Body Weight Assisted Locomotive Therastride Training in Multiple Sclerosis

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Abstract

Introduction: Being mobile is an important aspect of life, however, more than 85% of individuals with Multiple Sclerosis (MS) report walking difficulties. They typically walk slower, with reduced stride and step length and may have poor balance or weakness within the legs. As the disease progresses, individuals lose the ability to be mobile. Currently exercise prescription is not offered as a method of treatment for those with poor walking ability with MS. **Purpose:** The purpose of this study was to examine the effects of a 12 week body weight assisted locomotive training programme in individuals with poor walking ability and MS. **Methods**: Participants were recruited from the Palmerston North Multiple Sclerosis Society. Baseline testing consisted of the measurement of step and stride length, 6 minute walk test and balance tests. For the next 12 weeks, participants continued with their daily tasks. Following this participants repeated baseline tests and then completed 24 body weight assisted treadmill training sessions, twice per week, across a 12-week period. This was followed by post testing, step and stride length, 6-minute walk test and balance tests. **Results**: Six MS individuals with an expanded disability status scale (EDSS) score of 5.5-8 took part in the research over 26 weeks. The baseline results for step length were 36cm for the right side and 29cm for the left side. Stride length was 63.7cm for the right and 60.8cm for the left. For the 6-minute walk test the result was 126m. Following 12 weeks of no intervention the results were reduced for all measures (step length 34.7cm on the right side and 27.6cm on the left side, stride length 62.26cm for the right and 60.3cm for the left, and 6MWT 97.98m). After 12 weeks of locomotive therastride intervention, twice weekly, the results increased for all measurements (step length 43.5cm for the right side and 39.5cm for the left side, stride length 80.4cm for the right and 70.4cm for the left and 6MWT was 147m). The results demonstrated a significant improvement from testing 2 to testing 3 with the locomotive intervention in all areas but balance. **Conclusion**: This study demonstrates the important effect that body weight support treadmill training can have on improving mobility, MS symptoms and the benefit of an effective and safe method of training for individuals with a higher EDSS score.

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Contents

List of Appendices

List of Figures

List of Tables

List of Abbreviations

B

BMI	Body Mass Index
BP	Blood Pressure

C

cm	Centimetres
CNS	Central Nervous System

E

EDSS	Expanded Disability Status Scale
EMG	Electromyography

H

HR	Heart Rate
HDEC	Health and Disability Ethics Committee

K

Kg	Kilograms

M

M	Meters
MS	Multiple Sclerosis
MSNZ	Multiple Sclerosis New Zealand
MVC	Muscle Voluntary Contraction
6-MWT	6 - Minute Walk Test

N

NASC	Needs Assessment and Services Coordination
NZ	New Zealand

P

PPMS	Primary Progressive Multiple Sclerosis
PRMS	Progressive Relapsing Multiple Sclerosis

R

RM	Rep Max
RRMS	Relapse Remitting Multiple Sclerosis

S

SD	Standard Deviation
SPSS	Statistical Package for Social Sciences

Chapter One: Introduction

Multiple sclerosis (MS) is an inflammatory demyelinating disease (Platta et al., 2016) that impacts the central nervous system (CNS) (Goldenberg, 2012; Kahana & Milo, 2010). It can be characterised by a series of relapses and remission periods (Kahana & Milo, 2010) that lead to severe physical and/or cognitive disability as well as neurological defects (Ghasemi et al., 2016; Sospedra & Martin, 2005). MS is polysymptomatic; its symptoms and degree of effect are vast and often vary between individuals (Kister, et al., 2013). The North American Research committee on Multiple Sclerosis (NARCOMS) created a registry with data on 35,000 individuals, which clearly demonstrates the varying degrees of symptoms experienced in those diagnosed with MS. The most prominent 11 symptoms are reported to be; impairment in mobility, hand function, vision, fatigue, cognition, bowel/bladder function, sensory, spasticity, pain, depression, and tremor/coordination (Kister et al., 2013).

As the prevalence of MS worldwide and in New Zealand is increasing, so are the need for methods of symptom management. In New Zealand today, approximately 4000 individuals are living with Multiple Sclerosis (NZ MS Research Society, 2021). The last prevalence study for NZ was completed in 2008, and the current numbers are only estimates. In 2008, 2,994 individuals were identified to have MS, demonstrating a prevalence of 71.9 per 100,000. MS is more prominent in females in NZ with 75% than males at 25% (Taylor et al., 2008). Approximately 85% of those diagnosed with MS are diagnosed with relapsing remitting MS (RRMS), with 10% being diagnosed with primary progressive MS (PPMS) and 5% with progressive-relapsing MS (PRMS) (ACSM, 2018). Relapse-Remitting MS is the most common form of MS and is characterised by relapses or exacerbations of symptoms followed by periods of remission, where symptoms improve or disappear. Secondary Progressive MS is the continual deterioration following on from relapsing-remitting MS. Primary Progressive MS is the gradual worsening of symptoms with no relapses or remission periods, but it may have the occasional plateaus. Progressive-relapsing MS is progressive from the beginning with intermittent flare ups of worsening symptoms and without periods of remission (Ghasemi et al., 2016; Goldenberg, 2012).

Currently in New Zealand symptom management and treatment is completed through medication with the number one product being Ocrelizumab. In New Zealand, as of December 1st 2019, Ocrelizumab became one of New Zealand's first fully funded medical lines of defence against MS. Ocrelizumab is a humanised monoclonal antibody designed to target and deplete specific immune cells (CD20-positive B cells), that are thought to be a key factor in the demyelination process and axon damage. The drug has shown to reduce relapses by 45-47% and lower the disability rate by 40% over a 96 week period (Hauser et al., 2017). However, the criteria required to access the drug means that many individuals miss out. Only individuals with RRMS are given the opportunity to obtain medical assistance, given they pass the criteria. As part of the eligibility criteria for the drug, individuals must have a score of 4 or less on the Expanded Disability Status Scale (EDSS) which indicates they can walk 500m continuously and unassisted. EDSS is a clinical measurement of disability severity for individuals with MS. Patients have their access to the medication stopped immediately if their EDSS score exceeds 4.5 or jumps by 2 points without showing signs of improvement within 6 months. This leaves individuals with PPMS and RRMS outside the testing criteria without the medical assistance of Ocrelizumab. Parallel to this, there currently is no referral pathway to physiotherapists or exercise therapists to help them achieve the 500m goal. After a six year battle, a proposal was put to have the testing criteria levels reduced to allow easier access to the medication for a wider range of levels. This, however, would still require individuals to walk 100m to qualify (NZ MS society, 2020). These individuals outside the criteria need a means of exercise that allows them to safely and effectively try to reach the goal distance. Being mobile is an important aspect of life and individuals with multiple sclerosis should be offered exercise therapy to enable them to stay mobile for as long as possible. Whilst in NZ, disability benefits are provided along with home help, there is no such treatment in the way of safe and effective physical activity for this population. Individuals with MS need a safe and effective way to achieve their goals with regards to their medication needs.

Exercise offers a rehabilitation strategy to aid against symptoms and disabling factors of the disease. Research has reported to show signs of reduced incidence of relapse (Pilutti et al., 2014; Tallner et al., 2012), along with improvements in muscle strength and cardiovascular function (Platta et al., 2016), improved walking speed and endurance (Pearson et al., 2015). Additionally, it has also been indicated that exercise has been recognised as a primary strategy for restoration of

physical function (Dalgas & Stenager, 2014). Despite knowing the benefits of exercise, the large majority of this population still remains inactive (Motl et al., 2017), due to the lack of exercise therapy programmes offered to those battling with MS in New Zealand.

This thesis outlines the details of MS via a comprehensive literature review in chapter two; covering the pathology of the disease, the symptoms and the benefits of physical activity including body weight assisted locomotive therastride training as an aid against the disabling factors of the disease. Chapter three covers the specific aims and objectives of the research project with the methods used being covered in chapter four. The results are presented in table format in chapter five followed by a discussion of the results, limitations and future recommendations in chapter six. Finally, chapter seven will draw a conclusion based on all evidence gathered and discuss the next steps for development.

Chapter Two: Literature review

2.1 Multiple Sclerosis Etiology

Multiple sclerosis (MS) is an inflammatory demyelinating disease (Platta et al., 2016; Petajan & White, 1999; Korn, 2008) that impacts the central nervous system (CNS) (Goldenberg, 2012; Kahana & Milo, 2010). It is characterised by a series of relapses and remission periods (Kahana & Milo, 2010) that lead to severe physical and/or cognitive disability as well as neurological defects (Ghasemi et al., 2016). The autoimmune disease causes the body's immune system to attack the myelin sheath thus causing the insulating covers of nerve cells (axons) protecting the brain, brain stem and spinal cord to be damaged (Platta et al., 2016; Motl et al., 2005). The demyelination is the primary incident, but the destruction due to lesions causes an increase in loss of axons, which has a significant correlation to permanent functional deficit (Lassmann et al., 2001). This can result in trouble with sensation, sight, coordination, balance, loss of function, pain, fatigue and muscle weakness (Motl et al., 2005; LaRocca, 2011; Petajan, & White, 1999). Multiple sclerosis affects all individuals in different ways and to differing degrees (Motl, McAuley, & Snook, 2005). The cause of MS is for the most part still unknown (Goldenberg, 2012; Dobson & Giovannoni, 2018; Sospedra & Martin, 2005; Ghasemi et al., 2016); however, it is indicated that a predisposing genetic factor (Sospedra & Martin, 2005; Kahana & Milo, 2010; Ghasemi et al., 2016) along with exposure to environmental factors play a role (Kahana & Milo, 2010; Goldenberg, 2012). Triggers of MS have been repeatedly recorded across a wide range of research. These include diet and metabolism, smoking, vitamin D levels, viral infection and quality of life (MS Trust, 2021; Goldenberg, 2012; Sospedra & Martin, 2005; Ghasemi et al., 2016; Kalb, 2011).

2.1.1 Types of MS

There are four categories MS can be grouped into, based on the course of disease (Goldenburg, 2012). These are important to know for prognosis and treatment (Ghasemi et al., 2016).

1. Relapse-Remitting MS: This is the most common form of MS. It affects an estimated 85% of people with MS. It is characterized by flare-ups, known as relapses, or exacerbations of symptoms followed by periods of remission, where symptoms improve or disappear.
2. Secondary Progressive MS: Can develop in patients that already have relapse-remitting MS. The disease continues on a path of deterioration with or without periods of remission or plateaus
3. Primary Progressive MS: Affecting only around 10% of MS Patients. It is defined by a gradual worsening of symptoms. There are no relapses or remissions, but there may be the occasional plateaus.
4. Progressive-relapsing MS: The rarest form of MS, affecting only 5% of the MS population. It is progressive from the start, with intermittent flare-ups of worsening symptoms along the way. There are no periods of remission.

(Ghasemi et al., 2016; Goldenberg, 2012)

2.2 Prevalence of MS Worldwide and in NZ

Multiple Sclerosis International Federation (MSIF) gathered data from 115 countries covering 87% of the world's population to discover the epidemiology of MS worldwide. The data gathered was used to make conclusive evidence that statistically shows, since 2013 the incidence of MS has risen from a population of 2.3 million to 2.8 million world-wide, with it being estimated that someone is diagnosed with MS every five minutes (Walton et al., 2020; MSIF, 2020). A range of factors could be influencing this increase in incidence, including the improvement of data collection nationally and globally (53%), improved diagnostics (60%), and improvement of treatment and support of MS patients (56%) potentially increasing life span (Walton et al., 2020). In New Zealand 2,994 people have been diagnosed with MS (1 in every 1,500) as reported by the MSIF, (2020).

2.2.1 Gender

The literature suggests that females may be up to twice as likely, globally and nationally, to be diagnosed with MS compared to males. In some countries the ratio can be as high as 4:1 (Goldenberg, 2012; Kenealy, 2019; Dobson & Giovannoni, 2018; Walton et al., 2020; Duquette et al., 2015). In New Zealand, females are three times more likely to be diagnosed with MS than males (Alla et al., 2014). The evidential reasoning behind this difference in prevalence remains largely unexplained (Duquette, et al., 2015). However, it is suggested that a variety of factors influencing it could include genetic and hormonal differences (Russi et al., 2018; Duquette et al., 2015), as well as a range of different social, lifestyle and environmental elements such as vitamin D (Sellner et al., 2011).

2.2.2 Age

Multiple Sclerosis usually affects individuals aged between 20 to 45 years old (Goldenberg, 2012). Early onset of MS before 17 is infrequent (Matthews & Rice-Oxley, 2001) and it is rarely diagnosed after 60 (Matthews & Rice-Oxley, 2001; Kalb, 2011). Only 2 -10% of patients have been over 50 years of age when diagnosed (Sturum et al., 2014). According to the MS International Federation (2020), the average age worldwide for MS diagnosis is 32 years old. However the average age within New Zealand for diagnosis is 42 years old (MSIF, 2020).

2.2.3 Location and Ethnicity

The prevalence of MS in each population ranges due to a variety of factors. Location and ethnicity differences have shown to be a factor in MS susceptibility (Kalb, 2011; Taylor et al., 2010; Rosati, 2001). MS appears to be most prevalent in Northern Europe, North America, Australia and New Zealand (MS Trust, 2021). The commonality between these countries is that they all have large numbers of Scandinavian, Nordic and European heritage populations, indicating the potential link between MS and the 'Viking genes' (MS Trust, 2021; Rosati, 2001). Genetic diversity comes from the variable pattern of proteins on the surface of your cells, known as your haplotype, inherited from a single parent. It has been discovered that many haplotypes are associated with a

higher risk of MS. These are commonly found in European and Scandinavian populations, although not restricted to these populations (MS Trust, 2021; Rosati, 2001). Other than genetic similarities these countries also share similar diets, lifestyles, obesity rates, and industrialisation that may contribute to MS susceptibility (MS Trust, 2021). MS on the other hand is rare among Samis, Turmen, Uzbeks, Kazakhs, North and South Amerindians, Kirghizis, Chinese, Japanese, African blacks, native Siberians, and New Zealand M$\underline{a}$ori (Rosati, 2001). In NZ, an incidence study recording data from 2012-2014 found that only 15 people of the 463 recruited for the study were of New Zealand M$\underline{a}$ori heritage. This statistically shows that only 24.2 persons per 100,000 cases would be identified as M$\underline{a}$ori heritage as opposed to the 73.1 per 100,000 identified as New Zealand Pakeha (Alla & Mason, 2013). This again hints at the differences in susceptibility of distinct racial and ethical groups. It is therefore indicated that racial and ethical factors play a significant role of MS susceptibility. However, we can see that although often dictated by location, it is also dependent on environmental susceptibility (Alla & Mason, 2013; Rosati, 2001). These determinants make up the geographic prevalence of MS (Rosati, 2001).

2.2.4 MS in NZ

It is confirmed that NZ is a high risk country in regards to MS (MS Trust, 2021) and is increasing in numbers of MS cases (Alla & Mason, 2013), with around 134 people diagnosed every year (MSNZ, 2021). In NZ, there are only 6 neurologists who specialise in MS. From the current data on MS statistics in NZ this suggests that there is only one neurologist for every 499 MS patients (MS international foundation, 2020). In 2006, it was reported that 80% of those with MS worldwide are unemployed. In NZ this number sits at 54.6% without paid employment (Alla & Mason, 2013). In the NZ health system, individual's diagnosed with MS are eligible for care services and support services. Needs Assessment and Service Coordination (NASC) are a government funded service employed by The Ministry of Health designated to identify home and living needs and providing funding to support them. NZ Ministry of Health offer support in areas of transportation, house adaptations, mobility aids, and weekly income through benefits to help support individuals with MS. However, there remains a lack of accessibility to critical treatments and support that will aid in mobility. There is currently no research on the economic toll of MS in

NZ, though international studies suggests it can range from $12,000-$143,000 in disability specific bills (Murphy et al., 1996).

2.3 Symptomology and the effect on quality of life

Multiple Sclerosis has a range of symptoms that can have varying impacts on quality of life (Ghasemi et al., 2016). Primary symptoms often include sensory disturbance, gait and vison impairment, urinary system dysfunction, along with cognitive and emotional difficulties. The SF-36 survey was designed to be a generic measure of health status, using 36 questions to help identify an individual's health status (Ware, 1999). It is one of the most widely used patient-based measures of health. It has been used in research alongside other measures to help identify quality of life for those with MS, with the incorporation of the individual's perspective. The categories cover physical function, physical role limitations, bodily pain, general health perception, energy/vitility, social functioning, emotional role limitations, and mental health (Burholt & Nash, 2011). Using the SF-36 survey it was easily identified that people with MS had significantly worsened health than the general population, more so in the physical function domain and less so in the mental health domain (Riazi et al., 2003). Literature uses the SF-36 survey in correlation with the EDSS scale to determine an individual's quality of life in regards to the deterioration of MS (EDSS). This gives us an understanding of the symptoms more commonly impacting individuals at different stages of MS, with those at an EDSS score of 0-3 being more commonly impacted by bodily pain and reduced vitality, and those with an EDSS score of greater then 6 being more impacted by physical function and mobility (Delgado-Mendilivar et al., 2005). This indicates the type of symptom management needed at each stage of MS and that those with an EDSS score greater than 6 need more mobility and physcial therapy intervention to maintain a high quality of life.

2.3.1 Gait impairment and walking function

Multiple sclerosis is largely associated with gait impairment (LaRocca, 2011; Givon et al., 2009). It is stated that more than 85% of individuals with MS report having some walking difficulties (Allali et al., 2014; Martin et al., 2006; Givon et al., 2009). Individuals with MS typically walk slower, with a reduced stride and step length and a more prolonged support phase than those of

healthy status (Martin et al., 2006; Motl et al., 2013). This is often due to the compensation of factors such as balance deficits and postural control (Martin et al., 2006). Neurological deficits such as spasticity, motor weakness and sensory disturbances that are early signs of MS often contribute to the later impairment of gait (Givon, Zeilig & Achiron, 2009). A study by Nicholas LaRocca (2011), investigated the impacts of multiple sclerosis on 1,011 people, discovering 90% struggled with mobility problems, 70% struggled with walking ability and 50% had impaired standing ability. Gait impairments can be a result of damage to the nerve pathways (National MS Society, 2010), interfering with coordination when walking causing weakness, balance issues, numbness and/or spasticity (Nikzad, 2016; National MS Society, 2010).

2.3.2 Fatigue

Fatigue has been reported to be the first sign of MS in over one third of patients, (Flensner,et al., 2011), and is the most prevalent symptom of MS (Krupp et al., 2007; Comi et al., 2001). Evidently, fatigue affects 85% of multiple sclerosis patients resulting in a general reduction in exercise and physical activity amongst this population (Petajan & White, 1999; Krupp et al., 2007; Comi et al., 2001). Fatigue often impacts on ones' quality of life, influencing other secondary symptoms such as depression, anxiety, motor function, sleep patterns (Krupp et al., 2014) walk patterns, and movement ability (Ghasemi et al., 2016). Of those MS individuals who have been surveyed on fatigue, 40% reported that the fatigue experienced was the most disabling of all symptoms experienced by them (Comi et al., 2001; Bakshi, 2003). Fatigue often impacts walking function in MS individuals through a reduction in walking endurance. Savci et al. (2005), made a comparison between thirty individuals with multiple sclerosis and thirty healthy individuals in a six-minute walk (6MWT) to measure exercise capacity. The results of the 6MWT revealed that those with MS walked half of the distance compared to the healthy control subject. On average the MS subjects walked 380.22m whilst the healthy subjects walked 614m. There are many links made throughout the literature between MS and fatigue as a symptom, however the pathophysiology of fatigue in relation to MS still remains unclear (Bakshi, 2003; Comi et al., 2001; Krupp et al., 2007). Therefore, as one of the most disabling symptom of MS, fatigue management, is a must.

2.3.3 Temperature control

Sensitivity to increased body temperature is a factor that is commonly associated with MS. It is reported that 60% - 80% of those diagnosed with MS have indicated a sensitivity to heat (Flensner et al., 2011). Body temperature is found to impact nerve impulses (Wolf, 1970; Marino, 2009), with heat blocking the action potential of a demyelinated neuron (damaged nerve). This results in slower nerve conduction as the axons fire at a lower frequency, and messages to the brain are interrupted resulting in the onset of other MS Symptoms (Wolf, 1970; Marino, 2009; Flensner et al., 2011). It has been determined that heat sensitivity is highly correlated with other symptoms such as pain, concentration difficulty, urination urgency and most commonly fatigue (Krupp, 2003; Lerdal et al., 2007; Flensner et al., 2011). In a study focused on temperature sensitivity in MS patients by Flensner et al. (2011), it was concluded that individuals found fatigue as a result of heat, was their most disabling symptom. A significantly high portion of those who were heat sensitive also struggled with high levels of fatigue, as opposed to those who were not heat sensitive.

2.3.4 Balance

Compromised balance is common amongst MS individuals (Fjeldstad et al., 2009; White & Dressendorfer, 2004), and because of this, the risk of falling is increased amongst this population (Cattaneo, et al., 2007). The symptoms of MS, such as sensory deficits, motor control, and compromised strength, play a significant factor on balance (White & Dressendorfer, 2004). Cognitive deficits can occur in early stages of MS, impacting information processing, attention, decision making, error correction, and execution of function, which may result in poor decision making and slow responses, increasing the risk of balance loss (White & Dressendorfer, 2004). O'Malley et al. (2020), discovered that between 47% and 70% of people with MS will fall at some point during a three month period. These abnormalities often prevent people from living their daily life and performing independent tasks (Cattaneo et al., 2007), and often the heightened awareness of the risk of falling, can cause a further reduction in ability and quality of life.

2.3.5 EDSS

The Expanded Disability Status Scale (EDSS) developed by neurologist John Kurtzke (1983), is a commonly used clinical outcome assessment used for measuring MS and its progression (Healy et al., 2013; Meyer-Moock et al., 2014; White & Dressendorfer, 2004). EDSS is a clinician administered assessment used to measure functional systems of the central nervous system (CNS). EDSS is frequently used as a measure for the effectiveness of therapeutic interventions. It measures 8 different areas including pyramidal, cerebellar, brainstem, sensory, bowel and bladder, visual, and cerebral (White & Dressendorfer, 2004). It uses a 0-10 ordinal rating system (see appendix 3), zero being a normal neurological status and ten being death due to MS. The scale progresses in 0.5 increments, with the lower end of the scale measuring impairments based on a neurological examination, and the top end of the scale is based predominantly on functional disabilities (Meyer-Moock et al., 2014). 0-4 shows no disability to moderate disability, remaining functional and without aid. 5-6 on the scale indicates ambulation impairment, and 7-10 indicates wheelchair restriction (White & Dressendorfer, 2004).

2.4 Exercise and MS

MS leads to impaired muscle function resulting in weakness, muscle dystrophy, fatigue, and decreased ambulatory ability (de Souza-Teixeira et al., 2009). These factors have been linked to loss of independence, reduction in daily activities, and as a consequence impacts on the quality of life through components such as a reduction in social interaction, along with recreational activities. (Dalgas et al., 2010). Exercise has proven to be a promising intervention for those with progressing multiple sclerosis (Snook & Motl, 2009; Comi et al., 2001). Exercise is an effective management strategy for MS (Comi et al., 2001), and has been reported to result in an improvement in fatigue (Bakshi, 2003; Dalgas et al., 2009), strength, muscular endurance, functionality (De Souza-Teixeira et al., 2009), cardiovascular fitness, and mobility; whilst also enhancing quality of life and reducing the incidence of secondary disease risks (White & Dressendorfer, 2004; Snook & Motl, 2009; Rietberg et al., 2005; Dalgas et al., 2009).

Exercise has been demonstrated to be an important factor for managing everyday physical demands of the disease (Motl et al., 2005). A meta-analysis of thirteen scientific articles examining the effects of exercise on quality of life with multiple sclerosis patients reported particularly that aerobic exercise can have a positive impact on quality of life (Motl and Gosney, 2008). A number of exercise modes were examined including non-aerobic (such as resistance training and yoga), aerobic and non-aerobic combined. Although no specific details about the exercise intervention methods were mentioned, a positive correlation between aerobic exercise and quality of life was reported, however, they were unable to make a conclusive finding on exercise types such as resistance training and yoga as there were too few studies in this area. Overall, exercise should be adjusted to suit the participant and their demands with the consequence of positive significant impacts on quality of life and reduced risks of other health factors such as type two diabetes, obesity, and some types of cancer (Motl & Gosney, 2008).

Since exercise is an important tool for the management of MS, different types of therapies have been examined to understand the impact of exercise in those with MS. Rietberg et al., (2005), examined nine randomised controlled trials with 260 participants. It was reported that therapy specific exercise programs in the forms of rehabilitation, physical therapy, functional training, home based physical training, and aquatic were no more successful than other forms of exercise, such as aerobic and resistance, but still indicated that exercise therapy was better than no exercise. The review by Rietberg et al., (2005) did not examine intensity, duration and frequency when comparing MS specific exercise therapy to aerobic and resistance training and therefore no conclusive exercise variables can be stated based on this article as this is imperative when measuring exercise outcomes.

The overall effect of exercise after taking into consideration a variety of factors such as time period, mode of training, intervention setting, and EDSS, was that although small, the exercise showed a clinically meaningful improvement in mobility for MS individuals (Snook et al., 2009). Although not statistically significant ($p= 0.09$), the effect in comparison to disease modifying medication could be considered large to people with MS showing a reduction in disease progression and an improvement in EDSS scores. The results came to some notable conclusions such as the effect of training under supervision having a more significant impact on mobility

improvement then those who were unsupervised. A duration of exercise intervention less than 3 months showed statistically significant improvements, whilst 3 or more months showed no signs of significant improvements. This could be due to limited programme progression. It is well known that a tapering effect can occur when a program is not adjusted. To maintain progression it would be expected that variety and incremental changes to intensity would be prescribed. Motl and Gosney (2008), also researched the effect of exercise on quality of life amongst those with multiple sclerosis using a review of 25 published journal articles. The conclusion drawn states that exercise leads to improved quality of life amongst those with multiple sclerosis. Exercise has a positive impact on cognitive function, mood, fatigue (Motl & Gosney, 2008; Dalgas et al., 2010), and improved mobility and function. This is important as enhancing quality of life is the main therapeutic intervention goal.

From this critical review of the literature, it is obvious that there is a vast range of information regarding the effects of exercise on MS. However, it has its limitations when examining the long term effects. Current literature is all based on research using an examination period of 3 months or less, with only a handful examining the effect of exercise over a longer period. The inclusion of long term follow up testing of 6 months and more, following the completion of the trial, would be beneficial in examining the impacts of exercise training with the ensuing trajectory of disability progression (Snook & Motl, 2009). This would give a better insight into the life changing impacts exercise potentially has in hindering the symptom progression, symptom management, and quality of life. Most if not all research to date is short (12 weeks), it is important to examine the long term effects of such interventions along with examining exercise in individuals with an EDSS scores of 6 or more, which is also rarely cited. Research tends to focus on individuals with a lower EDSS score over a shorter period of time. This research often demonstrates significant improvements following exercise intervention, but is heavily limited to that specific population due to only covering the initial impacts of MS. As MS is a deteriorating disease that only progresses, the research needs to be inclusive of those with an EDSS score greater then 6. Current literature could be considered biased as it is heavily orientated around individuals that have an EDSS scores of 0-6 (refer to appendix 3), indicating individuals included can still walk at least 500 meters. By only basing it on data gathered from those with low EDSS scores, it results in the exclusion of those wheelchair bound and/or heavily aid dependent individuals (EDSS score >6). As it is known that

exercise improves function and mobility, current research needs to be constructed on all populations of MS. Investigating this population would come with complications as 30% of individuals with MS have significant mobility impairments and are constrained to a wheelchair (Silveira et al., 2020). However, this is an important field to research as there is a concern for this population that there are no exercise methods demonstrated to combat MS symptoms or research proving the long term benefit of exercise on symptom management.

2.4.1 Current exercise recommendations

It is suggested that exercise aids against MS deterioration, although there is no conclusive evidence pointing in the direction of any specific type. To gain a greater understanding of the most effective exercise interventions for individuals with multiple sclerosis more research is required in determining intensity, type, and for a greater EDSS range to be explored (Snook & Motl, 2009). Currently most research around exercise prescription for the MS population is limited to a small percentage (Dalgas et al., 2009), reiterating that the majority of research uses an MS population with EDSS scores up to 6, indicating only moderate disability.

The few studies that have looked at resistance training using individuals with an EDSS score less then 6.5, have shown that it can help improve chair transfer, gait, and stair climbing (Dalgas et al., 2009; DeBolt & McCubbin, 2004), which all have a great effect on quality of life. Research documents the importance of individuals with MS performing resistance training in a supervised environment where they can be monitored. When performing resistance training, MS patients should be supervised by an expert within the field of resistance training, as well as understanding of the effects of MS (Dalgas et al., 2009), to monitor and observe signs of muscle weakening and/or loss of coordination during exercise training (White & Dressendorfer, 2004). Resistance programs should be individualised to meet the current needs and adapted to the individuals goals, whilst also accounting for their disabilities and limitations (Dalgas et al,. 2019). It has been recommended that in the initial stages of exercising, resistance training for MS patients should be performed using machines instead of free weights to provide safe, specific, and directed training, however, this will often be influenced by the individuals capability. High capabilities may be more suitable for weight machines (EDSS 1-5) whereas lower capabilities (EDSS6.5 +) are often more

suited to elastic stretch bands (White & Dressendorfer, 2004). Resistance exercise should range between 8-15 rep max (RM), with the initial phases of the program beginning at 15RM and over several months working towards 8-10 RM (Dalgas et al., 2009; White & Dressendorfer, 2004). Sets are recommended to be 1-3 and can be slowly increased as the individuals show improvement, recommended rest periods of 2-4 minutes are suggested (Dalgas et al., 2009). To show signs of improvement it is recommended that an individual with MS trains 2-3 days per week, following a full body specific training program. As fatigue is common in MS individuals, it is important to be flexible with resistance training, adapting to the demands of the day (Dalgas et al., 2010). It is a focus on lower extremity training as the impact on the gait in MS is large. Resistance training has been linked to improvement in muscular strength and functional capacity, improving fatigue, mood, and quality of life following a 12 week progressive resistance training program specific to their condition (Dalgas, 2010), and an 8 week progressive lower limb resistance training program (White & Dressendorfer, 2004). It is also seen as an important tool for effective disease management, as it delays functional deterioration (Souza-Teixeira et al., 2009).

Whilst aerobic exercise has shown significant effects on improvements in quality of life (Motl & Gosney, 2008), has been demonstrated to reduce disability and mobility (Andreu-Caravaca et al., 2021; Kileff & Ashburn, 2005) through improvements in cardiovascular fitness (Petajan et al., 1996). MS patients with an EDSS score of less than 6 can participate in aerobic exercise 5 times per week for 15-30 minutes without having an effect on disability (Petajan et al., 1996). Recommendations for aerobic exercise for individuals with MS are 2-3 sessions per week for 20-30min at 60-80% heart rate max for symptom improvement (Dalgas et al., 2009). These recommendations are however for individuals with an EDSS of EDSS < 7 (Dalgas et al., 2009). Suggested training modes have included stationary cycling for lower extremities, especially for those with significant foot drop, upper body ergometer for upper extremities, swimming and aquatic exercise (White & Dressendorfer, 2004). Once again these recommendations are gathered from literature that researched exercise for MS individuals with an EDSS score less than 6.

Table 1: Aerobic exercise recommendations for MS individuals with an EDSS less than 6. Sourced from; White & Dressendorfer, 2004.

Frequency	Exercise intensity	Exercise duration
2–3 sessions/wk	65–75% HR_{peak}	20–30 min/session or 2 × 10–15 min/session
	50–70% $\dot{V}O_{2peak}$	
	RPE (11–14)	

HR_{peak} = highest value for heart rate found on symptom-limited exercise testing; **RPE** = rating of perceived exertion; **$\dot{V}O_{2peak}$** = highest value for oxygen uptake found on symptom-limited exercise testing.

Conclusively, there is strong evidence that suggests exercise is beneficial for symptom management of MS. Although recommendations are varied throughout the literature, a pattern suggests that exercising twice weekly at moderate intensity exercise has an impact in increasing aerobic capacity and muscular strength (Latimer-Cheung et al., 2013).

It is evident that the current literature lacks details around specific exercise recommendations. The majority of the literature discussing the benefits of exercise is written without the details of the chosen methods of exercise, often only stating aerobic or nonaerobic. There are no reoccurring details on the intensity, volume, and period of training used to demonstrate such improvements and to gain this suggested benefit that exercise provides. This means that although we know that exercise is beneficial, we do not know the most beneficial way to train individuals with MS. Currently there are a number of different exercise modes and durations reported within the literature, each suggesting benefits. However most concentrate on those individuals who are able to walk and have an EDSS <6. It is therefore important to understand what difference and how exercise can be of help in those with an EDSS of >7.

2.5 Locomotive training?

Locomotive treadmill training is a modern form of rehabilitation intervention (Singh et al., 2018), one method many trainers use to help develop lower limb strength, coordination, and improve ability to walk independently again through neuromuscular memory and strength gains (Backus & Tefertiller, 2008). The development of technologies has allowed the improvement of locomotive training through the use of body weight assisted treadmill training, with machines such as the therastride. Bodyweight assisted treadmill training is used as a repetitive task-specific treatment

for gait rehabilitation (Høyer et al., 2012). Locomotive training was an early translation of the repetitive treatment concept (Hesse, 2008), and is based on the principle that the movement of the legs will generate sensory information coherent with locomotion, consequently improving walking ability (Geisser et al., 2007). Locomotive training also allows the neurological system to work with the affected parts of the body to rewire damaged pathways of nerve impulses (University of Alabama, 2008).

Body weight assisted treadmill training consists of the individual being harnessed over the treadmill by an overhead support system. The system is designed to facilitate balance and manually assists with trunk and leg movement, whilst practicing gait cycles repetitively (Geisser et al., 2007; Backus & Tefertiller, 2008). Retraining gait is the main aim of body weight assisted treadmill training (Mudge et al., 2003). Benefits are multiple and include physical and functional aspects (Singh et al., 2018). Functional components such as improved walking endurance and speed, increased muscle strength, and improved balance have all been evidently included as benefits to locomotive training (Singh et al., 2018): health-related benefits include improved cardiovascular function, blood glucose regulation, preserved bone density, reduced muscle spasticity (Singh et al., 2018), and an increased cross sectional area of muscle (Backus & Tefertiller, 2008).

One of the most significant aspects of locomotive training is the safety factor. Individuals who are wheelchair restricted (EDSS >6) or have limited functional ability are able to take part in full body movement exercise due to the safety and use of the harness. The harness provides an environment where an individual can feel secure and have a reduced risk of falling (Backus & Tefertiller, 2008). For individuals with paralysis, extremity weakness, sensory deficits, and spasticity, walking overground can be difficult. The use of body weight assistance from the harness allows safe repetitive task-specific training to be carried out, allowing weight bearing on lower extremities that would otherwise not be activated (Backus & Tefertiller, 2008).

2. 6 MS and Locomotive exercise

Limited research is available on the association between multiple sclerosis and locomotive training. There is however enough research on a variety of similar neurological conditions and

locomotive to discern a correlation. In research directed by Giesser et al. (2007), it suggests that spinal forms of multiple sclerosis show clinical similarities to that of incomplete spinal cord injuries. Individuals that have one of either conditions often display weakness in their limbs, spasticity, hyper-reflexia, and loss of sensation, consequently affecting mobility and function. Giesser et al. (2007), stated that it is therefore reasonable to suggest that the therapy methods proven to be beneficial to those with incomplete spinal injuries are also applicable to those with multiple sclerosis in terms of improving mobility. There is a trend through research (Giesser et al., 2007; Morrison et al., 2012; Mudge et al., 2003; Beer et al., 2008), that shows the link between symptoms of spinal cord injuries, strokes, and multiple sclerosis, and the positive effects of body weight assisted locomotive therastride training. The idea is that if the individuals with neurological conditions are all facing similar symptoms then the same therapy interventions that work for one should work for another.

Researchers have investigated the link between locomotive training and the impact it has on neurological conditions via functional walking tests. A study conducted by the NeuroRecovery Network investigated locomotive training with an incomplete spinal cord patient in order to provide a standardized training program. The participants took part in one hundred rehabilitation sessions, incorporating on ground walking, therastride treadmill training, and ambulation skills, over an estimated 20 week period. The research used methods such as the ten-meter walk test and six-minute walk test, the results showed an indication in improvement in gait speed, walking function and endurance from start to finish, whilst overall enhancing the individual's independence (Morrison et al., 2012). Morrison et al. (2012), provides findings that strongly support body-weight assisted treadmill training and provides evidence of outcome benefits. This is proven in the results, as the individual's 6-minute walking test improved from 299m to 632m (111% increase in improvement). However, this research also incorporates other rehabilitation methods (on ground walking training and ambulation skills) that could strongly impact the findings. Studies following on from this may find it beneficial to control some variables, so as to demonstrate the significance of an individual rehabilitation intervention rather than multiple.

A study by Hesse (2008), stated that restoring gait function is a key goal for patients who have had a stroke. Hesse, in his study, showed evidential clinical results that partially-supported body-

weight treadmill training can have improvements on gait function and on ground walking speed in comparison to conventional physiotherapy. Following a 6 week training period, a comparison of body-weight support (BWS) and no-BWS, showed significant differences for the BWS group, indicating a significantly higher score for functional balance ($p=0.001$), motor recovery ($p=0.001$), overground walking speed ($p=0.029$), and over ground walking endurance ($p=0.018$). This continued when the groups were reassessed in a follow up evaluation 3 months on. Hesse's (2008), study demonstrated patients' ability to complete up to 1000 gait cycles on the treadmill during a session, as opposed to the 50 completed in a regular physiotherapy sessions. These treadmill sessions were not only beneficial for walking and gait functionality, but showed signs of greater improvements in cardiovascular fitness among the individuals, which positively impacted their quality of life (Hesse, 2008).

A second study by Mudge et al. (2003), indicated balance was heavily improved following locomotive training using a male stroke patient. An assessment using the Berg Balance Scale (BBS) and the 10-meter walk test, showed conclusive evidence that there was significant improvements in balance, but not in gait speed or the number of steps taken following intervention. Balance reportedly improved from 18 to 33 on the BBS following the locomotive intervention of body weight assisted treadmill training of 3 times weekly for 4 weeks. This demonstrates the effect of body weight assisted treadmill training on balance improvement. The study, although not showing its own improvements in gait, reviewed numerous other studies and stated that body weight assisted treadmill training had shown signs of improvements in gait speed, gait symmetry, and functional ambulation following locomotive training (Mudge et al., 2003). The study did make a valid and influential note that results from training were very specific to the task being trained. Mudge et al. (2003), observed that training needs to be task-specific due to their being "very little cross-over effect" to other functional aspects. This may be why the balance of the patients improved heavily, whilst gait function did not.

Research by Hornby et al. (2005), indicated that there was an improvement in motor function following 3 robotic-assisted body-weight support training sessions per week for 16 to 20 weeks, for individuals with incomplete spinal cord injuries. This was assessed through clinical measures such as the 10 metre walk test, timed up and go, functional reach test, and 6-minute walk test. The

individuals in this study by Hornby et al. had similar conditions as to many of those with multiple sclerosis. The symptoms of incomplete spinal cord injuries often mirror those of multiple sclerosis such as reduced walking ability, reduced muscular strength, poor balance, fatigue and a decline in functional ability (White & Dressendorfer, 2004; Motl et al., 2005; Teixeira-Salmela et al., 2001). It is stated that individuals with gait dysfunction due to damage of the central nervous system show a significant improvement in functional ability, balance, and motor skills following body weight assisted treadmill training, more so than traditional methods of rehabilitation (Martha et al., 1998; Barbeau, 2003). In research by Martha et al. (1998) one hundred subjects were used. Half the subjects trained with 40% reduced body weight while the other half used full weight bearing rehabilitation techniques over a six-week period and then a three-month period. The group using body weight assisted training scored significantly higher in all testing areas of functional ability; functional balance, motor recovery, over ground walking speed, and over ground walking endurance (Martha et al., 1998). This is supported by multiple research articles based on spinal cord patients that were able to conclude that locomotive training has a positive impact on general walking ability, speed, and distance (Backus & Tefertiller, 2008; Morrison et al., 2012; Hornby et al., 2005). Evidently, it is suggested that walking was improved and maintained for several months up to years after locomotive training (Backus & Tefertiller, 2008; Morrison et al., 2012).

A study by Van Den Ber et al., (2006) makes a link between multiple sclerosis and treadmill training in their pilot study, which demonstrated the first connection between the two. Whether or not they used body weight assisted treadmill training is unknown. The authors of the study used nineteen individuals, male and female, with an age range of 30 to 65 years. Individuals took part in three sessions weekly for four weeks. Sessions consisted of 30-minute bouts with three rest periods and intensity set at 55-85% age predicted heart rate max. Results from the study by Van Den Ber indicated a significant increase in walking speed and in walking endurance measured using the 2 minute walk test. The study concluded that the increased speed and endurance during intervention showed a strong correlation with improved mobility and independence. During this research significant discovery was made by Van Den Ber et al. indicating that there was a return to baseline ability in the follow up period 12 weeks after training ceased. This indicates that a short-term program may be less suited for individuals with multiple sclerosis and a long term or

maintenance program would be more beneficial to this population due to the continual deterioration.

The only research on MS that used body weight assisted locomotive training is a pilot study by Geisser et al. (2007). This study is the only one to be found where treadmill training was completed using body weight assisted methods of intervention as opposed to a standard treadmill training. This study uses four subjects with spinal cord specific multiple sclerosis in a research project testing their mobility improvement, following forty locomotive training sessions over several months (Geisser et al., 2007). The researcher's purpose was to determine whether individuals with spinal cord multiple sclerosis, who are very compromised functionally, are able to endure the demands and benefit from body weight assisted treadmill training. The results Geisser et al. (2007), discovered demonstrated that every participant could tolerate the demands of each training session, this being comprised of a sixty-minute weight bearing session with twenty minutes being stepping. Participants also expressed benefits including increased energy, greater standing endurance, and an increased ease of everyday tasks. Following training, individuals improved walking speed and three out of four participants improved walking endurance. One participant that previously couldn't even walk completed the 10 meter on ground walk test following the treadmill training. Three out of four also improved balance by a great deal, showing a clinically significant difference from pre-testing to post-testing. Muscle testing was the final aspect measured, showing an increase in voluntary muscle strength by all participants. Overall three out of four participants rated an increase in quality of life.

2.7 Conclusion

The research gathered for this review comes from a wide range of articles selected from the early 2000's, up till 2021. The information compiled for this review is used to gain an overall picture of the current knowledge and information about MS and exercise. It indicates a need for more current research using the modern advances in technology and knowledge. With the advancement of technology, body weight assisted treadmill training will be more common; however, the need for more research and literature to support these theories is warranted. So far the information reviewed supports body weight treadmill training for other neurological conditions, such as stroke and

incomplete spinal cord injuries, and is vast. However, the need for research and literature to support individuals with multiple sclerosis is still in demand. This literature review was able to find an abundance of research for a strong case supporting the benefits of locomotive training in general. The review, however, lacks depth in the area of current information and a valid link between multiple sclerosis and locomotive due to the lack of information that is currently out there. Most information that is available around MS and exercise is directed at those with an EDSS score of less than 5, indicating they have limited disability and are still functional. There is currently a lack of available information for those that have severe or even restricted functionality. The aim of this thesis is to research this area and provide a valid connection for the multiple sclerosis community and hope that an increase in locomotive training provides a safe and suitable means of exercise for this population to enhance mobility.

Chapter Three: Aims and Hypothesis

3.1 Introduction

From the analysis of the literature and previous research it was obvious that there was a lack of contextual evidence in the area of locomotive exercise training in multiple sclerosis individuals with a lower score of EDSS. The purpose of the study was to investigate the effects of locomotive exercise on balance, physical fitness, and the effectiveness on walking ability through clinical measures of step and stride length, balance, and the 6 minute walk test.

3.2 Aims

The aims of this research project were:

To examine and provide physical evidence on changes during 12 weeks of locomotive exercise in individuals with multiple sclerosis.

To examine the changes of step and stride length, 6 minute walk time, and balance following locomotive exercise. This will provide outcome measures which are integral components to assessing the effectiveness of our programme.

3.3 Hypothesis

Following 12 weeks of the locomotive training programme, individuals will:

- Increase step and stride length and improve balance.
- Increase distance over 6 minutes.

Chapter Four: Materials and Methods

4.1 Experimental Overview

The design of the study is a pilot study.

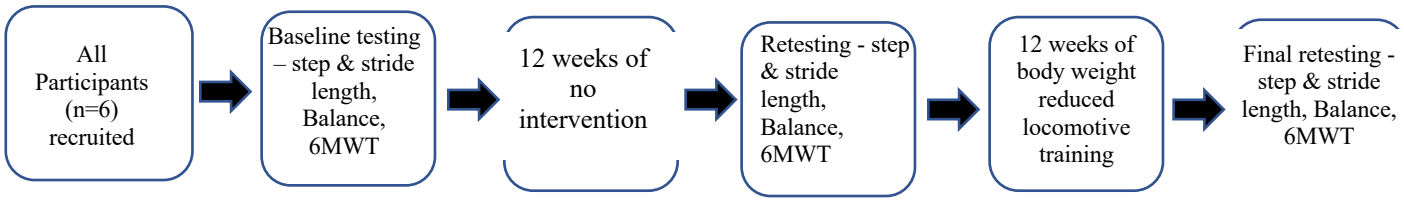

Figure 1: Experimental overview of procedures and protocols summarised

4.2 Participant Recruitment

After receiving ethics approval from the Health and Disability Ethics Committee (20/CEN/84), participants were recruited via the local Multiple Sclerosis Society and local Neurologist. Potential participants were contacted by researchers through phone or email regarding the details of the research project and offered detailed written information outlining what the project would entail, before making a decision to attempt the baseline testing procedure. Fifteen individuals were contacted and invited to participate in the study. However, only eight participants met the criteria of an EDSS score between 6.0 and 8.0, and met the testing requirements and locomotive training commitments. The study took 48 weeks duration and consisted of 6 testing sessions, 12 weeks of no active rehabilitation methods, and 24 sessions of locomotive training. Due to the nature of the individuals, sessions were missed and had to be made up the following week. This extended the training period by a few weeks to ensure all 24 sessions were completed. Each session was individualised to each participant to meet their current level of ability and needs (see appendix).

4.3 Sample Size Calculation

Previous studies examining locomotive training have used sample sizes between 4 and 6 participants. This pilot study will aim to use a sample size of 6 which will achieve a power above

0.8, and statistical significance of 0.05. A sample size of 10 in this project would not have been feasible, as Massey University had a maximum of 12 hours across the week for training, allowing only two sessions per week for participants.

4.4 Participant Characteristics

Six participants between the ages of 25-60 years, with primary progressive or secondary progressive MS and an EDSS score of 5.5-8.0 completed the research study. Of the six participants 3 (50%) were female and 3 (50%) were male.

4.5 Procedures and Protocols

Following recruitment, participants were asked to take part in a series of tests to create baseline data. On day one, in order, participants were asked to complete step and stride length measurements. Step length is a measure of lower limb strength and a good indication of left to right imbalances between the lower limbs (Flegel et al., 2012). The participants walks for 10 steps across a hall or flat area. The tester marks the heel placement of each foot for ten consecutive steps. Step length is measured using the three middle steps measuring between ipsilateral and contralateral heel contacts. Stride length is measured by marking the left heel strikes only for the left stride and right heel strikes only for the right stride. Balance measurements are taken on the in ground force plate (Kistler force plate and BioWare software, version 3.2.6.104, type 2812À-3). Measurements for participants were taken three times in a parallel stance. Participants were offered assistance as they were positioning and in some situations during the test, this was recorded. Participants lastly took part in the 6-minute walk test on ground. This was completed in a temperature controlled room, in the same format for all participants. The 6-minute walk test is a practical and simple test used to measure maximum walking capacity within a 6-minute period. It is a self-paced submaximal test, making it perfect for individuals with neurological conditions (Dean et al., 2001).

For the next 12 weeks, participants were asked to continue their ordinary daily routine and were not given any active rehabilitation strategies to follow. This allowed us to use the participants as their own control group.

Following the 12 week period, participants repeated the two day baseline testing procedures and commenced the locomotive training program. This consisted of 24 sessions across a 12 week training period. At the start of each session, participants were asked how they were feeling and the effects of the previous session and week. This helped determine the workload for the commencing session. Participants were then put into a harness (medium or small). Each training session was 60 minutes in duration and consisted of a warm-up (slow paced walking for 3 min) followed by three to five 3-minute intervals of step training, depending on the participants ability. Step training is what occurs whilst the participant is supported by the locomotive treadmill. As the therapists move the individual's legs at the walking pace selected, sensory information from the legs and the trunk are repeatedly sent to the spinal cord. The idea behind step training is to encourage the nervous system to relearn the motor patterns associated with walking (Reeve, 2021). Motor skills are also being built through supported standing and walking. Each interval was followed by a rest period and a stretch. Body weight assistance and speed was determined by the ability and mental wellbeing of the individual on each specific day. Training sessions advanced as time went on, and ability improved. For each session training variables were recorded, such as speed, amount of body weight reduced, training sets, and interval time.

Following locomotive intervention, individuals then completed the testing procedures in the same order of events again; step and stride length, balance, and 6MWT. This concluded the trial.

4.6 Statistical Analysis

The Statistical Package for Social Sciences (SPSS, version 28.0, IBM, New York, USA), was used. The statistical significance was programmed at <0.05 and the data results were displayed in tables as the mean and standard deviation of each component. Data normality was found using the Shapiro Wilk test of normality. The data was analysed using a paired samples t-test (2 tailed) to identify differences that the locomotive exercise had made to step and stride length, balance,

and 6MWT, as well as the effect of usual training/activities. Following this we performed an ANOVA test to compare the differences in means among the three time periods. The dependent variables were the time frames of pre-testing, post 12 weeks of no locomotive intervention, and post 12 weeks locomotive intervention. The independent variables were the step and stride length, balance, and 6MWT.

Chapter Five: Results

From the sample of six individuals recruited with MS, three were male and three were female. This is an unusual ratio as usually you would have 3 females to 1 male. Table 2 provides mean and standard deviation of participant characteristics including height, weight, body mass index and age.

Table 2: Participant characteristics

	Mean	**SD**
Age (years)	51	14
Height (cm)	168	13
Weight (kg)	69.7	9.3
BMI (kg/m^2)	23.6	3.8

5.1 Step, Stride, and Walk Test Mean and Standard Deviation

Table three demonstrates the mean and standard deviation of the step and stride length of each participant's left and right foot, and the 6MWT from testing sessions one, two, and three. It can be seen that from test one to test two (no exercise) that participants' ability declined in all fields. Following the locomotive intervention period it can be seen from test two to test three participants improved in all testing fields. The standard deviation is considered large, which indicates the large range of ability amongst the participants.

A test of normality, using the Shapiro-Wilk test, was completed indicating a normal distribution of data for all tests except stride length left test one. This showed that the data was skewed to the left, meaning that they had poor stride length and that there was little variation within the group.

Table 3: Step Length, Stride Length, and Walk Test Means and Standard Deviation

	Test 1		Test 2		Test 3	
Measurement (cm)	**Mean**	**SD**	**Mean**	**SD**	**Mean**	**SD**
Step length (cm): right	36.01	10.61	34.72	13.69	43.53	16.49
Step length (cm): left	29.30	12.70	27.61	15.71	39.49	19.26
Stride length (cm): right	63.76	19.09	62.26	19.20	80.43	31.77
Stride length (cm): left	60.82	21.12	60.30	20.45	79.38	30.26
6-minute walk test (m)	126.03	65.99	97.98	52.86	147.04	79.75

The graphs below (figure 2-3) demonstrate change in step length (right and left), (figure 4-5) stride length (right and left), and the 6-minute walk test. Control is classified as T1-T2 no intervention, T2-T3 is the locomotive intervention. From these figures it is easy to see the difference that locomotive training made on the participants in terms of increasing both step and stride length.

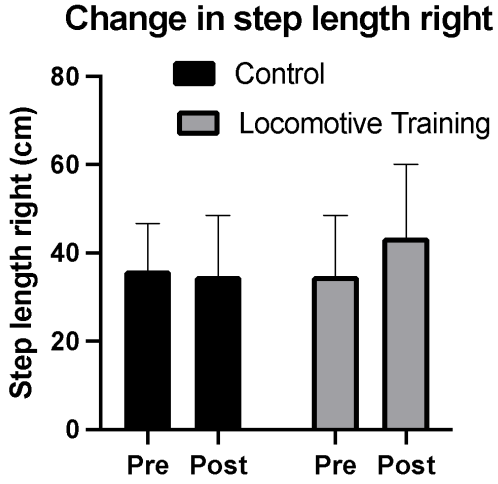

Figure 2: Change in step length, right.

Figure 2 illustrates the changes in step length for the right foot of the participants pre and post 12 weeks of no locomotive intervention and pre and post 12 weeks of 24 sessions of locomotive therastride training. The graph demonstrates that the control group shows a minimal decline in step length post no intervention. The locomotive training group demonstrates a big increase of 25.4% in step length following locomotive intervention.

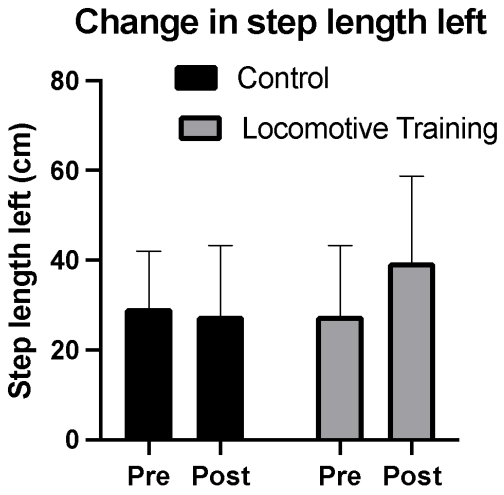

Figure 3: Change in step length, left.

Figure 3 illustrates the changes in step length for the left foot of the participants pre and post 12 weeks of no locomotive intervention and pre and post 12 weeks of 24 sessions of locomotive therastride training. The graph demonstrates that the control group shows a minimal decline in step length post no intervention. The locomotive training group demonstrates a big increase of 43% in step length following locomotive intervention.

Figure 4 illustrates the changes in stride length for the right foot of the participants pre and post 12 weeks of no locomotive intervention and pre and post 12 weeks of 24 sessions of locomotive therastride training. The graph demonstrates that the control group shows no change in step length post no intervention. The locomotive training group demonstrates an increase in step length of 29.2% following locomotive intervention.

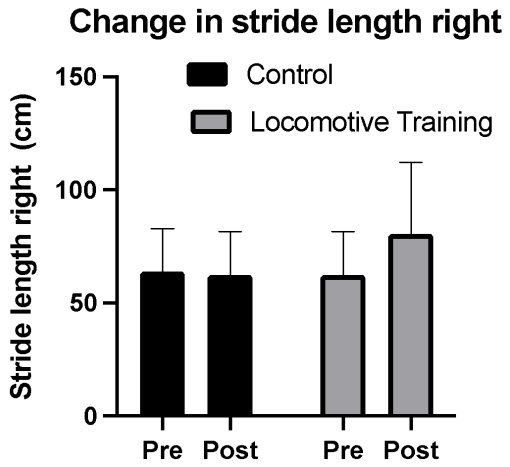

Figure SEQ Figure * ARABIC 4: Change in stride length, right.

Figure 5 illustrates the changes in stride length for the left foot of the participants pre and post 12 weeks of no locomotive intervention and pre and post 12 weeks of 24 sessions of locomotive therastride training. The graph demonstrates that the control group has no change in step length post no intervention. The locomotive training group demonstrates an increase in step length of 31.6% following locomotive intervention.

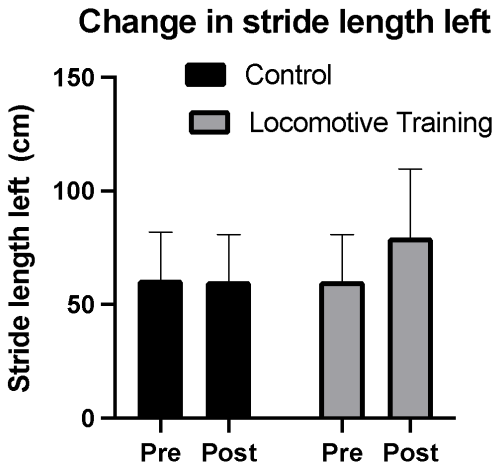

Figure SEQ Figure * ARABIC 5: Change in stride length, left.

Figure 6 illustrates the changes in the distance covered in the 6-minute walk test of the participants pre and post 12 weeks of no locomotive intervention and pre and post 12 weeks of 24 sessions of locomotive therastride training. The graph demonstrates that the control group showed a significant decrease of 22% in distance covered post testing after no intervention. The locomotive training group demonstrates a big increase in the distance covered post locomotive intervention, increasing the distance covered over the 6 minute period by 50%.

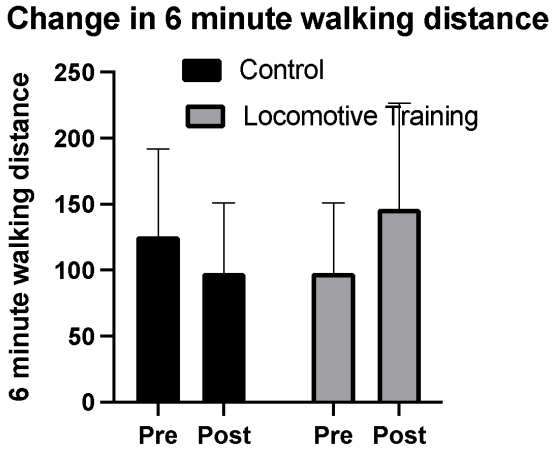

Figure SEQ Figure * ARABIC 6: Change in 6 minute walk test (m).

Table four shows a significance in improvement in all testing fields through paired t-test analysis. Test one vs. test two shows a lack of improvement during the 12 weeks of no active rehabilitation, whereas the results of tests two and three indicate a significant improvement following locomotive training.

Table 4: Paired T-Test; Step Length, Stride Length, and Walk Test

	Test 1 vs Test 2	**Test 2 vs Test 3**
Step Length: Right	.644	P<0.05*
Step Length: Left	.460	P<0.05*
Stride Length: Right	.695	.059
Stride Length: Left	.877	P<0.05*
6- Minute Walk Test	.238	P<0.05*

*Indicates statistical significance

5.2 ANOVA

From the repeated measures of Anova it is indicated that there is no significant difference for the majority of the measures. It is clear using the Greenhouse-Geisser statistic (Table 6) that there is also no significant difference between tests for all measures except step length, left. However, it can be seen that an improvement have been made and results are veering towards significant. This suggests that if there were more individuals involved in the study, then it may be possible to reach significance with locomotive exercise. However, because the standard deviation was large due to such a difference in abilities, it has hindered a possible statistical significance. Table 5 shows pairwise comparisons and indicates that step length left has a significant difference from test 2 to test 3, suggesting an improvement.

Table 5: Pairwise comparisons

Measures	Test 1 vs Test 2	Test 1 vs Test 3	Test 2 vs Test 3
Step Length: Right	1.000	0.831	0.093
Step Length: Left	1.000	0.116	P <0.05
Stride Length: Right	1.000	0.580	0.176
Stride Length: Left	1.000	0.368	0.053
6- Minute Walk Test	0.713	0.926	0.096

Table 6: Greenhouse- Geisser

Measures	Significance
Step Length: Right	0.178
Step Length: Left	P<0.05
Stride Length: Right	0.133
Stride Length: Left	0.078
6- Minute Walk Test	0.078

5.3 Balance Test Results

Table 7 shows the mean and standard deviation of the 3 time periods (pre and post no intervention and then post locomotive training) of balance testing for the parallel stance. There were no significant changes to balance testing at any timepoints. However, there were changes seen in the balance x and y from pre and post locomotive training, however this did not reach significance.

Table 7: Balance Test Means and Standard Deviation

	Test1X	**Test1Y**	**Test2X**	**Test2Y**	**Test3X**	**Test3Y**
Mean	.0244	.0264	.0250	.0225	.0137	.0286
Standard Deviation	.00996	.01304	.01284	.01716	.00635	.00756

Table 8 indicates that there was no improvement between test one to test two in balance ability. It is seen that after 12 weeks of locomotor training between test two and test three no significance in improvement has occurred, however, there is a good improvement being seen in the balance results indicating that with more time a significant improvement could occur.

Table 8: Paired T-Test; Balance

	Test One VS Two	**Test Two VS Three**
X Value (side to side)	.930	.059
Y Value (forward to back)	.409	.349

Chapter Six: Discussion

6.1 Overview of Study

The purpose of this research was to demonstrate the effectiveness of bodyweight assisted locomotive therastride training on individuals with MS. Six multiple sclerosis participants completed 12 weeks of normal treatment, followed by 12 weeks of reduced bodyweight assisted locomotive therastride training, twice a week. Step and stride length, 6 minute walk test, and balance were measured pre and post each 12 week period.

6.2 Statement of Findings

This study demonstrated a statistically significant increase in step and stride length, and 6-minute walk distance. There was statistical indication that balance showed improvements. This supported the original hypothesis and demonstrates the evidence for the successful implementation of locomotive therastride training for individuals with multiple sclerosis.

6.3 Step Length Results

Multiple sclerosis leads to impaired muscle function, often resulting in weakness, muscle dystrophy, fatigue and decreased ambulation. A reduction in ambulation is oftern bought about by poor gait which affects independence, function, social interaction, and consequently quality of life (Givon et al., 2009. It is also reported as the most commonly impaired body function amongst those with MS (Flegel et al., 2012), affecting more then 85% (Allali et al., 2014; Martin et al., 2006; Givon et al., 2009). Step length has been reported to be a reliable indicator in detecting subtle gait dysfunction. It is a valid test for measuring gait function improvement for those with MS (Flegel et al., 2012), and a good indication of left to right imbalances between lower limbs (Flegel et al., 2012). Step length is the distance measured between ipsilateral and contralateral heel contact. As gait is one of the most commonly impaired functions resulting from MS, step length measurement was used to identify this dysfunction and bring to light the purpose of locomotive in

aid against impaired gait. Step length for healthy individuals has been measured to be 69.5cm on average, for males this is 74cm and for females it is 66cm (Burnfield & Christopher, 2006). From the results of this study, it can be seen that the step length for MS individuals is significantly reduced compared to healthy populations, with the mean step length for the right foot being 36cm and the left foot being 29cm. Following the 12 weeks of locomotive therapy training, individuals improved 25% to achieve a 44cm step length on the right foot and 43% improvement on the left foot at 39cm. This indicates to us that although still heavily impaired, compared to the healthy population, these individuals improved significantly. As a result of heavily impaired step length it is common for MS individuals to experience a lack of balance. Individuals with MS often walk slower, and take much smaller steps, with a wider base of support, in order to provide themselves with the feeling of stability (Kalron et al., 2014). The heightened awareness of the risk of falling can result in a decrease in step length and a reduction in ability (Cattaneo et al., 2007). Locomotive body weight assisted treadmill training provides an exercise format that removes the fear of falling due to the safety of the harness. In the current study individuals were able to feel safe while exercising which may have in turn boosted confidence, that is needed to increase step length and repetitively practice an extended step length. This consequently improved balance and gait function.

For the majority of individuals, the left side of the body was more imparied than the right, so to see a greater improvement on the left side is worth acknowledging. Other studies investigating gait found similar impairments in step length as a result of multiple sclerosis (Motl et al., 2013). Motl et al. (2013), found that when measuring step length in 256 individuals with MS and an EDSS score ranging from 0-4, there was an average step length of 61.2cm. This is less impaired than our results, however, this is largely EDSS dependent. The range of EDSS scores of participants for this study was 6-8, indicating a lot more severity in their disability. This difference in EDSS is important to acknowledge as it highlights the importance of EDSS score in the current research and lack of research around those with a higher EDSS score and consequently functional ability.

Comparatively, Guner and Inanici (2015), completed a study measuring step length pre and post yoga therapy for individuals with MS (EDSS 0-6). The results concluded a step length improvement from 45cm to 49cm after 12 weeks of biweekly 60 minute yoga sessions. This is an

8.8% improvement in step length. In the current study, step length for the left foot improved by 43% and for the right foot by 25%. This indicates that locomotive is a more beneficial form of treatment for improving step length. There is a lack of current data regarding exercise types and MS, this made it difficult to provide a comparison between other forms of exercise and locomotive. More research is required to make comparisons between modes of exercise for MS individuals.

6.4 Stride Length Results

Stride length is the distance measured from heel to heel ground contact of the same foot during a gait cycle. A healthy individual has an average stride length of 139cm, with males on average having a longer stride of 148cm than females at 132cm (Burnfield & Christopher, 2006). In comparison, the current study indicates that individuals with MS have an impaired stride length of 61.5cm. With locomotive exercise training this can be improved to 80cm. The significance in improvement indicates the benefit of locomotive training. Participants declined by 2.3% on the right side and 0.8% of the left side following 12 weeks of inactive rehabilitation. After participating in 12 week of locomotive therastride training individuals improved by 29% on the right side and 31.6% on the left side. Similarly, Gehlsen et al. (1986), investigated gait characteristics in multiple sclerosis individuals pre and post a 10 week aquatic exercise training program and found notable differences in stride length. The mean result of the 11 participants pre training was 120cm with a 2.5% increase in stride length following the exercise intervention. This comparative to the current studies shows a less significant improvement. This may be due to the non-specific nature of aquatic exercise to gait characteristics (Gehlsen et al., 1986). Notably, there was mention of the decrease in asymmetrical differences in the right to left stride length, and although insignificant, it points to the effect of exercise in correcting the bodies imbalances. This similarly was seen in the current study as the imbalances between the left and the right side reduced by 46.4%. Locomotive exercise therapy not only improves gait through stride length, but helps align the differences in imbalances between the left and the right leg. This is beneficial for gait patterns, balance, and future body function.

6.5 Six Minute Walk Test Results

Walking function is heavily impaired through symptoms of MS such as gait, motor control, fatigue, and balance. Our results indicate that body weight assisted treadmill training can result in significant improvements in walking functions, demonstrated through a clinical measurement of the 6MWT. The 6MWT is used as a clinical measurement of sub-maximal exercise capacity and is a perfect testing measure for individuals with neurological conditions (Dean et al., 2001). Collectively, the individual's baseline distance for the 6MWT in the current study was 126.03m, and when compared to the health population at 660m, there is a 424% difference (Dean et al., 2001). This indicates some significant differences in walking ability between healthy individuals and those in the current study with MS. Following 12 weeks of no locomotive intervention the individual's performance in the 6MWT dropped by 28%. This is expected and supported in literature in the study by Rietberg et al. (2005), which shows that no intervention or exercise therapy for individuals with MS is detrimental in regards to muscle function and mobility. On the contrary, locomotive body weight assisted treadmill training shows a significant improvement in results following the 12 week training period. The results indicated a 50% improvement in 6MWT as individuals improved from 97.98m to 147.04m. Although still significantly less than a healthy population, it is a significant improvement in walking ability ($p=0.032$). This finding is supported in current literature in suggesting that individuals with multiple sclerosis have a significant reduction in walking function and ability, but can be aided through exercise (Snook & Motl, 2009).

Similar to our results, Lo & Triche (2008), found in their own study on body weight assisted treadmill training using 13 individuals with MS, that gait showed significant improvements following as short as 3 weeks of BWSTT from baseline to conclusion of intervention. The study used 6MWT as a form of treatment measurement and found that the participants showed significant improvements of 38.5% after just 5 sessions of locomotive training. Overall the study by Lo and Triche (2008), concluded that as little as 3 weeks of BWSTT showed a reduction in gait disability and showed no negative impact on induced fatigue or weakness. Morrison et al., (2012), also found that when using body weight assisted treadmill training with incomplete spinal cord injuries, 6MWT was improved following 100 sessions with a 111% improvement in walking distance over the 6 minute period. Comparatively, this current research was only performed over

a 12 week period of 24 sessions and indicated a 50% improvement. This demonstrates that using the results from Morrison's study, it can be suggested that a continual improvement in 6MWT would be seen following another 12 weeks of locomotive intervention.

Other forms of exercise therapy, such as endurance training, in a study by Sabapathy et al. (2011), shows improvements of only 3.9% in the 6MWT after a twice weekly, 8 week aerobic training program. This same study also measured resistance training over an 8 week period and saw only an 8.7% increase in walking ability following the 6MWT. The 16 subjects' disabilities were measured using the Disease Steps Scale, and ranged from 1 to 3 (equivalent of 1-6 on the EDSS scale). This indicates that locomotive therapy is the better form of exercise intervention for more heavily impaired individuals with multiple sclerosis when aiming to improve walking performance as measured by the 6MWT. Overall, it can be said that body weight assisted treadmill training provides a significant impact on 6MWT results, improving exercise capacity for individuals with MS.

6.6 Balance Test Results (Force Plate Measurement)

Balance is a heavily impaired factor in regard to multiple sclerosis. The force plate balance test results showed us that locomotive training had a positive impact on the individual's balance. As the participants are of a vulnerable nature, requiring them to balance without any means of support would not be possible. Mobility aids are commonly used for rehabilitation from neuromuscular injuries. This means that the balance measurements were taken with the possibility of individuals using support aids. However, as each individual was set up in the same testing procedure each round, the same advantages and disadvantages were considered each time. John J Jenka (1997), performed a study on the effects of mobility aid such as canes and crutches on balance. He stated that mobility aids are commonly used for neuromuscular rehabilitation and suggested that individuals with gait disorder, due to neurological dysfunction, are often capable of generating enough force to maintain stable ambulation, but due to neurological damage often need sensory information input (i.e., walking aid) to bridge the gap from neurological trauma. The addition of a walking aid can often be a result of the comfort it provides and less to do with the physical support with its primary function to reduce risk of falls and increase confidence. In this study, all

participants used a walking aid to get to and from the facility, but once on the locomotive therastride treadmill were supported by the overhead harness. Our results suggest that locomotive therapy improves balance. The side-to-side movement shows indication of approaching significant improvements ($p=0.059$). The forward and backwards movement shows improvement although not significant ($p=0.349$). All participants stated that balance was improved following locomotive training and that everyday tasks were easier to attend to. Similarly, the study by Cattaneo et al. (2007), investigated the effects of balance exercise on individuals with MS, using a range of rehabilitation methods such as sensory tasks and motor control activities to secure a result. The limitation, however, is that the inclusion criteria was for individuals to have the ability to stand independently for 30 seconds or more, and for the individual to be able to walk for 6 meters. As this makes it easier to conduct an investigation it once again limits the results to individuals with an EDSS score of less than 6. This points to why individuals in this current study had to be given the use of a walking aid to perform balance measurements. Without aid, the current study would have only been able to use people with an EDSS score of less than 6. The aim of this study is to show the benefits of locomotive therastride training on individuals with MS and provide results for individuals with a higher EDSS score. Locomotive therastride training uses the harness as a support mechanism so that those with balance issues from MS were still able to participate in the study. Although the results do not suggest a significant improvement in balance, it can definitely be indicated that balance is improved. Had the locomotive therastride intervention been extended we may have seen a significant improvement in the results.

6.7 Limitations

This study was a pilot study, with a small sample pool of six. As the standard deviations indicated, the range in abilities between participants was large. This meant that there was a slight lack of sufficient statistical power due to the strong impact of the outliers. Having a larger sample pool would have eliminated the strength of this impact within the data. It can be assumed that this is a common consequence of research involving high scoring EDSS individuals, as this population has a higher severity/variation of MS symptoms.

A second limitation to the study that is uncontrollable is the nature of the participants. This meant that not all sessions were completed twice weekly for consecutive weeks. At the initial phase of the training, it was common for participants to experience feelings of nausea, faintness, and overheating. This meant that there were sessions that were cut short, and the build-up to a complete training session took a couple weeks. These symptoms took about 2-3 weeks to subside as the participants adjusted to taking part in exercise, and showed positive progression from then on. This added a further limitation to the initial progression of the training, as we were limited by the nature of the participant, and the side effects of exercise exertion as the participants adjusted to taking part in exercise. This also demonstrated the secondary side effects that are imposed on these individuals because of their limited ability to move and the lack of access to exercise they are offered. This also meant that some participants only completed 20 sessions over the 12 weeks, and some participants took a couple extra weeks to complete the 24 sessions.

6.8 Recommendations for Future Studies

Based on the outcome of this study, future studies may benefit from increasing the sample pool size. This current research was performed using a sample pool of six participants. Although effective, for a pilot study it would be more valid if the sample size was increased to demonstrate the significance in improvement of locomotive training that was shown in the paired t-test but not in the ANOVA. Due to the small sample size, the variance in ability played a significant role on the final statistics due to the standard deviation. As the standard deviation was so big, and the abilities were so broad an impact was had on final results.

Secondly, a larger sample pool would allow more factors to be considered when examining the small data such as gender and age. As males and females have different normative data, it would be beneficial to break the future studies into different groups, allowing for a more accurate comparison of data between normative and impaired individuals. Age would be a factor that could be heavily influential on EDSS, as more time passes the more progressed the disease may be. As these are factors that contribute to normative data and disease progression, it would be ideal to be able to incorporate them into the results.

Significantly, future studies should consider to continue looking at EDSS scores of 6 or above. This is an area where individuals need greater support and knowledge on exercise therapies that suit their needs. Safety and accessibility to exercise methods that will allow even the most impaired to have a chance at improving. As the majority of studies all use individuals with EDSS scores of lower than 6 (relatively functional), this then limits the use of the information for the advanced MS population. This specific study did incorporate higher EDSS scores, and would encourage other studies to do the same, as this is where the information is lacking most.

A future investigation into locomotive and MS should consider extending the period of training time past three months, to examine the potential of plateaus, or the impacts of relapses and deterioration. As MS is a degenerative disease, examining the impacts of locomotive following an extended period of time would be beneficial to solidify the impact it could potentially have in aiding against the long term effects of MS. This would give greater indication as to why locomotive therapy should be offered as a treatment method, implemented by the healthcare system.

For future studies, I recommend taking measures of electromyography (EMG). This would give an understanding of the changes in neuroplasticity that could occur over the 12 weeks of locomotive training, and give a better understanding of the activation occurring in the muscles. Due to the population being measured, it would be recommended to take muscle voluntary contraction (MVC) measurements lying down. This way participants are more likely to isolate the muscle being tested, and less likely to depend on another muscle in assisting the movement. This enables a more accurate measurement of full muscle strength of a particular muscle. Due to the nature of the participants, standing measurements can be ineffective as it means balance is compromised and participants do not produce maximum force.

Chapter Seven: Conclusion

The purpose of this study was to examine the effect that locomotive therastride training has on individuals with MS. The study demonstrated that locomotive training is a beneficial and safe means of exercise for people with multiple sclerosis. Areas that were particularly examined were; the components of gait function, step and stride length, balance, and the 6 minute walk test to measure overall walking capacity. Through analysing all of the variables, it is hoped that it will become widely known that locomotive body weight assisted training is a beneficial and safe mode of training for individuals with MS, particularly those with an EDSS score above 6.

The study identified some exceptional physical responses of body weight assisted locomotive training. The study indicated the decline or stationary effect of not taking part in any form of exercise through a 12 week period of no active rehabilitation. This demonstrated that if individuals with MS do not partake in any form of exercise, their symptoms will worsen and deterioration is inevitable. After the 12 weeks of locomotive therastride training, participants all showed significant improvements in the majority of tested variables. 6MWT, step length, and stride length, all improved substantially. Balance results showed no clinical significance in improvement, but demonstrated strong indications that, had the sample pool been bigger, statistical improvements would be seen. This research demonstrated admirable results in favour of locomotive therapy. It also demonstrated an effective form of safe exercise for individuals with a higher EDSS score that other forms of exercise do not provide. The hope is for this information to provide some support for body weight assisted locomotive therapy, so it can be utilized for the multiple sclerosis population, in aid of symptom management and to provide a better quality of life. All individuals with MS should be offered exercise as a form of therapy or treatment to aid daily functioning and quality of life as well as reducing falls and deterioration of their symptoms.

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Chapter Nine: Appendices

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Private Bag 11 222
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New Zealand
Telephone: 64 6 350 4336
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PARTICIPANT INFORMATION SHEET

Study title:	*Multiple Sclerosis Activity Based Locomotive Exercise Therapy Program*		
Locality:	**Massey University, Palmerston North**	Ethics committee ref.: 20/CEN/84 Provisionally approved	
Lead investigator:	**Dr Lynette Hodges**	Contact phone number:	**063569099**

You are invited to take part in a pilot study which is part of a Master's research project. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time.

This participant information sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the consent form on the last page of this document. You will be given a copy of both the participant information sheet and the consent form to keep.

This document is 7 pages long, including the consent form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Individuals with multiple sclerosis can struggle to maintain independence and may need the assistance of a wheelchair or crutches as the disease progresses. The purpose of the study is to produce evidence-based research demonstrating the importance of locomotor bodyweight support treadmill training on regaining muscle activation, independent walking, increasing step and stride length and balance in individuals with multiple sclerosis.

The study is being carried out by Dr Lynette Hodges at Massey University, from the School of Sport and Exercise. Lynette can be contacted by telephone on 063569099 or by e-mail: L.d.hodges@massey.ac.nz and would be happy to answer any questions you may have. P-20/CEN/84- Provisionally Approved Application – 20th April 2020.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been identified for the study because you have been diagnosed with Multiple Sclerosis and are unable to walk further than 500m independently. Ten individuals will take part in the study. All individuals at individual times will visit the Human Performance Lab, at Massey University Palmerston North.

Entry Testing

On entry to the program all participants with have their Expanded Disability Status identified, muscle activity, step, stride length and balance measured as well as completing the 10m and 6-minute walk test.

Locomotive bodyweight support treadmill training program

All participants will complete 36 sessions of locomotive bodyweight support treadmill training across a 12-week period. Each session will be one-hour in duration. You will be required to wear a harness which will be provided. The exercise will consist of 20 squats and 5 x 5 minutes of body weight supported treadmill walking at speeds ranging from 0.5 mph to 1.5 mph depending on ability and support required.

Exit Testing

All participants with have their Expanded Disability Status identified, muscle activity, step, stride length and balance measured as well as completing the 10m and 6-minute walk test.

Muscle activity assessment

Each participant will need to wear shorts. Whilst lying down, electrodes will be placed on the upper and lower legs (bicep femoris, rectus femoris, tibialis anterior and gastrocnemius). The equipment will then be calibrated to zero before proceeding with maximal voluntary contractions (MVC). MVC are performed prior to testing to provide a normalized reference point for each participant. The participants will put on the Therastride harness and will complete two bouts of 3 minutes of assisted walking (1 x bout at 0.5 mph and 1 x bout at 0.9 mph). Following this they will complete a further assisted walk on the Therastride treadmill for 1 minute at a speed of 0.9mph, where a segment of muscle activity will be recorded.

Step and stride length assessment

Step length is measure of left to right imbalance. You will be asked to walk for 10 steps. Each time your heel strikes the ground a mark will be placed at the heel. The distance will be measured between left and right heel strikes.

Stride length is the distance between two successive placements of the same foot. You will be asked to walk for 10 steps. Each time your left foot strikes the ground, a mark will be placed at the heel. The distance will be measured between your left heel strokes. You will be asked to repeat this on your right foot. The distance will be measured between your right heel strokes.

Balance measurement

Balance will be assessed using the inground force plate. You will be asked to stand on the force plate with the feet in a

- normal parallel position, with eyes open for up to 15 seconds
- instep pf one foot so it is touching the big toe of the other foot, with eyes open for up to 15 seconds.
- In the stance of heel-to-toe with eyes open for up to 15 seconds

10m Walk Test

This is a test of lower limb strength. You will be asked to walk 10m at a comfortable speed. You can use mobility aids if required. The time taken from an average of 3 tests, is used to calculate gait speed.

6-minute walk test

The 6-minute walk test will assess your functional exercise capacity. Your blood pressure and heart rate will be measured before the walk. You will be asked to walk up and back long a 30m track for up to 6 minutes. The test can be reduced to 2 minutes if you are finding this difficult. During the test, you are allowed to stop and rest. You can also use mobility aids if required. Your heart rate will also be measured following completion of the walking test.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The procedures involved in this study are of low risk. Nevertheless, as in any invasive procedures there are small risks and some discomfort may be experienced

Exercise testing

There is the possibility of certain changes occurring during and after intense exercise. These may include; abnormal blood pressure, dizziness, fainting, abnormal heart rate or rhythm, muscular soreness, sprains, strains and fractures, nausea and vomiting, mild to severe breathlessness, and in rare circumstances heart attack, stroke or even death, and feeling more fatigued than usual.

Every effort is made to minimise these risks by careful evaluation of the information supplied by you regarding the state of your health and current fitness level and by careful observations of heart rate, blood pressure.

In the event of a medical emergency, whilst laboratory personnel are trained in basic life support procedure, the local ambulance service will be summoned in the usual way. The human performance lab has a defibrillator and all staff are trained in its use. All researchers have current first aid at work qualifications.

Benefits

The results obtained in this study will be used to develop and guide exercise prescription for individuals with multiple sclerosis and help those with significant mobility difficulties regain independence.

WHO PAYS FOR THE STUDY?

All costs incurred by the study will be funded by Massey University. Participants will not incur any costs. Any parking costs associated with the study will be reimbursed.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible to apply for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

- *You are free to withdraw or can decline to participate from the research at any time without any penalty.*
- *You can request information from the data collection about you at any time during the research study.*
- *We will tell you any new information about locomotive exercise training for MS including any adverse or beneficial effects that we find during the study that may have an impact on your health.*
- *All information will be stored on a password protected computer and a locked filing cabinet during the study to maintain the privacy and confidentiality of all individuals.*

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If a participant withdraws during the study any information that is collected about that participant up until the point they withdraw will be continued to be processed in the study.

With permission, we may contact you for future research studies.

Study data will be stored for in a locked filing cabinet at Massey University, sport and exercise facility and a password protected computer for 10 years. Dr Lynette Hodges, primary investigator and co-investigator Rebecca Smith will have access to the stored information. The auditors of HDEC can also access the data if required. After 10 years, all information will be destroyed by the researcher via a confidentiality waste refuse bin.

The findings of the study will be communicated to the patients, on completion of the study via a report which will be sent to each patient and a presentation which will be completed at the local groups for MS within 6 months of the cessation of the study.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns or complaints about the study at any stage, you can contact: Lynette Hodges, Lecturer in Sport and Exercise, Phone: 063569099 or E-mail: L.d.hodges@massey.ac.nz.

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800555050
Fax: 08002SUPPORT(080027877678)
Email: advocacy@hdc.org.nz

For Maori health support please contact :

Bevan Erueti: Maori Cultural Advisor
Phone: 06 356 9099 Ext 83087
E-mail: B.Erueti@massey.ac.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

MASSEY UNIVERSITY
School of Sport, Exercise and Nutrition
Private Bag 11 222
Palmerston North
New Zealand
Telephone: 64 6 350 4336
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INFORMED CONSENT FORM

If you need an INTERPRETER, please tell us.

Please tick to indicate your consent to the following

1. I have read or have had read to me in my first language, and I understand the Participant Information Sheet
2. I have been given sufficient time to consider whether or not to participate in this study
3. I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
4. I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
5. I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
6. I consent to the research staff collecting and processing my information, including information about my health.
7. I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.
8. I understand that there may be risks associated with the treatment
9. I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
10. I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
11. I understand the compensation provisions in case of injury during the study.
12. I know who to contact if I have any questions about the study in general.
13. I understand my responsibilities as a study participant.

Do you agree to be contacted in the future about other relevant studies Yes No

Do you wish to receive a summary of the results from the study Yes No

Declaration by participant:

I hereby consent to take part in this study.

Participant's name:

Signature: Date:

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name:

Signature: Date:

Kurtzke Expanded Disability Status Scale (EDSS)

❑ 0.0 - Normal neurological exam (all grade 0 in all Functional System (FS) scores*).

❑ 1.0 - No disability, minimal signs in one FS* (i.e., grade 1).

❑ 1.5 - No disability, minimal signs in more than one FS* (more than 1 FS grade 1).

❑ 2.0 - Minimal disability in one FS (one FS grade 2, others 0 or 1).

❑ 2.5 - Minimal disability in two FS (two FS grade 2, others 0 or 1).

❑ 3.0 - Moderate disability in one FS (one FS grade 3, others 0 or 1) or mild disability in three or four FS (three or four FS grade 2, others 0 or 1) though fully ambulatory.

❑ 3.5 - Fully ambulatory but with moderate disability in one FS (one grade 3) and one or two FS grade 2; or two FS grade 3 (others 0 or 1) or five grade 2 (others 0 or 1).

❑ 4.0 - Fully ambulatory without aid, self-sufficient, up and about some 12 hours a day despite relatively severe disability consisting of one FS grade 4 (others 0 or 1), or combination of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 500 meters.

❑ 4.5 - Fully ambulatory without aid, up and about much of the day, able to work a full day, may otherwise have some limitation of full activity or require minimal assistance; characterized by relatively severe disability usually consisting of one FS grade 4 (others or 1) or combinations of lesser grades exceeding limits of previous steps; able to walk without aid or rest some 300 meters.

❑ 5.0 - Ambulatory without aid or rest for about 200 meters; disability severe enough to impair full daily activities (e.g., to work a full day without special provisions); (Usual FS equivalents

are one grade 5 alone, others 0 or 1; or combinations of lesser grades usually exceeding specifications for step 4.0).

❑ 5.5 - Ambulatory without aid for about 100 meters; disability severe enough to preclude full daily activities; (Usual FS equivalents are one grade 5 alone, others 0 or 1; or combination of lesser grades usually exceeding those for step 4.0).

❑ 6.0 - Intermittent or unilateral constant assistance (cane, crutch, brace) required to walk about 100 meters with or without resting; (Usual FS equivalents are combinations with more than two FS grade 3+).

❑ 6.5 - Constant bilateral assistance (canes, crutches, braces) required to walk about 20 meters without resting; (Usual FS equivalents are combinations with more than two FS grade 3+).

❑ 7.0 - Unable to walk beyond approximately 5 meters even with aid, essentially restricted to wheelchair; wheels self in standard wheelchair and transfers alone; up and about in wheelchair some 12 hours a day; (Usual FS equivalents are combinations with more than one FS grade 4+; very rarely pyramidal grade 5 alone).

❑ 7.5 - Unable to take more than a few steps; restricted to wheelchair; may need aid in transfer; wheels self but cannot carry on in standard wheelchair a full day; May require motorized wheelchair; (Usual FS equivalents are combinations with more than one FS grade 4+).

❑ 8.0 - Essentially restricted to bed or chair or perambulated in wheelchair, but may be out of bed itself much of the day; retains many self-care functions; generally has effective use of arms; (Usual FS equivalents are combinations, generally grade 4+ in several systems).

❑ 8.5 - Essentially restricted to bed much of day; has some effective use of arm(s); retains some self-care functions; (Usual FS equivalents are combinations, generally 4+ in several systems).

❑ 9.0 - Helpless bed patient; can communicate and eat; (Usual FS equivalents are combinations, mostly grade 4+).

❑ 9.5 - Totally helpless bed patient; unable to communicate effectively or eat/swallow; (Usual FS equivalents are combinations, almost all grade 4+).

❑ 10.0 - Death due to MS.

*Excludes cerebral function grade 1.

Note 1: EDSS steps 1.0 to 4.5 refer to patients who are fully ambulatory and the precise step number is defined by the Functional System score(s). EDSS steps 5.0 to 9.5 are defined by the impairment to ambulation and usual equivalents in Functional Systems scores are provided.

Note 2: EDSS should not change by 1.0 step unless there is a change in the same direction of at least one step in at least one FS.

Sources: Kurtzke JF. Rating neurologic impairment in multiple sclerosis: an expanded disability status scale (EDSS). Neurology. 1983 Nov;33(11):1444-52. Haber A, LaRocca NG. eds. Minimal Record of Disability for multiple sclerosis. New York: National Multiple Sclerosis Society; 1985.

Training Log Summary

	Date	Session Number	Average Speed	Average time	BW Reduced	Average quantity	Notes
Participant 1 (Martin)	15.2.2021	1	0.8mph	3	32%	5	
	16.2.2021	2	0.8mph	3	30%	5	
	22.2.2021	3	0.8mph	3	30%	5	
	23.2.2021	4	0.8mph	3	15%	4	
	2.3.2021	5	0.8mph	3	15%	6	
	8.3.2021	6	0.8mph	3	15%	6	
	22.3.2021	7	1.0mph	3	15%	6	
	29.3.2021	8	1.0mph	3	15%	6	
	30.3.2021	9	0.8mph	3	15%	6	
	13.4.2021	10	1.0mph	3	15%	6	
	27.4.201	11	1.0mph	3	15%	6	

	3.5.2021	12	1.0mph	4	15%	4	
	4.5.2021	13	1.0mph	4	10%	5	
	105.2021	14	1.0mph	4	10%	5	
	11.5.2021	15	1.0mph	5	20%	4	Pretty tired and stiff pre session
	17.5.2021	16	1.0mph	5	15%	4	
	18.5.2021	17	1.0mph	6	15%	4	
	25.5.2021	18	1.0mph	6	15%	4	
	Date	**Session Number**	**Average Speed**	**Average time**	**BW Reduced**	**Average quantity**	**Notes**
Participant 2 (Berni)	18.2.2021	1	0.5mph	3	30%	3	
	22.2.2021	2	0.5mph	3	30%	2	
	1.3.2021	3	0.5mph	3	30%	3	
	8.3.2021	4	0.5mph	3	30%	3	
	11.3.2021	5	0.5mph-0.8mph	3	30%	4	Client states they have better lift in their foot
	15.3.2021	6	0.8mph	3	30%	4	Massage practitioner stated

							she was feeling better and more agile. Caregiver also said it is much easier to shower her
	18.3.2021	7	0.8mph	3	30%	4	
	22.3.2021	8	0.5mph-0.8mph	3	30%	4	
	8.4.2021	9	0.8mph	3	30%	5	
	12.4.2021	10	0.8mph	3	30%	5	
	15.4.2021	11	0.8mph	3	30%	5	
	19.4.2021	12	0.5mph-0.8mph	3	30%	5	
	3.5.2021	13	0.8mph	3	30%	5	
	10.5.2021	14	0.8mph	3	30%	5	
	17.5.2021	15	0.8mph	3	30%	5	
	20.5.2021	16	0.8mph	4	30%	4	
	24.5.2021	17	0.8mph	4	30%	4	
	27.5.2021	18	0.8mph	4	30%	4	

	Date	Session Number	Average Speed	Average time	BW Reduced	Average quantity	Notes
Participant 3 (Joanne)	9.2.2021	1	0.5mph-0.8mph	3	30%	5	
	11.2.2021	2	0.5mph-0.9mph	3	30%	5	
	16.2.2021	3	0.5mph-0.9mph	3	30%	5	
	18.2.2021	4	0.9mph	3	30%	4	
	25.2.2021	5	0.5mph-1.0mph	3	15%	5	
	2.3.2021	6	0.5mph-1.0mph	3	15%	5	
	4.3.2021	7	0.5mph	3	15%	4	Really tired and fatigued, long day yesterday
	9.3.2021	8	0.5mph-0.8mph	3	15%	5	
	11.3.2021	9	0.8mph	3	15%	5	
	16.3.2021	10	0.8mph	3	25%	5	
	18.3.2021	11	0.5mph-0.8mph	3	25%	5	
	30.3.2021	12	0.8mph	3	15%	5	

	1.4.2021	13	0.8mph	3	15%	5	
	8.4.2021	14	0.8mph	3	15%	5	
	13.4.2021	15	0.8mph	3	25%	6	
	15.4.2021	16	0.8mph	3	25%	6	
	21.4.2021	17	0.8mph	3	15%	5	
	27.4.2021	18	0.8mph-1.0mph	3	15%	6	
	29.4.2021	19	0.8mph-1.0mph	3	15%	6	
	10.5.2021	20	1.0mph	3	15%	6	
	18.5.2021	21	1.0mph	4	15%	5	
	20.5.2021	22	1.0mph	4	20%	4	
	25.5.2021	23	1.0mph	4	15%	4	
	27.5.2021	24					
	Date	**Session Number**	**Average Speed**	**Average time**	**BW Reduced**	**Average quantity**	**Notes**
Participant 4 (Deanna)	18.2.2021	1	0.5mph	3	30%	3	

	23.2.2021	2	0.5mph	3	15%	3	Pale after finishing, said she was ok but didn't look great
	25.2.2021	3	0.5mph	3	15%	3	
	2.3.2021	4	0.5mph	3	15%	4	
	4.3.2021	5	0.5mph-0.8mph	3	11%	4	
	9.3.2021	6	0.5mph-0.8mph	3	11%	4	
	23.3.2021	7	0.8mph	3	15%	5	
	25.3.2021	8	0.8mph	3	15%	5	
	30.3.2021	9	0.8mph	3	20%	5	
	1.4.2021	10	0.8mph-1.0mph	3	20%	5	No Help
	8.4.2021	11	0.8mph	3	15%	5	No Help
	13.4.2021	12	0.8mph	3	15%	5	No Help
	15.4.2021	13	0.8mph	3	15%	5	No Help
	21.4.2021	14	0.8mph	3	15%	5	No Help
	27.4.2021	15	0.8mph	3	15%	6	No Help

	4.5.2021	16	0.8mph	3-4	10%	4	No Help
	6.5.2021	17	0.8mph	3	20%	5	Not feeling great today, had a small melt down so we took it easier. No Help
	18.5.2021	18	0.8mph	4	20%	4	No Help
	20.5.2021	19	0.8mph	4	15%	4	No Help
	25.5.2021	20	1.0mph	4	15%	4	No Help
	Date	**Session Number**	**Average Speed**	**Average time**	**BW Reduced**	**Average quantity**	**Notes**
Participant 5 (Stewart)	11.2.2021	1	0.5mph	3	50%	5	
	15.2.2021	2	0.5mph	3	45%	5	
	18.2.2021	3	0.2mph-0.5mph	3	45%	4	
	22.2.2021	4	0.2mph-0.5mph	3	45%	5	
	25.2.2021	5	0.5mph	3	45%	5	
	1.3.2021	6	0.5mph	3	45%	4	

	4.3.2021	7	0.5mph	3	45%	5	Client states it is easier to go to the toilet as he has more balance now
	8.3.2021	8	0.5mph	3	45%	5	Client states he finds it easier to get to the kitchen after dinner and is more likely to be active around the house as it is easier to do so makes more of an effort.
	11.3.2021	9	0.5mph-0.8mph	3	45%	5	
	15.3.2021	10	0.5mph-0.8mph	3	45%	5	
	18.3.2021	11	0.5mph-0.8mph	3	45%	5	
	22.3.2021	12	0.5mph-0.8mph	3	45%	5	
	25.3.2021	13	0.5mph	3	45%	4	Left foot lifted when walking to the toilet in the morning instead of dragged for a moment.

	29.3.2021	14	0.5mph	3	45%	5	
	1.4.2021	15	0.5mph	3	45%	5	
	8.4.2021	16	0.5mph	3	45%	5	
	12.4.2021	17	0.5mph	3	40%	5	
	15.4.2021	18	0.5mph	3	40%	5	
	19.4.2021	19	0.5mph	3	40%	6	
	3.5.2021	20	0.5mph	4	40%	5	
	6.5.2021	21	0.5mph	3	35%	5	
	17.5.2021	22	0.5mph	3	35%	5	
	20.5.2021	23	0.5mph	4	35%	4	
	24.5.2021	24	0.5mph	4	35%	4	
	Date	**Session Number**	**Average Speed**	**Average time**	**BW Reduced**	**Average quantity**	**Notes**
Participant 6 (Jonathan)	9.2.2021	1	0.5mph-0.8mph	3	30%	4	
	22.2.2021	2	0.5mph-0.8mph	3	30%	5	

	23.2.2021	3	0.8mph-1.0mph	3	15%	5	
	1.3.2021	4	0.8mph-1.0mph	3	15%	5	
	2.3.2021	5	0.8mph-1.0mph	3	15%	5	
	8.3.2021	6	0.8mph-1.0mph	3	15%	5	
	9.3.2021	7	1.0mph	3	15%	4	
	15.3.2021	8	1.0mph	3	25%	5	
	16.3.2021	9	1.0mph	3	25%	5	
	22.3.2021	10	1.0mph	3	15%	5	
	23.3.2021	11	1.0mph-1.2mph	3	15%	6	
	29.3.2021	12	1.0mph-1.2mph	3	25%	6	
	12.4.2021	13	1.2mph	3	25%	5	No Help
	13.4.2021	14	1.0mph	3	15%	6	No Help
	19.4.2021	15	1.0mph-1.2mph	3	15%	4	Treadmill Broke No Help
	21.4.2021	16	1.0mph-1.2mph	3	15%	6	No Help
	27.4.2021	17	1.2mph	4	15%	5	No Help
	3.5.2021	18	1.2mph	4	15%	5	No Help

	4.5.2021	19	1.2mph	4	10%	5	No Help
	10.5.2021	20	1.2mph	4	25%	4	Ran out of time No Help
	11.5.2021	21	1.2mph	4	10%	5	No Help
	17.5.2021	22	1.2mph	5	10%	4	No Help
	23.5.2021	23	1.2mph	5	10%	4	No Help
	25.5.2021	24	1.2mph	5	10%	4	No Help