Vocational Rehabilitation for People with Multiple Sclerosis

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Abstract

The aim of this research was: to explore the published literature and the experiences of people working with multiple sclerosis (MS); to use information collected to develop and trial a vocational rehabilitation (VR) service; to evaluate the cost utility and impact on service users; and to implement a randomised control trial (RCT).

The Medical Research Council's framework 'Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health' was used to structure the study and facilitated the use of mixed methodologies. These included focus groups, patient reported outcome measures, semi-structured interviews and an RCT.

Barriers to working with MS were identified in the literature and in the focus group discussions. Focus group participants helped design the VR service. This service cost a mean of £730 to provide and appeared effective in maintaining participants in their working roles. The need for early intervention was described at all stages of this study and formed the basis for the VR service trialled in the RCT. The RCT has a five year follow up period and therefore only preliminary results are reported here.

This study demonstrates how service users can be usefully engaged in the development of a service. The results define the VR intervention offered and analysis shows the service was relatively inexpensive to provide. Although only small numbers were recruited at each stage of the study the results still add to the growing evidence for the provision of VR for people with long term neurological conditions.

Statement of Originality

I, Joanna Sweetland confirm that the work presented in this thesis is my own. Where information has been derived from other sources, I confirm that this has been indicated in the thesis. The discussion on MS, work and methodology in chapters 1, 2 and 3 are the results of my own review of the literature. The literature review reported in chapter 4 was my own work.
The original concepts behind this whole study and the design of the focus groups and exploratory trial (chapters 5,6 and 7) were from Dr Diane Playford. I worked out the execution of these stages of the study and completed the research apart from the interviews described in chapter 7 were completed by Bronwyn Jellie (an occupational psychologist from Australia). Analysis of the transcribed data from the focus groups and from the interviews was completed by myself with the research team consisting of Dr Playford, Dr Afsane Riazi and Dr Stefan Cano. For chapter 6 and 8 I designed the questionnaires, prepared the databases, and analysed the data with guidance from Dr Playford and Dr Cano, with some support from the UCL statistics service and Dr Dominic Heaney (consultant Neurologist with experience in health economics). Dr Playford and I designed the RCT reported in chapter 8 with further statistical support from the ION Statistician and Dr Heaney. My supervisors Dr Playford and Dr Cano have reviewed each draft of each chapter. Ideas or quotations from the work of other people are fully acknowledged in accordance with standard referencing practice.

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Thank you to Stefan Cano and Afsane Riazi who have both taught me so much and taken time to supervise my research journey. Especially to Stefan for inspiring me to think about outcome measurement in a different and exciting way.

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List of Abbreviations

Abbreviation:	Meaning:
CBT	Cognitive Behavioural Therapy
CNS	Central Nervous System
COT	The College of Occupational Therapists
COTSS work	COT Specialist Section - Work
CSF	Cerebrospinal fluid
DDA	Disability Discrimination Act
DH	Department of Health
DLA	Disability Living Allowance
DMD	Disease Modifying Drugs
DWP	Department of Work and Pensions
EFD	Employers' Forum on Disability
IB	Incapacity Benefit
ION	Institute of Neurology
EEG	Electroencephalography
ESA	Employment and Support Allowance
FG	Focus group
IVMP	Intravenous Methylprednisolone
MDT	Multi-disciplinary Team
MRC	Medical Research Council
MRI	Magnetic Resonance Imaging
MS	Multiple Sclerosis
NHNN	National Hospital for Neurology & Neurosurgery
NSF LTC	National Service Framework for Long Term Conditions
OT	Occupational therapy
OTWPP	OT in Work Practice and Productivity
PROMS	Patient Reported Outcome Measures
PT	Physiotherapy
RCT	Randomised control trial
SLT	Speech and language therapy
UCL	University College London
UCLH	UCL Hospitals
UN	United Nations
VEP	Visual evoked potentials
VR	Vocational rehabilitation
WHO	World Health Organisation

Some fail,
a handful endure with their lights a little fogged,
but most thrive,
and many return to work in some form:
work – the ultimate badge of health.

(*Saturday* by Ian McEwan 2005. Vintage, London)

Chapter 1. Multiple Sclerosis

1.1 Overview

Multiple Sclerosis (MS) is the most common neurological condition for young adults. People are normally diagnosed at what is considered the prime of life between the ages of 20 – 40. It is at this stage of life that people are often starting their journeys in the world of employment, a time of seeking independence and financial security through work as well as social identity. To be given the diagnosis of MS at such a young and vulnerable age can be life changing. Although many people start off with good intentions that life will go on and work will continue, the reality is that for many, even if symptoms are mild, that unemployment quickly becomes a reality.

This thesis examines the reality of this departure from the workforce and the impact that MS has on working life. Initially, existing research was reviewed looking at the impact of MS on employment. The literature clearly identifies the many difficulties experienced in employment by people with MS. Some of the literature discusses rehabilitation strategies that could have a positive impact on this population. These strategies are based on expert opinion rather than evidence based research. The thesis explores focus group opinions on how a service to support people who are working with MS should be designed. This service is then evaluated in an exploratory trial with cost data, quantitative outcomes and qualitative outcomes collected. A further service was designed and trialled in a randomised control trial (RCT) looking at an early intervention approach with newly diagnosed people. The aim of the RCT was to trial an intervention that would effectively support people with MS to maintain their employment; within this to identify what components were needed to provide this service and to look at whether such a service is cost effective. For the RCT a long-term follow up of five years is to be completed. Only preliminary data has been analysed at this stage. Full data will be analysed after five years and therefore will not be reported in this thesis.

In order to create a basis for the thesis and to provide an understanding of MS that will inform the subsequent chapters and the research they report, this first chapter presents an overview of MS. This chapter describes the pathology, aetiology and prevalence of the disease. Then goes on to describe the diagnostic process, the symptoms MS may cause and the impact that they can have on an individual and society. This chapter will also provide an introduction to the importance of employment for people with MS.

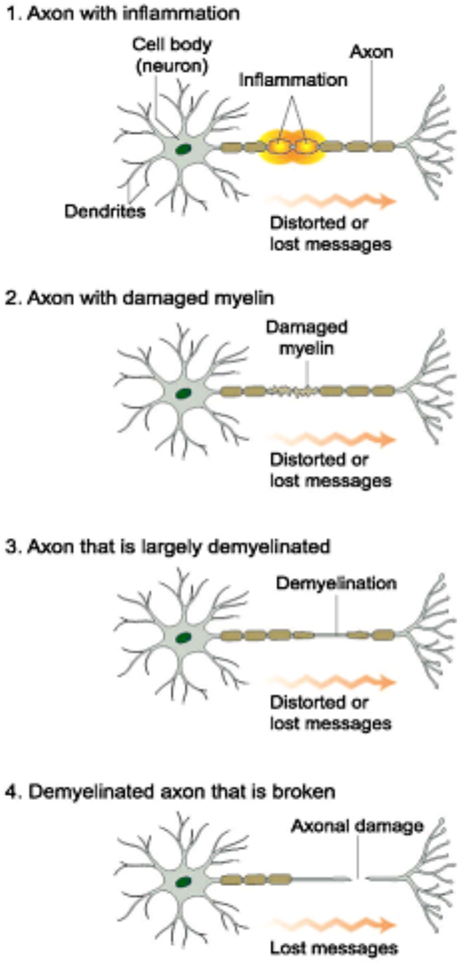
1.2 Introduction

MS is an inflammatory autoimmune disorder of the central nervous system (brain and spinal cord). For the patient, MS threatens with an apparently infinite variety of symptoms but with recurring themes and an unpredictable course[3]. The disease process is one of episodes where white matter within the brain or spinal cord becomes inflamed and eventually destroyed by the person's own immune system. These inflamed areas become scarred, giving the disease its name. The word sclerosis comes from the Greek 'skleros' meaning hard. In multiple sclerosis, hard areas called 'plaques' (also known as lesions or scars) develop around the damaged nerves. 'Multiple' refers to the many different areas of the central nervous system that may have damaged myelin[4]. Many of these episodes do not cause any symptoms, but when sudden symptoms occur that last longer than 24 hours the person is said to have had a relapse[5].

1.3 Pathogenesis

The central nervous system (CNS) consists of the brain and spinal cord which are connected to cranial nerves (12 pairs) and spinal nerves (31 pairs). These networks of nerves signal electrical and chemical messages to each other at great speed, controlling body functions. The nerves are surrounded by myelin, a fatty protective sheath. In MS the disease process is one of episodes of autoimmune inflammation, demyelination and gliosis. The process of demyelination begins at the Nodes of Ranvier, causing them to widen. This damage to the myelin sheath results in a reduction in the amount of current available for depolarisation, which will result in slowing down of conduction speed and ultimately, conduction block[6].

Figure 1.1 Nerve Conduction



Copyright MS Society. Taken from 'Helping you explain MS: A teaching resource for healthcare professionals' 2004[7].

In an acute attack of MS, T-lymphocyctes cross the blood-brain barrier into the CNS where they attack oligodendrocytes (these cells normally form and maintain a protective myelin sheath around the neurones). Three things occur: inflammation, demyelination and axonal loss. The MS attack will lead to inflammation and scarring[8] impeding conduction of nerve impulses. With reduced inflammation, an improvement in nerve conduction is seen (explaining somewhat the recovery that can be seen and variability in symptoms). This axonal damage then results in a permanent loss of conduction. This therefore, explains the progressive disability seen with the disease.

However, early plaque development appears to be focused around small blood vessels, often around the ventricles within the brain, and is composed of cellular infiltration and breakdown of the normally tight blood-brain barrier. There is some controversy about the relationship between the blood-brain barrier breakdown and demyelination, but the two events do appear to be associated. Trying to gain an understanding of the cause and the triggers and responses to a clinical episode (relapse) is an active area of MS research[9].

1.4 Aetiology

The cause of MS is unknown. MS is not directly inherited and, unlike some conditions, it is not caused by one faulty gene. However, there does appear to be a genetic component that makes some people more susceptible to developing MS[4] it is this genetic component combined with some other trigger, maybe environmental or an infection, that activates the disease process.

1.5 Genetics

There is a small genetic link of 4.4% for sister, 3.2% for brother, 0.6% for son or daughter however a 1 in 3 chance of identical twins both having the condition[9].

1.6 Geographical factors

MS is recognised throughout the world as affecting an estimated 2.5 million people. It predominantly affects North Europeans, although Canada has the highest incidence rate. Within the tropics (about 23 degrees north to 23 degrees south) MS is very rare. As latitude increases, MS becomes more common, with the highest rates being found in areas above 50 degrees north and below 50 degrees south. The exception to this is Japan where disease rates are very low[10].

1.7 Prevalence

MS affects twice as many women as it does men. The disease has an incidence of about seven per 100,000 every year, prevalence of around 120 per 100,000 and a lifetime risk of 1 in 400. Figures released by the MS Society in May 2009 indicate that approximately 100,000 people in the UK have MS. The majority of people with MS are diagnosed with the condition when they are aged between 20 and 40, though it can, of course, occur in older people and, more rarely, in children[4].

1.8 Diagnosis

Due to its complexity and variety of symptoms MS is not easy to diagnose. There is no single diagnostic test and other conditions with similar symptoms need to be ruled out before a diagnosis can be made. Most people start their MS with an episode of neurological dysfunction attributable to the CNS and called a ‘clinically isolated syndrome’; not everyone goes on to develop further episodes. Once further episodes occur a diagnosis of MS can be made[9].

The main tests used are:

- A medical neurological examination (checking movement, reflexes and sensory abilities);

- Magnetic Resonance Imaging (MRI) the image may show areas of tissue that are inflamed or damaged in the CNS;
- A lumbar puncture to take a sample of the cerebrospinal fluid (CSF) that surrounds the brain and spinal cord. People with MS are often seen to have antibodies (called oligoclonal bands) in this fluid, showing the immune system has been at work in the CNS; and
- Evoked potential measure how quickly electrical signals travel between the eye, the ear or the skin and the brain. Small electrodes linked to an Electroencephalography (EEG) machine are taped to the scalp. In MS, the electrical impulses within the nerve cells will be slower.[4]

The most frequently used criteria to assist in diagnosis is the ‘McDonald Criteria’ [1;11] and use of MRIs.

Table 1.1 The McDonald Criteria[1]

Clinical Presentation	Additional data needed
- 2 or more attacks (relapses) - 2 or more objective clinical lesions	None; clinical evidence will suffice
- 2 or more attacks - 1 objective clinical lesion	Dissemination in space demonstrated by: - MRI - Or positive CSF and 2 or more MRI lesions consistent with MS - Or further attack involving different site
- 1 attack - 2 or more objective clinical lesions	Dissemination in time, demonstrated by: - MRI - Or second clinical attack
- 1 attack - 1 objective clinical lesion - (monosymptomatic presentation)	Dissemination in space demonstrated by: - MRI - Or positive CSF and 2 or more MRI lesions consistent with MS AND Dissemination in time, demonstrated by: - MRI - Or second clinical attack
Insidious neurological progression suggestive of MS (PPMS)	Positive CSF AND Dissemination in space demonstrated by: - MRI evidence of 9 or more T2 brain lesions - Or 2 or more spinal cord lesions - Or 4-8 brain and 1 spine cord lesion - Or positive VEP with 4-8 MRI lesions - Or positive VEP with <4 brain lesions plus 1 spinal cord lesion AND Dissemination in time, demonstrated by: - MRI - Or continued progression for 1 year

To clarify what an ‘attack’ is the following is considered:

- Neurological disturbance of kind seen in MS;
- Subjective report or objective observation;
- 24 hours duration, minimum;
- Excludes pseudo attacks, single paroxysmal episodes[1].

The definition of a relapse (currently used in clinical trials) is an episode of neurological dysfunction attributable to a lesion within the CNS lasting for at least 24 hours, not attributable to fever and with objective evidence from examination for change, against a stable clinical background of at least one month. The approximate rate of relapse for the average person with MS is around one relapse every 1 – 2 years (this varies according to age and population studied)[9].

1.9 Course and progression

MS has been classified into three differing patterns[1]: relapsing remitting; secondary progressive; and primary progressive.

- **Relapsing remitting MS**

This is the most common form of MS with 80% of newly diagnosed people having this type of the disease. Periods of good health or remission are followed by sudden symptoms or relapses. Relapses happen when inflammatory cells attack nerve fibres in the brain and spinal cord. If inflammation blocks messages in an area that has a specific function, such as the optic nerve, then symptoms occur. The myelin sheath can be damaged and, sometimes, the nerve fibre (or axon) itself is damaged too. When the inflammation subsides, symptoms settle down or entirely disappear. This is known as a remission. Remissions can last any length of time, even years. However, with time patients tend to develop increasing disability due to incomplete recovery after a relapse. In approximately 10% of the MS population there is no accruing disability, and after 10 -15 years these patients are said to have benign MS.

- **Secondary progressive MS**

MS enters the secondary progressive phase when there is accruing disability even between relapses. There are gradually more or worsening symptoms with fewer remissions for a diagnosis of secondary progressive MS. The progression probably results from the loss of nerve fibres (axons) during past relapses. The pathology of secondary progressive MS reflects the chronicity of the inflammatory process, plaques can be of varying age, with evidence of new inflammation often mixed with scarring and areas of complete demyelination. Although remyelination is possible axons cannot fully repair themselves. It is unusual to develop secondary progressive MS until at least three years after diagnosis and about 50% of people will be in this stage after 10 years[9].

- **Primary progressive MS**

10 – 15% of people are diagnosed with primary progressive MS. From the beginning symptoms gradually develop and worsen over time[5]. People tend to be diagnosed later in life (after 40) and men are just as likely as women to be diagnosed. The majority of lesions tend to be found in the spinal cord. People with primary progressive MS never have any distinct attacks or remissions but begin with subtle problems that slowly worsen over time, the disease is progressive from the beginning.

1.10 Prognosis

There is a slight reduction in survival rate for people with MS although death from MS itself is rare. MS maybe associated with a 5-10 year reduction in overall life expectancy[9].

1.11 Disability and cost

A frequently quoted statistic is that after 15 years of MS about 50% of people will be independent, in terms of walking, and 50% will be more disabled and use a stick or a wheelchair[9]. There is increasing evidence that when people are getting to the point of requiring persistent help with walking that they are likely to decline in general functional abilities, irrespective of whether they are having superimposed relapses, primary or secondary progressive MS[9]. In the majority of cases MS can cause serious physical and psychological impairments and is accompanied by considerable social cost[12]. It is estimated that £1.2 billion is spent on individuals with MS per annum in the UK[13]. Present treatment of MS modifies the course of the disease by lowering relapse rates and aims to provide some symptomatic relief for the myriad of symptoms that people with MS may have. However, the variability and unpredictable nature of the condition provides a challenge to promoting health and independence, and in researching effective treatment and management techniques.

1.12 Treatment

There is extensive research being carried out worldwide to increase the understanding of the disease and possible treatments both in terms of cure and management of symptoms. The aim of the research is to limit, repair and prevent the damage caused by MS. However, as yet, there is no cure for MS despite the high levels of research in this area. Due to the fluctuating nature of the disability, people with the disease will need to be managed throughout their lifetime to allow them to lead the best quality of life available. Therefore, it is important that evidence regarding management and symptomatic relief of symptoms is integrated into clinical practice to assist in improving individual's quality of life, and to assist in reducing levels of care[14]. There is strong evidence to support multi-disciplinary team (MDT) intervention providing therapy to remediate symptoms and improving the experience of people with MS in terms of activity and participation[15].

- **Disease Modifying Drugs**

The aim of immunotherapies or disease modifying drugs (DMDs) is not only to reduce relapse frequency but also to prevent transition to the secondary progressive stage of the illness. Currently, the disease modifying drugs generally available are beta interferon (two kinds: 1a and 1b) and glatiramer acetate. The trade names for beta interferon 1a are Avonex and Rebif. Beta interferon 1b has the trade name Betaferon. The trade name for glatiramer acetate is Copaxone. On average, beta interferon and glatiramer acetate reduce the frequency of attacks in relapsing remitting MS by about 30%[4;9].

- **Intravenous Methylprednisolone**

Intravenous Methylprednisolone (IVMP) or corticosteroids can help speed up recovery from a relapse but do not improve the recovery or slow the progression of MS. They are given intraveneously over a period of three days, normally in a hospital setting, although pilot schemes are starting in the country to facilitate this process happening at home, led by a specialist MS nurse[16].

Newer treatments which are now available include Natalizumab (Tysabri) and Mitoxantrone. Natalizumab has been shown to significantly reduce relapse rate, plus MRI results suggest that levels of inflammation are also substantially reduced over a two year treatment period[9]. A Cochrane review of Mitoxantrone concluded it reduced the progression of disability and the relapse rate[17]. Both are used in more aggressive forms of the disease and have side effects that need to be considered and carefully monitored for. There is hope that within two years oral DMDs will be available to patients although these studies are still in final stage trials.

1.13 Symptoms and their management

MS is unpredictable and symptoms can occur randomly. They may last for a few hours, days, weeks, or months. Many MS symptoms, such as fatigue, are not visible to other people. Some common symptoms in order of prevalence are: fatigue, poor balance, muscle weakness, decreased mobility, muscle stiffness, memory problems, muscle spasm, loss of dexterity, sensory loss/numbness, muscular pain, constipation, concentration problems, and urinary urgency[9]. The coordinated management of interrelated symptoms is the key to successful management of MS[9].

As Table 1.2 illustrates the disease can affect multiple sites, which can lead to widespread disability. The table also reflects the variable nature of the disease itself. Not only does the disease vary from individual to individual, depending on the unpredictable patterning of the demyelination, but is also very variable within individuals. It is important to acknowledge this variability when researching this population, for not only does this make finding homogenous samples difficult, but can also complicate obtaining stable baselines or treatment/intervention courses.

Table 1.2 Sites of Lesions Causing Signs and Symptoms in MS (adapted from figure 1[3])

Site	Symptoms	Signs	Comments / Loss of Participation
Cerebrum	Cognitive Impairment Depression Epilepsy	Reduced short term memory, sustained attention, conceptual reasoning, information processing, executive functions and visuospatial skills, low mood and seizures	Can affect 65% of individuals with MS. Can have a significant impact on ability to perform activities of daily life and employment. Treatment focuses on strategies to aid memory, and cognitive rehabilitation[18].
Optic nerve	Loss of vision, poor control of eye movement	Reduced colour acuity, double vision, can cause loss of vision.	Optic Neuritis common as an initial symptom. Can affect individual's ability to read, write, watch television or drive[19].
Cerebellum and cerebellar pathways	Tremor Ataxia	Postural and action tremor Limb in coordination	Can significantly affect abilities to perform functional activities and is very variable[14]. Also one of the most resistant and complex symptoms to treat[20] with limited drug treatment.
Brainstem	Diplopia, oscillopia Vertigo Impaired speech and swallowing	Nystagmus Constant feeling of dizziness Dysarthia and psudobulbar palsy	Can significantly affect abilities to perform functional activities and reported to be a common symptom[14].
Spinal cord	Spasms Spasticity Weakness Bladder dysfunction Erectile impotence Constipation	Upper motor neurone signs	Most commonly reported symptoms and a major contributor to disability [21].Treatment aims to improve function[14]. Weakness treated with muscle training and energy conservation programmes[22] .
Others	Pain Fatigue Sensory loss Temperature sensitivity		Varies widely in individuals, but are serious problems in this population[23].50% of people with MS complain of pain[24].

Two symptoms which are particularly pertinent to those in employment are:

- **Fatigue**

Fatigue is frequently reported as the single most important symptom interfering with everyday life. In a recent study[25] fatigue was given as the most common reason for loss of employment. It may occur at any stage in the disease trajectory and is often increased at times of relapse[26]. Not only do patients experience extreme tiredness but also the effect of fatigue is often that symptoms are exacerbated. Described as primary fatigue and secondary fatigue these categories delineate between those aspects of fatigue which are related directly to MS (primary fatigue), e.g. short circuiting or nerve fibre fatigue, and those which are secondary contributors but cause fatigue, e.g. high room temperature, infections and poor lighting. It is important when assessing fatigue that the social, environmental, mood and drug factors are addressed before the fatigue is attributable to MS. Initial therapy should be aimed at optimizing sleep and the person's daily routine, often supported through fatigue management programmes[27] by occupational therapists (OT) which educate about the theories of the cause of fatigue and energy conservation strategies to minimise the impact it can have on daily activities. Pharmaceutical measures tend to only be used in extreme cases as they tend to only be effective on less than half the population. The two main drugs which target fatigue and have been shown to be effective are amantadine and modafanil[9].

- **Cognitive difficulties**

Cognitive dysfunction can be a prominent feature in MS where it is unrelated to disease duration or level of physical disability[26]. The pattern of cognitive decline in MS is predominantly sub cortical with the main deficits being; short-term memory, attention, conceptual reasoning and speed of processing. There is often a need for neuropsychological assessment with support from a MDT to manage the functional impact[28]. People rarely report cognitive problems but instead notice a decline in their functional abilities, for example at work people may report they feel less productive. Cognitive impairment can have a devastating impact on psychosocial functioning and is also linked to low mood. Although relatively mild people with MS may also develop mood disorders such as low mood, irritability, poor concentration and anxiety. Psychological support of cognitive behavioural therapy (CBT) is often sufficient to manage such symptoms although the need for medication is indicated at times.

1.14 Disease stages and management

Appropriate symptom management is essential in aiding rehabilitation and promoting wellbeing[26]. Treatments aimed at reducing disease activity will have little or no impact on existing impairments therefore management of a person with MS will focus on optimizing function and control of symptoms. This approach necessitates effective MDT working with the individual at all stages to facilitate learning and self-management techniques. There is not one uniform management plan but an individualised approach is required for each person as MS manifests itself in many different ways. Management plans often combine education, therapy (usually physiotherapy (PT) and OT) and drug treatment with the need at times for inpatient rehabilitation or more invasive techniques such as intrathecal baclofen (for the management of severe spasticity). It is essential that the person with MS is central to the management process and is actively involved in monitoring the impact on symptoms and the effectiveness of therapeutic interventions.

- **Diagnosis**

Ideally a diagnosis will come from a consultant neurologist with support from a MS nurse specialist. People who are newly diagnosed seek further information from their neurologist or the internet[29]. In the UK both the MS Society and the MS Trust are charities actively providing information and support to people with MS. Often in these early stages there is not the need for any other MDT input although referrals to other professionals maybe required if specific problems persist or further advice is required. The psychosocial impact of a diagnosis of MS can be vast, affecting patients and their families in a myriad of ways including income loss, employment issues, impact on relationships, impact of parental roles, emotional burden and adjustment difficulties. *'It takes a sentence and probably 10 seconds to tell a person they have MS… and a lifetime to deal with it'*[30]

Key issues for people at the point of diagnosis are:

- Certain clear diagnosis;
- Appropriate support at diagnosis;
- Access to information;
- Continuing education[9].

It is therefore essential that management of the condition is undertaken within a MDT[26].

- **Minimal impairment**

From diagnosis and through the early stages of the disease progression, people with MS tend to experience relapses from which they make a full recovery. During these stages support maybe required from one or more of the MDT for example; fatigue management strategies from the OT, advice on good exercise from the PT, management of some of the psychological adjustments required thorough CBT. Interaction with other professionals tends to take place in an outpatient setting within the hospital.

- **Moderate disability (symptomatic management and neuro-rehabilitation)**

Disease progression is associated with loss of abilities and life roles which activates grief and the need for adaptation. People need support to identify new goals and make different life plans. An integrated MDT approach that aims to increase occupational performance and improve quality of life can be essential. Periods of inpatient rehabilitation can be beneficial to maximise function and increase confidence. Following a hospital admission care is often continued in to the community through liaison with the community rehabilitation teams.

- **Severe disability (palliation)**

Management in the end stages of MS is generally completed at home with support from the community care teams and palliative services if required.

1.15 Consequences of the disease

The progressive course and early onset of MS with long survival time can have considerable consequences on personal activities, social participation and quality of life[31]. In the wider aspects the direct and indirect annual costs of MS have been estimated in the U.K to cost £1.2.billion, with lost earnings (33%) accounting for a large proportion of that cost. The estimated costs also correlated positively with a rise in disability[13]. Fifteen years after disease onset 15% of MS patients will need to use some sort of mobility aids and 29% will need to use a wheelchair[32]. Other statistics show that during the ten years after diagnosis 50-80% of people with MS will be out of work[33], with people with MS entering nursing homes at a younger age than the average[34] which has huge financial implications for wider society.

The specific symptoms of MS can also have a significant impact on activities of daily life, care and quality of life. Spasticity, spasms, pain and fatigue with muscle weakness can affect all aspects of a person's life[14]. Effortful mobility due to spasticity and weakness can be frustrating, embarrassing and tiring[35]. Changes in posture and contracture can lead to complications when trying to move and find a comfortable position in lying, sitting or standing[36]. Lack of activity due to fatigue, and fatigue itself can cause low mood, while fatigue can affect performance in all activities[23]. Poor sleep, with altered sleep patterns, as a result of spasm and pain will heighten the general level of fatigue. Tremor and ataxia can lead to problems with fine movements and coordination causing difficulties with activities of daily life, washing, dressing and toileting[35]. These symptoms can also cause social isolation and fear of venturing outside due to the embarrassment of being labeled disabled or ‘drunk’[36]. Bladder problems can also lead to social isolation with embarrassment and pain[35]. Cognitive impairments can be overwhelming to patients and their families[18]. It is reported that cognitively impaired individuals are less likely to be employed or participate in social activities, and are more likely to need help with financial and household care as well as personal care than cognitively intact individuals with the same level of physical disability[37].

The escalating cost of MS to the individual, their families and the health service is substantial. Keeping people with MS as independent as possible or slowing down the progression of the disease even by a few years has very significant impact on quality of life and has financial implications for both the individual, their families and society[13]. This directly correlates with the need to keep people with MS in employment to reduce their economic burden and improve health through work.

1.16 Summary

This first chapter has identified that MS is a long-term complex disease that affects a significant number of young adults for the duration of their lifetime. MS with its unpredictable nature and risk of severe disability impacts on adults at the time when they are marking major life decisions about careers, housing, life partners, and having a family. The progressive nature of MS can cause significant disability, with resulting implications on cost and provision of care. With the disease symptoms varying it is obvious that maintaining employment, or attempting to return to it, becomes a crucial intervention not only on an individual level but also for society by the resulting increased costs and burden of care that result if no intervention is provided. In a recent report on the global prevalence of MS and the resources available worldwide 30% of respondents identified work related issues as of major importance[38]. A more detailed look at work/employment and the issues surrounding work plus the concept of vocational rehabilitation (therapeutic intervention to support people with work related issues) will be presented in the following chapter.

Chapter 2. Work and vocational rehabilitation

Chapter one describes MS and the impact it can have on individuals diagnosed with the disease. The combination of the young age of diagnosis, the unpredictable nature of the symptoms and unknown disease trajectory leaves employed people with this condition feeling vulnerable and they often struggle to maintain their employment[39;40]. Evidence is growing that work is good for health[41] and there is an increasing interest from health professionals to support people in their employment. This interest is supported by Governmental guidance in both Department of Health (DH) and the Department of Work and Pensions (DWP). This chapter discusses the concept and importance of work. It also explores the guidelines, the concept of vocational rehabilitation (VR) and the role the OT profession has within this form of rehabilitation. It outlines the recent political drivers as well as the societal and cultural changes which have firmly put VR onto the rehabilitation agenda. Finally it addresses what this means directly for people with MS.

2.1 Introduction

There are numerous definitions of work but no accepted universal definition of work and ongoing debate as to whether work and employment are different concepts. Work involves the application of physical or mental effort, skills, knowledge (or other personal resources), and usually involves commitment over time. Work can be a source of status and identity. It enables the individual to structure and occupy time and gives a sense of personal achievement[42]. Work is not only a 'job' or paid employment, but includes unpaid or voluntary work, education and training, family responsibilities and caring[41]. The College of OTs (COT) describes work in this way: 'Not everyone wants to be employed, but almost all want to 'work', that is to be engaged in some kind of valued activity that uses their skills and facilitates social inclusion'[43]. Work fulfils survival and psychological needs of individuals. Income generated through employment helps people secure the goods and services they need to exist, and participating in work offers individuals a sense of meaning and identity[44]. Employment is often viewed as different to work as the below definition shows:

Employment is a job that typically takes the form of a contractual relationship between the individual worker and the employer over time for financial (and other) remuneration, as a socially acceptable means for earning a living. It involves a specific set of technical and social tasks located within a certain physical and social context[41]. Employment can be interpreted as productive activity that extends beyond enjoyment of the activity itself.

The United Nations (UN) Declaration of Human Rights article 23[45] states that:

> (1) Everyone has the right to work, to free choice of employment, to just and favourable conditions of work and to protection against unemployment.
>
> (2) Everyone, without any discrimination, has the right to equal pay for equal work.
>
> (3) Everyone who works has the right to just and favourable remuneration ensuring for himself and his family an existence worthy of human dignity, and supplemented, if necessary, by other means of social protection.
>
> (4) Everyone has the right to form and to join trade unions for the protection of his interests.

In 1995 the UN and the World Health Organisation (WHO) expanded article 23 to say “Every citizen of the world has a right to healthy and safe work and to a work environment that enables him or her to live a socially and economically productive life”[46]. Globally it is obvious to see that this statement is rarely met for a multitude of reasons and, that once disability becomes part of the equation this can further complicate the need, desire, or ability to work.

2.2 Work as a ‘social’ construct – benefits for individuals

• Work and well-being

Well-being is the subjective state of being healthy, happy, contented, comfortable and satisfied with one’s quality of life. It includes physical, material, social, emotional (‘happiness’) and development and activity dimensions[41]. In our Western society work is often seen as defining who we are. Work is our contribution to society and is a central part of most peoples’ lives and is therefore an intrinsic part of our wellbeing. ‘What do you do?’ is often the question one is asked on meeting a person for the first time. A letter written to British Journal of OT[47] stated “Few human activities are regarded with such universal approval as work. In most societies, some form of work is, in itself, a prerequisite for life’s essentials. Constructive employment is a fundamental adult experience. Not only is it a means of participating in families and social organisations, but work also assumes a role and identity and channels energy into activities, which are generally seen as desirable for the community at large as well as for the individual.” Work is important for human beings it confers financial benefit and contributes to adult identity[48] and status[49], it can improve quality of life[50] and has been shown to reduce ill health[41]. Roosevelt said in 1903 “Far and away the best prize that life has to offer is the chance to work hard at work worth doing”[51]. Work of course comes in many forms, Ross describes work under the following four headings[52]:

- Paid: employment or job with a contract. Worker receives material reward, usually financial. This has the highest status in our society.
- Unpaid: Plays an important supporting function towards maintaining our society, despite the worker not receiving payment. It may take place at home e.g. household work or care giving, or outside of it e.g. volunteering, training or education.
- Hidden: illegal or morally questionable activities. This could include services provided for cash but not declared for taxation purposes, forced labour, drug trade or prostitution.

- Substitute: contrived work for disabled people in a segregated environment e.g. sheltered workshops, work projects or day centres. It is unpaid or minimal therapeutic earnings, it risks being exploitative.

- **Work and health (impact of work on health)**

Health comprises of physical and mental well-being, and (despite philosophical debate) is usually understood in terms of the absence of symptoms, illness and morbidity[41]. There is a growing literature examining how maintenance in a working role when disabled not only helps improve quality of life but also reduces ill health. Waddell & Burton[41] synthesised 412 different pieces of relevant literature (papers, reviews, policies, briefings, texts, editorials, books, reports, research summaries, codes of practice, guidance, handbooks) that were reviewed from the period of 1980 - 2006. Although the report primarily focused on mild/moderate mental health problems, musculoskeletal and cardio-respiratory problems it was felt the findings are widely applicable. It generated the following key findings:

- employment is generally the most important means of obtaining adequate economic resources, which are essential for material well-being and full participation in today's society;
- work meets important psychosocial needs in societies where employment is the norm;
- work is central to individual identity, social roles and social status;
- various aspects of work can be a hazard and pose a risk to health;
- the nature and quality of work is important to health;
- job insecurity has an adverse effect on health;
- there is a powerful social gradient in physical and mental health and mortality, which probably outweighs (and is confounded with) all other work characteristics that influence health. Lower social economic groups have poorer physical and mental health; and

- paid employment generally has beneficial or neutral effects and, importantly, has no significant adverse effects on the physical and mental health of women.

There is also strong evidence that unemployment is generally harmful to health and that re-employment leads to improved self-esteem, improved general and mental health, and reduced psychological distress. The review reported a consensus across multiple disciplines, disability groups, employers, unions, insurers and all political parties. It was based on extensive clinical experience and on principles of fairness and social justice. When health conditions permit, people should be encouraged and supported to remain in or re-enter work as soon as possible because it:

- is therapeutic;
- helps promote recovery and rehabilitation;
- leads to better health outcomes;
- minimises the harmful physical, mental and social effects of long term sickness absence;
- reduces the risk of long-term capacity;
- promotes full participation in society, independence and human rights;
- reduces poverty; and
- improves quality of life and well-being.

2.3 Work as a ‘political’ construct – benefits to society

In the sixteenth century English society started to recognize the importance of employment. Within local parishes workhouses were established where people in extreme poverty would live and work. In the seventeenth century this continued with the development of Almshouses (a form of charitable housing) and the start of child apprentices. Children were taken in by a master of a trade and taught the skills so they could earn a living through this work. The eighteenth century brought the industrial revolution and with it a belief that there were moral cures for the ills of society, the use of work and occupation was built upon these beliefs. By the late nineteenth century people were living in towns and working in mining or manufacturing. It was an age of migration and a sudden increase in population growth from nine million to 41 million. In the nineteenth century the philanthropy model was introduced and for some workers there was provision for those injured in industrial accidents[53].

In the twentieth century medical advances were occurring and a social insurance was introduced in 1911. In the United States of America the Vocational Rehabilitation Act was introduced in 1920. By the 1930's the UK had its first curative workshop attached to the military to support and help the rehabilitation of injured army personnel back into the work place. In 1944 the United Kingdom introduced the Disabled Persons (employment) Act which was influenced by the circumstances surrounding the end of the Second World War. Chapter ten stated its aims as 'to give better provision for enabling persons handicapped by disablement to secure employment and/or work on their own account.' This was the first time people with disabilities had rights protected in law.

The 1980s saw the increase of sheltered workshops and substitute work. Social security became more complex with a focus on ways to help people return to work. However the late 1980s brought high unemployment and in a politically motivated effort to manipulate the numbers down people were moved from unemployment benefit to incapacity benefit.

Since the passing of the Disabled Persons Act in 1944 employment and disability legislation and the associated services provided by the Government had changed very little. No significant further legislation was brought in during the next 50 years[54]. The introduction of the Disability Discrimination Act (DDA)[55] was in 1995. This combined with a change in government in 1997 saw a massive welfare reform "although there has been no worsening of health since the 1980's labour market participation and sickness remains an issue"[56].

2.4 Concepts of employment vs unemployment

Until mid 2009 UK employment had been at an all time high and unemployment rates at an all time low. However, the recent global economic recession in 2009 saw unemployment rates rising significantly. Employment levels are seen as an intrinsic part of the country's wellbeing and economic stability. In economic terms unemployment is the state of an individual looking for a paying job but not having one. Unemployment does not include full-time students, the retired, children, or those not actively looking for a paying job[52]. People are unemployed for a myriad of reasons and the Government now puts emphasis on getting people back to work through the benefits it offers. Job Seekers Allowance and the recently introduced Employment and Support Allowance (ESA) are examples of such benefits.

2.5 Days lost to sickness and cost to the economy

Recent statistics from the office of National Statistics[57] show that currently in the UK there are 28.83 million people of working age with less than 2.51 million people in unemployment. Alongside this figure there were 8.17 million working age inactive people (the report does not break down how many of these are on sickness related benefits).The Government in 2006 launched 'A New Deal for Welfare: Empowering People to Work'[58] clearly laying out the plans to facilitate this happening with major changes to Incapacity Benefit (IB) and how it is claimed starting to be enforced from 2007. To understand the figures it is important to look back a few decades. In the 1980's unemployment figures were growing at a rapid rate, unemployment was at an all time high and the Government needed to address the problem. IB was introduced and people who were off work sick moved from an unemployment status to a 'too sick to work' status. The number of unemployed dropped and numbers on IB rose. This situation remained until mid 2009 when the

Government needed an increase in the work force and with unemployment at an all time low; the issue of large numbers of people on IB was finally being addressed.

2.6 Changing demographics

The UK has an ageing population. The current ratio of people in work to people in retirement is 4:1 by 2050 it is estimated this will have changed to 2:1. This has serious implications for the Government as there will not be enough people working to support the economy. The Government has predicted that it needs to increase the current employment rate from 75% to 80%. One area to be addressed is the number on IB. The DWP spent £12.6 billion on incapacity benefits during 2008-09. There are currently 2.63 million people (7.2 per cent of working age population) in Great Britain who receive incapacity benefits because of disability or ill health. Great Britain has the ninth highest rate of incapacity benefits claimants across 28 Organisation for Economic Cooperation and Development (OECD) countries (OECD average 5.8 per cent). The volume of people on incapacity benefits increased markedly from 0.74 million in February 1979 to 2.78 million in November 2003. This was despite improvements in the nation's health[59]. 90% of people on IB (2.6 million) report that they expected to return to work when they took sick leave. Of these 2.6 million 98% have musculoskeletal and minor symptoms[60] and 5% of IB claimants have a neurological condition; of whom 14% have MS. Therefore people with a neurological condition form only a small part of the population that is unable to work because of health related problems.

The average duration of IB claims is 8 years and most alarmingly after 2 years on IB people are more likely to retire or die than return to work. It is not just the existing caseload every year an additional 600,000 people move on to IB[61]. The economic cost of sickness absence and unemployment associated with working age ill-health are over £100 billion a year which is greater than the annual budget for the NHS and the equivalent to the entire GDP of Portugal[61].

The DWP has completed a major review of the current situation[58] it aims to revolutionise the way people claim incapacity benefits its goal being to get people back to work. The new system which took effect in October 2008 introduced the ESA to replace IB. Work is currently high on the government agenda and since 1995 the following Government papers and legislation have been published or implemented:

Table 2.1 Government Publications and New Legislation

- The *Disability Discrimination Act* 1995 and 2005[55]
- *1997 change in Government*
- The New Deal for Disabled People. Dept of Social Security (1998)[62]
- National Service Framework in Mental Health. Dept of Health (DH) (1999)[63]
- Disability Rights Commission (DRC) Act 1999 (Code of practice on employment and occupation 2004)[64]
- Securing Health Together. Health and Safety Executive (HSE) 2000)[65]
- Pathways to Work: Helping People into Employment. DWP (2002)[60]
- The *Employment Act* 2002[66]
- Building a capacity for Work: A UK Framework for Vocational Rehabilitation – DWP (2004)[67]
- A Strategy for Workplace Health and Safety in Great Britain to 2010 – Health and Safety Council[68]
- Choosing Health: Making Healthier Choices Easier – DH (2004)[69]
- Prime Minister's Strategy Unit: Improving the life chances of disabled people[70]
- Health, Work and Well-being – Caring for our future. DWP, DH, HSE (2005)[41]
- National Service Framework for Long-term conditions - DH (2005) [71].
- A New Deal for Welfare: Empowering people to work. DWP[58] (2006)
- *The Commission for Equality and Human Rights started integrating the DRC 2007*
- *UK Rehabilitation Council formed 2007*
- Lord McKenzie commissioned an investigation into the evidence of vocational rehabilitation 'What works, for whom, and when?' (2008)[72]
- The *Welfare Reform Act* 2009[73]
- Working for a Healthier Tomorrow - Dame Carol Black (2008)[61]
- High quality care for all – Lord Darzi (2008)[74]
- *2010 change in Government*

The focus has been on returning people to the work force however there is a shift in focus more recently to look at maintenance of working roles. In a 2006 House of Commons report[75] it was stated "…preventing a person losing a job because of their disability merits further attention as it seems more efficient than providing assistance and support after this has happened" also Dame Black's review[61] strongly argues that early interventions can prevent short term sickness absence from progressing to long-term sickness absence and ultimately worklessness.

2.7 Changing views of disability

The DDA[55] provides legal protection for people with disabilities and slowly attitudes within society are changing as the legislation is enforced and used to educate the population. As people’s disability awareness increases and as more high profile people take the public stage, opinions are starting to change. Recent Government policy should help facilitate the change. There is also a growing awareness that there is an urgent need to have some kind of support service to facilitate disabled people returning to or remaining in employment; this is called vocational rehabilitation (VR).

2.8 Vocational rehabilitation

There are many definitions for VR the DWP in 2004 called it “a process to overcome the barriers an individual faces when accessing, remaining or returning to work following injury, illness or impairment. It involves procedures to support an individual and or the employer or others. It involves practically managing the delivery of VR services.”[67]

VR was clearly defined by the British Society of Rehabilitation Medicine (BSRM) as the concept of enabling individuals with either temporary or permanent disability to access, return to, or remain in, employment[51]. It considers the complex relationship between personal and environmental factors, availability of services and the legislative/benefit framework on a worker’s occupational ability or disability. The reports clearly states that VR aims to maximise the ability of an individual to return to meaningful employment. Best rehabilitation practice:

- improves work and activity tolerance;
- avoids illness behaviour;
- prevents deconditioning;
- prevents chronicity; and
- reduces pain and the effects of illness or disability.

The Vocational Rehabilitation Association (VRA) describes it as a process of facilitation, grounded by a belief in the dignity and worth of all people, designed to assist people with impairments or health conditions to secure employment and integrate into the community. The process is interdisciplinary by nature and may involve functional, biopsychosocial, behavioural and/or vocational interventions[76]. The techniques utilised within this process may include, but are not limited to:

- assessment and appraisal;
- goal setting and intervention planning;
- provision of health advice and promotion, in support of returning to work;
- support for self management of health conditions;
- career (vocational) counselling;
- individual and group counselling focused on facilitating adjustments to the medical and psychosocial impact of disability;
- case management, referral, and service coordination;
- programme evaluation and research;
- interventions to remove environmental, employment, and attitudinal obstacles;
- consultation services among multiple parties and regulatory systems;
- job analysis, job development, and placement services, including assistance with employment and job accommodations; and
- the provision of consultation about and access to rehabilitation technology.

2.9 History of vocational rehabilitation

VR is not a new concept. Hippocrates, known as the author of modern medicine, understood much of the place of ‘natural’ occupation such as labour, intellectual and recreational pursuits and like modern day OTs recommended particular activities for particular purposes[47]. Occupation has been used as a ‘cure’ for over 200 years and was one of the founding concepts behind OT in America in 1917[77]. Occupation is the inbuilt mechanism that enables humans and other animals to obtain the requirements for living, for survival and for health. OTs claim that what people do can influence physical, mental, social and spiritual health[47]. OT led VR was used extensively after both world wars and then the political climate changed and VR in the UK declined. VR is now rising to prominence again in the corporate world and that of health care, with interested parties looking to countries such as Australia and America for insights into this form of rehabilitation.

2.10 The history of occupational therapy and the relationship with work

In the early 1900s occupation based programmes were started in psychiatric hospitals around the country and for the first time schools opened for mentally and physically handicapped children. World War I with its thousands of casualties lead to the opening of curative workshops with the aim being to retrain and rehabilitate injured soldiers. Jones in 1916 notes on military orthopaedics "Those of us who have any imagination cannot fail to realise the difference in atmosphere and morale in hospitals where patients have nothing to do but smoke, play cards, or be entertained, from those where for part of everyday they have regular, useful and productive work"[78]. Curative workshops were shut down post war. In 1918 in America OT as a profession was founded. The first OT in the UK was not appointed until 1925 with Dorset House, the first OT training school, opening in 1930. During the 1950's – 60's work was a focal area of practice for OT across the country with heavy workshops being used to retrain and rehabilitate the disabled. OTs were used to facilitate the resettlement of patients from hospital to community. OTs used work assessments to test physical and mental capacity within stimulated work situations and job analysis to estimate the demands of an occupation within its authentic environment. During the 1970's – 80's there was a drive within the profession to be reductionist and work more closely within the medical model. Heavy workshops started to close. OTs stopped addressing issues of work, as priorities changed to manage increasing bed pressures in the acute setting. In 1995 OT in Work Practice and Productivity (OTWPP) special interest group was established both to provide support and also raise the profile of OT in work related issues. It was recently renamed to the COT Specialist Section – Work (COTSS work). Its establishment was one indication that rehabilitation aimed at ‘return to work’ was once more assuming importance[78]. The BRSM report states OTs have an important role to play in VR and yet currently very few posts exist[51].

OTs are skilled in activity analysis and can assist employers and trainers in devising reasonable adjustments to work tasks to enable those with disabilities to be valued employees[51]. Despite these skills there is very little written in the OT literature. A review of the literature commissioned by the COT stated ‘The main body of research into OT work rehab interventions has concentrated upon work hardening techniques’ used in the heavy workshops of the 1970’s – 1980’s[42]. The key policy message from this review was “Challenges for OTs and other rehab specialists are being presented by initiatives geared towards helping individuals retain jobs. The goal is early identification and response to needs for rehabilitation and support with the aim of avoiding long term sickness and ultimately loss of employment.”

Key findings were:

- The need for more research especially on service delivery;
- The NHS focus was on acute illness not on the consequences of chronic conditions[42].

2.11 Historical development of vocational rehabilitation in the UK

Despite the fact that VR is poorly developed in the UK there is still a scant history, which shows that numerous attempts to start a VR service were tried. The following table is taken from the BSRM report[51]:

Table 2.2 Historical Developments in Vocational Rehabilitation

Year	Development
1914 - 1918	Government and professional interest started – move to retrain disabled ex service men and the establishment of remedial work – post war interest lapsed.
1939 - 1945	Interest revived, aim to reduce disability, retrain disabled service men, employ disabled civilians in occupations where workers had been called up to the forces. RAF established 7 rehab centres.
1942	Beveridge Report 'a national health service for prevention and cure of disease and disability by medical treatment'.
1943	- Miners Welfare commission established 7 rehab centres for miners and the first industrial rehab unit established. - Tomlinson Report focused on 'proposals for the introduction at the earliest possible date of a scheme for the rehabilitation and training for employment of disabled persons'.
1956	Piercy Report addressed the provision for rehabilitation, training and resettlement of disabled people.
1962	A Report from a committee of the Sheffield Regional Hospital Board recommended the establishment of comprehensive medical and industrial rehabilitation centres near district general hospitals. The centres were not built.
1972	- Tunbridge Report (published by the DoH and Welsh Office) – gave reasons for the failure of provision and focussed on the 'future provision of rehabilitation services, their organisation and development'.
Consistent themes in these reports were the lack of provision, lack of coordination and the division of responsibility between government departments and other agencies. Implementation of recommendations has been sparse. Divisions growing between the health and employment agencies.	
Late 1970's – 1980's	There existed a diverse range of rehabilitation and vocational rehabilitation units; miners rehabilitation centres, medical rehabilitation departments, RAF rehabilitation units, medical rehabilitation centres (e.g. Employment rehabilitation centres); special training centres, demonstration centres and centres established by voluntary organizations.
1990's +	A slow demise of facilities and initiatives, less interest from the NHS.

The 2003 BSRM report concludes that the development of services has been piecemeal, uncoordinated, lacked adequate investment and been inadequate for society's needs. Services today are woefully inadequate in scope, content and standards which might reasonably be considered appropriate for the beginning of the twenty-first century[51]. VR has been poorly developed in the UK and services remain sparse and ad hoc in nature[51]. Services in other countries such as Canada and Australia are better developed and have been shown to be cost effective[79].

2.12 The Disability Discrimination Act

The DDA[55] aims to end the discrimination faced by many disabled people. In April 2005 the Act was extended. One of the key changes is that people with MS are covered from the point of diagnosis rather than from the point when the condition has adverse effects on their ability to carry out normal day-to-day activities.

The DDA[55] applies to all employers, whatever their size, and everyone who provides a service to the public, except the armed forces. It protects the rights of everyone with MS, except elected councillors or those working mainly outside the UK. Under the DDA[55], it is unlawful for employers to treat a disabled person less favourably than others because of their disability, whether they are a client or an employee. All businesses and other organisations such as shops, restaurants, leisure centres and places of worship are required to take reasonable steps to make their premises accessible to disabled people who want to use their services. It may mean removing, altering, or providing a reasonable means to avoid physical features that make access impossible or unreasonably difficult for disabled people. If an employer can see that someone needs adjustments at work because of a disability, they must undertake them regardless of whether or not the person has told them about the disability.

- **Types of discrimination**

Under the DDA[55] discrimination occurs where there is:

- Direct discrimination (e.g. refusal to employ a disabled person);
- Failure to make reasonable adjustments at work;
- Disability-related discrimination (e.g. dismissing someone after a long period of sick leave due to an MS relapse); and

- Victimisation and harassment (eg. because someone wishes to take action under the DDA).

The DDA in the UK is strong and regularly tested in the courts, so that an increasing body of case law exists[80].

2.13 MS and Work

People are often diagnosed with MS between 20 – 40 years of age when careers are starting and work is an important part of daily routine. Over the years, numerous medical, psychological, allied health, and rehabilitation researchers have sought to understand why people with MS make a premature mass exodus from the labour force (explored further in chapter three), usually of their own choosing and often before the disease has rendered them incapable of working[39]. The unpredictable course of MS combined with fluctuating symptoms can lead to people exiting employment. When a mismatch between a person's functional capacities and the demands of the job occurs it is described as work instability[81]. Although multidisciplinary rehabilitation is generally available to support people with MS when relapses occur too often the issue of work is not addressed[38] and work instability becomes a growing problem. The guidelines discussed below aim to address this shortfall in service provision and clearly outline what people with MS should expect.

2.14 The National Institute of Clinical Excellence guidelines

The National Institute of Clinical Excellence (NICE) Guidelines 'The Management of MS in Primary and Secondary Care'[82] highlight the areas of key priorities for clinicians working with people with MS covering areas such as: guidance; general principles; teamwork; diagnosis; treatment; altering risks of relapses; rehabilitation and maintenance of functional activities and social participation; managing specific impairments; implementation in the NHS and research. The report is comprehensive and used as a guide in many health care settings. Of particular interest to this study is section 1.6.2

‘Vocational activities: employment and education’ which states the following provisions should be available:

Table 2.3 NICE Guidelines - Vocational Activities

Any person with MS who is in work or education should be asked specifically whether they have any problems, for example motor, fatigue or cognitive difficulties.
Any individual who has problems that affect their work or education should be seen for further assessment of their difficulties, preferably by a specialist vocational rehabilitation service, or specialist neuro-rehabilitation service.
The results of the assessment should be used: o to advise the person with MS on strategies, equipment, adaptations and services available to assist with vocational difficulties; and/or o to advise the employer or others, with permission from the person with MS, on strategies, equipment and adaptations to assist; and/or o to give information to the disability employment advisor, if involved.
The person should always be informed about available vocational support services (currently including Disability Employment Advisers and the Access to Work Scheme), and that there may be adjustments at work to which they are entitled under the DDA.
Any individual who cannot stay in or find alternative employment should be advised about other options such as voluntary work and where to find information about these options. (*evidence from an expert committee*)

The recommendations from the NICE guidelines correlate and are echoed by The National Service Framework for Long Term Conditions[71].

2.15 The National Service Framework for Long Term Conditions

The National Service Framework for Long-term Conditions (NSF LTC) was launched in March 2005[71]. The NSF LTC aims to transform the way health and social care services support people to live with long-term neurological conditions. It is a key tool for delivering the government’s strategy to support people with long-term conditions.

Of the eleven quality requirements, quality requirement number six is vocational rehabilitation. The aim is to enable people with a long term neurological condition to work or engage in alternative occupation. The quality requirement states people with long term neurological conditions are to have access to appropriate vocational assessment, rehabilitation and ongoing support to enable them to find, regain or remain in work and access other occupational and educational opportunities. The Government had given ten years for these requirements to be implemented although there are no direct recommendations or time scales as to how this should be done. Currently the BSRM are finalising a document which would provide such guideance[83]. Both pieces of literature form a strong case for future development in VR services.

2.16 Cost benefit

Services in other countries such as Canada and Australia are better developed and have been shown to be cost effective[79]. The Commonwealth Rehabilitation Service (CRS) is the largest and oldest VR service in Australia with over 60 years of history. Its role is to provide an expert vocational assessment process and vocational rehabilitation. In 2003 CRS Australia reported that a typical vocational rehabilitation intervention costs approximately Aus$4,398 and returns 17 fold to the individual and 14 fold to the state[84]. A Cochrane review in 2009[85] 'Effectiveness of vocational rehabilitation intervention on the return to work and employment of persons with multiple sclerosis' found no evidence could be assimilated for changes in proportions of persons in supported employment or on disability pensions, nor for cost-effectiveness. Overall there was inconclusive evidence to support VR for people with MS.

2.17 Service delivery

Although in Britain the DWP is developing strategies to help people with disabilities come off benefits and return to work, health services are slow to react[86]. For people who acquire a disabling illness in adult life the issue is not one of work return but of work retention. These individuals look to health care professionals for advice and support, yet many clinicians feel that their limited occupational health expertise makes it difficult to give advice about the interaction between a condition and work, and express concerns about litigation[87]. A recent survey of individuals with MS suggested that only 5% of participants had received useful advice from their doctor, and that these participants had not been informed about resources available to them[33]. Many of those surveyed indicated they were interested in support to remain in or return to work[33].

Health care professionals can play a key role supporting patients to remain in work. For this to occur clinicians need to ask patients not only about their occupation but also about any perceived impact of their illness/disability on work and of work on their disability. General practitioners need to be aware that the person's best chance to return to work is by early intervention through prompt rehabilitation[80]. All clinicians need to be aware of sources of help and resources for their patients, and they need to signpost patients in the right direction, including to specialist VR services.

2.18 Summary

This chapter has identified that work is important for well-being and that employment can become problematic for people with disabilities. It highlights that even though work is a fundamental right, people with disabilities in general have been neglected and as a result have high rates of unemployment. VR declined in the 1980s partly due to a poor economy and high unemployment rates; the deskilling of professionals, including OTs and doctors, occurred as a result of decreasing bed numbers and pressures to facilitate discharge. At the end of the 1990s came the gradual realisation that this was not in the best interests of either individuals or Society, this was formally recognised as a specific issue in the NICE MS guidelines and the NSF LTC. These guidelines highlight that a VR service should be provided for all and that VR is now increasingly being seen as an important part of rehabilitation. However, in the UK it remains ad hoc on a national basis and has no evidence of cost effectiveness. VR originated post war with the OT profession being a leader in this service provision. Now, as it rises on the political agenda this provision appears to be coming from many different professionals with the OT profession being one of them. It appears that the barriers to working with MS are evident and that support should be given to enable people to overcome these barriers through VR. The research reported in this study aimed to further explore the experiences of people with MS who are working, identify support which may enable them to maintain their employment and evaluate the effectiveness of such an intervention. The following chapter describes the framework chosen that supported the development of this study and facilitated the use of a mixed methodological approach.

Chapter 3. Methodology

3.1 Introduction

Chapter two discussed the importance of work, described employment figures, and the growing development VR with published guidelines to support its provision. It describes the unpredictable nature of MS, and the symptoms it can cause, and how these can lead to employment becoming a problem. Neurological rehabilitation, of which VR can be a part, is an educational and problem solving approach for individuals with disabling neurological illnesses that enables them to achieve their optimum physical, psychological and social function[88]. It involves both active change by the individual who has become disabled to acquire the skills necessary to participate in society, and the use of resources to reduce societal barriers[89]. Neurological rehabilitation may be conceptualised as a complex intervention. Complex interventions are built up from a number of components, which may act both independently and inter-dependently e.g. behaviours, parameters of behaviours (e.g. timing, frequency) and methods of organising those behaviours (e.g. type of practitioner, setting, location). Evaluating such interventions is challenging[90]. The MRC published 'A framework for development and evaluation of RCTs for complex interventions to improve health' in 2000[91] and revised this in 2008[90]. This work described in this thesis followed the approach defined in the framework, using a combination of both quantitative and qualitative methodology. This mixed methods research approach combines elements from both qualitative and quantitative paradigms to produce converging findings in the context of research questions[92]. This can provide a greater richness in the data gathered.

This chapter will describe the general principles of the MRC framework and then discuss first, the qualitative methods chosen and then secondly discuss the quantitative methodologies used to develop and evaluate a model of VR.

3.2 The Medical Research Council framework

The framework was designed to facilitate good research practice and to provide investigators with guidance in recognising the unique challenges which arise in the evaluation of complex interventions. Re-written in 2008 both publications recognised the iterative approach needed for this type of research. The recently updated version 2008[90] emphasised this, whereas the original [91] focused on a step-wise approach. The work completed in this thesis is described using the stages described in the 2000 publication as this was used from the start of the whole study. The framework describes five separate stages[91]:

Pre-Clinical (Theory)

- Explore relevant theory to ensure best choice of intervention and hypothesis and to predict major confounders and strategic design issues.

Phase I (Modelling)

- Identify the components of the intervention, and the underlying mechanisms by which they will influence outcomes to provide evidence that you can predict how they relate to and interact with each other.

Phase II (Exploratory trial)

- Describe the constant and variable components of a replicable intervention and a feasible protocol for comparing the intervention to an appropriate alternative.

Phase III (Definitive RCT)

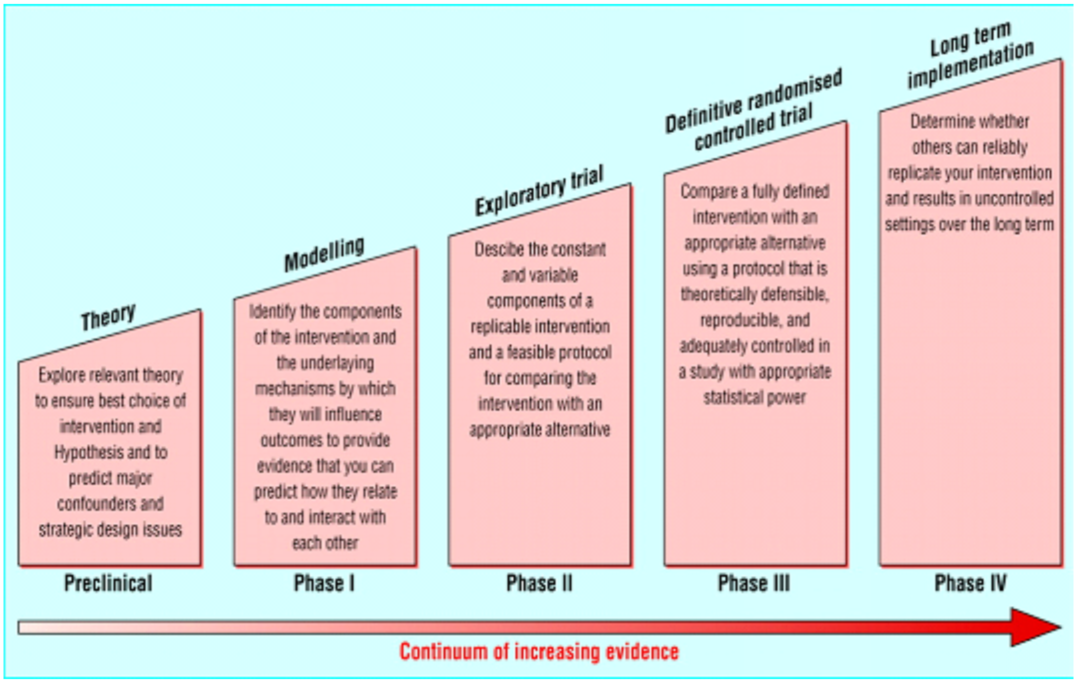
- Compare a fully-defined intervention to an appropriate alternative using a protocol that is theoretically defensible, reproducible and adequately controlled, in a study with appropriate statistical power.

Phase IV (Long term implementation)

- Determine whether others can reliably replicate your intervention and results in uncontrolled settings over the long term.

This thesis is laid out using the five headings above. The remainder of this chapter will also use the same headings.

Figure 3.1 MRC Framework



3.3 Pre-clinical (theory)

It is important to establish a theoretical basis that suggests the intervention may have an expected effect. A number of approaches are used to develop the theory that underpins the subsequent development of a complex intervention. These include an analysis of individual experience, consensus views and a review of relevant literature. The literature review is an important part of any study; completed at the start of a study to help with deciding a topic; reviewing the published and unpublished literature it is often returned to throughout the study with the original search being expanded on[93]. An iterative process is often used to develop the search terms[94] and used in the Cochrane review processes; the aim being to develop a search that is as inclusive as possible and therefore yield the most papers. After each search the terms are revised and the searches re-run.

Aim of Pre-clinical stage

- To review all published literature using a comprehensive search strategy to identify barriers to working with MS and any support that could be beneficial.

The literature review is described in chapter four.

3.4 Phase I (Modelling)

The Pre-clinical and Modelling stages are often inter-related and issues highlighted in one are confirmed in the other. It is important at this stage is delineate an intervention's components and how they inter-relate, and the influence they may have on outcomes. The MRC framework highlights the need to define the intervention so that its contents and delivery can be standardised. Consideration should be given to which components of the intervention can be controlled and is it possible to compare the intervention to 'standard practice'. Using a flow diagram can be a useful starting point to identify weaknesses and stabilise an intervention. The barriers to working with MS were clearly articulated in the literature review (Pre-clinical stage).

Aim of Phase I

- To confirm service users perspectives on the evidence; and
- To further explore what could be done to address those barriers and establish what a VR service should offer.

It was felt that a qualitative method of research was required as this method of naturalistic enquiry describes in words rather than numbers the qualities of the social phenomena[93]. These words would be from the service user and could facilitate service development. Qualitative research should allow themes to emerge rather than researcher driven responses to be chosen. This research approach can also help identify which are the 'active' ingredients' of a complex intervention[91].

There are a wide range of approaches to qualitative research and selecting the correct approach is as important as choosing the correct statistical test. Choosing the wrong approach may result in incomplete or poorly targeted data. This section explores some of the qualitative approaches available all of which were explored for Phase I and explains the reasons for selecting the approaches chosen.

- **Observation**

Use: This type of research can be participative (overt or concealed) or unobtrusive (direct and open), structured (with a checklist, rating scales) or unstructured (direct recording of events)[93]. For this type of research to work the researcher needs to spend as much time as is possible in the observational setting.
Advantages: A common method used frequently in social studies as it provides rich data. Ideally it should be used as part of a triangulated research methodology so that observed behaviours can be verified by independent sources (e.g. records/interviews).
Disadvantages: There is a large demand on time and objective observations are impossible to achieve.
Conclusion: It was felt this was not an appropriate method to use as there was no setting in which any observation could be undertaken as it was a new service that was to be developed. This method was therefore discounted as an option for this study.

- **Unstructured interviews**

Use: This is a face-to-face interview using an interview schedule with topics listed but very few specific questions. The aim is to complete in-depth interviews facilitating people to tell their own stories and share their experiences in greater depth. The interviews are recorded and transcribed. Data is then coded to allow themes to develop and quotes are taken to highlight issues raised[93].

Advantages: This is an effective method of collecting people's opinions and can provide rich data.

Disadvantages: It can be time consuming and therefore expensive. Because of the depth of data gathered it can prove difficult to collate and analyse. Such interviews can lead to a greater opportunities for interview bias and are really only feasible in small samples. It can be difficult to reach data saturation, which could lead to questioning the representativeness of the data.

Conclusion: For these discussed disadvantages this method was discounted for Phase I of study.

- **Structured interviews**

Use: This is similar to the above with a face-to-face interview using specific questions to guide the session in a structured manner but allowing for deeper exploration of ideas.

Advantages: It provides the same rich data as unstructured interviews.

Disadvantages: It had the same disadvantages as listed above.

Conclusion: This method was discounted for Phase I of study. For Phase II this method was chosen in a semi structured interview design to collect the qualitative data from the exploratory trial.

- **Focus groups**

Use: Focus groups (FGs) are unstructured or semi structured interviews with small groups of people who interact with each other and the group leader[93]. It is essential that a number of groups are held until data saturation is reach i.e. no new themes emerge. FG discussions are audio-taped and then transcribed. This data is then analysed. It is still a lengthy process but can generate good data.

Advantages: They have numerous benefits including:

- Group dynamic stimulate discussion and can generate ideas[93];
- Facilitate exploration of concepts[93];

- Provides an opportunity for discussion between participants with similar and diverging views[95];
- Provide direct evidence about similarities and differences in opinions/experiences[96];
- Can be most cost effective and most efficient in time[97];
- Can be the best method of gathering a consensus view[96];
- Provide opportunity to observe a large amount of interaction on a topic in a limited period of time[98].

“The method is particularly useful for exploring people’s knowledge and experiences and can be used to examine not only what people think but how they think and why they think that way.”[99]

Disadvantages: Groups provide information that is in less depth and detail about experiences[96] and therefore does not have the richness that interviews can provide; it can be practically more difficult to organise a group of people meeting; and, discussions can go off on a tangent and therefore a certain level of skill required by group facilitator to hold group focus[97]. There can also be a tendency for conformity within the group, with some participants having high involvement and others having low[98].

Conclusion: This methodology was chosen because it had the potential to provide data about the design of a VR service that was widely applicable and transferable. Pragmatically FGs are quicker and easier to organise and can provide rich data for evaluation, they are likely to identify common themes for basis of service, whereas individual interviews may focus on unique rather than common experience. FGs formed Phase I of the study and were used to explore people’s experiences of working with MS and also what intervention/support could help them maintain their employment.

- **Analyses**

To facilitate the process of data analysis a grounded theory approach[100] was taken which enables theory to emerge through systematic analysis of the data[92]. Within this iterative study design a constant comparison method was used where emerging theoretical constructs are continually being refined through comparisons with ‘fresh’ examples from ongoing data collection. This should produce the rich data typical of ground theory analysis[92].

All data gathered in the FGs (Phase I) and interviews (Phase II) was recorded and transcribed verbatim. This data was analysed to identify overarching themes and more specific codes. Two or more researchers took an iterative approach which allowed themes to evolve and a full set of codes to be established. This process is known as a constant comparative method. It is important the researcher doesn’t simplify and "overcode" the text by coding everything as one code. The aim is that the complexity of the data can be reflected in the codes and themes identified. The end product of this process is an explanatory framework with which to understand the phenomenon under investigation[101]. It is this explanatory framework that would be used to structure the exploratory trial.

3.4.1 Researcher bias

The FGs were to be organised and carried out by the primary researcher for this study. Although there would be a research assistant present in the FGs there was an awareness that the primary researcher could add bias. The reason for this was that the primary researcher was also a therapy practitioner and care would need to be taken to ensure this did not bias the responses of the participants. One way to ensure this did not happen was the use of an interview guide for the discussions. This is described further in chapter five.

3.5 Phase II (exploratory trial)

Quantitative questions such as ‘how much’ and ‘how often’ remain unanswered by the previous stages and the exploratory trial can be used to obtain such evidence in preparation for the larger study (Phase II Definitive RCT). Method or content of delivery can be investigated and for this study it was content that needed to be evaluated. The exploratory trial allows the effects of an intervention to be seen and measured and where weaknesses in the study design exist[91].

Aim of Phase II (exploratory trial)

- To develop and evaluate a VR intervention based on data obtained from preclinical (literature review) and Phase I studies (FGs).

Phase II was the development and evaluation of a VR intervention; designed by the focus groups and informed by clinical experience of the research team and based on the literature reviewed. The objectives of Phase II were:

i. To put into practice the intervention defined by the focus groups;
ii. To define the intervention;
iii. To capture the benefits of the intervention through outcomes;
iv. To cost the intervention;
v. To capture intangible benefits;
vi. To inform further understanding of intervention; and
vii. To select an appropriate outcome measure to power the RCT.

Phase II required both quantitative and qualitative methodologies to be applied to the research. This mixed methodological approach is explored in the following paragraphs using the above objectives as headings:

i. To put into practice intervention defined by the focus groups

The information gathered in the literature review and the data from the FG study helped define an intervention that could address the difficulties people with MS have maintaining their work. Therefore, the first aim of the exploratory trial was to put into practice the intervention.

ii. To define the intervention

The literature review and FGs gave the structure to the intervention that would be trialled. However at this stage it was unclear as to what the specifics of the intervention would be in clinical practice. Therefore, the aim in the exploratory trial was to define the actual intervention.

iii. To capture the benefits of the intervention through outcomes

To formally evaluate the intervention it would be essential that outcome measures were chosen that would capture the benefits of the intervention. To evaluate an intervention, data collection is required pre and post intervention. Historically outcomes were traditionally measured with clinician rated outcomes e.g. the Expanded Disability Status Scale (EDSS) which is a method of clinicians quantifying disability in MS[102]. However, this type of outcome misses a large aspect of change which the patient experiences. It is these experiences from the patient's perspective, which bring a wider understanding of the impact of an intervention or treatment. Prompted by the need for evidence based health care there has been a transition from these clinician rated outcomes to a more holistic approach that encompasses a wider range of health variables[103]. Researchers have increasingly turned to developing measures that capture this broader concept of health including psychological well-being and satisfaction with treatment. These outcomes are generically called patient reported outcome measures (PROMS).

- **Patient reported outcome measures**

Use: PROMS are described as a measurement of any aspect of a patient's health status that come directly from the patient (i.e., without the interpretation of the patient's responses by a physician or anyone else)[104]. A PROM can be used to measure the impact of an intervention on one or more aspects of a patients' health status, ranging from purely symptomatic (e.g. response of a headache) to more complex concepts (e.g. ability to carry out activities of daily living) to extremely complex concepts such as quality of life. Data generated can provide evidence of a treatment benefit from the patient's perspective. For this data to be meaningful, however, there should be evidence that the PROM effectively measures the particular concept that is studied[104].

Advantages:

- Some treatment effects are only known to the patient;
- There is a desire to know the patients perspective about the effectiveness of the treatment; and
- Systematic assessment of the patient's perspective may provide valuable information that can be lost when filtered through a clinician's evaluation.

Disadvantages: PROMS require the respondents to be literate and cognitively intact to a level where they can respond to closed questions with a choice of set responses. Pre-coded response choices may not be sufficiently comprehensive, and not all answers may be easily accommodated. Some respondents therefore maybe 'forced' to choose inappropriate responses[93].

Conclusion: PROMS were chosen for Phase II and Phase III of this study as it was felt they would best capture participants' experiences of the intervention. Phase III of the study would require questionnaires to be mailed out therefore, PROMS were the necessary choice.

3.5.1 Choosing PROMS

To facilitate the process of finding suitable PROMS the appropriateness, reliability, validity and responsiveness of the scale were all considered.

- **Appropriateness**

Appropriateness requires that investigators consider the match of an instrument to the specific purpose and questions of a trial[105].

- **Validity**

Validity is an assessment of whether an instrument actually measures what it purports to measure. It can be broadly defined as the extent to which the instrument measures the concept it purports or is intended to measure[105;106]. There are three types of validity:

- Content validity is the extent to which the measure is representative of the conceptual domain it is intended to cover (also known as face validity);
- Criterion related validity is the degree to which a measure correlates with a gold standard (the criterion);
- Construct validity is a process used to establish the validity of a measurement instrument through a series of studies examining the relation between the measure and other measures or behaviours[93;106].

- **Reliability**

A reliable measure is one which produces results that are accurate, consistent, stable over time, and reproducible. Reliability is an estimate of the reproducibility and internal consistency of an outcome measure[105]. There are four types of reliability:

- Internal consistency is the extent to which items comprising a scale measure the same concept – that is measure of the homogeneity of the scale;
- Test-retest reliability is the stability of a measuring instrument over time;
- Rater reliability is an agreement between rates or within an individual rater. There are two types:
    - Interrater reliability is the agreement between two or more raters;
    - Intrarater reliability is the agreement between two ratings made by a single observation of the same patient;
- Parallel forms reliability is the degree of agreement between two identically constructed forms of the same measure[93;106].

- **Responsiveness**

This is the ability of a measure to detect clinically significant change[105;106]. It is a measure of the association between the change in the observed score and the change in the true value of the construct. For this to occur there needs to be sensitivity which is the ability of the actual gradations in the scale's scores to reflect these changes adequately[93].

- **Administration of outcomes**

After selecting a scientifically sound outcome measure that captures the construct or constructs of interest, it is necessary to administer it to participants. The most common form of administering outcome measures is through questionnaires (often postal) and this was the most appropriate for both phases of this study (Phase II and III). Telephone interviewing and face-to-face interviewing were not considered for this research due to time and cost constraints. Good questionnaire design is the most important element in securing high response rates[107]. Dillman has long been the proponent of proper questionnaire design to obtain the best response "The Total Design Method"[108]. Using the same style across pre- and post-mailing reminders and a "motivational" insert produces the best response rate. All these are issues, which are identified as things that encourage respondents to complete the questionnaires. The outcome measures chosen are described in further detail in chapter six and chapter eight.

iv. To cost the intervention

An intervention could have a fantastic outcome but it is always essential to look at the costs involved to produce the outcome especially in our health care system where budgets are restricted and have to be justified. There are different economic appraisal techniques which can be used. They are:

- Cost-benefit analysis is when a monetary value is assigned to the benefits of a programme, and comparisons are made with the monetary costs of the programme for an assessment of efficiency.

Often comparisons are made between two similar programmes to establish which has the best cost-benefit.

- Cost-effectiveness analysis is the comparison of different programmes producing the same type of non-monetary benefit in relation to their monetary costs for an assessment of efficiency.
- Cost-utility analysis relates the cost of a project to a measure of its usefulness or outcome (utility).

For this study it was decided to establish the cost utility of the intervention i.e. what it cost and what were the benefits for participants. Therefore to cost the intervention a comprehensive database was established to record time spent by the treating therapist. This time data gathered would then be costed using standardised measures of costs to establish how much the service cost to run. All intervention time was recorded on this database during the trial both in Phase II and III. A health economist was identified at the start of the study to support analysis of this data.

v. To capture intangible benefits

Intangible benefits are often described as such as they can’t be seen by others and are known only by the patient. Although PROMS are good outcomes the closed questions and pre-coded response choices can lead to some of the intangible benefits of the intervention being missed. To ensure these benefits were captured the qualitative approach of face-to-face interviews were chosen. This would allow an experienced interviewer to follow a semi-structured interview guide and ask more probing questions about the effect of the intervention that could be missed by the PROMS chosen.

vi. To inform further understanding of intervention

Due to concerns about the poor quality of relevant outcome measures for this type of intervention and condition group it was felt essential that interviews should be completed as participants left the study. This would ensure the full impact of the intervention was captured. Face-to-face semi-structured interviews were chosen, as they would allow the interviewer to ask the same questions of each participant however, not be restricted to explore themes should new areas arise. This process would allow rich data to be gathered from the participants, which could then be explored to identify the impact of the intervention.

vii. To select an appropriate outcome measure to power the RCT

Once all the data had been collected and results analysed it would then be possible to identify which outcome was most sensitive to change and captured the impact of the intervention. This outcome would then be used to power the next Phase of the study.

3.5.2 Researcher bias

It was acknowledged at the start, that the study could be affected by researcher bias as the primary researcher was a therapy practitioner. The primary researcher was involved with the development of the intervention as well as providing the intervention. The benefit of this was that the primary researcher understood very well the service she was working in as well as the client group the service was targeted at. To address this potential bias in the interview stage, an independent researcher was chosen to complete the interviews. This is discussed further in chapter seven. The interviewer and the primary researcher however, completed together data analysis of the results at this stage of the study.

3.6 Phase III (Definitive RCT)

Quantitative research describes the accurate assessment of the outcome or effects of an intervention that necessitates the careful manipulation of that intervention (experimental variable), in controlled conditions, and a comparison of the group receiving the intervention with an equivalent control group. It is essential that systematic errors (bias) and random errors (chance) are minimized. This requirement necessitates carefully designed, rigorously carried out studies, using reliable and valid methods of measurement, and with sufficiently large samples of participants who are representative of the target population[93]. A RCT involves the random allocation of participants between an experimental group whose members receive the treatment or intervention and control group who receive standard treatment. The outcome of the groups is then compared. Phase III of the framework is the definitive RCT described as 'to compare a fully defined intervention to an appropriate alternative using a protocol that is theoretically defensible, reproducible and adequately controlled, in a study with appropriate statistical power"[91].

Aim of Phase III (definitive RCT)

- To evaluate the effectiveness of an early intervention VR service

The objectives for this study were:

i. To define an early intervention service and put into practice;
ii. To capture nature of intervention through outcomes;
iii. To cost an early intervention service;
iv. To compare intervention and control group;
v. To inform further understanding of intervention.

Only quantitative methodologies were used in the design of this phase of the research. The objectives of the RCT are described in further detail below:

i. To define an early intervention service and put into practice

The information and data collected in the Pre-Clinical (Theory), Phase I (Modelling) and Phase II (Exploratory trial) was used to develop the early intervention service to be evaluated in the RCT.

ii. To capture nature of intervention through outcomes

To formally evaluate the intervention, PROMS were chosen as described above in the Phase II exploratory trial. The chosen PROMS are described in further detail in chapter eight. In this phase the Dillman[107] method of questionnaire design and techniques such as reminders and motivational inserts was used to elicit a good response rate. This was especially important for the control group as apart from the initial telephone call there would be no further input from the research team. These questionnaires would be completed on starting the study, at six months and then annually over a five year follow up period.

iii. To cost an early intervention service

As with Phase II of the study the RCT data gathered to establish the cost of the intervention. A similar time log of intervention would be kept. To ensure the intervention could be evaluated for cost effectiveness the Client Service Receipt Inventory (CSRI)[109] was included as part of the outcomes measures. To establish cost utility, which would include looking at quality of life assisted years then the EuroQol EQ-5D[110] was used. All participants were followed up over a five year period completing annual questionnaires. The design of the booklet was based on Dillman's "Total Design Method"[107] as described above. A health economist was identified at the start of the study to help with appropriate selection of PROMS and for data analysis at the end.

iv. To compare intervention and control group

Comparison of the two groups would be through data analysis of the questionnaires using SPSS a statistical software package which would enable the two groups to be compared. Support from a UCL statistician was engaged to help power the study and also to establish the appropriate statistical tests that would be needed for analysis. As it was anticipated numbers could be small non-parametric tests such as the Mann Witney U test would be used in the analysis. This is described further in chapter eight.

v. To inform further understanding of intervention

The codes developed in the Phase II study would also be used to code the intervention in the RCT, however, it was expected that some new codes would develop as the intervention was expected to be different. Through this coding and combined with the PROMS data gathered further understanding of the intervention could be gathered and reported.

3.6.1 Reporting RCTs

Poorly designed and reported trials are common in the literature[111] and to combat this problem the Consolidated Standards of Reporting Trials (CONSORT) statement[112] was written and first published in 1996 and updated in 2001 and 2010[111]. It is these guidelines, which are used to structure the reporting of the RCT reported in chapter eight. Within these guidelines the following need to be considered:

- **Sample size**

The sample size for a trial needs to be considered carefully as ideally it needs to be large enough to have a high probability (power) of detecting a statistically and clinically difference if such a difference exists[111]. It was essential to ensure the right numbers were recruited for the RCT and therefore, a power calculation was used. Statistical power is a measure of how likely the study is to produce a statistically significant result for a difference between groups of a given magnitude[93]. For this the statistician from University College London (UCL) was engaged to complete this calculation and the process is described further in chapter eight.

- **Randomisation**

Participants should be assigned to comparison groups in a trial on the basis of a chance (random) process characterised by unpredictability[111]. Random allocation between experimental and control groups means that study participants were allocated to the groups in such a way that each has an equal chance of being allocated to either group. Pure randomisation based on a single allocation ratio is known as simple randomisation (a 1:1 allocation ratio analogous to a coin toss). Further details of the process used for Phase III are described in chapter eight.

- **Allocation concealment**

The method used to implement random allocation is called allocation concealment which seeks to prevent selection bias, protects the assignment sequence until allocation, and can always be implemented[111].

- **Blinding**

Blinding refers to withholding information about the assigned intervention from people involved in the trial who may potentially be influenced by this knowledge. It seeks to prevent performance and ascertainment bias, protects the assignment sequence after allocation, and cannot always be implemented[111].

3.7 Phase IV (Long term implementation)

The final stage of the MRC framework highlights the importance of disseminating results and establishing the long term effectiveness of the intervention in ‘real life’. This phase was not fully possible in the time restrictions within this thesis but the research team continue to be involved in reporting the results and implementing change in their clinical work. However, some of the research completed in the first three stages of this study has had impact on clinical service provision and the wider MS community. This is described in the chapter nine.

3.8 Summary

This chapter has discussed different designs within the mixed research methodological approach and the importance of such concepts as validity, reliability and responsiveness. The aims of each Phase of the MRC framework are identified. The following chapters describe fully the methodologies used in each of the stages of the study and the results that they generated as well as implications for practice.

Chapter 4. Literature review MS and work

4.1 Introduction

The aim of this chapter was to review the literature published that explores working with MS; to identify the barriers to employment, support that could be offered, and review any studies which have evaluated an intervention. This chapter will describe the process used to synthesise the evidence, using the NSF LTC guidelines[71], to capture the full range of reported studies in this area. Many of the published papers are qualitative in their approach and although only small scale still contribute to the growing evidence base. The following sections outline the approach taken to complete the literature review and clearly identify the issues and potential solutions to working with MS.

The Cochrane library is widely cited as a source of robust systematic reviews and research syntheses. A recently published Cochrane review[85] clearly showed that there was little evidence available in this specific area of VR and MS. The review found two reported research studies which met the Cochrane review standards (only includes studies which are run as RCTs or controlled clinical trials). The two that were reviewed were small studies (43 and 37 participants), had low methodological quality (as defined in the Cochrane review process) and as they both emanated from the USA may have limited generalisability within other cultural settings. The review clearly highlighted that there was no conclusive evidence to support VR programmes. Also that there is the need for further research in this area which should include:

- Evaluating VR programmes using robust methodology;
- Addressing both effectiveness and cost effectiveness; and
- The development of appropriate outcomes measures is required.

The review recognised that VR is multi-faceted and combines many different factors. This chapter aims to expand on the work of the Cochrane review to include all published research into the area of VR, employment and MS.

4.2 The National Service Framework Typology

Rehabilitation for people with MS is a complex intervention and the area of VR is a relatively new concept. A RCT is often viewed as the gold standard, the optimal study design, to minimise bias and provide the most accurate estimate of a complex interventions benefits. However, there are circumstances where such a design is not possible[91]. The complexity of rehabilitation interventions creates a major challenge for clinical research, which confounds traditional RCT designs. It is increasingly recognised that RCTs cannot be applied to address all the questions that need to be answered. RCTs and other quantitative methodologies can't always answer research questions involving long term outcomes; varied populations with complex needs and assessment of impact needs to be on quality of life rather than cure[71].

Other methods have been developed for assimilating a broader range of evidence which encompass other research designs, qualitative studies and different techniques allowing the evaluation of individual experience. One such evidence is the research typology developed for the UK is the NSF LTC[71]. This was used to evaluate the evidence base that was assembled to underpin the NSF standards. This typology focuses on the quality of research, and the appropriateness of research design to answer the question in hand, as opposed to restricting evidence to any one type of design. The quality assessment is designed to be applicable across both quantitative and qualitative research designs.

The typology includes the following two main groups of evidence:

a) Expert evidence (E): expressed through consultation or consensus processes rather than formal research designs. It could be professional opinion, or that of users and/or carers or other stakeholders.

b) Research evidence (R): gathered through formal research processes.

Each piece of research-based evidence is awarded a rating based on three categorisations: Design, quality and applicability. Research design is categorised as shown in the table below.

Table 4.1 Categories of Research Design within the NSF Typology

Primary Research-based Evidence	
P1	Primary research using quantitative approaches
P2	Primary research using qualitative approaches
P3	Primary research using mixed methods (qualitative and quantitative)
Secondary Research-based Evidence	
S1	Meta-analysis of existing data analysis
S2	Secondary analysis of existing data
Review-based Evidence	
R1	Systematic reviews of existing research
R2	Descriptive or summary reviews of existing research

Quality rating is based on the five quality items shown in Table 2. ‘High quality’ research studies are those which score at least 7/10; ‘Medium quality’ studies score 4-6/10 and ‘Poor quality’ studies score 3/10 or less.

Table 4.2 Quality Rating Within the NSF Typology

Quality Criteria	Score
Are the research question/aims and design clearly stated?	
Is the research design appropriate for the aims and objectives of the research?	
Are the methods clearly described?	
Is the data adequate to support the authors' interpretations/ conclusions?	
Are the results generalisable?	
Total	/10
Each quality item is scored as follows: 2 = Yes, 1 = In part, 0 = No.	

Applicability is determined by whether the research was derived directly from the population of people with long term neurological conditions (Direct evidence) or extrapolated from other conditions (Indirect Evidence). In this way, each study carries a typology and quality rating (e.g. P1 High Direct - meaning a high quality quantitative study of direct applicability).

All the papers reviewed in this chapter have been summarised in a table and scored using the typology described above. They can be found in appendix 4.1.

4.3 Methodology

The topic 'employment and MS' was explored to determine significant issues (conceptual mapping). From this, a search strategy was devised with the use of the following terms: MS + employment, unemployment, vocational rehabilitation, occupational health, job, work adjustment. With these terms, an electronic bibliographic search was completed to find relevant papers from 1950 to the present. Comprehensive searches were performed in the following databases: AMED (1985 to Feb 2010) CINAHL (1982 to Feb 2010) PsycINFO (1806 to Feb 2010) EMBASE (1974 to Feb 2010) Medline (1950 to

Feb 2010) and PubMed (1950 to Feb 2010). To find relevant articles not detected in the electronic bibliographic search a follow up review of references was also performed.

The search of the literature revealed the following: 462 papers were identified in total. The following were removed: 67 not English, 43 not MS, 44 not research, 167 not work, a further 42 were MS magazine opinions, 4 editorials commenting on special editions, and 6 were duplicates. The search therefore had found 89 relevant papers in total; these were then reviewed in detail. The following sections report the results.

4.4 Extent of employment problem

Most people with MS are in full-time education or employment at diagnosis[33] and 90% have a work history[113;114]. People with MS who are working report being healthier, more financially secure, more socially active and experiencing a better quality of life than those who are unemployed[50;115;116]. As the condition progresses, however, the number of people able to remain in work decreases[33;114;117-120]. Estimates of work retention vary between 20% and 30% employed by 5 – 15 years after diagnosis[33;114;121;122]. The common pattern is to move from a high demand job to a less demanding job and then to retire[123]. In terms of disability, employment rates are reduced from 82% in early disease to 2% at an EDSS score of 8[124]. People with MS are disproportionately unemployed given their educational and vocational histories[116]. Not only is there is a lower rate of employment for people with MS than for the general population[116;125] but people with MS experience some of the highest unemployment rates among groups of individuals with severe and chronic disabilities[126;127]. 40% of people with MS who are unemployed report that they would like to return to work[117].

4.5 What factors lead to unemployment for people with MS?

Within the general population maintaining successful employment depends upon both employer and employee having the necessary skills and attitudes to ensure that the demands of the job can be met within a defined working environment.

The causes of unemployment are rarely simple but a complex interaction of many factors[128]. The reasons for unemployment in MS may be related to the disease itself and/or to the working environment (both social and physical) and/or the demands of the job[33;114;117;120;129]. This multitude of issues confronts this experienced well-trained and yet all-too-often disenfranchised group of workers as they attempt to maintain their careers[39]. The complexity of these interacting factors is demonstrated by the literature and discussed below. The vocational needs of people with MS can be addressed properly by analysing all factors that contribute to the employment problems. These are grouped based on the International Classification of Function (ICF)[130] and also include the area of work demands.

4.5.1 Disease related factors – Disease course, impairments, activity limitation and participation restriction

- **The International Classification of Functioning, Disability and Health**

The International Classification of Functioning, Disability and Health (ICF)[130] can be useful to enable description of a person's functional capacity and the impact health problems can have on activity and participation. Difficulties at work can be due to numerous factors: impairments (e.g. muscle weakness, pain), activity limitation (e.g. walking, lifting) and participation restriction (e.g. work, social events). Alongside this work environmental factors (e.g. environmental and social) and personal factors (e.g. age, sex, coping strategies) influence as well[80].

- **Disease course** [114;126;131;132]

In the early stages MS typically has a relapsing remitting course. Relapses can mean people with MS are unable to work for a period, which may be as short as two weeks or as long as six months. The unpredictable nature of the relapse causes particular problems for employers who have deadlines to meet, and can be difficult to accommodate. In addition the impact of a relapse can be undermining to the individual with MS so that they lose confidence in their ability to work effectively.

Later on the disease becomes progressive and disability more overt. The more disabled the person with MS is the more likely they are to be unemployed[33;117;121;125;129;131-135]. Typically people with MS who are working, have less disability than those who are not working but the levels of reported disability are not severe enough to explain the levels of unemployment. A few studies suggest that many people with MS stop working before the onset of significant physical disability[114;119].

- **Impairments**

People with MS experience a wide range of symptoms and these are most frequently cited as the reason for people with MS to leave their employment[25]. Early in the disease course the symptoms that impact most on individuals ability to work include fatigue[25;33;116;121;123;126;131;132;136-140], anxiety and depression[116;126;141]. People with MS also describe problems with pain and heat intolerance[25;116;121]. People with MS do not report cognitive changes as the reasons for change in work status[132;142;143] although concern about memory and concentration difficulties is often cited as a reason for unemployment[25;116;129;134;144;145]. Only two papers[37;146] identified the extent of the cognitive deficits which tend to be mild. One paper describes how certain cognitive tests could be predictors of employment retention[147] and that cognitive ability is strongly linked with work capacity[148]. Even a mild decrease in cognitive ability can be worrisome for individuals with white-collar, professional-technical backgrounds and this can be a challenge for VR providers[149]. The nature of all these deficits described above is that they represent ‘invisible disability’[131].

With disease progression people with MS develop weakness, balance problems, spasticity, sensory disturbance, sexual dysfunction, difficulties with vision, and bladder and bowel disturbances[33]. At this point the activity limitation becomes overt. Severity of impairment does not always correspond to the restrictions in participation[136] but people with MS with worsening symptoms are at particular risk for future employment loss[150;151]. One study reported the type of immunomodulatory therapy affected time missed from work[151]. Losses in a person’s quality of life and ability to work can be avoided or delayed if functional status is maintained for a longer period of time[152].

- **Activity limitation and participation restriction**

With disease progression people with MS report greater physical disability[114;117;121;132;138;143;146] that can impact on work in many ways for example:

  - Limitation in mobility making travel to work and access to work difficult plus movement within the workplace effortful [25;33;114;116;121;123;126;131;136;139;140;143], two studies particularly highlighted that as mobility impairment increased employment levels reduced[145;153];
  - Poor dexterity affecting handwriting, keyboard use and other manual tasks[33;123;131;144];
  - Visual impairment resulting in difficulty with reading both written and on computer screens[121;123;126;139;143];
  - Urinary and faecal frequency and urgency with fear of incontinence[116;123;126;138;139];
  - Dysarthria resulting in difficulty using the phone, general communication and poor presentation skills[141;144].

It is essential that health care professionals remember that measures of physical and cognitive function can only aid in the process of evaluating a worker, but do not solely define or determine ability to work[154].

4.5.2 The working environment

- **Environmental factors**

Environmental factors are one of the important factors that contribute to reduced participation in work[155]. Physical barriers include difficulty accessing work and moving around within the work environment. Other barriers include hot rooms aggravating fatigue and weakness, open plan offices making concentration more difficult, and inaccessible toilets increasing the risk of incontinence[33;116;123;126]. Professionals report their patients often leave work before any attempt has been made to adjust their work environment to meet their needs[156].

- **Social factors**

A 2007 study reported men were more likely to leave their employment[25]. However, most studies report women with MS are more likely to withdraw from workforce[48;117;119;131;134;138;157;158]. This may reflect the fact that many women have additional responsibilities at home and take on the 'home maker' role. Support from family and friends are associated with women remaining in the work place[17;131.] Remaining in work may be at the expense of leisure and social activity[126;137;141]. However, difficulty participating in work related social activities can isolate people from their peer group and make working lonely. The economic impact of loss of employment has huge implications impacting both families and society[49;109;159;160]. Quality of life was found to be a positive function of employment related variables such as employment status and that employed people with MS have a higher quality of life[115].

- **Workplace factors**

Many people with MS withdraw from the workplace citing lack of information about legal rights and the support available[116;131;161], poor support with job retention through workplace accommodations[33;116], inflexible employment structures[116;126], and lack of employer/colleagues support which may develop into active discrimination[116;119;126;131;157;162;163]. Physicians may advise unemployment to manage fatigue and other symptoms[116;120;131;164], and once unemployed, benefits systems may act as disincentives to work return[60]. There is also some evidence that people with MS do not seek help until employment crisis develops[141]. It seems clear that many people with MS do not understand their legal rights[116;131;165]. In the UK people are protected under the DDA[55] from the point of diagnosis with MS. In the USA people with MS are more likely to file discrimination cases about the failure of employer to provide reasonable accommodations, demotion and terms of employment than the general disabled population, but are less likely to allege discrimination in areas of discharge, harassment and hiring[118]. The choice to leave the workforce is most often made by the person with MS it is not known to what extent discrimination 'helps' people make this choice[39].

4.5.3 Work demands

As physical disability increases physical tasks become too demanding[126;131;166;167]. However, other work demands also pose problems including jobs that require multitasking, long hours and full time work[123], stressful high demand jobs are problematic for people worried about their health[137]. Eventually there develops a mismatch between the job demands and the individual's capacity resulting in work instability[114;131;168].

- **Personal factors**

Personal factors have a significant impact on people's ability to cope with workplace demands. High educational levels protect against unemployment[129;134;158;169], the reasons for this have not been clearly delineated but are likely to be related to working in an office based environment[114;117;121;123;129;132;138;143;146]. Increasing age is associated with increasing unemployment (beyond that of the general population); this is likely to reflect increasing disability[114;138;143;146;158].

Prior experience clearly influences people's response to a diagnosis of MS. The literature comments on people's concerns about disclosure in the work place[116;121;126;138;161], their reluctance to anticipate future problems[126;141], and fear of income loss[116;131;170]. As a result of these factors people with MS devote inordinate amounts of energy to working to keep crisis away[131;141], waiting until symptoms become severe[126] and leaving it too late[25] before addressing the employment barriers they cause. Managing the psychological adjustment to a diagnosis of MS is challenging[114]. Dealing with this and a high demand job can lead to stress and early withdrawal from the workplace. Levels of stress and people's perceived ability to manage this stress, plus the level of job satisfaction an employee experiences are all indicators to whether someone maintains their employment or not[44]. Little has been written about individual coping styles and how this may impact on work retention in MS[117], although one study does explore the different coping strategies used by women to facilitate their work and home life roles[171]. There is evidence that suggests that good self management is directly linked to maintained employment[128]. A recent Australian study reported a loss of self-confidence was a prominent risk factor for employment loss, with respondents saying they did not feel they were doing a good enough job[25]. Linked closely with this is the importance of self-efficacy and diminished self-efficacy could explain difficulty with work maintenance[172]. Overall work is seen as a good thing but a diagnosis of MS can change the level of importance placed on it as an activity[173].

4.6 Recommendations from the review

From the literature review the following recommendations have been made:

4.6.1 What helps people with MS remain in work?

- **Specialist VR services with access to a MDT**

Little has been written about the delivery and outcomes of VR for people with MS in the UK. This may reflect the fact that most government sponsored programmes focus on return to work whereas for many people with MS the problem is largely one of work retention. VR is being delivered by local teams but this is largely ad-hoc without formalised funding, referral patterns, evidence based interventions, specialist training or outcome measurement. Health care professionals with expertise in MS have reported they feel poorly equipped to manage work related issues[116;174]. In a 2007 study, 27.8% of people stated a doctor's or health professional's advice to stop working as the reason for leaving employment[25], which is not problematic unless the health care professional is ill equipped to provide the necessary support. Nevertheless there is considerable evidence that specialist VR services for people with long term neurological conditions need access to a range of health care professionals including OT, PT, neuropsychology, physicians, and nurses. This number of health care professionals reflects the complexity of the problems. It is possible that such multidisciplinary services may be best provided within the NHS. Ideally specialist services[33;116;126;142;175] should employ both health care professionals and employment specialists who have expertise in managing the interaction between the impairments caused by MS, the physical environment and the demands imposed by the work. This trans-disciplinary collaboration could be the key to success[176] and as part of this process the team should offer thorough assessments[177;178]. Such specialist services may benefit from a geographical base, regular meetings for case discussion, and a commitment to service development and training[179]. A recent study also showed there was a positive link between the use of DMDs and employment[128], which would highlight the need for this client group to have access to a hospital based neurology team.

- **Early intervention, open access, responsive and personal services**

The research has highlighted the benefits of timely intervention in people with accruing disability who are in work[61;180] with a focus on sustaining employment[169]. Early intervention is likely to be most helpful[25;33;113;116;118;129;132;137;141;142;146;153;157;167;168;175;175;181-183] providing information[29] and support before barriers become insurmountable[25;162;163;175]. People primarily turn to their neurologist or the Internet to source this information so it would appear essential that this employment related information is up to date and relevant[29]. There is some evidence that people with MS do not generally wish to take advantage of job retention schemes until a crisis develops, therefore it could be important to ensure retention programmes are easy to access, responsive and 'light-touch', that is; providing brief, accurately tailored intervention to a specific problem at a single point in time, rather than long term career counselling to solve potential employment problems[120;175;184]. The strategy of least intervention may be the most sensible, i.e. assist the person in retaining employment in the same job with the same employer[177]. One study of people receiving support from an MS employment assistance service focusing on solving specific problems, reported participants had high levels of job mastery and high levels of job satisfaction[144]. These findings could provide a rationale for early intervention to reduce or remove job-related barriers before they undermine job satisfaction and, eventually, threaten job retention. Although input may be brief the progressive nature of the disease means that people with MS need to be able to re-access services as and when required, consequently services should be open access[129;134] and could benefit from empowering the person to take control of their situation[177].

Long waits for intervention could result in unemployment. People with MS highlight the need for a responsive service. Some services have used a telephone/ email employment assistance hotline to ensure a responsive service[161]. A number of studies have highlighted the need for the services to be individualised to the needs of the people with MS as each person accessing the service is different[116;136;185;186].

- **Support managing work performance**

A recent report identified what people with MS wanted from a VR service and highlighted the importance of managing task performance[142]. They highlighted the need to either improve performance e.g., through physiotherapy to improve mobility, compensate for changing performance e.g., taking a taxi to work, or modify performance i.e., by reducing the demands of the task. Strategies should not focus on reducing the impairment but on performance of an activity[136;142], and may require referral to OT, PT, speech and language therapy, neuropsychology and specialist rehabilitation and neurological services, both medical and nursing[116;120]. These services could minimise the impact of symptoms on work such as cognitive difficulties[28;116;129;134;141;187], visual decline[187], fatigue [121;126;137;185;187], heat sensitivity[187] and poor mobility[187]. An essential component in work performance is increasing self belief[25], developing good self management skills[128] and self efficacy[172].

- **Liaison with employers to ensure work-place accommodations and redeployment**

It is clear that employment levels could be maintained if people with MS had access to appropriate assessment, job redeployment, and work-place accommodations including the use of assistive devices. Work-place accommodations and redeployment are most likely to occur when appropriately skilled staff work with both the person with MS[118;126;127] and their employer[44;127;138;157;168;172;178;188-190], in partnership supporting both. The work-site visit is a core activity in VR interventions. OTs and other qualified staff can undertake both task and environmental analysis allowing tasks to be broken down into manageable steps and ensuring the demands of the job are minimised. Employers would also require education[142;161;162;168;191] yet little or no work has been done exploring employers concerns about managing employees with MS. They may benefit from advice as to where they can access support conflict resolution to prevent breakdown of employer/employee relationship[165]. Accommodating unpredictable absences from work can pose significant problems for employers. Anecdotally, many employers express concern that work may aggravate the condition and their lack of knowledge about how to manage the condition in the workplace is evident. One possible way of reducing the demands of working and diminishing associated fatigue is by reducing travel time. Advances in technology means that home-working is a viable option for many people with MS.

- **Education and support**

People with MS may require support with emotional self-management, and many benefit from advocacy and support with disclosure and issues around discrimination[142]. One of the aims of a VR service should be to empower the individual[118;119;161;168;175;192] often through education and support. Self-confidence and skills in self-efficacy are seen as part of self management which has found to be positively related to employment[128;172]. These skills could be developed to enable people with MS to cope with discrimination, to solve problems systematically, request accommodations in an effective manner, negotiate solutions and communicate effectively in the work place[172;178;190]. Knowing how to solve on-the-job problems before they become so salient as to result in a formal complaint or premature exit from the work place, may be key in avoiding discrimination claims[191].

People with MS could benefit from education[118;123;129;131;142;163;183;190] about relevant legislation and how it applies to them[118;120;131;157;161;163;178;193], the nature of 'reasonable accommodation'[113;131;190;193], advice about how to disclose to line managers and colleagues[138;142;186] and advice on how to document clearly any discrimination they face should they wish to later pursue a discrimination claim[165].

People with MS may also benefit from support with work planning – effective decision making[113;181;187], defining and implementing accommodations

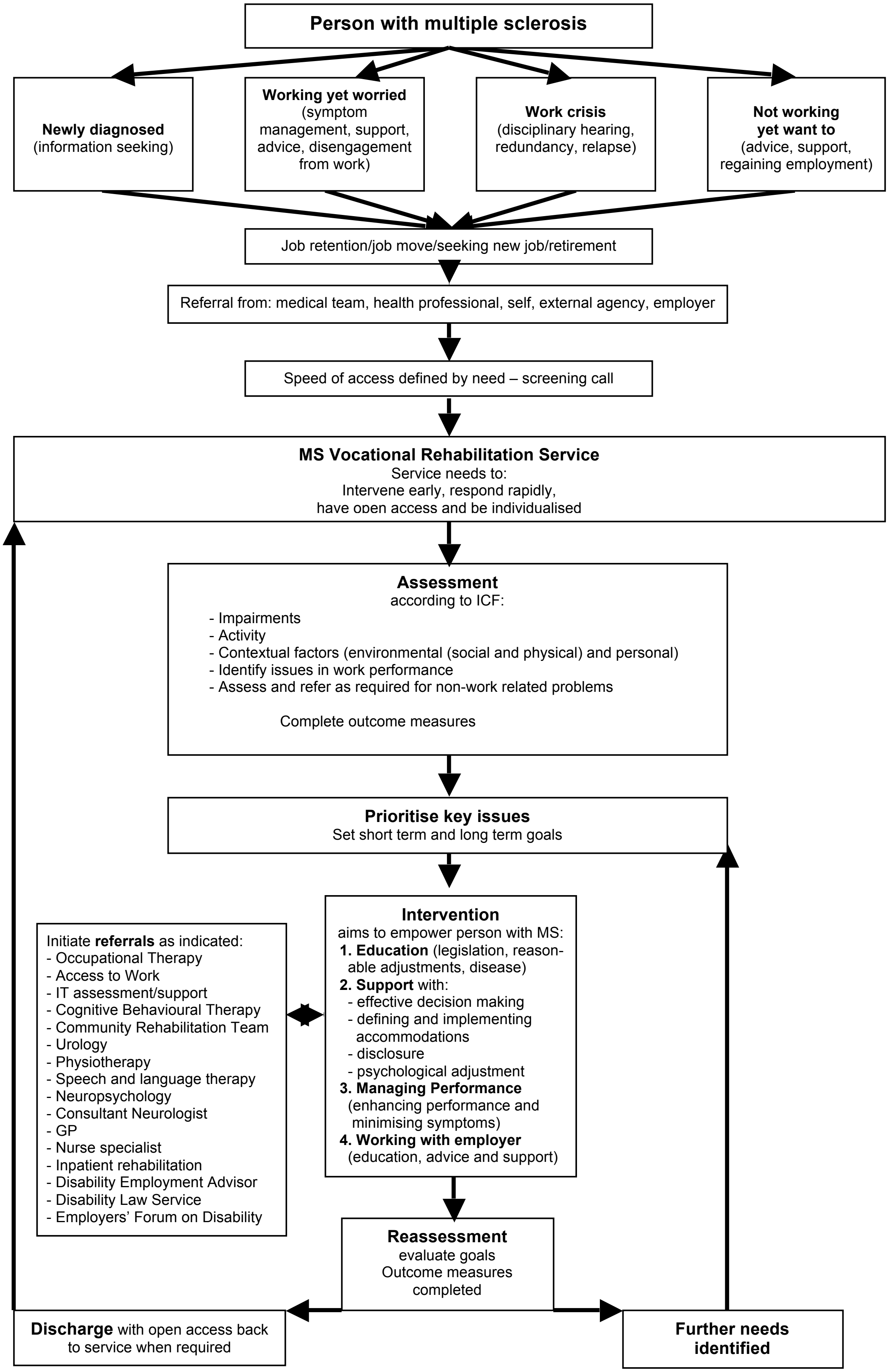
[33;116;121;123;126;129;141;142;168;172;175;187;188;192]. These could include reducing hours/part time working/flexible working/working at home [123;126;132;157;181;185;188;189;194], changes to occupational environment[121;126;138;167;194] including job modification & technological support, and access to resources[194].

4.6.2 Support to re-enter the workplace

Employment status is a dynamic process and therefore there is a need to support people with MS to re-enter the workplace[150]. One study identified that half of the population who had stopped working wanted to return to work[33]. One essential factor highlighted in the literature is a person's 'self-reported readiness' in their belief about their ability to work[195]. Further research is needed in this area.

From the literature the following flow diagram (Figure 4.1) has been developed. It shows a process through which an employed (or wanting to return to work) person with MS may access and progress through a VR service. It reflects the results of the literature review and was conceptualised by the primary researcher for this study. This figure will be used in the BSRM guidance to be published in late 2010[83].

Figure 4.1 Flow Diagram to Show VR Process



4.7 Criticisms of the literature

Five key issues can be identified:

- **Barriers**

There are numerous papers describing the barriers to working with MS. The first one reviewed was published in 1981[180]. Newer papers which are published on this topic do not appear to add much more to the discussion, as the barriers reported over the past three decades do not appear to have changed.

- **American studies**

The majority of the published research has come from the USA where there is a comprehensive VR service provided for the general population. As a country it also has an insurance lead health care system. It is essential that this be considered when reviewing the results as this could lead to the results not being generalisable in the UK. However these results are transferable if it is held in consideration as to the different health background they come from.

- **Not focused on employment**

Many of the studies although they comment on employment it is not the focus of the research, for example the study may be looking at quality of life where employment is identified as a contributor. It is important therefore that this is considered when interpreting the results they report.

- **Little intervention research**

Although there is a significant amount of work published in this area the focus is primarily on identifying the barriers to working with MS. There is little published which evaluated VR programmes for these conditions. As the Cochrane review[85] showed only two studies out of all of those reviewed evaluated an intervention and these studies were poor. Many of the papers reviewed identify what an intervention should provide and when/how it should be provided. It is important to remember that this is a professional opinion from the authors and not evidence based on an exploratory trial or RCT of an intervention.

- **Small studies**

Many of the studies are small-scale qualitative research where less than 30 people have been interviewed for the study. Although rich data is gathered from this type of research it is important this is considered when results are interpreted, as results could be biased by the group interviewed and therefore not generalisable.

4.8 Summary of the literature

The literature highlights that the following could be important for a VR service:

- Specialist VR services with access to a MDT;
- Early intervention, open access, responsive and personal services;
- Support managing work performance;
- Liaison with employers to ensure work-place accommodations and redeployment;
- Education and support;
- Support to re-enter the work-place.

The analysis of the literature using the NSF LTC[71] typology showed there is a body of high quality research evidence describing the barriers to working with MS and also what a VR service should provide. There is a clearly reported consensus from experts (both professional and service user opinions) as to what would support people with MS to maintain their employment. Despite the literature identifying the support that may be needed, it is not known what individuals with long term progressive conditions want from a VR service. This contributed to the further development of this study with a focus to discover what individuals with long term progressive conditions want from a VR service and if they want such a service at all.

4.9 Summary

The aim of the whole of this study was to build on the already published literature and to identify what individuals with MS wanted from a VR service in terms of its promotion, delivery, and content in order for them to more effectively manage their work. The results have informed the development of a VR Service, which was offered therapeutically in an exploratory trial where the effectiveness of the intervention was evaluated and a cost utility analysis completed. On completion of the exploratory trial an RCT was defined and developed to explore an early VR intervention; the cost effectiveness and clinical effectiveness of such a service will be evaluated over a five year period.

The next chapter describes the research completed in Phase I of the MRC framework[91]: the use of focus groups to understand the barriers to working with MS and identify what support this client group would want through a VR service and how this service should be provided.

Chapter 5. Focus Group study

5.1 Introduction

Chapter four identifies from the published research what the barriers to working with MS are and highlights intervention that could make a difference. What the literature does not describe is what service users would like from a VR service. This chapter describes how FGs were used to establish the type of support people with MS would like from a VR service and how such a service should be provided. Results are reported together with a further discussion exploring what these results could mean and how they lead to the next stage of the study.

5.2 Methodology

Phase I of the MRC framework[91] describes the need to identify the components of the intervention, and the underlying mechanisms by which they will influence outcomes to provide evidence that can predict how they relate to and interact with each other. In order to develop the service closely linked with the potential service user, it was important that employed people with MS were consulted in the process contributing to the development of the intervention. As discussed in chapter three FG methodology was chosen because it provided an opportunity for discussion between participants with similar and diverging views[95] and had the potential to provide data about the design of a VR service that was widely applicable and transferable. “The method is particularly useful for exploring people’s knowledge and experiences and can be used to examine not only what people think but how they think and why they think that way[99]”. Ethical approval for the study was obtained from the joint research ethics committee of the National Hospital for Neurology and Neurosurgery (NHNN) and the Institute of Neurology (ION) (see appendix 5.1). All participants gave their informed written consent.

5.2.1 Setting

At the NHNN has a central London setting and provides a comprehensive MS service which meets the needs of people from the early stages post diagnosis through to the palliative stages of the disease. The team of consultant neurologists is supported by the MS nurses who actively run relapse clinics, follow up clinics and drug related clinics. There is also a full MDT with expertise in MS and other medical related services such as an urology nurse specialist, cognitive behavioural therapy and a neuropsychology team. The whole team is actively engaged with the large MS population that accesses the services at the NHNN.

5.2.2 Participants

The selection of possible participants was through convenience and purposive sampling[93]. Convenience sampling refers to the sampling of subjects for reasons of convenience i.e. easy to recruit, near at hand. Purposive sampling is a deliberate non random method of sampling which aims to sample a group of people with a particular characteristic (in this case in employment). This method of sampling was felt to be most appropriate as it allowed the right people to be selected who fitted the criteria and therefore would potentially best contribute to the discussions. But it did not add significant extra work to an already very busy clinical MS team. The MS nursing team identified people who fitted the following inclusion criteria:

- definite diagnosis of MS;
- in employment or full time study or have been so in the past six months (thus keeping the focus on maintaining people at work and how best to do this rather than address the issues to trying to return to employment after a period of time, these issues are deemed to be different to maintenance of employment);
- functional spoken English.

A level of cognition was not specified as it was presumed that if someone was employed there was a certain level of cognition required from them to be able to maintain their job and therefore be able to participate and contribute to a discussion. Although the selection process was completed through convenience and purposive sampling, the broad inclusion criteria allowed a large percentage of the MS population at the NHNN to potentially be selected and therefore a degree of randomness was presumed.

5.2.3 Study design

From the literature review an interview guide was developed. A guide formed by a series of open ended questions was used to encourage research participants to explore issues of importance to them, in their own vocabulary, generating their own questions and pursuing their own priorities[93]. Krueger and Casey[96] recommend question categories which facilitate the flow of a FG discussion they are: opening questions, introductory questions, transition questions, key questions and ending questions. This framework was used to structure the interview guide developed for the FG and shown below:

Table 5.1 Focus Group Interview Guide

Interview Guide

Introductory statement:

I want to explore issues around vocational rehabilitation. Vocational rehabilitation is about supporting people with disabilities to help them remain in their current work, to modify their work, find new work, or to give up work in a planned and coordinated manner such that financial constraints and leisure opportunities are considered.

1. If we can go around the group and you introduce yourself – who you are and what your current work is?
2. Generally speaking what do you perceive some of the issues of having MS and maintaining work or study could be? [be careful possible exposing question]
3. Beyond the definition I gave at the start have you heard of vocational rehabilitation?
4. Do you know what it is?
5. Have you ever had any help that could be termed vocational rehabilitation?
6. If so what?
7. What would you like from a vocational rehabilitation service?

If ideas are not forthcoming in question 7 some or all of the following prompts will be offered:

- Fatigue management/24 hour time management
- Relaxation and anxiety management
- Tone management
- Exercise programmes and their incorporation into work
- The DDA and how this affects you
- Modelling disclosure
- Work planning (covers part time work, working from home, retirement on ill health grounds, maintaining occupation, voluntary options, benefits)
- Work place visit
- Ergonomics/Aids and gadgets to make life easier
- Cognitive problems and how to deal with them
- Access to work
- Employer session (?at work place or in out patients?)

8. How do you feel a service would be useful or not?
9. What would stop you accessing a service?
10. How would you like the service to be accessible?
11. How would you like the service to be promoted?

If ideas are not forth coming after question 8 some or all of the following prompts will be offered: by consultant, by GP, word of mouth, MS society, advertisements in MS matters, internet.

12. How would you have liked these services delivered?

If ideas are not forthcoming after question 7 some or all of the following prompts will be offered:

a. Group or individual
b. Ten 2 – 3 hour sessions
c. One full time week
d. Two full weekends
e. Intermittent sessions
f. Hospital/community/health centre/home/distance learning

13. Of all the things discussed what is the most important to you?
14. Summary - is this an adequate summary?
15. Have we missed anything – anything you would like to add?

It can be important to test the questions and ensure they are clear and understandable to the population they will be used on. The guide was discussed with four people with MS on the NHNN's neuro-rehabilitation unit (NRU). One area which was discussed at length was question two initially written as 'from your personal experience what do you perceive some of the issues of having MS and maintaining work or study are?' as to whether this was too personal at the start of the group. The question was amended to depersonalise it from 'your experiences' to 'generally what do you think…'? Following this change, no other comments were made; the interview guide was confirmed and ready for use in the FGs. As no further problems were identified and due to time constraints it was felt feedback from two people was sufficient.

5.2.4 Data collection

Basic demographic data was collected from all the participants asking them to give their age, date of diagnosis, type of MS if known and walking ability. An information sheet was written for participants using UCLH guidelines, this sheet gave further information about the study, the nature of FGs and how the data collected would be used (see appendix 5.2). Each participant read the information sheet prior to agreeing to participate in the groups. Once verbal agreement was reached a consent form was then signed (see appendix 5.3). Everyone approached agreed to participate in the groups.

5.2.5 The location

A decision was made to hold the FGs in the hospital as it was a familiar setting to the participants and easily accessible for them. From the researchers point of view it was also an easy setting for a room to be organised and it provided a suitable environment for discussion (noise and distraction free the methodological issues should be highlighted in previous chapter, .i.e. location, free from distractions, scribe). Despite the hospital setting, attempts were made to keep the meeting relaxed and informal by providing an opportunity for participants to make informal introductions prior to the formal start of the group and the provision of refreshments[96]. Participants sat in a circle to encourage interaction and had name badges[95].

5.2.6 The focus groups

The groups were formed in the following ways:

- **Focus Group one**

The MS team was in the process of completing an evening education course for the newly diagnosed. This is a seven week course and has approximately 30 attendees (both people with MS and their family/partners/friends). It was decided to recruit from this group for the first focus group as criteria was matched by all attendees with MS and also as the attendees were in the routine of turning up each week at the hospital. At the end of the final group an announcement was made describing the study and inviting people to be involved. There were twelve people who responded, study information sheet given and date confirmed for the following week for eight of the participants. This is described as a naturally occurring group[93] or 'piggyback' focus groups[96]. The benefits of such a group are that they knew each other and were happy to talk, share and interact. The rest agreed to participate at a later group. On the day of the group, one participant withdrew due to feeling unwell and one failed to turn up. So FG1 had six participants.

- **Focus Group two**

From the respondents identified in the process above two withdrew from the project and two remained. The MS nurses reviewed their active case load and identified potential participants who fitted the criteria. Contact was then made firstly by sending an introductory letter and study information sheet and followed by a phone call. People were offered the choice of an evening group (FG2) or an afternoon group (FG3). Five more people were recruited to this FG. On the day one person withdrew. FG2 had six participants.

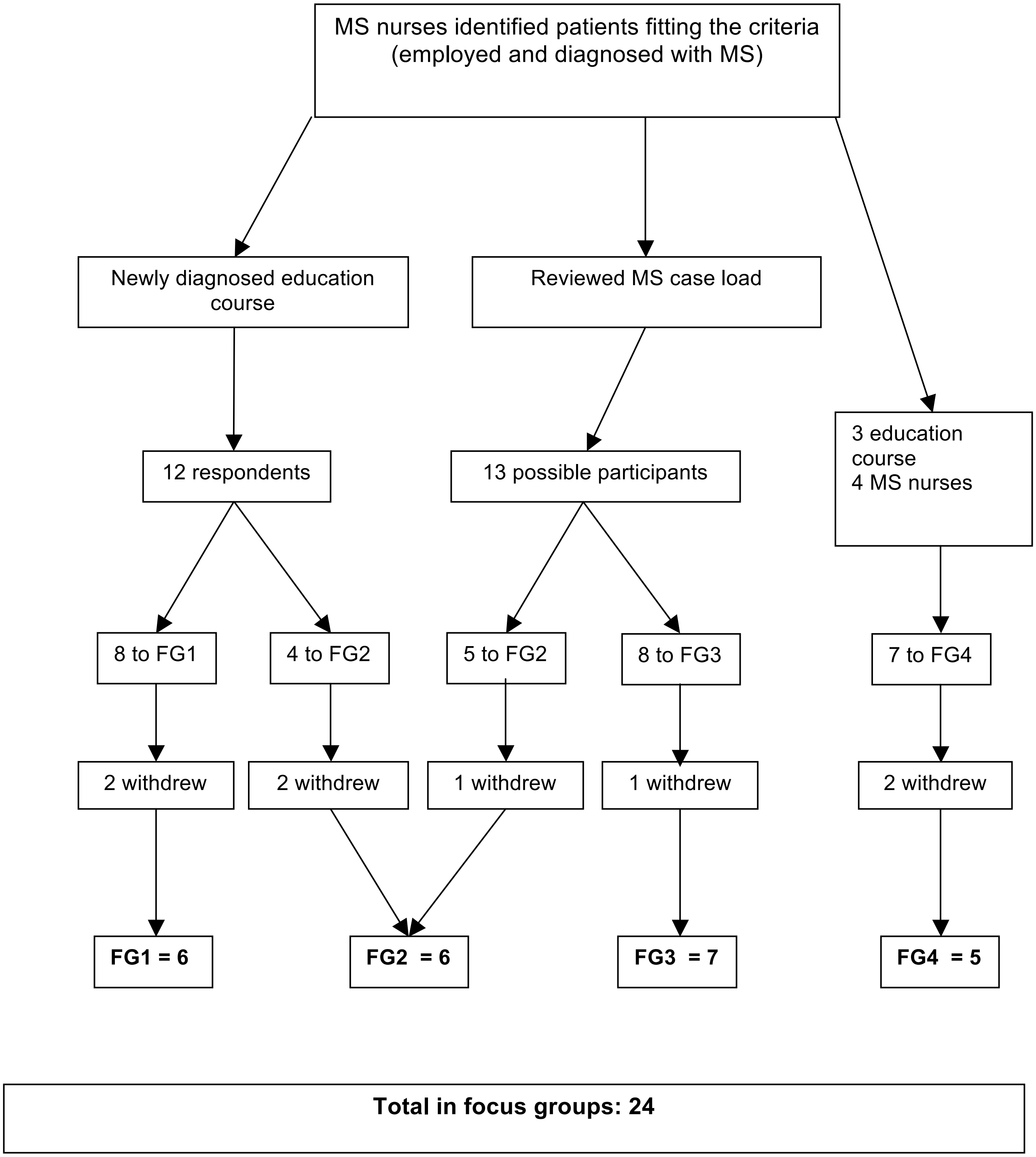
- **Focus Group three**

The same process identified above was undertaken to recruit for this group and seven people were identified by the MS nurses. FG3 had seven participants.

- **Focus Group four**

This was held at a later date. This was to ensure we had reached data saturation with no new emergent themes. Participants were recruited via the MS nurses and also through the same education evenings. From the evenings there were three recruits and four were recruited via the MS nurses. On the day, one lady called to say she was unable to make it and one lady did not turn up. So the FG4 only had five participants.

Figure 5.1 Flow Diagram to Show the Recruitment Process



The total number of participants was 24, the data collection and analysis during the time period were conducted concurrently; data saturation was felt to be complete after FG3 but FG4 confirmed this. The group dynamics through all four groups were good, there was a degree of formality but participants interacted in a relaxed manner and there was a balance of contributions across the groups; often participants encouraging each other to share views and personal stories.

Table 5.2 Participants' Demographic Details

Participants	
Number of participants:	24
Male:	7 (29%)
Age (median, range)	42 (25-59)
Type of MS	
Primary Progressive	1 (4%)
Secondary Progressive	4 (17%)
Relapsing Remitting	19 (79%)
Time since onset years (mean, sd)	10 (7.7)
Walking ability	
Walking independently:	17 (71%)
Using an aid indoors and outdoors:	6 (25%)
Using wheelchair:	1 (4%)

5.2.7 Structure

Each of the FGs ran with a similar structure: 30 minutes given from identified start time to allow for people to arrive, take refreshments and complete the demographic information sheet. The group facilitator introduced the topics, asked questions and encouraged participation of all group members. Also in the group was a research assistant; to support and facilitate the logistics of the group (turning on the tape recorder, collecting forms, serving drinks etc). The discussion ran for approximately one hour this was recorded using two tape recorders, one used as a backup. The groups were started with an explanation of the study and a short introduction to VR (see box 1). This definition is similar to that used in the NSF LTC[71].

Box 1

"Vocational rehabilitation is about supporting people with disabilities to help them remain in their current work, to modify their work, find new work, or to give up work in a planned and coordinated manner such that financial constraints and leisure opportunities are considered."

An explanation was given to encourage participation with each other not the researchers. The researchers did not participate in the discussion. The interview guide was used in all the groups. The first topic was introduced so that the participants could share their views about the impact of MS on work and work on MS. Question two allowed participants to share their own experiences. This discussion provided a shared background from which prompts were then introduced to explore in more depth the issues around service provision, delivery and promotion. At the end of each group as discussion finished, the research assistant gave a brief summary of all that was discussed in the group and invited people to make final comments about what they felt was most important, and any other issues they wished to raise before the session ended. Each participant was individually encouraged to comment at this point and all were willing to do so.

It was found when the formal group had finished participants enjoyed continuing conversations and sharing stories and their experiences, this was not recorded and frequently diverged from the theme of work. Therefore, in total the groups took two hours. Despite initial concerns about the personal nature of question two people very quickly talked and shared their own personal experiences and were very willing to do so.

5.2.8 Analysis

The FGs were all tape recorded with a back up tape recorder also used in case of first recorder failure. Recordings of the focus groups were transcribed verbatim. The primary researcher and one of the research team independently read the data and identified themes. Themes are described as over arching constructs within which more defined coding can occur. Themes can come from already-agreed-upon professional definitions, from local common sense constructs, and from researchers' values, theoretical orientation and personal experience with the subject matter[196].

Once the broader themes were agreed upon the process of coding was undertaken. The 'smaller' codes sit under the umbrella of the themes. Coding is a method of conceptualising research data and classifying them into meaningful and relevant categories for the participants in the study[93;100]. Coding is the process of marking passages of text that are about the same thing, say the same thing or discuss things in the same way. Similar passages are marked with a code. Codes support a thematic analysis of the content of the text and enable the rapid retrieval of text that represents common ideas, themes, rhetoric and approaches[196]. Glaser and Strauss[100] argued that coding is essential for the invariable analysis of qualitative data. A single item is permitted to be coded in more than one category in order to permit cross-referencing and generation of hypotheses. Categorisations are then compared and any discrepancies discussed until consensus is agreed[93]. The end product of this process is an explanatory framework with which to understand the phenomenon under investigation[101].

A constant comparison technique[100] was used aiming to let new grounded codes emerge from the data but it was acknowledged that *a priori* ideas could also have an impact on codes (e.g. from the researchers understanding of the subject matter, previous research or theory already published). For a constant comparison approach every time a passage of text was selected and coded, it was compared with all those passages already coded. This ensured that the coding is consistent. Techniques for coding include:

- Word repetitions – looking for commonly used words and words whose close repetition may indicated emotions;
- Key-words-in-context – looking for the range of uses of key terms in the phrases and sentences in which they occur; and
- Compare and contrast – essentially asking 'what is this about?' and 'how does it differ from the preceding or following statements?'

Using these techniques is called descriptive coding because it essentially forms a summary description of what is in the transcript[197].

A hierarchy was used to help sort the codes often known as tree coding which is a hierarchical arrangement of codes with a branching arrangement of sub-codes. Ideally, codes in a tree relate by being 'examples of...', or 'contexts for...' or 'causes of...' or 'settings for...' and so on (shown in the Results section table 5.3)[196].

Data was coded line by line using the computer software this ensures data is grounded as it is taken directly from the transcripts. The data were managed with Winmax software[198], which enables a code-and-retrieve function that retrieves text segments depending on the code words and their co-occurrence.

The first interview transcript was coded independently by the primary researcher and two of the research team and then compared. The remaining three interviews were coded independently by the primary researcher and one member of the research team and then compared. There was a high degree of consensus with the codes. Where there was a disagreement there was discussion with a third member of the research team and resolution was found through consensus. In a final meeting with all three researchers a consensus of coding categories and a final list of key themes was achieved. This was done iteratively through discussion and re-reading of transcripts until there was saturation and complete agreement on codes.

5.3 Results

In total twenty-four people participated in the FG discussions. The first three FGs were held in July and August 2005 and the fourth FG to ensure that data saturation had been reached in June 2006. The questions asked were designed to help identify the type of support people with MS would like from a VR service, and how such a service should be provided. Therefore the results come under two main headings: ‘Impact/support required’ and ‘what people want from a service’. In the process of analysing the data six themes over-arching were identified: the physical impact, the psychological impact, lack of knowledge, the service, the delivery/structure, and service promotion. Within each of these themes different codes were identified and data coded accordingly. However, in reality topics were rarely raised, that related to only one theme. The themes and codes are shown in the table below.

Table 5.3 Themes and Codes from Focus Groups

IMPACT/SUPPORT REQUIRED	**WHAT PEOPLE WANT FROM THE SERVICE**
Physical impact/barriers Physical ability - fatigue - walking - changes in sensation - visual disturbance Travel to work Environment - access - toilet - *Psychological impact/barriers* Disclosure Lack of Support - sympathy - half hearted Anxiety - performance at work - toilet - disclosing Fear - disclosure - MS unpredictability Lack of confidence Denial Discrimination *Lack of knowledge* Rights and the law - person - employer Services available - person - employer Benefits - person MS - employer - colleagues	*The service* Support with disclosure Fatigue Education - employers - colleagues - person re: the law Benefits advice Work options Work place visits Support/advocate Empowerment *The delivery/structure* One to one basis Groups Self referral *Service promotion* Health care professionals - MS nurses - consultants - GP's Written - posters - leaflets - internet

Topics raised by the participants around the barriers to work related to previous research published discussed in chapter four and there were no new emergent themes. Upon further analysis it was felt that under the section 'Impact/support required' the results were better understood if reported under the following themes: Managing performance with the sub-themes of 'Improving performance', 'Compensating for performance' and 'Modifying performance' then 'Managing social and personal expectations' with the sub-themes 'Disclosure', 'Discrimination' and 'Lack of knowledge'. Table 5.4 illustrates how the old themes fit into the revised themes; the new themes are written in capitals. There was no change to the second section.

Table 5.4 Revised Themes from Focus Groups

IMPACT/SUPPORT REQUIRED	**WHAT PEOPLE WANT FROM THE SERVICE**
MANAGING PERFORMANCE *- IMPROVING PERFORMANCE* *- COMPENSATING FOR PERFORMANCE* *Physical impact/barriers* *- MODIFYING PERFORMANCE* *Psychological impact/barriers* *MANAGING SOCIAL AND PERSONAL EXPECTATIONS* *- DISCLOSURE* *- DISCRIMINATION* *Psychological impact/barriers* *- LACK OF KNOWLEDGE* *Lack of knowledge*	*The service* *The delivery/structure* *Service promotion*

Therefore, the results below describe the discussion generated by participants about what should be done to address these issues. The revised themes are discussed below and illustrative quotes are given where appropriate. Appendix 5.4 has table 5.5 giving further examples of quotes and shows how the research team's clinical experience translates the theoretical to practical.

5.3.1 Managing performance

A key issue was how the impairments associated with MS interacted with the physical environment and/or demands of the job to limit function. One of the issues that emerged was how the physical demands of the jobs, which were extrinsic factors, interacted with the effects of the disease, the intrinsic factors. To manage their performance the participants felt the following three areas were important:

- **Improving performance**

Many of the participants had experienced a physical decline in function either temporary or permanent. This impacted on their performance at work:

> *'I can't go up ladders anymore as my balance is terrible' (FG3 p3)*

> *' Well I had to sell my company I couldn't physically do it anymore – I needed a lot of get up and go… I've now got a boring part time job' (FG1 p5)*

Participants felt that rapid and early access to services, such as physiotherapy, would be useful in helping them manage these physical barriers. They all reported that they were committed to maintaining their work, save for one participant who had recently taken retirement on grounds of ill health. One participant stated "*when your whole world is reeling with the diagnosis of MS, work is something you do not want to lose*" (FG1 p4). One barrier which was consistently raised was how the affects of fatigue significantly impacted on their day but they had no ideas as to how to deal with this symptom.

> *'I honestly thought I was going to have to retire last year as the fatigue was getting appalling – going on buses and trains and arriving totally shattered – I'd have to sit down for an hour' (FG3 p4)*

> *'Fatigue… the daily issue' (FG1 p6)*

- **Compensating for performance**

It was felt by some participants that as physical changes occur, support with looking at work environments would be beneficial. One woman described how her occupational health team had moved her desk closer to the toilets in her office to help her accommodate her bladder weakness. She said that this had made a significant impact on her ability to remain at work. Access to work, the physical getting into and home from work, was identified as a barrier. Only one participant had heard of or used the 'Access to Work' taxi scheme. Other ideas such as work environment assessments to review the ergonomic set up of work stations was also discussed by the groups.

> *' I had two massive attacks and I still went to work and I sat there and I could see two computer screens, I couldn't hold a pen and I kept slipping off my chair as I couldn't feel my bum! I just couldn't feel what I was doing… so… then I worked through all of that' (FG2 p2)*

> *'There are too many stairs now… if I fall down who is going to take responsibility? Would it be my fault because I went up the stairs?' (FG2 p4)*

- **Modifying performance**

It was felt it would be helpful to be able to consider different work options with what the groups called a 'work specialist therapist'. For these participants whose diagnosis was making them reprioritise their lives the discussion came up in each group about how they would like the kind of support addressing work options or 'work planning':

> *'In the beginning it is very confusing so if you don't know the options, you need to sit down and have a long think about things – if you know you have got the support there and you work it out with somebody… it would be good to have someone to help plan…' (FG3 p6)*

People felt that having someone to support them and facilitate making informed choices about the options available to them would be beneficial.

5.3.2 Managing social and personal expectations

In all the groups, the general consensus was that the more hidden problems presenting in the psychological barriers were the hardest to overcome, and that these were most influential when a participant felt that society generally, or the employment environment in particular was unsupportive. Participants felt they needed support to manage the social and personal expectations they experienced through support with disclosure and issues around discrimination.

- **Disclosure**

All the participants saw disclosure as a high risk but necessary strategy, requiring considerable courage. Participants felt that support with disclosure was a significant priority for any specialist work service and that support in this area was deemed to be of high importance.

> *'If you have taken the courage to disclose to your employer, I think it would be good to have somebody else who went and talked to them about it: "what would you need" and they would be a lot more dispassionate and, you know, you'd feel like you weren't being pressurised to, sort of… it would help your employer, understand it better because it is coming from a professional' (FG3 p2)*

Participants described situations of working harder to prove themselves, including going to work whilst having a relapse, in an effort to fight to keep hold of their job. A few people described that the thought of having to speak to their employer at this stage would be horrifying whereas disclosure earlier on would probably be a better choice. It was felt that support to do this would be invaluable.

All the groups felt that a lack of support was leading to difficulties in the work place for them. Some people felt that having someone to talk to about their anxieties would be helpful. With support from a ‘work specialist therapist’ they felt that they would feel: more empowered to take the time off they needed; have someone who could help maximise their potential; ask for accommodations to be made at work; and generally feel more confident and not alone in managing their condition. Despite the anxieties and lack of support, participants wanted to work and felt it was important for their sense of wellbeing.

> *‘If you think your whole world is unravelling, if you can work, even in a compromised way, it’s fantastically important …because you feel useful as a human being’ (FG2 p3)*

- **Discrimination**

It was felt that discrimination primarily resulted from poor education or lack of knowledge about MS. All participants perceived the need to have support to educate their employers about MS was a priority. One suggestion was a work site visit where the ‘work specialist therapist’ could come and meet the employer. One participant described how when he was diagnosed he wrote to the MS Society and received their information leaflet for employers. He felt this was a good starting point to help him educate his employer. But it was felt that more support to empower people with MS would help reduce this discrimination.

> *‘After my first attack my job was left open, but when I came back I never moved up in positions, my pay never increased, my work load got bigger and yet he wouldn’t promote me. He would always say ‘well you are better staying where you are, you know your condition, it is better not to take on too much’ yet unofficially he was giving me more work’ (FG1 p2)*

As the discussion developed, the overriding theme was the need for an advocate. It was felt that having an advocate would help deal with many of the issues that were of concern to them.

> *‘I think you would need a key contact really, a support network, someone who knows you, someone you could go and have lunch with whatever, that they know your issues, rather than ringing up and having to start again to talk to another person you have never met…’ (FG1 p2)*

With an advocate to help guide, support and direct them around the barriers, they felt they would be able to retain their jobs even if in a reduced capacity.

- **Lack of knowledge**

Lack of knowledge about the DDA and support services was a recurrent code. There was significant confusion about the DDA[55] and Government run support services, the groups all felt that offering a service which would provide advice in this area would be invaluable. With information provided and explained to them the participants believed that they would be able to self manage their condition more effectively in the future. They also felt they would be more empowered to disclose at work if they better understood how they were protected legally and what was expected from their employers in terms of supporting them.

> *‘The legal knowledge is important… you need to know what your rights are... the legalities of MS and how I am supposed to be treated in terms of employment’ (FG3 p1)*

Some of the participants felt if they could understand their rights better they could cultivate an environment where the confidence, should a relapse occur, would be there to request time off or ask for adjustments to be made. As opposed to the present situation which often results in participants living in fear of a negative reaction to their needs or requests.

5.3.3 Service delivery

Participants in all groups felt that they would like to have support in this area early on when diagnosed or shortly after. It was felt an early intervention service would help in the longer term and provide valuable advice, education and support to prevent many of the issues discussed occurring in the first place.

> *‘I think when you are coming in and you have been diagnosed – your doctors or the nurse could tell you they could give you a leaflet – these are the kind of places you can get support’ (FG2 p1)*

> *‘I am picturing this they diagnose you then they go here is your information pack and land you with a load of stuff… it has to be a period of time... you are diagnosed on the first of the month, they say we give you two months to get used to it then schedule in some sessions you know’ (FG2 p6)*

Discussion centred around what structure should be offered, some participants felt groups could work well but overwhelmingly all the groups felt a one to one relationship was best. This was keenly felt as a result of MS being a unique experience for everyone. Participants believed that having one person that they could speak with, who knew them as an individual, would be most beneficial. No one highlighted how often this should be as it was felt it should be individual specific and needs-lead rather than prescriptive. Generally participants felt that the service could be offered from the hospital setting but felt that at times a work site visit would be beneficial.

> *'I think it would be good to have a one to one service not just a blanket service as everyone with this diagnosis is so different…' (FG2 p2)*

People spoke of how they would like to be able to self refer into the service, an 'open access' service. The unpredictability of MS led them to want to be able to self-refer when there was a problem without the lengthy red tape of having to start each time with a consultant/GP referral process.

5.3.4 Service promotion

On discussing VR, not one of the participants had heard of the concept and only one woman had received any support that could be described as such, this had been from an occupational health physician. Every participant felt that a work related service would be beneficial and definitely needed. When asked to describe what they thought VR was one participant stated:

> *'What we are talking about, vocational rehab is much more about how do you actually manage to live your life and stay on the payroll and keeps you occupied during the day so that you don't feel useless, worthless by not working… I have got to struggle with this stuff… whatever we put forward has to be specialised, elite, and specific to work not just something anyone can do' (FG3 p4)*

There were long discussions about how the service should be promoted: leaflets; Internet; and posters were the most popular suggestions.

5.4 Discussion

This study provided data about what people with MS feel they needed to help them remain in work. It demonstrated that individuals with MS wanted an 'open access' VR service, promoted through leaflets, posters and web-based information, available from diagnosis and delivered on an individual 'one-to-one' basis.

5.4.1 Weaknesses

There are weaknesses with the study. A potential weakness of FG design is the tendency for the group to develop a consensus. However, the aim of this study was to establish the general needs of a group, not individual specific problems, this therefore, may have been an advantage. A conformity of opinion within a FG is therefore an emergent property of the group context, rather than an aggregation of the views of the individual participants[98]. With this specific study the demographic data shows that participants generally had a short disease duration (10yrs) and therefore presented with low levels of disability. It is not known if results would be different should a more disabled group be involved in a discussion. The NHNN represents an inner-city population, thus the findings may not be applicable to a more rural population. In addition to that most of the participants (mean 42yrs (25-59 range)) were young working professionals who were well educated, which also reflects the population who attend the NHNN. This could have skewed results. In addition, the numbers studied were relatively small. Nevertheless, the data reached saturation and no new themes emerged in the fourth FG which was completed at a later date to ensure data saturation.

5.4.2 Codes and themes

The second question in the FG discussions addressed the barriers to working with MS and the discussions were consistent with results reported in the literature review in chapter four. These studies have focused on the barriers to work, not how people with MS feel they could be supported to manage such barriers. This is the first study to identify what individuals with MS feel would help them remain in work.

The FG participants reported they all valued work and were committed to maintaining their employment roles; they identified two clear domains where they felt support could be helpful to enable them to continue this working role. First, with regard to performance, they reported needing support with managing their performance in the workplace. This may be achieved through improving performance (e.g. exercises to improve mobility, fatigue management), modifying performance (e.g. relocating desk nearer the toilets to manage bladder weakness) and compensating for performance (e.g. reducing hours, using a taxi for travel to work). Second, with regard to managing social and personal expectations, they reported wanting support with disclosure, managing anxiety and dealing with discrimination. It is these two areas, which influenced the design of the service provision in the exploratory trial (described in Chapter 6 section 6.2.4).

5.4.3 Missing codes

It was interesting that a few codes were conspicuous by their absence. No group mentioned cognitive difficulties, although it has been highlighted in literature review (chapter three) as a significant problem when managing a demanding working role. There was no discussion around retirement, even though changing occupational roles was included in the initial description of VR. There was little awareness of the role of an OT or how OT, as a discipline, could assess and problem solve some of the issues identified. Thus, although fatigue was identified as a barrier, there was no discussion around fatigue management, an approach that was seemingly unknown to the groups. The fact that the inclusion criteria required that people were still working, or within six months of leaving work, and that most were in the early stages of MS may be significant to the findings of this study. The findings strongly suggest that this population is likely to benefit from a VR service aimed at work retention.

5.4.4 Professional intervention

The two key themes of managing performance and managing social and personal expectations suggest that there is need for a professional who has expertise in managing the interaction between the impairments caused by MS, the physical environment and the demands imposed by the work. An OT could perform this role. OT concerns itself with 'occupational performance' for which the context of occupation is the ‘doing’ of everyday life, it is focused at looking at these activities (personal care, domestic, productive, leisure and social) within the setting of the environment (physical, cultural and social) and with an understanding of the person (emotional/social, physical and cognitive). OTs are skilled at providing therapy to improve people’s performance, modifying tasks and the environment and compensating where required to maximise a person’s occupational performance. The service would also need to provide expert knowledge about the employment environment and the needs of employers, an awareness of the relevant legislation and the counselling in supporting people to adapt, adjust and resolve complex issues.

5.5 Summary

This chapter has described the FG methodology used in Phase I of the MRC framework[91]. It has discussed the advantages and disadvantages of FG design and why it was chosen as the most appropriate method for this study. It has described the process of analysing the data using a constant comparative method, and has then reported and discussed the results. The results showed that there appears to be a need to provide support to manage changes in performance as well as personal and social expectations within a VR service. The following chapter will describe how the results have been used to model, develop, and subsequently trial a VR service as described by the FGs in this chapter and the literature review in chapter four.

Chapter 6. Phase II Exploratory Trial

6.1 Introduction

Chapter five described the results from the FG study (modelling phase) which showed what people with MS find are barriers to working and described what they would want from a VR service. This chapter will discuss how these results and the results obtained from pre-clinical stage (literature review), were used to develop a VR service for people with MS who wanted to maintain their employment. The aim of this stage was to develop and evaluate a VR intervention. The study had multiple objectives, which were firstly, to put into practice the intervention designed by the FGs and to define what this service was. Secondly, to capture the benefits of the intervention through PROMS and to record time spent with each participant so that the intervention could be costed. Thirdly, to select an appropriate outcome measure to power the RCT used in Phase III (chapter eight). This feasibility study allowed variations of the intervention to be tested and formed Phase II of the MRC framework[91]: the exploratory trial. Phase II of the framework facilitates both quantitative and qualitative designs being used. This chapter will report how all the quantitative data was collected and discuss the results. The following chapter will discuss the qualitative data collected through semi-structured interviews at the end of the period of intervention.

- **Working yet worried**

The exploratory trial was called ‘Working yet Worried’ as a way to capture those patients who were in work yet had problems ranging from small to significant issues in the work place. Ethical approval for the study was obtained from the joint research ethics committee of the NHNN and the ION (see appendix 5.1). All participants gave their informed written consent.

6.2 Methodology

The VR service was provided for one year offering the type of interventions discussed in the FGs and supported by the literature review. In order to put into practice the intervention, participants were recruited for the study through the MS service within the NHNN setting.

6.2.1 Setting

The NHNN has a central London setting and provides a comprehensive MS service which meets the needs of people from the early stages post diagnosis through to the palliative stages of the disease. The team of consultant neurologists is supported by the MS nurses who actively run relapse clinics, follow up clinics and drug related clinics. There is also a full MDT with expertise in MS and other medical related services such as a urology nurse specialist, cognitive behavioural therapy and a neuropsychology team. Participants would initially be seen by the OT in the hospital Outpatient department, locations of further sessions would be at the discretion of the OT who decided which was the most appropriate setting to meet the participants needs e.g. work site visits or hospital.

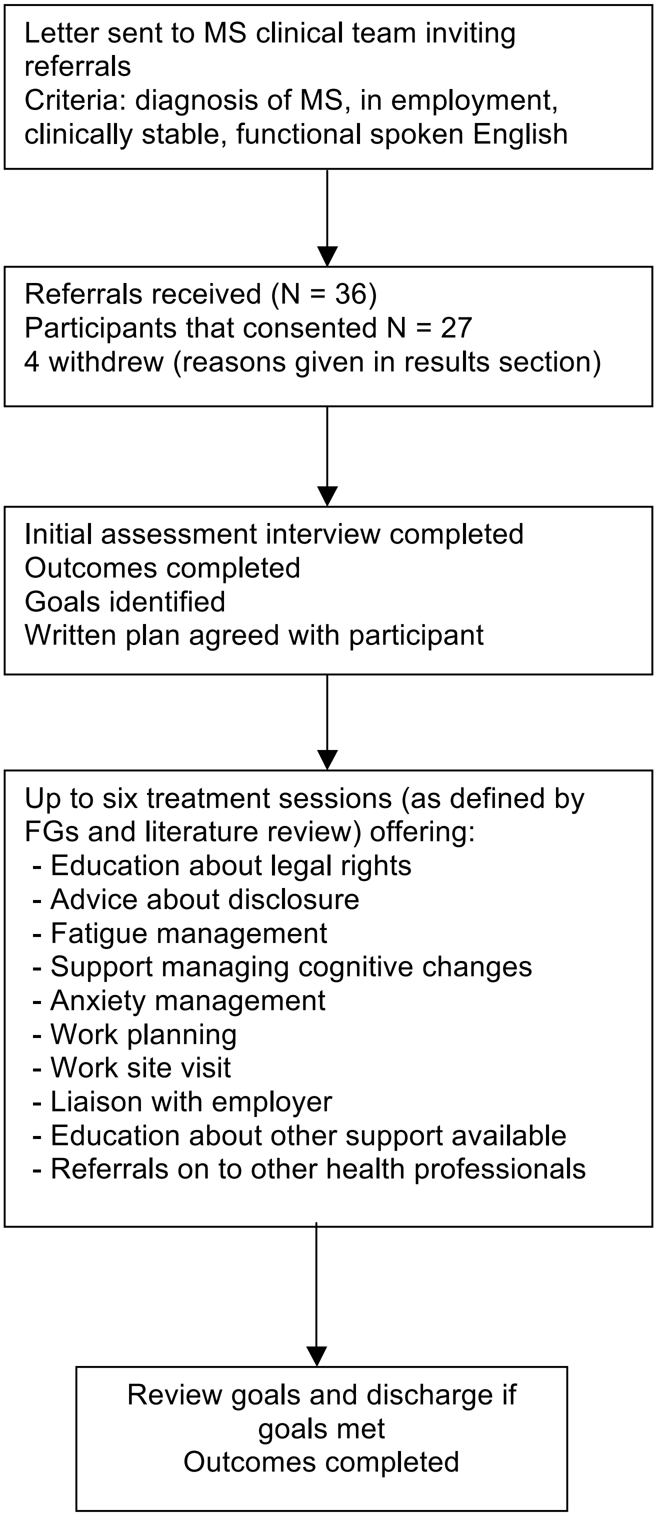
6.2.2 Participants

A letter was sent out to all the MS consultants, the MS nursing team and the clinical specialist OT and PT to explain that referrals would be accepted from October 2005 for ‘Working yet Worried’. The same inclusion criteria used in the FG study was used for this trial: a definite diagnosis of MS; in employment or education; clinically stable; and functional spoken English. The current outpatient OT service waiting list was reviewed and contact was made with six patients on the list who had referrals related to work. This enabled the service to start whilst awaiting direct referrals from the MS team. All the referrals received a letter of introduction sent with the patient information sheet (see appendix 6.1). The referred patients were then invited to make contact with the OT to show they were interested in participating and an appointment was made.

6.2.3 Study information

The information sheet for participants was written using UCLH guidelines; this sheet gave them further information about the study, possible interventions and how the data collected would be used (see appendix 6.1). Each participant read the information sheet prior to agreeing to participate in the service. Once verbal agreement was reached a consent form was then signed. The consent form was developed using UCLH guidelines (see appendix 5.3).

Figure 6.1 Flow Diagram of Exploratory Trial Process



6.2.4 Intervention

Once recruited to the service each participant was comprehensively assessed by a senior neurological OT experienced in VR.

- **Developing an assessment form**

To facilitate an OT initial interview and to help define the intervention the standard NHNN OT interview form was developed to be more work focused. Contact during this time was made with the CRS Australia and their interview form was sent across as reference and relevant parts taken for the new form. The themes and codes identified in the FG discussions were also considered in the development of the form to ensure all areas were covered. The end product was a comprehensive initial interview guide, which covered work as well as a brief section to review other activities of daily living (see appendix 6.2). It was strongly felt that as the service was OT lead it was important to address these areas as well, so necessary referrals could be made to community or social service OT departments where required.

- **Initial session**

The initial assessment was held in outpatients and involved obtaining a description from the participant of their education and training, the tasks they performed at work, and the physical and social environment within which they worked. In addition during this assessment the OT worked with the participant to identify their strengths and weaknesses, define problems and solutions, and establish the various factors that contributed to any difficulties and the individual's work-related goals.

- **Treatment sessions**

At the start of the study the research team used the results from the literature review and FGs to map the possible interventions to be provided. The tables in Appendix 5.4 with examples of quotes from the FGs show how these quotes and subsequent codes (shown in chapter 5 table 5.3) were developed into possible service provision with the research team's clinical experience translating the theoretical to practical.

Potential approaches to problems included managing performance through:

1. Improving performance e.g., through symptom management, PT, fatigue management;
2. Compensating for impaired performance e.g., removing environmental barriers, improving the ergonomics of work stations, strategies to manage cognitive decline;
3. Modifying performance e.g. by working with employer to reduce the demands of the task e.g., by structuring the day by setting aside specific times for different elements of the work.

Further sessions to manage social and personal expectations included the provision of advice and support about disclosure, information about the DDA, work planning including work place accommodations and information about the Access to Work scheme[142]. After each session an action plan was developed for both OT and participant. Each participant had access to as many treatment sessions as were necessary to complete the plan; where appropriate referrals were made to other rehabilitation professionals including PT and neuro-psychologists. The initial plan was to have up to six sessions with each participant on consecutive weeks lasting 1.5 hours per session. It was therefore calculated that all participants could be seen, assessed, treated and discharged by July 2006.

6.2.5 Outcome measures

In order to capture the benefits of the intervention through PROMS, questionnaire packs were completed both at recruitment and completion of the intervention. A selection of PROMS were used to cover areas of work performance, health status and well-being. This enabled all aspects of this complex (multi-faceted) intervention to be evaluated. The PROMS were chosen based on their validity, reliability, responsiveness and appropriateness (as described in chapter three) to reflect the following domains work status, disability and well-being. A copy of the outcome measure pack can be found in appendix 6.3.

- **Work status**

Generic work impact measures

These have been developed to examine the relationship between health status and ability to work. The measures were designed to be used in any sample of workers, irrespective of the nature of their employment or their illness. For this study the **Work Limitations Questionnaire**[199] (WLQ) was chosen. Developed on a population with a range of chronic health problems it has eight questions with 1-6 response categories. Summing up the responses in all eight items would yield a composite score within a range from 8 – 48. A low score indicates that health problems are impacting on work. The scale reported high internal consistency, test-retest reliability and construct validity in the literature[199].

Disease-specific work impact measures

A number of disease-specific work impact questionnaires have been published, developed to examine the relationship between a specific medical condition and patients' ability to perform their work. There have only been two reports of an MS specific employment questionnaire in the literature: The **MS Impact on Work Questionnaire**[33] (IWQ) which identifies barriers to work caused by symptoms and by the environment. It consists of 17 questions with five response categories. The results are reported in two sections: the Environment scale (walking difficulties, balance, access at work, travel to work, weakness, public attitudes, handwriting, continence) where responses yield a composite score of 17-40; and the Symptom scale (concentration, memory, speech, swallowing, visual problems, coordination, mood, pain, fatigue) where responses yield a composite score 17-45. A high score indicates symptoms extremely impacting on work. It was shown to be reliable and valid but no studies of responsiveness have been performed;

i. The **MS work assessment scale**[200] (WAS) is a 52 items questionnaire that asks people to rate items that may impede or enhance their ability to work. It demonstrates adequate internal consistency but other forms of reliability and acceptability were not tested. However, every participant reported that they found the questionnaire difficult to complete and there was significant missing data as participants left blank questions that they did not understand. With many incomplete data sets it was decided not to analyse these results and this outcome was removed from the results; and

In addition one unpublished scale was identified: the **MS work instability scale**[201] (WIS). Work instability is the mismatch between an individual's functional abilities and the demands of his or her job. It is formed of 21 questions with true and false response categories. A true response would score 1 and therefore a maximum score of 21 can be reached. Within this score three levels are determined: 0-7 no risk, 8-16 advice or intervention needed, 17+ severe problem indicated. This scale is under development, and preliminary work suggests it is valid and reliable[202]. It has been developed in a similar way to the Work Instability Scale for rheumatoid arthritis[81]. This scale has been developed primarily as a screening tool so there was uncertainty as to how it would perform as an outcome measure.

To add to these three work impact outcomes **a seven-point transition question** was written by the research team to ask participants about their belief in their ability to cope with the demands of their work. Response choices were: much worse, somewhat worse, slightly worse, no change, slightly better, somewhat better, much better.

- **Health status**

There are a multitude of different health questionnaires designed to capture the impact of a medical condition on daily life. For this study the following were chosen:

i. The **self-report Barthel Index** (BI) an activities of daily living scale. It is an ordinal scale that measures functional independence in the domains of personal care and mobility. A self-completed postal version with ten multiple-choice questions was chosen. These multiple choice questions map onto the responses in the conventional Barthel. The test retest reliability of the self report BI indicated at least moderate reliability[203];

ii. The **Multiple Sclerosis Impact Scale** (MSIS -29) a patient based rating scale to assess the impact of multiple sclerosis (MS). It has 29 questions; there are two subsections 'physical' questions 1-12 and 'emotional' 13-29. Response categories are from 1-4 from 'not at all' to 'extremely'. Summing up all the responses to all 29 items would yield a composite score in a range of 29-116 (Physical: 12-48 and Emotional: 17-68). A low score would indicate no impact of MS symptoms on daily life. This scale has been shown extensively to have high reliability, validity and responsiveness[204-206];

iii. The **Multiple Sclerosis Walking scale** (MSWS-12). A patient-based measure of walking ability in MS with twelve items describing the impact of MS on walking. The twelve items have 1-5 response categories from 'not at all' to 'extremely'. Added together a final score could range from 12-60, with a high score indicating an extremely limited walking ability. Item test-retest reproducibility, reliability and validity are high with a high level of responsiveness[207].

- **Well-being**

Well-being was measured using:

i. The **Medical Outcomes Survey Short Form 36** (SF-36) A 36-item short-form was constructed to survey health status that assesses eight health concepts over two domains; physical health (physical functioning, physical role limitation, pain and general health perceptions) and mental health (emotional role limitation, vitality, social functioning and mental health). It has eleven questions. The eight scaled scores are the weighted sums of the questions in their section. Each scale is directly transformed into a 0-100 scale on the assumption that each question carries equal weight. Reporting the eight individual domains is the most informative and frequently used response. Used extensively in research with many studies showing good reliability and validity[208-210];

ii. The **General Health Questionnaire** (GHQ-12) an instrument for detecting current, diagnosable non-psychotic/psychiatric illnesses. It has twelve questions with 1-4 response categories. Summing the responses to all twelve questions would yield a composite score with a range of 12-48. This is then collapsed into a dichotomous scoring scale where the maximum score is 12. A low score would indicate good health. Used extensively in research with many studies showing good reliability and validity[211].

6.2.6 Defining the service and collecting cost data

To ensure the service could be costed time spent with each participant was recorded. Both contact and non-contact time was recorded describing both the task performed and the time taken to undertake the task. In addition the time spent by other health care professionals at the NHNN was also recorded. A database recorded 15-minute units of time. Codes were written to be used as identifiers for these 15-minute slots. At the start of the study the list of codes was hypothesised. The list of codes developed as the service progressed and helped to define the intervention delivered at the end of the study.

The cost of the intervention was calculated as the product of total time spent and mean hourly rates defined in The Units Costs of Health and Social Care Report[2] [See table 6.1]. A health economist at UCLH was involved to help with this process. 95% confidence intervals were calculated using a bootstrap method (10,000 re-samples, with replacement).

Table 6.1 Costings[2]

Health care professional	Unit cost 15 minutes (mean face-to-face and non-contact)
Occupational Therapist	£8.71
Speech and Language Therapist	£8.07
Physiotherapist	£8.85
Neuropsychologist	£9.82
Social Services Occupational Therapist	£7.60

6.2.7 Data analysis

Pre- and post-intervention scores (i.e. WLQ, IWQ, WAS, WIS, BI, MSIS-29, MSWS-12, SF-36 and GHQ) were compared using paired t-tests for normally distributed score differences and Wilcoxon matched pairs tests for skewed score differences plus effect size (ES) calculations[212]. The ES is a standard unit of responsiveness in which <0.20 relates to a small change, 0.50 a moderate change, and >0.80 a large change. It is defined as the difference between two means divided by the standard deviation for the data (cohen's d). The data set was small and not normally distributed and therefore we chose to use non parametric statistical test. Through analysis of the results an appropriate outcome measure was chosen to power the RCT in Phase III, one of the objectives of the exploratory trial. The MSIS-29 was chosen due the large ES and the fact that in clinical terms it was most accurately targeted towards our patients. It was felt that the other scales with large ES's such as the GHQ and SF36 (emotional role limitation sub-scale) did not cover the range of difficulties experienced by this population.

6.2.8 Qualitative data

With the above methods focusing on quantitative data collection it was important that qualitative experiences of the service were also captured. This was to ensure that the full impact of the intervention was captured and the participants' experiences reported. The process of collecting qualitative data and the results of the interviews are described in chapter seven.

6.3 Results

Over a ten month period (October 2005 – July 2006) 36 referrals were received from the MS nursing team and 27 of the referrals agreed to participate in the service.

Table 6.2 Participants’ Demographic Details

Participants	
Number of participants:	27
Female:	18 (67%)
Age (median, range)	40 (24-63)
Type of MS	
Primary Progressive	7 (26%)
Secondary Progressive	2 (7%)
Relapsing Remitting	18 (67%)
Time since onset years (mean)	6.3
Walking ability	
walking independently:	18 (67%)
using an aid indoors and outdoors:	6 (22%)
using wheelchair:	3 (11%)
Years in Education	
No Qualifications	1 (4%)
GCSEs	5 (19%)
A levels	3 (11%)
Degree	5 (19%)
Post graduate	11 (41%)
Not stated	2 (7%)

Of the 27 recruited four people withdrew; two due to severe relapses requiring hospital admission, one due to death in family and subsequent return to Ireland, and one withdrew but gave no reason. Therefore 23 people completed the study.

6.3.1 Defining the intervention

Using the timing codes collected, the types of intervention offered as part of the VR service were:

Interventions with face-to-face contact:

- Initial interview lasting approximately 1.5 hours with an aim of understanding the person's work situation both in terms of their role at work, their perceived performance, the work environment (both physical and social), identifying problems and establishing (and agreeing with the participant) goals for the overall intervention. At the end of these sessions a report was written (costed under non-contact time see below) summarising the session and included the aims and goals of future sessions. An example of an aim would be 'Mrs B will complete a fatigue management programme' and the goal would be 'Mrs B would understand the impact of fatigue on her work and be able to implement fatigue management strategies into her day'. Referrals made to other health professionals where required (also costed under non-contact time).
- Fatigue management, which was either short education session about the impact of MS related fatigue or a longer fatigue management programme, which would include identifying where fatigue impacted a person's day and discussing strategies that could be implemented in the person's work life. For this the COT Fatigue Management programme was used[27].
- Outpatient reviews were the follow on sessions after the initial interview. These were directed by the aims and goals established in the initial interview. The sessions could include discussions around

disclosure (for people who had not disclosed this often revolved around discussing the pros and cons of disclosure and for some people practising what they were actually going to say), education about legal rights under the DDA[55] including looking at what could be considered reasonable adjustments for them in their work situation, symptom management strategies for example using a diary or Dictaphone to manage perceived memory problems, and travel to work was frequently addressed with discussions about how to modify this to maximise performance at work (e.g. limited energy not wasted on commuting by tube but looking at working at home options or using the Access to Work taxi service.)

- Work site visits, which included meeting employers/human resources/occupational health nurses. In these meetings discussions were held around what was MS, legal responsibilities of the employer under the DDA[55], symptom management in the work place, reasonable adjustments which the employer could be expected to make). Also assessment of work environment and ergonomic set up would be completed where required. Where possible the participant was encouraged to lead these meetings to encourage autonomy and reduce dependence on therapist.
- Work planning discussions around reducing hours (discussions often around moving from a five day week which many people found exhausting due to fatigue to a four day week), changing role either a small change with n a company or a more radical change to a different job, and in one case retirement was discussed where the lady wanted to exit the workplace in a well managed and thought through way moving from full time paid work to part time voluntary work.

Interventions with non face-to-face contact:

- Telephone discussions with participants included many of the above interventions. Often people struggled to attend outpatients as it felt to them like further time out of work for yet another hospital appointment. So follow up sessions were conducted by phone often during a lunch break or at the end of the day. A letter was written at the end of these sessions by the therapist summarising the discussion and any subsequent aims/goals identified (non-contact time).

- Letters or emails to participant – a letter or email was sent after every session to ensure a constant communication. Employers were included where required (and with full consent of person).

Interventions with non-contact time:

- Initial assessment report
- Telephone calls (e.g. to the Access to Work scheme, the Disability Law Service)
- Referrals to other professionals (PT, MS nurses, Neuropsychology, neuro-urology)
- Note writing (medical notes)
- Reports/summaries
- Minutes from meetings with employers; these were always written immediately after the meeting and sent to all parties involved to be agreed upon and signed off quickly to ensure an accurate record was kept of the meeting. This was especially important when the employer had things they needed to complete such as reasonable adjustments in the work place.
- Discharge summaries to the participant's consultant and other medical professional involved. This was not only standard practice in the OT outpatient department but was felt by the research team that it increased understanding of a possible VR service if one was to be provided in the future.

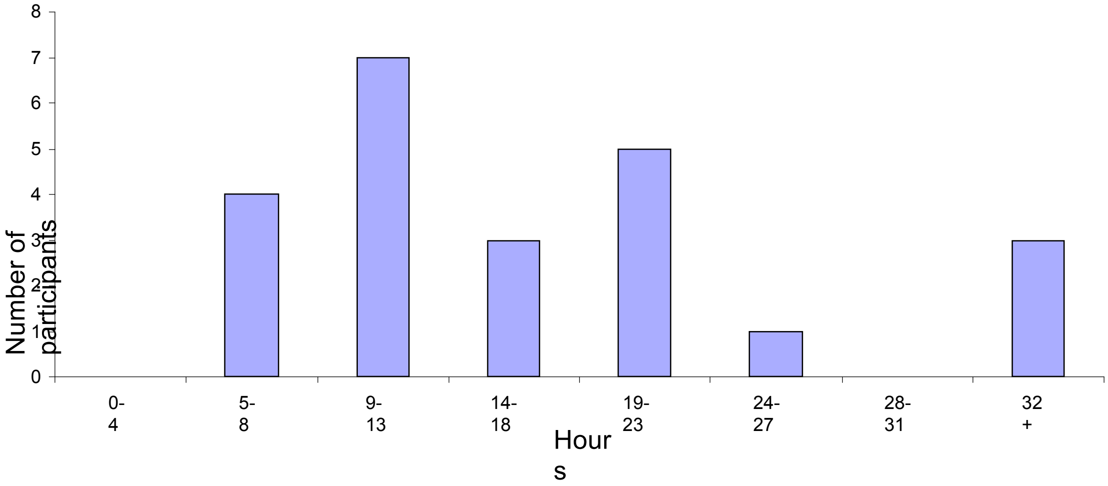
6.3.2 Total intervention

The individual mean total intervention time was 21 hours but this data was skewed by three individuals who had long interventions of more than 32 hours. Two of these had complex work situations in which there were ongoing issues at the end of the study; one had a complex disability being registered partially sighted, cognitive decline and a wheelchair user. The median total intervention time was 16 hours. The individual mean total cost per patient was £730 (95% CI £540 - £960).

- **Occupational therapy input**

OT accounted for 87% of the total hours spent undergoing the intervention. The individual mean OT time was 18 hours with a range from 5.5 to 62.5 hours (mode 11.75 hours and median 14 hours) shown in Figure 6.2. This figure also shows how the three participants who needed more than 28 hours of OT time skewed the distribution of the time taken.

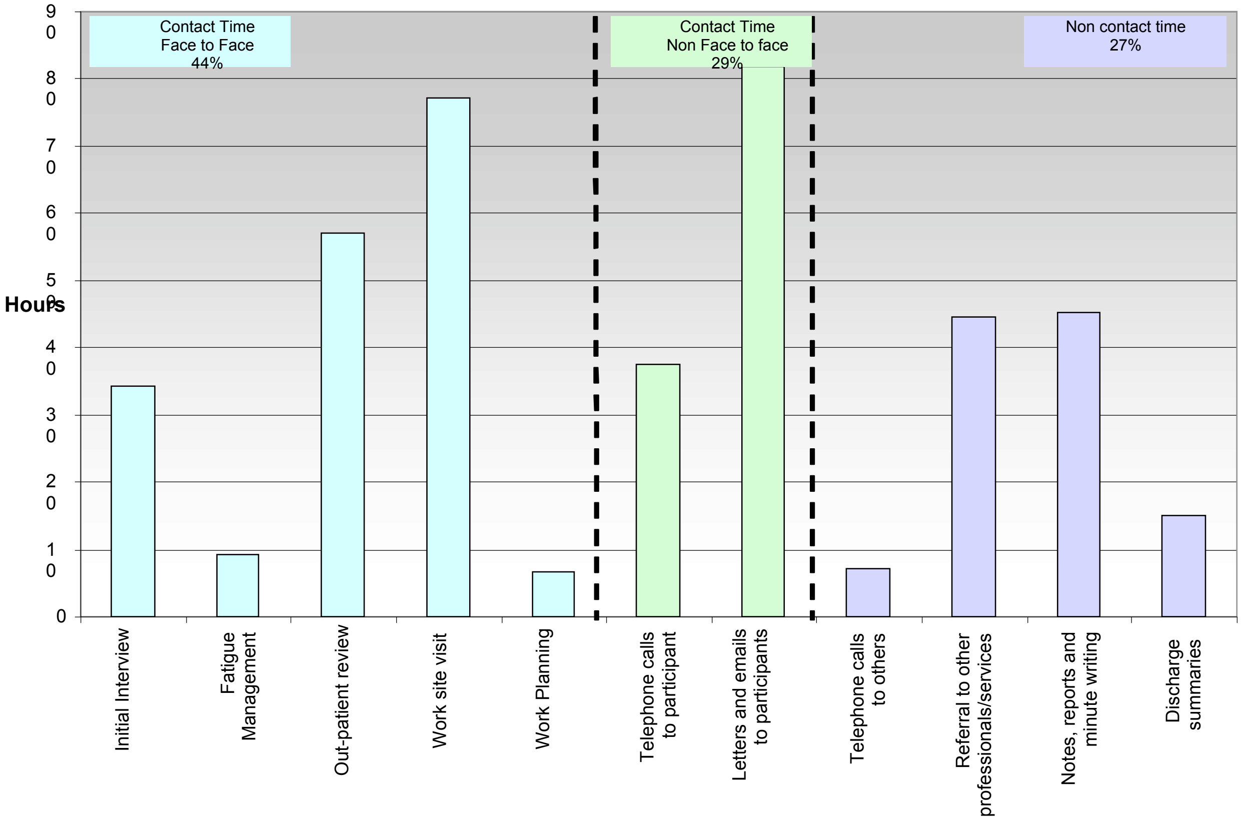
Figure 6.2 Occupational Therapy Mean Intervention Time



Of the OT time 43% (8 hours) was spent in direct patient contact, 29% (5 hours) in non face-to-face contact i.e. on the telephone to the patient and sending e-mails, and 28% (5 hours) in non-contact time (see Figure 6.3). The direct contact time was divided between the initial interview (median: 1.5

hours), followed by review sessions (median: 2.0 hours), then a work site visit, including meeting with employers (median: 2.0 hours). In addition, a significant proportion of participants benefited from participating in a fatigue management education (median: 0.5 hours), although for those participants who underwent a fatigue management programme this typically lasted a mean 1.5 hours. On average 4 hours (median: 4.3 hours) was spent communicating with participants through telephone, e-mails and letters. The remainder of the time was administration including consultation summaries, writing minutes of meetings for employers and participants, and making referrals to other disciplines including the Access to Work scheme. The mean cost of the OT intervention was £630 (95% CI £470 - 830).

Figure 6.3 The Distribution of Occupational Therapy Time



- **Physiotherapy input**

A total of nine individuals received PT. The PT accounted for a total of 6.5% (1.37 hours) of total hours of intervention in this study. The main aims of PT were to provide advice about posture, particularly when sitting at a desk, and mobility. Individuals referred to PT received a mean of 3.5 hours of treatment (range: 1 hour - 5.75hours). The group mean time taken was 1.37 hours with a range from 0 – 5.75 hours. The mean individual PT cost was £48.00 (95% CI £21 – £80).

- **Neuropsychology input**

A total of seven individuals were referred to neuropsychology for a cognitive assessment and advice. This accounted for 6.6% (1.39 hours) of the total hours of intervention in this study. Individuals referred to neuropsychology received a mean of 4.6 hours of treatment (range: 2hours - 10hours). The group mean time taken was 1.39 hours with a range from 0 hours to 10 hours. The mean individual neuropsychology cost was £54 (95% CI £19.00 - £99.00)

It was not possible to calculate cost or time of external referrals made to the government run Access to Work scheme as there was no access to this data.

6.3.3 Outcome measures

Overall the VR intervention resulted in changes in the measures of psychological status (including the psychological subscale of the MSIS-29) with improvements in well-being. The measures of physical status showed no change, with the exception of the MS walking scale. Table 6.3 shows pre and post intervention values of measures of work status, health status and well-being with significance values and effect size. There was no missing data in the questionnaires aside from on the MS WAS (described above in section 6.2.5 with reasons why results not reported.) The reason for full completion of questionnaires was it was a small group of respondents who established a good relationship with the treating therapist. The questionnaires were filled in at the start of the first and then end of the final session, they were always returned fully completed.

Results from the transition question showed that following the intervention 17 out of the 23 participants felt that their ability to cope with the demand of the work place had improved with eleven stating that it was 'much better', six reporting it was moderately or slightly better, three reporting no change and three reporting things were slightly or moderately worse.

Table 6.3 To Show Pre and Post Intervention Values with Significance Values and Effect Size

(n-23 for all sections)	Pre intervention Mean +/- SD	Post intervention Mean +/- SD	Change scores	Significance	Effect size
Work					
IWQ -Environment scale	18.3 +/- 6.7	14.4 +/- 6.3	3.9 +/- 4.9	0.004	0.58
IWQ -Symptom scale	20.9 +/- 6.8	16.3 +/- 5.0	4.7 +/- 1.3	0.003	0.74
MSWIS	27.5 +/- 3.0	30.0 +/- 4.1	2.4 +/- 3.6	0.005	0.7
WLQ	23.9 +/- 4.2	29.83 +/- 7.0	5.9 +/- 7.8	0.001	0.64
Well-being					
SF 36 Emotional role limitation	34.8 +/- 37.8	71.2 +/- 40.2	36.4 +/- 42.3	0.001	0.96
SF 36 Physical role limitation	18.1 +/- 33.8	38.6 +/- 44.8	20.5 +/- 39.8	0.025	0.61
SF 36 Pain	27.4 +/- 23.0	28.3 +/- 22.5	0.87 +/- 17.03	0.809	0.04
SF 36 Vitality	29.3 +/- 20.7	42.3 +/- 21.5	13.0 +/- 21.58	0.01	0.63
SF 36 General Health perception	43.7 +/- 23.4	45.3 +/- 24.6	1.60 +/- 24.5	0.764	0.07
SF 36 Social functioning	44.6 +/- 25.8	63.0 +/- 26.0	18.5 +/- 29.9	0.007	0.5
SF 36 Mental health	49.9 +/- 22.2	66.7 +/-19.2	16.8 +/- 22.5	0.003	0.75
SF 36 Physical functioning	50.0 +/- 32.5	48.9 +/-30.7	1.1 +/-12.5	0.681	0.03
GHQ-12	6.9 +/- 4.2	2.2 +/- 2.2	4.7 +/- 5.0	<0.001	1.07
Health					
Barthel Index	18.1 +/- 2.8	18.0 +/- 2.0	0.1 +/- 1.4	0.77	0.11
MSWS	38.8 +/- 14.7	32.5 +/- 15.5	6.3 +/- 12.3	0.044	0.43
MSIS – physical subscale	44.7 +/- 23.9	39.9 +/- 31.5	4.8 +/- 27.04	0.4	0.2
MSIS - psychological subscale (n-23)	54.6 +/- 23.1	35.1+/- 22.0	19.4 +/- 25.4	0.001	0.84

6.4 Discussion

6.4.1 The intervention

The participants in the study were referred by their consultant as they were struggling to manage their work, despite this most had relatively minimal impairment. It is likely that without an intervention these participants were at high risk of becoming unemployed. The mean duration of MS in this group was 6.3 years. A retrospective study of MS suggested that employment rates drop from 90% to 55% between five and fifteen years[33]. The intervention was categorised in three sections: face-to-face contact time, non face-to-face contact time and non-contact time. The first and the third headings are often normal practice in recording time spent in outpatient departments. The second heading non face-to-face contact time was felt to be different. These interventions were often instead of a face-to-face contact; it was found during the trial that due to the participants busy jobs attending therapy appointments were an added demand to a busy week. Therefore, therapy sessions were on the phone or discussions were had via email.

The results imply that the presence of an OT to guide both employee and employer may have helped allay anxieties. This then appeared to produce positive changes in the participants' belief about their ability to remain in work.

6.4.2 Costs and quantitative data

The study focused on work retention; delivering an intervention that was designed with involvement of participants through FGs[142] (described in chapter five) and then tailored to the individual. This VR service consisted of a median input of 22 hours with direct staff costs of £730. The majority of this was OT input with some participants also benefiting from PT and neuropsychology input. The methodology did not allow calculation of the indirect costs or the costs of referral to the Access to Work scheme.

As a result of this intervention participants reported they felt more confident about their ability to manage the demands of their work. The results demonstrated changes in scales of work status and experienced an increase in measures of well-being as measured by the SF-36, GHQ, and MSIS-29 psychological subscale. There were no significant changes in physical parameters such as pain, BI and the MSIS-29 physical subscale, general health perception and physical scale of the SF-36. These findings show that the intervention did not impact by improving physical disability, but imply that it increased confidence about work ability which could be associated with improved well-being.

This intervention described is relatively brief. The time to perform the intervention is comparable to that reported by CRS Australia in their study of work return (although some individuals had jobs held open for them), where patients with neurological diagnoses other than acute brain injury required 27.9 hours of direct intervention[84]. It is of note that three individuals in this study had an intervention lasting more than 32 hours. Of these, one person had significant disabilities and required joint OT and neuropsychological input, two had difficult employers who did not engage in the process and delayed accommodations being implemented. This suggests that more disabled people require greater therapeutic input and it is essential to have the employer actively involved with any intervention.

The intervention costed a mean of £730 per patient. The total costs may be underestimated as the cost of use of the Access to Work scheme or direct non medical costs (travel to hospital, and time lost from work) are not included. However these health costs are comparable to costs quoted by CRS Australia of Aus$3,490 for patients with neurological diagnoses other than acute brain injury[84]. CRS Australia also reported very high cost benefit ratios. These ratios have not been reproduced in other studies of work return, although studies suggest that at very least such an intervention is cost neutral[79].

6.4.3 Future studies

Future studies need to demonstrate whether a VR intervention is cost-effective. A larger and more detailed longitudinal control study would be needed to capture all the costs and also the savings to the individual and the state.

6.4.4 Weaknesses

This exploratory trial is limited by small numbers and the central London setting. The participants were characterised by high educational levels and office based largely sedentary jobs. It is therefore unclear whether the findings could be generalised to a rural or industrial setting. When developing the study it was anticipated that participants would have up to six sessions on consecutive weeks lasting 1.5 hours per session. The reality was this did not happen with some participants having input throughout the whole year of the study. This in some cases was due to complex needs in the workplace and for others was a process of adjustment as they came to realise that support in the work place would make a difference and accepted that help was needed.

A further weakness is the nature of the service which was OT led and not by a MDT. There is overwhelming evidence to show the benefits of MDT intervention for people with MS[15] and that with complex long-term conditions a MDT approach is necessary[80]; this exploratory trial is not able to see whether a MDT approach would be more successful. However, the OT made a referral where there was need for different disciplines to intervene. As they were not interventions directly linked to management of working role (e.g. further questions about medications, need for advice on bladder management), these were not costed in the intervention neither were they recorded in data collected other than time spent making referrals. It is evident that making referrals to other professionals was an integral part of managing a person with MS, and therefore it could be important data to capture should the study be replicated on a larger scale and could indicate the importance of MDT intervention.

6.5 Summary

This exploratory trial reports the impact of an OT based intervention supporting people with MS remaining in work through optimising work performance and providing education for employee and employer. Although small in numbers it adds to the growing body of evidence that health professionals should be aware of the challenges facing people with disabilities in the work place early after diagnosis, and the importance and benefits of maintaining work[51].

To ensure all impact of the intervention was captured, especially as there was not a specific outcome measure designed for a work retention service for people with MS, interviews were also completed after the intervention. The following chapter describes the qualitative design used, the interviews completed and reports the data gathered and discusses the implications this may have for future practice and further research.

Chapter 7. Qualitative study

7.1 Introduction

Chapter six describes how the exploratory trial was undertaken and completed. It reports the findings from the study in terms of PROMS collected and also cost data gathered. Evaluation of the exploratory trial included quantitative measures which demonstrated improvements in psychological status on the MSIS-29 outcome measure. However, measuring the impact of this work retention intervention was difficult due to no appropriate outcome measure being available. Therefore, a qualitative approach was used to capture the impact of the VR intervention. This chapter describes the interview process used and explores the experiences of nineteen of the participants in the exploratory trial. It discusses how the data collected has enabled themes to be generated, which could be used in future outcome measurement development for the area of VR with people with MS.

7.2 Methodology

In order to capture the individual experiences of the participants, semi-structured interviews were chosen for the design of this stage of the study. The advantages and disadvantages of interviews are explored in the Methodology chapter (chapter three). The semi-structured interviews used an interview guide to lead questions but allowed the interviewee to further explore their experiences as they arose. Although time consuming, and therefore more expensive, interviews are an effective method of collecting people's opinions and can provide rich data. The interviews were recorded and transcribed. Data was then coded to allow themes to develop and quotes are taken to highlight issues raised[93].

Following the VR intervention described in the previous chapter all participants were invited to be interviewed by an occupational psychologist to explore their experiences of the service. The occupational psychologist, who had had no involvement with the intervention, was chosen to complete the interviews to encourage honesty in the responses; the analysis was undertaken by the primary researcher and research team. Ethical approval for this stage of the study was obtained from the joint research ethics committee of the NHNN and the ION. All participants signed a consent form (see appendix 5.3).

7.2.1 Setting

Once discharged from the service participants were contacted by phone to ask if they would be willing to be interviewed. The interviews were conducted in the participant's home at a time that suited them; some were completed on weekends to avoid further interruption to their working days. By conducting the interviews in their homes, it was felt people would be relaxed and more willing to be honest and to openly share their experiences.

7.2.2 Participants

Nineteen out of 23 people with MS (mean age 40 years, range 24-63 years, 16 female) who participated in the exploratory trial reported in chapter six were recruited to the interview stage. Of the 23 people in the exploratory trial, two people refused to be interviewed; one had not yet finished the intervention and one had time constraints preventing participation. Of the participants who agreed to be interviewed sixteen patients had relapsing remitting MS, two secondary progressive MS, and five primary progressive MS. Fifteen of the patients were university educated (mean duration of MS was 6.3 years). Sixteen were walking independently, six using a stick and one was a wheelchair user.

7.2.3 Interviews

Interviews were conducted by an experienced interviewer at the participants' homes at an average of two weeks after the VR intervention. The interviewer was not involved in the delivery of the intervention and the interviews were conducted in people's own homes to ensure that participants did not feel they had to report favourably on the intervention. All interviews were tape recorded. Each interview covered the same general topics, although the participant was free to structure the conversation within each topic. Guiding questions were developed by the interviewer, the primary researcher and the primary investigator of the whole study. They focused on three elements: a description of work situation prior to intervention, a description of experience and impact of intervention, focussing on different elements including initial meeting, actions undertaken, completion and closure; and, finally a description of current work situation. New topics brought up by the participants were discussed as and when they arose.

7.2.4 Analysis

The interviews were all tape recorded with a back up tape recorder also used in case of first recorder failure. Recordings of the interviews were transcribed verbatim. These were then read by at least two of the research team (four readers in total). Each reader read the transcript alone and identified specific parts of the transcript where the participant described the impact of the intervention upon them, from this the themes were derived. Then each reader compiled a list of codes under which the various sections of the transcripts would fit. Consensus of coding categories and a final list of key themes were achieved iteratively through discussion and re-reading of transcripts. The process of coding is described in more detail in chapter five section 5.2.8. The data were managed with Winmax software[198] as described in section 5.2.8. Where there was a disagreement there was discussion with a third team member and resolution was found through consensus. In a final meeting with all four researchers a consensus of coding categories and a final list of key themes was achieved. This was done iteratively through discussion and re-reading of transcripts until there was saturation and complete agreement on codes.

7.3 Results

During analysis seven key themes emerged. Five were related to individual's experiences of having MS and impact of the VR intervention; 'symptom management', 'managing emotions', 'self-worth', 'self-efficacy', and 'managing the work place' including relationships with both the employer and colleagues. The sixth theme was the impact of the VR intervention on 'adjustment to disability'. The seventh theme focussed on the value individuals attributed to the intervention used in this study, that is, an intervention delivered by a single expert - 'the role of the expert'. These themes and the codes within them are shown in the table below:

Table 7.1 Themes and Codes from the Interviews

Symptom Management
- Fatigue
- Travel to work
- Changes in health
  - Physical change
- Increased disability
- Referral to other (health or external)

Emotions
- Denial
- Not coping
- Changes in health

Self worth
- Value of work
- Perceived self worth

Self efficacy
- Empowerment
- Advocacy
- Disclosure
- Sacrifice for work
- Information about options

Workplace relationships
- Communication
- Plans and structures
- Disclosure
- Rights and responsibilities
- Disability discrimination
- Disclosure
- Work culture
- Employers
  - Reasonable accommodations
  - Discriminations
  - Negativity
  - Supportive
  - Ignorance
  - Education
  - Information about options

Adjustment to disability
- Travel to work
- Adjustment
- Diagnosis
- Management
- Career choice

The service
- Expectation
- Initial meeting
- Qualities
- Advocacy
- Problem solver
- Closure
- Benefits
- Challenges
- Promotion
- Location

• Impact of VR intervention on symptom management

Participants had experienced a range of MS symptoms including fatigue, difficulties with memory and concentration, difficulties with mobility, and bowel and bladder symptoms. The commonest problem was fatigue. Participants had limited understanding of the nature of fatigue or how it could be managed.

> *'I didn't understand what this fatigue was really….I kept getting told that I would have to manage it but what do you mean manage?' Participant 12*

The VR intervention addressed fatigue with one to one education to increase understanding of the process of MS related fatigue, and personalised strategies to address specific issues of fatigue. One of these strategies, the process of journal keeping with the objective of recording fatigue levels throughout an identified period, enhanced the preparedness of some participants to change by highlighting patterns and relationships between tasks and fatigue.

> *'She sort of made me more aware…. you have to fill in a questionnaire which is saying about how tired you get. …what you feel like 1 to 10 at this time of the day …..so filling it in you realise that you are quite exhausted half of the time and you don't really think about it … so basically she sort of took different things and suggested things you could do to make it better'. Participant 4*

Fatigue management was also assisted by the provision of taxi travel to and from work through the Access to Work scheme. Almost all participants were unaware of this service prior to participation in the study. Its impact on participants` self-management was significant.

> *'Because I was getting to a point where just getting in to work the journey and the pushing and shoving on the train and trying to keep out of the way and waiting for trains that were cancelled was stressing me out. I suppose you don`t realise it but it does. By the time I got to work it was taking me an hour before I felt ready to do any work.' Participant 11*

Negotiation of hours of work, most commonly a reduction, was also an intervention prompted by the need for fatigue management.

> *'It is very useful to also have someone there who can explain your options to you, you know, you can have flexi time and all these other things and your employer can't just fire you and it is just very helpful I think.' Participant 26*

In many instances compromised mobility required a referral to PT and OT intervention to modify tasks and address occupational safety issues.

> *'65 stairs there were down and then you have to walk right across the other side of the building if you want to get a cup of tea and if they insist I go in the staff room there is another whole heap of stairs the other side. … Now they have supplied me, they will get me bottled water and a kettle so that is easier, much easier.' Participant 4*

Bowel and bladder functioning were rarely mentioned by participants, however participants with reduced mobility often mentioned the difficulties created by having long distances between workspace and toilet and other facilities. Decreasing walking distances to such facilities by relocation of workspaces was helpful.

> *'And there were instances where just to go to the toilet I had to go through about six doors all of which were stiff even going from the kitchen with a glass of water through three doors.' Participant 7*

Issues with the functioning of their memories and their concentration caused participants anxiety. They perceived difficulty with organising and managing their work tasks.

> *'Understanding the whole memory thing and she also sent me material to read about memory and that was really good understanding that. It wasn't so horrible and scary then and also that I wasn't going mad.' Participant 13*

Neuropsychological assessments often reassured people that these concerns were perceived rather than real.

> *'At the same time as being physically fatigued I was mentally fatigued and I think the stress and worry and everything just impacted and I wasn't remembering things well so she referred me to the Neuropsychology for assessment and she said really I don't think there is anything wrong with you mentally.' Participant 12*

The OT designed strategies for structuring and organising workplaces to address individual issues with memory, concentration and organisation these were helpful.

> *'One thing I had stopped doing was organising my time a little bit more. And I just didn't have enough time to do everything I needed to do because I wanted to do everything at the same time and they just gave me some tips on how things could be organised that would give me a little more time.' Participant 19*

Acceptance of alteration of patterns of working and living to accommodate symptoms such as fatigue did not always appear to be easy for participants, however once undertaken these changes often surprised them by their positive impact.

> *'Well I suppose there is an element of I should be able to just do it by myself rather than go through what are quite obvious things but*

> *actually discussing them in relation to my situation was useful.' Participant 8*

- **Impact of VR intervention on emotions particularly anxiety and worry**

Initially participants presented with anxiety about their performance at work. Specific worries included job security, job performance both now and in the future, disclosure and the judgments of their manager and peers.

> *'(At) the end of my probation period I was told that my services were no longer required. Which maybe under different circumstances wouldn't have bothered me but I had been sitting on my worries in relation to the MS diagnosis and the various different symptoms and I didn't really want to be left alone with them. I wanted to be working and not to be suddenly left alone with those worries.' Participant 8*

> *'I have that (support in the workplace) by virtue of the fact that I have been in the same job for a long time. People know me and they knew that I wasn't pulling a fast one, if I said I was tired I was tired and if I say I can't do this then they respect the fact that I am not just pretending because it isn't visible whereas I can imagine if you are in an environment that is less caring you have got less longevity within it.' Participant 17*

The VR intervention supported participants in managing performance and managing both their expectation of themselves and those of line–managers and colleagues, thus managing worry and decreasing anxiety.

- **Impact of VR intervention on self-worth**

Self-worth, which is how people valued themselves, in relation to their past selves and in relation to others including colleagues, changed during the study. Once participants had become aware of disability impacting on their work, they felt vulnerable. They were aware of potentially losing not only desired lifestyles, but also access to amenities associated with their employment and the status associated with their work role. Some participants` sense of self-worth was significantly impacted by their experiences of not being able to complete previously routine work tasks. Negative performance feedback from their employers, and apparent lack of understanding and response to their requests for accommodations in the workplace resulted in loss of self-worth.

> *'I wasn't feeling particularly self confident at the time. I needed I suppose reassurance as well that I could actually do my job that I had been doing for years, that I knew I could actually do but I needed somebody to almost show me. Yes, you can actually continue to do it and there is no real reason to have this lack of confidence.' Participant 15*

Many were also struggling with what they perceived as an expectation that from the community or their families that because they had MS they would not or could not continue to work.

> *'Whenever I have spoken to people … they were all surprised that I work.' Participant 6*

Participants reported they experienced the process of the VR intervention as validating and enhancing of self-worth. This process included the initial comprehensive interview, application of individual strategies to address concerns such as fatigue and transport, workplace visits and OT support.

> *'You can have someone saying this is what you have to do when you go back to work but she made me feel confident enough that I could go back*

> *to work. I had a real problem with the fatigue thinking I couldn't do a full day but she just kind of changed my head around, she was like well being positive about it. We will get you Access to Work you will get a cab, the journey won't tire you just stuff that I had never thought about….. I had no confidence at that point and she actually came in with me to see him and just having that authoritative figure with me made me feel a bit empowered.' Participant 12*

- **Impact of VR intervention on self-efficacy**

At the stage they entered the study, participants sense of their own value was reduced, with associated loss of confidence in being able to address and positively impact on their working situations. Education about legal rights was an important factor in participants being empowered to change adverse work conditions. This information, given with impartiality by the OT, was a relief to patients who then felt that they had a choice of options rather than being disempowered. It allowed participants to make informed decisions about how they wished to manage their employment.

> *'I suppose although I haven't actually exercised those possibilities but to know about Access to Work and to consider the possibility of not working full time… to actually think about these things seriously although I haven't actually done anything, because I haven't felt the need to, but to understand the parameters of the possibilities is quite useful. May be I will need to in the future or maybe I won't but to know what is there now is quite helpful.' Participant 8*

- **Impact of VR intervention in the workplace**

Within the workplace two themes emerged: first the role the employers' knowledge skills and attitude; and, secondly the impact of colleagues' behaviour which was felt to be a feature of the workplace culture. Successfully managing work requires support from employers. Some participants experienced their managers acknowledging their difficulties and making accommodations.

> *'But my boss was very helpful and she said “look we will just see how it goes. If you have another relapse we will just take it one day at a time and you have to tell me if you can’t do something” and then we agreed on that, it was fine.' Participant 26*

However, in some cases despite making such accommodations employers continued to expect performance that could not be delivered within the new arrangements.

> *'He would say “yeah fine if you are not feeling good” and when it actually came to it when you said I am going to go he would say “could you just do that first” and that was what he was like and “you are not really being helpful are you”.' Participant 11*

Other participants were distressed by employers behaving in ways that demonstrated lack of awareness of issues of discrimination.

> *'He was awful. He was phoning me all the time expecting me to go in. When I went in he would like make jokes about me having …I just had a stick, I didn’t have the crutches then and he would make fun of me. He would like humiliate me to all the other people and so I felt really pressured into telling, when I was diagnosed in August I felt really pressured because he was literally phoning me every week like when are you coming back in, I am going to have to get somebody else if you are not coming back in.’ Participant 23*

There were also issues of lack of clarity within organisations about who had responsibility for effecting reasonable accommodations. Some employers did not respond to requests for information or action from patients to address issues such as physical barriers, or occupational health and safety risks.

> *'I wouldn't say he means to be mean, he doesn't really think about it. He says things like oh yes we will do that because that will help you but it doesn't come out in practice'. Participant 11*

Some employers also threatened to make redundant, or sack employees, citing decreased performance as their reason before considering or implementing reasonable accommodations.

> *'Ultimately they got rid of me in that post, basically, I believe because I couldn't do some of the work I was doing before because of my illness.' Participant 5*

Physical accommodations such as creating a car parking space close to a building appeared easier for employers to instigate than more complex accommodations such as working from home or reduced hours.

Participants who allowed the OT into their workplace described the education of their employers about MS and the negotiations that then took place as facilitating positive changes. These included increased understanding of disabilities and acceptance of responsibilities by the employer to accommodate their employee's needs. Changes to factors such as physical location of desks, working hours and workplace support occurred.

> *'She came with me and met with my manager and she discussed the expectations from… She wasn't intruding too much but at the same time from a professional point of view I really liked the fact that she was there because it meant, not that they wouldn't believe me but it helped and my manager actually said afterwards that she was really*

> *glad she was there so that she had met her. And it just gave it a different edge her being there and made it real. Gave it that sense of seriousness and without making it a massive issue. I don't want to stand out… but at the same time I do have specific needs that need to be recognised.' Participant 7*

For some employers and employees the issues of how to terminate employment were central and the VR intervention in these circumstances was mediation. This was a complex process requiring the OT to assist both participant and employer to negotiate an appropriate resolution, aided by independent legal advice.

For others, the intervention was one of advocacy and employers who attempted to dismiss participants without consideration of reasonable adjustment were advised of their legal responsibilities. Where this was an issue, increased employer awareness of their responsibilities resulted in the introduction of accommodations negotiated for the participant.

> *'That made him realise and I think he read up completely on the DDA laws. It is a requirement for the disabled people working in the organisation and whether it is shop outlet or an office. After that meeting with my boss he got on to personnel and read into it and he can't be more helpful where initially he was basically let me know when you can't do the job and bye really.' Participant 1*

A workplace visit to meet employers by the OT positively impacted employer knowledge of MS. Once made aware of the relevant legislation and their legal responsibilities, most employers made significant attempts to accommodate the needs of participants.

- **Impact of VR intervention on adjustment**

Adjustment is the process of accepting limitations imposed by disability and using this awareness to compensate for difficulties. This was a significant theme for the participants. Denial of the extent of their disability was common.

> *'There is no point getting benefits because maybe I will be able to go back to work and everything will be like normal.' Participant 12*

> *'…and also aspects of denial. This isn't really happening. I can do it. I can go back to normal. In fact my normal has changed enormously. To look at me it hasn't but it has.' Participant 17*

Functional deterioration was hidden from employers by excuses of accidents and illness with participants assuming discrimination would occur in the work place and at job interviews if their disability were known. Disclosure of disability was therefore a significant issue.

> *'It is not that I don't like to tell people. It just doesn't quite come up and it is just very awkward. When it has come that I have to tell people I have MS just I was going to mention it I think …they don't want to know, they don`t want to know and I just stop, I don't tell them.' Participant 13*

The support of the OT was reported as critical to disclosure. In some instances the OT was present at the time of disclosure to advise employers of their legal obligations and to educate them about MS.

> *'It was quite useful to have someone there with me talking to her (the employer) because she (the occupational therapist) has seen, knows about other people who have MS and are working and she knows what employers feared and I feared.' Participant 26*

Information about their rights as a person with a disability and the responsibilities of employers under legislation significantly increased their confidence in disclosing to their employers. Participating in the study itself was seen as providing authority to discuss issues around accommodations with employers. Participants commented on the role of the OT in this context as one of providing support and confidence that it was legitimate to address workplace issues that were troubling for them.

At times, accepting the assistance that was offered through the VR intervention was difficult for participants. Experiencing positive outcomes from the intervention, and in many cases increased confidence, did however lead to emotional adjustment.

> *'It really opened doors for me because it meant that I had to address things that needed addressing whether I wanted to or not and it meant that there was another person there who could give me another point of view...not say you must do it this way ..Just someone to give me a different …like a sounding board …yeah but an information outlet as well. ….I think it is invaluable really and if people knew that there was something along these lines out there then they might be encouraged too.' Participant 7*

Support from the OT enabled participants to accept any accommodations they required as enabling of employment rather than perceiving them as symbolic of increasing disability.

- **The role of the expert**

Although the VR intervention impacted on symptoms, adjusting to disability, self-worth, self-efficacy, managing the work place including relationships with both the employer and colleagues, and managing emotions, an underpinning theme was the role of an OT and the support she offered during the process.

The OT was seen as providing a range of roles including offering general emotional support when people had lost confidence, providing specific support through emotionally demanding tasks, such as analysing fatigue, providing an educational role, giving information and describing different options, and acting as a sounding board for future planning. Participants valued a professional presence when working with line mangers, which they felt provided significance to the process that would otherwise have been missing. The importance attributed to this role is reflected in many of the quotations presented throughout this chapter.

7.4 Discussion

7.4.1 Related Themes

The first six themes described above were related. Individuals described the impact of MS symptoms, and the ensuing emotional distress about the diagnosis and its uncertain prognosis, on their perceived work-performance. Relationships with colleagues and line mangers were an important factor influencing participants' perceptions of work performance; inappropriate expectations and behaviours aggravated the situation and supportive behaviours improved it. At worst severe symptoms, marked distress and poor relationships with colleagues led to low self worth and poor self-efficacy, rendering individuals impotent to change the situation.

The results suggest that as individuals with MS become aware of the impact of their symptoms in the work place they feel their work performance is not as they expected. As a result of this, they become anxious and this compounds the uncertainty they already feel as a result of the diagnosis and its uncertain prognosis. Anxiety can exacerbate feelings of fatigue and result in poor attention, concentration and memory; all symptoms associated with MS. Thus, a vicious cycle is established. The individual’s perceptions of poor work performance can then impact on feelings of self-worth and self-efficacy resulting in difficulty requesting work-place accommodations. These difficulties are aggravated by inappropriate expectations and behaviours from colleagues and line managers.

Given support, particularly around symptom management, managing emotions and work-place accommodations, as well as information about their legal rights under the DDA[55], individuals with MS reported adjusting to disability, and managing work and work place relationships more effectively. Interventions designed to manage symptoms and, support participants and their employers, appeared to assist in the process of a person's adjustment to disability. This resulted in establishing new norms allowing restoration of self-worth and self-efficacy.

Other authors have also examined how people adapt to increasing disability. Baltes and Baltes[213] further explored in Gignac et al's paper[214], identify four adaptational processes; 'selection' which involves restricting or limiting activity; 'optimisation' which involves augmenting or enriching people's reserves so that can continue functioning; 'compensation' which involves substituting one activity for another; and the fourth process is 'receiving help' from other people. These adaptational processes fit well with both the results from the interviews and the results reported in chapter five. Two key needs were identified; managing performance and managing expectations. Managing performance used three distinct approaches, modifying performance analogous to Baltes and Baltes[213] selection, improving performance equating to optimisation, and compensating for performance. These adaptational processes are coherent with the results reported in this chapter.

7.4.2 Role of the professional

In addition to the core themes there was a crucial underpinning theme, the role of the professional co-ordinating the intervention. The combination of the multidisciplinary input into the VR process and its management by a single

OT was perceived by the participants as important, enabling them to make informed choices about their working lives.
The findings are strengthened by the quantitative data reported in chapter six which show a marked impact on measures of psychological well-being shown on the MSIS-29 while showing few changes on physical function. In comparing the results from the work related PROMS (WLQ, IWS, WIS) reported in chapter six it is clear they did not map onto the responses given in the interviews. The results from the work related PROMS indicate there was little significant change pre and post intervention (MSWIS and WLQ) and only some significance on the IWQ. Yet all three outcomes profess to capture the impact of symptoms on work ability therefore it would be expected that there would be some evidence of change in these results.

The findings are also consistent with the results from the literature review in chapter four that describe the barriers to working with MS. These barriers are often described as physical or cognitive, but are more often a result of an interaction between the environment and the activity limitation imposed by MS, such as an inaccessible work-place coupled with poor mobility or the difficulties caused by working in open plan offices if attention is poor[116]. However, barriers may also be emotional and social such as the problems posed by disclosure and discriminatory attitudes within the workplace[126].

Previous studies have highlighted the association between perceived cognitive impairment and mobility limitations in predicting unemployment. However, measures of disability in these same studies suggest that many participants are able to walk[117;133] and have no significant cognitive decline[37]. These levels of disability do not explain why patients become unemployed. The participants in the exploratory trial were recruited because they were aware of problems at work that had in many cases resulted in anxiety, loss of self-efficacy and decreased self worth. By exploring participants experiences there is increased understanding as to why people with MS with no significant cognitive decline and who are able to walk, albeit for some with an aid, become unemployed.

7.4.3 Weaknesses in the study

As described in chapter six the exploratory trial was limited by the central London setting. The participants were characterised by high educational levels and office based, largely sedentary jobs. It is unclear whether the findings could be generalised to a rural or industrial setting, and further work needs to be done to establish this.

7.4.4 Future work

The reported results from both the qualitative and quantitative data imply that the PROMS used were ineffective in capturing change in this VR. The data gathered and themes identified through the interviews will be used in a future study to create the development of an outcome measure for people with MS undergoing a VR intervention to support work maintenance.

7.5 Summary

This chapter describes the qualitative experiences of 19 people who participated in the exploratory trial and undertook interviews to report their experiences. The interviews, performed in parallel with the quantitative study reported in chapter six, demonstrated that an OT led VR service had a positive impact on the working lives of the participants.

Results from the interviews in the exploratory trial and data from the FG indicate that participants in both studies were advocates for early intervention. From this the following chapter reports on the early intervention service that was designed and trialled as a RCT.

Chapter 8. Phase III Definitive RCT

8.1 Introduction

Using the MRC framework[91] the previous chapters reported the initial stage, the FGs (Phase I) and then the exploratory trial (Phase II) where both quantitative data and qualitative data gathered. The qualitative data from Phase II provided data that indicates that people with MS would like work related information, advice and support early in the disease progression. Participants clearly identified they would like to have information early in the disease process to empower and equip them should any work problems occur. This theme was also identified in the FG discussions reported in chapter five (Phase I). Early intervention was also defined in the literature review as an important part of a VR intervention. With early intervention a key theme in all stages of the study, this chapter describes how a RCT of an early intervention service for VR was developed and trialled. The aim of the study was to evaluate the effectiveness of an early intervention VR service. This study is a five year study and therefore this chapter reports preliminary results only, and does not analyse all the data collected.

8.2 Objectives

In this study the hypothesis tested was that an early intervention VR service offering support and education to people with MS around work related issues would prevent premature departure from their employment over the next five years. The aims were to:

i. To define an early intervention service and put into practice;
ii. To capture nature of intervention through outcomes;
iii. To cost an early intervention service;
iv. To compare intervention and control group;
v. To inform further understanding of intervention.

8.3 Methodology

8.3.1 Trial design

Phase III of the MRC framework[91] describes a definitive RCT which aims to compare a fully-defined intervention to an appropriate alternative using a protocol that is theoretically defensible, reproducible and adequately controlled, in a study with appropriate statistical power. This was a single centre study using simple randomisation into two groups: treatment and control. There were no major changes to the study protocol during the two year recruitment period February 2008 – Feb 2010.

8.3.2 Recruitment

As the study was due to start the department of neuroinflammation, UCL, the ION adopted new guidelines for approaching patients for research within the MS team. The process adopted was new patients at the NHNN had to give consent to be put on a research database at the hospital. This would then allow researchers to approach them with further information about studies for them to then decide if they would like to be involved. The eligibility criteria for the participants were that they were newly diagnosed or had minimal symptoms. This was typically within one year of diagnosis but sometimes as much as five years, and they were in employment or full time studies. It was also identified that potential participants must not have work related issues as it was a control trial, and should they need specific work related interventions they needed to be referred to outpatient OT for interventions. The recruitment process for this study started when the patient had agreed to be on the research database, met the criteria for the study and was subsequently referred to the research team via a referral letter from the MS nursing team. The majority of referrals came from the nurse led newly diagnosed clinic with some also coming from the nursing team in their subsequent follow up clinics. The primary researcher also attended three ‘newly diagnosed study days’ run by the MS service where information about the study was briefly presented, and people interested could give their details to the MS nurse. This recruitment therefore was through self-selection.

Once a referral was received, the primary investigator sent a patient information sheet and an introductory letter to the patient referred. At this point the referral was screened to ensure the patient met the criteria (primarily to ensure they were employed). Then the patient was put on the database and allocated to the control or treatment group. The primary researcher made follow up contact by telephone two to four weeks after the initial letter was sent. This telephone conversation gave the person opportunity to ask questions and to give verbal consent to be involved in the study or to decline with no further contact. If the person declined involvement then they were removed from the list.

Ethical approval for this stage of the study was obtained from the joint research ethics committee of the NHNN and the ION (see appendix 8.1). All participants gave their informed written consent.

8.3.3 Setting

As described in chapter five the NHNN has a comprehensive MS service which meets the needs of people from the early stages post diagnosis through to the palliative stages of the disease. The team of consultant neurologists are backed by the MS nurses who actively run relapse clinics, follow up clinics and drug related clinics. There is also a full MDT with expertise in MS and other medical related services. The intervention sessions would be offered in the therapy outpatient setting and if required would included a work site visit to the participants’ place of work.

8.3.4 Interventions

Once the referral was received the person was given the next available place on the Excel spreadsheet that had the random number string in. This allocated them to either control or treatment group. All participants received an information sheet (see appendix 8.2) about the study and a letter of introduction from the primary researcher. Contact by the primary researcher was made by phone and if verbal consent was gained the following then happened:

- **Control group:**

The control group received an information sheet about sources of help available for people with a disability who were in employment (see appendix 8.3). It covered the role of occupational psychologists and disability employment advisors (DEAs) at JobCentre Plus, the potential role of OT and a list of useful publications including those published by the MS Society. This information was also made available to those who declined to participate in the study and may therefore be regarded as current best practice. The control group also received a questionnaire booklet containing PROMS (see appendix 8.4), and consent sheet (see appendix 8.5) with explanation given that the questionnaire booklet would be sent out over the following five years.

- **Treatment group:**

The treatment group were sent the same questionnaire booklet and consent sheet plus an offer by phone to make an appointment to discuss their work situation and receive education about support available, legal rights and early symptom management. It was anticipated that the intervention would consist of a maximum of nine hours of OT time. These nine hours would be made available whenever it suited the patient, but would be offered at the point of referral. Participants could choose to use the service at diagnosis, or after a second or subsequent relapse. The service would consist of:

(1) An initial assessment covering the impact of MS on the individuals work, discussion about disclosure in the workplace and provision of information;
(2) A work place visit – meeting with manager, and if requested colleagues, to support the individual and their employer through education about MS, legal rights and reasonable adjustments; and
(3) A debriefing session will result in a summary of the meetings and discussion for the individual and their employer.

An explanation was given that further questionnaires would be sent out over the following five years. People who did not want an appointment were given the option to call back at any time should questions/issues arise to make an appointment. All of the participants in the treatment group were sent a contact card (standard business card size) with information about the service and contact details of the treating OT.

8.3.5 Outcomes

All participants were asked to complete a questionnaire booklet (see appendix 8.4) that included the following questions: age, years of education/level of education, current employment, whether full or part time, and date of diagnosis. The primary outcome for this study was:

- **MS Impact Scale – 29 (MSIS-29)** the reason this was chosen was the psychological subscale was the most sensitive to change in the exploratory trial, and used to power the RCT.

Other PROMS were also selected as secondary outcomes. They were:

- **MS Work Instability Scale (WIS)**
- **MS Impact on Work (IWQ)**
- **Barthel Index (BI) postal version**

All the above outcomes are described in detail in chapter six section 6.2.5. In addition the Generalised Self-Efficacy Scale (GSES) was included as it was felt that information, advice and support given in an early intervention service may improve people’s self efficacy skills and ability to self manage their condition. It was felt these outcomes should enable any change in this area to be captured.

- **Self Efficacy scale**

The GSES is a self-administered 10-item psychometric scale that is designed to assess optimistic self-beliefs to cope with a variety of difficult demands in life. The ten questions have 1-4 response categories, summing up the responses to all ten items would yield a final composite score with a range from 10-40. Designed to be used with adults in a general population it has been used extensively in research. It has demonstrated good validity and reliability[215].

- **Transition questions**

The following transition questions were written for the RCT based on the themes identified in the interviews. Each one started with ‘compared to six months ago...’

a. How much do you feel your MS symptoms have impacted on your working life?
b. How much do you feel your worries/concerns because of your MS have impacted on your working life?
c. How well do you think you have adjusted to working with MS?
d. How confident are you at managing situations at work with regards to your MS?
e. How satisfied are you with the support offered by your colleagues?
f. How satisfied are you with the support offered by your line manager?

Response categories were: much less, a bit less, no change, a bit more and much more.

As one of the primary aims of the RCT was to look at the implications for health economics two further outcomes were added to the questionnaire pack:

- **EuroQol EQ-5D**

EuroQol (EQ-5D) is a standardised instrument for use as a measure of health outcome[110]. It can be used in a wide range of health conditions and treatments. It aims to provide a simple descriptive profile and a single index value for health status. It is designed for self-completion by study participants and is ideally suited for use in postal surveys. The EQ-5D consists of five domains: mobility, self-care, usual activities, pain/discomfort and anxiety/depression. Each domain can be rated as 1 (no problems), 2 (some problems) or 3 (major problem). This results in a five-figure score for each respondent that reflects a unique health state[109]. There was also a visual analogue scale, which asked participants to mark on a line showing 1 – 100 their perceived state of health.

- **Client services receipt inventory (CSRI)**

CSRI was used to collect service use data[109] it was originally designed for use in mental health services. It was adapted for this study by the health economist at UCLH to reflect the treatments and interventions a person with MS may receive. The CSRI asked firstly, for information about their employment including asking for a salary band and recording any time off work in past six months. Secondly, for details of medical costs (use of services) during the previous six months because of their MS or for other reasons including hospital care, primary health care, tests and investigations, and medication. Thirdly, for non-medical costs including social care, provision of aids and home adaptations, and informal care provided by family members and/or friends.

The same questionnaire pack would then be posted to participants at six months then annually for five years. This five year time scale was chosen as it was felt by the research team, both from clinical experience and results from the literature review, that it was this period that patients were vulnerable to losing their jobs. The design of the booklet was based on Dillman's "Total

Design Method”[107], as outlined in Chapter three, to ensure the greatest response rate. There were no changes to trial outcomes once the study had commenced.

8.3.6 Statistics and Health Economic analysis

In the context of assessing a VR intervention a cost effectiveness and cost utility analysis would be completed using the EQ-5D and the CSRI. A health economist was identified at the start of the study to help with this data analysis at the end.

8.3.7 Sample size

The study needed to be large enough to have a high probability (power) of detecting as statistically significant a clinically important difference of a given size if such a difference exists[111]. The sample size for this study was determined with support from a statistician at UCL. The MSIS-29[204] psychological subscale was chosen to power the study as it had been the most responsive to change during the exploratory trial. It is considered clinically important to detect at least a difference in scores on the psychological MS Impact sub-Scale of ten points. Using an estimated standard deviation of 23 points[206] the study required 112 patients per group to detect a ten point difference with 90% power and a significance level of 5%. In order to allow for up to 30% dropout over the five year follow-up period, the target sample size was inflated to 146 per group. This sample size calculation assumed the primary analysis would be a two sample t-test and that assumptions of normality are appropriate for the primary outcome[216].

8.3.8 Randomisation

Pure randomisation based on a single allocation ratio is known as simple randomisation. It has a 1:1 allocation ratio, which is analogous to a coin toss. A sequence generation was completed through a random number string using an Excel spreadsheet formula. This was done with support from the IT department at UCL.

8.3.9 Allocation concealment

The primary researcher was aware of the random number string and which place was available next. However, the MS nurses did not know if a treatment or control slot was next they simply referred those that met the criteria. As referrals letters were received, after screening to ensure suitability (a few referrals were received where the person was unemployed and therefore not appropriate) the person was put on the excel spreadsheet in the next available position (A or B denoting treatment or control).

8.3.10 Implementation

All potential participants received the information sheet, which clearly outlined the two different groups. The researcher called and informed the participant which group they were allocated to prior to asking for their consent to be involved in the study. Only one of the control group upon hearing she was in the control was unhappy and withdrew from the study.

8.3.11 Blinding

There was no blinding of the primary researcher in this study, as pragmatically this was not possible.

8.3.12 Statistical methods

The original plan, assuming 148 recruited in each group, was to check the normality of the data, and then if appropriate it was planned that a two sample t-test would be used for analysis of the primary outcome (Psychological MS-impact subscale) and reported along with an estimate of the difference in mean score and a 95% confidence interval.

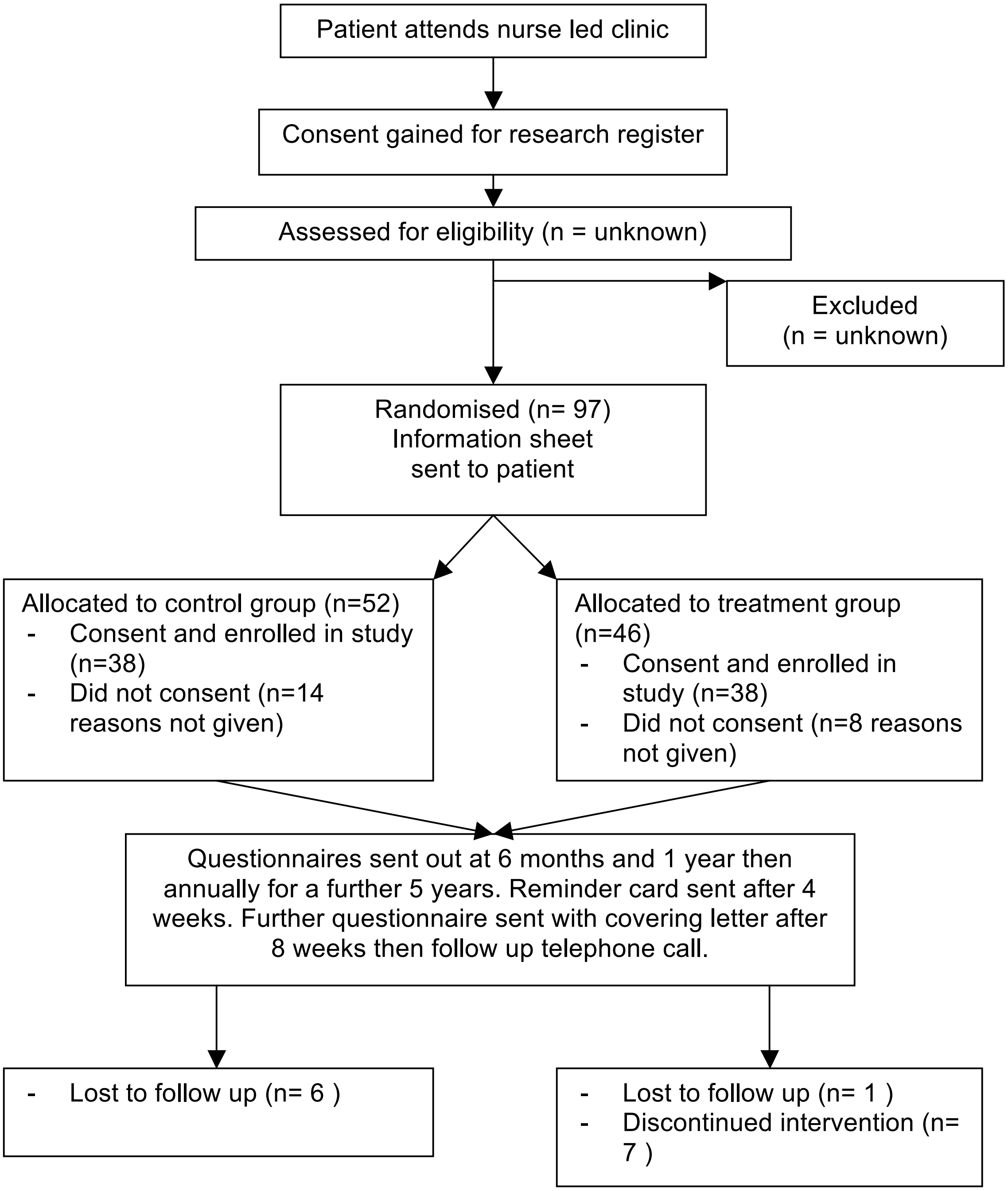
Results from analyses of the secondary outcomes were interpreted cautiously and considered as hypothesis generating rather than providing conclusive results. All analyses would be carried out on an intention to treat basis. In cases where the five year data is missing, sensitivity analyses imputing missing values on the basis of earlier measurements would be completed.

A UCL statistician was engaged to facilitate the data analysis at this stage. Due to data not being normally distributed non-parametric tests were used to analyse the data. The Fishers exact test (a version of the Mann Witney U) was used. This is considered an appropriate statistical test to complete when testing the relationship between the two categorical variables[217]. In order to take account of change scores the Altman approach for analysis of covariance (ANCOVA) was used. This adjusted each participant follow up score for his or her baseline differences, and thus had the advantage of being unaffected by baseline differences[218].

Preliminary analysis was completed to compare baselines on gender data, age data, BI and the MSIS-29. Analysis was completed six months following randomisation to identify whether there were any statistically significant differences in the six-month changes in MSIS-29, the BI and the transition questions between treatment arms.

8.4 Results

Figure 8.1 Participant Flow



8.4.1 Recruitment

Recruitment started in February 2008 and finished in February 2010. Unfortunately numbers did not reach the numbers needed to power the study. There were felt to be numerous factors:

- The MS nurse consultant was involved with a new service development within the UCLH Trust and therefore not involved in everyday clinical practice;
- An OT was appointed to manage the MS nursing team and started to run the newly diagnosed clinics – she asked more thorough questions about work and often identified work related issues at this point and therefore would refer the patient to outpatient OT for therapy input;
- The research team were dependent on a busy and stressed MS nursing team to remember to consent patients for research and refer to the study;
- The newly diagnosed clinics were reduced by half in number due to other service demands; and
- Effective promotion of VR issues in exploratory trial within the hospital meant work was identified as an issue to be discussed by consultants and referrals often made directly to Outpatient OT where as prior to the exploratory trial this would have been missed.

8.4.2 Baseline data

The table below shows the demographic and clinical characteristics of the participants recruited to the trial.

Table 8.1 Participants' Demographic Details

	Treatment **N=38**	**Control** **N=38**
Mean age (range)	33 (23-49)	39 (26-56)
Sex – female	29 (76%)	29 (76%)
Years since diagnosis (range)	3.4 (1-10 years)	3 (1-6years)
Type of MS:		
Relapsing remitting	37 (97%)	38 (100%)
Primary progressive	1 (3%)	0
Years of education:		
No qualification	2 (5%)	3 (8%)
GSCE or equivalent	4 (11%)	9 (24%)
A level or equivalent	8 (21%)	7 (18%)
Degree	11 (29%)	12 (31%)
Post graduate qualification	11 (29%)	7 (18%)
Other	2 (5%)	0

8.4.3 Numbers analysed

At this stage only preliminary analysis was undertaken as full study will run for five years. In the control group there were 38 and in the treatment group there were 38, equalling a total of 76 individuals. Due to the RCT being carried out over a five year period only baseline data are reported here as subsequent data was not available to analyse. There were missing data sets in both treatment and control groups; however this was significant in the control group. There are numerous possible reasons for this which could include: the nature of the questionnaire which was demanding, and that the participants have a lot to cope with already.

Table 8.2 Baseline Data

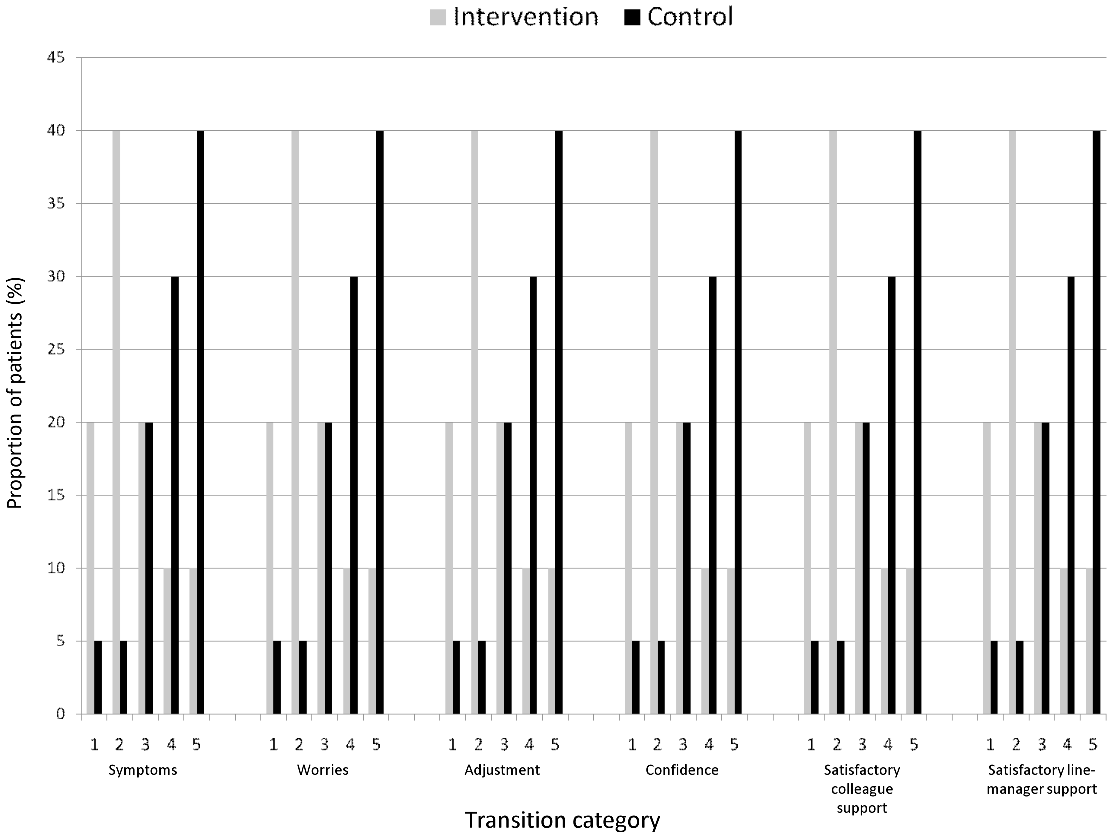
Baseline data		
	Control	**Intervention**
MSIS psychological scale	19.7 (sd 5.9) n=26	23.8 (sd 7.7) n=31
MSIS Physical scale	31.2 (sd 10.1) n=26	38.1 (sd 11.9) n=29
WIS	30.3 (sd 7.5) n=26	31.9 (sd 4.5) n=29
IWQ environmental scale	12.8 (sd 6.8) n=26	15.9 (sd 6.5) n=30
IWQ Symptom scale	16.1 (sd 7.1) n=26	17.6 (sd 5.7) n=31
BI	19.3 (sd 1.2) n=26	18.8 (sd 2.1) n=29
GSES	32.3 (sd 4.6) n=26	30.7 (sd 5.7) n=32
EQ-5D	7.2 (sd 1.4) n=25	7.5 (sd 1.5) n=31

8.4.4 Transition questions

The following figure reports the preliminary results from the transition questions from baseline to six months. These results were calculated on control group having a number of 26 (complete responses to transition questions) and the treatment group a number of 29. These early results imply that the participants' perceived ability to manage the demands of their work in the six areas of: symptoms, worries, adjustment, confidence, colleague support and line manager support, were better in the treatment group.

However, the low numbers and missing data all need to be taken into account when reading these results.

Figure 8.2 Early results from transition questions



8.4.5 Health economics

Following analysis by a health economist there were no differences between the two groups on the first year data sets.

8.4.6 Adverse events

There were no adverse events during the duration of this study.

8.5 Discussion

Only preliminary analysis has been completed at this stage therefore discussion is somewhat limited without understanding the full results over the five year follow up period.

8.5.1 Limitations

This RCT has many weaknesses, which are listed and explored below:

- The study was not blinded: the participants were not blinded and neither was the therapist providing the intervention. This could have had some impact on the results and could be one of the reasons for the high dropout rate of the control group.
- There were low numbers recruited. The reasons for which are explored in the results section. The numbers recruited are below 100 and not even half of what was needed to power the study. This makes it difficult to extrapolate any meaning from the future results and all results will need to be reviewed with caution.
- There was a poor response rate on questionnaires sent out, mostly in the control group but also the treatment group. Poor response rates are often expected with postal questionnaires. Plus the questionnaire was perceived as a demanding one and may reflect that many of the participants had a lot to cope with already. The study was initially powered to accommodate for some of this anticipated drop out, however numbers overall were low and therefore this affects the results.
- The treating therapist also received the referrals, allocated the referrals and made the telephone calls to recruit participants. This could cause bias in the results.
- As with the studies, before it needs to be considered if the results are generalisable due to the central London setting and therefore the type of person the hospital attracts. Many of the participants had white collared job and were relatively well paid office based professionals.

- The MRC guidelines state it is essential that the same intervention is offered to each participant. This was not the case in this study. Although the basic information and education provided was the same there was a significant variance in the time given to each participant, as input was need led not standardised. Further evaluation needs to be done of input provided. This evaluation would also facilitate a definition of what an early intervention service would provide.

8.5.2 Generalisability

At this stage due to small number reported and only preliminary data analysis completed early results are not generalisable.

8.5.3 Interpretation

The study has methodological flaws and is underpowered therefore no interpretation can be made of the results.

8.6 Summary

This preliminary analysis of this RCT to evaluate the effectiveness of an early intervention VR service does not provide any sound evidence that there is a benefit for early intervention. This may be because the analysis is too early, or due to methodological flaws or because it doesn’t work. Further analysis will be completed at the end of the five year period. All results will need to be reviewed cautiously due to low numbers involved.

Chapter 9. Final discussion

This thesis describes Phase I-III (in MRC terms) of the development and evaluation of a VR service for people with MS. This chapter provides a summary of its theoretical contribution, the implications for practice, strengths and weaknesses of the project, and future research. This study was primarily a piece of health services research; it was grounded in the patients' experiences of living with MS and working. The study was funded with the purpose of providing an effective VR service to help this specific group of patients maintain their employment.

9.1 Theoretical Contribution

MS is the commonest cause of neurological disability in the western world. It is progressive and unpredictable which leads many in employment to struggle with maintaining their jobs. Chapters one and two set the scene for the research introducing MS as a disease and VR as a concept, including the history of and practice of VR. Chapter three discusses the theoretical underpinnings of the research and the MRC framework[91] that was utilised to guide the research. It explores different research methodologies and the approaches that were chosen for the different stages of the study. The MRC framework provides a good foundation for the research; it guides the development of the study and is also used to structure this thesis. Although recently reviewed and updated[90] the original framework had already been utilised so a decision was taken to continue using this one. Chapter four is an extensive literature review in which the barriers to working with MS are well described. From this review it was clear there is little evidence as to what interventions could be offered to support people with MS to maintain their employment and any benefits of such interventions. The work reported in this thesis aimed to address this gap.

9.1.1 Focus groups

Focus groups were chosen for Phase I (modelling stage) as they provided an opportunity for discussion between participants with similar and diverging views[95] which could inform the design of a VR service. The groups ran well with some good discussion held. Four FGs were held to ensure there was data saturation. The discussions were recorded and transcribed with some rich data analysed for the results. The data collected described the barriers to working with MS, which clearly correlated with reports from the literature review. From the FGs the participants reported they wanted the following:

1. Early intervention, support with disclosure and to understand their rights in the work place;
2. Support to manage their condition through symptom control (e.g. fatigue management), better access to PT to improve walking and advice about managing the demands of the workplace through reasonable adjustments. This was conceptualised by the themes in the data analysis as managing their performance through: improving, compensating and modifying their performance within the work place; and,
3. Support and education to manage the social and personal expectation that the demands of work and their MS placed on them.

These findings mirror those found in other disabling disorders where patients have to adapt to increasing disability[219]. As disability starts to impact on everyday activities rehabilitation can make an important contribution to the adjustment process. It can do this by improving the fit between the person's understanding, hopes and expectations on one hand, and 'reality' on the other[220]. The need to effectively address this issue of adjustment to disability within all areas of a patient's life is essential for a MDT. The patient must actively participate in this process[221]. Although MDT rehabilitation is generally available to support people with MS when relapses occur too often the issue of work is not addressed[38] and work instability becomes a growing problem.

Strengths

Some rich data was collected through the FGs which demonstrated that employed people living with MS and experiencing varying degrees of work instability felt a service to provide support them would be valuable.

Weaknesses

It is acknowledged that the choice of FGs was also a pragmatic one. In the time available it allowed a larger number of people to contribute to the data than would have been possible should individual interviews been undertaken. One of the weaknesses of FGs is they provide information that is in less depth and detailed about experiences[96] and therefore can miss the richness that interviews can provide; and, discussions can go off on a tangent and therefore a certain level of skill required by group facilitator to hold group focus[97]. There can also be a tendency for conformity within the group, with some participants having high involvement and others having low[98]. Specifically in this study the researcher was dependent on the MS nursing team providing suitable people to be approached to participate. This may have had an impact on the results as selection was not randomised.

Summary

The data gathered was analysed for emergent themes and codes. These data were used in Phase II of the research to structure the service both in terms of what should provide and how it should be offered.

9.1.2 Exploratory trial

Informed by the literature review and results from the FG discussions a VR service was designed. Although a grounded theory approach was adopted it was acknowledged that *a priori* ideas could also have an impact on codes (e.g. from the researchers understanding of the subject matter) therefore it was accepted that the clinical experience of the research team also contributed towards the development of the service. The overarching themes from the FGs of improving performance, compensating for performance, modifying performance and managing social and personal expectations helped shape the intervention. The intervention was also provided as directed by the FG data as a one on one intervention.

The intervention

The VR service was trialled in an exploratory trial with 23 participants, there had been hope more participants but time restraints and initial difficulties with recruiting kept numbers low. Also sadly four participants withdrew from the study (reasons given in chapter six). The VR service offered different interventions as described in the FGs such as:

- improving performance:
  - fatigue management
  - PT referral to improve mobility
- modifying performance:
  - relocating desk nearer to toilets to manage bladder weakness
  - active use of diary
  - voice activated software for computer
- compensating for performance:
  - reducing hours
  - using a taxi to work
- managing social and personal expectations:
  - education about legal rights
  - support with disclosure
  - meetings with employers

This intervention differs from people’s normal experiences of rehabilitation which tend to focus on symptom management and restoration of function. It was a proactive top down response to difficulties reported in the work place.

The results

The quantative results are reported in chapter six and the qualitative results reported in chapter seven.

The quantative data

There was a significant improvement in psychological well being and health reported in the MSIS-29 and the SF 36: emotional role limitation section both reporting a 0.001 significant change. These would both relate to the adjustment that is required both emotionally and practically to manage MS and work. It was felt that the majority of the PROMS chosen did not capture the impact of the intervention little change was seen in the pre/post figures except in the outcomes reported above. This did not map onto the results of the transition question that showed 17 of the participants felt their ability to cope with the demands of their work had improved. The qualitative data also reflected positive change (see below).

The cost data

The intervention was defined through coding therapeutic time spent and was provided primarily by an OT with some PT and neuropsychological intervention. Results showed the mean cost of the intervention was £730 per participant which is relatively inexpensive to provide if a person is maintained in their work. It is acknowledged that referrals were made to external agencies such as Access to Work. The time spent here could not be recorded and therefore calculated, neither could input from the MS nurses, CBT and Speech and Language therapy. It is difficult to show if the average cost of intervention would be significantly higher with all agencies time calculated for as not every participant was referred to every agency. The majority of intervention was completed by the OT, with most of the ‘extra’ referrals being made to PT and neuropsychology. However when reviewing the cost data results these factors need to be considered.

The qualitative data

The qualitative results from completed interviews are reported in chapter seven. It was felt that choosing interviews was the best choice as it allowed the participants to speak openly of their experience of the service. The interviews being completed by an external person who was bought into the research team for this purpose, allowed the participants to speak freely. The

19 interviews completed provided some rich data although it is acknowledged that due to the small number (plus four participants were not interviewed) it is difficult to know if data saturation was achieved; this could lead to questioning the representativeness of the data.

Participants described the intervention as having a positive impact on: symptom management; anxiety and worry; self-worth, self-efficacy; the workplace; and adjustment to disability. Participants described the impact of having OT support as good. On reviewing these themes the majority of them are around the issue of adjustment to disability; the psychological changes needed to continue in a working role. The need to manage symptoms caused by MS, although part of this process, appears to be relatively small. This links with reports from the literature (chapter three) where rehabilitation counsellors often take the role of supporting this population in VR interventions. The results reflect back onto the support requested from the FGs around help with disclosure, education and managing expectations.

The themes of where the intervention had made an impact highlight that the work related PROMS used in this study were ineffective in capturing the impact of the intervention. The themes and codes identified from the interview data will be used in a future study to develop an outcome measure for use in VR service development in the NHS (discussed further below).

Strengths

This service was designed by service users and was run alongside an excellent well established MS service at a tertiary referral centre. The database of timings allowed the service to be costed as well as defined in terms of actual intervention offered. The interviews completed allowed rich data to be collected about the actual experiences of the participants. This data could be used in further service development in the future.

Weaknesses

This is a study limited by small numbers and the central London setting; this led to participants being characterised by high educational levels and office based sedentary jobs. It is unclear if the results would be generalisable to a rural or industrial setting. The service was OT led despite the fact that the benefits of MDT intervention in MS are clearly researched, this study does not enable the reader to see if an MDT approach would have provided different results. Due to some referrals on to external agencies it is neither possible to capture the true cost of all the professionals involved only that of the OT, neuropsychologist and PT. Therefore it is impossible to ascertain the real cost of this kind of intervention. It was also evident from the interviews that the PROMS used were not effective in capturing the depth of impact the service had on the participants working lives.

Summary

This exploratory study had some strong results which describe how a patient developed VR service can appear to produce positive changes in the participants' belief about their ability to manage the demands of their job.

9.1.3 The RCT

Consistent throughout the early phases of this study was the theme of early intervention. The need to intervene early is a frequent comment in the literature. Both participants in the FGs and the exploratory trial felt if they had intervention early then many problems that had arisen in their work place would not have occurred. For the RCT the intervention offered in the exploratory trial was taken and modified. This modification was not within the MRC guidance which states the same intervention from the exploratory trial should be offered in the RCT. This is a major fault with this phase of the research. The nature of the intervention remained generally the same in that is offered support with disclosure, advice on legal rights and early symptom management but it was still different. Plus the RCT the population was different in that they did not present with any reported work instability.

Within this Phase once a referral was received it was randomly allocated (through the use of a random number string) to either treatment or control group. The whole recruitment process was carried out by the primary researcher therefore not blinded; this was another major fault in the design of the RCT.

To provide a wider range of data for analysis, plus to gather cost data, the EQ-5D, the CSRI and the GSES were added to the outcomes measure pack. This made the questionnaire pack a long one which took at least 25 minutes to complete. The questionnaire was perceived as a demanding one and from the very early stages it was difficult getting all participants, especially the control group, to return the questionnaires. The study was initially powered to accommodate for some of this anticipated drop out, however numbers overall were low and therefore this will significantly affects the results.

Results

Only base line data has been presented in this thesis as questionnaires at the time of analysis were still being received and numbers were so low anyway. There will be full data analysis completed at the end of the study in five years although there is significant concern that the numbers will be too low.

Strengths

This study clearly follows the MRC framework and demonstrates that such an approach can work effectively in a clinically based research setting. Although there is no data to analyse at this stage the verbal feedback from the treatment group was that they found the information given and service offered useful.

Weaknesses

Common throughout this study is the weakness that it was a single centre study completed in central London which provides a specialised MS service; the participants were highly educated, office based and often travelling long distances to work and as such was not typical of the general MS population. Specifically regarding the RCT it had very low numbers due to difficulty with recruitment, there was difficulty with selecting appropriate PROMS, it was not blinded, there was at an early stage a poor response rate from the control group, and it provided a slightly different intervention to a different population of people with MS which does not follow the MRC guidelines.

9.2 Limitations of the study

This thesis describes an approach of developing a VR service with a strong theoretical underpinning and that followed a clear methodological framework. However, this study generally has many weaknesses:

1. It was a single centre study completed in a central London settingwhich provides a specialised MS service;
2. The participants were highly educated, office based and often travelling long distances to work and as such was not typical of the general MS population therefore the intervention designed and offered may not be applicable to manual occupations or rural settings;
3. It had very low numbers throughout each stage of the study which makes it difficult to generalise results to the wider MS population. The RCT particularly had very poor recruitment which meant numbers were less than half of that needed to power the study;
4. There was difficulty selecting appropriate PROMS for both trials which could have affected the results. The MSIS 29 was most sensitive to change in the exploratory trial and therefore was used to power the RCT. The work related PROMS chosen (IWQ, WIS, WLQ) were not responsive to change, only the transition questions in the exploratory trial appeared to reflect the responses of the interviews completed;
5. The RCT was not blinded;
6. There has been a very poor response rate with the postal questionnaires in the RCT and within the returned questionnaires significant missing data. It is uncertain whether any meaningful results will be produced; and,
7. The RCT provided a slightly different intervention to a different population of people with MS which does not follow the MRC guidelines.

9.3 Clinical implications

In general, despite these weaknesses, the earlier stages of the study make a valuable contribution to this growing area of interest. There are indications in this work that:

1. It can be beneficial to involve service users in the design of a new intervention;
2. An OT led VR intervention designed to support people maintain their work can have a positive impact;
3. Collecting quantative and qualitative data can enrich the results; and
4. People with MS need support and education to maintain their work or they are at greater risk of becoming unemployed.

9.4 Recommendations for future research

9.4.1 Long term implementation

Within the hospital MS service

The next stage of any study is the long term implementation. The updated MRC Framework[90] discusses how the research informing the implementation is iterative and that it will occur throughout the research process. This was evident throughout this research in that the development of the study had a direct impact on clinical service provision. This included a significant increase in the proportion of OT outpatient referrals for work related issues and the development of a multidisciplinary VR clinic led by a consultant neurologist, OT and a psychologist. These changes also had an impact on recruitment for the RCT as many potential referrals were sent directly to outpatients with work identified as a possible area of concern. This happened when the MS nurse or consultant asked patients about their work, an area which previously (before Phase II of the study was started) was rarely discussed in the early stages of their management. This needs to be considered in the future design of studies which are based, as this one was, directly in clinical services. Strategies may need to be developed as to how clinical service change can be monitored, and captured as a potential outcome from the intervention.

Within the NHNN a VR service is now provided as an integral part of the OT service in Out Patients. There is wider discussion as to how such a service can be offered to all diagnoses as well as other hospitals within the Trust. The MS Society as well as keen that such a service should be available across the country. However despite all the political drivers (discussed in chapter two) that state the need for VR the NHS is experiencing difficulties with funding and shrinking services. There also remains an ongoing discussion as to whether VR should be funded by the DoH or the DWP. For therapists treating patients who want support in their work settings this remains a frustration as due to financial service restraints these work related issues often cannot be addressed.

Within the MS Society

This study was part funded by the MS Society. From this research a web site called 'Worklife' www.yourworkhealth.com (funded by the DWP and supported by the MS Society) was launched in July 2010. This websites function is to provide information to employees who have long term health problems, employers and health care professionals on work related issues. The two of the primary researchers in this study were an integral part in this website development.

Another practical output from the exploratory trial was the writing of a Tool Kit to equip people with MS to better manage their work. This tool kit has been published by the MS Society[222] and is included in the new 'MS and Work' booklet[223] as well. This booklet recently was 'Highly Commended' in the BMA Patients Information Awards 2011.

9.4.2 Future research

It is evident further research is required in this area and this could include:

- Consultants who refered to the exploratory trial would ask if they could refer someone who had no work but wanted to find employment. The design of the trial would not allow receipt of these referrals. This request, combined with the results in the literature review, highlights the need to address this issue of return to work. The development and design of a return to work intervention to support people regain employment would be an important part of future VR service provision. A grant has been secured from the MSS to allow this research project to be undertaken, it will start in early 2012;

- The research completed has lead to the development of a relationship with the Employers' Forum on Disability (EFD). Work was completed with the EFD in writing an 'Advance Directive for people with MS' which provides a template for use in recording discussions with employers around reasonable adjustments. Further discussions with them, combined with experience gained through Phase I and II highlights the need to increase understanding of employers' needs and the support they require so they can effectively manage people with MS within their workforce. A grant has been secured from the MS Society to allow this research project to be undertaken. It will involve interviews being undertaken with 20 employers and their employees with MS, the analysis of this data which will form the basis of an information pack for employers. This will then be trialled with up to 50 employers who will provide feedback on its utility. With relevant changes made the information pack will then be published by the MSS. This research starts in October 2011;
- As discussed the results from both the qualitative and quantitative data imply that the PROMS used were ineffective in capturing change in this VR. Themes identified through the interviews will be used in a future study to develop an effective outcome measure that will capture work stability and should be correlated with work retention. This process is underway and a questionnaire is being trialled in the NHNN outpatient service. It is expected that enough data should be collected by mid 2012 and then analysis of the questionnaire using the Rasch measurement model[224] will be undertaken. The final output should be

a relevant, valid, reliable and responsive outcome to be used for people with MS involved in a VR service.

- The exploratory trial reported cost utility of the intervention and the RCT may provide data on cost benefit and cost effectiveness however numbers involved are small. In an increasingly financially pressured NHS this cost data will be essential for any nationwide VR service provision. Therefore, it would be beneficial to run a multi-centre RCT trialling a VR intervention with cost effectiveness and cost benefit data being gathered. This would also allow results from different populations within the UK to be analysed and reported.

9.5 Summary

The literature review at the start of the study showed the barriers to working with MS are clearly documented but that the solutions to these barriers have not been researched. It is felt that this study starts to bridge this gap and adds to the literature already published. By using people with MS to design the service a VR intervention was trialled and evaluated. This VR service was both grounded in the literature and the service users own experiences. Although data from the RCT cannot be included in this summary it is felt that Phase I and II of this study contribute to the current evidence that people with MS benefit from support to maintain their employment whilst managing their MS and that this service is relatively cheap to provide. It presents a case to suggest it is important that an effective VR service is provided across the UK to support the MS population to maintain their working roles; so that they are able to recognise their own self-worth, productivity and value to society within the limitations of their condition. It is hoped this study will encourage further research into this area to strengthen the case for the establishment of a nationwide VR service to support the MS population.

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Appendix 4.1 All papers reviewed using NSF typology

Authors	Purpose	Methodology	Results & key findings	Quality score
O'Connor 2005[33] Factors influencing work retention for people with multiple sclerosis: cross-sectional studies using qualitative and quantitative methods	To identify factors that impact on the ability of patients with MS to remain in work in order to make recommendations for future clinical management	Design: interview and questionnaires Sample: Stage I: 62 patients Stage II: 100 patients	The issues that prevent people with MS from working tend to be disease related, as well as work related. Many patients are isolated as they are unaware of sources of help. Effective management by healthcare professionals has a potentially important role in helping people with MS to remain in work.	R 10 P3 High Direct
Gordon 1994[113] Multiple Sclerosis: Strategies for Rehabilitation Counsellors	This article reviews the medical, psychological and vocational aspects of MS.	Expert opinion	Employment possibilities can be increased if appropriate assessment measures, alternative types of employment, and accommodations and assistive devices are utilized. Special attention should be aid to work disincentives.	E2 Direct
Kornblith 1986[114] Employment in individuals with multiple sclerosis	a) To examine unemployment in the MS population on a national level, and b) to identify factors which might influence an MS individual's employment status.	Design: Stage I: survey Sample: Stage I: 8,800 physicians and 725 hospitals Stage II: 949 PwMS	91.9% had a work history but 79.7% were unemployed at time of interview. Mobility important for remaining employed. Age a predictor plus the 'fit' of the individual to the demands of the job. When the physical disability may not yet be so incapacitating to leave job, the individual maybe frightened of exacerbations and prematurely leave their job.	R 8 P1 High Direct
Johnson 2004[116] Medical, psychological, social and programatic barriers to employment for people with multiple sclerosis	The literature was reviewed to identify variable that contribute or serve as barriers to employment for people living with MS.	Literature review	Employment is associated with perceived QOL for people living with MS, that people with MS are disproportionately unemployed given their educational and educational histories and that health care and rehabilitation professionals may not adequately advocate for and support continuing employment for their clients with MS.	R 9 P2 High Direct
Busche 2003[125] Short term predictors of unemployment in multiple sclerosis patients	To determine variables associated with unemployment and risk factors for development of unemployment in people with MS.	Design: questionnaire plus one interview closed question re: unemployment Sample: 96 PwmS	Confirms the low employment rate among people with MS. PwMS who are over the age of 39 or have moderate disability and are still employed can now be identified as at risk for becoming unemployed over the next 2.5 years.	R 6 P1 Medium Direct
Roessler 2003[126] Multiple sclerosis and employment barriers: a systemic perspective on	In this article, Hershenson's systematic model of rehabilitation counseling is presented as a diagnostic scheme for identifying barriers to employment.	Expert opinion	By consulting with people with MD and their employers regarding reasonable accommodations, rehabilitation counselors can intervene in the functional environment, one of the most important systems affecting return to work and job retention rates.	E2 Direct

diagnosis and intervention				
Fraser 2003[127] Progression onto disability benefits: A perspective on multiple sclerosis	The aim of the article is to describe the progression on to disability benefits for individuals with MS vs. all other disabilities and identify similarities, differences and variable in the groups.	Design: retrospective analysis of disability claims at Unum provident (insurance providers) Sample: group of diverse disabilities 77,096, group with MS 201 and, group with epilepsy 59.	There is a dramatic movement of the MS sample onto social security disability income 35.3% MS vs 3.8 general disability sample and 8.5% for epilepsy sample. Communication pathways between employer and employee need to improve in order to maintain employees with MS on the job.	R 8 P1 High Direct
La Rocca 1985[117] Factors associated with unemployment of patients with multiple sclerosis	To define the role which demographic and disease characteristics play in determining an individual's employment status.	Design: Highly structured clinical interviews conducted by professionals experienced with working with PwMS, plus a standard neurological examination and a Personal Assessment Form (subjective assessment of functioning in ADLs) Sample: 79 males and 233 females with MS	Disability level, age, sex, and level of education accounted for 14% of the differences in employment status with less disabled, older more educated males being the most likely to be employed. Employment status was unrelated to marital status or type of occupation. The patients' premorbid personalities and coping styles, as well as their ability to maintain an image of themselves as productive, working individuals may play a significant role in vocational adaptation.	R 8 P2 High Direct
Unger 2004[118] A comparative analysis of employment discrimination complaints filed by people with multiple sclerosis and individuals with other disabilities	A0 describe the types of discrimination complaints that PwMS have filed with the Unites States Equal Employment Opportunity Commission (EEOC) since 1993 under the ADA and b) compare the pattern of complaints received from PwMS to the pattern of complaints received from all other people with disabilities	Design: Retrospective data analysis Sample: PwMS: 4,059 people with other disabilities 287,811	PwMS are more likely than all other complainants to charge discrimination related to benefits, health insurance, demotion, reasonable accommodations, and the terms of employment. PwMS are less likely than other complainants to file ADA Title I complaints alleging unlawful discharge, harassment and discriminatory hiring practices. VR professionals must adopt early intervention strategies to assist PwMS in addressing potentially discriminatory employment situations before they deteriorate to the point where a formal complaint is needed.	R 9 S2 High Direct
Rumrill 2000[120] Issues in	This article describes the employment experiences and	Expert opinion	PwMS prematurely disengage from the work force. By understanding the factors that are associate with unemployment among PwMS, and by	E2 Direct

employment and career development for people with multiple sclerosis: Meeting the needs of an emerging vocational rehabilitation clientele	concerns of people with MS.		considering modifications in the policies and practices of the current service delivery system for people with disabilities, rehabilitation professionals have opportunity to improve the career development prospects for this qualified, capable and yet all-too-often disenfranchised group of people.	
Roessler 2005[157] Gender and perceived illness severity: Differential indicators of employment concerns for adults with multiple sclerosis	In this study the question of whether evaluations of employment issues differ for males and females with differing levels of perceived MS severity.	Design: postal survey Sample: 1,310 PwMS	The findings indicate that similar support is required in the workplace in the form of: a) ensuring nondiscriminatory treatment, b) meet reasonable accommodation needs, c) increase access to external supports (transportation, stress management, understanding MS in the workplace, training to return to work and opportunities for home based employment). Early intervention is essential to prevent job loss and helping PwMS maintain their confidence in the ability to hold their jobs.	R 10 P1 High Direct
Kobelt 2006[124] Costs and quality of life of multiple sclerosis in the United Kingdom	The aim of this study, part of a Europe wide study, was to analyse the costs and QOL related to the level of disease severity.	Design: postal questionnaire Sample: 2048 PwMS	The mean total annual costs per patient from a societal aspect is estimated to be £30263. 44.3% had retired early due to MS. Employment rates in early disease were 82% reduced to 2% when EDSS was 8.	R 9 P1 High Direct
Gulick 1989[121] Work performance by persons with multiple sclerosis: conditions that impede or enable the performance of work	To determine what conditions impede or enhance the ability of PwMS to perform work inside and outside the house.	Design: Two open ended questions: 1 – what makes it more difficult to perform your work or chores? 2 – what makes it easier to perform your work or chores? 2 questionnaires Sample: 508 PwMS	Conditions reported to impede the performance of work and tasks were related to three categories: physical restrictions, person-environment interaction and MS related symptoms. Conditions reported to enhance the performance of work and tasks were related to five categories: assistive devices, human support, personal attributes, health promotion behaviours, and person-environment adjustment.	R 8 P3 High Direct
Jackson 1991[123] Effects of multiple sclerosis on occupational and career patterns	To identify problems associated with MS that have the greatest impact on a person's occupation and career pattern.	Design: postal questionnaire Sample: 210 PwMS	For most participants the outcome of their diagnosis of MS was career disruption, decreased earning power, forced retirement or unemployment. Symptoms, which had the greatest impact on employment, were fatigue and muscle weakness. Identified work related problems included inability to work full time and inaccessible environments.	R 6 P1 Medium Direct
Bishop 2009[128]	The purpose of the study was to	Design: Survey	Both self-management and DMT use are significantly related to	R 10

The relationship of self-management and disease modifying therapy use to employment status among adults with multiple sclerosis	evaluate the relationship between MS self-management and employment status, including the use of and adherence to treatment therapies.	Sample: 175 PwMS	employment. Therefore the results suggest that DMT use and engaging in self management behaviours may be important elements to the employment maintenance of PwMS.	P1 High Direct
Roessler 2004[129] Predictors of employment status for people with multiple sclerosis	This study examined the relevance of the disease-and-demographics model for explaining the employment outcomes of adults with MS. It discusses the relationship of the findings to the psychosocial and career development models of rehabilitation and to training, educational, accommodation planning and cognitive interventions.	Design: Survey with questions regarding demographic and disease related variables Sample: 1310 PwMS	Educational attainment, symptom severity, persistence of symptoms, and presence of cognitive limitations combined significantly to predict employment status These findings indicate the need for rehabilitation interventions that include education and training services, early and repeated assessment of on the job barriers to productivity, and the development of related accommodation plans; and provision of cognitive retraining.	R 10 P1 High Direct
O'Day 1998[131] Barriers for people with multiple sclerosis who want to work: A qualitative study	To illustrate and expand on the personal and societal barriers outlined in the literature and to explore the hypothesis that policies contained within federal programmes themselves, such as income maintenance, health care, and vocational rehabilitation, constitute a third set of barriers to employment for people with MS.	Design: structured interviews Sample: 16 PwMS	Public programmes seem to place additional obstacles in the path to employment. Due to the tremendous financial disincentives to work no more than on a limited part time basis those with MS are not likely to be seeking work. People with MS had limited knowledge concerning job restructuring or accommodations – issues of critical importance given the nature of their disability.	R 8 P2 High Direct
Smith 2005[132] Factors related to employment status changes in individuals with multiple sclerosis	This study compares groups of people with MS who: 1) are still able to work full time; 2) had to cut back on their hours due to their MS symptoms; and 30 had to leave their jobs entirely due to their MS symptoms. It examines whether these groups lie on a spectrum of disease severity, with the unemployed experiencing the most severe symptoms. It also examines the possible cognitive differences between the groups using neuropsychological measures.	Design: Questionnaire one week prior to assessment then psychosocial interview, neuropsychological assessment and depression, fatigue and cognitive measures. Sample: 50 PwMS	The socio economic and demographic factors such as occupational prestige and years of education pay and important role in the ability of individuals with MS to maintain their employment while coping with their MS symptoms by reducing their hours. 90% of the part time working group reported that fatigue was a primary symptom responsible for their work status change; whereas 86% of the not working group reported that broad physical/neurological symptoms were responsible for their change in work status.	R 7 P3 Medium Direct
McDonnell 1998[133] An epidemiologic	To investigate the clinical and demographic characteristics of	Design: interview and assessment	PPMS in N Ireland has a generally later age of onset, lower female preponderance and predominantly motor onset compared with other	R 8 P2

study of multiple sclerosis in Northern Ireland	primary progressive MS in Northern Ireland and to establish a database of such patients for genetic and immunological studies and future therapeutic trials.	Sample: 111 (63 women) mean age of onset 39.5 (range 17-66 years)	subgroups of MS. There are high levels of unemployment in the group at 85.55% and financial dependence (93.6%).	High Direct
Roessler 2001[134] Determinants of employment status among people with MS	This study identified factors predicting employment or lack of thereof among adults with MS.	Design: postal questionnaire Sample: 139 PwMS	PwMS who are at greater risk of unemployment are less likely to have a college education and more likely to report cognitive limitations, a persistent course of symptoms and multiple and severe physiological effects of MS. They are in need of immediate and long term rehabilitation interventions if they are to retain their jobs or reenter the workforce.	R 9 P1 High Direct
Hammond 1996[135] Multiple Sclerosis in Australia: socioeconomic factors	This study analyses the data from the Australian epidemiological study of MS to compare the prevalence of MS across different socioeconomic groups as measured by education. The association between level of disability and marital and employment status was also examined.	Design: retrospective analysis of data Sample: 2307 PwMS	The study shows there is a significantly higher frequency of MS in people who leave school at an older age and achieve a higher educational level. The findings of a greater level of divorce and separation and lower rates of participation in the paid workforce in more disabled patients is consistent with other studies. This all highlights the need to consider the social issues related to MS.	R 8 P1 High Direct
Rumrill 2007[119] Gender as a differential indicator of the employment discrimination experiences of Americans with multiple sclerosis	The purpose of this study was to compare and contrast the employment discrimination experiences of women and men with MS from the vantage point of the United States' EEOC Integrated Mission System database.	Design: retrospective data analysis of complaints filed. Sample: 3663 allegations filed by 2167 PwMS	Both men and women were most likely to allege discrimination related to discharge and reasonable accommodations, although women were more likely to file harassment charges than men. Men with MS were more likely to allege discrimination regarding hiring and reinstatement. Women with MS were more likely to file allegations against employers in the service industries, and men were more likely to file allegations against employers in the construction, manufacturing, and wholesale industries.	R 10 P1 High Direct
Simmons 2010[25] Living with multiple sclerosis: longitudinal changes in employment and the importance of symptom management	To identify reasons by which employment had been lost or was perceived at risk of being lost.	Design: survey (x2) Sample: 1st survey: 1135 2nd survey: 1329 Both surveys: 667	The main reasons report by PwMS for their loss of employment involved the ineffective management of symptoms of MS in the workplace, rather than work place related factors including insufficient flexibility of employment conditions or being asked to leave or being sacked. Listed symptoms include: fatigue, mobility related symptoms, arm and hand difficulties, and cognitive deficits. Planning for effective symptom management and accommodations are left until too late to be effective.	R 9 P1 High Direct
Yorkston 2003[136] Getting the work done: a qualitative study of individuals with multiple sclerosis	The aim of this study is to examine the experiences of individuals with mild to moderate MS as they carry out everyday activities both inside and outside the home.	Design: semi structure interviews with follow up interview 6-8 months later, open ended questions Sample: 14 PwMS	Individuals with MS develop strategies and utilise resources in order to get the work done. Comparisons are made between existing interventions theories or programmes and the experiences described by participants in this study. There is a need for additional research to fully explore self generated strategies that maybe helpful to individuals with MS to participate fully in work activities.	R 10 P2 High Direct

Johnson 2004[137] The cost and benefits of employment: a qualitative study of experiences of persons with multiple sclerosis	To attain a better understanding of the benefits and barriers faced by persons with MS in the work place.	Design: a series of semi structured interviews. Sample: 16 (14 women) employed or recently employed	Health care providers must consider the complexity and timing of decisions by people with MS to continue or leave employment before recommending either action. Identifying critical periods of intervention to stabilise this cost benefit balance is a critical next step for understanding issues of employment and MS.	R 10 P2 High Direct
Dyck 2000[138] Women with multiple sclerosis and employment issues: a focus on social and institutional environments	Employment issues for women diagnosed with MS and their work place experiences, focusing on the social and institutional dimensions of the environment.	Design: semi structured interviews and postal questionnaire Sample: interviews: 54 women Questionnaires: sent to 864 women with 66% response rate.	The findings suggest that inclusion of environmental analysis in clinical practice broadens the range of intervention strategies to be considered and raises the issue of occupational therapists' role in advocacy.	R 9 P3 High Direct
Gulick 1992[139] Model for predicting work performance among persons with multiple sclerosis	To examine the role of selected demographic factors, work impediments, and work enhancers as predictors of activities essential for performing outside employment, home making and for personal care.	Design: postal questionnaires Sample: 201	Use of the Work Performance Model to predict the outcome of vocational training is warranted.	R 3 P1 Low Direct
Genevie 1987[140] Job retention among people with multiple sclerosis	To contrast the characteristics of those MS patients who have continued to work with those who have dropped out of the labour market.	Design: survey Sample: 439 PwMS	While symptom severity and functional impairment played an important role in predicting job retention, other factors such as government benefits and demographic status must be considered.	R 6 P1 Medium Direct
La Rocca 1996[141] A program to facilitate retention of employment among persons with multiple sclerosis	To develop and evaluate the feasibility of a medical-community job-retention service	Design: RCT Sample: 43 PwMS at risk of losing their jobs 23 in experimental group and 20 in control group	A combined medical-community job-retention program is feasible in MS. However patients do not generally wish to take advantage of job-retention services until an employment crisis develops. Future programs should develop more effective approaches to early intervention to realize their maximum potential.	R 6 P1 Medium Direct
Sweetland 2007[142] Vocational rehabilitation services for people with MS: what patients want from clinicians and employers	To identify what PwMS require from a vocational rehabilitation service in terms of content and delivery.	Design: Focus groups Sample: 24 PwMS	PwMS need support in the workplace in two distinct ways**.** First, by managing the interaction between the impairments caused by MS, the physical environment, and the demands imposed by the work. Second, by providing expert knowledge about the employment environment and the needs of employers, an awareness of the relevant legislation and counseling in supporting people to adapt, adjust and resolve complex issues.	R 10 P2 High Direct

Edgley 1991[143] A survey of multiple sclerosis. Part 2: Determinants of employment status	The study was designed to determine the relative contributions of several occupationally-related variable to employment status including age, gender, modility, duration of illness, education, occupation and perceived cognitive deficits. It also examines patients' perceptions of the causes of their unemployment.	Design: postal survey questionnaire Sample: 1180 PwMS	66% of participants unemployed (age bet. 18 – 55) Mobility problems, perceived cognitive problems and lower education significant determinants of employment status. 78% or unemployed indicated they discontinued their employment due to symptoms – with mobility and fatigue most common symptoms.	R 9 P1 High Direct
Roessler 1995[144] The relationship of perceived work site barriers to job mastery and job satisfaction for employed people with multiple sclerosis	The purpose of this study is to describe the on-the-job barriers that employees with MS experience and the relationship of those barriers to two constructs that influence job retention: self ratings of job mastery and job satisfaction.	Design: face to face interviews or telephone interviews with questionnaires completed Sample: 50 PwMS	The findings highlight barriers to working with MS and underscore the need for early intervention to: (a) educate employees about their legal rights (b) remove work site barriers (c) resolve job mastery problems relating to self confidence and planning for the future. These early interventions would increase the likelihood that employees with MS would retain their jobs.	R 9 P3 High Direct
Johnson 2009[145] Disease and demographic characteristics associated with unemployment among working-age adults with multiple sclerosis	The aim of this study was to examine the association of secondary conditions, including pain, fatigue, sleep problems, anxiety, and incontinence, with employment status in individuals with MS.	Design: survey Sample: 1125 PwMS	40.4% of the individuals were employed half time or more an increase from 20 years ago may be due to more effective medications and other symptom-ameliorating strategies. Variables significantly associated with unemployment were severity of disease, difficulties in thinking, female sex, increased age, and increased duration of MS. The combined impact of cognitive changes and overall severity of mobility impairment significantly influenced employment status.	R 9 P1 High Direct
Rao 1991[37] Cognitive dysfunction in multiple sclerosis	To assess the specific contribution of cognitive dysfunction to multiple sclerosis patients' problems in daily living.	100 MS (52 cognitively intact 48 cognitively impaired 100 control underwent neuropsychological assessment, OT evaluation, self report measures, relative/friend ratings of emotional adjustment	There were no significant differences between the two MS groups on measures of physical disability and illness duration, patients in the cognitively impaired group were less likely to be working, engaged in fewer activities social and avocational activities, reported more sexual dysfunction, experienced greater difficulty in performing routine tasks, and exhibited more psychopathology than the cognitively intact patients. Cognitive dysfunction is a major factor in determining the quality of life of patients with MS. In particular in determining the work status. This highlights the need for timely and accurate assessment of cognitive deficits. Results of testing can alter an employer's expectations of the patient, allowing adaptations to occur in the work place and enabling the patient to maintain employment.	R 7 P3 High Direct

Beatty 1995[146] Demographic, clinical, and cognitive characteristics of multiple sclerosis patients who continue to work	The aim of the study was to compare the demographic, clinical, and cognitive characteristics of MS patients who continue to work with those of patients who had retired prematurely.	Design: neuropsychological assessment. Sample: 38 patients still working, 64 retired.	The results show that cognitive deficits as well as physical disability and age contribute to premature retirement. The measures of memory and information processing speed were the cognitive variable that contributed most to the prediction of work status. More than 80% of patients who were still working had only mild to moderate physical disabilities and more than 75% had negligible to mild cognitive difficulties. Early assessment and treatment is required to enable PwMS maintain their employment.	R 10 P1 High Direct
Fraser 2009[147] Predictors of vocational stability in multiple sclerosis	To identify the specific factors relating not simply to initial employment procurement, but employment stability once a job was secured.	Design: questionnaires, job placement outcome analysis, neuropsychological assessment Sample: 95 PwMS	Vocational stability linked significantly with the FAS Controlled Oral Word Association Test 3 (a measure of verbal fluency and executive functioning). Therefore this relatively brief, simple test of verbal association fluency appears to be a tangible predictor of one's ability to both secure and retain employment.	R 7 P3 High Direct
Benedict 2005[148] Predicting quality of life in multiple sclerosis: accounting for physical disability, fatigue, cognition, mood disorder, personality, and behaviour change	The aim of the study was to determine which domain (disease characteristics, physical disability, fatigue, cognitive function, personality traits, mood disorder, and behavioural dysfunction) is most closely linked with HQOL. The researchers predicted depression would most strongly predict HQOL and that vocational status would be predicted more by objective measures of cognitive and physical capacity.	Design: neuropsychological evaluation and questionnaires Sample: 120 PwMS and 44 healthy volunteers	Overall HQOL in MS is strongly associated with psychological factors such as depression, and its measurement is hampered by report bias. Employability, which has more to do with work capacity than a subjective sense of well being, is predicted by cognitive ability and not depression.	R 8 P1 High Direct
Clemmons 2004[149] An abbreviated neuropsychological battery in multiple sclerosis vocational rehabilitation: findings and implications	To establish the utility of an economic neuropsychological battery for use in MS vocational rehabilitation.	Design: review of prior batteries, test selection and use with consecutive referrals, descriptive statistics, and review of normative data. Sample: 37	Results showed that memory function, problem solving/abstraction, and cognitive efficiency (multitasking) were lower than would have been predicted from intellectual ability. Counseling implications include the possibility that clients/counsellers over estimate the clients' abilities on the basis of verbal presentation alone; clients may experience confusion or frustration when job performance is not on par with verbal performance; appropriate job match may be problematic due to overall decline of those cognitive abilities critical in complex professional jobs. Average verbal skills may not be sufficient.	R 8 P1 High Direct
Julian 2008[150] Employment in multiple sclerosis: exiting and re-entering the workforce	The purpose of the investigation was to evaluate patient and disease characteristics as temporal predictors of work cessation and re-entry into the work force.	Design: cross sectional and longitudinal analysis Sample: 8,867 NARCOMS registry	60% of participants are unemployed. Over 18 months 6% became unemployed and 3% reemployed. Patients with worsening symptoms are at particular risk of future employment loss. Employment should be considered a dynamic process. Specific symptoms predict employment loss better than general estimates of disability.	R 10 P1 High Direct

		participants	MS related symptoms and limitations should be considered in tandem with work place demands and job characteristics in order to promote maintenance of employment.	
Lage 2006[151] Effect of immunomodulatory therapy and other factors on employment loss time in multiple sclerosis	The purpose of this study was to examine the factors that potentially affect time missed from work for individuals diagnosed with MS. Also to discover whether the use of immunomodulatory agents affects time missed from work. Therefore to expand on what is known about the large indirect costs associated with MS.	Design: retrospective analysis of databases Sample: 284 PwMS	Results indicate that lost time from work is affected by severity of illness and type of immunomodulatory therapy. Only glatiramer acetate was associated with significantly few days missed from work for short term disability (18.24 fewer days P< 0.03), workers compensation (29.50 fewer days, P < 0.04).	R 7 P1 High Direct
Grima 2000[152] Cost and health related quality of life consequences of multiple sclerosis	The study's objectives were to i) quantify the cost of MS to the Canadian health care system and society, ii) measure health utility in MS, and iii) examine the influence of disability on patient utility and health care costs.	Design: survey and chart review Sample: 153 PwMS	The results reported were that annual admission costs increased with EDSS levels (EDSS 1 $7596 and EDSS 6 $33206). At all EDSS levels the largest costs were due to inability to work. The average cost per relapse was $1367. MS produces substantial health care costs and reductions in quality of life and ability to work can be avoided or delayed if disease progression is slowed.	R 7 P1 High Direct
Salter 2010[153] Impact of loss of mobility on instrumental activities of daily living and socioeconomic status in patients with MS	To assess the effects of mobility loss on IADL and socioeconomic status in PwMS.	Design: survey Sample: 8180 PwMS	Mobility loss significantly correlated with reduced IADL scores and negatively correlated with employment. These were significant even with mild mobility loss, supporting the need for early treatment.	R 10 P1 High Direct
Pompeii 2005[154] Measures of physical and cognitive function and work status among individuals with multiple sclerosis: a review of the literature	The purpose of the review was to critically evaluate the MS literature that has examined physical and cognitive function in relation to ability to work.	Literature review	Work ability extends beyond measures of impairment to include level of education, job characteristics and disease symptoms such as fatigue. Measures of physical and cognitive function can only guide physicians when clinically evaluating an individual with MS, but are poor indicators for precluding an individual from working.	R 6 R2 Medium Direct
Prodinger 2010[155] A Delphi study on environmental factors that impact work and social life	The aim of this study was to gain knowledge about environmental factors that impact work and social life participation of people with MS in Austria and Switzerland to extend	Design: Expert opinion – Delphi: first round questionnaires, second and third expert panel	Content analysis revealed 768 environmental factors. 5 categories revealed to be highly important, 12 moderately important, 6 fairly important, and 10 important. Results indicate that participation in work or social life is influenced by physical, social, attitudinal and policy factors.	R 9 E2 High Direct

participation of individuals with multiple sclerosis in Austria and Switzerland	knowledge of participation and to identify key areas for measuring participation.	Sample: 112 Austrian experts, 109 Swiss experts		
McCabe 2008[156] Work and recreational changes among people with neurological illness and their caregivers	This study investigated the changes in work and recreational activities among people with four different progressive neurological illnesses.	Design: individual interviews Sample: 28 MS, 27 motor neurone disease, 31 Parkinson's disease, 24 Huntingdon's disease, 28 health professionals	The results demonstrated a high level of agreement from each of the participants. Most of the people with illnesses and many carers had reduced their level of paid work. All respondents perceived these changes as negative. Changes in recreational activities were also seen to be primarily negative. The results highlight the need for rehabilitation professionals to offer support to both carers and people with illnesses to maintain their working roles.	R 10 P2 High Indirect
Dyck 1995[48] Hidden geographies: the changing life worlds of women with multiple sclerosis	The aim of the paper is to discuss the microgeographies of unemployed women with MS as they manage physical, social and economic consequences of their illness.	Design: in-depth interviews Sample: 23	The majority of the women were found to experience shrinking social and geographical worlds. Attention to the body in its geographical as well as social context is important when looking at the processes, which shape the illness experience.	R 7 P2 High Direct
La Rocca 1982[158] The role of disease and demographic factors in the employment of patients with multiple sclerosis	The aim of the study was to define the role that demographic and disease related characteristics played in determining a person's employment status.	Design: highly structured clinical interview accompanied by a standard neurological assessment Sample: 79 men and 233 women with MS	77% unemployed yet 96% had an employment history. The EDSS, age, sex and education had a direct association with employment. Factors such as pre-morbid personality, coping style, characteristics of the work place and social support systems all contribute as well.	R 5 P2 Medium Direct
Green 2008[159] 'Restricting choices and limiting independence': social and economic impact of multiple sclerosis upon households R 9by level of disability	To examine the relationship between the social and economic impact of MS and the levels of MS related disability upon households in the following domains: household composition, housing modification, employment, standard of living, children, intimate and close relationships, and social life.	Design: survey Sample: 920	Analysis of the data suggests the impact of MS can be conceptualised as a gradual process of 'restricting choices' and 'limiting independence' for both people with MS and their households. MS restricts social and economic opportunities for people with MS and those they live with.	R 5 P3 Medium Direct
Catanzaro 1992[49] Economic status of families living with multiple sclerosis	The purpose of this paper is to describe the economic impact of MS on a national sample of families.	Design: survey Sample: 604 PwMS	39% of men and 19% of women had retired because of disability. Income was inadequate to pay for medical expenses in 21% of families and 25% had inadequate funds to meet basic living expenses. A comprehensive assessment of economic status is needed by health care providers.	R 5 P1 Medium Direct

Iezzoni 2007[160] Health, disability, and life insurance experiences of working-age persons with multiple sclerosis	This study examined health, disability and life insurance coverage, as well as associations with economic and related worries, for working age US residents with MS.	Design: 30 minutes questionnaire used in telephone interview. Questionnaire created through four focus groups and literature review Sample: 983 PwMS	Overall 96.3% had health care insurance, 56.7% had long term disability insurance and 68.3% had life insurance. 27.4% indicated that since being diagnosed with MS, health insurance concerns had significantly affected employment decisions. Overall, 26.6% reported considerable worries about affording basic necessities such as food, utilities and housing. The findings confirm that dealing with the physical impact of MS is only one aspect. The financial consequences are large and potentially threaten emotional health, equanimity and well-being.	R 9 P3 Direct High
McCrone 2008[109] Multiple sclerosis in the UK: Service use, costs, quality of life and disability	The aim of the study was to investigate the links between service use, costs, quality of life and disability for people with MS	Design: questionnaire Sample: 1942 PwMS	35.4% of the sample reported they were retired due to ill health. The mean cost of lost employment through early retirement due to illness, decreased working hours and sick days for those of usual working age was £4240 for the 6 month period reviewed. Overall people with high levels of disability and low levels of HR-QOL tend to have higher costs.	R 9 P1 High Direct
Rumrill 2004[115] Vocational rehabilitation-related predictors of quality of life among people with multiple sclerosis	The aim of the study was to evaluate the strength of illness-related, employment –related and psychosocial variables as predictors of QOL among people with MS.	Design: questionnaire Sample: 1310 PwMS	QOL was found to be positively related to educational level and employment status and negatively related to number of symptoms, persistence of symptoms and perceived stress level. VR professionals need responsive interventions to assist clients in minimizing symptoms, reducing stress, receiving training, obtaining/retaining employment.	P1 High 10 Direct
Roessler 2003[161] Perceived strengths and weaknesses in employment policies and services among people with multiple sclerosis: results of a national survey	The purpose of this article is to present findings from a national survey of issues affecting job acquisition and retention of PwMS.	Design: Survey and focus groups Sample: survey1310 FG: 59 PwMS and 29 service providers	Retaining employment is important. Knowing one's rights and rules on disclosure is important. Need for education on the legal rights. Information for newly diagnosed is important. PwMS need to learn self advocacy skills. Most important strength was PwMS educating themselves and employers about the disease, identifying and implementing accommodations and empowering themselves to actively participate in medical treatment.	R 10 P3 High Direct
Neath 2007[162] Patterns in perceived employment discrimination for adults with multiple sclerosis	The aim of this study was to look at the allegation patterns by PwMS of discrimination and to establish which were the most common.	Design: retrospective analysis of data files. Sample: 3668 allegation filed	Themes identified were around perceived discrimination form employer including threats to retention, employer hostility, informal and formal employer actions, and barriers to career mobility. Results support the need for rehabilitation counseling interventions to help adults with MS identify and address precipitants to discharge or constructive discharge.	R 9 P1 High Direct

Rumrill 1999[163] Surveying the employment concerns of people with multiple sclerosis: a participatory action research proposal	The purpose of this study is to examine the employment concerns of a sample of PwMS. Secondly to discuss ways by which rehabilitation practitioners, researchers, and policy makers can develop interventions to fill gaps between respondents' stated needs for career development services and the supports that are available.	Design: postal survey Sample: 227	Results show that service provision has improved but employers and PwMS continue to need education about the legal protection provided under the ADA. Early intervention to identify barriers to productivity and solutions to reduce or remove these barriers before the person looses their job would also be beneficial. Respondents described subtle discrimination occurs from employers. Rehabilitation professionals can assist by communicating to employers not only the range of effective accommodations that exist but also the minimal costs involved.	R 10 P1 High Direct
Rumrill 1996[164] Job placement interventions for people with MS	The authors examine the following job placement programmes: a) MS back-to-work: Operation Job Match, b) the Job Raising Programme, c) the Return to Work Programme, and, d) the Career Possibilities Project.	Expert opinion	When working with a person who is trying to re-establish their career and cope with a serious illness such as MS, the emphasis of a job placement programme should be on people's interests, abilities, and experience – not their disabilities and accompanying limitations.	E2 Direct
Rumrill 2004[165] Title I of the ADA and Equal Employment Opportunities Commission case resolution patterns involving people with MS	The aim of this study was to examine the manner in which the United States EEOC resolves ADA employment discrimination complaints by people with MS.	Design: retrospective data analysis Sample: 2,541 PwMS all others 187,317	Over half the cases were dismissed as 'groundless' – possibly people with MS are not familiar with what constitute employer discrimination, or know how to communicate/document instances of discrimination. Rehabilitation professionals should help people understand their legal rights, identify employer discrimination when it does occur, solve on-the-job problems proactively and non-adversarially and follow the EEOC's formal complaint procedure when necessary.	R 10 P1 High Direct
Gronning 1990[166] Multivariate analyses of factors associated with unemployment in people with multiple sclerosis	The aim of this study was to answer the following question: Can patient characteristics at the onset of MS indicate high risk patients for subsequent unemployment.	Design: not clear Sample: 79 PwMS	The report concludes that patients with a non-remittent clinical course, aged 30 years and over, and heavy physical work should be considered as high risk patients for early unemployment due to MS.	R 3 P1 Low Direct
Verdier-Taillefer 1995[167] Occupational environment as risk factor for unemployment in multiple sclerosis	The aim of this study was to assess what in their occupational environment differentiate patients who are still employed form those who have left their job.	Design: Case-control study: Neurological examination and questionnaire Sample: PwMS unemployed = 77 and controls were PwMS still employed = 94	Employment in the public sector, sedentary jobs and possibility of obtaining specific improvements in work environment were protective factors, while jobs needing force, rigid work schedule, manual precision, frequent moves and daily work duration of +8 hours were risk factors. Simple early changes in the occupational environment could maintain PwMS in work.	R 7 P3 High Direct
Roessler 2004[168]	This study investigated the relevance	Design: Questionnaire	Results indicate that a model predicting job satisfaction should include	R 10

Factors affecting the job satisfaction of employed adults with MS	of income, disease, and perceived employment situation variables for predicting job satisfaction among employed adults with MS.	Sample: 555 PwMS	variables related to income adequacy and perceived job match. There is a need for early rehabilitation interventions in the work place to address concerns regarding perceived adequacy of income and job/person match.	P1 High Direct
Patti 2007[169] Effects of education level and employment status on HRQoL in early relapsing-remitting multiple sclerosis	To evaluate the effects of education level and employment status on health related quality of life (HRQoL) in a large cohort of patients affected by relapsing remitting MS	Design: questionnaires Sample: 648 Pw MS	Employed patients scored significantly higher than other patient groups in the majority of the MSQoL-54 domains. Patients with higher levels of education had higher scores. Occupation and educational levels were found to be significant and independent predictors of HRQoL. Results suggest the importance of sustaining employment after recent diagnosis of MS. A higher level of education may determine a stronger awareness of the disease and better ability to cope with the challenges of MS.	R 7 P1 Direct High
De Judicibus 2007[170] The impact of the financial costs of multiple sclerosis on quality of life	This study was designed to investigate the objective direct and indirect costs of MS, the impact of the costs of MS on subjective QOL and relationships, and coping strategies used by PwMS and their families.	Design: Interviews Sample: 12 professionals 26 PwMS 11 relatives	MS had a substantial impact on the financial situation of families both direct and indirect costs. Loss of employment had a negative impact on QOL; loss of self esteem, social contact and increased financial stress. The financial strain must be discussed and education/intervention provided to assist PwMS and their families.	R 8 P2 Direct High
Pack 2007[44] Prediction of turnover among employed adults with multiple sclerosis	This study examined a prediction model for turnover intention.	Design: Survey Sample: 388 PwMS	Severity of symptoms, perceived stress levels and coping abilities, job satisfaction and employer support were significant predictors for turnover intention. The support of the employer is critical in helping a person with MS retain employment.	R 10 P1 High Direct
Gulick 1996[171] Health status, work impediments, and coping related to work roles of women with multiple sclerosis	The purpose of this study was to compare the health status, perceived work impediments and coping strategies for women with MS by: 1) determining if differences exist according to work role and age group; and 2) for women under 45, determining if differences exist according to work role and parent status.	Design: self report questionnaires Sample: 408 women with MS	Results showed that lower ADL functioning and increased MS symptoms and work impediments among middle age women compared to young women. Unemployed women had more motor symptoms and perceived more work impediments than homemakers and employed women. Knowledge of health status, perceived work impediments and available coping strategies is essential for health providers in planning relevant interventions.	R 7 P1 High Direct
Roessler 1994[172] Strategies for enhancing career maintenance self efficacy of people with multiple	The purpose of the article is to apply a psychosocial theory for human behaviour (self efficacy theory) to the career maintenance problems encountered by people with severe disabilities such as MS.	Opinion	Self-efficacy appears to explain why people with MS have difficulty maintaining their careers. The unpredictability of the MS symptoms undermines the individual's belief that they can (a) perform adequately on the job, (b) overcome barriers in the work place, (c) solicit the employer's assistance in barrier removal. By identifying their accommodation needs and solutions, understanding their legal rights,	E2 Direct

sclerosis			being encouraged to act on those needs and developing skills to present needs to their employers, people with MS should become more skilled and confident in requesting an accommodations. It is critical the employer is willing to engage in these discussions.	
Salomone 1998[173] The impact of disability on career development of people with multiple sclerosis	The aim of the study was to gather information concerning the manner and extent to which MS influences the career development of people who have developed the disease.	Design: semi structured interviews Sample: 12 PwMS	Categories that formed in the data were: 1) the meaning of career and work; comprised of a) understanding career, b) purpose of work, c) importance of work, and d) work values, needs and personal qualities, and 2) the implications of MS; comprised of a) living with a disability, b) the meaning of disability, and c) barriers associated with disability.	R 7 P2 High Indirect
Townsend 2008[174] Supporting people with multiple sclerosis in employment: a United Kingdom survey or current practice and experience	The aims of the study were, first, to explore the knowledge and experience of MS specialists, occupational therapists and disability employment advisers of employment and MS, second, to identify the current practice of professionals supporting people with MS in work.	Design: postal questionnaires Sample: 70 (32 OTs, 26 nurse specialists, 4 Pts and 8 DEAs)	The results showed that the impact of MS on employment was well understood, but that there was less awareness of wider social influences on the ability to retain employment. There was evidence of a range of support being offered by some participants, but their appeared to be a gap between the problems reported and interventions offered.	R 9 P1 High Direct
Rumrill 2004[175] Workplace barriers and job satisfaction among employed people with MS: an empirical rationale for early intervention	The purpose of this study was to replicate an important empirical finding supporting the relationship between work place barriers and job satisfaction. The overall hypothesis is that job satisfaction is a function of the number of barriers that workers with midcareer disabilities encounter in their work.	Design: telephone interviews Sample: 59 PwMS	Respondents in this study reported relatively few on the job barriers, high levels of job mastery and high levels of job satisfaction. The findings provide an empirical rationale for early intervention to reduce or remove job-related barriers before they undermine job satisfaction and, eventually, threaten job retention for employees with MS.	R 10 P2 High Direct
Rumrill 1996[176] Factors associated with unemployment among persons with multiple sclerosis	The purpose of this article is to examine the correlates of unemployment that inhere to MS and thereby, clarify the specific employment barriers that people with MS encounter.	Opinion piece	Trans-disciplinary collaboration among professionals in allied health and human services will be the key to success in service developments to support people with MS remain in the workforce.	E2 Direct
Roessler 1996[177] The role of assessment in enhancing vocational success of people with multiple sclerosis	To enhance the vocational success of people with MS, assessment must be clarify both the way that MS has impaired functioning in career roles and produced psychological uncertainty about the future. In this paper measures of person and environment constructs are	Opinion piece	Various measurement strategies discussed. The importance of assessing the environment as well as the person highlighted. The need for accurate assessment information to: improve quality of VR provision; help employers improve their disability management services; help people with MS have accommodations; and, help people with MS take control of their work situation.	E2 Direct

	presented.			
Rumrill 1996[178] Job retention interventions for persons with multiple sclerosis	The purpose of this paper is to (a) examine what on-the-job conditions make it difficult for employees with MS to continue working, (b) describe the core components of several job retention strategies for people with MS.	Opinion piece	Two services reviewed one project run by Rumrill and one called Project Alliance. The key to removing barriers is three fold: on-the-job assessment required to identify work limitations and strategies to solve these; employees need information of their legal rights coupled with self advocacy training; consultation with employers is essential.	E2 Direct
Scheinberg 1981[180] Vocational disability and rehabilitation in multiple sclerosis	The article presents data which will be of help to the physician and other health professionals in understanding and improving the employment situation of patients with MS.	Design: survey Sample: 257	19.5% of sample gainfully employed with 85.9% not having worked for 2+ years Few of the patients received any vocational rehabilitation Physicians not referring people with MS to vocational rehabilitation providers Unemployment associated with MS is a significant social complication of the disease physicians must assist them obtaining necessary specialized help to re-enter the job market.	R 6 P2 Medium Direct
Szymanski 1999[181] Disability, job stress, the changing nature of careers and the career resilience portfolio	This article explores the implications of increased job stress and changed individual career patterns for people with disabilities.	Literature review	Rehabilitation counselors need to be aware of the complexities of job stress. The changing nature of careers and the increase of stress in the work place suggests the need for a prevention approach to career planning.	E2 Indirect
Putzki 2009[182] Quality of life in 1000 patients with early relapsing remitting multiple sclerosis	The purpose of this study was to examine the quality of life in a large cohort of untreated patients with relapsing remitting MS and to investigate the impact of intramuscular interferon beta-1a treatment.	Design: Prospective, observational, open label, multi-centre study Sample: 1157 PwMS	At baseline QOL was considerably lower than the general population. High disease activity and inability to work were negative predictors of QOL. Treatment with interferon beta-1a attenuates MS disease activity and improves QOL. Inability to work early during the disease is a major challenge for the social security systems.	R 10 P1 High Direct
Rumrill1996[183] Employment and multiple sclerosis: Policy, programming, and research recommendations	This article presents recommendations for policy makers, service providers and consumers to improve the bleak career prospects for Americans with MS.	Opinion	-	E2 Direct
Bishop 2009[29] Sources of information about multiple sclerosis: information seeking	The purpose of this study was to explore the information seeking behaviour of people with MS and to analyse the extent to which	Design: questionnaires	The most frequently identified sources of information about MS and its treatment was physicians or neurologists, followed by the Internet. Age was an important variable in distinguishing the primary information source between the groups. Younger patients were using the Internet	R 10 P1 High Direct

personal, demographic, and MS variables	information source was associated with personal, demographic and illness variables.	Sample: 409 PwMS	and older patients their neurologist. The information is useful in effectively targeting MS information and understanding how people with MS access information.	
Rumrill 1998[184] Improving the career re-entry outcomes for people with MS: a comparison of two approaches	The purpose of this article is to 10 describe the medical and psychological aspects of MS, 2) examine the toll that the illness exacts on career development; and 3) present findings form a quasi-experimental study that attempted to re-engage unemployed people with MS in remunerative work roles.	Design: pre and post telephone interviews including a questionnaire. Group 1: career counseling interview then job match, meet new employer and VR specialist – half day training seminar and then telephone follow up call. Group 2: two telephone contacts and pack of instructional information. Sample: 37 group 1= 23 and group 2 = 14	16 weeks after intervention 30% of participants were employed. Both interventions were equally effective in helping participants secure jobs which provides support for the least intervention approach to the employment needs of people with MS.	R 10 P2 High Direct
Fraser 2003[185] Vocational rehabilitation in MS: A profile of clients seeking services	The present study overviews intake and psychosocial status data gathered during the initial stages of a VR research project at the University of Washington.	Design: questionnaires and interview Sample: 79 PwMS	PwMS present diverse challenges. In addition to the cognitive, physical and sensory problems facing people with MS, they are mid-career professionals who expect to perform well and be commeasurably compensated. Creative home based options, often part time, need to be developed within the context of fatigue experienced by this population over a full working day, especially if work related travel is required. In addition to the financial planning issues, individual psychotherapy or group therapy options need to be available for assisting in emotional self management particularly during the job seeking effort. Individual assessment is critical in understanding these people’s financial and emotional contexts.	R 8 P3 High Direct
Bishop 2000[186] Multiple sclerosis and epilepsy: vocational aspects and best rehabilitation practices	The purpose of this paper is to review the problems that epilepsy and MS present to vocational rehabilitation and the rehabilitation practices that have proved effective in the vocational rehabilitation of people with MS and epilepsy.	Literature review	The literature provides the following vocational assessment practices that should be included in a full assessment: Ecological assessment including: individual factors, functional capacities, cognitive factors, psychosocial factors, environmental factors. The importance of work retention is discussed. While there are similarities in the conditions and the barriers they present to employment there is an acknowledgment that an individual approach needs to be taken with all.	E2 Direct
Johnson 2005[187]	A review of the symptoms, benefits,	Expert opinion	A number of cost benefits need to be weighed by PwMS choosing to	E2

Mitigating the impact of multiple sclerosis on employment	legal rights and resources for people working with MS.		continue/discontinue employment or to pursue a new job path. Professionals providing health care to PwMS should routinely ask about employment and support thoughtful decision making about employment status.	Direct
Fuchs 2009[28] Neuropsychologist	This article describes the evaluation process and the role of the neuropsychologist on a multidisciplinary MS health care team.	Opinion piece	Highlights common cognitive difficulties encountered by people with MS. Identifies how the neuropsychologist may support and interventions that may help the person maintain employment.	E2 Direct
Phillips 2006[188] Predicting continued employment in person with multiple sclerosis	The purpose of this study is to examine the predictors of continued employment among PwMS participating in an ongoing longitudinal study of health promotion and quality of life in MS. TO focus on the employment trends among a cohort of PwMS over a 7 year period.	Design: self report questionnaires Sample: 176 PwMS	At Time 1 all participants were employed and 75% reported full time employment. At Time 7 only 55% reported continued employment. t is important to consider work-environmental factors in addition to disease and demographic factors in the prediction of employment outcomes for PwMS.	R 7 P1 High Direct
Messmer Uccelli 2009[189] Factors that influence the employment status of people with multiple sclerosis: a multi-national study	The aim of this study was to assess the factors that people with MS believe to contribute to their employment status and to determine whether any of these differentiate people with MS who are employed from those who are not employed.	Design: questionnaire Sample: 1141 PwMS	The items that significantly differentiated the groups were related to MS symptoms, workplace environment and financial considerations. While MS influences employment status for many people who face difficult symptoms, aspects like a flexible work schedule and financial security are important and perhaps key to promoting job maintenance among people with MS.	R 6 P1 Medium Direct
Roessler 2007[119] Workplace discrimination outcomes and their predictive factors for adults with multiple sclerosis	The purpose of this articles was to investigate treatment of people with disabilities in the workplace, in this case adults with MS, both in terms of perceived discrimination and discriminations validated by a third party. Also to look at the cause of the discrimination such as discharge, reasonable accommodation and harassment.	Design: retrospective analysis of reports to EEOC Sample: 3258	People with MS in the work force are experiencing stress in their efforts to maintain their employment, especially with respect to the most common issues: discharge, reasonable accommodation, and terms and conditions of employment. Employees with MS can develop the skills needed to cope with discrimination encountered at work based on their capacities to improve job performance if necessary, to solve problems systematically, to request accommodations in an effective manner, to negotiate solutions when conflict occurs, and to communicate work place problems and solutions more appropriately.	R 10 P1 High Direct
Rumrill 2005[191] Multiple sclerosis and work place discrimination: The national EEOC ADA research project	The research questions were what are the employment discrimination experiences of Americans with MS with respect to (1) the demographic characteristics whom file allegations with the EEOC? (2)	Design: retrospective analysis of reports to EEOC Sample: 3258	People with MS were proportionally more; likely than the comparison group to allege discrimination related to reasonable adjustments, terms or conditions of employment, constructive discharge and demotion Also more likely to file allegations of discrimination against employers in the service and financial/insurance/real estate industries, employers with 500 or more workers and employers in the North USA.	R 10 P1 High Direct

	the nature of discrimination alleged to occur? (3) the industry designation, size and location of employers. Plus what are the legal outcomes of charges made?			
Varekamp 2006[192] How can we help employees with chronic diseases to stay at work? A review of interventions aimed at job retention and based on an empowerment perspective	The objective of this study was to describe the characteristics, feasibility and effectiveness of vocational rehabilitation interventions.	Literature review	There is some evidence that vocational rehabilitation interventions that pay attention to training in requesting work accommodations and feelings of self confidence or self efficacy in dealing with work related problems are effective. Medical specialists should pay more attention to work.	E2 Indirect
Gordon 1997[193] Employment issues and knowledge regarding the ADA of person with multiple sclerosis	The purpose of this study was to survey both the illness and employment patterns of persons with MS as well as examine their knowledge about the potential impact the ADA might have on their careers.	Design: postal survey Sample: 141 PwMS	Only 67% had even heard of the ADA. Only 57% reported they felt the ADA would be helpful. Improving the employment status of PwMS depends not only educating employers about the work potential of PwMS, but also providing PwMS with knowledge that employers them to take an active role in identifying needed accommodations.	R 9 P1 High Direct
Crooks 2009[194] Multiple sclerosis and academic work: socio-spatial strategies adopted to maintain employment	The study aims to answer the question: what is it about the specific workplaces in which academic workers are employed that facilitate maintained employment after the onset of MS?	Design: semi-structured interviews Sample: 10	Respondents' adoption of socio-spatial strategies related to travel, spatio-temporal routines, and social networks was central to maintaining a place in the academic workforce. Factors such a flexibility, access to resources, and symptom fluctuation enabled these strategies.	R 7 P2 High Direct
Pack 2009[195] Predicting readiness to return to work in a population with multiple sclerosis	This study aims to show that the following variables entered into a prediction model in the stated order will predict a person's readiness to return to work. The variables, in order of entry were: A) severity of symptoms of MS, B) sufficiency of income, C) educational level, and D) number of services received.	Design: questionnaire Sample: 663 PwMS	Severity of symptoms appeared to predict reported readiness to return to work over other factors however results overall were less than impressive. The results indicated the variable, readiness to return to work, is different than actual return to work and further research is needed in this area.	R 8 P1 High Direct

Appendix 5.1 Ethics: Focus Groups and exploratory trial

NHS

The National Hospital for Neurology and Neurosurgery
& Institute of Neurology Joint REC
(Research and Development)
1st Floor Maple House
149 Tottenham Court Road
London
W1P 9LL

Telephone: 02073809940
Facsimile: 02073809937

KJ/mg/05L 377

26 September 2005

Dr Diane Playford
Senior Lecturer/Honorary Consultant Neurologist
Institute of Neurology
National Hospital for Neurology and Neurosurgery
Queen Square
London
WC1N 3BG

Dear Dr Playford

Full title of study:	**Working yet worried: Evaluation of a model of occupational rehabilitation in MS**
REC reference number:	**05/Q0512/91**

The Research Ethics Committee reviewed the above application at the meeting held on 15 September 2005.

Ethical opinion

The members of the Committee present gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Application Part C		07 August 2005
Application A & B		07 August 2005
Investigator CV Dr Diane Playford		
Protocol	1	
Questionnaire Outcome Measures	1	

Letter of invitation to participant	1	
GP/Consultant Information Sheets	1	16 August 2005
Participant Information Sheet	1	08 August 2005
Participant Consent Form	1	10 August 2005
Funding approval letter from Multiple Sclerosis Society		20 December 2004

Research governance approval

The study should not commence at any NHS site until the local Principal Investigator has obtained final research governance approval from the R&D Department for the relevant NHS care organisation.

Membership of the Committee

The members of the Ethics Committee who were present at the meeting are listed on the attached sheet.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

05/Q0512/91 **Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

Katy Judd.

Ms Katy Judd
Vice-Chair

Email: michael.gilberthorpe@uclh.nhs.uk

Enclosures:	*List of names and professions of members who were present at the meeting and those who submitted written comments* *Standard approval conditions* *Site approval form (SF1)*
Copy to:	*UCL/UCLH* *R&D Department* *1st Floor, Maple House* *149 TCR* *London* *W1P 9LL*

Appendix 5.2 Patient information sheet – focus groups

Patient Information Sheet
Version 3.
Date 18.07.05
Project ID: 05/Q0512/32

1. Study title

Development of a model of occupational rehabilitation for people with Multiple Sclerosis.

2. Invitation

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

Work contributes to adult identity, confers financial benefits and status and can improve quality of life. At diagnosis most people with multiple sclerosis are in full-time education or employment, but many people with MS become unemployed with time. Most studies estimate only 23% to 32% of all those with MS are in work. The reasons for unemployment have been clearly delineated and may be related to the disease itself, or to the working environment and demands of the job. Vocational rehabilitation that aims to help people remain in work, should they want to, is poorly developed in the UK.

The aim of this study is to ask people with MS

1. What they feel a vocational rehabilitation service should offer?
2. How they feel it should be promoted to people with MS?
3. How it should be delivered?

4. Why have I been chosen?

You have been chosen because you have multiple sclerosis and are currently employed or have only recently left your place of work. We want to know what you would find helpful when considering the impact your MS has on your life and work.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Decisions to withdraw at any time, or a decision not to take part, will not affect your future medical care.

6. What will happen to me if I take part and what do I have to do?

You will be asked to attend the hospital for an extra two hours to take part in a 'focus group'. This is a group of 8 to 10 people with MS who, like you, are currently employed or have only recently left work. A researcher will facilitate a discussion around vocational rehabilitation, what you feel such a service should offer, how it should be promoted, and how it should be delivered.

The discussion will be recorded and later, transcribed and anonymised. The recording will be kept for seven years and then destroyed. The recording will be kept in a locked drawer in a locked room and only the research team will have access to it. Similarly the transcription will be kept on password protected computer on a secure network. The transcription will be destroyed after seven years. All data will be stored at the National Hospital for Neurology and Neurosurgery, UCLH Foundation NHS Trust. Dr Diane Playford will be responsible for safety and security of the data

The transcripted discussion will be analysed for ideas which will be grouped into themes. These themes will be used to develop a vocational rehabilitation service which will be the subject of the later study. If you want to, you will be able to attend this vocational rehabilitation service.

Your travel expenses for attendance at this focus group will be reimbursed.

7. What are the alternatives for treatment

Currently vocational rehabilitation services are provided by Disability Employment Advisors (DEA) who are based at 'Jobcentre plus'. You may wish to visit a DEA whether or not you decide to take part in this study.

8. What are the possible disadvantages and risks of taking part?

The disadvantages of taking part in this study is that it will require approximately half a day of your time and this may interfere in you lifestyle or ability to work. You will also be asked to talk about the impact your MS has had on your working life, and this may be upsetting.

9. What are the possible benefits of taking part?

There are no clear benefits to you from taking part in a focus groups. The information we get from this study may help us to provide effective and appropriate vocational rehabilitation services to other patients with MS. If you wish to participate in the study of the vocational rehabilitation service developed from these focus groups you are welcome to do so. We hope that the vocational rehabilitation service will be helpful. However, this cannot be guaranteed.

10. What if something goes wrong?
If you feel that your treatment as part of this study is inappropriate please let Joanna Sweetland, occupational therapist, or Dr Playford know. If you wish to complain you may do so using the UCLH complaints procedure.

11. Will my taking part in this study be kept confidential?
All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

Your GP and your Neurology Consultant will both be informed that you are taking part in the study, unless you prefer that they are not informed.

12. What will happen to the results of the research study?
The results of the research will be available in the summer/autumn 2007. They will be published in a medical journal the following year. The MS society will also publish the results of the study through their magazines and websites. You will not be identified in any report/publication.

13. Who is organising and funding the research?
The Multiple Sclerosis Society is funding the research

14. Who has reviewed the study?
The study has been reviewed by the National Hospital for Neurology and Neurosurgery/Institute of Neurology Joint Research Ethics Committee.

15. Contact for Further Information
If you require any further information please contact Dr Diane Playford, Consultant Neurologist, on 020 7837 3611 ext 3166.

Appendix 5.3 Consent form –focus groups

Form version and date: version 3: 20.07.05

CONSENT FORM

Title of project: Development of a model of occupational rehabilitation for people with Multiple Sclerosis.

Name of Principal investigator: Dr E D Playford
Name of research occupational therapist: Joanna Sweetland

Please initial box

1. I confirm that I have read and understood the information sheet dated 18.07.05 (version 3) for the above study and have had the opportunity to ask questions. ☐
2. I confirm that I have had sufficient time to consider whether or not want to be included in the study ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
4. I understand that sections of any of my medical notes may be looked at by responsible individuals from UCLH Trust or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
5. I agree to take part in the above study. ☐

Continued on next page/

1 form for Patient;
1 to be kept as part of the study documentation,
1 to be kept with hospital notes

Centre Number:
UCLH Project ID number:
Patient Identification Number for this study:
Form version: version 3

CONSENT FORM

Title of project: Development of a model of occupational rehabilitation for people with Multiple Sclerosis.

Name of Principal investigator: Dr E D Playford
Name of research occupational therapist: Joanna Sweetland

_________________________ ____________________ ______________________
Name of patient Date
Signature

___________________ ______________________ ______________________
Name of Person taking consent Date
Signature

Joanna Sweetland j.sweetland@ion.ucl.ac.uk t: 0207837 3611 x 3821
___________________________ _______________________
Researcher (to be contacted Email/phone number

if there are any problems)

Comments or concerns during the study

If you have any comments or concerns you may discuss these with the investigator. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write or get in touch with the Complaints Manager, UCL hospitals. Please quote the UCLH project number at the top this consent form.

Appendix 5.4 Examples of quotes from the Focus Groups

Table 5.5 Quotes from participants identifying problems with performance in the work-place and potential solutions *Quotations are in italics*

Problems	Solutions
Improving task performance restricted by mobility limitation	
I can't go up ladders anymore as my balance is terrible (FG3)	*A quick referral to physiotherapy would help (FG1)*
Improving task performance restricted by fatigue	
I honestly thought I was going to have to retire last year as the fatigue was getting appalling – going on buses and trains and arriving totally shattered – I'd have to sit down for an hour (FG3)	Participants not aware of approaches to fatigue management
Compensating for task performance restricted by bladder dysfunction	
bladder weakness	*My company said they would change my table and move me closer to the toilets FG2*
Compensating for task performance restricted by mobility limitation	
They (the company) encouraged me to take an office on the ground floor so I didn't have to run up and downstairs – there will come at time where I may have to seriously consider working at home (FG3)	*Adapting your work environment such that it is easier for you to get around even to get to and from work would be good. FG1* *I know someone who works for BT and nice; he has got MS and is in a wheelchair, they supplied him a motorised wheelchair, they moved the furniture around and they moved the furniture around – fantastic! FG1*
Compensating for task performance restricted by fatigue	
I honestly thought I was going to have to retire last year as the fatigue was getting appalling, going on tubes and buses, I was arriving totally shattered and would have to sit down for an hour (FG3)	*My company put me onto the Access to Work Scheme; they provided a taxi for me to get to work. It is amazing to arrive at work with energy (FG3) –* information about access to work

Modifying task performance	
I feel like a burden to them that is why I am going part time… (FG3)	*In the beginning it is very confusing and you need to sit down and think, it you know you have somebody it would be good to have somebody to plan (FG3)* - Work specialist therapist to discuss work options with.
Support with disclosure	
When do I disclose? – I don't know (FG2) *If I do disclose prior to getting a new role and then I don't get the promotion, how do I know I have not been discriminated against? (FG1)*	*I think it would be good to have somebody else who went and talked to them about it: "what would you need" … it would help your employer, understand it better because it is coming from a professional. (FG3)*
Support with discrimination & lack of knowledge	
When I came back I never moved up in positions, my pay never increased, my work load got bigger and yet he wouldn't promote me. He would always say 'well you are better staying where you are, you know your condition, it is better not to take on too much' yet unofficially he was giving me more work. (FG1)	*I think you would need a key contact really, a support network, someone who knows you, someone you could go and have lunch with whatever, that they know your issues, rather than ringing up and having to start again a talk to another person you have never met… (FG1)* - Advocate
Most people do not know about the Disability Discrimination Act (DDA) and how it protects them (FG4)	*The legal knowledge is important… you need to know what your rights are... the legalities of MS and how I am supposed to be treated in terms of employment. (FG3)* - Access to Information
Service Delivery	
i) Early following diagnosis	*I think when you are coming in and you have been diagnosed – your doctors or the nurse could tell you they could give you a leaflet – these are the kind of places you can get support. (FG2)* *I am picturing this they diagnose you then they go here is your information pack and land you with a load of stuff… it has to be a period of time... you are diagnosed on the first of the month, they say we give you two months to get used to it then schedule in some sessions you know. (FG2)*

ii) One to one	*I think it would be good to have a one to one service not just a blanket service as everyone with this diagnosis is so different… (FG2)*
iii) Open access	*I think it would be good to have a key contact, someone who knows you, that knows your issues, someone you could go and have lunch with, rather than ringing up and having to talk to a person you have never met (FG2)* *It needs to be ongoing; your symptoms may worsen or suddenly an organisation announces changes (FG4)*
iv) Responsive	*When you need advice or are in a crisis, somebody from the service would be able to get back to you with a reasonably quick response (FG4)*

Appendix 6.1 Patient information sheet – exploratory trial

Version 1.
Date 08.08.05
Project ID: 05/Q0512/91

1. Study title

Working yet worried: development and evaluation of a model of occupational rehabilitation for people with Multiple Sclerosis (MS).

2. Invitation

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

Work contributes to adult identity, confers financial benefits and status and can improve quality of life. At diagnosis most people with MS are in full-time education or employment, but many people with MS become unemployed with time. Most studies estimate only 23% to 32% of all those with MS are in work. The reasons for unemployment have been clearly delineated and may be related to the disease itself, or to the working environment and demands of the job. Vocational rehabilitation that aims to help people remain in work, should they want to, is poorly developed in the UK.

The aim of this study is to run a vocational rehabilitation service specifically to support people with MS in their current places of employment; either to help them maintain their current role, find ways of effectively adapting their role or helping them find alternative employment should they so wish. This will be through either sessions with an occupational therapist or appropriate referral to services which maybe required e.g. physiotherapy or government run schemes.

4. Why have I been chosen?

You have been chosen because you have MS and are currently employed or have only recently left your place of work or are in full time education. We want to involve you with developing the vocational rehabilitation service to meet your needs in the area of work. We aim to recruit at least 25 people to participate in the study.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. You will be given a copy of this consent form for your records. If you decide to take part you are still free to withdraw at any time and without giving a reason. Decisions to withdraw at any time, or a decision not to take part, will not affect your future medical care.

6. What will happen to me if I take part and what do I have to do?

You will be asked to come for an initial assessment, similar to an interview, this will help the occupational therapist to determine your needs and ensure that the service is appropriate to meet your needs; it should last between 1 – 2 hours. You will be asked to complete a pack of questionnaires which should take approximately 20 – 30 minutes. You will then be involved in the service with the time scale being dependant on your needs. We anticipate approximately 6 sessions each of one and half hours duration. These sessions maybe carried out at your home, work place or in therapy outpatients. The frequency of these sessions will be dependent again on your needs so may vary from a weekly meeting to a meeting once a month. At the end of this time you will be asked to complete the same pack of questionnaires, and you could be asked to participate in an interview with a research assistant.

All data will be stored for seven years at the National Hospital for Neurology and Neurosurgery, UCLH Foundation NHS Trust. Dr Diane Playford will be responsible for safety and security of the data

Your travel expenses for attendance at these sessions can be reimbursed.

7. What are the alternatives for treatment

Currently vocational rehabilitation services are provided by Disability Employment Advisors (DEA) who are based at ‘Jobcentre plus’. You may wish to visit a DEA whether or not you decide to take part in this study.

8. What are the possible disadvantages and risks of taking part?

The disadvantages of taking part in this study is that it will require some of your time and may require you to travel to outpatients and this may interfere in you lifestyle or ability to work. You will also be asked to talk about the impact your MS has on your working life, and this may be upsetting.

9. What are the possible benefits of taking part?

The benefits are that you would be participating in a unique service that primary aim is to maintain you in your current job or full time education should you so wish or to explore alternative options with you. It aims to be a bespoke service that meets your needs and offers the appropriate support as required. You will also have opportunity to feedback on the service through participating in an in-depth interview at the end; this will feed into future service development.

10. What if something goes wrong?

If you feel that your treatment as part of this study is inappropriate please let Dr Playford know. If you wish to complain you may do so using the UCLH complaints procedure.

11. Will my taking part in this study be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it.

Your GP and your Neurology Consultant will both be informed that you are taking part in the study, unless you prefer that they are not informed.

12. What will happen to the results of the research study?

The results of the research will be available in the summer/autumn 2007. They will be published in a medical journal the following year. The MS society will also publish the results of the study through their magazines and websites. You will not be identified in any report/publication.

13. Who is organising and funding the research?

The Multiple Sclerosis Society is funding the research

14. Who has reviewed the study?

The study has been reviewed by the National Hospital for Neurology and Neurosurgery/Institute of Neurology Joint Research Ethics Committee.

15. Contact for Further Information

If you require any further information please contact Dr Diane Playford, Consultant Neurologist, on 020 7837 3611 ext 3166.

6.2 OT initial interview form

Name: d.o.b.: Preferred Name:

Hospital No: O/P ☐ Other:

Consultant: M / F M / S / W / D / SEP / CoH

Address: Hand Dominance:

Occupation:

Telephone:

Reason for OT referral:

Referral date:

Role of OT explained ☐

Consent to OT ☐

Consent to Reports ☐

Date of Acceptance:

Date of 1st Session:

Next of Kin: GP:

Telephone: Telephone:

Name of Therapist Signature: Initials:

1.

2.

Precautions:

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

Medical Diagnosis:-

Medical History:-

Medication:-

Performance Components:-

Motor:

Sensory:

Cognitive/Perception:

Interpersonal:

Intrapersonal:

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

SOCIAL/ HOME/WORK ENVIRONMENT

Indicate N/A if not applicable	**Satisfied**	**Intervention: Yes or No**
Social Situation: (Including cultural issues, family role & expectations)		
Home Environment: (Type, ownership, layout, access, stairs)		
Social Work environment: (teamwork, cultural diversity, opportunity to socialise, supervision, friendships, social events)		
Work Environment: (where, office/home, large/small, background noise, spacious/cluttered, light, protective clothing required, safety issues equipment, distance from toilet, stairs, seating, working inside/outside etc)		

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

TIMETABLE AND ROUTINE

	Usual	**Non-usual** - state reason for change
AM		
PM		
Evening		
Midnight ⇓ **AM**		

Weekly Routines:		
Weekend Routines if Different:		

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

PRODUCTIVITY / ROLES

Work ☐ Full time ☐ Part time ☐ Voluntary	Time in current role:
Job Title:	
Employer:	
Work History: (Summary of employment history (paid and unpaid), Patterns of unemployment including how client obtained work, reasons for leaving, periods of unemployment/employment)	
Education and training: (Licences/certificates, Previous experience of education and training including likes, dislikes and interests, Attitude to further education/training, Literacy/numeracy skills, Interest in further study)	
Financial considerations: (Salary, Hours worked, When/how paid, Benefits, Other income into household)	
Other members of household employed:	

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

Main Duties/responsibilities:

Likes/dislikes:

Perception of employer's support: Disclosed: yes ☐ no ☐ If yes when? Response:	**Satisfied**	**Intervention: Yes or No**
Attitude of colleagues:		

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

	Satisfied	Intervention: Yes or No
Travel to work: (e.g. method of transport to work, ease of journey)		
Ergonomic set up:		
Other responsibilities: (e.g. committees/boards etc)		
Supportive factors: (flexibility of hours, child care, IPR, supportive boss, breaks, mentor system)		
Human Resource Management issues: (leave requirements, disciplinary procedures, workload, challenge, working relations, personnel practices, organisational culture, any changes, stress management, discussion of personal life/issues in workplace, training, overtime, promotion opportunities)		
Communication network (diagrammatic representation of network maybe useful, who worker speaks to and what about, mode, informal/formal, written/oral/sign/email)		

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

Perceived problems at work:	**Satisfied**	**Intervention Yes or No**

LEISURE

Past/present Interests/Activities: (Hobbies/interests, club memberships, community involvement responsibilities)	**Satisfied**	**Intervention Yes or No**

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

DAILY ACTIVITIES CHECKLIST

Indicate N/A if not applicable ☐ ☐ ☐ 1 = independent 2 = moderate dependence 3 = totally dependent	**Satisfied**	**Intervention: Yes or No**
Bed: (include type; mobility and transfers) ☐ ☐ ☐		
Indoor Mobility: (include walking aids; wheelchair mobility; general transfer technique; falls) ☐ ☐ ☐		
Toileting: (include aids; transfer) ☐ ☐ ☐		
Bathing/Showering: (include type; aids; transfer) ☐ ☐ ☐		
Personal Washing/Grooming: ☐ ☐ ☐		
Dressing: ☐ ☐ ☐		
Meal Preparation: (include appliances; lifting; reaching; carrying) ☐ ☐ ☐ Breakfast ☐ ☐ ☐ Lunch ☐ ☐ ☐ Dinner ☐ ☐ ☐ Snack		
Feeding: ☐ ☐ ☐		
Management of Medication: ☐ ☐ ☐		
Chair: (include posture/stability in usual chair or wheelchair) ☐ ☐ ☐		

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name: **Therapist:**

Hospital No: **Date:**

☐ ☐ ☐ 1 = independent 2 = moderate dependence 3 = totally dependent	**Satisfied**	**Intervention: Yes or No**
Control of Indoor Environment: (include lights; appliances; doors) ☐ ☐ ☐		
Communication: ☐ ☐ ☐ Verbal (inc. communication aids) ☐ ☐ ☐ Phone ☐ ☐ ☐ Writing ☐ ☐ ☐ Computer		
Housework: ☐ ☐ ☐		
Laundry: ☐ ☐ ☐		
Household Maintenance: ☐ ☐ ☐		
Community Mobility: (include walking; wheelchair mobility; driving; use of public transport) ☐ ☐ ☐		
Shopping: ☐ ☐ ☐		
Finances/Money Management: (include State Benefits) ☐ ☐ ☐		
Other: ☐ ☐ ☐		

Name:	**Therapist:**
Hospital No:	**Date:**

OCCUPATIONAL THERAPY ASSESSMENT SUMMARY

Impairments:

Problems with Activity and Participation: ***** Patient

Priorities

Summary of Initial Assessment:

Therapy and Rehabilitation Services

Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

Long Term Goal / Aim:

Short Term Goals:

Date Set:

Date to be Achieved by:

The National Hospital for Neurology and Neurosurgery
Therapy and Rehabilitation Services
Occupational Therapy Initial Assessment

Name:	**Therapist:**
Hospital No:	**Date:**

NOTES PAGE

CONTACTS

Employer: **Telephone:**	Consent for contact ☐
Disabled Employment Advisor: **Telephone:**	Consent for contact ☐
Occupational Therapist/physiotherapist: **Telephone:**	Consent for contact ☐
MS Nurse: **Telephone:**	Consent for contact ☐
Other: **Telephone:**	Consent for contact ☐

Appendix 6.3 Outcomes measures booklet – exploratory trial

Demographic data:

1. **Are you? (please circle one):**

1	female	2	male

2. **What is your age?** …… (years), **and date of birth?** …...day.….month.….year

3. **To which ethnic group do you belong ?** (please circle one):

National Statistics interim standard classifications for presenting ethnic and national groups data

White	
1. British	2. Irish
3. Other white background	
Mixed	
4. Mixed white and black Caribbean	5. Mixed White and Black African
6. Mixed White and Asian	7. Other mixed background
Asian or British Asian	
8. Indian	9. Pakistani
10. Bangladeshi	11. Other Asian Groups
Black or Black British	
12. Caribbean	13. African
14. Other black backgrounds	
Chinese or other ethnic group	
15. Chinese	
16. Any other ethnic group (please specify) ……………………………..……	

4. **Roughly, when did your MS START?** ……month …… year

5. **Roughly, when was your MS DIAGNOSED?** ……month …… year

6. **Concerning your mobility indoors, please tick the most appropriate box.**

☐ I walk unaided

☐ I use a stick or frame, or hold onto furniture or somebody when walking

☐ I use a wheelchair

7. **Are you? (please circle one):**

1	Single	2	Separated
3	Married	4	Divorced
5	With a partner	6	Widowed

Please check that you have answered all the questions before going on to the next page

8. **Do you live?** (please circle one):

1 Alone

2 With others (e g family, friends)

9. **Are you?** (please circle one):

1 Employed

2 Retired due to your MS

3 Self-employed

4 Retired for other reasons

5 Unemployed

6 A student

10. **Educational levels:** (please tick the one which is most relevant)

a. No qualification

b. Other qualification

c. GCE’s, GCSE’s, NVQ level 1or equivalent

d. A levels, NVQ level 2/3 or equivalent

e. Degree or equivalent

f. Post graduate qualification e.g. masters, Phd

Please specify your highest qualification: ……………………………………………………

11. **(a) Details of past or present job**:

What is (or was) your **main** occupation?………………………………………………………..

Full job title? ……………………………………………………………………………………

What do (did) you actually do in this job?……………………………………………..............

…………………………………………………………………………………………..………..………

……………………………………………………………………………………..

What does (did) your employer make or do (or you, if you are or were self-employed)?

………………………………………………………………………………………………

11. **(b) And for people with partners**:

What is (or was) your husband/wife/partner’s **main** occupation?

…………………………………………………………………………………………...

Full job title?..

What does (did) he/she actually do in this job?

………

……………………………..……..……………….………………………

What does (did) his/her employer make or do (or if he/she is or was self-employed)?

……………………………………………………………………………………………..……

Please check that you have answered all the questions before going on to the next page

Transition Question

Do you feel you can meet the demands of your work?

Please tick the statement which most applies to your current situation.

☐ I cannot meet any of the demands of my work
☐ I cannot meet most of the demands of my work
☐ I can meet some of the demands of my work
☐ I can meet most of the demands of my work
☐ I can meet all of the demands of my work with ease

Only answer the question below if you have been actively involved with the service and are completing this booklet for the second or third time.

How much did the service change whether you feel you can meet the demands of your work? Compared to before, do you now feel you can meet the demands of your work?

☐ Much worse

☐ Moderately worse

☐ Slightly worse

☐ No change

☐ Slightly better

☐ Moderately better

☐ Much better

Please check that you have circled ONE number for EACH question

MS work Instability Scale

Please read each statement thinking about your Multiple Sclerosis.
Please choose the response that applies to you *at the moment:*

Please tick ✓ one

	TRUE	NOT TRUE
1. I push myself to keep working	☐	☐
2. I don't have enough energy to do my job like I used to	☐	☐
3. As the day goes on my condition gets worse	☐	☐
4. My job is physically impossible	☐	☐
5. People treat me differently	☐	☐
6. There are some things I can't do any longer at work	☐	☐
7. I have to pace myself	☐	☐
8. I feel guilty about getting others to help me	☐	☐
9. It takes me longer to do some things at work	☐	☐
10. I don't like to ask for help	☐	☐
11. It is affecting the feeling in my hands	☐	☐
12. My hands are clumsy now	☐	☐
13. My employers are not supportive	☐	☐
14. Its painful walking	☐	☐
15. My hands don't seem to work properly	☐	☐
16. Sometimes in the afternoon I can get really, really tired	☐	☐
17. I push myself to go to work because I don't want to give in to my condition	☐	☐
18. If I don't reduce my hours I may have to give up work	☐	☐
19. I have to be careful not to overdo it at work	☐	☐
20. I have to rely on other people for some parts of my job	☐	☐
21. I am more tired than I used to be	☐	☐

Please check you have ticked a box for every statement on this page

Please check that you have circled ONE number for EACH question

MS Walking Scale

- These questions ask about **limitations to your walking** due to MS **during the past two weeks**.
- For each statement, please **circle** the **one** number that best describes your degree of limitation.
- Please answer **all** questions even if some seem rather similar to others, or seem irrelevant to you.
- **If you cannot walk at all**, please tick this box. ☐

In the past two weeks, how much has your MS …	Not at all	A little	Mod-erately	Quite a bit	Extrem-ely
1. Limited your ability to walk?	1	2	3	4	5
2. Limited your ability to run?	1	2	3	4	5
3. Limited your ability to climb up and down stairs?	1	2	3	4	5
4. Made standing when doing things more difficult?	1	2	3	4	5
5. Limited your balance when standing or walking?	1	2	3	4	5
6. Limited how far you are able to walk?	1	2	3	4	5
7. Increased the effort needed for you to walk?	1	2	3	4	5
8. Made it necessary for you to use support when walking indoors (e.g. holding on to furniture, using a stick, etc)?	1	2	3	4	5
9. Made it necessary for you to use support when walking outdoors (e.g. using a stick, a frame, etc)?	1	2	3	4	5
10. Slowed down your walking?	1	2	3	4	5
11. Affected how smoothly you walk?	1	2	3	4	5
12. Made you concentrate on your walking?	1	2	3	4	5

Please check that you have circled ONE number for EACH question

Postal Barthel Index

These are some questions about your ability to look after yourself. They may not seem to apply to you. Please answer them all. Tick one box in each section

1. **Bathing…** **In the bath or shower, do you:**

   ☐ manage on your own? (Remember - tick one box only)

   ☐ need help getting in and out?

   ☐ need other help?

   ☐ never have a bath or shower?

   ☐ need to be washed in bed?

2. **Transfer…** **Do you move from bed to chair:**

   ☐ on your own? (Remember - tick one box only)

   ☐ with a little help from one person?

   ☐ with a lot of help from one or more people?

   ☐ not at all?

3. **Dressing…** **Do you get dressed:**

   ☐ without any help? (Remember - tick one box only)

   ☐ just with help with buttons?

   ☐ with someone helping you most of the time?

Please check that you have circled ONE number for EACH question

4. **Feeding… Do you eat food:**

☐ without any help? (Remember - tick one box only)

☐ with help cutting food or spreading butter?

☐ with more help?

5. **Mobility… Do you walk indoors:**

☐ without any help?

☐ without any help apart from a frame?

☐ with one person watching over you?

☐ with one person helping you?

☐ with more than one person helping?

☐ not at all?

☐ or do you use a wheelchair independently (e.g. round corners)?

6**. Stairs… Do you climb stairs at home:**

☐ without any help? (Remember - tick one box only)

☐ with someone carrying your frame?

☐ with someone encouraging you?

☐ with physical help?

☐ not at all?

☐ don't have stairs?

Please check that you have circled ONE number for EACH question

7. **Toilet use… Do you use the toilet or commode:**

☐ without any help? (Remember - tick one box only)

☐ with some help but can do something?

☐ with quite a lot of help?

8. **Grooming. Do you brush your hair and teeth, wash your face and shave:**

☐ without help? (Remember - tick one box only)

☐ with help?

9. **Bladder… Are you incontinent of urine?**

☐ never (Remember - tick one box only)

☐ less than once a week

☐ less than once a day

☐ more often

☐ or do you have a catheter managed for you?

10. **Bowels… Do you soil yourself?**

☐ never (Remember tick one box only)

☐ occasional accident

☐ all the time

☐ or do you need someone to give you an enema?

Please check that you have circled ONE number for EACH question

General Health Questionnaire (GHQ-12)

- We should like to know if you have had any medical complaints and how your health has been, over the past few weeks
- Remember that we want to know about present and recent complaints, not about those you have had in the past

Have you recently:

1. Been able to concentrate on whatever you're doing?	better than usual	same as usual	worse than usual	much worse than usual
2. Lost much sleep over worry?	not at all	no more than usual	rather more than usual	much more than usual
3. Felt that you are playing a useful part in things?	more so than usual	same as usual	less useful than usual	much less useful
4. Felt capable of making decisions about things?	more so than usual	same as usual	less so than usual	much less capable
5. Felt constantly under strain?	not at all	no more than usual	rather more than usual	much more than usual
6. Felt you couldn't overcome your difficulties?	not at all	no more than usual	rather more than usual	much more than usual
7. Been able to enjoy your normal day-to-day activities?	more so than usual	same as usual	less so than usual	much less than usual
8. Been able to face up to your problems?	more so than usual	same as usual	less able than usual	much less able
9. Been feeling unhappy and depressed?	not at all	no more than usual	rather more than usual	much more than usual
10. Been losing confidence in yourself?	not at all	no more than usual	rather more than usual	much more than usual
11. Been thinking of yourself as a worthless person?	not at all	no more than usual	rather more than usual	much more than usual
12. Been feeling reasonably happy, all things considered?	more so than usual	about same as usual	less so than usual	much less than usual

Please check that you have circled ONE number for EACH question

MS Impact Scale (MSIS-29)

- The following questions ask for your views about the impact of MS on your day-to-day life **during the past two weeks**
- For each statement, please **circle** the **one** number that **best** describes your situation
- Please answer **all** questions

In the past two weeks, how much has your MS limited your ability to …	Not at all	A little	Mod-erately	Quite a bit	Extreme-ly
1. Do physically demanding tasks?	1	2	3	4	5
2. Grip things tightly (e.g. turning on taps)?	1	2	3	4	5
3. Carry things?	1	2	3	4	5

In the past two weeks, how much have you been bothered by …	Not at all	A little	Mod-erately	Quite a bit	Extreme-ly
4. Problems with your balance?	1	2	3	4	5
5. Difficulties moving about indoors?	1	2	3	4	5
6. Being clumsy?	1	2	3	4	5
7. Stiffness?	1	2	3	4	5
8. Heavy arms and/or legs?	1	2	3	4	5
9. Tremor of your arms or legs?	1	2	3	4	5
10. Spasms in your limbs?	1	2	3	4	5
11. Your body not doing what you want it to do?	1	2	3	4	5
12. Having to depend on others to do things for you?	1	2	3	4	5

Please check that you have circled ONE number for EACH question

In the <u>past two weeks</u>, how much have you been bothered by …	Not at all	A little	Mod-erately	Quite a bit	Extreme-ly
13. Limitations in your social and leisure activities at home?	1	2	3	4	5
14. Being stuck at home more than you would like to be?	1	2	3	4	5
15. Difficulties using your hands in everyday tasks?	1	2	3	4	5
16. Having to cut down the amount of time you spent on work or other daily activities?	1	2	3	4	5
17. Problems using transport (e.g. car, bus, train, taxi, etc.)?	1	2	3	4	5
18. Taking longer to do things?	1	2	3	4	5
19. Difficulty doing things spontaneously (e.g. going out on the spur of the moment)?	1	2	3	4	5
20. Needing to go to the toilet urgently?	1	2	3	4	5
21. Feeling unwell?	1	2	3	4	5
22. Problems sleeping?	1	2	3	4	5
23. Feeling mentally fatigued?	1	2	3	4	5
24. Worries related to your MS?	1	2	3	4	5
25. Feeling anxious or tense?	1	2	3	4	5
26. Feeling irritable, impatient, or short tempered?	1	2	3	4	5
27. Problems concentrating?	1	2	3	4	5
28. Lack of confidence?	1	2	3	4	5
29. Feeling depressed?	1	2	3	4	5

Please check that you have circled ONE number for EACH question

Medical Outcomes Study Short-Form 36-item Health Survey (SF-36)

- This survey asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities
- Answer every question by marking the answer as indicated
- If you are unsure about how to answer a question, please give the best answer you can

1. In general would you say your health is:

	Circle one
Excellent……………………………………..	**1**
Very good……………………………………	**2**
Good…………………………………	**3**
Fair……………………………………..	**4**
Poor…………………………………….	**5**

2. Compared to one year ago, how would you rate your health in general now?

	Circle one
Much better now than one year ago………	**1**
Somewhat better now than one year ago..	**2**
About the same……………………………..	**3**
Somewhat worse now than one year ago..	**4**
Much worse than one year ago……………	**5**

Please check that you have answered all the questions.

3. The following are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

Circle one number on each line	Yes limited a lot	Yes limited a little	No not limited at all
a. **Vigorous activities, such as running, lifting heavy objects participating in strenuous activities**	**1**	**2**	**3**
b. **Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf**	**1**	**2**	**3**
c. **Lifting or carrying groceries**	**1**	**2**	**3**
d. **Climbing several flights of stairs**	**1**	**2**	**3**
e. **Climbing one flight of stairs**	**1**	**2**	**3**
f. **Bending, kneeling or stooping**	**1**	**2**	**3**
g. **Walking more than a mile**	**1**	**2**	**3**
h. **Walking half a mile**	**1**	**2**	**3**
i. **Walking 100 yards**	**1**	**2**	**3**
j. **Bathing and dressing yourself**	**1**	**2**	**3**

Please check that you have answered all the questions.

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Circle one number on each line	Yes	No
a. **Cut down on the amount of time you spent on work or other activities**	**1**	**2**
b. **Accomplished less than you would like**	**1**	**2**
c. **Were limited in the kind of work or other activities**	**1**	**2**
d. **Had difficulty performing the work or other activities (e.g. it took extra effort)**	**1**	**2**

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Circle one number on each line	Yes	No
a. Cut down on the amount of time you spent on work or other activities	**1**	**2**
b. Accomplished less than you would like	**1**	**2**
c. Didn’t do work or other activities as carefully as usual	**1**	**2**

Please check that you have answered all the questions.

6. **During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?**

	Circle one
Not at all	**1**
Slightly	**2**
Moderately	**3**
Quite a bit	**4**
Extremely	**5**

7. **How much bodily pain have you had during the past 4 weeks?**

	Circle one
None	**1**
Very mild	**2**
Mild	**3**
Moderate	**4**
Severe	**5**
Very severe	**6**

8. **During the past 4 weeks, how much did pain interfere with your normal work (including work both outside the home and housework)?**

	Circle one
Not at all	**1**
Slightly	**2**
Moderately	**3**
Quite a bit	**4**
Extremely	**5**

Please check that you have answered all the questions.

9. These questions are about how you feel and how things have been during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks

Circle one number on each line	**All of the time**	**Most of the time**	**A good bit of time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and low?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

Please check that you have answered all the questions.

10. During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends, relatives etc?

Circle one

All of the time……………………………….. 1
Most of the time…………………………… 2
Some of the time…………………………… 3
A little of the time…………………………... 4
None of the time..………………………….. 5

11. How true or false is each of the following statements for you?

Statement	**Definitely true**	**Mostly true**	**Not sure**	**Mostly false**	**Definitely false**
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Please check that you have answered all the questions.

Work Limitations Questionnaire ©

Instructions

Health problems can make it difficult for working people to perform certain parts of their jobs. We are interested in learning about how your health may have affected you at work during the past 2 weeks.

(1) The questions will ask you to think about your physical health or emotional problems. These refer to any ongoing or permanent medical conditions you may have and the effects of any treatments you are taking for these. Emotional problems may include feeling depressed or anxious.

(2) Most of the questions are multiple choice. They ask you to answer by placing a mark in a box.

Questions 1 through 5 ask about how your health has affected you at work during the past 2 weeks. Please answer these questions even if you missed some workdays.

- Mark the “Does not apply to my job” box only if the question describes something that is not part of your job.
- If you have more than one job, report on your main job only.

1. In the past 2 weeks, how much of the time did your physical health or emotional problems make it difficult for you to do the following?

	Difficult all of the time (100%)	Difficult most of the time	Difficult some of the time (about 50%)	Difficult a slight bit of the time	Difficult none of the time (0%)	Does not apply to my job
a. get going easily at the beginning of the workday	☐1	☐2	☐3	☐4	☐5	☐6
b. start on your job as soon as you arrived at work	☐1	☐2	☐3	☐4	☐5	☐6

(Mark one box on each line a. and b.)

Please check that you have answered all the questions.

These questions ask you to rate the amount of time you were able to handle certain parts of your job without difficulty.

2. a. In the past 2 weeks, how much of the time were you able to sit, stand, or stay in one position for longer than 15 minutes while working, without difficulty caused by physical health or emotional problems?

(Mark one box.)

Able all of the time (100%)	☐1
Able most of the time	☐2
Able some of the time (about 50%)	☐3
Able a slight bit of the time	☐4
Able none of the time (0%)	☐5
Does not apply to my job	☐6

b. In the past 2 weeks, how much of the time were you able to repeat the same motions over and over again while working, without difficulty caused by physical health or emotional problems?

(Mark one box.)

Able all of the time (100%)	☐1
Able most of the time	☐2
Able some of the time (about 50%)	☐3
Able a slight bit of the time	☐4
Able none of the time (0%)	☐5
Does not apply to my job	☐6

Please check that you have answered all the questions.

This question asks about difficulties you may have had at work.

3. In the past 2 weeks, how much of the time did your physical health or emotional problems make it difficult for you to concentrate on your work?

(Mark one box.)

Difficult all of the time (100%)	☐1
Difficult most of the time	☐2
Difficult some of the time (about 50%)	☐3
Difficult a slight bit of the time	☐4
Difficult none of the time (0%)	☐5
Does not apply to my job	☐6

The next question asks about difficulties in relation to the people you came in contact with while working. These may include employers, supervisors, coworkers, clients, customers, or the public.

4. In the past 2 weeks, how much of the time did your physical health or emotional problems make it difficult for you to speak with people in-person, in meetings or on the phone?

(Mark one box.)

Difficult all of the time (100%)	☐1
Difficult most of the time	☐2
Difficult some of the time (about 50%)	☐3
Difficult a slight bit of the time	☐4
Difficult none of the time (0%)	☐5
Does not apply to my job	☐6

Please check that you have answered all the questions.

These questions ask about how things went at work overall.

5. In the past 2 weeks, how much of the time did your physical health or emotional problems make it difficult for you to do the following?

(Mark one box on each line a. and b.

	Difficult all of the time (100%)	Difficult most of the time	Difficult some of the time (about 50%)	Difficult a slight bit of the time	Difficult none of the time (0%)	Does not apply to my job
a. handle the workload	☐1	☐2	☐3	☐4	☐5	☐6
b.. finish work on time	☐1	☐2	☐3	☐4	☐5	☐6

Please check that you have answered all the questions.

Impact on Work Questionnaire

We are interested in how each of the following impacts on your ability to work. For each statement, please circle one answer that best describes your situation.

How much does…	Impact on your work (please circle)				
Fatigue	Not at all	A little	Moderately	Quite a bit	Extremely
Balance	Not at all	A little	Moderately	Quite a bit	Extremely
Walking difficulties	Not at all	A little	Moderately	Quite a bit	Extremely
Visual problems	Not at all	A little	Moderately	Quite a bit	Extremely
Weakness	Not at all	A little	Moderately	Quite a bit	Extremely
Handwriting	Not at all	A little	Moderately	Quite a bit	Extremely
Pain	Not at all	A little	Moderately	Quite a bit	Extremely
Coordination	Not at all	A little	Moderately	Quite a bit	Extremely
Speech	Not at all	A little	Moderately	Quite a bit	Extremely
Swallowing	Not at all	A little	Moderately	Quite a bit	Extremely
Continence	Not at all	A little	Moderately	Quite a bit	Extremely
Concentration	Not at all	A little	Moderately	Quite a bit	Extremely
Memory	Not at all	A little	Moderately	Quite a bit	Extremely
Mood	Not at all	A little	Moderately	Quite a bit	Extremely
Travel to work	Not at all	A little	Moderately	Quite a bit	Extremely
Access at work	Not at all	A little	Moderately	Quite a bit	Extremely
Public attitudes	Not at all	A little	Moderately	Quite a bit	Extremely

Please check that you have answered all the questions.

Work Productivity and Activity Impairment Questionnaire:

Specific Health Problem V2.0 (WPAI:SHP – MS)

The following questions ask about the effect of your multiple sclerosis (MS) on your ability to work and perform regular activities. *Please fill in the blanks or circle a number, as indicated.*

1. Are you currently employed (working for pay)? _____ NO ___ YES

If NO, check "NO" and skip to question 6

The next questions are about the **past seven days**, not including today.

2. During the past seven days, how many hours did you miss from work because of problems associated with your MS? *Include hours you missed on sick days, times you went in late, left early, etc., because of your MS. Do not include time you missed to participate in this study.*

_____ HOURS

3. During the past seven days, how many hours did you miss from work because of any other reason, such as vacation, holidays, time off to participate in this study?

_____HOURS

4. During the past seven days, how many hours did you actually work?

_____HOURS *(If "0", skip to question 6.)*

5. During the past seven days, how much did your MS affect your productivity while you were working?

Think about days you were limited in the amount or kind of work you could do, days you accomplished less than you would like, or days you could not do your work as carefully as usual. If MS affected your work only a little, choose a low number. Choose a high number if MS affected your work a great deal.

Please check that you have answered all the questions.

Consider only how much MS affected
productivity while you were working.

MS had no effect on my work	0	1	2	3	4	5	6	7	8	9	10	MS completely prevented me from working

CIRCLE A NUMBER

6. During the past seven days, how much did your MS affect your ability to do your regular daily activities, other than work at a job?

By regular activities, we mean the usual activities you do, such as work around the house, shopping, childcare, exercising, studying, etc. Think about times you were limited in the amount or kind of activities you could do and times you accomplished less than you would like. If health problems affected your activities only a little, choose a low number. Choose a high number if health problems affected your activities a great deal.

Consider only how much MS affected your ability
to do your regular daily activities, other than work at a job.

MS had no effect on my daily activities	0	1	2	3	4	5	6	7	8	9	10	MS completely prevented me from doing my daily activities

CIRCLE A NUMBER

WPAI:SHP V2.0 (US English)

Please check that you have answered all the questions.

Work Assessment Scale For Persons With Multiple Sclerosis ©

Some situations make it difficult for some persons with MS to do their work and/or chores. Lists of these situations are described below. Tick (√) the frequency that you experience difficulty in these situations while doing your work and/or chores.

Makes Work Difficult	Never 0	Almost Never 1	Occa-sionally 2	Usually 3	Almost Always 4	Always 5
Physical Restrictions Balance						
Coordination						
Standing						
Walking						
Climbing						
Restricted mobility						
Use of cane/crutches						
Grasping objects						
Writing						
Typing						
Cutting things						
Cooking						
Other finger/hand activities						
Lifting objects						
Using heavy equipment						
Other, describe___________						

Please check that you have answered all the questions.

Makes Work Difficult	Never 0	Almost Never 1	Occa-sionally 2	Usually 3	Almost Always 4	Always 5
Symptoms Fatigue						
Spasms						
Numbness/tingling						
Weakness						
Stiffness						
Headache						
Backache						
Pain						
Dizziness						
Visual problems						
Memory loss						
Confusion						
Disinterest						
Anxiety						
Environment ***Non-barrier free**						
Carpeted floors						
Displaced objects						
Other, describe__________						

***Non-barrier free** means that accommodations have not been made for handicapped persons (for example, no ramps or railings, narrow doorways, etc.).

Please check that you have answered all the questions.

Even when various situations make it difficult for you to do your work and/or chores, a number of conditions and activities make it easier. A list of some of these conditions and activities are described below. Check (√) the frequency that you use them in doing your work and/or chores.

Makes Work Easier	Never 0	Almost Never 1	Occa-sionally 2	Usually 3	Almost Always 4	Always 5
Job Adjustments Sit down job						
Adjusted work schedule						
Self-paced activities						
Plan tasks when energy is Highest						
Other, describe______						
Environmental Adjustment/ Adaptive Devices Adaptive equipment/devices						
Convenience supplies/ food/equipment						
Conveniently arranged Supplies						
Barrier-free environment						
Other, describe_______						
Support Emotional support						
Financial support/insurance						
Assistance with tasks						
Other, describe____________						

Please check that you have answered all the questions.

Makes Work Easier	Never 0	Almost Never 1	Occa-sionally 2	Usually 3	Almost Always 4	Always 5
Personal Attributes Positive attitude						
Sense of humor						
Faith and hope						
Control of stress						
Other, describe____________						
Personal Health Habits Good night's sleep						
Intermittent rest periods						
Good nutrition						
Peaceful atmosphere						
Other, describe____________						

Please check that you have answered all the questions.

Appendix 8.1 Ethics: RCT

National Research Ethics Service
The National Hospital for Neurology and Neurosurgery
& Institute of Neurology Joint REC
Research & Development
1st Floor, Maple House
Ground Floor, Rosenheim Wing
25 Grafton Way
London
WC1E 5DB
Tel: 020 7380 9940
Fax: 020 7380 9937
Email: sasha.vandayar@uclh.nhs.uk
Website: www.uclh.nhs.uk
4130
Facsimile: 0207 905 2201

Dr Diane Playford
Senior Lecturer/Honorary Consultant Neurologist
Institute of Neurology
National Hospital for Neurology and Neurosurgery
Queen Square
London
WC1N 3BG

Our Ref: 07L 243

06 September 2007

Dear Dr Playford

Full title of study:	**To evaluate an early intervention model of occupational rehabilitation for people with Multiple Sclerosis**
REC reference number:	**06/Q0512/71**

Thank you for your letter of 13 August 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Sub-Committee of the REC held on 22 August 2007. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the research site(s) taking part in this study. The favourable opinion does not therefore apply to any site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at sites requiring SSA.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application	5.1	14 July 2006

Investigator CV		12 July 2006
Protocol	1	12 July 2006
Covering Letter	1	10 August 2007
Statistician Comments	1	01 August 2007
Questionnaire: MS work Instability Scale	1	12 July 2006
Questionnaire: MS Impact Scale	1	12 July 2006
Questionnaire: General Health Questionnaire	1	12 July 2006
Questionnaire: Impact on Work Questionnaire	1	12 July 2006
Questionnaire: Transition Question	1	12 July 2006
Participant Information Sheet	1	10 July 2006
Participant Information Sheet	2	17 October 2006
Participant Consent Form	1	10 July 2006
Response to Request for Further Information	1	13 August 2007
Response to Request for Further Information	1	01 August 2007
Email		07 February 2007
Grant Reference Confirmation	1	13 June 2006
Adapted Client Service Receipt Inventory	1	12 July 2006

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from http://www.rdforum.nhs.uk/rdform.htm.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Feedback on the application process

Now that you have completed the application process you are invited to give your view of the service you received from the National Research Ethics Service. If you wish to make your views known please use the feedback form available on the NRES website at:

https://www.nresform.org.uk/AppForm/Modules/Feedback/EthicalReview.aspx

We value your views and comments and will use them to inform the operational process and further improve our service.

06/Q0512/71	**Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

pp

Mrs Katy Judd
Chair

Email: S.Vandayar@ich.ucl.ac.uk

Enclosures: *List of names and professions of members who were present at the meeting.*

Copy to: R&D office for UCLH

Appendix 8.2 Patient information sheet

Patient Information Sheet
Version 2.
Date 23.01.07
UCLH Project ID number: 06/Q0512/71

1. Study title

To evaluate an early intervention model of occupational rehabilitation for people with Multiple Sclerosis (MS).

2. Invitation

You are being invited to take part in a research study. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

3. What is the purpose of the study?

There is growing awareness that a diagnosis of MS has an impact on how people feel about working. At diagnosis most people with multiple sclerosis are in full-time education or employment. However, people may experience a number of practical and emotional difficulties at work including how to tell their colleagues. We have already conducted some research that suggests many of these difficulties can be managed. Services that work towards managing these difficulties are said to provide 'vocational rehabilitation'. Currently we do not know whether vocational rehabilitation for people with Multiple Sclerosis is useful or cost effective. Thus, the aim of this study is to identify whether a vocational rehabilitation intervention provided by an occupational therapist at or shortly after diagnosis with MS is effective at helping people remain in work in the long term.

4. Why have I been chosen?

You have been chosen because you have been recently diagnosed with multiple sclerosis and are currently employed or studying.

5. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Decisions to withdraw at any time, or a decision not to take part, will not affect your future medical care.

6. What is involved in the study?

If you agree to take part you will be assigned to one of two different groups. Because we do not know if the vocational rehabilitation intervention will be helpful, we need to make comparisons.   You will have a fifty-fifty chance of being in either group A or group B.

One group, group A, will undergo ‘current best practice’. They will be provided with an information sheet that describes sources of help and advice for people with MS in the work place. If they have any questions about working with MS, the MS nurse will be able to offer advice.

The second group, group B, will be offered a vocational rehabilitation intervention with an occupational therapist. An occupational therapist (OT) is a health care professional who works with people on everyday tasks such as managing work and leisure. We anticipate that each person in this group will meet with the OT on three occasions. In total we think that this will take no more than 5 hours with the OT and any associated travelling time. Travel expenses for attendance at these sessions can be reimbursed.

At the initial meeting the individual and the occupational therapist will work to identify any current or potential difficulties in the work place and their solutions. The second session will focus on the practical implementation of any proposed solutions. The third session will be a review to ensure all the areas identified at the first meeting have been addressed. These meetings maybe carried out at the hospital or the work place. The timing of these sessions will be determined by the participant.

Whether you are in group A or group B we will you ask to complete some questionnaires which focus on the impact of MS on work. These will also ask for details about your occupation and income. They will be sent to your home by post and will take no more than 30 minutes to complete. You will be asked to complete these at the beginning of the study and every 6 months for five years.

7. What is the procedure being tested?

A brief vocational rehabilitation intervention delivered by an occupational therapist for people with MS in the period following diagnosis. This intervention has been designed with people with MS and used in a small number of people with MS to check that it is both practical and acceptable.

8. What are the alternatives for treatment?

Currently vocational rehabilitation services are provided by Disability Employment Advisors (DEA) who are based at ‘Jobcentre plus’. You may wish to visit a DEA whether or not you decide to take part in this study.

9. What are the possible disadvantages and risks of taking part?

The disadvantages of taking part in this study is that it will require some of your time and may require you to travel to outpatients and this may interfere in you lifestyle or ability to work. You will also be asked to talk about the impact your MS has on your working life, and this may be upsetting.

10. What are the possible benefits of taking part?
The benefits are that you would be participating in a new service that aims to support you in your working life. It aims to be a service that responds to your needs and offers information and support as required.

11. The information held about the research subject.
All information which is collected about you during the course of the research will be kept strictly confidential. The information we collect from you during the study will be stored on a computer during this research project. All data will be stored for seven years after completion of the project at the National Hospital for Neurology and Neurosurgery, UCLH Foundation NHS Trust. Dr Diane Playford will be responsible for safety and security of the data. The data will not made available to anyone other than the research team lead by Dr Playford.

Your GP and your Neurology Consultant will both be informed that you are taking part in the study, unless you prefer that they are not informed. With your consent, letters and reports will be sent to your consultant and GP to update them on your contact with the service.

12. What happens when the research study stops?
Currently there are no vocational rehabilitation services tailored to the needs of people with MS, thus we cannot guarantee that there will be a continuation of the service after completion of the study. However, we will be able to suggest alternative services such as those based at your local Jobcentreplus or provided by community rehabilitation teams.

13. What if something goes wrong?
If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain, or have any concerns about this study, the normal National Health Service mechanisms re available to you.

14. What will happen to the results of the research study?
The preliminary results of the research will be available in the summer/autumn 2009. They will be published in a medical journal the following year. The MS society will also publish the results of the study through their magazines and websites. You will not be identified in any report/publication.

The final results will be available in 2012 and will be published in a medical journal and via the MS Society.

15. Who is organising and funding the research?

The Multiple Sclerosis Society and the College of Occupational Therapists are funding the research

16. Who has reviewed the study?

The study has been reviewed by the National Hospital for Neurology and Neurosurgery/Institute of Neurology Joint Research Ethics Committee.

17. Contact for Further Information

If you require any further information please contact Dr Diane Playford, Consultant Neurologist, on 0845 155500 ext 723166.

Appendix 8.3 Control Group information sheet

Employment Information sheet

There are sources of support available in the community to address issues around work:

Occupational Therapy (OT)

Occupational therapy enables people to achieve health, well being and life satisfaction through participation in every day activities. OTs work in hospital and community settings. OTs are skilled at providing therapy to improve people's performance, modifying tasks and environment and compensating where required to maximise a person's abilities. You can contact an OT either through your hospital or or your local community services asking for the community neurology team. Be sure to ask your OT if they address work related problems. For online advice go to: www.cot.org.uk/public/findinganot/intro.php

Disabled Employment Advisor (DEA)

DEAs provide specialist support to people who are recently disabled, or those whose disability or health condition has deteriorated and who need employment advice. They provide advice to disabled people applying for work and also to employed people who are concerned about losing their job because of a disability. They're based in JobcentrePlus www.jobcentreplus.gov.uk. It is worth remembering they are not experts in MS and may need educating about the condition.

Access to Work Scheme (AtW)

AtW is available to help overcome the problems resulting from disability. It offers practical advice and help in a flexible way that can be tailored to suit the needs of an individual in a particular job. AtW does not replace the normal responsibilities of the employer to implement Health and Safety regulations or replace the responsibilities required by the Disability Discrimination Act. It does this by giving advice and information to disabled people and employers, Jobcentre Plus pays a grant, through AtW, towards any extra employment costs that result from a person's disability.
You can self refer (London telephone: 020 8218 2734) or go through a DEA.

MS Society legal advice

The disability law service has a dedicated line for people with MS. They can offer one off advice but are unable to offer support www.dls.org.uk
Telephone: 020 7791 9816 Email: advice@dls.org.uk

MS and Work booklets

- 'Working with MS' the MS Society booklet. Can be ordered directly from the MS Society website www.mssociety.org.uk or telephone: 020 8438 0700
- 'At work with MS' the MS Trust booklet. Can be ordered directly from the MS Trust website www.mstrust.org.uk or telephone: 01462 476700

Occupational Health

Many firms have an occupational health physician who they can utilise. Either based in the company or contracted in as required. This physician can assess your medical status and advise your firm on changes that maybe required at work. If your company does not have one you can look on the NHS website for further support www.nhsplus.nhs.uk

Union representation
Union representatives can often be a strong a powerful advocate should you require this support in difficult circumstances www.tuc.org.uk

Useful websites:

Equality and Human Rights Commission is working to eliminate discrimination, reduce inequality, protect human rights and to build good relations, ensuring that everyone has a fair chance to participate in society. It has a dedicated directorate of expert lawyers who are specialists in equality law. This means that the commission is well equipped to take legal action on behalf of individuals, especially where there are strategic opportunities to push the boundaries of the law. It also has a free and confidential conciliation service offering an effective alternative route to court action, when a breach of the Disability Discrimination Act may have occurred.
www.equalityhumanrights.com
Helpline: 08457 622 633 (Mon, Tue, Thu, Fri 9:00 am-5:00 pm; Wed 8:00 am-8:00 pm)
Email enquiries: englandhelpline2@equalityhumanrights.com

Advisory, Conciliation and Arbitration Service (ACAS) improve organisations and working life through better employment relations. They provide up-to-date information, independent advice, high quality training and we work with employers and employees to solve problems and improve performance.
www.acas.org.uk

Directgov Informative government site covering a range of issues including work including a summary of The Disability Discrimination Act (DDA).
www.direct.gov.uk

Department of Work and Pensions (DWP)
A summary specifically for employers offering them advice on the DDA. www.dwp.gov.uk/employers/dda
DWP website providing information for people with MS about protection offered by the DDA www.pointofdiagnosis.org.uk

Benefit Enquiry Line
General advice on benefits for people with disabilities, their carers and representatives.
Telephone: 0800 88 22 00 Textphone: 0800 24 33 55

Employers Forum on Disability
National organisation helping employers to recruit and retain employees with disabilities; provides numerous information booklets for its members and offers a helpline. There is a list of members on the website.
Telephone: 020 7403 3020
www.employers-forum.co.uk

This information sheet has been produced as part of the research project: 'Evaluation of an early intervention vocational rehabilitation service for people with Multiple Sclerosis' at the Institute of Neurology, Queen Square, London WC1N 3BG.

Appendix 8.4 Outcomes measures booklet – RCT

Thank you for agreeing to participate in the '**Evaluation of an early intervention model of occupational rehabilitation**' research project. We would be grateful if you could help us by filling out this questionnaire. All of the information you provide is COMPLETELY CONFIDENTIAL any information shared will be anonymised to protect your identity.

The overall goal of our research is to develop a service that will support people with MS to maintain their jobs. We can only do this really well when people, like you, who participate in this trial of a service share your experiences and allow us to collect information that we can use to prove the service can make a difference.

Your answers will not be shared with anyone. There are no right or wrong answers. If you are unsure how to answer a question, please give the best answer you can. Please feel free to make comments in the margins. There is also room for comments on the back page of the questionnaire. Do take a break if you need to as you work through the questionnaire.

Once you are finished, your completed questionnaire can be returned in the prepaid envelope provided. If you need help with any questions, please call Jo Sweetland, researcher, on **08451 555000 x723821** or send an email to **j.sweetland@ion.ucl.ac.uk**

Please tell us today's date:

☐ Day ☐ Month ☐ Year

This study is funded by the MS Society and the College of Occupational Therapists.

Thank you,

Joanna Sweetland	Dr Diane Playford
Research Occupational Therapist	Consultant Neurologist

Name: ………………………………………………………………………..

Contact telephone number: ………………………………………………..

Current address:

Reference number for study: ☐ (To be completed by research team).

Section 1

- **The following questions ask for your views about the impact of MS on your day-to-day life during** the past two weeks.
- **For each statement, please circle the one number that best describes your situation. Please answer all questions.**

In the past two weeks, how much has your MS limited your ability to …	Not at all	A little	Moderate-ly	Extreme-ly
1. Do physically demanding tasks?	1	2	3	4
2. Grip things tightly (e.g. turning on taps)?	1	2	3	4
3. Carry things?	1	2	3	4

In the past two weeks, how much have you been bothered by …	Not at all	A little	Moderate-ly	Extreme-ly
4. Problems with your balance?	1	2	3	4
5. Difficulties moving about indoors?	1	2	3	4
6. Being clumsy?	1	2	3	4
7. Stiffness?	1	2	3	4
8. Heavy arms and/or legs?	1	2	3	4
9. Tremor of your arms or legs?	1	2	3	4
10. Spasms in your limbs?	1	2	3	4
11. Your body not doing what you want it to do?	1	2	3	4
12. Having to depend on others to do things for you?	1	2	3	4

Please check you have answered all questions before going onto the next page

In the past two weeks, how much have you been bothered by …	Not at all	A little	Moderate-ly	Extreme-ly
13. Limitations in your social and leisure activities at home?	1	2	3	4
14. Being stuck at home more than you would like to be?	1	2	3	4
15. Difficulties using your hands in everyday tasks?	1	2	3	4
16. Having to cut down the amount of time you spent on work or other daily activities?	1	2	3	4
17. Problems using transport (e.g. car, bus, train, taxi, etc.)?	1	2	3	4
18. Taking longer to do things?	1	2	3	4
19. Difficulty doing things spontaneously (e.g. going out on the spur of the moment)?	1	2	3	4
20. Needing to go to the toilet urgently?	1	2	3	4
21. Feeling unwell?	1	2	3	4
22. Problems sleeping?	1	2	3	4
23. Feeling mentally fatigued?	1	2	3	4
24. Worries related to your MS?	1	2	3	4
25. Feeling anxious or tense?	1	2	3	4
26. Feeling irritable, impatient, or short-tempered?	1	2	3	4
27. Problems concentrating?	1	2	3	4
28. Lack of confidence?	1	2	3	4
29. Feeling depressed?	1	2	3	4

Please check you have answered all questions before going onto the next page

Section 2

The following questions ask for your views about the impact of MS on your working life during the past two weeks. Please answer all questions.

- For each statement please **circle** the **one** number that **best** describes your situation.

The following statements are about symptoms you may have experienced due to your MS. Please circle the number in the box that best describes your situation.

During the past 2 weeks, how often did you experience the following problems because of your MS?	**None of the time**	**A little of the time**	**Most of the time**	**All of the time**
1) My journey to work exhausts me	1	2	3	4
2) It takes twice as long to do anything at work	1	2	3	4
3) I get distracted by my MS symptoms at work	1	2	3	4
4) I achieve nothing at work	1	2	3	4
5) Everything at work is an effort	1	2	3	4
6) I get distracted easily at work	1	2	3	4
7) I find it difficult to focus at work	1	2	3	4
8) I feel overwhelmed by my work	1	2	3	4
9) I need rests at work	1	2	3	4
10) I feel that my working day is too long	1	2	3	4
11) I have difficulty doing my job safely	1	2	3	4
12) I feel I lack energy at work	1	2	3	4
13) Pain interferes with my ability to work	1	2	3	4
14) My problems with dexterity let me down at work	1	2	3	4
15) My walking difficulties let me down at work	1	2	3	4
16) My balance causes difficulties at work	1	2	3	4
17) The clarity of my speech lets me down at work	1	2	3	4

Please check you have answered all questions before going onto the next page

During the <u>past 2 weeks</u>, how often did you experience the following problems because of your MS?	**None of the time**	**A little of the time**	**Some of the time**	**All of the time**
18) My concentration lets me down at work	1	2	3	4
19) My memory lets me down at work	1	2	3	4
20) The co-ordination of my arms lets me down at work	1	2	3	4
21) My tremor impacts on my work	1	2	3	4
22) My problems with vision let me down at work	1	2	3	4
23) My swallowing difficulties impact on me at work	1	2	3	4
24) My spasms impact on me at work	1	2	3	4
25) My stiffness impacts on me at work	1	2	3	4
26) My bladder function causes difficulties at work	1	2	3	4

The following statements are about <u>emotions</u> you may have felt the past two weeks. Please circle the number in the box that best describes your situation.

During the <u>past 2 weeks</u>, how often did you experience the following worries or concerns at work because of your MS?	**None of the time**	**A little of the time**	**Some of the time**	**All of the time**
1) I worry about my MS symptoms affecting work	1	2	3	4
2) I worry about my memory letting me down at work	1	2	3	4
3) I worry about my ability to concentrate at work	1	2	3	4
4) I worry about my ability to communicate at work	1	2	3	4

Please check you have answered all questions before going onto the next page

During the <u>past 2 weeks</u>, how often did you experience the following worries or concerns at work because of your MS?	None of the time	A little of the time	Some of the time	All of the time
5) I feel embarrassed by my performance at work	1	2	3	4
6) I feel guilty about my performance at work	1	2	3	4
7) I worry about meeting targets	1	2	3	4
8) I get upset at work	1	2	3	4
9) I get anxious at work	1	2	3	4
10) I feel vulnerable at work	1	2	3	4
11) I am unhappy at work	1	2	3	4
12) I feel lonely at work	1	2	3	4
13) I get emotional at work	1	2	3	4
14) I feel people do not listen to me at work	1	2	3	4
15) I feel isolated at work	1	2	3	4
16) I feel people do not trust my judgement at work	1	2	3	4
17) I worry what people at work will think	1	2	3	4
18) The way I am treated by my employer makes me angry	1	2	3	4
19) The way my colleagues treat me makes me angry	1	2	3	4
20) I worry that I may be made redundant	1	2	3	4

Please check you have answered all questions before going onto the next page

The following statements are about any adjustments you may have made due to your MS.
Please circle either agree/disagree to each statement that best describes your situation.

Considering working with MS, during the past 2 weeks, do you agree/disagree with the following statements ...	**agree**	**disagree**
1) I know when I need to take a break	agree	disagree
2) I am realistic about my work situation	agree	disagree
3) I have learnt to delegate	agree	disagree
4) I no longer say yes to everything	agree	disagree
5) I can't do everything I used to but that is fine	agree	disagree
6) I have felt able to look at the weekly structure rather than just get by day to day	agree	disagree
7) I know when to push myself and when I can't	agree	disagree
8) I accept my limitations	agree	disagree
9) I don't apply pressure to myself anymore	agree	disagree
10) I want to change my working pattern	agree	disagree
11) I use strategies to manage my MS at work when I know they will help me	agree	disagree
12) I use equipment at work when I know it will help me	agree	disagree
13) I have a long term plan that deals with the impact of my MS at work	agree	disagree

Please check you have answered all questions before going onto the next page

The following statements are about your ability to speak up for yourself or take charge of your situation (self efficacy).
Please circle the number in the box that best describes your situation.

During the past 2 weeks, how often did you feel…	**None of the time**	**A little of the time**	**Some of the time**	**All of the time**
1) In charge of your working life	1	2	3	4
2) Confident to deal with problems at work	1	2	3	4
3) Confident in yourself at work	1	2	3	4
4) Able to accept new challenges at work	1	2	3	4
5) Able to negotiate the demands of your work	1	2	3	4
6) Able to come up with solutions to your work problems	1	2	3	4
7) Able to manage the pace of your job	1	2	3	4
8) Capable of overcoming barriers at work	1	2	3	4
9) Confident in your ability to manage your MS at work	1	2	3	4
10) Confident in your ability to continue working	1	2	3	4
11) Confident in your ability to organise your work	1	2	3	4
12) Confident in your ability to meet all the demands of your work	1	2	3	4
13) Confident that you made good decisions about your working life	1	2	3	4
14) Confident that you were doing your job properly	1	2	3	4
15) Able to deliver the quality of work that is necessary	1	2	3	4
16) Able to achieve the things at work that you want to achieve	1	2	3	4
17) Able to structure your day to minimise the impact of MS on your job	1	2	3	4
18) Able to cope in the work environment	1	2	3	4
19) Able to push to make changes happen if necessary	1	2	3	4
20) Able to be persistent about your needs at work	1	2	3	4

Please check you have answered all questions before going onto the next page

If you work alone or have **NOT** disclosed tick this box ☐ and go to page 13

The following statements are about the culture you work in and the colleagues you work with. Please circle the number in the box that best describes your situation.

With regard to working with MS, during the past 2 weeks how often have you felt…	**None of the time**	**A little of the time**	**Some of the time**	**All of the time**
1) My colleagues were comfortable talking with me about my MS	1	2	3	4
2) My colleagues respected the difficulties I experience due to my MS	1	2	3	4
3) My colleagues value my work	1	2	3	4
4) My colleagues understood why I have difficulties	1	2	3	4
5) I was able to socialise at work	1	2	3	4
6) I had opportunity to participate fully in the social life of the office	1	2	3	4
7) I fitted in with the culture at work	1	2	3	4
8) I was supported at work	1	2	3	4
9) There was someone I could confide in at work	1	2	3	4
10) My colleagues attitudes to me were unchanged	1	2	3	4
11) My colleagues had a realistic understanding of my MS	1	2	3	4
12) I received appropriate help	1	2	3	4
13) My colleagues respected my limitations	1	2	3	4
14) My colleagues have tried to protect me	1	2	3	4
15) My colleagues have tried to help although it has not been effective	1	2	3	4
16) My colleagues acknowledge my difficulties	1	2	3	4
17) My MS added to the feeling of being different at work	1	2	3	4

Please check you have answered all questions before going onto the next page

If you are self employed please tick this box ☐ and go to page 13

The following section will ask you to answer **one question under three different headings.** Thinking about the past 2 weeks please indicate by circling either "yes" or "no" as to whether your line manager understood, was willing to help and was able to help with the following issues at work?

EXAMPLE ANSWER: Consider the following statement 'I have difficulty getting a coffee from the coffee machine' if your response to this question is your line manager understood you can't get coffee from the machine because you can't walk there; she was willing to help because she sees it as a problem but was unable to help because health and safety prevented moving the coffee machine, then your answer would look like the following:

EXAMPLE	**My line manager understood this issue**	**My line manager was willing to help me with this issue**	**My line manager was able to help with this issue (ie had the skills)**
I have difficulty getting a coffee from the coffee machine	[✓ yes] no	[✓ yes] no	yes [✓ no]

The following statements ask about the person who has been your line manager in the past two weeks. Please circle either yes/no to best describe your situation.

With regard to working with MS, during the past 2 weeks…	**My line manager understood this issue**	**My line manager was willing to help me with this issue**	**My line manager was able to help with this issue (ie had the skills)**
1) I felt able to approach my line manager when I had a problem	yes no	yes no	yes no
2) I needed my line manager to understand my illness	yes no	yes no	yes no
3) I needed my line manager to understand the process of getting me help	yes no	yes no	yes no
4) I was able to access quick support from my line manager	yes no	yes no	yes no

Please check you have answered all questions before going onto the next page

With regard to working with MS, during the past 2 weeks…	**My line manager understood this issue**		**My line manager was willing to help me with this issue**		**My line manager was able to help with this issue (ie had the skills)**	
5) I needed to be able to trust the advice from my line manager	yes	no	yes	no	yes	no
6) I required accommodations that matched my needs	yes	no	yes	no	yes	no
7) I required support that matched my needs	yes	no	yes	no	yes	no
8) I needed to be able to work with my line manager to solve problems	yes	no	yes	no	yes	no
9) I needed flexibility from my line manager	yes	no	yes	no	yes	no
10) I needed adaptations to my work place	yes	no	yes	no	yes	no
11) I needed to change my working practices	yes	no	yes	no	yes	no
12) My problems required a long term solution as opposed to a quick fix	yes	no	yes	no	yes	no
13) I needed my line manager to be effective in managing changes	yes	no	yes	no	yes	no
14) I relied on my line manager to deliver on what s/he had promised	yes	no	yes	no	yes	no

Please check you have answered all questions before going onto the next page

An overview of your work situation.
Please tick the box that best describes your situation.

A:	**Overall how much do you feel your MS symptoms have impacted on your working life?**
☐	Not at all
☐	A little
☐	Quite a bit
☐	Moderately
☐	Extremely

B:	**Overall how much do you feel your worries/concerns because of your MS have impacted on your working life?**
☐	Not at all
☐	A little
☐	Quite a bit
☐	Moderately
☐	Extremely

C:	**Overall how well do you think you have adjusted to working with MS?**
☐	Not at all
☐	A little
☐	Quite a bit
☐	Moderately
☐	Extremely

D:	**Overall how confident are you at managing situations at work with regards to your MS?**
☐	Not at all
☐	A little
☐	Quite a bit
☐	Moderately
☐	Extremely

If you work alone or have **NOT** disclosed your MS please tick this box ☐ and go to page 15

E:	**Overall how satisfied are you with the support offered by your colleagues?**
☐	Not at all
☐	A little
☐	Quite a bit
☐	Moderately
☐	Extremely

If you are self employed please tick this box ☐ and go to page 15

F:	**Overall how satisfied are you with the support offered by your line manager?**
☐	Not at all
☐	A little
☐	Quite a bit
☐	Moderately
☐	Extremely

Please check you have answered all questions before going onto the next page

An overview of your work situation.
Please circle the number in the box that best describes your situation.

Compared with six months ago…	**Much less**	**A bit less**	**No change**	**A bit more**	**Much more**
A: How much do you feel your MS symptoms have impacted on your working life?	1	2	3	4	5
B: How much do you feel your worries/concerns because of your MS have impacted on your working life?	1	2	3	4	5
C: How well do you think you have adjusted to working with MS?	1	2	3	4	5
D: How confident are you at managing situations at work with regards to your MS?	1	2	3	4	5

If you work alone or have **NOT** disclosed your MS tick this box ☐ and go to page 16

Compared with six months ago…	**Much less**	**A bit less**	**No change**	**A bit more**	**Much more**
E: How satisfied are you with the support offered by your colleagues?	1	2	3	4	5

If you are self employed please tick this box ☐and go to page 16

Compared with six months ago…	**Much less**	**A bit less**	**No change**	**A bit more**	**Much more**
F: How satisfied are you with the support offered by your line manager?	1	2	3	4	5

Please check you have answered all questions before going onto the next page

Section 3

We are interested in how each of the following impacts on your ability to work. For each statement, please circle one answer that best describes your situation.

How much does…	**Impact on your work** (please circle)				
Fatigue	Not at all	A little	Moderately	Quite a bit	Extremely
Balance	Not at all	A little	Moderately	Quite a bit	Extremely
Walking difficulties	Not at all	A little	Moderately	Quite a bit	Extremely
Visual problems	Not at all	A little	Moderately	Quite a bit	Extremely
Weakness	Not at all	A little	Moderately	Quite a bit	Extremely
Handwriting	Not at all	A little	Moderately	Quite a bit	Extremely
Pain	Not at all	A little	Moderately	Quite a bit	Extremely
Coordination	Not at all	A little	Moderately	Quite a bit	Extremely
Speech	Not at all	A little	Moderately	Quite a bit	Extremely
Swallowing	Not at all	A little	Moderately	Quite a bit	Extremely
Continence	Not at all	A little	Moderately	Quite a bit	Extremely
Concentration	Not at all	A little	Moderately	Quite a bit	Extremely
Memory	Not at all	A little	Moderately	Quite a bit	Extremely
Mood	Not at all	A little	Moderately	Quite a bit	Extremely
Travel to work	Not at all	A little	Moderately	Quite a bit	Extremely
Access at work	Not at all	A little	Moderately	Quite a bit	Extremely
Public attitudes	Not at all	A little	Moderately	Quite a bit	Extremely

Please check you have answered all questions before going onto the next page

Section 4

Please read each statement thinking about your Multiple Sclerosis.
Please choose the response that applies to you *at the moment:*

Please tick ✓ one

	TRUE	**NOT TRUE**
1. I push myself to keep working	☐	☐
2. I don't have enough energy to do my job like I used to	☐	☐
3. As the day goes on my condition gets worse	☐	☐
4. My job is physically impossible	☐	☐
5. People treat me differently	☐	☐
6. There are some things I can't do any longer at work	☐	☐
7. I have to pace myself	☐	☐
8. I feel guilty about getting others to help me	☐	☐
9. It takes me longer to do some things at work	☐	☐
10. I don't like to ask for help	☐	☐
11. It is affecting the feeling in my hands	☐	☐
12. My hands are clumsy now	☐	☐
13. My employers are not supportive	☐	☐
14. Its painful walking	☐	☐
15. My hands don't seem to work properly	☐	☐
16. Sometimes in the afternoon I can get really, really tired	☐	☐
17. I push myself to go to work because I don't want to give in to my condition	☐	☐
18. If I don't reduce my hours I may have to give up work	☐	☐
19. I have to be careful not to overdo it at work	☐	☐
20. I have to rely on other people for some parts of my job	☐	☐
21. I am more tired than I used to be	☐	☐

Please check you have answered all questions before going onto the next page

Section 5

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

Mobility

I have no problems in walking about ☐

I have some problems in walking about ☐

I am confined to bed ☐

Self-Care

I have no problems with self-care ☐

I have some problems washing or dressing myself ☐

I am unable to wash or dress myself ☐

Usual Activities (*e.g. work, study, housework, family or leisure activities)*

I have no problems with performing my usual activities ☐

I have some problems with performing my usual activities ☐

I am unable to perform my usual activities ☐

Pain/Discomfort

I have no pain or discomfort ☐

I have moderate pain or discomfort ☐

I have extreme pain or discomfort ☐

Anxiety/Depression

I am not anxious or depressed ☐

I am moderately anxious or depressed ☐

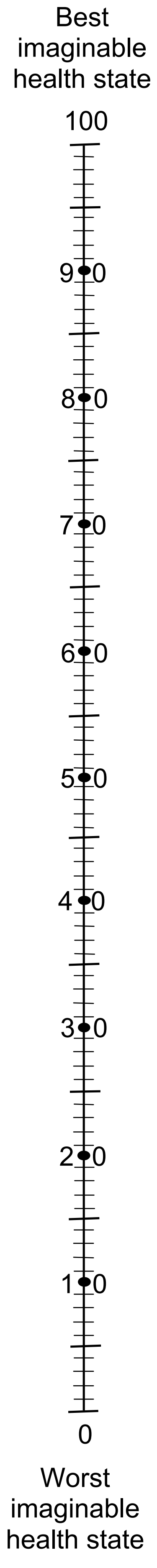
I am extremely anxious or depressed ☐

Please check you have answered all questions before going onto the next page

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

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

Your own health state today



Please check you have answered all questions before going onto the next page

Section 6

The following questions ask about your ability to speak up for yourself or take charge of your situation.

- For each statement, please **circle** the **one** number that best describes your situation.
- Please answer **all** questions.

	Not at all true	**Hardly true**	**Moderately true**	**Exactly true**
1. I can always manage to solve difficult problems if I try hard enough.	1	2	3	4
2. If someone opposes me, I can find the means and ways to get what I want.	1	2	3	4
3. It is easy for me to stick to my aims and accomplish my goals.	1	2	3	4
4. I am confident that I could deal efficiently with unexpected events.	1	2	3	4
5. Thanks to my resourcefulness, I know how to handle unforeseen situations.	1	2	3	4
6. I can solve most problems if I invest the necessary effort.	1	2	3	4
7. I can remain calm when facing difficulties because I can rely on my coping abilities.	1	2	3	4
8. When I am confronted with a problem, I can usually find several solutions.	1	2	3	4
9. If I am in trouble, I can usually think of a solution.	1	2	3	4
10. I can usually handle whatever comes my way.	1	2	3	4

Please check you have answered all questions before going onto the next page

Section 7

This section asks for your views about your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

- Answer every question by marking the answer as indicated.
- If you are unsure about how to answer a question, please give the best answer you can.

1. In general would you say your health is:

	Circle one
Excellent………………………………………..	**1**
Very good…………………………………….	**2**
Good………………………………………….	**3**
Fair…………………………………………...	**4**
Poor…………………………………….……..	**5**

2. Compared to one year ago, how would you rate your health in general now?

	Circle one
Much better now than one year ago……….	**1**
Somewhat better now than one year ago…	**2**
About the same……………………………..	**3**
Somewhat worse now than one year ago...	**4**
Much worse than one year ago…………. .	**5**

3. The following are about activities you might do during a typical day. Does your health limit you in these activities? If so, how much?

Circle one number on each line	**Yes limited a lot**	**Yes limited a little**	**No not limited at all**
a. Vigorous activities, such as running, lifting heavy objects participating in strenuous activities	1	2	3
b. Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling or playing golf	1	2	3
c. Lifting or carrying groceries	1	2	3
d. Climbing several flights of stairs	1	2	3
e. Climbing one flight of stairs	1	2	3
f. Bending, kneeling or stooping	1	2	3
g. Walking more than a mile	1	2	3
h. Walking half a mile	1	2	3
i. Walking 100 yards	1	2	3
j. Bathing and dressing yourself	1	2	3

4. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?

Circle one number on each line	**Yes**	**No**
a. Cut down on the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Were limited in the kind of work or other activities	1	2
d. Had difficulty performing the work or other activities (e.g. it took extra effort)	1	2

Please check you have answered all questions before going onto the next page

5. During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?

Circle one number on each line	**Yes**	**No**
a. Cut down on the amount of time you spent on work or other activities	1	2
b. Accomplished less than you would like	1	2
c. Didn't do work or other activities as carefully as usual	1	2

6. During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbours or groups?

	Circle one
Not at all………………………………..………	**1**
Slightly…………………………………….....	**2**
Moderately…………………………………..	**3**
Quite a bit…………………………………...	**4**
Extremely…………………..………………..	**5**

7. How much bodily pain have you had during the past 4 weeks?

	Circle one
None…..……………………………..………	**1**
Very mild………………………………….....	**2**
Mild……...……………………………………..	**3**
Moderate..…………………………………...	**4**
Severe……………………..…………………..	**5**
Very severe………………………………….	**6**

Please check you have answered all questions before going onto the next page

8. During the past 4 weeks, how much did pain interfere with your normal work (including work both outside the home and housework)?

	Circle one
Not at all…………………………..………	**1**
Slightly…………………………………….....	**2**
Moderately…………………………………..	**3**
Quite a bit…………………………………...	**4**
Extremely…………………..……………..	**5**

9. These questions are about how you feel and how things have been during the past 4 weeks. For each question, please give the one answer that comes closest to the way you have been feeling. How much of the time during the past 4 weeks:

Circle one number on each line	**All of the time**	**Most of the time**	**A good bit of time**	**Some of the time**	**A little of the time**	**None of the time**
a. Did you feel full of life?	1	2	3	4	5	6
b. Have you been a very nervous person?	1	2	3	4	5	6
c. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
d. Have you felt calm and peaceful?	1	2	3	4	5	6
e. Did you have a lot of energy?	1	2	3	4	5	6
f. Have you felt downhearted and low?	1	2	3	4	5	6
g. Did you feel worn out?	1	2	3	4	5	6
h. Have you been a happy person?	1	2	3	4	5	6
i. Did you feel tired?	1	2	3	4	5	6

Please check you have answered all questions before going onto the next page

10. **During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities like visiting with friends, relatives etc?**

Circle one

All of the time………………………………..	**1**
Most of the time…………………………….	**2**
Some of the time……………………………	**3**
A little of the time…………………………...	**4**
None of the time..…………………………..	**5**

11. **How true or false is each of the following statements for you?**

Statement	**Definitely true**	**Mostly true**	**Not sure**	**Mostly false**	**Definitely false**
a. I seem to get ill more easily than other people	1	2	3	4	5
b. I am as healthy as anybody I know	1	2	3	4	5
c. I expect my health to get worse	1	2	3	4	5
d. My health is excellent	1	2	3	4	5

Please check you have answered all questions before going onto the next page

Section 8

These are some questions about your ability to look after yourself.

They may not seem to apply to you.

Please answer them **all**.

Please tick **one** box in each section.

1.	**Bathing… In the bath or shower, do you:**
☐	manage on your own?
☐	need help getting in and out?
☐	need other help?
☐	never have a bath or shower?
☐	need to be washed in bed?

2.	**Transfer… Do you move from bed to chair:**
☐	on your own?
☐	with a little help from one person?
☐	with a lot of help from one or more people?
☐	not at all?

3.	**Dressing… Do you get dressed:**
☐	without any help?
☐	just with help with buttons?
☐	with someone helping you most of the time?

Please check you have answered all questions before going onto the next page

4.	**Feeding… Do you eat food:**
☐	without any help?
☐	with help cutting food or spreading butter?
☐	with more help?

5.	**Mobility… Do you walk indoors:**
☐	without any help?
☐	without any help apart from a frame?
☐	with one person watching over you?
☐	with one person helping you?
☐	with more than one person helping?
☐	not at all?
☐	or do you use a wheelchair independently (e.g. round corners)?

6.	**Stairs… Do you climb stairs at home:**
☐	without any help?
☐	with someone carrying your frame?
☐	with someone encouraging you?
☐	with physical help?
☐	not at all?
☐	don't have stairs?

7.	**Toilet use… Do you use the toilet or commode:**
☐	without any help?
☐	with some help but can do something?
☐	with quite a lot of help?

Please check you have answered all questions before going onto the next page

8.	**Grooming… Do you brush your hair and teeth, wash your face and shave:**
☐	without any help?
☐	with help?

9.	**Bladder… Are you incontinent of urine?**
☐	never
☐	less than once a week
☐	less than once a day
☐	more often
☐	or do you have a catheter managed for you?

10.	**Bowels… Do you soil yourself?**
☐	never
☐	occasional accident
☐	all the time
☐	or do you need someone to give you an enema?

Please check you have answered all questions before going onto the next page

Section 9

Employment Status / Size of Organisation

The following questions refer to your current main job, or (if you are not working now) to your last main job. The questions ask for more details about the kind of job you do. If there are any questions you do not understand please call the contact number at the start of this pack to ask for advice.

Please tick **one box** only per question.

1. Employee or self-employed

Do (did) you work as an employee or are (were) you self-employed?

☐	Employee
☐	Self-employed with employees
☐	Self-employed / freelance without employees (go to **question 4**)

2. Number of employees

For employees: indicate below how many people work (worked) for your employer at the place where you work (worked).

For self-employed: indicate below how many people you employ (employed). Go to **question 4** when you have completed this question.

☐	1 to 24
☐	25 or more

3. Supervisory status

Do (did) you supervise any other employees?
A supervisor or foreman is responsible for overseeing the work of other employees on a day-to-day basis.

☐	Yes
☐	No

4. Occupation

Please tick **one box** to show which **best** describes the sort of work you do.
(If you are not working now, please tick a box to show what you did in your last job).

Please tick only ONE box.

A	☐	**Modern professional occupations** *such as:* teacher - nurse - physiotherapist - social worker - welfare officer - artist - musician - police officer (sergeant or above) - software designer
B	☐	**Clerical and intermediate occupations** *such as:* secretary - personal assistant - clerical worker - office clerk - call centre agent - nursing auxiliary - nursery nurse
C	☐	**Senior managers or administrators** (usually responsible for planning, organising and co-ordinating work and for finance) *such as:* finance manager - chief executive
D	☐	**Technical and craft occupations** *such as:* motor mechanic - fitter - inspector - plumber - printer - tool maker - electrician - gardener - train driver
E	☐	**Semi-routine manual and service occupations** *such as:* postal worker - machine operative - security guard - caretaker - farm worker - catering assistant - receptionist - sales assistant
F	☐	**Routine manual and service occupations** *such as:* HGV driver - van driver - cleaner - porter - packer - sewing machinist - messenger - labourer - waiter / waitress - bar staff
G	☐	**Middle or junior managers** *such as:* office manager - retail manager - bank manager - restaurant manager - warehouse manager - publican
H	☐	**Traditional professional occupations** *such as:* accountant - solicitor - medical practitioner - scientist - civil / mechanical engineer

5. Salary and time off work (if in employment):

What is your gross salary (before tax and other deductions)?
Tick one box:

☐ **Less than £15,000**
☐ **£15 – 25,000**
☐ **£25 – 40,000**
☐ **£40 – 55,000**
☐ **£55 – 70,000**
☐ **£70,00 +**

If willing please specify exact amount of gross salary ………………..

How many hours do you work on average a week? ☐

Please check you have answered all questions before going onto the next page

Have you had to stop or reduce work because of your MS?

☐	Yes – if yes how many days in the last three months? ……………………………
☐	No

If unemployed or retired:

	How long have you been unemployed or retired? …………………………………………………………………………………………
 ☐ ☐ ☐	**What is the reason for you no longer working?** MS Other illness Not illness related (please specify) …………………………………………………..

Medical Costs

These following questions ask for information about the input you have received from the health service over the past six months. There are no right and wrong answers and we understand that the figures you give maybe approximates.

6. Have you used the following services in the past SIX months?

☐	Neurology Outpatients	number of hours (approx):	☐
☐	Other Outpatients	number of hours (approx):	☐
☐	Neurology Inpatients	number of hours (approx):	☐
☐	Other please specify: ……………………………………… ………………………………………	number of hours/days (approx): (Delete either hours/days as applicable)	☐

7. Please list any investigations or diagnostic tests over the last SIX months:

☐	MRI	total number in past six months:	☐
☐	CT	total number in past six months:	☐
☐	Blood tests	total number in past six months:	☐
☐	Other please specify: ……………………………………… ………………………………………	total number in past six months:	☐

Please check you have answered all questions before going onto the next page

8. Have you taken any medication in the last SIX months (e.g. disease modifying drugs)?

☐ No

☐ Yes - please specify:

1. **name**:……………………………………………………………

Dose: …………………………… Frequency: ……………………………

Start date: …………………………… End date (if applicable): ……………………

2. **name**:……………………………………………………………

Dose: …………………………… Frequency: ……………………………

Start date: …………………………… End date (if applicable): ……………………

3. **name**:……………………………………………………………

Dose: …………………………… Frequency: ……………………………

Start date: …………………………… End date (if applicable): ……………………

4. **name**:……………………………………………………………

Dose: …………………………… Frequency: ……………………………

Start date: …………………………… End date (if applicable): ……………………

9. Have you used any of the following primary/community care services over the last SIX months?

☐ **GP**
☐ surgery ☐ home no. of contacts: ☐ Average duration: ☐ mins

☐ **Other doctor**
☐ surgery ☐ home no. of contacts: ☐ Average duration: ☐ mins

☐ **Physiotherapist**
☐ surgery ☐ home no. of contacts: ☐ Average duration: ☐ mins

☐ **Occupational Therapist**
☐ surgery ☐ home no. of contacts: ☐ Average duration: ☐ mins

☐ **Other service please specify**……………………………………………………………
☐ surgery ☐ home no. of contacts: ☐ Average duration: ☐ mins

10. Have any of the following aids or devices been supplied over the last SIX months (e.g. walking stick)?

☐	Yes – please specify …………………………………………………………………………
☐	No

Non-Medical Costs

11. Have there been any adaptations to your home because of illness in the last SIX months?

☐	Yes – please specify …………………………………………………………………………
☐	No

12. Over the last 6 months, have you received any informal care from friends or relatives e.g. with cooking, cleaning, shopping, bathing?

☐	Yes - please specify what and the number of hours each week: ………………………………………………………………………………………………
☐	No

If yes - what is the principal reason for extra care?
☐ MS
☐ Other illness
☐ Not illness related (please specify) ……………………………………………………..

13. Have any friends or relatives stayed off work to assist you because of MS

☐	Yes
☐	No

If yes: please estimate how long they have stayed off work? ☐

If yes: please estimate average income lost per week? ☐

14. Over the last 6 months, have any journeys been made in order for you to receive care for your condition?

☐	Yes - please specify transport used, number of journeys and average cost …..…………..……………………………………………………………………………
☐	No

Please check you have answered all questions before going onto the next page

Section 10

The following questions ask for some general demographic data.

1. Are you?

☐	Female
☐	Male

2. What is your age? ☐

3. What is your date of birth? ☐Day ☐Month ☐Year

4. To which ethnic group do you belong? (Please tick one):

1	☐	White British
2	☐	White Irish
3	☐	Other white background
4	☐	Mixed white and black Caribbean
5	☐	Mixed white and black African
6	☐	Mixed white and Asian
7	☐	Other mixed background
8	☐	Indian
9	☐	Pakistani
10	☐	Bangladeshi
11	☐	Other Asian groups
12	☐	Caribbean
13	☐	African
14	☐	Other black backgrounds
15	☐	Chinese
16	☐	Any other ethnic group (please specify) ………………………………………
17	☐	Not stated

(Taken from the National Statistics interim standard classifications for presenting ethnic and national groups data 2001)

5. Roughly, when did your MS START? ☐Month ☐Year

6. Roughly, when was your MS DIAGNOSED? ☐Month ☐Year

Please check you have answered all questions before going onto the next page

7. Concerning your mobility indoors, please tick the most appropriate box:

☐	I walk unaided
☐	I use a stick or frame, or hold onto furniture or somebody when walking
☐	I use a wheelchair

8. Are you? (please tick one):

1	☐	Single
2	☐	Separated
3	☐	Married
4	☐	Divorced
5	☐	With partner
6	☐	Widowed

9. Are you? (please tick the one which is most relevant):

1	☐	Employed
2	☐	Retired due to MS
3	☐	Self employed
4	☐	Retired due to other reasons
5	☐	Unemployed
6	☐	A student
7	☐	Other please specify …………………………………………………

10. Your highest educational level: (please tick the one which is most relevant):

1	☐	No qualification
2	☐	GCE’s, GCSE’s, NVQ level 1or equivalent
3	☐	A levels, NVQ level 2/3 or equivalent
4	☐	Degree or equivalent
5	☐	Post graduate qualification e.g. masters, PhD
6	☐	Other qualification please specify …………………………………………………

Appendix 8.5 Consent form - RCT

UCLH Project ID number: 06/Q0512/71
Patient Identification Number for this study:
Form version and date: version 2: 23.01.07

CONSENT FORM

Title of project: To evaluate an early intervention model of occupational rehabilitation for people with Multiple Sclerosis (MS).

Name of Principal investigator: Dr E D Playford
Name of research occupational therapist: Joanna Sweetland

Please initial box

1. I confirm that I have read and understood the information sheet dated 23.01.07 (version 2) for the above study and have had the opportunity to ask questions. ☐
2. I confirm that I have had sufficient time to consider whether or not want to be included in the study ☐
3. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. ☐
4. I understand that sections of any of my medical notes may be looked at by responsible individuals from UCLH Trust or from regulatory authorities where it is relevant to my taking part in research. I give permission for these individuals to have access to my records. ☐
5. I understand that my general practitioner will be informed that I am participating in this study. ☐
6. I agree to take part in the above study. ☐

Continued on next page

1 form for Patient;
1 to be kept as part of the study documentation,
1 to be kept with hospital notes
UCLH Project ID number: 06/Q0512/71
Patient Identification Number for this study:

Form version and date: version 2: 23.01.07

CONSENT FORM

Title of project: To evaluate an early intervention model of occupational rehabilitation for people with Multiple Sclerosis (MS).

Name of Principal investigator: Dr E D Playford
Name of research occupational therapist: Joanna Sweetland

____________________ __________________ _____________________
Name of patient Date
Signature

____________________ __________________ ____________________
Name of Person taking consent Date
Signature

Joanna Sweetland j.sweetland@ion.ucl.ac.uk t: 0845 1555000 x 723821
Researcher (to be contacted *Email/phone number*
if there are any problems)

Comments or concerns during the study

If you have any comments or concerns you may discuss these with the investigator. If you wish to go further and complain about any aspect of the way you have been approached or treated during the course of the study, you should write or get in touch with the Complaints Manager, UCL hospitals. Please quote the UCLH project number at the top this consent form.

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