are not representative of users' experiences.

There is great interest in using technology to promote healthful walking in seniors. There are only a handful devices that are commercially available and as this population is expected to grow there is need for major investment and research to address this gap.

A first manuscript (Chapter 6) showed that 60% of older Canadians reported that they did not or only somewhat walk well (Chapter 6; Table 2). The most important elements for walking well endorsed by older Canadians and gait experts were foot, ankle, hip and knee mobility. Interestingly, walking fast was the least important walking element that was endorsed by Canadian seniors. This suggests that the general public is more interested in quality of gait and not speed although this is a strong focus of clinicians. Older people who self-identified with gait vulnerabilities and poor health were willing to pay up to \$200 for technology to help them improve walking. Wearables devices that improve walking are poised to help people with gait-vulnerabilities to walk better. The results from manuscript 1 established the size of the market and guided the development of a self-management tool (i.e. The Walk-BEST Workbook ©) to assist

seniors to self-assess their walking pattern, set goals, identify activities to improve walking, and track their progress towards healthful walking.

Technology alone will not be sufficient to alter gait patterns sustainably or as rapidly as needed. There are many body structures and functions that need to be optimized to support the better walking pattern, including: (i) foot and ankle strength and mobility, (ii) strength and power of large muscles of the leg and calf, (iii) core strength; (iv) balance; (v) posture; (vi) arm swing; and (vii) trunk. To provide assistance to people to identify and improve these areas, I developed the Walk-BEST Workbook © and accompanying app. The content of the Walk-BEST Workbook ©, shown in Appendix 3, is based on best-practice physical therapy modalities for improving seniors' gait incorporating principles of self-management. The areas of assessment and recommended exercises were chosen based on the literature and consensus from a snowball sample of Canadian and international gait experts.

There are commercially available and accessible technologies (pedometers) that provide data on daily step count. A second manuscript (Chapter 8) showed how these data can be informative to personalizing therapy for people with fractures, and likely generalize to other gait vulnerable populations. The vast amount of data collected over time from a simple pedometer can be used to describe the activity pattern of seniors who have sustained a fracture. The number of steps taken per day could be an indicator for walking capacity and reserve. Typically, the suggestions are to 'walk more', often walking is done to accomplish activities of daily living not as purposeful goal directed physical activity to improve capacity and reserve. Instead on taking the average, the median and 90thile over a long period of time indicated, not only typical patterns but also, the potential "reserve" the person could tap into for participating in activities that demand additional walking. Four activity-levels were identified: (1) sedentary, low reserve; (2) limited activity, low reserve; (3) active, high reserve; and (4) very active, very high reserve. Slow gait, muscle weakness, and low mood were identified as limiting walking reserve and would provide therapeutic targets to build up walking reserve.

Manuscript 2 showed how a simple technology, the pedometer, can be used to promote walking capacity and reserve who would potentially benefit from a personalized walking program. This large amount of data generated by even simple technologies can show areas of improvement for each individual and potentially enable more informed treatment plans[229]. The vast amount of

data collected from a pedometer over time can be used to develop predictive algorithms, using methods from artificial intelligence and machine learning, as to who will meet step count targets and who will progress. The new era, Health 4.0, is targeted towards making health care applications more personalized[229].

In future work, I propose to provide seniors and people with gait-vulnerabilities with a way of interpreting daily step count data and with personalized feedback for improving walking capacity and reserve based on the targets 3000, 5000, 7000 and 9000 steps per day. However, it is of no use to anyone to increase the number of steps without these steps being “BEST”. It is no use increasing the number of steps without also addressing reserve factors (pain, fatigue, low mood, poor health). Therefore, the use of the Walk-BEST workbook © is an essential component to achieving health promoting walking targets.

For technology to be used by people with gait-vulnerabilities, usability and user experience should be measured. In the last manuscript (Chapter 10), I demonstrated among people with PD the user experience of the Heel2Toe, a sensor that focuses on walking capacity and gait quality. Adopting a new technological innovation presented itself with some usability concerns among people with PD. These concerns were related to Bluetooth connection between the Heel2Toe sensor and the application, the device attachment and the comfort.

As technology is ever evolving according to consumers feedback, the Heel2Toe was refined throughout the course of the feasibility trial going from version REV-B to REV-E. Much positive feedback was received from people with Parkinson’s on how their walking pattern improved, despite some technological challenges.

In research, when new interventions (i.e., the Heel2Toe sensor in this context) are developed the uptake into clinical practice is driven by implementation science using methods for knowledge translation. In the clinical context, the users are usually clinicians who have no input into the product (intervention) to be implemented (Chapter 3; Figure 5). Even with a growing “implementation science” community and methods, only 14% of original research findings are translated into practice and it takes some 17 years for research evidence about interventions that are safe and efficacious to reach clinical practice[142, 178]. Part of this gap and delay is that researchers are not in the best position to do the translation and do not have the infrastructure (marketing, sales, supply and demand expertise and know how etc.) to develop the processes that

need to be put into place to successfully take the innovation to the community. No business would survive with this time frame. In the context of technology, it is the business world that carries out the implementation. The value of a business model approach is in its immediacy, as companies will not survive if their products are not used in a timely fashion

The business aim is to have a successful product that is usable, operationally defined as being functional, learnable, and leading to the ability of the person to carry out a task successfully by using the product. Having a usable product is essential for sales which generates revenue for the business. This thesis proposes the integration and complementarity of business and knowledge translation models to promote the adoption of technologies leading to a positive user experience.

There are many constructs that relate to preparing for and measuring outcomes of market uptake. Figure 1 is a model of how I linked the various constructs together. The end-product is a positive user experience which will facilitate diffusion of the technology through positive reviews. The green check marks indicate areas that are necessary for a positive user experience of technology.

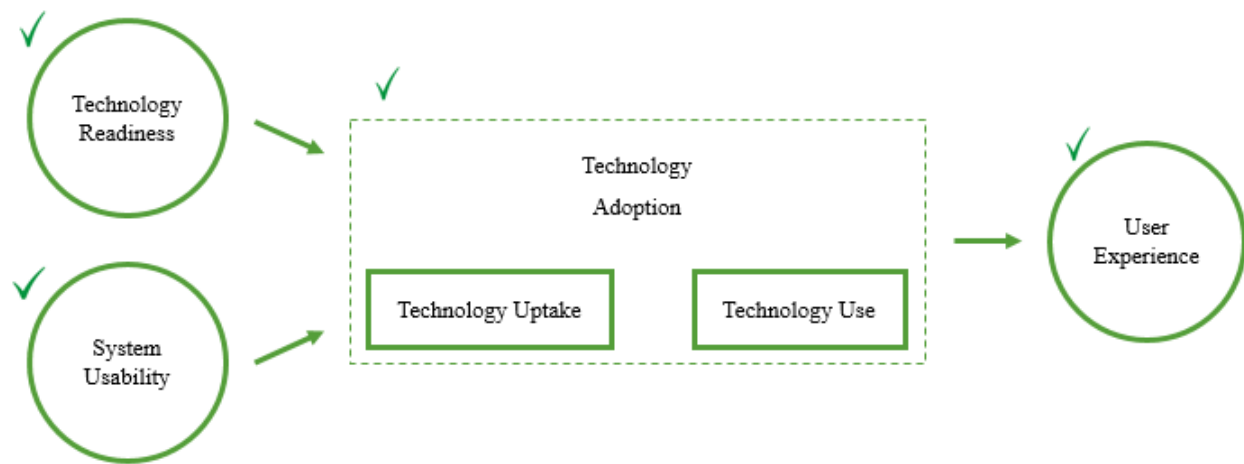


Figure 1 User Experience Model

The process starts with technology readiness and system usability (Figure 1). The usability is formed by the aesthetics, functionality, design, and complexity of the technology. Whereas technology readiness is reflected to the person's attributes such as (skills, attitudes, perceived usefulness, perceived ease of use) (Figure 2). For technology adoption, I have separated the process into the early uptake, first impressions, which are very important for technological interventions. If the early experience is favourable, longer term use is more likely. All of these components

influence the user experience: the person needs to be ready to accept the technology, the technology has to be optimized, the person needs to try the technology (uptake) and they have to use it for the appropriate amount of time to see benefits. All four conditions need to be satisfied to have a positive user experience. These would be necessary conditions but none of them are sufficient on their own. When all are optimized, the stage is set for a perfect rainbow.

While the construct of usability and its components were discussed in the thesis, technology readiness has not been discussed needs to be considered for future work. Figure 2, below, shows the components of usability (topic of manuscript 3) and technology readiness (topic of future work).

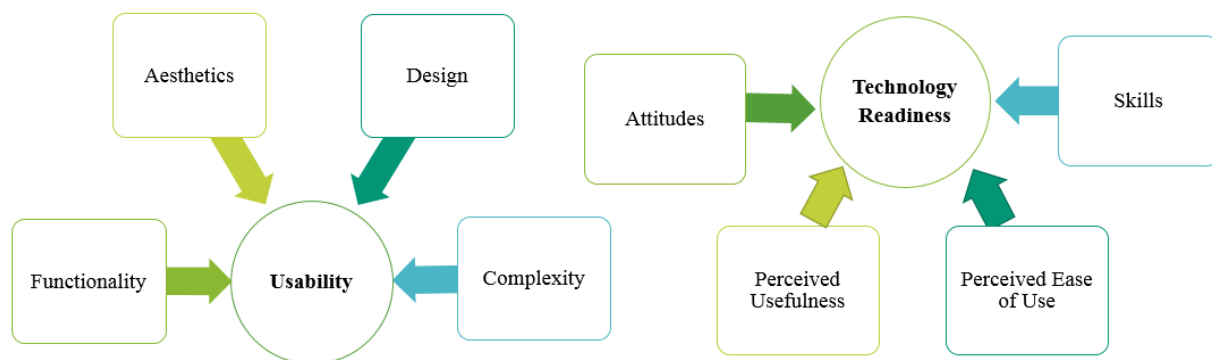


Figure 2 Usability and Technology Readiness Models

Technology Readiness (TR) is defined as “people’s propensity to embrace and use new technologies for accomplishing goals in home life and at work” [225]. Although not measured here, this is the topic of the work extending the Parkinson trial (Chapter 10; Manuscript 3) into the community at large.

Different populations will have different challenges with adopting technologies. In fact, people with PD used the Heel2Toe sensor more when the Physiotherapist and caregiver helped. Thus, support for the technology was needed for the participants to learn how to use the Heel2Toe sensor. Confidence and motivation to learn new things is an important asset for walking.

One of the participants in the Heel2Toe trial for people with Parkinson’s, remarked that everyone will have a different reason for adopting a particular technology. These reasons may differ from that of the developers. For example, I as a developer of the Heel2Toe technology am focused on improving the angular velocity of the ankle during gait so that the quality of the gait cycle is

optimized. This improves stride length, power, foot lift, balance, muscle strength and also reduces joint pain. While of interest to me as a clinician, I was made aware that users had different goals such as being able to walk for exercise and elevate heart rate, to improve balance, to be able to walk without a walking aid, as examples.

The philosophy of human action proposed by Aristotle, relates to today's challenges with technology adoption. For the goal to be achieved, which is what drives the reason for adopting the technology, it must be clear and certain conditions need to be satisfied. The model of necessary and sufficient contributors to participation[230], is applicable in this context. In the article by Mayo et al (2014)., "participation" is the goal the person wants to achieve, such as walking for exercise [230]. The adapted model from this article is shown in Figure 3 in the context of technology adoption. In the context of this thesis, necessary material causes for walking would be the capacity to walk and social support as people need to be supported for their goal. Necessary moving causes are motivation and positive mood as goals require effort. Formal causes would represent the Heel2Toe sensor as well as the built environment offering a secure place to practice walking. Most important is the final cause, belief that the goal is worth attaining. All of these causes are necessary causes, but only the final cause is a sufficient cause. If the goal is not worth attaining, that will be sufficient to prevent adoption.

This consideration of what is necessary and what is sufficient is for technology adoption is highly relevant in the business case: all conditions are necessary; none are sufficient except in their absence.

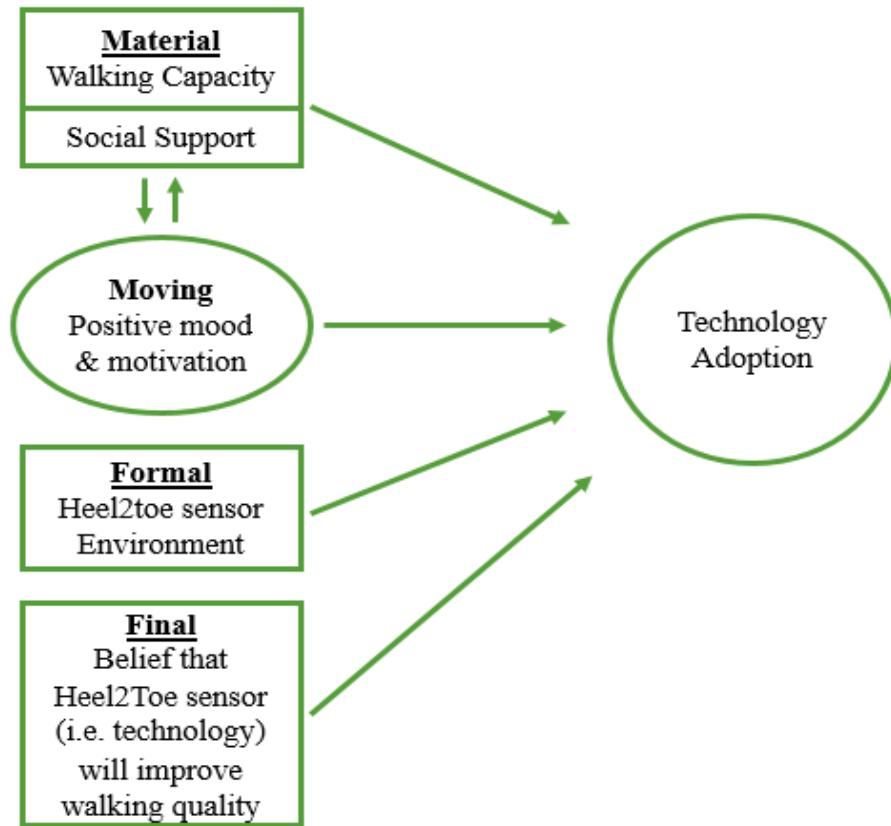


Figure 3 Theoretical Representation of Aristotle’s Causes of Technology Adoption (Adapted from Mayo et al. (2014)) [230]

Conclusion

This thesis work is timely and relevant to increasing proportion of the older and gait vulnerable population and builds upon the potential of technology to stimulate innovation thereby advancing Canadian economic and social development. This thesis proposes the complementarity of Knowledge translation and Business Models for technologies targeting walking capacity and performance in people with gait vulnerabilities.

Physiotherapists need to embrace technology to have a population, societal and economic health impact. This thesis provides a view about how the future of clinical practice could be through the integration of business-research models to promote healthful walking behavior. Designing and developing safe and effective health technologies requires sustained and intensive interdisciplinary teamwork, involving clinicians from different disciplines, engineers (software, mechanic),

research methodologists, measurement experts, and, most importantly, the active involvement of the person with the targeted health or functional challenge.

The development of a technological innovation based on the integration of context-specific theoretical research-business models may lead to health technologies reaching people in need at a faster rate than peer-reviewed research publications. A research-business model is a plausible approach to design, develop and commercialize health technological innovations for people that need them the most.

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APPENDICES

Appendix 1 Oxford Centre for Evidence-based Medicine Levels of Evidence [53, 128]

Level	Therapy/Prevention, Aetiology/Harm	Prognosis	Diagnosis	Differential diagnosis/symptom prevalence study	Economic and decision analyses
1a	SR (with homogeneity*) of RCTs	SR (with homogeneity*) of inception cohort studies; CDR† validated in different populations	SR (with homogeneity*) of Level 1 diagnostic studies; CDR† with 1b studies from different clinical centres	SR (with homogeneity*) of prospective cohort studies	SR (with homogeneity*) of Level 1 economic studies
1b	Individual RCT (with narrow Confidence Interval‡)	Individual inception cohort study with > 80% follow-up; CDR† validated in a single population	Validating** cohort study with good††† reference standards; or CDR† tested within one clinical centre	Prospective cohort study with good follow-up****	Analysis based on clinically sensible costs or alternatives; systematic review(s) of the evidence; and including multi-way sensitivity analyses
1c	All or none§	All or none case-series	Absolute SpPins and SnNouts††	All or none case-series	Absolute better-value or worse-value analyses ††††
2a	SR (with homogeneity*) of cohort studies	SR (with homogeneity*) of either retrospective cohort studies or untreated control groups in RCTs	SR (with homogeneity*) of Level >2 diagnostic studies	SR (with homogeneity*) of 2b and better studies	SR (with homogeneity*) of Level >2 economic studies
2b	Individual cohort study (including low quality RCT; e.g., <80% follow-up)	Retrospective cohort study or follow-up of untreated control patients in an RCT; Derivation of CDR† or validated on split-sample§§§§ only	Exploratory** cohort study with good††† reference standards; CDR† after derivation, or validated only on split-sample§§§§ or databases	Retrospective cohort study, or poor follow-up	Analysis based on clinically sensible costs or alternatives; limited review(s) of the evidence, or single studies; and including multi-way sensitivity analyses
2c	*Outcomes* Research; Ecological studies	*Outcomes* Research		Ecological studies	Audit or outcomes research
3a	SR (with homogeneity*) of case-control studies		SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies	SR (with homogeneity*) of 3b and better studies
3b	Individual Case-Control Study		Non-consecutive study; or without consistently applied reference standards	Non-consecutive cohort study, or very limited population	Analysis based on limited alternatives or costs, poor quality estimates of data, but including sensitivity analyses incorporating clinically sensible variations.
4	Case-series (and poor quality cohort and case-control studies§§)	Case-series (and poor quality prognostic cohort studies****)	Case-control study, poor or non-independent reference standard	Case-series or superseded reference standards	Analysis with no sensitivity analysis
5	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on physiology, bench research or "first principles"	Expert opinion without explicit critical appraisal, or based on economic theory or "first principles"

Produced by Bob Phillips, Chris Ball, Dave Sackett, Doug Badenoch, Sharon Straus, Brian Haynes, Martin Dawes since November 1998.

Appendix 2 Dissemination and Implementation Models in Practice Reproduced and adapted from Tabak et al. (2012) [158]

Dissemination and/or implementation model	Socio-ecological levels (I = Individual; O = Organization; C = Community; S: System; P = Policy)	Field of origin	Construct	Number of cited articles
"4E" Framework for Knowledge Dissemination and Utilization	I, O, C	Aging and mental health	Adopter/implementer/decision maker characteristics, dissemination, knowledge and knowledge synthesis, strategies, translation	35
A Model for Evidence-Based Practice			Adoption, implementation, knowledge and knowledge synthesis, maintenance and sustainability, outcomes – quality improvement/ practice or policy change, process, stakeholders	
Active Implementation Framework	I, O, C	Any domain	Adoption, awareness, barriers and facilitators, communication channels, evaluation, fidelity, implementation, innovation characteristic, maintenance and sustainability, pre-implementation, process, readiness, strategies	904
Availability, Responsiveness & Continuity (ARC): An Organizational & community Intervention Model	O, C	Mental Health	Adopter/implementer/decision maker characteristics, context – inner setting and outer setting, innovation characteristics, outcomes- quality improvement/practice or policy	89

			change, patient/target audience characteristics and needs, stakeholders	
Behaviour Change Wheel	I, O, C, S, P	Health Psychology		1814
Blueprint for Dissemination	O, C	Quality of health care	Barriers and facilitators, champion/field agent, compatibility, complexity, context – inner setting, outer setting, engagement, evaluation, fit, innovation characteristic, trialability, relative advantage, strategies	6
Caledonian Practice Development Model	I, O, C		Knowledge and knowledge synthesis, strategies	
Canadian Institutes of Health Research Knowledge Translation within the Research Cycle Model or Knowledge Action Model	O, S	Public Health	Adopter/implementer/decision maker characteristics, adoption, context – outer setting, evaluation, innovation characteristics, outcomes, strategies	1050
CDC DHAP's Research-to-Practice Framework	O, C	HIV/AIDS prevention	Adaption and evolution, dissemination, implementation, knowledge and knowledge synthesis, maintenance and sustainability, pre-implementation	77
Collaborative model for Knowledge Translation Between Research and Practice Settings	I, O	Clinical healthcare settings	Champion/ field agent, context- inner setting, evaluation, implementation, knowledge and knowledge synthesis, strategies	30

Community Based Participatory Research (CBPR)	O, C, S	Participatory Action Research in healthcare	Adaption and evolution, context – outer setting, engagement, evaluation, stakeholders, strategies	2333
Conceptual Framework for Research Knowledge Transfer and Utilization	O	Workplace health and safety	Adaption and evolution, champion/ field agent, dose, context – inner setting, knowledge and knowledge synthesis, knowledge transfer and utilization, outcomes – implementation, process, readiness, strategies	32
Conceptual Model for the Diffusion of Innovations in Service Organizations	O, C	Health services	Adaption and evolution, communication, communication channels, context – inner and outer setting, implementation, innovation characteristics, knowledge and knowledge synthesis, readiness	1190
Conceptual Model of Evidence-based Practice Implementation n Public Service	O, C	Public sector services	Adopter/implementer/decision maker characteristics, adoption, communication channels, context – inner and outer setting, development of an intervention, fidelity, fit, implementation, knowledge and knowledge synthesis, strategies	18
Conceptual Model of Implementation Research	I, O, C, S	Mental Health	Fidelity, innovation characteristics, maintenance and sustainability, outcomes – health/Quality of Life (QOL)/Satisfaction/Clinical, outcomes – implementation, outcomes- quality	71

			improvement/practice or policy change, reach, strategies	
Conceptual Model of Knowledge Utilization	C, S, P	Knowledge utilization in public policy	Adopter/implementer/decision maker characteristics, barriers and facilitators, context – inner and outer setting, evaluation, identification, strategies	52
Conceptualizing Dissemination Research and Activity: Canadian Heart Health Initiative	O, C	Public health	Barriers and facilitators, champion/field agent, context – inner and outer setting, dissemination, knowledge and knowledge synthesis, outcomes-health/QOL/Satisfaction/Clinical, outcomes- quality improvement/practice or policy, process, stakeholders, strategies	31
Consolidated Framework for Implementation Research	O, C	Health services	Adaption and evolution, adopter/implementer/ decision maker characteristics, champion/field agent, communication, communication channels, compatibility, complexity, context – outer setting, cost, engagement, evaluation, goals, implementation, innovation characteristics, triability, knowledge and knowledge synthesis, patient/target audience characteristics and needs, process, readiness, relative advantage	91

Contextual Frameworks for Research on the Implementation of Complex System Interventions	S	Health Services		
Convergent Diffusion and Social Marketing Approach for Dissemination	O, C	Public Health	Context, identification, strategies	56
Coordinated Implementation Model	I, O	Healthcare	Adopter/implementer/decision maker characteristics, awareness, barriers and facilitators, context-inner and outer setting, knowledge and knowledge synthesis, patient/target audience characteristics and needs	111
Critical Realism & the Arts Research utilization Model (CRARIUM)	I, O	Clinical practice guidelines	Adopter/implementer/decision maker characteristics, adoption, context – outer setting, evaluation, implementation, innovation characteristics, knowledge and knowledge synthesis, outcomes, strategies	27
Davis' Pathman-PRECEED Model	I, O, C	Public health	Adoption, awareness, barriers and facilitators, innovation characteristics, outcomes – Health/QOL/Satisfaction/Clinical, patient/target audience characteristics and needs, pre-implementation, strategies	339
Determinants of Innovation within Health Care Organizations	I, O, P	Health care		301

Diffusion of Innovation	I, O, C	Agriculture	Compatibility, complexity, trialability, relative advantage	39,364
Dissemination of Evidence-based interventions to Prevent Obesity	O, C	Obesity prevention	Adopter/implementer/decision maker characteristics, adoption, awareness, barriers and facilitators, context – inner and outer setting, development of an intervention, dissemination, implementation, innovation characteristics, maintenance and sustainability, outcomes-quality improvement/practice or policy change	
Dynamic Sustainability Framework	I, O, C, S, P	Health services research		267
Effective Dissemination Strategies	I, O, C	Nursing	Adopter/implementer/decision maker characteristics, communication channels, knowledge and knowledge synthesis, patient/target audience characteristics and needs, stakeholders	24
Evidence Integration Triangle	I, O, C, S, P	Public health; Health Policy and Practice		113
Explaining Behavior Change in Evidence-Based Practice	I, O, C	Implementation in health care		441
Facilitating Adoption of Best Practices (FAB) Model	O, C	Medicine	Adopter/implementer/decision maker characteristics, adoption, barriers and facilitators,	

			communication, communication channels, context – inner setting, innovation characteristics, knowledge and knowledge synthesis, maintenance and sustainability, outcomes, outcomes-implementation, process, strategies	
Framework for Analyzing Adoption of Complex health Innovations	I, O, C, S	Health systems	Adoption, context- inner setting, identification, innovation characteristics	34
Framework for Dissemination of Evidence-Based Policy	I, O, C	Public Health	Adoption, awareness, champion/field agent, development of an intervention, implementation, maintenance and sustainability	
Framework for knowledge translation	I, O, C	Knowledge translation	Adopter/ implementer/ decision maker characteristics, dissemination, identification, knowledge and knowledge synthesis	34
Framework for Spread	O, C		Adopter/implementer/decision maker characteristics, adoption, barriers and facilitators, communication channels, context – inner and outer setting, development of an intervention, dissemination, evaluation, fit, goals, identification, implementation, knowledge transfer and utilization, patient/target audience	32

			characteristics and needs, stakeholders, strategies	
Framework for the Dissemination & Utilization of Research for Healthcare Policy & Practice	I, O, C	Health policy and clinical decision making	Adopter/implementer/decision maker characteristics, adoption, context – inner and outer setting, cost, dissemination, implementation, innovation characteristics, knowledge and knowledge synthesis, maintenance and sustainability, outcomes, outcomes – health/QOL/satisfaction/clinical, outcomes- quality improvement/practice or policy change, process, strategies	125
Framework for the Transfer of Patient Safety Research into Practice	O, S	Patient Safety	Adoption, dissemination, maintenance and sustainability, process, stakeholders, strategies	16
Framework for Translating Evidence into Action	O, C, S, P	Public health	Fit, identification, innovation characteristics, knowledge and knowledge synthesis, process	41
Framework of Dissemination in Health Services Intervention Research	O, C, S	Health services	Adopter/implementer/decision maker characteristics, adoption, context – inner and outer setting, development of an intervention, dissemination, evaluation, implementation, maintenance and sustainability, outcomes, outcomes – health/QOL/satisfaction/clinical, outcomes- quality	44

			improvement/practice or policy change, process, strategies	
General Theory of implementation			Adaption and evolution, adopter/implementer, decision maker characteristics, context – inner and outer setting, knowledge and knowledge synthesis, maintenance and sustainability, strategies	
Health Promotion Research Center Framework	O, C, S, P	Public Health	Communication channels, context-inner setting, patient/target audience characteristics and needs, stakeholders	
Health Promotion Technology Transfer Process	O, C	Health promotion technology transfer	Adaption and evolution, development of an intervention, dissemination, evaluation, identification, outcomes – implementation	54
Implementation Effectiveness Model	I, O	Management	Adopter/implementer/decision maker characteristics, adoption, barriers and facilitators, communication channels, context – inner setting, fidelity, fit, implementation, innovation characteristics, outcomes – implementation, readiness, strategies	830
Interacting Elements of Integrating Science, Policy, and Practice	C, S	Dissemination and implementation	Adaption and evolution, complexity, cost, development of an intervention, evaluation, external validity/ generalizability, fidelity,	

		in health research	identification, implementation, innovation characteristics, knowledge and knowledge synthesis, maintenance and sustainability, outcomes – Health/QOL/satisfaction/clinical, strategies	
Interactive Systems Framework	I, O, C, S	Violence prevention	Adopter/implementer/decision maker characteristics, context – inner and outer setting, strategies	116
Intervention Mapping	I, O, C	Health education and promotion research		1113
Iowa Model of Evidence-Based Practice	I, O	Nursing	Adoption, context – outer setting, knowledge and knowledge synthesis, strategies	
Joint Venture Model of Knowledge Utilization	I, O	Nursing		13
Knowledge Exchange Framework	I, O, C, S	Knowledge transfer	Adaptation and evolution, adopter/implementer/decision maker characteristics, barriers and facilitators, communication channels, context – inner and outer setting, dissemination, identification, knowledge and knowledge synthesis, maintenance and sustainability, outcomes – implementation, process, strategies	27
Knowledge Transfer and Exchange	I, O, S	Knowledge Transfer and exchange for	Adopter/implementer/decision maker characteristics, barriers and facilitators, communication,	384

		health policy decision making	communication channels, context – inner setting, engagement, knowledge and knowledge synthesis, stakeholders, strategies	
Knowledge Translation Model of Tehran University of Medical Sciences	I, O	Health science		13
Linking Systems framework	I, O, C	Public health	Communication channels, implementation, stakeholders	29
Marketing and Distribution System for Public Health	I, O, C, S	Public Health	Adaption and evolution, champion/field agent, communication channels	
Model for Improving the Dissemination of Nursing Research	I, O, C	Nursing	Barriers and facilitators, communication, communication channels, development of an intervention, dissemination, evaluation, external validity/generalizability, fit, identification, innovation characteristics, knowledge and knowledge synthesis, readiness, relative advantage	49
Model for Locally Based Research Transfer Development	O, C	Local health and social service delivery agency	Communication	50
Multi-level Conceptual Framework of Organizational innovation Adoption	I, O	Marketing and management in innovation adoption and technology acceptance		388

Normalization Process Theory	I, O, C, S	Healthcare	Evaluation	53
Organizational Theory of Innovation implementation	O	Worksite health promotion	Context – inner setting, fit, implementation, innovation characteristics, outcomes-implementation, readiness	28
Ottawa Model of Research Use	I, O, C	Healthcare		147
Outcomes-Focused Knowledge Translation	I, O	Knowledge translation in nursing practice		57
OutPatient Treatment in Ontario Services (OPTIONS) Model	I, O, C	Mental health	Adoption, communication channels, dissemination, evaluation, implementation, knowledge and knowledge synthesis	57
Pathways to Evidence Informed Policy	I, O, C, S, P	Public Health	Adaptation and evolution, adopter/implementer/decision maker characteristics, adoption, context – inner and outer setting, development of an intervention, implementation, knowledge and knowledge synthesis, knowledge transfer and utilization, outcomes – quality improvement/practice r policy change	166
Policy Framework for Increasing Diffusion of Evidence-based Physical Activity Interventions	O, C, S, P	Public health		54
Practical, Robust Implementation and Sustainability Model (PRISM)	I, O	Public Health	Adaption and evolution, adopter/implementer/decision maker characteristics, barriers and	22

			facilitators, communication, complexity, context – inner and outer setting, cost, innovation characteristics, trialability, maintenance and sustainability, outcomes – health/Quality of Life/satisfaction/clinical, outcomes-quality improvement/practice or policy change, patient/target audience characteristics and needs, readiness, stakeholders	
Pragmatic-Explanatory Continuum Indicator Summary 2	I, O, C, S	Health services research		209
Precede-Proceed Model	I, O, C	Health	Barriers and facilitators, communication channels, innovation characteristics, outcomes – health/QOL/satisfaction/clinical, pre-implementation	391
Promoting Action on Research Implementation in Health Services (PARIHS)	I, O, C	Health services	Adoption, context – inner setting, implementation, innovation characteristics, readiness	590
Pronovost's 4E's Process Theory	I, O, C	Health care	Barriers and facilitators, engagement, evaluation, implementation, innovation characteristics, reach	91
Push-Pull Capacity Model	I, O, C, S	Physical Activity	Context – inner setting, goals, process	39
RAND Model of Persuasive Communication and Diffusion of Medical Innovation	I, O, C	Medical information	Adopter/implementer/decision maker characteristics,	56

		technology assessment	communication channels, context – inner setting	
RE-AIM Framework	I, O, C	Public health	Adoption, implementation, innovation characteristics, maintenance and sustainability, reach	728
Real-World Dissemination	O, C	Health care	Communication channels, context- inner and outer setting, development of an intervention, engagement, innovation characteristics, process, stakeholders	690
Replicating Effective Programs Plus Framework	O, C	Clinical and health services intervention in community-based organizations	Adaptation and evolution, communication channels, context- inner setting, evaluation, fit, identification, implementation, maintenance and sustainability, pre-implementation	32
Research Development Dissemination and utilization Framework	I, O, C, S	Research utilization	Communication, communication channels, knowledge transfer and utilization	420
Research Knowledge Infrastructure	I, O, C, P	Knowledge translation		437
Rosswurm & Larabee ‘Research Utilization model’	I, O			4
Six-Step Framework for International Physical Activity Dissemination	I, O, C, S, P	Physical Activity	Adopter/implementer/decision maker characteristics, barriers and facilitators, communication, communication channels,	27

			evaluation, innovation characteristics, strategies	
Stages of Research Utilization Model	O, C, S, P	Public Health		2
Stetler Model of Research Utilization	O, S	Nursing	Adaptation and evolution, evaluation, outcomes-implementation, pre-implementation, translation	224
Sticky Knowledge	I, O, C	Strategic management and medicine	Implementation, maintenance and sustainability	4377
Stirman framework and coding system for modifications and adaptations of evidence-based interventions			Adaptation and evolution	
Streams of Policy Process	O, C, S, P	Political Science	Identification	8091
Technology Transfer Model	I, O, C, S, P	Technology transfer for HIV	Adaptation and evolution, evaluation, identification, implantation, maintenance and sustainability, pre-implementation, stakeholders	43
Theoretical Domains Framework	I, O, C	Health Psychology		745
Translation Framework for Public Health Research	O, C, S, P	Translational Research for public health		59
Translational Research Framework to Address Health Disparities	I, O, C, S	Health disparities/public health		8

US Department of Veterans Affairs (VA) Quality Enhancement Research Initiative (QUERI)	O, S, P	Veterans Affairs	Evaluation, identification	103
Utilization-Focused Surveillance Framework	O, C, S	Public Health	Development of an intervention, dissemination, outcomes – health/QOL/satisfaction/clinical, outcomes-implementation, patient/target audience characteristics and needs	67
Vratny & Shriver Model for Evidence Based Practice	I, O	Evidence-based Practice		41

Appendix 3 Walk-BEST Workbook ©

Walk-BEST Workbook

Learning to Walk Better, Faster, Longer, Stronger



*This book is for anyone who needs to improve one or more aspects of walking:
quality, quantity and enjoyment.*

PhysioBiometrics Inc.

INTRODUCTION

We all know about the health benefits of staying physically active throughout our lives. However, maintaining physical activity as people age, are injured, or develop joint problems or neurological conditions is challenging. But walking is still one of best types of physical activity. It is the most recommended physical activity for seniors and for people with other reasons for limited mobility. Walking is a meaningful activity, easy to perform, promotes independence, allows for exploring the environment, and provides mental stimulation.

Many older persons or those with injuries and other health conditions do not walk well enough to gain health benefits from walking. As a result of a poor walking pattern, walking long enough and at a pace that promotes health is unattainable.

The Walk-BEST Workbook is designed to help you assess your capacity for safe and efficient walking and provides simple exercises for areas of your walking that need work. The Walk-BEST Workbook illustrates necessary components of safe, efficient and healthful walking so that walking becomes more enjoyable and sustainable. The aim is to help you walk your way to better health.

Walk-BEST Workbook covers 15 elements important to walk well identified from 34 national and international gait experts. In addition, 22 community-dwelling seniors endorsed these elements as being important to them and a survey of 677 people across Canada said “YES” to these elements. Research conducted by the Walk-BEST team at McGill University showed that workbook was judged by clinicians, researchers and seniors to be relevant, useful and user-friendly, with the potential to benefit seniors with walking impairments.

Funding for this workbook came from the Edith Strauss Foundation and the Helen Hutchinson Foundation. The development team are Dr Nancy Mayo (James McGill Professor), Dr. Kedar Mate (Postdoctoral Fellow), M. Ahmed Abou-Sharkh (PhD Candidate) from the School of Physical and Occupational Therapy as well as members of the OutcomesRUS research team at the McGill University Health Centers.

Open the workbook and walk BEST.

This work protected by copyright under the name Walk-Well Workbook© (Canada: 900867) and is a product of the company PhysioBiometrics Inc.

Getting Started

Welcome to the Walk-BEST Self-Management Workbook. If you have not done much physical activity for a while, get the all-clear from your doctor before starting. Specifically, make sure there are no physical reasons why you should not (eventually) walk for 30 minutes a day, every day. That is a good long term walking goal to set. Carry out the assessment in the workbook and take the assessment sheet with you to your doctor and discuss any findings or concerns you have. For example, you may have foot problems that need attention or if you walk with a limp, the reason for that should be known. You could also consult a podiatrist for foot problems and/or a Physiotherapist.

The Walk-BEST Workbook includes:

- Self-assessment plan with pictures and step by step instructions on how to perform the assessment
- Set of exercises that match the walking element assessed with pictures.
- Instructions for how to access an app that you can use on your phone or ipad.

Self-assessment of Walking Challenges

The self-assessment pages are designed for you to assess your feet, joint mobility, posture, balance, and walking pattern. Some of the assessments are best done with an observer. So pair up with your spouse, friend, or family member and assess each other. It is also safer if there is someone beside you as you assess your balance and mobility. At the end of the workbook there is a summary sheet so you can keep track of the areas you assessed and those that need work and those that are good to go. You can use this summary sheet to track you progress.

Some walking challenges need professional assessment and treatment. Please consult your physician for any deformities or persistent pain or limping. This assessment is not as complete as the one you would get by a Physiotherapist. So if you find the assessment challenging and you are concerned about your walking, book an appointment with a Physiotherapist.

Exercises to Walk-BEST

Each element of the assessment is accompanied by one or two exercises that you can do on your own to improve your walking. Pick the ones that you need and make a plan to do them everyday. Even 5 minutes a day will make a difference, but 5 minutes three times a day will make an even a greater difference.

Walking Plan

Now that you have identified areas of your walking that need work, and you are actively working to fix these problems, you need to put into practice what you have learned. You need a walking plan. The best way of getting started with a walking plan is to set walking goals.

Remember, you have two things to work on:

1. Exercises you need to do for each of the assessment areas that need work
2. Practicing walking and applying the information in the workbook.



Tips for Setting SMART Goals

To adopt a healthier lifestyle, it is important to set effective goals. People who set their own health goals and define them well, manage their health better. Here are some tips that might help you set your own goals for walking well. And DON'T JUST THINK IT, INK IT

MAKE SURE YOUR GOALS ARE **SMART**.

SPECIFIC: A general goal would be: "Do my exercises" or "Walk more".

A specific goal would say: *"I will do the exercises in the workbook 5 minutes in the morning and 5 minutes in the evening, every day for two weeks and then I will reassess"*

"I will practice walking using a heel-to-toe pattern in my corridor for 2 minutes, twice a day, every day, for 2 weeks and then reassess".

MEASURABLE: To determine if your goal is measurable, ask yourself: How will I know when it is accomplished?

For this you can keep a diary and check off each time you do the activity.

ATTAINABLE: You can attain a goal you set when you plan wisely and establish a time frame that allows you to carry out steps towards the goal.

So setting the time, the frequency, and for how long will ensure the goal is attainable particularly if you start small and work up. Don't start with a plan of 30 minutes, start with 5 minutes. If this is attainable, you can set a different kind of goal.

REALISTIC: Your goal is probably realistic if you truly believe that it can be accomplished. Think about the other activities and responsibilities you have. Goals that will be disruptive to your day will not be realistic to accomplish.

TIME: Set a specific time frame for you to accomplish the goal. Set short term goals first. Think about what you can accomplish in a week, or two weeks at a time. You may also have a medium term goal such as a plan to do a particular activity in the near future, next month, next few months. A long term goal could be something you want to do in the future, plan a trip, join a walking group. These medium and long term goals are good to set in order to encourage you to work on your short term goals.



Your goal should reflect what you need and want to do!

Whenever you see this sign, think GOAL!

Safety First

It is important to carry out the assessment safely so do it with a partner.

When doing your exercises or practicing walking:

1. Always use your best judgment about where, when, and for how long:
 - a. Scan the environment and make sure the space is safe and clear of objects
 - b. Stop the exercises at any time if you are feeling unwell or unsafe.
2. Wear shoes with flat, non-skid soles that have good heel support and a flexible sole. Avoid shoes with high heels and backless shoes such as slippers, flip-flops, or clogs.
3. Build up gradually, and stop while you are still enjoying the walking activity.
4.  Any assessment or exercise that has a “red flag” have a caution associated with it.

What Does Walking Well Look Like

1. Heel first
2. Foot roll
3. Arm swing
4. Upright
5. 150 minutes per week in bouts of 10 minutes

Walk-BEST

This book is designed for you to use to improve your walking to the point that you can achieve a level of physical activity that is health promoting. Walking BEST will improve your independence as your walking will be smoother and safer and also less tiring.

PhysioBiometrics Inc.

This workbook is one of a suite of products that we, at PhysioBiometrics Inc., have developed to improve people’s walking, mobility, and posture. More information will soon be available at physiobiometrics.com. Our products include this workbook, as well as apps, workshops, inertial measuring devices, along with signal processing and machine learning algorithms to personalize feedback and treatment recommendations. For more information contact Dr_Nancy_Mayo@physiobiometrics.com.

Terms and conditions!!

This workbook was developed for people to self-manage walking quality. If you have medical conditions, consult a physician before performing this or any exercise program. All information contained in this workbook including but not limited to text, graphics, images, information, exercises, are for informational and educational purposes only.



We Would Like to Hear from You: Send us Your FEEDBACK

Click this active link

[Walk-BEST Feedback Survey](#)

OR

Copy or type the link into your browser

OR

Physiobiometrics.com and leave us a message

Checklist

☐	Foot deformities	2
☐	Walking Symmetry	4
☐	Foot mobility	6
☐	Ankle mobility	8
☐	Knee mobility	10
☐	Hip mobility in extension (backward)	12
☐	Hip mobility in flexion (forward)	14
☐	Hip mobility in rotation	16
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FOOT DEFORMITIES

Do you have any of the following:

- ☐ Bunions
- ☐ Calluses
- ☐ Cracked heels
- ☐ Crossed toes
- ☐ Hammer toe(s)
- ☐ Thick toenail(s)
- ☐ In-grown toenails(s)
- ☐ Nail fungus
- ☐ Heel pain
- ☐ Redness
- ☐ Blistering
- ☐ Cold feet
- ☐ Swollen feet



WHY DO THIS?

Just as you would not go a day without brushing your teeth, you shouldn't go a day without taking care of your feet.

EXERCISE PLAN

Professional assessment and diagnosis (e.g. primary care physician, podiatrist, pedicurist, physiotherapist)

Personalized foot care plan

Proper footwear recommendations

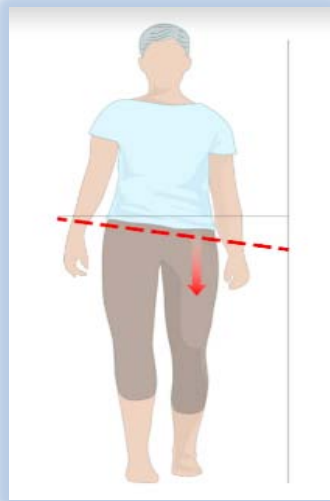
WALKING SYMMETRY

When you walk, do both legs move **equally** (i.e. no limp)?

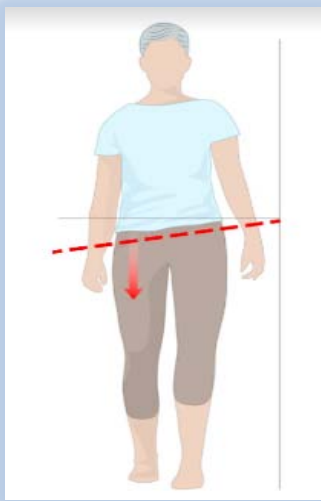
Check off whichever photo you feel best applies to you.

- A Does one leg take a longer step?
- B Do you favor one leg?
- C Do your shoulders dip to one side when walking?

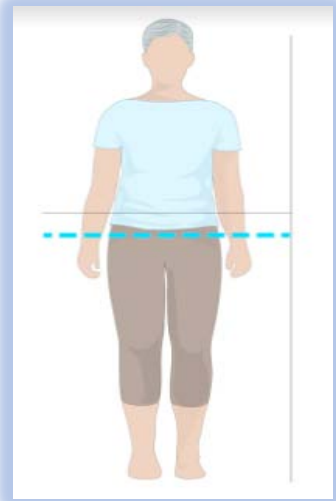
Left limp

☐

Right limp

☐

No Limp

☐

Recommendations

EXERCISE PLAN

Professional assessment of causes of asymmetrical walking

Professional treatment recommendations

Professional follow-up plan

FOOT MOBILITY

Are your feet **stiff** or **painful** to move? If so, circle on the diagrams where the stiffness or pain is, and then check off whichever box applies.

PLANTAR SURFACE



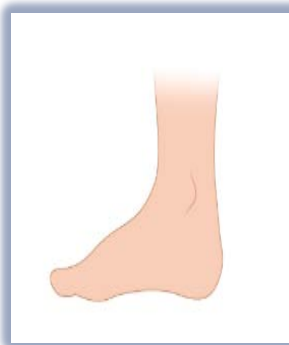
- ☐ Pain
- ☐ Stiffness
- ☐ *Both*
- ☐ None

DORSAL SURFACE



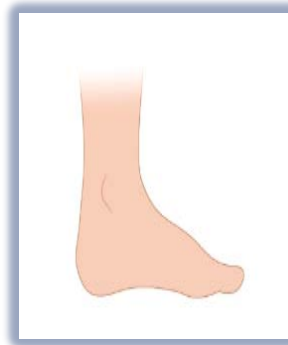
- ☐ Pain
- ☐ Stiffness
- ☐ *Both*
- ☐ None

RIGHT FOOT



- ☐ Pain
- ☐ Stiffness
- ☐ *Both*
- ☐ None

LEFT FOOT



- ☐ Pain
- ☐ Stiffness
- ☐ *Both*
- ☐ None

WHY DO THIS?

The force of your entire body weight is transmitted to your feet – together only about the size of a piece of paper. Your feet must be in good condition to accept those forces

EXERCISE PLAN

Roll your foot on a ball

Instructions:

Find a tennis ball, or a ball that is similar in firmness and size

1. Roll your foot on this ball in standing or in sitting, in all directions (right, left, forward and back)
2. Repeat on other side

★ If you decide to do the exercise in standing, make sure to hold on to something for support (i.e. kitchen counter)



Notes

ANKLE MOBILITY

When sitting, are you able to.....

Raise your toes



- ☐ Yes
- ☐ Somewhat
- ☐ No

Raise your heels



- ☐ Yes
- ☐ Somewhat
- ☐ No

If you answered yes or somewhat to both, do they raise the same amount?

- ☐ Yes
- ☐ No

WHY DO THIS?

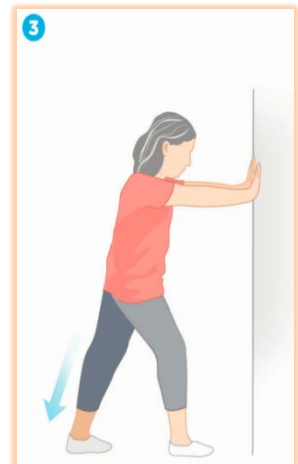
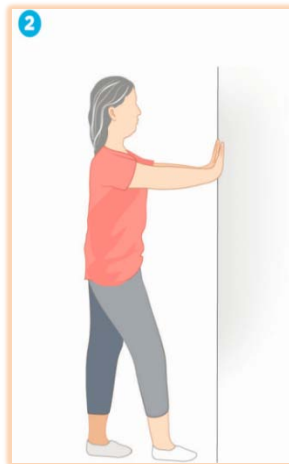
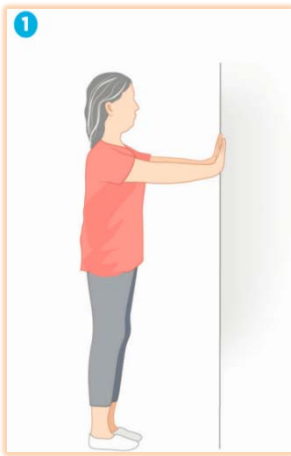
The force of your entire body weight is transmitted to your feet – together only about the size of a piece of paper. Your feet must be in good condition to accept those forces

EXERCISE PLAN

a) Calf Stretch

Instructions:

1. Find a wall and place hands flat on the wall at shoulder height.
2. Keeping hands on the wall, place one knee in front of the other.
3. Bend the front knee until you feel a stretch in the other leg.
4. Repeat on the other side.



b) Ankle Rotations

Instructions:

1. In a sitting position, cross one lower leg over the thigh of the other, holding your foot to assist with the motion. .
2. Rotate the ankle in a circular motion, in both directions.
3. Repeat on the other side.



How long?

30 seconds

How often?

Every day

KNEE MOBILITY

Instructions:

1. **Sit on a firm surface** with your **legs straight out**. Make sure that your back is well supported on a wall. You can also lie flat on your back. Chose a position that is comfortable to you.
2. Place a small **towel under one knee**
3. **Push knee** into the towel so that **heel lifts** off the ground
4. Repeat on the other side



Do your heels lift off the ground when you do this?

- ☐ Yes
☐ No



Do your heels lift off the ground the same amount?

- ☐ Yes
☐ No

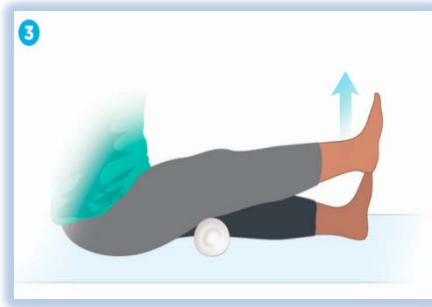
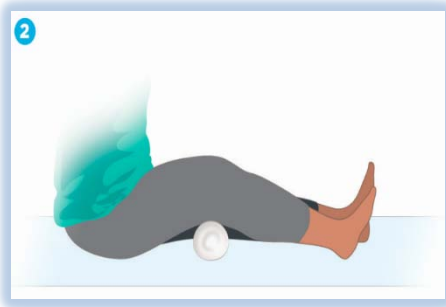
WHY DO THIS?

To work the muscle on the front of the thigh. The knee extension targets the quadriceps muscle. Strong quadriceps muscles make it easier to walk.

EXERCISE PLAN

Instructions:

1. Sit on a firm surface with your legs straight out. Make sure that your back is well supported on a wall. You can also lie flat on your back. Chose a position that is comfortable to you.
2. Place a small towel under one knee
3. Push knee into the towel so that heel lifts off the ground
4. Repeat on the other side



How long?

5 seconds

How many times?

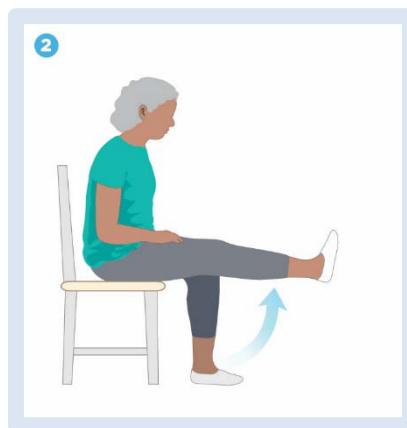
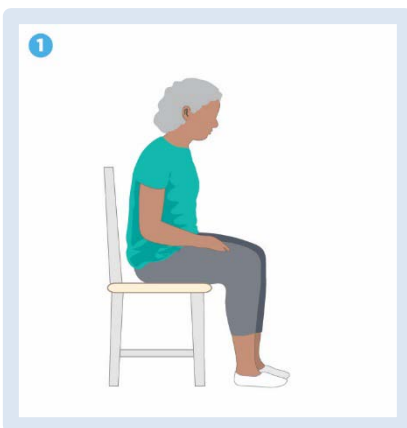
10 times

How often?

Every day

Instructions:

1. Sit on a chair.
2. Place feet flat on the floor.
3. Straighten your knee so that your foot does not touch the floor and that your knee becomes straight.
4. Repeat on the other side.



How long?

5 seconds

How many times?

10 times

How often?

Every day

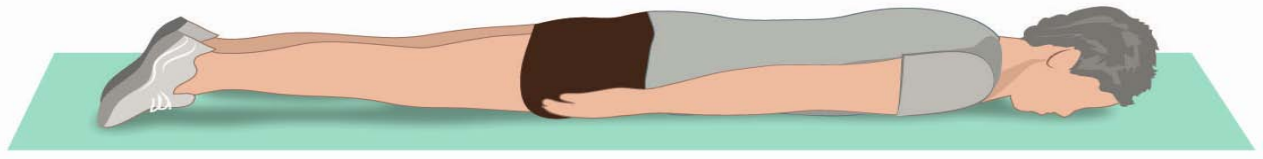
HIP MOBILITY IN EXTENSION

A Instructions:

1. Lie on your stomach
2. Slide your hand under the front of your hip.

WHY DO THIS?

To know if your hips are tight. If they are, they need to be stretched out to be able to stand tall



Is there space between the front of your hip and the surface, such that your hand slides easily between the gap.

☐ Yes

☐ No

If no, proceed to Test B.

B. Instructions:

1. Stand **facing a wall**, keeping your hips **close as possible to the wall**. Try to make your hips touch the wall. Keep knee straight and bring one foot a few inches behind opposite heel.
2. Repeat on the other side.



Does each leg extend back more than 18 inches (45 cm)?

☐ Yes

☐ No

EXERCISE PLAN

Instructions:

1. Standing facing a wall, try and make your hip touch the wall.
2. Keep knee straight, and extend leg backwards.
3. Repeat on the other side

WHY DO THIS?

To preserve your independence! Many daily activities – such as walking and getting in and out of a car – require good hip extension.



How long?

5 seconds

How many times?

10 times

How often?

Every day

Notes

HIP MOBILITY IN FLEXION

A Instructions:

1. Lie flat on your back.
2. Pull one **knee as close to chest as possible**.
3. Keep opposite leg as straight as possible.
4. Repeat on other side.



Does each leg move the same amount?

- ☐ Yes
☐ No

Is the movement painful?

- ☐ Yes
☐ No

Can you get your knees close to your chest?

- ☐ Yes
☐ No

Notes

EXERCISE PLAN

A Instructions:

1. Lie flat on your back.
2. Pull one knee as close to chest as possible.
3. Keep opposite leg as straight as possible.
4. Repeat on other side.



WHY DO THIS?

Hip flexion helps to keep the pelvis in line.

How long?

5 seconds

How many times?

10 times

How often?

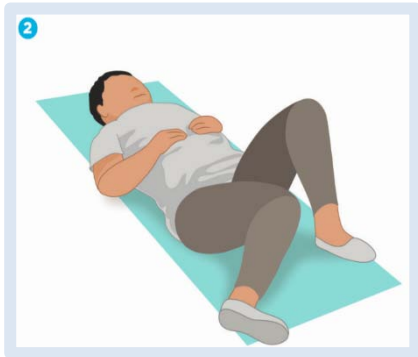
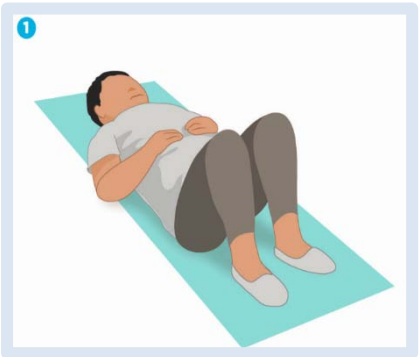
Every day

Notes

HIP MOBILITY IN ROTATION

A Instructions:

1. Lie flat on your back with knees bent and feet spread apart.
2. Rotate one **knee** at a time to **touch the surface between your feet**, like windshield wipers.



Does each leg move the same amount?

☐ Yes

☐ No

Is the movement painful?

☐ Yes

☐ No

Can you get your knees close to the floor?

☐ Yes

☐ No



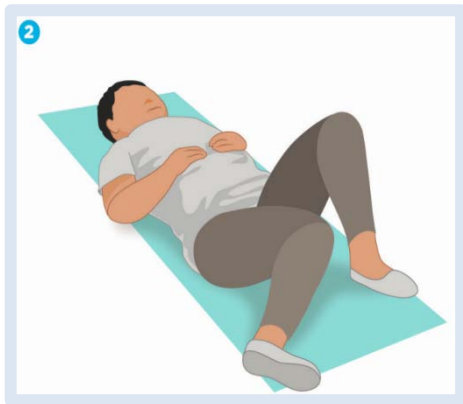
Notes

If you have had hip surgery in the past year, do not try this movement.

EXERCISE PLAN

A Instructions:

1. Lie flat on your back with knees bent and feet spread apart.
2. Rotate one knee at a time to touch the surface between your feet, like windshield wipers.



How long?

5 seconds

How many times?

10 times

How often?

Every day

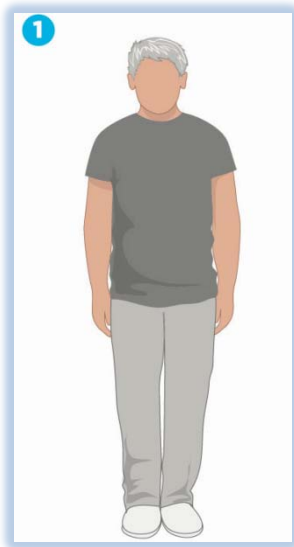


Notes

If you have had hip surgery in the past year, do not try this exercise.

BASE OF SUPPORT WHILE WALKING

When you walk, how are your feet typically positioned? Select one.

☐☐☐

When you walk, how are your feet typically positioned? Select one.

☐☐

EXERCISE PLAN

LEG EXERCISES: Instructions:

1. Sit in a chair
2. Place a medium-sized ball in between your legs
3. Holding the ball in place, extend your legs outwards
4. Repeat on the other side



How long?

5 seconds

How many times?

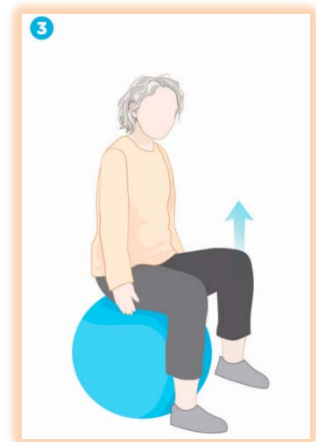
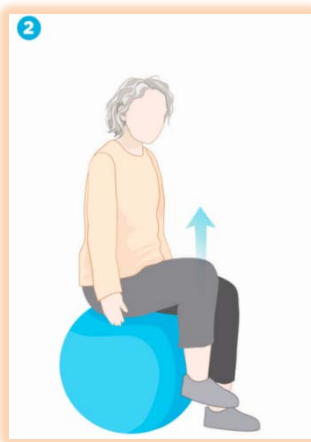
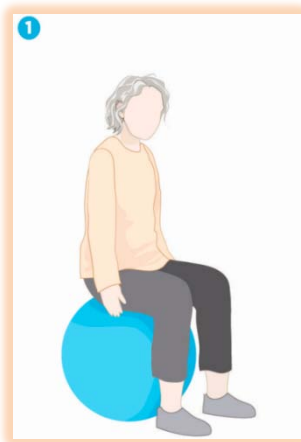
10 times

How often?

Every day

BALANCE EXERCISES: Instructions:

1. Sit and center yourself on an exercise ball.
2. If unable to balance yourself on exercise ball, sit on a chair.
3. Staying as still as possible, lift one leg up as high as you can
4. Repeat on the other side



HEEL TO TOE GAIT

When you walk, CAN you walk from heel to toe? The image below demonstrates what this means.

☐ Yes

☐ No



When you walk, DO you walk from heel to toe?

☐ Yes

☐ No

Notes



EXERCISE PLAN

LEG EXERCISES: Instructions:

1. Stand in front of a counter.
2. Place one foot in front of the other so that the heel of the front foot touches the toes of back foot (tandem stance).
3. Apply a very light touch on the counter.



How long?

30 seconds

How many times?

10 times

How often?

Every day

BALANCE EXERCISES: Instructions:

1. Stand straight with a steady object in front of you. Put only the tips of your fingers on the object only to keep your balance.
2. Lift one knee toward your chest while keeping your balance.
3. Return to the starting position and repeat with the other side.



How long?

5 seconds

How many times?

10 times

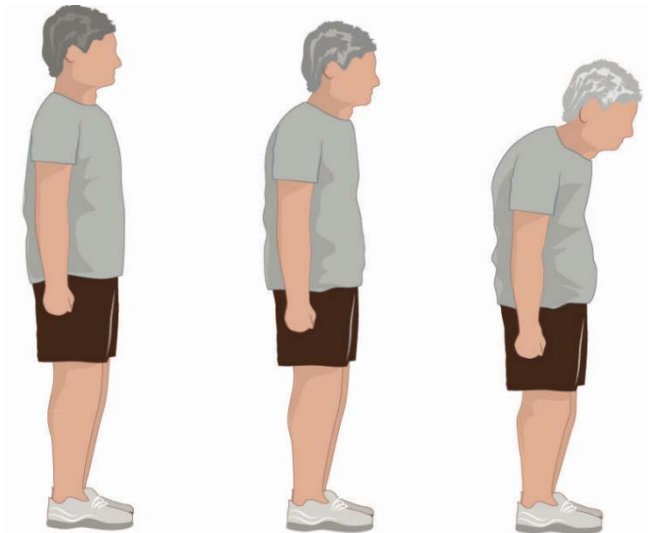
How often?

Every day

POSTURE AND POSTURE CHANGE

Is your posture straight, slightly stooped, or stooped?

- ☐ Straight
- ☐ Slightly stooped
- ☐ Stooped



Straight

Slightly stooped

Stooped

What happens to your posture when you walk backwards?

- ☐ Back straightens
- ☐ Back remains stooped
- ☐ Can't walk backwards

Notes


My Goals

EXERCISE PLAN

FLAT LYING

Tight chest muscles play a big role in stooped posture.

Lying flat on your back

(or with a thin pillow under your head, if it's too painful at first)
can help to stretch these muscles out and improve your posture!

BACKWARD WALKING

Try to spend a few minutes walking backwards every day. It sounds funny, but it really does help to improve posture!



WALKING WITH GOOD POSTURE

Whenever you think of it, try to correct your walking posture. Eventually, proper posture will become effortless!



ARM POSITION AND ARM SWING

When you walk, are your arms swinging? You might ask somebody to watch you.

At sides



Swinging



FOR WATCHER (if present):

Which of the following best describes their arm swing?

- ☐ Rhythmical
- ☐ One arm different from the other
- ☐ Arms don't swing

Notes

EXERCISE PLAN

LEG EXERCISES: Instructions:

1. Lie flat on your back with your knees bent.
2. Without your upper body moving, let both knees fall to one side.
3. Place the hand on that side on your upper thigh and pressure, such that you feel a slight stretch
4. Repeat on the other side.

1



How long?

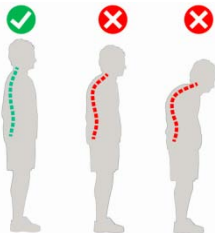
5 seconds

How many times?

10 times

How often?

Every day



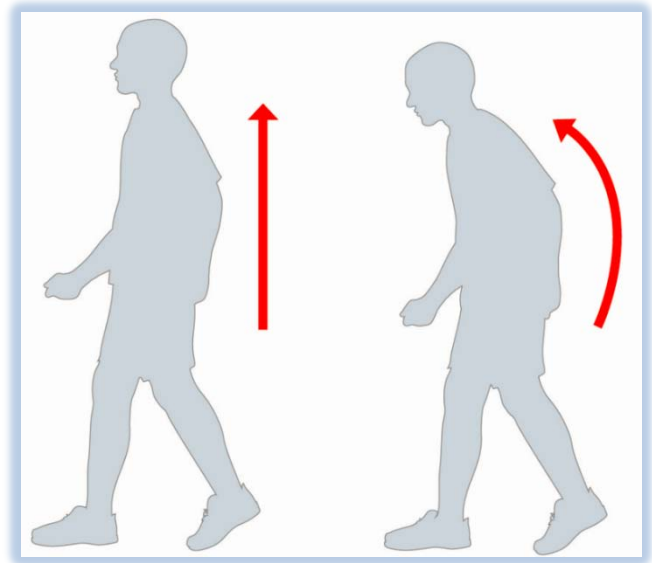
PRACTICE GOOD POSTURE

Posture is really important! Proper posture allows your arms to swing the way they're supposed to when you walk. In turn, it may help to prevent falls and injuries!

WALKING AND LOOKING

When you walk, where are you looking? Select one.

- ☐ Ahead and around the environment
- ☐ Ahead
- ☐ The ground in front
- ☐ My feet



VIP: Practice not looking at your feet when you walk.



Notes

EXERCISE PLAN

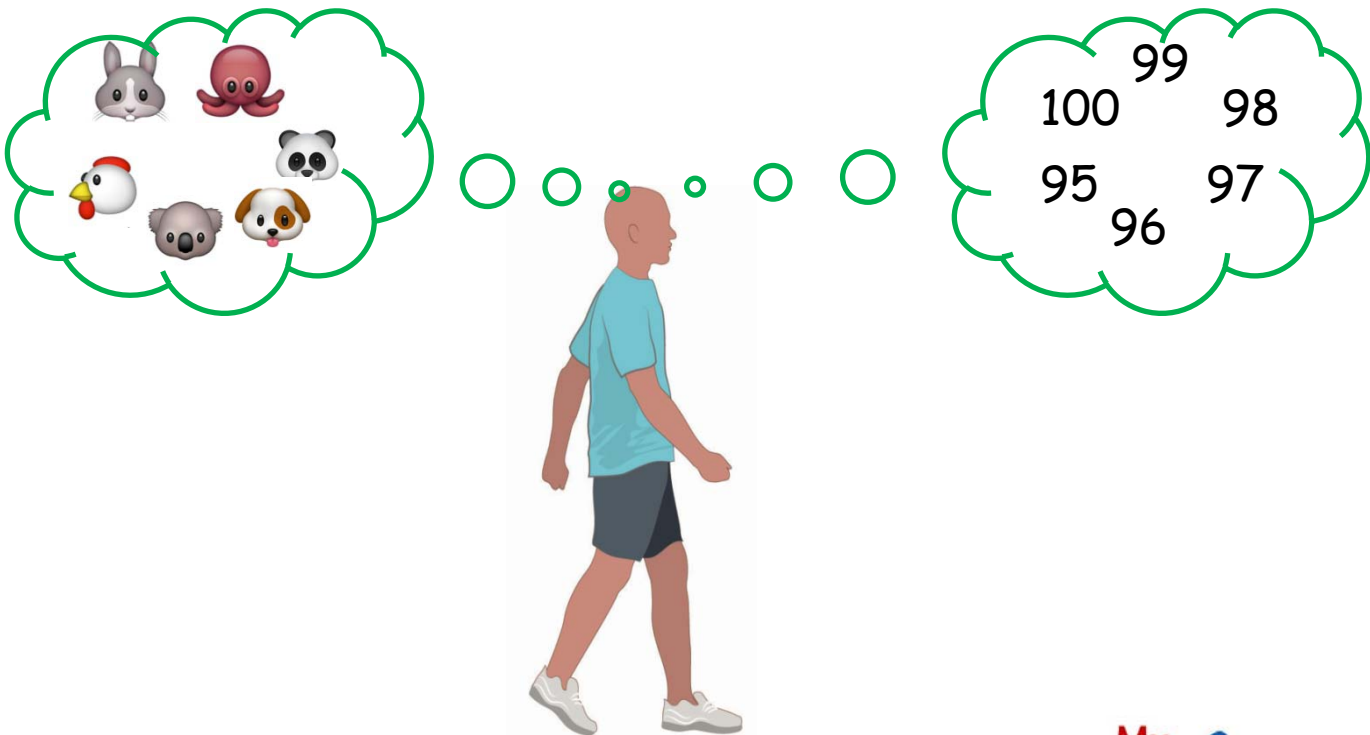
WALKING AND TALKING : Instructions:

1. Go for a walk.
2. While walking, count down from 100 to 0.
3. You can also try to name animals, words starting with each letter or alphabet.



IMPOTANT: Try NOT to let the counting interfere with your walking!

The goal is for you to eventually be able to do both at the same time, with few or no mistakes. .



PRACTICE GOOD WALKING

Remember, walk Heel-to-toe, swing your arms, good posture!

CHANGING DIRECTION

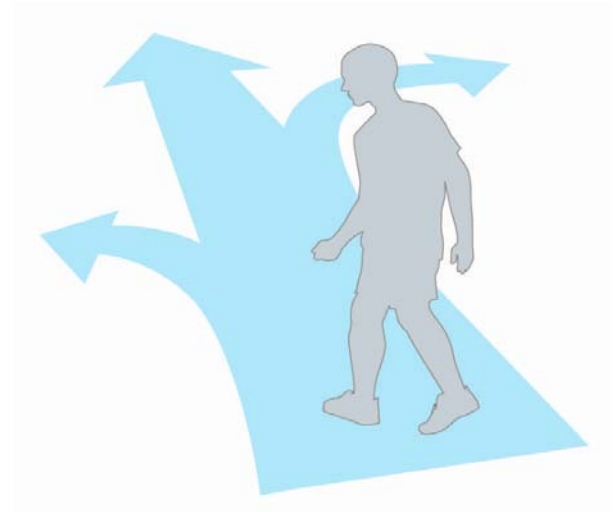
When you are walking and need to change direction, how do you do it? Select one

Changing Direction?

- ☐ Stop and turn
- ☐ Slow down and turn
- ☐ Make a long curve
- ☐ Pivot

Equally on both sides?

- ☐ Yes
- ☐ No

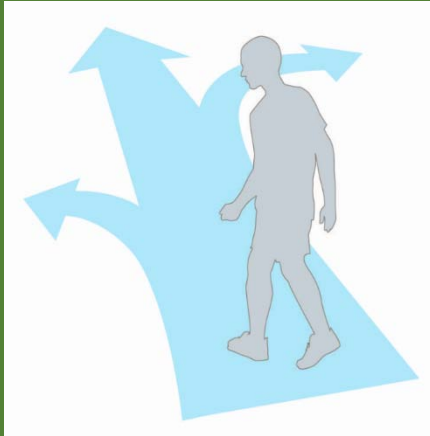


Notes

EXERCISE PLAN

PRACTICE

At least 5 minutes a day, practice walking and **TURNING!**



PRACTICE

At least 5 minutes a day, practice **PIVOTING!**



WALKING SPEED, EFFORT, AND ENDURANCE

How fast do you walk? ☐ Very slow ☐ Stroll ☐ Normal ☐ Fairly Brisk ☐ Fast

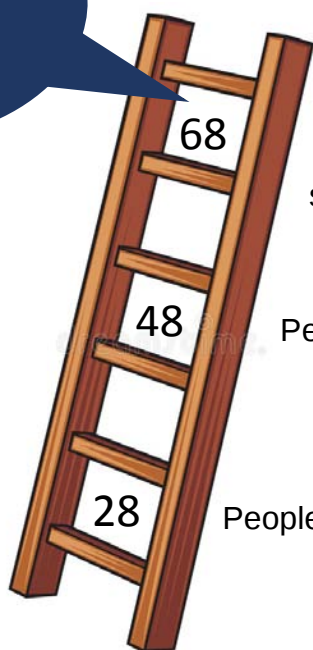
	Activities	Extreme Difficulty or Unable to Perform Activity	Quite a Bit of Difficulty	Moderate Difficulty	A Little Bit of Difficulty	No Difficulty
	Hopping.	0	1	2	3	4
	Making sharp turns while running fast.	0	1	2	3	4
	Running on uneven ground.	0	1	2	3	4
	Walking a mile.	0	1	2	3	4
	5 Running on even ground.	0	1	2	3	4
	Squatting.	0	1	2	3	4
	Standing for 1 hour.	0	1	2	3	4
	Going up/down 10 stairs (about 1 flight of stairs)	0	1	2	3	4
	Performing heavy activities around your home.	0	1	2	3	4
	Your usual hobbies, recreational or sporting activities.	0	1	2	3	4
	Any of your usual work, housework, or school activities.	0	1	2	3	4
	Walking 2 blocks.	0	1	2	3	4
	Lifting an object, like a bag of groceries	0	1	2	3	4
	Getting into or out of a car.	0	1	2	3	4
	Getting into or out of the bath.	0	1	2	3	4
	Walking between rooms.	0	1	2	3	4
	Performing light activities around your home.	0	1	2	3	4
	Putting on your shoes or socks.	0	1	2	3	4
	Sitting for 1 hour.	0	1	2	3	4
	Rolling over in bed.	0	1	2	3	4

more WALKING SPEED, EFFORT, AND ENDURANCE

We asked 677 seniors whether they thought they walked BEST and this is how they scored on the questions from the page before!



How do you
measure up?



People who walk BEST
scored 68/80

People who somewhat walk BEST scored 48/80

People who do not walk BEST scored 28/80

Find your place on the
measure on the page before
and work to move up the
ladder.

more *WALKING SPEED, EFFORT, AND ENDURANCE*

How long was the longest walk you took today?

☐ < 1 minute

☐ 1-2 minutes

☐ 2-5 minutes

☐ longer than 5 minutes

How much effort does it take for you to walk upstairs or up a hill? Please indicate your answer by checking off one of the boxes.

RPE Scale	Rate of Perceived Exertion	
10	Max Effort Activity Feels almost impossible to keep going. Completely out of breath, unable to talk. Cannot maintain for more than a very short time.	☐
9	Very Hard Activity Very difficult to maintain exercise intensity. Can barely breath and speak only a few words.	☐
7-8	Vigorous Activity Borderline uncomfortable. Short of breath, can speak sentence.	☐
4-6	Moderate Activity Breathing heavily, can hold short conversation. Still somewhat comfortable, but becoming noticeably more challenging.	☐
2-3	Light Activity Feels like you can maintain for hours. Easy to breathe and carry a conversation.	☐
1	Very Light Activity Hardly any exertion, but more than sleeping, watching TV, etc.	☐

Notes

TEST YOURSELF

Please answer each of the following!

	Activities	Extreme Difficulty or Unable to Perform Activity	Quite a Bit of Difficulty	Moderate Difficulty	A Little Bit of Difficulty	No Difficulty
	Hopping.	0	1	2	3	4
	Making sharp turns while running fast.	0	1	2	3	4
	Running on uneven ground.	0	1	2	3	4
	Walking a mile.	0	1	2	3	4
5	Running on even ground.	0	1	2	3	4
	Squatting.	0	1	2	3	4
	Standing for 1 hour.	0	1	2	3	4
	Going up/down 10 stairs (about 1 flight of stairs)	0	1	2	3	4
	Performing heavy activities around your home.	0	1	2	3	4
	Your usual hobbies, recreational or sporting activities.	0	1	2	3	4
	Any of your usual work, housework, or school activities.	0	1	2	3	4
	Walking 2 blocks.	0	1	2	3	4
	Lifting an object, like a bag of groceries	0	1	2	3	4
	Getting into or out of a car.	0	1	2	3	4
	Getting into or out of the bath.	0	1	2	3	4
	Walking between rooms.	0	1	2	3	4
	Performing light activities around your home.	0	1	2	3	4
	Putting on your shoes or socks.	0	1	2	3	4
	Sitting for 1 hour.	0	1	2	3	4
	Rolling over in bed.	0	1	2	3	4

KEEP TRACK

Evidence shows that WALKING is the best way to stay healthy.

Most smart phones that you carry with you every day have the capacity to track how many steps you take per day. It will give you a continuous record of how you are doing.

You can also just use a simple pedometer available in many stores for under \$10.

Here is a guide for you to decide HOW MANY STEPS are enough.

