Physiotherapy Interventions for Non-Ambulatory People with Multiple Sclerosis

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A thesis submitted in the fulfilment of the requirements for the degree of Master of Science at the University of Limerick

Supervised by Dr. Susan Coote

Submitted to the University of Limerick, May 2012
Abstract

This thesis is comprised of three papers that aim to examine the literature surrounding physiotherapy interventions in non-ambulatory people with Multiple Sclerosis (PwMS), to gather information from a pilot scheme of the Exercise Buddy system in community physiotherapy and to evaluate the system formally.

Multiple Sclerosis (MS) is an inflammatory neurological disease that has a considerable physical and psychological impact on those affected. Approximately one quarter of PwMS are non-ambulatory, but the amount of physiotherapy received by this population is limited. An Exercise Buddy system is where professional carers are employed to conduct home exercise programmes with PwMS under the guidance of physiotherapists, and may augment the amount of physiotherapy currently received by a non-ambulatory subgroup.

A systematic review on physical rehabilitation interventions in non-ambulatory PwMS was carried out that found very little high quality studies for this population. A series of semi-structured interviews were then carried out with the participants of a pilot scheme of the Exercise Buddy system. The system was found to have excellent potential to benefit PwMS and their carers both physically and psychologically, and that adequate communication and training of Exercise Buddies were crucial to the success of the system. A randomised crossover trial of 29 non-ambulatory PwMS and their carers was carried out which found significant improvements in the physical and psychological self-perceived impact of MS in PwMS. Disability levels in PwMS were maintained and large dropout rates in carers made it difficult to make definite conclusions about the effect of either intervention.

The thesis concludes with a summary of the findings and a discussion of the implications of these papers for current practice and future research.
Declaration

I declare that this thesis is entirely my own work and that it has not been submitted as an exercise for a degree at this or any other University. I am the author of this thesis and the principle author of the three articles which form the core of the thesis.

_______________________  (Printed Name)
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List of Tables

<table>
<thead>
<tr>
<th>Chapter 2: Paper I</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1.</td>
<td>Search strategies for databases 24</td>
</tr>
<tr>
<td>Table 2.</td>
<td>Exercise Interventions 25</td>
</tr>
<tr>
<td>Table 3.</td>
<td>Rehabilitation Interventions 26</td>
</tr>
<tr>
<td>Table 4.</td>
<td>Cooling Suit Interventions 27</td>
</tr>
<tr>
<td>Table 5.</td>
<td>Other Interventions: Therapeutic Standing 28</td>
</tr>
<tr>
<td>Table 6.</td>
<td>GRADE quality of studies 29</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 3: Paper II</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1.</td>
<td>Topic Guide for Interviews 55</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Chapter 4: Paper III</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Table 1.</td>
<td>Baseline characteristics 80</td>
</tr>
<tr>
<td>Table 2.</td>
<td>Carryover and period effect data 81</td>
</tr>
<tr>
<td>Table 3.</td>
<td>Summary of outcome measures and changes in outcome measures in PwMS 82</td>
</tr>
<tr>
<td>Table 4.</td>
<td>Carer outcome data 83</td>
</tr>
</tbody>
</table>
# Table of Figures

<table>
<thead>
<tr>
<th>Chapter 2: Paper I</th>
<th>Figure 1. Flowchart of included/excluded studies</th>
<th>30</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chapter 3: Paper II</td>
<td>Figure 1. Process of Exercise Buddy system</td>
<td>56</td>
</tr>
<tr>
<td>Chapter 4: Paper III</td>
<td>Figure 1. Flowchart of participants through study</td>
<td>84</td>
</tr>
</tbody>
</table>
### List of Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACQoL</td>
<td>Adult Carer Quality of Life</td>
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<td>ADL</td>
<td>Activities of daily living</td>
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<tr>
<td>AFO</td>
<td>Ankle-foot orthosis</td>
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<tr>
<td>BP</td>
<td>Blood pressure</td>
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<tr>
<td>EDSS</td>
<td>Expanded Disability Severity Scale</td>
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<td>EMG</td>
<td>Electromyography</td>
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<td>GNDS</td>
<td>Guy’s Neurological Disability Scale</td>
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<td>HEP</td>
<td>Home exercise programme</td>
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<td>HR</td>
<td>Heart rate</td>
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<tr>
<td>HSE</td>
<td>Health Service Executive</td>
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<tr>
<td>ICF</td>
<td>International Classification of Functioning, Disability and Health</td>
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<td>LL</td>
<td>Lower limb</td>
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<tr>
<td>MDR</td>
<td>Multidisciplinary rehabilitation</td>
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<td>MDT</td>
<td>Multidisciplinary team</td>
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<td>MRC</td>
<td>Medical Research Council</td>
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<td>MS</td>
<td>Multiple Sclerosis</td>
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<td>MSI</td>
<td>Multiple Sclerosis Ireland</td>
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<td>MSIS</td>
<td>Multiple Sclerosis Impact Scale</td>
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<tr>
<td>NRS</td>
<td>Numerical rating scale</td>
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<td>PCCC</td>
<td>Primary Community Continuing Care</td>
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<tr>
<td>PeMax</td>
<td>Expiratory muscle strength</td>
</tr>
<tr>
<td>PiMax</td>
<td>Inspiratory muscle strength</td>
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<tr>
<td>PROMs</td>
<td>Patient-reported outcome measures</td>
</tr>
<tr>
<td>PT</td>
<td>Physiotherapy</td>
</tr>
<tr>
<td>PwMS</td>
<td>People with Multiple Sclerosis</td>
</tr>
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<td>RCT</td>
<td>Randomised controlled trial</td>
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<td>RoM</td>
<td>Range of motion</td>
</tr>
<tr>
<td>UL</td>
<td>Upper limb</td>
</tr>
<tr>
<td>VAS</td>
<td>Visual analogue scale</td>
</tr>
</tbody>
</table>
# Table of Contents

Abstract .............................................................................................................................................. iii  
Declaration ........................................................................................................................................ iv  
Acknowledgements ............................................................................................................................... v  
List of Tables ........................................................................................................................................ vi  
List of Figures ....................................................................................................................................... vii  
List of Abbreviations ............................................................................................................................ viii  
Chapter 1: Introduction ............................................................................................................................ 1  
Chapter 2: Paper I “Physical rehabilitation interventions in non-ambulatory People with Multiple Sclerosis: a systematic review ” .......................................................... 8  
Chapter 3: Paper II “Augmenting physiotherapy in the community with ‘Exercise Buddies’: A series of semi-structured interviews investigating a pilot scheme ......................................................................................................................... 36  
Chapter 4: Paper III “Augmenting community physiotherapy with Exercise Buddies in non-ambulatory people with Multiple Sclerosis: a pilot randomised crossover study ” ........................................................................................................... 61  
Chapter 5: Conclusion ............................................................................................................................ 90
Chapter 1.

Introduction
**Introduction**

**Multiple Sclerosis**

Multiple Sclerosis (MS) is an inflammatory neurological disease which is associated with demyelination and widespread axonal loss within the central nervous system (Compston and Coles 2008). It is a chronic progressive condition that presents with a wide variety of physical symptoms including muscle weakness, spasticity, pain and abnormal coordination (Compston and Coles 2008). It can also have a considerable effect on other aspects such as cognitive abilities, psychological well-being and general daily function in those affected (Lynch et al. 2005; das Nair et al. 2012). Ireland has some of the highest prevalence rates of MS in Europe, with prevalence rates ranging from 120.7/100,000 to 184.6/100,000 (McGuigan and Hutchinson 2004). People with MS (PwMS) comprise the largest single diagnostic category on the Irish National Physical and Sensory Disability Database in people under 65 years of age (Doyle et al 2010).

Though no cure exists for MS, physiotherapy has been shown to be an important part of the management of this condition, with benefits documented for strength, fitness, psychological and quality of life outcomes (Rietberg et al 2005; Anthony et al 2011). Despite the expanding wealth of research in exercise in PwMS (Dalgas et al 2008; Motl and Gosney 2008), most of these studies focus on people with mild to moderate MS (Expanded Disability Severity Scale (EDSS) ≤ 6.5), and very few studies have examined exercise interventions in people more severely affected by MS (Rietberg et al 2005; Anthony et al 2011). As MS is a progressive condition, a substantial proportion of PwMS gradually become non-ambulatory and confined to wheelchairs. In a Swedish survey, 23% of PwMS surveyed were unable to walk (Einarsson et al 2003), whereas 26% of the total
MS population who presented for physiotherapy in a recent Irish profiling study were non-ambulatory (Coote et al 2010). Coote et al (2010) also found that the amount of physiotherapy actually received by this population in Ireland is very limited, with non-ambulatory PwMS receiving an average of just 3.55 hours over the timeframe of three months. It is doubtful that this amount of intervention is sufficient to bring about change when compared to the amounts reported in the existing studies of management options in ambulatory PwMS (Rietberg et al 2005).

**Exercise Buddy System**

The ‘Exercise Buddy’ system is where a ‘buddy’ is specifically employed to work under the guidance of a physiotherapist to carry out certain prescribed home exercise programmes (HEPs) with a service user. This model of care was conceived by staff at MS Ireland for use in the community with non-ambulatory PwMS, using paid professional carers as buddies and Primary Community and Continuing Care (PCCC) physiotherapists to design, prescribe and monitor HEPs. It was felt that the current amount of physiotherapy being received by this population was low and that this system would increase the amount of treatment received without increasing demands on PCCC physiotherapists. Very little published evidence exists that describes the implementation of a system such as the buddy system. A similar system was used previously in the development of a falls prevention programme in PCCC physiotherapy, Cork, Ireland, where rehabilitation assistants were used to carry out a physiotherapist-directed HEP with people partaking in the programme. Though anecdotally the programme has been successful, no corresponding literature has been published to date.
Thesis Outline

This thesis is presented in a research paper based format. Chapters 2, 3 and 4 are papers that have been submitted for publication. Figures, tables, references and appendices are presented within the papers as submitted for publication and some minor formatting and structural changes have been made to adhere to University of Limerick guidelines. Unless otherwise stated, the lead researcher in all papers is Elaine Toomey (ET) and the second investigator Dr. Susan Coote (SC).

Thesis Aims

The aims of the thesis were to evaluate the existing literature surrounding physiotherapy interventions in non-ambulatory PwMS, to gather information from a pilot scheme of the Exercise Buddy system in Cork community physiotherapy and to evaluate the system formally, investigating its feasibility and effectiveness as a potential intervention for non-ambulatory people with MS.

To do this, a systematic review of physical rehabilitation interventions in non-ambulatory PwMS was conducted. Qualitative interviews were completed with participants who had been involved in the pilot scheme of the Exercise Buddy programme, and finally a clinical trial was carried out to evaluate the Exercise Buddy intervention.

Paper I is a systematic review of physical rehabilitation interventions in non-ambulatory PwMS. The paper aims to evaluate all of the existing evidence regarding this topic.
Paper II discusses the process and findings of seven semi-structured interviews investigating a pilot scheme of the Exercise Buddy system in Cork Community Physiotherapy. The aim of this paper was to retrospectively investigate the development, implementation and outcomes of the Exercise Buddy system as a pilot system. The objectives were to explore the experiences and opinions of the various stakeholders of the ‘Exercise Buddy’ system and to learn from the stakeholders experience in order to further develop the model of care and inform the design of a clinical trial.

Paper III is a pilot randomised crossover study that aimed to compare the effects of Exercise Buddy care to standard community physiotherapy care for PwMS and their carers.
References


(MSIS-29) is a reliable and sensitive measure', *J Neurol Neurosurg Psychiatry*, 75(2), 266-269.


Chapter 2.

Paper I

Physical rehabilitation interventions in non-ambulatory people with Multiple Sclerosis: A systematic review

Submitted to Clinical Rehabilitation on the 16th May 2012 for first round of submission.
Physical rehabilitation interventions in non-ambulatory people with Multiple Sclerosis: a systematic review

Abstract

Background
There is an expanding body of research for exercise and multidisciplinary rehabilitation in Multiple Sclerosis (MS). Most of this research focuses on people with mild/moderate MS who can walk. As the costs of care increase with increasing disability it is important to evaluate the evidence for interventions in non-ambulatory subjects.

Objective
To evaluate the evidence regarding physical rehabilitation interventions in non-ambulatory PwMS.

Methods
The databases of AMED, CINAHL, MEDLINE, EMBASE and PSYCHARTICLES were searched up to May 31st 2011. Reference lists, Google Scholar and PEDro were also searched. Trials of physical rehabilitation interventions for non-ambulatory PwMS that analysed the non-ambulatory results separately were included. Pharmacological, surgical, medical and assistive device interventions were excluded. Risk of bias was assessed and the GRADE approach was used to classify the quality of evidence.

Results
Sixteen low grade studies, only three of which were RCTs, were included. There are trends for improvement following some interventions such as cooling suits, respiratory training and multidisciplinary rehabilitation, but there is no high grade evidence regarding the benefits of interventions for this population.
Conclusions

A small number of poor quality studies were found. Though trends in the results suggest positive benefits, conclusions cannot be made about the effectiveness of interventions for this population due to the low grade of studies. As approximately 25% of PwMS are non-ambulatory and considerable costs are associated with their care, it is imperative that efforts are made to increase the quality of evidence for non-ambulatory people with MS.

Key Words

Multiple Sclerosis, non-ambulatory, severe disability, EDSS ≥ 7, rehabilitation, management
Background

Multiple Sclerosis (MS) is a demyelinating disease that causes widespread axonal loss within the central nervous system. MS presents with a wide variety of physical symptoms including deficits in strength, sensation, flexibility, balance and co-ordination, but can also affect vision, cognition, energy levels and a multitude of other functions such as continence and speech (Compston and Coles 2002). Due to the debilitating nature of MS, and the fact that it predominantly manifests in early adulthood, it has a significant effect on the social participation, daily function and consequentially, the emotional well-being of the individual (Wynia et al 2008; Benito-León et al 2003). In Ireland, MS is particularly prevalent, with prevalence rates ranging from 121/100,000 to 185/100,000 (McGuigan and Hutchinson 2004). People with MS (PwMS) comprise the largest single diagnostic category on the Irish National Physical and Sensory Disability Database (Doyle et al 2010). In 2006, the mean annual incidence rate of MS in Europe was estimated at 4.3 cases per 100,000 (Pugliatti et al 2006), with total mean annual costs ranging from 18,000 euro for people with mild disability to 62,000 euro for those with severe disability levels (Kobelt et al 2006).

To date, there is an expanding body of research in the area of multidisciplinary rehabilitation and specific exercise interventions for PwMS. In 2005 a Cochrane systematic review of exercise therapy in MS (Rietberg et al 2005) was carried out, followed by numerous other reviews and published recommendations on physical activity and exercise in MS (Motl et al 2005; Dalgas et al 2008; Asano et al 2009; Motl 2010; Garrett and Coote 2009; Hogan and Coote 2009). These reviews conclude that while the methodological quality of studies can be improved, there is a consistent message that exercise does not cause harm, and that overall the effects are positive across the spectrum of impairment.
of body functions, activity limitations and participation restrictions. A Cochrane review of multidisciplinary rehabilitation (MDR) in 2007 concluded that though MDR does not change the level of impairment, it can improve the experience of PwMS at activity and participation level (Khan et al. 2007).

Most of the studies in these Cochrane reviews, however, focus on people with mild to moderate MS (Expanded Disability Severity Scale (EDSS) ≤6.5) who are defined as being able to walk with or without aids. In a Swedish survey, 23% of PwMS surveyed were unable to walk (Einarsson et al. 2003), and 26% of the total MS population who presented for physiotherapy in a recent profiling study were non-ambulatory (Coote et al. 2010). Though compiling approximately one quarter of the MS population, few studies have examined interventions in people more severely affected by MS (Rietberg et al. 2005), and those that have included this population often combine the results with those of less disabled PwMS (Miller et al. 2011; Pilutti et al. 2011). Due to the vast differences in impairments of body functions, activity limitations, and participation restrictions between PwMS who are able to walk and non-ambulatory PwMS, it is inappropriate to extrapolate results pertaining to mild or moderate MS or a combination of disability levels, to a non-ambulatory subgroup.

The objective of this review was therefore to assess the evidence surrounding physical rehabilitation interventions in non-ambulatory people with Multiple Sclerosis.

**Methods**

**Criteria**

The following criteria were established prior to implementing search strategies:

*Types of studies and interventions:*
All trials of any type concerning physical rehabilitation interventions in non-ambulatory people with MS were sought for this review. Both inpatient and outpatient interventions were included. Pharmacological, surgical, and medical trials were excluded, as were interventions using assistive devices when the device served purely to compensate for lack of function rather than attempting to restore function, e.g. wheelchairs.

*Types of participants:*

Men and women of all ages who are non-ambulatory with a diagnosis of MS have been included. For this review, non-ambulatory was defined as requiring a wheelchair to mobilise indoors and outdoors, or bed-bound. This equates to EDSS scores of 7.0 and higher. All types of MS were included.

*Types of outcome measures:*

Studies that considered physical function as an outcome were included. Studies that did not analyse results of non-ambulatory PwMS separately to participants who could walk were not eligible for inclusion.

*Search methods*

*Electronic searches:*

The databases of AMED, CINAHL, MEDLINE and PSYCHARTICLES were searched from the earliest date available up to May 31st 2011. In addition, reference lists of retrieved articles were examined for further eligible studies and Google Scholar was used to identify potentially eligible trials that had cited retrieved articles. The databases of EMBASE and PEDro were subsequently checked to ensure that all eligible articles had been included. Search strategies for each database are listed in table 1. Reference lists of studies sourced and narrative reviews were also examined for relevant publications.
Other sources:

Experts in the relevant field were contacted with the aim of identifying any further articles. No extra articles were retrieved using this method.

Data collection and analysis

Selection of studies and data extraction:

The titles and abstracts of retrieved studies were examined and ineligible articles excluded. Full text reports were obtained for articles with insufficient information in the abstracts to determine eligibility. Inclusion and exclusion of studies was confirmed by a second reviewer, there were no cases of disagreement between reviewers. The following data were systematically extracted: study design, characteristics of the participants and recruitment details, description of the study, outcome measures, results and limitations or potential sources of bias.

Assessment of risk of bias in included studies:

The risk of bias was assessed using the tool outlined in the Cochrane Handbook for Systematic Review of Interventions version 5.1.0 (Higgins and Green 2011). The tool aims to determine the internal validity of a study through assessment of risk of bias rather than assessment of methodological quality, as studies can be of a high quality and carried out to the highest possible standard, but still retain unavoidable aspects of bias. For example, it is often impractical or impossible to blind participants to intervention allocation, but this does not mean that the study results are free from potential performance bias through knowledge of group allocation. The tool assesses randomisation (selection bias), blinding of participants and assessors (performance and detection bias), incomplete outcome data (attrition bias) and selective reporting (reporting bias) as well as other possible sources of bias. For each bias aspect, studies are rated as having ‘high
risk’, ‘low risk’ or ‘unclear risk’. The use of this approach as opposed to scales that calculate summary scores is recommended, as scales have been shown to be unreliable for validity assessment and are not supported by the published evidence (Jüni et al 1999). Study authors were contacted where possible for additional information regarding ‘unclear’ risks of bias.

**Data synthesis and interpretation:**

The GRADE approach as recommended by the Cochrane Collaboration (Higgins and Green 2011), was used to classify the quality of evidence in each of the studies as ‘high’, ‘moderate’, ‘low’ or ‘very low’ based on study design and the assessed risk of bias (table 6). Randomised trial evidence is classified as ‘high’, but can be downgraded based on the amount of bias reported. Observational studies are categorised as ‘low’ quality but may be downgraded or upgraded accordingly. Case studies and reports are classified as ‘very low’ quality evidence. Findings were confirmed by a second reviewer.

A meta-analysis of data was not carried out as the majority of eligible studies were not randomised trials, and data were of a heterogeneous nature. Alternatively, a descriptive qualitative analysis was carried out with reference to the assessed risk of bias and GRADE quality for interpretation of the results and findings.

**Results**

Five hundred and ninety five citations were retrieved from the database search. After examination, 585 articles were excluded (figure 1) and ten were included. From the reference lists and citations of the ten eligible articles, a further six articles were identified as eligible. A total of 16 studies were included for the review. (Smith and Hale 2006; Giesser et al 2007; Gosselink et al 2000;

Studies were varied in terms of methodologies, outcome measures and duration and frequency of treatment, even in the studies of similar focus, e.g. cooling suit studies or exercise interventions. These variations make synthesis and direct comparison of results difficult. In general studies were of a low quality, with 10 case studies, three randomised controlled trials (RCT), one cross-over study and two before-and-after comparison studies (table 6). Of all 16 studies, only eight consisted entirely of non-ambulatory participants (Smith and Hale 2006; Giesser et al 2007; Gosselink et al 2000; Klefbeck and Hamrah Nedjad 2003; Peterson 2001; Baker et al 2007; Hamer and Hills 1991; Baer and Lewis 1987).

Exercise Interventions (Aerobic, Respiratory Muscle Resistance, Lower Limb Resistance)

In total, five studies examined exercise interventions in non-ambulatory people with MS. Three case studies investigated aerobic exercise (Smith and Hale 2006; Giesser et al 2007) and lower limb strengthening (Svensson et al 1994). Two RCTs evaluated resistance exercise of the respiratory muscles (Gosselink et al 2000; Klefbeck and Hamrah Nedjad 2003). These studies are summarised in table 2.

Overall the results of the ‘very low’ grade studies (Smith and Hale 2006; Giesser et al 2007) suggest that aerobic exercise may improve the body area it targets at impairment level, but there is no evidence to suggest that this carries
over to function. The case study investigating strengthening exercises also used aquatic exercise making it difficult to know which treatment was responsible for the results seen (Svensson et al 1994). In this study by Svensson et al (1994) subjective improvements were found at impairment and participation levels, but objectively knee flexion strength (the target of the intervention) decreased in the only non ambulatory participant. The cumulative evidence from two ‘low’ grade RCTs suggests that expiratory or inspiratory muscle training improves respiratory muscle strength, with no changes in respiratory function. In addition, Gosselink et al (2000) found significant lasting improvements in cough efficacy, while Klefbeck et al (2003) showed that fatigue and physical exertion were unchanged.

Rehabilitation Interventions

Three case studies (Baer and Lewis 1987; Hamer and Hills 1991; Peterson 2001), one RCT (Freeman et al 1997) and one before-and-after comparison study (Grasso et al 2005) that examined rehabilitation interventions in non-ambulatory people with MS were included. The studies are summarised in table 3.

Two ‘very low’ grade case studies (Baer and Lewis 1987; Hamer and Hills 1991) only reported descriptions of improvement due to rehabilitation qualitatively. The ‘very low’ grade case study by Peterson (2001) combined aquatic exercise with inpatient and outpatient rehabilitation. In all three case studies improvements were noted at impairment and activity level; however in two of the studies participants were experiencing a severe deterioration in function at the start of the study (Baer and Lewis 1987; Peterson 2001) which may have influenced results. Additionally in the study by Peterson (2001) it is difficult to determine which aspect of the intervention caused the improvement seen.
Overall, the risk of bias in all three studies is too high to enable any definitive conclusions to be drawn.

Cumulatively, the group trials in MDR (Freeman et al 1997; Grasso et al 2005) found improvements at both impairment and activity levels. In the RCT by Freeman et al (1997) only results for the locomotion section of the Functional Independence Measure were separated for non-ambulatory PwMS. Interestingly, only the non-ambulatory group improved significantly on this measure while the ambulatory group did not. In contrast to this, Grasso et al (2005) found that those with mild and moderate MS showed significantly more improvement for mobility and ADLs than non-ambulatory PwMS. These results suggest that non-ambulatory people with MS respond differently than ambulatory subjects to the interventions. Neither study demonstrated changes at participation level and both were of ‘low’ (Freeman et al 1997) and ‘very low’ (Grasso et al 2005) grade respectively.

Cooling Suit Interventions

Table 4 summarises five eligible studies that appraised cooling suits in non-ambulatory people with MS. All studies were classified as ‘very low’ quality evidence (table 6). At impairment level, results were variable and inconclusive regarding strength as an outcome. In terms of activity measures, results were again varied but with a tendency towards improvements in gait and mobility. The studies that examined fatigue as an outcome (Flensner and Lindencrona 2002; Kinnman et al 1997; Kinnman et al 2000) found improvements after cooling. It is difficult to make conclusions regarding the effect on activities of daily living as studies used different measures and found conflicting results.
Other Interventions (Therapeutic Standing)

Table 5 summarises the final included study of therapeutic standing by Baker et al (2007). The home-based therapeutic standing intervention was found to have significant improvements in hip and ankle range of motion, with non-significant improvements in spasm and spasticity of the lower limbs. These improvements at impairment level did not translate to activity measures. The study was a ‘low’ quality blinded randomised crossover trial.

Discussion

The aim of this paper was to review the current evidence base for physical rehabilitation interventions in non-ambulatory people with MS. A comprehensive search of the literature found only 16 studies, of which only three were RCTs. The quality of all studies was of ‘low’ or ‘very low’ grade. Though there are trends for improvement following some interventions, and no suggestion that the interventions cause harm, there is insufficient evidence to make definite conclusions about the effect of interventions for this population.

Evidence from cooling suit interventions suggests that there may be some benefits such as improvements in gait, mobility, certain functional activities and fatigue, but the changes noted are heavily affected by poor methodologies. Further trials with low bias and greater numbers are required. The studies reviewed suggest that exercise may cause positive changes at impairment level with no evidence for effects on function or participation outcomes. MDR may have positive effects on mobility which is supported by a previous Cochrane review in the area (Khan et al 2007). Further studies of higher methodological quality are necessary to provide recommendations about the most appropriate and effective
intervention types, duration and frequency specifically for non-ambulatory people with MS in order to optimise clinical practice and outcomes accordingly.

Although non ambulatory PwMS make up 25% of the population (Einarsson et al 2003; Coote et al 2010) and a large proportion of those presenting for physiotherapy, there is a surprising lack of literature available to guide treatment. This population present with hugely varied and complex disabilities, from those who are bed bound and completely dependent to wheelchair users who are relatively independent and function well in the community and at home through the use of other assistive devices and technologies. This variety of symptoms and level of impairment creates difficulties in designing appropriate interventions and selecting appropriate outcome measures. In addition, their high level of disability often impacts hugely on daily living and participation in clinical trials may not be possible.

Despite these challenges it is essential that we increase the evidence base to guide interventions for non-ambulatory PwMS, especially as the economic cost of the disease is higher in those with increased levels of disability (Kobelt 2003). Future interventions for this population should reflect the Medical Research Council (MRC) guidance for complex interventions (MRC 2000) which consider the development, evaluation and implementation continuum for an intervention. Given the everyday challenges of the person/carer team it will be particularly important to involve these stakeholders in the development stage. Our comprehensive literature search did not find any qualitative studies exploring the issues specifically for this population and these are required in order to inform the development and evaluation of interventions. There is also a lack of quantitative studies outlining the main symptoms and resulting problems for non-ambulatory people with MS and their carers, this is also required in order to develop
interventions that are tailored to the needs of the population and enable them to take part in clinical trials.

The second key area that is lacking is the availability of suitable outcome measures to evaluate the effect of an intervention in this population. A positive outcome in non-ambulatory PwMS may be either to stop deterioration in a particular domain, or to improve symptoms or functioning. As studies in this review demonstrated that non-ambulatory PwMS responded differently to their ambulatory counterparts (Svensson et al 1994; Grasso et al 2005), it is important to recognise that commonly used rehabilitation outcome measures may not be appropriate for use in this population. An understanding of the impairments of body structures and functions, the impact of these on activity limitations and resulting participation restrictions is essential in the development and selection of measures for this non-ambulatory population. The lack of participation level outcome measures in the studies reviewed may be due to lack of available measures, but should be addressed in future studies. As outlined by the International Classification of Functioning, Disability and Health (ICF) guidelines (WHO 2001), participation in life situations are of critical importance to the lives and functioning of those with disabilities, and as such merit thorough evaluation in future intervention studies.

Of concern is that no studies were found that evaluated the effect of the intervention on formal or informal carers. The general management principles of the NICE guidelines for MS (NICE 2004) suggest that all interventions should involve the carers and family of PwMS. Both formal and informal carers play a key role in the lives and functioning of the more disabled non-ambulatory PwMS, and it is essential that the impact on carers is considered in future studies.
A potential limitation of this review is the inclusion of all levels and grades of evidence. However, as only three eligible RCTs were found it was considered essential to include all trials in order to fully evaluate the existing literature. Only studies in the English language were considered for this review, though no relevant other language studies were identified during the search. Within the studies themselves, certain discrepancies existed in the classification of participants’ ambulatory levels. Some studies stated that ‘all participants were wheelchair-bound or bed bound’, yet EDSS scores reportedly ranged from 6.5 to 9 (Gosselink et al 2000; Klefbeck and Hamrah Nedjad 2003). In one study, baseline EDSS scores were reported to be 7-7.5, yet some participants were able to complete a ten-metre walk test at baseline, at odds with the EDSS descriptions (Giesser et al 2007).

Undoubtedly, conducting clinical trials in a non-ambulatory MS population can be a difficult and challenging task, and many issues need to be overcome to conduct good quality studies in this population. However, despite the challenges facing researchers and non-ambulatory people with MS, it is unacceptable to continue with insufficient evidence to guide clinical practice. Not only do this population account for approximately 25% of the entire MS population, but the economic cost of the disease is also proportional to level of disability (Kobelt 2003). Therefore, it is imperative that more research is done within this population, using the MRC continuum of development, evaluation and implementation continuum, and that continuous efforts are made to increase the size and quality of evidence base for non-ambulatory people with MS.
Conclusions

There is insufficient evidence to make any definitive conclusions regarding physical rehabilitation interventions in non-ambulatory people with MS. A very small number of poor quality studies were found, with little standardisation across studies in terms of interventions or outcome measures. Though it may be challenging to conduct good quality studies with non-ambulatory people with MS, attempts must be made to improve the quality and quantity of research in this population.
<table>
<thead>
<tr>
<th>Database</th>
<th>Search Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>AMED, CINAHL, MEDLINE and PSYCHARTICLES</td>
<td>“MS” OR &quot;Multiple Sclerosis&quot; ) and ( non-ambulat* OR wheelchair* OR &quot;bed bound” OR immobil* OR &quot;severe disability“ OR &quot;severely disabled“ OR parapleg* ) and ( rehab* OR interven* OR &quot;physical therap*“ OR physiotherap* OR exercise OR manage* OR care*</td>
</tr>
<tr>
<td>EMBASE</td>
<td>'ms'/exp OR ‘multiple sclerosis'/exp) AND ('non ambulatory' OR 'wheelchair'/exp OR 'wheelchair bound' OR 'bed bound' OR'immobile OR 'immobility'/exp OR immobilised OR 'severe disability' OR 'severely disabled' OR 'paraplegic'/exp OR 'paraplegia'/exp) AND ('rehabilitation'/exp OR rehab OR intervention OR intervene OR 'physical therapy'/exp OR physical AND therapist OR'physiotherapy'/exp OR 'physiotherapist'/exp OR 'exercise'/exp OR 'management'/exp OR managing OR manage OR care OR caring) AND [humans]/lim AND [embase]/lim</td>
</tr>
<tr>
<td>PEDro</td>
<td>MS OR “Multiple Sclerosis”</td>
</tr>
</tbody>
</table>
### Table 2: Exercise Interventions

<table>
<thead>
<tr>
<th>Reference (Year)</th>
<th>Design: Smith and Hale (2006) Case report</th>
<th>Sample Characteristics</th>
<th>Intervention (Duration):</th>
<th>Outcome Measures</th>
<th>Main Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 male: Power wheelchair; secondary progressive MS; unknown disease duration; 49 years old</td>
<td>Arm cranking (3 sessions a week for 3 weeks (8 sessions - last session unfinished))</td>
<td>HR; BP; Cardiovascular endurance (time until voluntary fatigue maintaining target heart rate); Self-efficacy (MS Self-Efficacy Scale)</td>
<td>Increased duration cranking 13.36mins-21.20mins</td>
<td>Decreased HR recovery time (10mins-3mins)</td>
</tr>
<tr>
<td></td>
<td>1 male, 3 female: EDSS 7.0-7.5; secondary progressive MS; mean disease duration 20 years (range 14-25); mean age 47 years (42-54)</td>
<td>Locomotor training using body weight support on a treadmill (2 hourly sessions a week - varied from 39-42 sessions)</td>
<td>Strength (Manual Muscle Testing); Spasticity (modified Ashworth Scale); Mobility (10m walk test; Six Minute Walk Test); Balance (Borg Balance Scale); Disability (EDSS); Quality of life (MS Impact Scale)</td>
<td>Balance improved significantly (clinical significance) in 2/4</td>
<td>Muscle strength improved in 4/4, spasticity improved in 3/4</td>
</tr>
<tr>
<td></td>
<td>1 female (of 5 total sample): EDSS 7.0/Wheelchair dependent; unknown type of MS; disease duration 20 years; age 37 years</td>
<td>Strengthening for hip flexion, abduction and extension and knee flexion (isokinetic training dynamometer for knee flexion) Every second day – light, nonspecific aquatic exercise (5 weeks - 15 sessions)</td>
<td>EMG (mean peak frequencies); Strength and endurance (3 sets of 50 max knee flexions with isokinetic dynamometer); Perception of fatigue (Borg Scale); Psychological and physical wellbeing (VAS)</td>
<td>No significant changes in pulmonary function (p=0.41)</td>
<td>Respiratory function: Training Pimax significantly &gt; baseline (p&lt;0.05), but not &gt;control (p=0.06); Training PEmax &gt;control (p=0.07) and &gt;baseline (p=0.08), not significantly</td>
</tr>
<tr>
<td></td>
<td>1 female: EDSS 7.0/Wheelchair dependent; unknown type of MS; disease duration 20 years; age 37 years</td>
<td>Training: 3 sets of 15 contractions against an expiratory resistance (Twice a day for 3 months - 168 sessions)</td>
<td>Respiratory function (Spirometry: Forced vital capacity); Respiratory muscle strength (Pimax, PEmax); Cough efficacy (Pulmonary Index)</td>
<td>No significant changes in pulmonary function (p=0.41)</td>
<td>Respiratory Muscle strength: Training Pimax significantly &gt; baseline (p&lt;0.05), but not &gt;control (p=0.06); Training PEmax &gt;control (p=0.07) and &gt;baseline (p=0.08), not significantly</td>
</tr>
<tr>
<td></td>
<td>1 male: Power wheelchair; secondary progressive MS; unknown disease duration; 49 years old</td>
<td>Control: Breathing exercises as part of routine physiotherapy (3 months)</td>
<td>10m walk improved in 2/4, other 2/4 unable pre, 1/4 able to complete 10m walk post.</td>
<td>No modification in physical VAS</td>
<td>Respiratory function: Training Pimax significantly &gt; baseline (p&lt;0.05), but not &gt;control (p=0.06); Training PEmax &gt;control (p=0.07) and &gt;baseline (p=0.08), not significantly</td>
</tr>
<tr>
<td></td>
<td>1 male, 3 female: EDSS 7.0-7.5; secondary progressive MS; mean disease duration 20 years (range 14-25); mean age 47 years (42-54)</td>
<td>Respiratory function (Spirometry: Forced vital capacity, forced vital capacity, forced expiratory volume, peak expiratory flow); Respiratory muscle strength (Pimax,PEmax); Fatigue (Fatigue Severity Scale); Physical exertion (Borg scale); Extra daily activities (diary)</td>
<td>Respiratory function (Spirometry: Forced vital capacity, forced vital capacity, forced expiratory volume, peak expiratory flow); Respiratory muscle strength (Pimax,PEmax); Fatigue (Fatigue Severity Scale); Physical exertion (Borg scale); Extra daily activities (diary)</td>
<td>Respiratory function unchanged training and control</td>
<td>Respiratory function: Training Pimax significantly &gt; baseline (p&lt;0.05), but not &gt;control (p=0.06); Training PEmax &gt;control (p=0.07) and &gt;baseline (p=0.08), not significantly</td>
</tr>
</tbody>
</table>

**Abbreviations:** MS = Multiple Sclerosis; HR = heart rate; BP = blood pressure; EDSS = Expanded Disability Severity Scale; EMG = electromyography; RCT = randomised controlled trial; PImax = inspiratory muscle strength; PEmax = expiratory muscle strength; VAS = visual analogue scale
<table>
<thead>
<tr>
<th>Reference (Year)</th>
<th>Design</th>
<th>Sample Characteristics:</th>
<th>Intervention (duration):</th>
<th>Outcome Measures:</th>
<th>Main Results:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baer and Lewis (1987)</td>
<td>Case report</td>
<td>1 Female: Bed-bound; unknown type of MS; disease duration 10 years; age 32 years</td>
<td>Multidisciplinary inpatient rehabilitation (7 months)</td>
<td>n/a</td>
<td>Improved from bed-bound, maximum dependence for ADLs to wheelchair-bound, able to assist with ADLs and transfers</td>
</tr>
<tr>
<td>Hamer and Hills (1991)</td>
<td>Case report</td>
<td>1 Female: Wheelchair-bound; Primary Progressive MS; disease duration 23 years; age 62 years</td>
<td>Multidisciplinary inpatient rehabilitation and home management (2 weeks)</td>
<td>n/a</td>
<td>Improved from wheelchair-bound, dependency in all ADLs, extensor spasticity of limbs to subjectively reported physical and psychological benefit, easier ADLs, less LL stiffness in mornings</td>
</tr>
<tr>
<td>Freeman et al. (1997)</td>
<td>RCT</td>
<td>29 (of 66 total sample), gender unknown: EDSS 7.0-9.5; unknown type of MS; unknown mean disease duration; unknown mean age</td>
<td>Training: Multidisciplinary inpatient rehabilitation (6 weeks)</td>
<td>Disability (EDSS); Function and mobility (Functional Independence Measure); Mobility (London Handicap Scale)</td>
<td>Only locomotion scores of Functional Independence Measure stratified – treatment group improved significantly compared to control p=0.0315</td>
</tr>
<tr>
<td>Peterson (2001)</td>
<td>Case Report</td>
<td>1 Female: Wheelchair-bound; unknown type of MS; disease duration 3 years; age 33 years</td>
<td>Control: Waitlist (6 weeks)</td>
<td>Strength (Manual Muscle Test); BP; HR; Perceived physical exertion (Borg scale); Functional mobility (Patient Evaluation Conference System)</td>
<td></td>
</tr>
<tr>
<td>Grasso et al. (2005)</td>
<td>Before-and-after comparison study</td>
<td>132 (of 230 total sample), gender unknown: EDSS &gt;6.5/Wheelchair or bed-bound; unknown type of MS; unknown mean disease duration; unknown mean age</td>
<td>Multidisciplinary inpatient rehabilitation (Mean length of stay = 75.86 days)</td>
<td>Disability (EDSS); ADL effectiveness (Barthel Index); Mobility effectiveness (Rivermead Mobility Index)</td>
<td></td>
</tr>
</tbody>
</table>

**Abbreviations:** MS = Multiple Sclerosis; HR = heart rate; BP = blood pressure; EDSS = Expanded Disability Severity Scale; RCT = randomised controlled trial; ADL = activities of daily living; LL = lower limb; AFO = ankle-foot orthosis
<table>
<thead>
<tr>
<th>Reference</th>
<th>Sample Characteristics</th>
<th>Intervention (duration)</th>
<th>Outcome Measures:</th>
<th>Main Results:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capello et al. (1995)</td>
<td>1 Female (of 6 total sample): EDSS 7.5; Secondary Progressive MS; disease duration 12 years; age 44 years</td>
<td>Cooling suit (2 daily 45min sessions for one month)</td>
<td>Disability (EDSS); LL strength; UL strength and coordination; Fine Finger Movement; Electrophysiological (Motor Evoked Potentials, Sensory Evoked Potentials, Visual Evoked Potentials); Sensation thresholds (tactile, thermal, vibratory); Gait; Stairs; Handwriting</td>
<td>No change in EDSS acute (immediate) or chronic (long-term cooling)</td>
</tr>
<tr>
<td>Kinnmann et al. (1997)</td>
<td>3 Male, 3 Female (of 28 total sample): EDSS 7.0-7.5/Wheelchair-bound; unknown type of MS; mean disease duration range 8-21 years; mean age 48 years (range 33-59)</td>
<td>Cooling suit (2-40-45min sessions per week for 2 weeks)</td>
<td>Saticity (Ashworth Scale); Strength (deltoids, triceps, wrist extensors, ilioiopsoas, hamstrings, ankle dorsiflexors); Grip strength (dynamometer); Rectal temperature; Dexterity (pegboard); Mobility (distance walked in bars); Response speed (keyboard test); Serial subtraction; Subjective participant evaluation of cooling effect</td>
<td>5/6 improved mobility, 4 significantly (p=0.00001)</td>
</tr>
<tr>
<td>Flensner and Lindencrona (1999)</td>
<td>1 Male, 2 Female (of 10 total sample): Wheelchair-bound; Secondary Progressive MS; unknown mean disease duration; unknown mean age</td>
<td>Cooling suit (2-3 daily 30 - 45min sessions for 6-10 weeks)</td>
<td>ADLs (MS Self-Care ADL scale); Experience and Opinion of suit (Daily diary for 1 week; Open interviews)</td>
<td>1/3 with fatigue improved</td>
</tr>
<tr>
<td>Kinnmann et al. (2000)</td>
<td>1 (of 8 total sample), gender unknown: EDSS 8.0/Wheelchair-bound; unknown type of MS; unknown mean disease duration; unknown mean age</td>
<td>Cooling suit (Average use - daily 45min sessions for 6 weeks)</td>
<td>Saticity (Ashworth Scale); Strength (iliopsoas); Dexterity (pegboard); Grip strength (dynamometer); Rectal temperature; Effect of cooling on symptoms (questionnaire); Mobility (distance walked in bars); Response speed (keyboard test); Serial subtraction; Quality of ADLs (Time wheeling manual chair 8m, time to complete a meal, handwriting test); Subjective participant evaluation of cooling effect</td>
<td>5/6 improved mobility, 4 significantly (p=0.00001)</td>
</tr>
<tr>
<td>Flensner and Lindencrona (2002)</td>
<td>1 Male, 2 Female (of 8 total sample): Wheelchair-bound; Secondary Progressive MS; unknown mean disease duration; unknown mean age</td>
<td>Cooling suit (28 days over approx. 3 months)</td>
<td>Fatigue frequency, duration, severity and disabling effect during last month (VAS); Fatigue impact (Fatigue Impact Scale); Experience and opinions of suit (Daily diary for 1 week; Open interviews)</td>
<td>Decrease in sense of fatigue over test period</td>
</tr>
</tbody>
</table>

**Table 4: Cooling Suit Interventions**

**Abbreviations:** MS = Multiple Sclerosis; EDSS = Expanded Disability Severity Scale; LL = lower limb; UL = upper limb; ADL = activities of daily living; VAS = visual analogue scale
### Table 5: Other Interventions: Therapeutic Standing

<table>
<thead>
<tr>
<th>Reference (Year): Design</th>
<th>Sample Characteristics:</th>
<th>Intervention (duration):</th>
<th>Outcome Measures:</th>
<th>Main Results:</th>
</tr>
</thead>
</table>
| Baker et al. (2007) Single-blinded Randomised Crossover Trial | 1 Male, 5 Female: EDSS 7; unknown type of MS; mean disease duration 17 years (range 7-35); mean age 45.6 years (range 37-56) | Crossover between: 1. Standing frame (30mins daily for 3 weeks) 2. HEP (Daily for 3 weeks) | Spasticity (Ashworth Scale); Spasm (Self-reported spasm frequency scale); Passive ROM (Manual goniometry) | • Statistically significant improvement for hip ROM (p=0.039 left legs, p=0.020 right legs) and ankle ROM (p=0.020 left legs, p=0.036 right legs) in standing compared to HEP  
• Statistically significant improvement for hip and ankle ROM in standing compared to baseline  
• No significant improvement in HEP ROM compared to baseline.  
• Downward trend noted in knee and ankle spasticity in standing group, not significant  
• Downward trend noted in spasm with both interventions, not significant |

**Abbreviations:** MS = Multiple Sclerosis; EDSS = Expanded Disability Severity Scale; RoM = range of motion; HEP = Home Exercise Programme
<table>
<thead>
<tr>
<th>Reference (Year)</th>
<th>Design:</th>
<th>Initial Grade:</th>
<th>Grade Reduced/Increased:</th>
<th>Final GRADE Quality:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Smith &amp; Hale (2006)</td>
<td>Case report</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Giesser et al. (2007)</td>
<td>Case series</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Svensson et al. (1994)</td>
<td>Case report</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Gosselink et al. (2000)</td>
<td>RCT</td>
<td>High</td>
<td>Selection bias – Low risk (Outcome assessors not blinded) Performance bias – High risk (Participants and personnel not blinded, training group better at baseline though not significantly) Attrition bias – Unclear risk (Insufficient description of dropouts) Reporting bias – Unclear risk (No protocol published) Detection bias – High risk (Outcome assessors not blinded) Performance bias – High risk (Participants and personnel not blinded) Attendance bias – High risk (Dropout data excluded from analysis) Reporting bias – Unclear risk (No protocol published)</td>
<td>Low</td>
</tr>
<tr>
<td>Baer and Lewis (1987)</td>
<td>Case report</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Hamer and Hills (1991)</td>
<td>Case report</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Freeman et al. (1997)</td>
<td>RCT</td>
<td>High</td>
<td>Selection bias – High risk (No randomisation, no allocation concealment) Detection bias – Low risk (Blinding of outcome assessors for Barthel Index and Rivermead Mobility Index) Performance bias – High risk (Participants and personnel not blind to intervention) Reporting bias – Unclear risk (No protocol published)</td>
<td>Low</td>
</tr>
<tr>
<td>Peterson (2001)</td>
<td>Case report</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Grasso et al. (2005)</td>
<td>Before-and-after comparison study</td>
<td>Low</td>
<td>Selection bias – High risk (No randomisation, no allocation concealment) Detection bias – Low risk (Blinding of outcome assessors for Barthel Index and Rivermead Mobility Index) Performance bias – High risk (Participants and personnel not blind to intervention) Reporting bias – Unclear risk (No protocol published)</td>
<td>Very Low</td>
</tr>
<tr>
<td>Capello et al. (1995)</td>
<td>Case Report</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Kinnmann et al. (1997)</td>
<td>Before-and-after comparison study</td>
<td>Low</td>
<td>Selection bias – High risk (No randomisation, no allocation concealment) Detection bias – High risk (Outcome assessors not blinded) Performance bias – High risk (Participants and personnel not blinded) Reporting bias – High risk (Selective reporting – no protocol published, many outcome measures used not reported in results - only improved results reported)</td>
<td>Very Low</td>
</tr>
<tr>
<td>Flenesner and Lindencrona (1999)</td>
<td>Case series</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Kinnmann et al. (2000)</td>
<td>Case report</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
<tr>
<td>Flenesner and Lindencrona (2002)</td>
<td>Case series</td>
<td>Very Low</td>
<td>n/a</td>
<td>Very Low</td>
</tr>
</tbody>
</table>

Abbreviations: RCT = randomised controlled trial
Figure 1: Flowchart of included/excluded articles
References


Functional Ability and Quality of Life in Progressive Multiple Sclerosis: A Pilot Study', *Archives of Physical Medicine and Rehabilitation*, 92(1), 31-36.


Chapter 3.

Paper II

Augmenting physiotherapy in the community with “Exercise Buddies”: A series of semi-structured interviews investigating a pilot scheme
Augmenting physiotherapy in the community with “Exercise Buddies”: A series of semi-structured interviews investigating a pilot scheme

Abstract

Introduction
Approximately 25% of people with Multiple Sclerosis (PwMS) are non-ambulatory, but little evidence exists for interventions within this population. Primary community physiotherapy is an effective and realistic long-term option for managing chronic conditions such as Multiple Sclerosis (MS) in the community. A pilot programme has used Exercise Buddies (paid professional carers) to exercise with PwMS under the direction of community physiotherapists. This study aims to investigate the development, implementation and outcome of the programme.

Methods
Semi-structured interviews were carried out with the physiotherapists, Exercise Buddies, PwMS and the MS Ireland Co-ordinator that took part in the pilot programme. Results were analysed using thematic analysis.

Results
Results could be categorised as either Benefits or Communication Difficulties. Within Benefits, the main themes of Physical and Psychological Benefits for PwMS and Physical and Psychological Benefits for Carers emerged. Within Communication Difficulties, themes of Defining Roles and Expectations, and Feedback and Communication During Implementation emerged. A subtheme of
Insufficient Training of Buddies emerged within the theme of Defining Roles and Expectations.

**Conclusion**

Seven semi-structured interviews were carried out with participants of a pilot study of the Exercise Buddy system. The Exercise Buddy system is a home-based intervention delivered at a community level, and has potential as a model of care with both physical and psychological benefits reported for PwMS and their carers and time and cost-saving aspects. Issues were discussed mostly relating to communication and training that need to be addressed in future to ensure its success.

**Keywords**

Multiple Sclerosis, community physiotherapy, severe disability, Exercise Buddy, physiotherapy assistant
Introduction

Multiple Sclerosis (MS) is a progressive debilitating disease of the central nervous system which manifests in a variety of physical and cognitive symptoms (Compston and Coles 2002). Though no cure exists for MS, physiotherapy and exercise interventions are widely acknowledged to improve the quality of life (QoL), general health and well-being of people with MS (PwMS) (Rietberg et al 2005; McCullagh et al 2008; Busse et al 2008), and the life expectancy of those affected by MS is now almost normal, except for those with rapidly progressive types (NICE 2004). Consequentially, PwMS are living longer than before with increasing disability levels, a fact illustrated in a recent Irish profiling study that recorded 26% of the total MS population who presented for physiotherapy as non-ambulatory (Coote et al 2010). Despite this, there is very little literature on exercise or physical management interventions specific to PwMS of higher disability levels and those unable to mobilise. Few intervention studies have included non-ambulatory PwMS and studies often limit their inclusion to PwMS who are able to mobilise (Rietberg et al 2005). Furthermore, as increased economic costs have been shown to be significantly correlated with greater disability levels (Kobelt 2003; Bourdette et al 1993), in current economic times it is more pertinent than ever to find ways of reducing expenditure without reducing service for PwMS with more disability.

With chronic conditions such as MS, care needs to be continuous and consistent, spanning a lifetime rather than episodic (Freeman et al 2002). For many countries including Ireland, this is only realistic and feasible with a community-based healthcare approach. Globally, an increasing emphasis is being placed on multidisciplinary teams (MDTs) managing chronic conditions in primary care (WHO 2008), requiring community services to address the needs of
these patients (Freeman and Thompson 2000). In recent times, the Irish Health Service Executive (HSE) has undergone a rejuvenated focus towards community-based health care, with Primary Community Continuing Care (PCCC) teams being developed and introduced in a variety of locations across the country (Ireland, Department of Health and Children 2001). As a result, primary care physiotherapy is becoming an increasingly relevant treatment option for chronic conditions such as MS (MacLurg et al 2005). Though the majority of Irish PwMS are seen in a community setting for physiotherapy (Coote et al 2010), and physiotherapy was found to be the fourth most commonly accessed community service by PwMS in Northern Ireland (MacLurg et al 2005), there is a paucity of research examining community-based physiotherapy interventions in PwMS. The evidence that does exist suggests that the amount of physiotherapy currently received by this population is minimal, with an average of 3.55 hours of treatment received by PwMS over a three month timeframe (Coote et al 2010). This again highlights the need for interventions based in the community and research to document this.

**The “Exercise Buddy” System**

A pilot study by the MS Society of Ireland (MSI) in conjunction with an urban PCCC physiotherapy team has used an “Exercise Buddy” model of care to increase the amount of physiotherapy treatment received by PwMS in the community. This system aims to target those of higher disability, mostly non-ambulatory PwMS. An “Exercise Buddy”, or buddy for short, is a paid professional carer who is specifically employed to work on exercise with the client under the guidance of a PCCC physiotherapist. By process of a two-way referral system between the MSI and PCCC physiotherapists, PwMS considered
appropriate by the PCCC physiotherapists are offered the Exercise Buddy system. The MSI then hires an Exercise Buddy through a care agency and mediates contact between the Exercise Buddy and the physiotherapist. The physiotherapist and buddy then arrange a suitable time to meet with the PwMS. At this first visit the physiotherapist prescribes a 10-week home exercise programme (HEP) for the Exercise Buddy to carry out with the person with MS once a week. The physiotherapist maintains regular contact with the buddy to monitor progress. The aim of the Exercise Buddy system is to optimise the use of physiotherapists’ time whilst ensuring that people with MS get enough treatment to make a difference. The process is illustrated in figure 1.

The aim of this study was to retrospectively investigate the development, implementation and outcomes of an ‘Exercise Buddy’ pilot model of care for people with Multiple Sclerosis in Cork Community Physiotherapy. The objectives were to explore the experiences and opinions of the various stakeholders of the ‘Exercise Buddy’ system and to learn from the stakeholders experience in order to further develop the model of care.

Methods

Study Participants

Ethical approval for the study was granted by the University of Limerick Faculty of Education and Health Sciences Research Ethics Committee. Written informed consent was obtained from all participants. Participants were purposively sampled, recruited from physiotherapists, buddies and PwMS who had been involved in a pilot study of the development of an Exercise Buddy model of care. The original co-ordinator of the study from the MS Society was also invited to take part. Inclusion criteria for the study were that participants must
be over the age of 18 and must be fluent in English. PwMS who took part were required to be non-ambulatory.

**Study Design**

A qualitative design was deemed to be the most appropriate as the focus and aims of the study were exploratory and inductive (Maykut and Morehouse 1994). Semi-structured interviews were decided upon as they allow flexible expression of opinions and open-ended communication, yet guide participants enough to maintain the discussion on topic (Crabtree and Miller 1999). Focus groups or group interviews were deemed inappropriate due to the different roles and involvements of individual participants.

A topic guide was developed by the lead interviewer (ET) for each category of interviewee; physiotherapists, Exercise Buddies, PwMS and their carers and MSI co-ordinator (table 1). The questions in all topic guides were similar but tailored slightly for each category to reflect the different roles of the participants within the study. The guide was loosely structured detailing potential questions to explore the roles, experiences, attitudes and opinions of all participants at various stages throughout the study - background, development, implementation and outcome, but focused mainly on the pitfalls and issues with the service in order to inform future practice. Throughout the study, the guides did not change from their initial design, though new material relevant to the aims and objectives of the study was explored if brought up by participants. Participants were able to talk freely. Interviews were carried out by the lead researcher and took place at the homes of PwMS and their carers, and at the offices or clinics for the MSI Co-ordinator, physiotherapists and buddies.
Study Analysis

Interviews were audiotaped and transcribed verbatim. Data collection and analysis was performed by the lead researcher using an in-depth thematic analysis methodology (Braun and Clarke 2006) as advised by an expert in qualitative methodologies. No software technology was used. A reflective analytical memo was kept in order to achieve rigour or ‘trustworthiness’ of data, by demarcating the analysis process clearly (Sandelowski 2000). Initially, transcripts were read and reread a number of times with the aim of immersing the researcher in the data. Each line of the transcripts was analysed and coded to identify key concepts or ideas. Concepts discussed within transcripts were then summarised and coded and these codes were then collated into broad themes. Initial broad themes were then further refined until final themes and categories were identified. Quotes that best reflected the themes and categories were selected to illustrate the results. The final themes and categories were verified by independent checking of the transcripts and quotes by the second researcher (SC). To ensure high quality data interpretation, member checking was carried out with the participants by sending them a summary of the overall findings. All participants agreed with the results of the analysis and that it was an accurate representation of what had been discussed during the interview.

Results

Seven semi structured interviews were conducted with nine participants: two physiotherapists, two Exercise Buddies (with their supervisor present), the MSI co-ordinator, and two PwMS (one with his carer/wife present to facilitate communication due to his speech difficulties). Interviews ranged from 31 minutes to one hour and six minutes in length, with an average duration of 53 minutes.
One of the Exercise Buddies (Buddy 1) was a trained physiotherapist working as a Buddy. Both PwMS had been living with MS for over 15 years and both physiotherapists were experienced with working with PwMS.

Extensive thematic analysis found that results could be categorised as either Benefits or Communication Difficulties. Within the category of Benefits, the main themes of Physical and Psychological Benefits for PwMS and Physical and Psychological Benefits for Carers emerged. Within Communication Difficulties, themes of Defining Roles and Expectations and Feedback and Communication During Implementation emerged. A subtheme of Insufficient Training of Buddies emerged within the theme of Defining Roles and Expectations.

**Benefits**

The benefits and positive aspects of the Exercise Buddy model were mentioned by all nine participants. Some benefits for physiotherapists such as saving time and the peace of mind achieved in boosting patient care were briefly mentioned by the two physiotherapists and Buddy 1. However, benefits of the Exercise Buddy system were mostly expressed in relation to the PwMS and their carers, with the majority of benefits described in relation to the PwMS themselves. Improvements were noted by participants in physical and psychological terms for both carers and PwMS. It was generally regarded that these were not completely separate, but a combination of both made a difference to the overall well-being of the person, for both PwMS and their carers.

“[Improvements are] really down to the buddy system. It is incredible, it really is. It is something that you can’t even imagine. As well as just the emotional impact. Physically, and it gives us the independence.” – (Carer of PwMS 2)
Physical & Psychological Benefits for PwMS:

All nine interviewees spoke about the benefits for PwMS. A number of specific physical benefits such as pain relief, upper and lower limb mobility improvements and better positioning were mentioned by different participants, and positive outcomes in range of movement were described by both physiotherapists, both buddies, the MS co-ordinator and the carer. One of the physiotherapists also noted how maintenance of the existing function and physical ability of the person with MS was a major result of the intervention due to the nature of his disease, and that otherwise deterioration would more than likely have occurred. Psychologically, all nine participants reported positive findings including increased motivation levels, enhanced confidence and emotional satisfaction derived from the company of the buddy. The relationship between the buddy and the person with MS was considered important to the success of the intervention by most.

“It sort of boosts your enthusiasm a bit as well in that the buddy comes, puts you through these motions and then you feel well Jesus I must be...I am making an effort. And honest to God you know an awful lot of, now I can only speak of MS, but my experience for it is half is psychological and the other half is physical...” – (PwMS 1)

Overall, participants observed that the benefits to PwMS were multifaceted, and that the intervention worked on both physical and psychological levels mutually.

Physical & Psychological Benefits for Carers:

Both buddies and their supervisor, the MS co-ordinator, the carer, one of the physiotherapists and one of the PwMS spoke about the benefits the system had on carers of PwMS in terms of eased carer burden, both physically and psychologically. The increase in support gained by carers from the regular visits from the buddy was described by the MS co-ordinator, Physiotherapist 1 and the
carer to be beneficial because of the fact that the care load was being shared by another.

“I found it incredibly helpful because I am the main person who does physio with [PwMS 2], every day to the extent that I can do it. But the physiotherapists are incredibly resourceful from each and every one of them. They will give me tips how to work around my disability so to speak. Find another way of compensating and getting something similar” – (Carer of PwMS 2)

In addition to the psychological benefits accrued by the carers, the physical load of caring was also alleviated. This was postulated by most to be due to the enhanced range of movement experienced by the PwMS that made functional activities of daily living such as dressing, bathing and general handling easier.

“Theyir home helps and their carers say that it’s huge. That it makes the legs and the hips looser for turning.” – (Buddy 2)

Although benefits of the Exercise Buddy system was one of the largest themes in the study, and was talked about by all participants in the study, it is important to recognise that some pitfalls were experienced. This was summarised well by one participant who recognised the difficulties with communication and training that had been experienced during the study:

“I personally think it is great. It is potentially very challenging and it could be absolutely brilliant, but there are a good few issues to be dealt with.” – (Buddy 1)

Communication Difficulties

The pitfalls and difficulties experienced during the pilot scheme overlapped a lot with each other, and fell under the overarching category of Communication Difficulties.

“I think just the communication needs to be very much clarified from the beginning, and that was definitely something that kind of frustrated me....it would be better if we just had a very clear plan from the very start with *Care Agency*, where we could say ‘look, please contact me in five weeks. I don’t want it to be week ten and I not having heard anything from you’. We really need feedback.” – (Physiotherapist 2)
A substantial issue frequently discussed was the insufficient training of the buddies, which was deemed to be due to a lack of clarification of roles and expectations of the respective participants in the initial stages of the system development, a theme also thoroughly discussed in its own right. This lack of clarification was reasoned to have been caused by an overall deficiency in communication and feedback between all of the various groups of participants involved from the outset.

**Feedback and Communication During Implementation:**

Poor communication and feedback was observed by most to have occurred consistently throughout the implementation of the system. Though regular contact between the physiotherapists and the buddies was originally intended, it was reported that this did not occur sufficiently. Similarly, the MSI coordinator noted difficulties in making contact with the physiotherapists and the care agencies.

“It probably could have been a little more joined up, and I don’t think that’s a criticism of any one group, but I suppose barriers do crop up when you are dealing with totally separate organisations. Anyway, I think maybe everybody being informed in the same way (is important) so it probably would be no harm for there to be a sort of an almost training session on it, where everybody that is involved from different organisations would come together. Wouldn’t have to be long winded, even one or two hours of just clarifying how the whole system works together” – (Physiotherapist 2)

All participants, with the exception of the PwMS and their carers as they were not involved in the study from an organisational aspect, were in agreement regarding the issues surrounding communication between the three organisational entities – being the MS Society, the community physiotherapists and the buddies and their care agency.

“I personally think it is very disjointed at the moment. And I was saying this earlier on, there should be meetings of the three.” – (Buddy 1)
In general, most felt that the involvement of three separate bodies with no one coordinator overseeing relations and contact between all of the groups led to a somewhat disjointed implementation of the intervention. It was mostly felt that this could be easily rectified by outlining what the expectations of communication were from the start, and by establishing appropriate protocol for frequent communication and feedback between the three organisations.

**Defining Roles and Expectations:**

A theme discussed by the all participants except for the carer of PwMS 2 throughout the interviews was the need to define the roles and responsibilities of all stakeholders.

“I think we need to clarify the role, what is the role of the exercise buddy.” – (MS Coordinator)

Physiotherapists and PwMS expected buddies to have a certain level of training which was not realised initially by buddies, their care agency or the MSI coordinator. This training was expected by the MSI and physiotherapists to be undertaken by the care agencies, who recognised over the duration of the study that sufficient training was hugely important. Similarly, physiotherapists felt that the role of prescribing buddies to PwMS was solely that of the PCCC physiotherapists, an issue which required clarity at one point.

It was agreed by most participants that what was to be expected of each participant in the Buddy System should be clarified initially, and that it needed to be stated who was to organise and coordinate the various aspects of the programme.

“The bottom line is they still need the basic...there needs to be something set up as in who is going to organise it, who is going to do it.” – (Buddy 1)
Insufficient Training of Buddy:

A major pitfall of the pilot project appeared to be the lack of training or structured training that the buddies had before taking part in the study. The MS coordinator and the care agency discussed being unaware of how much training was needed, whilst the physiotherapists had assumed that the buddies would be sufficiently trained to work with people of this disability level. Responsibility for training of the buddy was ambiguous during the initial stages of the study, as most participants had not realised that it would be an issue.

“The pitfall we made really was that we didn’t ascertain how much training the exercise buddies had....we assumed...that the buddy would have a certain amount of training.....when we went out the buddy didn’t really have any training whatsoever.....I wasn’t happy for her to go ahead.” – (Physiotherapist 1)

Four participants described an unfavourable experience with an untrained buddy during the preliminary stages of the study, which highlighted the major importance of training. It was a recurrent issue commented on by seven out of nine participants, and that adequate and appropriate training was imperative in order for the system to be successful and safe.

“They must have had some level of training, because otherwise it could be dangerous. Or it wouldn’t be of much benefit because an ignorant buddy is a liability. They can’t do these things. They could cause more trouble than be helpful.” – (PwMS 1)

Overall, most felt that this was one of the key issues in the system, but again could be ameliorated by adequate communication during the planning stages of the program.

Discussion

In general, there appeared to be a combination of positive and negative aspects of the Exercise Buddy system. The positive aspects were the physical and psychological benefits experienced by both PwMS and their carers. The negative
issues were the insufficient training of the buddy due to ill-defined roles and expectations of those involved, along with insufficient communication and feedback throughout the implementation of the system. These pitfalls were mainly due to overall communication difficulties from the outset of the programme. Though problems were discussed more frequently than the benefits, this is unsurprising as the focus was to learn from the original study to inform future implementation. Consequently, emphasis during the interviews was placed more on describing the pitfalls and issues to learn from the experiences in order to facilitate the success of the system in future schemes.

Impairments such as range of motion, mobility, and pain and their effects on function are common in PwMS (NICE 2004; Coote et al 2009; Miller et al 2011), and all of the impairments mentioned by participants to have improved from Buddy Care featured highly in the main problems reported by 293 PwMS surveyed in Ireland (Coote et al 2010). Holistic and appropriate treatment of PwMS should also target the health and well-being of their carers, as carers’ ill-health can have a consequential effect on the people they care for (NICE 2004). It is widely recognised that informal and familial caregivers of people with disability experience a lower QoL than age matched peers, and have reported lower levels of self-esteem, self-confidence and higher levels of psychological stress (Carers UK 2004; Khan et al 2007). Though several qualitative and exploratory studies have been published that examine the needs and health of carers of PwMS, few intervention studies have directly examined the effects of the intervention in the participants’ carers (McKeown et al 2003). With severely disabled PwMS, the strain of caring may be even greater, as disability level has been proposed to be directly proportional to the level of assistance required from a carer (Kersten et al 2000; McCullagh et al 2005). It is therefore increasingly
important to develop interventions that positively impact both the PwMS and their carers in this more disabled population.

This study also highlights the fact that even with a model of care that is successful in many ways, the formalities of how a service operates cannot be overlooked. Underpinning all of the problems mentioned in the interviews was the lack of communication between the organisational entities of the system. Communication difficulties within MDTs have been well reported in the literature, including much research specific to community and primary care settings (Bélanger and Rodríguez 2008; Miller et al 2005). Interestingly, a research synthesis of existing qualitative literature on multi-disciplinary primary care teams noted similar findings to those of this study. The synthesis concluded that the development of clear roles was considered to be one of the main strategies to bring about effective cooperation within MDTs in the primary care setting (Bélanger and Rodríguez 2008). Other studies have suggested that role ‘blurring’ can bring about stress and confusion within MDT primary care teams (Miller et al 2005), and Bélanger and Rodríguez (2008) found that when the allocation of labour is unclear, conflicts may arise which can affect the quality of care provided. This study found that the lack of definition of roles and expectations should be addressed by maintaining reciprocal communication with ongoing feedback, similarly concluded by previous studies (Bélanger and Rodríguez 2008; Miller et al 2005; Brown et al 2000). Consequently, when working in MDTs the roles and expectations of all involved should be clearly delineated from the outset of the project, with regular communication and feedback in order to optimise outcomes.

The appropriate and adequate training of Exercise Buddies was found to be crucial to the success of the Exercise Buddy system. Though professional
carers funded by the MSI were used in the pilot model explored in this study, it is not realistic to depend on charitable funding for long term service provision in the community. An alternative viable option would be the introduction of physiotherapy assistants by the HSE into PCCC physiotherapy, as are currently in use in HSE hospitals nationwide. Physiotherapy assistants could be used as Exercise Buddies to increase the amount of treatment that people with MS and other chronic conditions receive without substantially increasing the PCCC physiotherapist workload. This would also reduce the number of stakeholders involved, making communication issues less problematic. Regardless of who performs the role of Exercise Buddy, sufficient training is still a key aspect. The existing literature on physiotherapy assistants suggests that they play a vital role in the delivery of physiotherapy, but must be well trained in order to give a high quality service (Parry and Vass 1997). As previously stated by Saunders (1995), investment in training of physiotherapy assistants would bring improvements in cost effectiveness and quality of care. The entity responsible for the training of the Exercise Buddy was ambiguous in this study, but the findings of this study would suggest that it should be decided by all of the various stakeholders involved, as a joint decision in the initial planning stage of the system.

Several limitations must be borne in mind when considering the implications of the study findings. A significant factor of note was that one of the buddies was a trained physiotherapist working as a buddy (Buddy 1). Certain benefits reported by clients of this buddy may be biased because of her level of training and experience. Nonetheless, it must be acknowledged that benefits were also reported by clients of buddies who were trained carers. Moreover, as all technical aspects of the HEP (assessment, diagnosis and prescription) are performed by the PCCC physiotherapists, the experience or background of the
buddy should not make a substantial difference in terms of benefits gained from the HEP. The content of the HEP is the same regardless of the buddy used. Aspects such as handling or background knowledge might differ between the two buddies, but this could be ameliorated with adequate training.

Another major limitation is that all reports of benefits were subjective. Physiotherapists did not use standardised outcome measures; therefore progress was based on visual feedback and reports from the carers and PwMS themselves. Also, the care agency supervisor for the buddies was present for both interviews, which could potentially have influenced the openness and expressiveness of the buddies. However, this did not appear to have occurred, as the supervisor was not excessively vocal during the interviews, and both tended to agree on the themes discussed. As with many qualitative studies, there was a small sample size in this study mostly due to time limitations. However, it is important to note that a spread of opinions from each of the different stakeholders of the intervention was obtained and that in general the level of consensus between participants was high.

Based on the findings of this study, a number of recommendations can be made for the future implementation of this programme. As the overarching issue in the study appeared to be the lack of communication between the groups, it is recommended that initial and on-going meetings of all organisational entities should take place, before the system is to be used in an area. The aims of this meeting should be to develop a ‘team’ ethos and to:

1. *Establish roles and expectations of all involved.*

All participants should explicitly state their own role and their expectations of the other participants. It should be decided upon by all who the main overseer and contact point of the system should be. Following on from this, the team should:

2. *Agree on and establish a regular contact/feedback protocol.*
This should be feasible and agreeable to all. At the beginning of the study, this contact and feedback should also facilitate:

3. Ensure adequate training of Exercise Buddies.

This is one of the most important aspects to be addressed for future use of the Exercise Buddy model of care. Realistic and appropriate levels of training should be decided upon initially by the PCCC physiotherapists to ensure safety of the PwMS and effectiveness of the interventions. This training should then be organised by the entity deemed responsible by the team as a whole. Documentation of the proceedings and outcomes of the meetings are essential.

**Conclusion**

Seven semi-structured interviews were carried out with participants of a pilot study of the Exercise Buddy system including PwMS and their carers, physiotherapists and Exercise Buddies. The Exercise Buddy system is a home-based intervention delivered at a community level, and appears to have excellent potential as a model of care with both physical and psychological benefits reported for PwMS and their carers and time and cost-saving aspects. Though the system has potential, issues were discussed mostly relating to communication and training that need to be addressed in future to ensure its success. To fully ascertain the effects and feasibility of the system, a pilot randomised, controlled trial should be completed taking the findings of this qualitative study into account.
<table>
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<th>Table 1. Topic guide for interviews</th>
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<tr>
<td><strong>Introduction</strong></td>
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<tr>
<td>All: Introduce self to participant</td>
</tr>
<tr>
<td>Thank participant for coming</td>
</tr>
<tr>
<td>Introduce project topic</td>
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<tr>
<td>Outline interview structure</td>
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<tr>
<td>All: All:</td>
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<td>All: PwMS, Carer, Buddy:</td>
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<td>All: PwMS, Carer:</td>
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<td>All: Buddy:</td>
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MSI Co-ord: Multiple Sclerosis Ireland regional co-ordinator; PT: physiotherapist; PwMS: person with Multiple Sclerosis
Figure 1: Process of Exercise Buddy System

1. Two-way referral
2. Hiring and funding Exercise Buddies
3. Organising first visit with PwMS
4. 10 weeks of assisted exercise
5. Regular contact and communication

MSI – Multiple Sclerosis Ireland; PCCC – Primary Continuing Community Care; PwMS – people with Multiple Sclerosis
References


Chapter 4.

Paper III

Augmenting community physiotherapy with Exercise Buddies in non-ambulatory people with Multiple Sclerosis: a pilot randomised crossover study
Augmenting community physiotherapy with Exercise Buddies in non-ambulatory people with Multiple Sclerosis: a randomised crossover pilot study

Abstract

Background
Access to physiotherapy services is limited for non-ambulatory people with MS (PwMS). One way of increasing the amount received is by using Exercise Buddies, where professional carers directed by physiotherapists work with PwMS. This method has been used previously in community physiotherapy.

Objective
To investigate the effects of the Exercise Buddy system in comparison to standard community physiotherapy care in non-ambulatory PwMS and their carers.

Methods
A randomised crossover study was conducted in 29 non-ambulatory PwMS and their carers. Interventions were: 10 weeks of exercise prescribed by community physiotherapists for PwMS and carried out by Exercise Buddies, or 10 weeks of standard community physiotherapy. Outcomes assessed in PWMS were MS Impact Scale (MSIS) Physical and Psychological, Guy's Neurological Disability Scale (GNDS) and their “three main problems”, whilst carer outcomes were the Adult Carer Quality of Life and their “three most challenging aspects of caring”.

Results
In PwMS there were significant improvements in both MSIS aspects due to exercise buddy care compared to standard care (p=0.05 for physical, p = 0.042 for psychological). There was little change with either intervention in GNDS or the
three main problems. In carers, large dropout rates (39%) made it difficult to make definite conclusions about the effect of either intervention.

Conclusion

Exercise Buddy care can significantly reduce impact of MS in PwMS in physical and psychological measures compared to standard care.
Introduction

Multiple Sclerosis (MS) has considerable effects on the physical function, cognitive abilities, psychological well-being and general social participation in those affected (Lynch et al 2005; das Nair et al 2012). Owing to improvements in healthcare and the management of MS, people with MS (PwMS) are now living longer than before and the life expectancy for PwMS is almost normal, except for those with rapidly progressive types (NICE 2004). Studies have shown that approximately 25% of PwMS have a more severe disability level and are non-ambulatory (Coote et al 2010; Einarsson et al 2003).

Despite compiling roughly one quarter of the MS population, few interventions have been published or documented that specifically target and guide interventions for those with higher disability (Dalgas et al 2008; Rietberg et al 2005; Toomey and Coote 2012b). Intervention studies that do exist are of low quality with poor methodologies using no blinding, control groups, or standardised outcome measures (Toomey and Coote 2012b). In addition to this, evidence suggests that non-ambulatory PwMS in Ireland receive a limited amount of physiotherapy, previously found to be an average of 3.55 hours over a three month timeframe (Coote et al 2010). There is a clear need for high quality studies on feasible interventions in this population.

Globally, an increasing emphasis is being placed on the long term management of chronic conditions such as MS within primary healthcare systems (WHO 2008). As the necessary care for these types of conditions should be consistent and continuous care over the lifetime of those affected (Freeman et al 2002), community-based physiotherapy is becoming more important than ever in the treatment of MS. Despite the relevance and suitability of community physiotherapy for managing MS, there is a significant lack of literature on
community-based physiotherapy interventions in PwMS, and again even less pertaining to a non-ambulatory sub-group.

It is also important to recognise that comprehensive treatment of PwMS should aim to include their carers in intervention. Familial (non-professional) carers often have a low quality of life with low levels of self-esteem and confidence (Khan et al 2007; Carers UK 2004) and it is known that poor health in carers can affect the people they care for (NICE 2004). A holistic approach to treating PwMS should include their carers, with the aims of reducing carer burden and improving carer quality of life.

In Ireland, an “Exercise Buddy” system of care was developed for use within the community in PwMS (Toomey and Coote 2012a). An Exercise Buddy, or buddy for short, is a paid professional carer who is specifically employed to work on exercise with PwMS under the guidance of a physiotherapist. At the first home visit, the physiotherapist prescribes a home exercise programme (HEP) for the Exercise Buddy to carry out weekly with the person with MS. At the discretion of the physiotherapist, the Exercise Buddy will conduct these sessions unsupervised, but monitored regularly by the physiotherapist. The aim of the Exercise Buddy system is to optimise the use of physiotherapists’ time whilst ensuring that people with MS get enough treatment to make a difference. Semi-structured interviews carried out with people who had previously used the system found that the Exercise Buddy system had perceived physical and psychological benefits for both PwMS and their carers (Toomey and Coote 2012a). It was also concluded that communication issues and adequate training of Exercise Buddies were crucial to the success of the system. From this study, it was hypothesised that this method of service delivery would augment current community
physiotherapy care without substantially increasing community physiotherapists’ workload, and subsequently improve familial carer quality of life.

The aim of this study was to investigate the effects of the Exercise Buddy system in comparison to standard community physiotherapy care in non-ambulatory PwMS and their carers.

**Materials and methods**

This pilot study was an assessor-blinded randomised crossover trial. Using the Medical Research Council (MRC) framework for complex interventions (MRC 2000) as a guideline, this study followed on from a design phase in which a systematic literature review (Toomey and Coote 2012b) and semi-structured interviews (Toomey and Coote 2012a) were carried out. A cross-over design was chosen to increase the sample size by evaluating the effect of both treatments on every participant. Ethical approval was granted by the Health Service Executive (HSE) Mid-West and West Research Ethics Committees. Written informed consent was provided by all participants.

**Participants**

Non-ambulatory people with MS and their carers, HSE Primary Community Continuing Care (PCCC) physiotherapists and Exercise Buddies employed by the MS Society of Ireland (MSI) were invited to take part through contact with the MSI and PCCC offices. Inclusion criteria for PwMS were a definite diagnosis of MS and an inability to take more than a few steps with assistance for transfer purposes. Potential participants were excluded if they were experiencing an exacerbation of symptoms, had any other unstable medical problems, were under 18 years of age, or were unable to communicate back to the
lead researcher what the study involved and that their participation was voluntary.

Buddies were professional carers, four of whom were already employed by the MSI, and three employed specifically for the study by the MSI through a care agency. Buddies needed to have Garda clearance, manual handling training and CPR training or first aid. In addition to this, all Buddies attended a standardised training course run by the lead researcher (ET).

Randomisation was carried out prior to baseline assessment by the second investigator (SC) by placing four slips of paper labelled ‘Standard Care’ or ‘Exercise Buddy’ (two of each) into a hat and randomly selecting a slip for each PwMS. In order to ensure even numbers in standard care and exercise buddy groups, the selected piece of paper were removed from the hat until all pieces had been drawn. All slips were then replaced and the next group of four were randomised. This method was chosen to ensure similar numbers in each group, as participant numbers and time for recruitment were limited. Though the fourth allocation from each group was not technically random, this last allocation was dependent on the random allocations that have gone before it, as such rendering it a random allocation also. The lead researcher was blinded to group allocation and the allocation sequence until the end of the final assessments.

**Exercise Buddy Training**

Exercise Buddies completed a training day with the lead researcher consisting of both practical and theoretical components. Objectives of the course for buddies were to understand the role and responsibilities of Exercise Buddies for the study, to gain a knowledge and understanding of MS, to revise manual and therapeutic handling techniques, to re-familiarise with exercise equipment and to review precautions when working with people with severe disabilities. Practical aspects
included bed, wheelchair and standing frame transfers, passive movements, joint range of motion (RoM) and positioning. The importance of exercise in severe disability was emphasised in addition to discussion of safety issues and aspects such as contractures or fatigue.

**Interventions**

The independent variables were the Standard Care and Exercise Buddy Care interventions, with the groups differing specifically in regards to dose of intervention and the individual delivering the intervention. PwMS in the Standard Care group received standard community physiotherapy care, where the PCCC physiotherapist was instructed to conduct community visits consisting of routine care as frequently as they normally would over a 10 week period. Results of a preliminary survey conducted suggested that the average number of visits during standard community physiotherapy care was approximately one visit in 10 weeks. PwMS in the Exercise Buddy group were allocated an Exercise Buddy to work with them at their homes for one hour per week for a 10 week period, on a home exercise programme (HEP) designed individually for each participant with MS by the PCCC physiotherapist. The HEP was prescribed and demonstrated by the physiotherapist in the first session and was to consist of the most appropriate and relevant exercises or physiotherapy intervention for that participant as deemed by the physiotherapist. The Buddy returned weekly unsupervised, or returned weekly in the presence of the physiotherapist until the physiotherapist was comfortable to allow the buddy to work unsupervised. The Buddy and the physiotherapist were instructed to make regular contact. In addition to this, safety issues and the general administration of the study were monitored during the study by regular communication between the various stakeholders in the study. Due to the blinding
of the lead researcher, the MSI and second investigator were used as liaison contacts between the PCCC physiotherapists, Exercise Buddies, PwMS and the lead researcher. PwMS and Exercise Buddies were provided with contact details for the MSI and PCCC physiotherapists, and asked to contact them if adverse effects or safety issues were noted during the study.

**Outcome Measures**

The study was a crossover design in two ten-week treatment phases. The first phase consisted of ten weeks of one participant group receiving Exercise Buddy care whilst the other group received Standard Care. The groups then crossed over, and during second phase the groups received the other treatment. Outcomes for PWMS and carers were assessed at baseline (T1), after the first treatment phase (T2), and after the second treatment phase (T3). Assessments were conducted by the lead researcher and another blinded physiotherapist assessor of similar experience levels who received training from the lead researcher to ensure that all assessments were conducted uniformly. T2 and T3 assessments were taken within two weeks of the last week of the intervention. Before the T2 and T3 assessments, PwMS and carers were explicitly asked not to discuss their treatment over the 10 weeks with the assessors during the assessment to maintain blinding.

Outcome measures used in PwMS were the Multiple Sclerosis Impact Scale version 2 (MSIS-29), Guy’s Neurological Disability Scale (GNDS) and a numerical rating scale (NRS) assessment of their self-perceived three main problems. The MSIS-29 was chosen as the primary outcome measure and is a disease-specific health-related quality of life assessment tool that measures the impact of MS (Hobart et al 2001). It has a physical and a psychological
component and is transposed to a score out of 100, and higher scores reflect higher impact of MS. The psychometric properties of the scale have been found to be valid and reliable for use in PwMS, including those with severe disabilities (Riazi et al 2002; Riazi et al 2003; McGuigan and Hutchinson 2004; Gray et al 2009). The GNDS is a simple clinical disability scale which measures levels of disability across 12 separate categories including cognition, mood, speech, upper and lower limb function, and fatigue (Sharrack and Hughes 1999). The GNDS is scored out of 60 and higher scores reflect higher disability levels. Its validity and reliability have been previously established in PwMS of varying disability levels, including those with severe MS (EDSS scores of up to 8.8) (Rossier and Wade 2002; Sharrack and Hughes 1999). The NRS was developed for this study by the lead researcher in addition to standardised outcome measures to allow the measurement of outcomes deemed most important to the PwMS themselves, in accordance with International Classification of Functioning, Disability and Health (ICF) guidelines that advocate the use of individualised goals and interventions (WHO 2001). PwMS were asked before and after the study what their main problems are, and on a numerical rating scale (Downie et al 1978) to show how much their daily activities are affected by them. The NRS was scored out of ten, one being not affected at all, ten being severely affected. For carers, the outcome measures used were the recently developed Adult Carer Quality of Life (AC-QoL) questionnaire (Elwick et al 2010), in addition to a NRS assessment scored as above to determine their self-perceived three most challenging aspects of care. At the end of the study, community physiotherapists completed a brief satisfaction questionnaire developed by the lead researcher using open and closed questioning to 1) evaluate their opinions of the system (good/bad/neither good nor bad; why) and 2) whether it should be used as part of community physiotherapy
(yes/no/indifferent; why). Participant characteristics were collected verbally from all PwMS and carers at baseline.

**Statistical Analysis**

Data were analysed using SPSS version 19. Differences in baseline data were calculated by using t-tests to compare the data. For non-parametric data, Mann-Whitney U tests were used, and Independent Samples t-tests were used in normally distributed data.

Data were analysed using the method of analysis for crossover trials as recommended by Altman (1991). Change variables (Change 1 – difference between T2 and T1, Change 2 – difference between T3 and T2) were created to reflect the change due to treatment due to each intervention. Carryover, period and treatment effects were tested for using methods described by Altman (1991). When there was no significant carryover or period effect, data from both groups for an intervention were combined, allowing the mean overall change due to Exercise Buddy care and Standard Care to be calculated. To compare between the groups independent samples t-tests were conducted in normally distributed data, and Mann-Whitney U tests were used in non-parametric data.

**Results**

Thirty-four PwMS volunteered for the study, of which five were deemed ineligible due to their ability to walk. Twenty-nine non-ambulatory PwMS and their carers, nine HSE PCCC physiotherapists and eight exercise buddies were recruited through the MSI and PCCC offices. Four physiotherapists employed by MSI were also recruited when PCCC physiotherapists were unable to participate. Of the 29 PwMS, 12 were seen by MSI physiotherapists. During Buddy Care,
people received a mean of 8.5 (range 4-10) buddy sessions, with only 33 sessions not carried out (13% of total possible sessions). Seventy-five percent of the missed sessions were due to PwMS reasons, e.g. sickness, dropouts. Twenty-five PwMS received one initial joint visit from a physiotherapist and buddy, while two PwMS received two joint visits during Exercise Buddy care. During Standard Care, 12 PwMS received a visit from a PCCC (n=10) or MSI (n=2) physiotherapist, and 17 received no documented intervention. Figure 1 presents the flow of participants through the study, providing details of recruitment, study design and withdrawals. During the study, five PWMS dropped out who are accounted for in figure 1. The data for mean changes and treatment, carryover and period effect were calculated on the 24 remaining participants. Out of 28 carers who took part, only 17 (61%) completed the final assessment. Three carers were unavailable at the time of assessment, three refused to be assessed, five dropped out due to PwMS withdrawal from the study. For carers, the large dropout rate at T3 meant that the above crossover analysis was invalidated (Altman 1991), therefore T1 and T2 data were analysed for differences instead using paired samples t-tests for within-group differences (two-related samples if non-parametric) and independent samples t-test for between-group differences (Mann-Whitney U if non-parametric).

**Baseline data**

At baseline Group 2 were found to be significantly older than Group 1 in PwMS, and the time since last walked was significantly longer in Group 1 than Group 2 (table 1). No other significant differences were found between groups. No significant differences were found for carers’ baseline characteristics or ACQoL scores between both groups.
HEP data

HEPs consisted of lower and upper limb passive, active and active assisted movements in addition to upper, lower and core strengthening exercises. Sit-to-stand practice and sitting balance exercises were also used and motorised exercise pedals were used in five HEPs. Exercises were carried out weekly with the Exercise Buddy for approximately one hour per session. No information was provided by the physiotherapists in relation to the intensity of exercise for each PwMS or progression of exercises throughout the ten weeks.

Outcome data

Analysis for carryover and period effect showed that there was no significant effect for either aspect in any measure, at an α level of 0.05 (table 2). There was a significantly greater change in MSIS physical and psychological scores with Exercise Buddy care than with standard care, with a trend towards disimprovement during standard care (table 3). Changes seen on GNDS were small and nonsignificant. Changes seen in rating of main problems were again small and nonsignificant with mean overall changes of mostly zero.

For carers, the results for both groups are conflicting, making it difficult to identify trends within the data (table 4). There was no significant change within either group from T1 to T2 for ACQoL scores or any of the three main challenging aspects, and no significant difference was found between groups at T2.

Out of 13 physiotherapists who took part, 10 completed the satisfaction questionnaire (four MSI, six PCCC physiotherapists). Eight believed the intervention was beneficial while two were unsure of the benefits. Eight believed
the intervention should continue to be a part of community physiotherapy due to long term benefits, one was unsure as to how the system would work long term (felt communication between physiotherapists and buddy may deteriorate over time), and one believed that it shouldn’t continue due to time constraints, unless reviews of the HEP and Exercise Buddy could be restricted to once a year or every two years.

**Discussion**

The aim of this study was to investigate the effects of Exercise Buddy care in comparison to standard community physiotherapy care in non-ambulatory PwMS and their carers. Significant differences were found between groups for the change in MSIS Physical and Psychological subscales. There were small, nonsignificant changes in other measures for PwMS. For carers, large dropout rates and conflicting results make it difficult to draw conclusions regarding the effects of the interventions.

For both MSIS Physical and Psychological subscales, the self-perceived impact of MS was significantly reduced with Exercise Buddy care in comparison to standard care. To the best of our knowledge, this is the only evidence for improvements in PwMS from physiotherapist-directed treatment delivered by a trained assistant. Previous stroke research by Lincoln et al (1999) also found that there was no difference between additional physiotherapist-directed treatment from a qualified physiotherapist or from a trained physiotherapy assistant. This suggests that this is a viable treatment model that may augment the amount of treatment currently received by non-ambulatory PwMS.

One explanation for the greater change in self-perceived impact of MS due to Exercise Buddy care may be the increased amount of treatment received during
the Exercise Buddy period. In stroke research, this dose effect has been well documented (Haines et al 2011; Kwakkel et al 2004). The social contact with the Exercise Buddy may also have had a positive effect, and psychological benefits from having the Exercise Buddy attend were mentioned subjectively by some participants to the lead researcher at the end of the study. Social contact from physiotherapy interventions has often been found to be beneficial for PwMS (Freeman and Allison 2004). In 2011, a systematic review (Anthony et al 2011) concluded that the benefits of exercise and physical activity on psychological and quality of life outcomes for PwMS may be partially due to the social support gained during group interventions. Though the intervention in this study was on a one-to-one basis, the individual interaction with the Exercise Buddies may have had a similar effect.

Though little or no change was noted with either treatment in self-reported disability as measured by the GNDS, it is encouraging that there was no deterioration of disability over the study period. In people with progressive neurological conditions such as MS, maintenance of function and prevention of deterioration may be considered as a positive outcome (Miller et al 2011; Romberg et al 2005). A previous study of home-based physiotherapy (Miller et al 2011) in participants with moderate to severe MS found that disability and quality of life were maintained in the intervention group, while deterioration was seen in the control group. Another study by Pozzilli et al (2002), including PwMS with disability levels of up to 8 on the Expanded Disability Severity Scale (EDSS), found that though quality of life significantly improved, neurological impairment and disability was unchanged in both intervention and control groups. Findings from these trials in conjunction with this study show that the maintenance of
disability level may be just as important as improvements for people with progressive MS.

Neither intervention had much effect on the three main problems of the PwMS. This is surprising as the most frequently documented problems were upper and lower limb weakness, muscle stiffness or tightness and insufficient support from physiotherapy, and Exercise Buddy HEP records showed that these issues were those most commonly addressed during the buddy intervention. The lack of self-rated change may be attributable to a number of factors. It is possible that the dosage and length of intervention was not adequate to bring about change or that the buddies didn’t have sufficient skills to truly address their impairments. A systematic review (Rietberg et al 2005) showing improvements from exercise in PwMS in outcomes of strength, mobility and general fitness found that the dosages varied between the included studies from five 30 minute sessions per week (Mostert and Kesselring 2002) to two 45 minute sessions per week (Wiles et al 2001), and all were of a much greater dosage than the weekly 60 minute session in this study. Also, the NRS outcome measures may not have been sensitive enough to capture change in the three problems, and these subjective outcome measures may also have been affected by issues with memory and cognition which are common in people with higher levels of physical disability (Sedighi 2011; Lynch et al 2005; das Nair et al 2012).

Trends in the results from the carer data differed between the two groups, but no significant changes were found due to either intervention. The Exercise Buddy intervention did not specifically target carers, and though it was hypothesised that any improvements in PwMS would reduce the burden in carers, this may not have actually been the case. It is possible that a change in disability level of the person with MS would have had the most effect on carers, and as little
or no change was noted in GNDS measures, this may account for the lack of significant change in carer outcomes. Although it is important to identify potential causes for the carer results in this study, the large dropout rate may be of greater significance. Though the predominant reason for dropout was attributed to carer unavailability at the time of assessment, a small number of carers declined to be assessed after baseline. It is possible that involvement in assessments were viewed as an extra unwanted responsibility by some carers or that the outcome measures used were not acceptable to carers, despite preliminary piloting of them.

The majority of physiotherapists who took part in the study believed that Exercise Buddy care was beneficial for PwMS with severe MS and that it should continue to be a part of community physiotherapy. The importance of this cannot be understated as for a health-care intervention to be implemented successfully, it must be acceptable to all involved. Unlike the findings of the previous qualitative exploration of the Exercise Buddy system (Toomey and Coote 2012a), communication and training difficulties appeared to have been alleviated in this study through the initial organisation of communication pathways and specific training for Exercise Buddies.

There were a number of limitations to this study. No measures of cognition or memory were used, therefore although all participants met the ethical requirements to take part, it is uncertain as to how this may have affected the patient-reported outcome measures (PROMs) used in PwMS in this study. The sample size of the study for both PwMS and carer groups was small and the large dropout in carers meant that the sample size was reduced even further. It also meant that carer data could not be analysed to the same depth as the PwMS data, and limited generalisability of the data. Future studies should explore potential reasons behind poor carer participation, such as inappropriate outcome measures.
or timing of assessments and examine how researchers can help carers to participate fully. Also, though both assessors were blinded, the direct contact with the participants during assessments made it difficult to remain blinded. However, as PROMs were used, this was not deemed to be a significant limitation. The use of PROMs also reduced the risk of assessment inconsistencies between the two assessors.

Despite these limitations, implications for clinical practice and future research can be gleaned from the study. Of concern is that standard care did not maintain or improve the physical or psychological impact of MS in a non-ambulatory population. Although it may have slowed the progression of MS, a control group receiving no intervention would be needed to confirm or refute this. In addition, several participants were not seen during their 10 weeks of the standard care intervention due to PCCC physiotherapist unavailability which further highlights the need for alternative services for this patient group. Baseline data also showed that 13 PwMS had not received any physiotherapy in the last year, and almost two-thirds of participants (n=19) were not receiving any treatment at the start of the study.

Finally, it can be concluded that Exercise Buddy care is beneficial for non-ambulatory PwMS. With chronic disease management moving towards community primary healthcare (WHO 2008; Ireland, Department of Health and Children 2001), the Exercise Buddy system is an effective and feasible system that could be utilised in community physiotherapy. For long term feasibility, use of physiotherapy assistants in the community as Exercise Buddies could be an ideal solution, lessening potential communication and administration issues and reducing the workload of physiotherapists whilst ensuring non-ambulatory PwMS get enough treatment to maintain and improve their MS. A cost analysis of using
Exercise Buddies needs to be undertaken to evaluate the cost effectiveness of Exercise Buddy care over standard care, taking into account the cost of hospitalisations and general medical care whilst receiving either intervention.

Conclusion

Exercise Buddy care significantly reduced the self-perceived physical and psychological impact of MS for non-ambulatory PwMS in comparison to standard community physiotherapy care. Though little or no change occurred with either intervention in measures of self-reported disability or participants’ three main problems, no deterioration occurred and maintenance of function and disability levels in people with progressive MS may be as important as improvements. There was a large dropout rate in carers and remaining data showed small nonsignificant changes in all carer outcome measures. This study shows that despite the challenges of conducting research in this population (Toomey and Coote 2012b), high quality clinical trials are feasible. The study also shows that physiotherapy interventions prescribed by physiotherapists and delivered by professional carers are feasible and effective in PwMS of higher disability levels.
<table>
<thead>
<tr>
<th>Table 1: Baseline Characteristics</th>
<th>Group 1</th>
<th>Group 2</th>
<th>P value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>PWMS:</strong></td>
<td></td>
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</tr>
<tr>
<td>Age (years (SD))</td>
<td>52.93 (8.3)</td>
<td>60.86 (9.5)</td>
<td>0.027†**</td>
</tr>
<tr>
<td>Sex (frequency (%))</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male</td>
<td>5 (33.3%)</td>
<td>6 (42.9%)</td>
<td>0.71‡</td>
</tr>
<tr>
<td>Female</td>
<td>10 (66.7%)</td>
<td>8 (57.1%)</td>
<td></td>
</tr>
<tr>
<td>Time since diagnosis (years (SD))</td>
<td>13.66 (7)</td>
<td>18.7 (14.9)</td>
<td>0.425†</td>
</tr>
<tr>
<td>Time since last walked (years (SD))</td>
<td>8 (5.3)</td>
<td>4.45 (3.13)</td>
<td>0.039†*</td>
</tr>
<tr>
<td>Self-reported regular (weekly) physical activity</td>
<td></td>
<td></td>
<td>0.215‡</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (60%)</td>
<td>12 (85.7%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>6 (40%)</td>
<td>2 (14.3%)</td>
<td></td>
</tr>
<tr>
<td>Current Treatment**</td>
<td></td>
<td></td>
<td>0.7‡</td>
</tr>
<tr>
<td>Yes</td>
<td>6 (40%)</td>
<td>4 (28.6%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>9 (60%)</td>
<td>10 (71.4%)</td>
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<tr>
<td>Physiotherapy in last year</td>
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<td></td>
<td>0.715‡</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (60%)</td>
<td>7 (50%)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>6 (40%)</td>
<td>7 (50%)</td>
<td></td>
</tr>
<tr>
<td>MSIS Phys Score (mean (SD))</td>
<td>63.33 (24.77)</td>
<td>63.21 (16.07)</td>
<td>0.988†</td>
</tr>
<tr>
<td>MSIS Psych Score (mean (SD))</td>
<td>40.99(29.81)</td>
<td>35.98 (27.92)</td>
<td>0.645†</td>
</tr>
<tr>
<td>GNDS Score (mean (SD))</td>
<td>29.27 (6.43)</td>
<td>25.26 (6.47)</td>
<td>0.106†</td>
</tr>
<tr>
<td>Problem 1 (median (SIR))</td>
<td>10 (0.5)</td>
<td>10 (2.5)</td>
<td>0.252†</td>
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<tr>
<td>Problem 2 (median (SIR))</td>
<td>10 (2)</td>
<td>9.5 (2.05)</td>
<td>0.949†</td>
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<tr>
<td>Problem 3 (median (SIR))</td>
<td>8 (2.25)</td>
<td>9.5 (1)</td>
<td>0.377†</td>
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<tr>
<td><strong>CARER:</strong></td>
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<td></td>
</tr>
<tr>
<td>Age (years, (SD))</td>
<td>51.13 (8.97)</td>
<td>48.62 (13.88)</td>
<td>0.568†</td>
</tr>
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<td>Sex (frequency (%))</td>
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<tr>
<td>Male</td>
<td>7 (46.7%)</td>
<td>5 (38.5%)</td>
<td>0.479‡</td>
</tr>
<tr>
<td>Female</td>
<td>8 (53.3%)</td>
<td>8 (61.5%)</td>
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<tr>
<td>Years caring for PwMS (SD)</td>
<td>9.32 (8.1)</td>
<td>13.5 (10.5)</td>
<td>0.263†</td>
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<td>Own medical conditions</td>
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<tr>
<td>Yes</td>
<td>4 (26.6%)</td>
<td>2 (14.3%)</td>
<td>0.443‡</td>
</tr>
<tr>
<td>No</td>
<td>11 (73.3%)</td>
<td>12 (85.7%)</td>
<td></td>
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<tr>
<td>ACQoL Score (mean (SD))</td>
<td>64.33 (28.02)</td>
<td>81.08 (22.27)</td>
<td>0.095†</td>
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<tr>
<td>No 1 Challenging Aspect of Care (median (SIR))</td>
<td>7 (2.5)</td>
<td>6 (2.5)</td>
<td>0.300†</td>
</tr>
<tr>
<td>No 2 Challenging Aspect of Care (median (SIR))</td>
<td>8 (3)</td>
<td>5 (1.5)</td>
<td>0.067†</td>
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<tr>
<td>No 3 Challenging Aspect of Care, (median (SIR))</td>
<td>7 (3.5)</td>
<td>5.5 (1.5)</td>
<td>0.628†</td>
</tr>
</tbody>
</table>

† Mann-Whitney U test, † Independent samples t-test, ‡ Fisher's Exact test, * p value <0.05, significant, **Any physical intervention delivered by a professional, e.g. acupuncture/physiotherapy/massage
Table 2: Carryover and period effect data

<table>
<thead>
<tr>
<th></th>
<th>Carryover Effect</th>
<th>Period Effect</th>
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<tbody>
<tr>
<td>MSIS Physical</td>
<td>P=0.095†</td>
<td>P=0.185†</td>
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<tr>
<td>MSIS Psychological</td>
<td>p=0.288†</td>
<td>p=0.670†</td>
</tr>
<tr>
<td>GNDS</td>
<td>p=0.843‖</td>
<td>p=0.671‖</td>
</tr>
<tr>
<td>Problem 1</td>
<td>p=0.695‖</td>
<td>p=0.177†</td>
</tr>
<tr>
<td>Problem 2</td>
<td>p=0.880‖</td>
<td>p=0.379‖</td>
</tr>
<tr>
<td>Problem 3</td>
<td>p=0.316‖</td>
<td>p=0.786‖</td>
</tr>
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</table>

† Independent samples t test, ‖ Mann Whitney U test, *p value <0.05, significant
<table>
<thead>
<tr>
<th></th>
<th>Group Mean Scores</th>
<th>Group Mean Change</th>
<th>Mean Overall Change Due to Buddy</th>
<th>Mean Overall Change Due to Standard</th>
<th>Treatment Effect</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>T1 (n=29)</td>
<td>T2 (n=27)</td>
<td>T3 (n=24)</td>
<td>Change 1 (T2-1) (n=24)</td>
<td>Change 2 (T3-2) (n=24)</td>
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<td><strong>MSIS PHYS</strong></td>
<td></td>
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<tr>
<td>(mean (SD))</td>
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<tr>
<td>Group 1 (Buddy, Standard)</td>
<td>63.33 (24.77)</td>
<td>55.1 (23.86)</td>
<td>62.92 (21.3)</td>
<td>-10.56 (14)</td>
<td>8.47 (17.87)</td>
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<tr>
<td>Group 2 (Standard, Buddy)</td>
<td>63.21 (16.07)</td>
<td>59.29 (14.79)</td>
<td>51.11 (16.3)</td>
<td>-4.51 (16.1)</td>
<td>-8.4 (13.76)</td>
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<td><strong>MSIS PSYCH</strong></td>
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<td>(mean (SD))</td>
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<tr>
<td>Group 1</td>
<td>40.99 (29.81)</td>
<td>32.54 (28.47)</td>
<td>37.04 (25.9)</td>
<td>-12.04 (13.13)</td>
<td>2.78 (21.72)</td>
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<tr>
<td>Group 2</td>
<td>35.98 (27.92)</td>
<td>36.47 (28.48)</td>
<td>33.02 (25.19)</td>
<td>4.32 (16.25)</td>
<td>-5.56 (14.26)</td>
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<tr>
<td><strong>GNDS</strong></td>
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<td>(mean (SD))</td>
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<tr>
<td>Group 1</td>
<td>29.27 (6.43)</td>
<td>25.98 (5.08)</td>
<td>24.92 (6.73)</td>
<td>-1.03 (4.26)</td>
<td>-2.14 (3.89)</td>
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<tr>
<td>Group 2</td>
<td>25.26 (6.47)</td>
<td>22.95 (6.31)</td>
<td>21.42 (4.58)</td>
<td>-2.17 (5.73)</td>
<td>-0.75 (3.02)</td>
</tr>
<tr>
<td><strong>Problem 1</strong></td>
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<tr>
<td>Group 1</td>
<td>10 (0.5)</td>
<td>9 (2.5)</td>
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<td>0 (1)</td>
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<td>Group 2</td>
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<td>8 (2.375)</td>
<td>-1 (2.315)</td>
<td>0 (2.315)</td>
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<td><strong>Problem 2</strong></td>
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<tr>
<td>(median (SIR))</td>
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<tr>
<td>Group 1</td>
<td>10 (2)</td>
<td>8 (2.5)</td>
<td>8 (1)</td>
<td>0 (3)</td>
<td>0 (0.5)</td>
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<tr>
<td>Group 2</td>
<td>9.5 (2.05)</td>
<td>8 (2.5)</td>
<td>8 (1.5)</td>
<td>-0.25 (1.25)</td>
<td>0.5 (2)</td>
</tr>
<tr>
<td><strong>Problem 3</strong></td>
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<tr>
<td>(median (SIR))</td>
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<tr>
<td>Group 1</td>
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<td>7.5 (2.5)</td>
<td>5 (2)</td>
<td>0 (1.5)</td>
<td>-1 (1.5)</td>
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<tr>
<td>Group 2</td>
<td>9.5 (1)</td>
<td>8 (2.5)</td>
<td>8 (1.875)</td>
<td>-2 (2.815)</td>
<td>0 (0.94)</td>
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**Mann Whitney U test, † Independent samples t test, *p value <0.05, significant**
## Table 4: Carer outcome data

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<tr>
<th></th>
<th>Group Mean Scores</th>
<th>Group Mean Change</th>
<th>Within-group difference - T1 and T2</th>
<th>Between-group difference at T2</th>
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<td>T1 (n = 28)</td>
<td>T2 (n = 22)</td>
<td>T3 (n = 17)</td>
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<tr>
<td><strong>ACQOL (mean (SD))</strong></td>
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<td>Group 1</td>
<td>64.33 (28.02)</td>
<td>68.42 (15.08)</td>
<td>71.88 (22.97)</td>
<td>9.67 (29.45)</td>
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<td>Group 2</td>
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<td>76.4 (16.69)</td>
<td>69.56 (21.89)</td>
<td>0.3 (10.15)</td>
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<tr>
<td><strong>No. 1 Challenging aspect of care (median (SIR))</strong></td>
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<tr>
<td>Group 1</td>
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<td>7 (1.88)</td>
<td>6 (1.63)</td>
<td>-0.5 (1.88)</td>
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<td>Group 2</td>
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<td>7 (3.5)</td>
<td>4.5 (3.75)</td>
<td>1 (2.25)</td>
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<tr>
<td><strong>No. 2 Challenging aspect of care (median (SIR))</strong></td>
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<td></td>
<td></td>
<td></td>
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<td>8 (3)</td>
<td>6 (3)</td>
<td>-1 (1.5)</td>
</tr>
<tr>
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<td>6.5 (1)</td>
<td>1 (2.13)</td>
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<tr>
<td><strong>No. 3 Challenging aspect of care (median (SIR))</strong></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>Group 1</td>
<td>7 (3.5)</td>
<td>5.5 (1.88)</td>
<td>5 (3.25)</td>
<td>-1 (3)</td>
</tr>
<tr>
<td>Group 2</td>
<td>5.5 (1.5)</td>
<td>8 (3.5)</td>
<td>6 (4.13)</td>
<td>2 (2.5)</td>
</tr>
</tbody>
</table>

† Independent samples t test,  ‡ Paired samples t test, ‡ Mann Whitney U test, ‡‡ Two related samples test. *p value <0.05, significant
Figure 1: Flowchart of participants through study

Enrollment

Assessed for eligibility:
PWMS (carers)
N=29(28)

Excluded: N=0(0)

Randomized: N=29(28)

GROUP 1
Allocated to Exercise Buddy intervention:
N=15(15)

Assessed N=15(15)

EXERCISE BUDDY CARE

Assessed N=14(12)
Not assessed N=1(3)
Reason: 1 PWMS and carer dropout due to unrelated illness, 1 carer unavailable for assessment, 1 carer refused to be assessed

STANDARD CARE

Assessed N=12 (9)
Not assessed N=2(3)
Reason: 1 PWMS and carer dropout due to unrelated illness, 1 PWMS and Carer dropout due to administration error - did not receive intervention, 1 carer unavailable for assessment

GROUP 2
Allocated to Standard Care intervention:
N=14(13)

Assessed N=14(13)

STANDARD CARE

Assessed N=13(10)
Not assessed N =1(3)
Reason: 1 PWMS and carer dropout as did not want to receive Standard Care first, 1 carer unavailable for assessment, 1 carer refused to be assessed

EXERCISE BUDDY CARE

Assessed N=12 (8)
Not assessed N=1(2)
Reason: 1 PWMS and carer dropout due to administration error - did not receive intervention, 1 carer refused to be assessed

Analysis

TOTAL:
PWMS N=24
Carers N=17
References


between cognitive impairment and physical disability in multiple sclerosis', *Multiple Sclerosis*, 11(4), 469-476.


hospital based samples’, *Journal of Neurology, Neurosurgery & Psychiatry*, 73(6), 701-704.


Chapter 5.

Conclusion
Conclusion

The overall aims of this thesis were to examine the current evidence surrounding physiotherapy interventions for non-ambulatory PwMS, to use an existing pilot Exercise Buddy model of care to inform a formal clinical evaluation of the model, and to carry out a randomised pilot trial of the Exercise Buddy system. This chapter will consider and discuss the limitations of and information gained from the systematic literature review, the semi-structured interviews and the randomised pilot crossover trial, making recommendations for future research and clinical practice.

Discussion

There is a lack of sufficient research to guide evidence-based interventions for non-ambulatory PwMS at present. From the results of a qualitative study and a high quality randomised crossover trial, the Exercise Buddy system appears to be an effective intervention for this population. The evidence shows that 10 weeks of a physiotherapy-led exercise programme, delivered by trained Exercise Buddies, can significantly improve the self-perceived physical and psychological impact of MS and maintain disability levels for non-ambulatory PwMS. Standard community physiotherapy care does not appear to maintain or improve the self-perceived impact of MS. Evidence for the effects of the intervention on carers is inconclusive.

A number of implications for future research and the clinical practice of physiotherapists can be identified from the combined results of the three papers detailed in this thesis. The Exercise Buddy is a safe and effective system with no adverse effects or deteriorations reported. As standard community physiotherapy care does not seem to be enough to improve or maintain the self-perceived impact
of MS, it is clear that Exercise Buddy care is required for this population. However there are a number of issues surrounding the implementation of the system; mainly those of cost, training of buddies and communication.

In terms of continuous lifelong care for people with chronic diseases and the long-term feasibility of the Exercise Buddy model, it may not be feasible to run the system by depending on charitable contributions via MSI to pay professional carers to act as Exercise Buddies. The introduction of physiotherapy assistants into community physiotherapy for use as Exercise Buddies would be an ideal long-term solution, though in order to realise this, cost analysis studies and combined lobbying from organisations such as MSI and PCCC would need to be carried out. However, the successful current use of physiotherapy assistants in community physiotherapy in the UK (Ellis et al 1998) and New Zealand (Lord et al 2008) and rehabilitation assistants in community falls prevention programmes in Ireland supports this as a logical and prudent step. Until this happens, the Exercise Buddy model will be an effective, evidence-based option for physiotherapy interventions in non-ambulatory PwMS, depending on the availability of funding.

The results of the randomised crossover trial emphasise the importance of using an MRC framework to develop interventions. Based on the findings of the qualitative interviews carried out initially, the necessary qualifications and criteria set out for buddies in addition to the specific Exercise Buddy training helped to ensure the success of the system and that inexperienced buddies was not an issue. As communication difficulties were identified in the qualitative study as a substantial hindrance to the success of the Exercise Buddy system, communication channels were established at the start of the randomised crossover trial to minimise these difficulties. Although this was successful for the most part
and issues with communication were not mentioned by any participant, the
blinding of the lead researcher was not ideal and may have contributed to the
administration error that caused the dropout of two PwMS/carer couples. As with
any multidisciplinary complex intervention, good communication is paramount to
its success (Bélanger and Rodríguez 2008; Miller et al 2005). For an effective
system, it would be recommended that one overall co-ordinator would establish
and maintain regular feedback between physiotherapists, PwMS, MSI, Exercise
Buddies and all involved in the system. The implementation of community
physiotherapy assistants would also alleviate issues with communication, as the
number of entities involved would be reduced.

In terms of research and clinical studies, non-ambulatory PwMS appear to
have been overlooked in the past. Due to the substantial differences between the
function and abilities of those with mild to moderate MS and those with severe
MS, findings from research pertaining to the former group cannot be extrapolated
to the latter. It would also be inappropriate to conduct research in both groups
together without stratifying results, as disability levels are so different, and
previous studies that have stratified results showed that non-ambulatory PwMS
can react differently to interventions to those who can walk (Freeman et al 1997;
Svensson et al 1994). Future studies should also consider potential issues with
memory and cognition during the development stages, particularly in choosing
outcome measures. Problems with cognition and memory are common and often
greater in people with higher levels of physical disability (Sedighi 2011; Lynch et
al 2005; das Nair et al 2012). This creates a dilemma for researchers as patient-
reported outcome measures (PROMs) measure what is important to participants
and are recommended by ICF guidelines (WHO 2001), but are more affected by
issues with memory and cognition than more objective outcome measures. The
use of measures of cognitive and memory function would be indicated for future use in this population in conjunction with PROMs.

It is very important to consider the effects of an intervention on carers, as their ill-health can have a detrimental effect on the health of those they care for (NICE 2004). In particular, carers of a non-ambulatory population often have a larger burden, as increased disability often necessitates higher levels of care (Kersten et al 2000; McCullagh et al 2005). However, as found in this and previous research, dropout rates and recruitment of carers for PwMS in clinical trials can be problematic (Preissner et al 2012). Future research should address the barriers to participation in clinical trials and physiotherapy interventions for carers, and explore ways of helping them to stay involved.

Finally, although the Exercise Buddy system was shown to be effective, future research should evaluate the cost effectiveness of using Exercise Buddies, looking at direct and indirect costs, including long-term outcomes such as illness and hospitalisations due to secondary complications.

**Limitations**

Though many findings of note can be gleaned from the three papers presented in this thesis, certain limitations must be acknowledged. An overall limitation of Paper I is that the systematic review focuses on evaluating the literature surrounding physical rehabilitation in non-ambulatory PwMS from a physiotherapy remit, excluding pharmacological, surgical or assistive device interventions which may be of great benefit to the physical function of non-ambulatory PwMS. However, bearing in mind that the focus of the thesis in its entirety is of physiotherapy interventions in non-ambulatory PwMS, this is a limitation that is not addressable within the scope of this thesis.
With regards to both Paper I and Paper II, the rigour and trustworthiness of the data analyses could have been strengthened by the use of an additional independent investigator in both article searches and selection (Paper I) and the identification of categories and themes (Paper II). However, owing to the financial and time constraints of the thesis study this was not possible.

For Paper II and Paper III, it is difficult to know how much of the recorded benefits of the Exercise Buddy system were due to social interaction and support as oppose to the physical exercise intervention. The issues of poor cognition and memory may also have substantially affected the findings in both of these papers. Outcome measurement is of the utmost importance for any clinical trial, and appropriate measures must be developed for use in this population that will consider the effects of these variables on the intervention in question.

**Concluding statement**

In conclusion, little evidence currently exists for non-ambulatory PwMS, who make up a substantial proportion of PwMS. This thesis has attempted to increase this evidence base using an MRC framework to develop a realistic intervention for non-ambulatory PwMS. Qualitatively, the model of care works if Exercise Buddies are sufficiently trained and adequate communication is implemented. Quantitatively, the model of care reduces the impact of MS in participants more than current standard care which appears to be unable to prevent deterioration. Issues such as cost, adequate outcome measurement within this population and the impact on carers need to be addressed in the future.
References


Sedighi, B. (2011) 'Memory Impairment in Multiple Sclerosis and it's determinant factors', Neurosciences Riyadh Saudi Arabia, 16(1), 24-28.
