

The development and testing of a novel intervention (Mii-vitaliSe) to support people with Multiple Sclerosis to be active - a pilot evaluation

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Abstract-Louise Fazakarley

Title

The development and testing of a novel intervention (Mii-vitaliSe) to support people with Multiple Sclerosis (MS) to be active - a pilot evaluation.

Background

There are many benefits of physical activity for people with MS, but also barriers to participation. Active home gaming might help to maintain enthusiasm to exercise over the longer term. Pilot research in the USA suggested the Wii™ can be used safely at home by mobile people with MS.

Aims

To develop and conduct preliminary testing of a home-based physiotherapist-supported Wii™ intervention (Mii-vitaliSe) for people with MS.

Trial design

A mixed method study incorporating service user involvement throughout. Mii-vitaliSe (incorporates off-the-shelf Wii™ software, physiotherapist support and resource materials) was developed and piloted

Methods

A mixed methods wait-list parallel arm randomised controlled trial. Thirty ambulatory people with moderate MS were randomised to receive Mii-vitaliSe (incorporating off-the-shelf Wii™ software, physiotherapist support and resource materials) either immediately (for 12 months) or after a 6 month delay (for 6 months).

Outcomes included assessments of balance, gait, mobility, hand dexterity, activity levels and adherence at baseline, 6 and 12 months. Interviews (n=25) sought participants' experiences of taking part and physiotherapists' (n=2) feedback.

Results

Recruitment (31%), screening and data collection (97% complete data at six months) procedures worked well and participants found randomisation to a delayed group acceptable. Preliminary estimates of effect size were calculated for the outcome

measures and the largest ($d=0.41$) positive effect found for the iTUG (instrumented Timed Up and Go). On average participants used the Wii™ twice a week for 30 minutes. Some continued to use the Wii™ for 12 months. Support and advice from the intervention resources were perceived to be helpful and a range of physical and psychological benefits reported.

Conclusions

A novel intervention using the Wii™ has been developed and undergone feasibility testing. Mii-vitaliSe offers a way for people with MS to increase physical activity levels but requires further development and evaluation.

Trial registration number

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Abbreviations

ABI	Acquired Brian injury
APDDS	Adapted Patient Determined Disease Steps Scale
ARAT	Action Research Arm Test
BU	Bournemouth University
BUCRU	Bournemouth University Clinical Research Unit
CI	Confidence Interval
CNS	Central Nervous System
CSP	Chartered Society of Physiotherapy
DOH	Department of Health
EDSS	Extended Disability Status Scale
LTC(s)	Long-term condition(s)
MDT	Multi-disciplinary team
MET	Metabolic Equivalent
MI	Motivational Interviewing
MRC	Medical Research Council
MS	Multiple Sclerosis
NHPT	Nine Hole Peg Test
NHS	National Health Service
NIHR	National Institute for Health Research
NRES	National Research Ethics Service
PD	Parkinson's disease
PPI	Patient and Public Involvement

PPMS	Primary Progressive Multiple Sclerosis
SPMS	Secondary Progressive MS
RCT	Randomised Controlled Trial
RRMS	Relapsing Remitting Multiple Sclerosis
SD	Standard Deviation
SPMS	Secondary Progressive Multiple Sclerosis
TUG	Timed Up and Go (iTUG Instrumented Timed Up and Go)
VR	Virtual Reality

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Chapter 1 Introduction

1.1 Overview

In 2011, the Bournemouth University Clinical Research Unit (BUCRU) was awarded a grant from the UK Multiple Sclerosis (MS) Society for a three-year study, Mii-vitaliSe: A pilot randomised controlled trial (RCT) of a home gaming system (Nintendo WiiTM) to increase activity levels, vitality, and well-being in people with MS. The Mii-vitaliSe protocol and grant application had been developed in collaboration with two physiotherapists and the lead neurologist from the Dorset MS Service. They had observed that the WiiTM was being used increasingly by people with MS.

The overarching aim for the Mii-vitaliSe study was to “investigate the feasibility of conducting a multi-centre definitive RCT to assess the clinical and cost-effectiveness of a home-based physiotherapist supported WiiTM intervention (Mii-vitaliSe) for people with MS” (Thomas et al. 2014). The protocol for the pilot RCT (Thomas et al. 2014) and the results (Thomas et al. 2017) have been published.

BUCRU is partly funded by the National Institute for Health Research (NIHR) and incorporates the Dorset office of the NIHR Research Design Service. BUCRU focuses on health research that is relevant to the NHS and has special interests in areas such as chronic disease and complex interventions (including interventions in nursing, physiotherapy, occupational therapy and psychology). In May 2011, BUCRU invited applications from within Bournemouth University (BU) to join the multi-disciplinary study team to co-ordinate the Mii-vitaliSe study for three years.

In August 2011, I joined BUCRU to work as a study researcher on the Mii-vitaliSe project. My role was to deal with the day-to-day management and co-ordination of the study and call on other members of the project team as appropriate. I had regular meetings with the study Chief Investigator and statistician to discuss study progress in order to meet the aims and objectives of the Mii-vitaliSe project. A study steering group met twice a year to discuss issues related to the project. In January 2012, I registered for my PhD with a focus on bringing my physiotherapy background and experiences to the Mii-vitaliSe study. This thesis presents my contribution to the Mii-vitaliSe study.

1.2 My personal background

This thesis has been influenced by the breadth of my clinical and academic physiotherapy experiences. I have worked as a physiotherapist in a variety of settings including the NHS (acute and community), the private sector, in research teams assessing and monitoring people with long-term conditions (LTCs) and as a physiotherapy lecturer in academic institutions. I have an interest in health psychology and motivating people with a LTC to manage their condition and to participate in rehabilitation programmes by supporting self-management. A key aim of self-management for people with a LTC is to help people choose healthy behaviours which can prevent and reduce their symptoms and therefore decrease disability and improve quality of life. Prior to my PhD studies, I had worked as a research co-ordinator on an RCT for people with Parkinson's disease, gaining relevant experience and skills such as recruiting people to a trial and assessing the effectiveness of a home-based intervention (Ashburn et al. 2007). From working on the RCT, it was evident that for people with a LTC (such as Parkinson's disease) there were challenges and barriers to adhering to home-based interventions (Pickering et al. 2013).

I therefore saw that the role of research co-ordinator on the Mii-vitaliSe study offered an opportunity to develop my knowledge of working with people with a LTC. This was an opportunity to draw upon my transferable skills but also to work towards a PhD. This would enable me to develop grounding in MS pathology and insights into the crucial preparatory stages of development and piloting prior to a full scale RCT (Craig et al. 2008). What particularly appealed to me was that multi-disciplinary team working was central to the project and the opportunity to develop a new and novel intervention to facilitate people to choose more healthy lifestyles by becoming more active. I had little experience of the Nintendo Wii™, either personally or in my clinical work, but was aware of a growing interest in the Wii™ for rehabilitation and in research. I was interested to learn more about the technology and how it could be used in rehabilitation.

1.3 My contribution

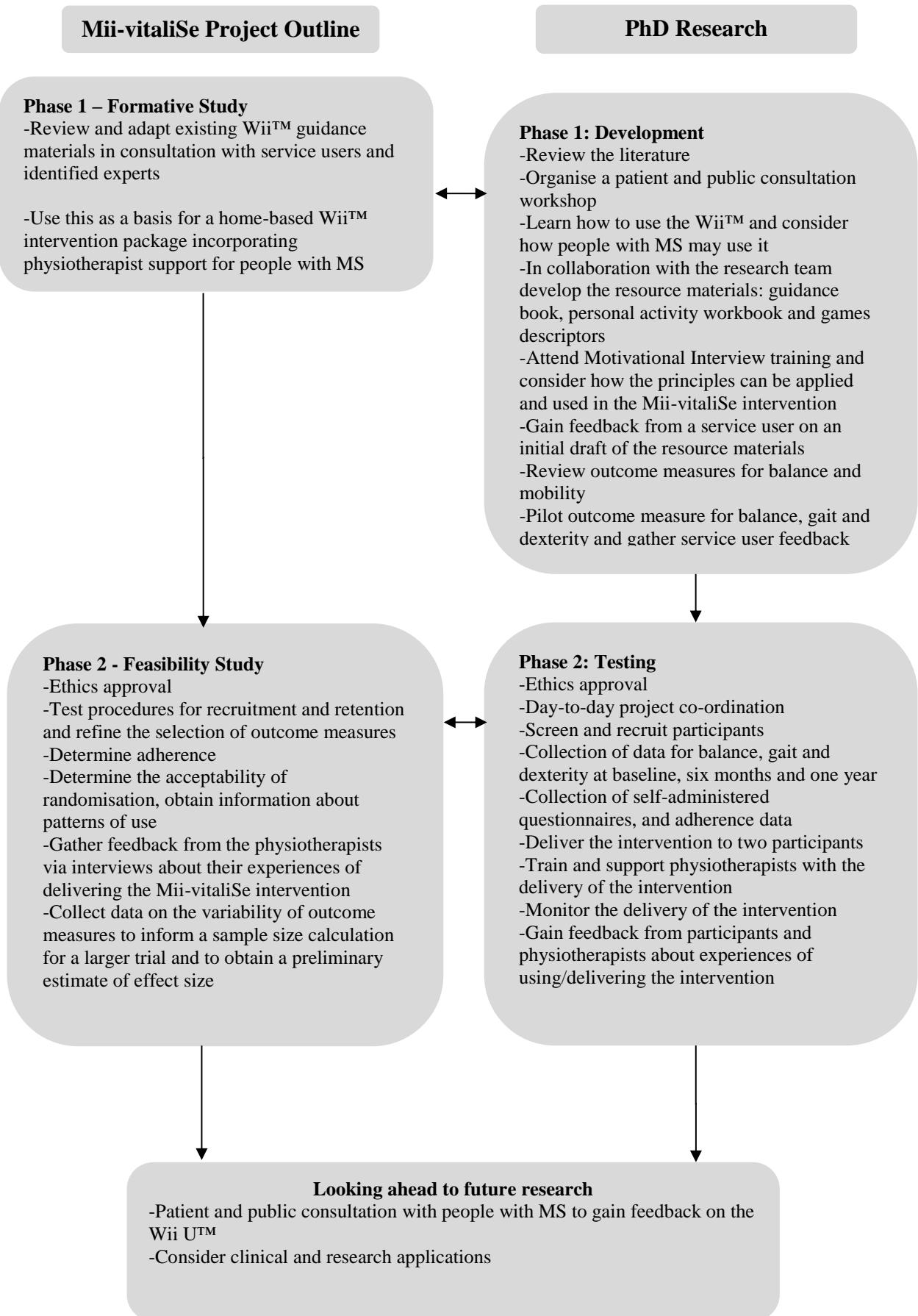
As a PhD student, my work in BUCRU as the study researcher included data checking and data analysis, the interpretation of the data and contribution to reports to the MS Society and other outputs. I led on the physiotherapy aspects of the study,

working in partnership with the clinical physiotherapy team at the Dorset MS Service.

The title of this thesis is “The development and testing of a novel intervention (Mii-vitaliSe) to support people with MS to be active - a pilot evaluation”. This title reflects the key areas of the Mii-vitaliSe study that I have made a contribution to, i.e. key aspects of the development, delivery and testing of the Mii-vitaliSe intervention. This chapter outlines this contribution and chapter five describes in full the methodology and procedures. A summary of my contribution and how it links to the funded study is shown in Figure 1-1.

Figure 1-1:

Schematic representation of programme of study



1.3.1 Developing

My contribution to the development of the Mii-vitaliSe intervention was to prepare for, organise, plan and contribute to a consultation workshop with service users. This included detailed and careful planning in order to make the best use of the time available in the consultation. Following the workshop, there was a thorough synthesis of the views and insights gained from the consultation to shape and refine the Mii-vitaliSe resource materials which would be used as part of the intervention. Service user involvement was key to the development of the Mii-vitaliSe intervention package and is a strand that runs throughout this thesis.

The initial ideas for the resource materials had been agreed in the protocol (Thomas et al. 2014) but I contributed to the more detailed content of these materials. The resource materials were a Guidance Book, a Personal Activity Workbook and Games Descriptors. During the development process, a service user (who had attended the consultation workshop) agreed to review the resources, use them and offer feedback. Feedback from the service user and other members of the research team informed the development of the resources.

The Mii-vitaliSe intervention is underpinned by psychological theory, incorporates behaviour change techniques and physiotherapist support. My experiences as a physiotherapy lecturer have shown me the importance of drawing on students' prior experiences as a sound basis for learning. This is based on educational theory (Biggs 2003) and known as student-led teaching, which puts a focus on the needs of the student as a learner. Learning is, therefore, an active construction of information and is individual (Daley 2001). The same is thought to apply to programmes that support people to manage a LTC, where a person may be supported by healthcare professionals to build knowledge as part of a self-management programme. The key to this support may be a flexible approach rather than taking a more structured, leading one (Jones et al. 2017). However, in order to take a less directive approach, health professionals need to find ways to be less didactic and more flexible. For this reason I attended Motivational Interviewing (MI) training at BU in 2012. The philosophy of MI is to embrace a person-centred, individual and flexible approach by active listening in order to facilitate behaviour change. MI was incorporated into the Mii-vitaliSe intervention, drawing upon the skills I had developed from the training. I also used these skills to orient the physiotherapists delivering the Mii-vitaliSe intervention to the ethos of MI.

1.3.2 Delivering

I offered on-going training and support to the two physiotherapists delivering the Mii-vitaliSe intervention. This involved encouraging them to embed MI principles when providing advice, support and monitoring to participants as part of the Mii-vitaliSe intervention package. The physiotherapists were able to report and comment to me regarding any issues that arose during the study related to the delivery of the Mii-vitaliSe. This was very important, as this was a new and novel intervention. I was also able to discuss any issues that arose with the research team. The recording and monitoring of adverse events was part of monitoring the intervention.

Sometimes adjustments needed to be made to action plans, which occasionally meant additional visits or contact from the physiotherapists. I carried out the intervention with two participants which gave me in-depth insight into the processes and practicalities involved in the delivery of the intervention, using the equipment and resource materials and as well as my application of MI.

1.3.3 Evaluating

My contribution to evaluating the feasibility of using the Mii-vitaliSe intervention involved the co-ordination of the study and running it on a day-to-day basis. A large part of this related to testing the feasibility and acceptability of study procedures.

These included procedures for recruitment, data collection and recording and monitoring adverse events. A key study objective was to refine the selection of outcome measures in preparation for a larger RCT to test the effectiveness of Mii-vitaliSe. I had an interest in and previous research experience of assessing balance, postural instability and falls risk with people with neurological conditions. The Nintendo Wii™ offers options for exercising in a variety of ways and includes a range of balance exercises. The aim of the Mii-vitaliSe intervention was to increase activity levels and not necessarily to improve balance. However, from the early days of learning to use the Wii™, I was particularly interested in the balance games in the Wii Fit Plus™. The games were fun and offered ways to test my own balance in a way that was challenging, interesting and motivating. Therefore, there seemed a need to be able to measure the subtle changes in balance that may result from people with MS using the Wii™. I carefully considered the balance outcome measures detailed in the study protocol and included another outcome measure to test dynamic standing balance. I created a protocol for administering the battery of assessments to consider

the order of their administration and participant burden. Service user feedback was gained and informed the protocol that was produced.

A specific objective of the funded study was to estimate participant adherence to the Mii-vitaliSe intervention. The service user consultation workshop offered an opportunity to gather feedback on how best to measure adherence. This feedback informed the content of the daily play logs. A specific role I played as the research co-ordinator was to ensure that participants were instructed how to complete these logs and to collect them from them.

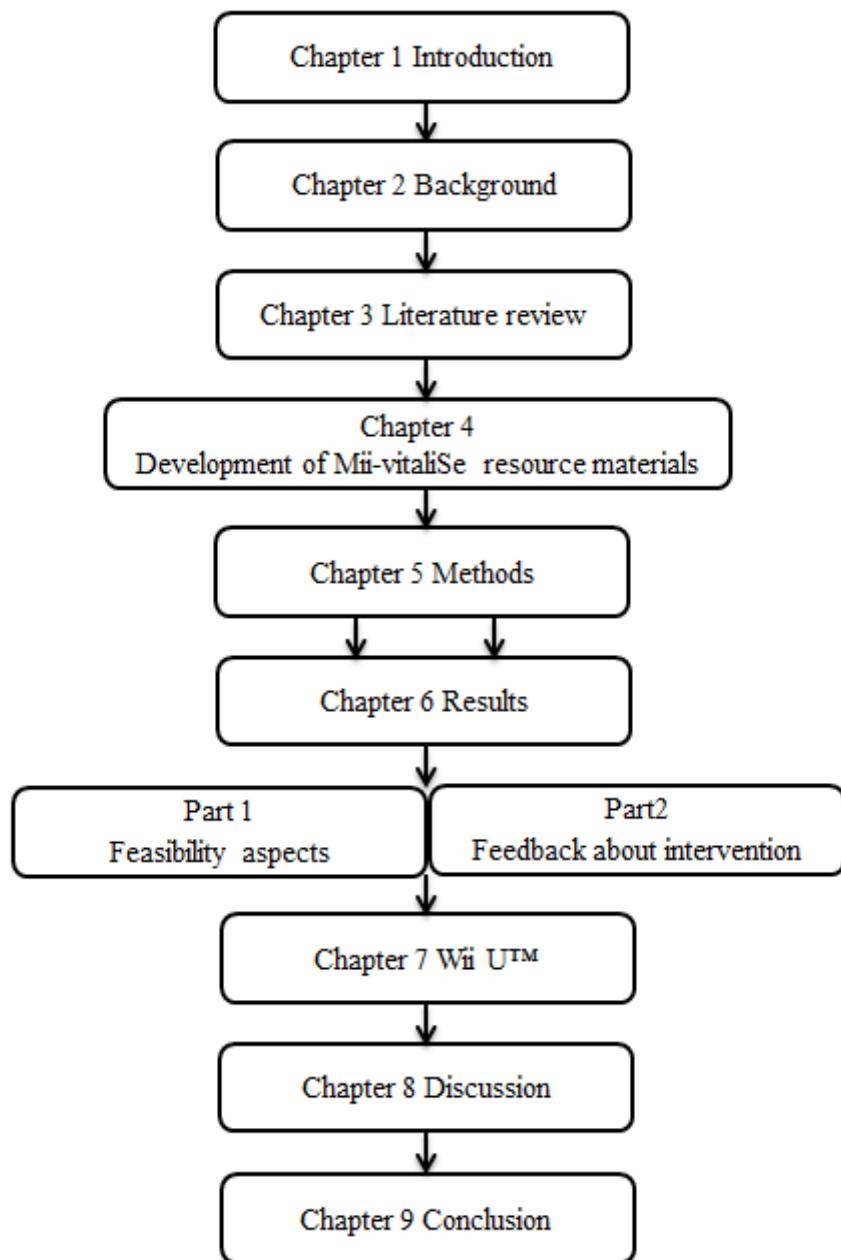
Determining the acceptability of participant randomisation and of the Mii-vitaliSe intervention were study objectives. These were achieved by gathering feedback from a subset of participants via interviews which I conducted. In the interviews, participants were also asked about their own patterns of and preferences for use of the Wii™ and any barriers they encountered. This qualitative component of the study also included interviews with the physiotherapists to gather feedback about the acceptability of the intervention package. These interviews were informed by my own personal use of the Wii™ and from delivering the Mii-vitaliSe intervention to two participants, as well as my insights from supporting the Mii-vitaliSe physiotherapists to deliver the intervention. These experiences gave me insights that informed the questions asked in the interviews.

1.4 Outline of the thesis and chapter outline

This thesis is divided into nine chapters (Figure 1-2). Having set the scene with explaining the relationship between this doctoral study and the Mii-vitaliSe funded study, chapter two presents a description of MS and how it is diagnosed and managed and the importance of physical activity for people with MS. Chapter three presents a review of the relevant literature which includes a consideration of the benefits and challenges of participating in physical activity for people with MS as well as the general benefits of physical activity. Literature regarding the use of the Wii™ in rehabilitation and with people with MS is then presented as well as the role of behaviour change techniques for supporting people to become more physically active. The third chapter ends with identifying the current gaps in the evidence base and a description of the rationale for the current study. Chapter four describes how the resource materials for the Mii-vitaliSe intervention package were developed using service user input. In chapter five, the rationale for a mixed methods design is

provided along with a detailed description of the data collection and analysis methods that were used. Chapter six presents both quantitative and qualitative results in two subsections. One part relates to the feasibility aspects of the trial and the second to aspects of the intervention which includes participant and physiotherapist feedback. Since this research commenced, the Nintendo Wii™ has been superseded by the Wii U™ and therefore chapter seven provides information about the Wii U™ and describes a consultation workshop that was conducted with a sub-group of participants from the study. Chapter eight discusses the findings in relation to the literature and the changing pace of technology of this kind. This includes how this study has contributed to the wider field of adherence to physical activity for people with MS. In chapter nine, the conclusions are presented including implications for clinical practice and future research. Finally, the appendices provide additional supporting information.

Figure 1-2: Flow diagram to illustrate chapter structure



Chapter 2 Background

2.1 Introduction

This chapter briefly describes the key aspects of MS and its management.

Definitions of physical activity and exercise are presented and the importance of encouraging and supporting people with MS to adopt healthier behaviours so that they can become more physically active is outlined.

2.2 Epidemiology

Approximately one in every 600 people in the UK has MS and each week 100 people are diagnosed (UK MS Society 2016). MS is the commonest cause of neurological disability in young adults and women are more likely to develop the disease than men (Döring et al. 2011). There are an increasing number of people living with MS which has important implications for clinical management, resource allocation and research. MS is described by the Department of Health (DOH) as a LTC (DOH 2005) which means that people need to find ways to adapt to living with the condition and manage the wide range of symptoms they experience.

MS is a chronic, neurodegenerative disease of unknown aetiology that is usually diagnosed between the ages of 20-40 years (Döring et al. 2011). It is almost three times more common in women than men (Bostrom et al. 2013). Based on data from Mackenzie et al. (2014) the UK MS Society (2016) has estimated that there are 77,790 women and 29,960 men with MS. MS has been classified into three main disease types, namely: relapsing remitting MS (RRMS), secondary progressive MS (SPMS) and primary progressive MS (PPMS) (McDonald et al. 2001). A less common benign MS (which may not result in any disability) is also sometimes seen. At diagnosis, the majority of people have a relapsing remitting form (RRMS), characterised by distinct attacks of symptoms which then resolve either fully or partially over time. People with SPMS experience an initial period of relapsing remitting disease, but this is followed by a steadily worsening disease course with or without occasional flare-ups, minor recoveries (remissions), or plateaus. In the case of PPMS, symptoms gradually get worse over time, rather than appearing as sudden attacks (relapses). On average, around 65% of people diagnosed with RRMS go on to develop SPMS and about 10-15% of people with MS have PPMS.

2.3 Aetiology

It is thought that MS is an autoimmune disease where the immune system attacks the myelin that covers nerves in the central nervous system (CNS). The reason for this attack is not clear but it may be that genetic and environmental factors contribute to the autoimmune response (Burnard et al. 2017). There may be other factors (e.g. infection, virus) that cause some people with a particular genetic make-up to develop MS. Despite extensive research, no specific infectious agent or virus has been found. MS is more prevalent in countries further from the equator, possibly due to a lower exposure of sunlight and less vitamin D being produced in the body. It has been suggested that the combined effect of low levels of vitamin D and exposure to the Epstein Barr virus could increase the risk of a person developing MS (Burnard et al. 2017).

Results of a meta-analysis suggest that there is a strong link between MS and chronic cerebrospinal venous insufficiency (Laupacis et al. 2011). There is also evidence to suggest that smoking at an early age can increase the risk of MS (Handel et al. 2011). However, there are no clear answers as to the exact cause of MS and the complex interaction of several environmental and genetic factors is an ongoing debate in the literature.

2.4 Diagnosis

A diagnosis of MS is made once there is evidence of two areas of demyelination in the CNS and following careful history taking, observation and assessment by a neurologist using the McDonald criteria (Thompson et al. 2018). Radiological evidence using magnetic resonance imaging (MRI) is carried out to provide evidence for specific areas of demyelination. This determines the dissemination of lesions which are separate in both time and location in the CNS (Polman et al. 2011).

2.5 Pathology

MS is defined as an inflammatory, demyelinating disease of the CNS (Petajan and White 1999). The demyelination can occur anywhere in the CNS, leading to widespread degeneration of myelin sheaths surrounding the axons of sensory and motor neurons. This causes disruption of saltatory conduction of axon potentials in the brain, spinal cord and optic nerves. This neurodegenerative disease process causes a build-up of irreversible neurological disability (Motl et al. 2013).

2.6 Signs and symptoms

Possible symptoms are motor problems (affecting mobility, gait, balance, dexterity and muscle strength), visual impairment (optic neuritis), dysarthria and dysphasia, co-ordination, ataxia, pain, sensory impairment, bowel and bladder dysfunction.

Changes in strength, tone and sensation in the lower limb may contribute to impaired mobility, balance and the risk of falling. Balance impairments can be an early symptom of MS and may be noticed before changes in mobility (Gunn et al. 2015).

Upper limb impairments in people with MS include ataxia, tremor, weakness, reduced range of active movement, altered muscle tone and sensory deficits. All these symptoms influence a person's quality of life and impact on their ability to participate in physical activity.

The majority of people with MS experience fatigue, which is a challenging symptom (Smith and Hale 2007) and it is the one of the main reasons why people with MS have to stop work (Van der Hiele et al. 2015). A narrative review exploring the nature of fatigue in people with MS concludes that fatigue maybe be more complex than in other LTCs and that people with MS often describe fatigue as their worst symptom (Smith and Hale 2007). A secondary complication of fatigue is that people with MS experience reduced mobility and cardiovascular fitness (Petajan et al. 1996). They may also experience emotional and cognitive changes (Döring et al. 2011). These diverse symptoms can present in many different combinations with variable severity and can fluctuate. MS is an unpredictable condition whereby no two people experience the same constellation of signs and symptoms (McConnell 2008).

2.7 Multi-disciplinary management

People with MS often have a near normal life expectancy. Over 80% of people live with MS for more than 35 years (Dalgas and Stenager 2012). There is no cure for MS and therefore it is important to identify evidence-based therapeutic options for the management of the wide range of possible symptoms (Motl et al. 2005). Timely therapeutic intervention is important to prevent the accumulation of physical disability associated with progression of the disease (Coote et al. 2009). Due to the chronic, long-lasting and disabling nature of MS, therapeutic intervention is important to maintain an independent lifestyle and quality of life. As many people

with MS are diagnosed at a young age, timely intervention is important in order to help to manage the symptoms caused by the disease.

Therapeutic intervention is provided by the knowledge and skills of a multi-disciplinary team (MDT) (Namaka et al. 2008). This includes three broad categories namely: prescribing disease-modifying drugs, relapse management and symptom management. Physicians are involved in prescribing disease-modifying drugs such as β-interferon which reduce relapse rates. They also monitor the effects of the medications and treat any secondary symptoms, e.g. infections. Nurses and allied health professionals (physiotherapists and occupational therapists) are involved with relapse and symptom management. As well as providing this management supporting people with MS to manage their condition and maintain quality of life (self-management support) is also necessary, so that people can manage their health as effectively as possible (The Health Foundation 2015).

2.8 Self-management

Self-management support aims to enable people with LTCs to take an active role in managing their symptoms and health. It embodies the notion that living with a LTC is ongoing and that the person with the condition possesses unique insights, expertise and knowledge. Self-management is defined as staying fit and maintaining good physical and mental health (DOH 2005) and has become prominent in health service provision in recent years (Morgan et al. 2017).

The purpose of self-management support is to assist people to ‘live well’ with their LTC by cultivating people’s self-efficacy and responsibility (Morgan et al. 2017). A person-centred approach with shared decision making with a health professional guides and supports this process (Jones et al. 2017). This approach concentrates on how the individual can be supported to live well which is empowering, holistic and flexible. Therefore the focus is on what matters to the individual, rather than on impairments and difficulties which can lead to dependency on the health professional (Morgan et al. 2017).

2.9 Physiotherapy

Many people with MS are referred to a specialist physiotherapist working as part of a multi-disciplinary service (Petty 2011). This may involve increasing participation in physical activity which has been described as a primary aim of rehabilitation

(Rietberg et al. 2004). Rehabilitation by a physiotherapist aims to reduce disability and increase independence. This can be achieved by improving the person's mobility and physical symptoms; e.g. leg weakness, balance problems. Repetitive practice of activities improves muscle strength to help recovery and contribute to the neuroplastic changes that occur in the CNS (Kleim 2011). A motivating environment can stimulate these neuroplastic changes in the brain at a cellular and molecular level (Reid et al. 2016). Motor relearning and brain plasticity form a basis for effective rehabilitation and interventions designed to increase physical activity (Ploughman 2017).

2.10 Physical activity in people with MS

Physical activity is defined as any type of physical movement carried out that requires energy (Döring et al. 2011). Therefore, any active movement that a person does is physical activity. Physical activity includes leisure time activities (e.g. sports, gardening, walks), and everyday activities (e.g. walking at work, climbing stairs, carrying and moving heavy objects) (Health and Social Care Information Centre 2008). Exercise is defined as planned and repetitive intentional movements, which aim to improve or maintain physical activity (Döring et al. 2011).

Given the near normal lifespan of the majority of people with MS, they are just as much at risk of other major chronic conditions such as diabetes and heart disease. Participation in physical activity can play a role in the prevention of these diseases (Wen et al. 2011, Reiner et al. 2013). Recent research evidence is encouraging as it points out that a small amount exercise performed regularly can make a difference to a person's health (Wen et al. 2011). The researchers concluded that 15 minutes of moderate intensity exercise a day or 90 minutes a week might be of benefit, even for individuals at risk of cardiovascular disease. Encouraging people with MS to remain physically active or increase their current levels of physical activity is therefore an important focus for physiotherapists and might help with self-management of their condition (See chapter three).

2.11 Summary

The National Institute for Health and Care Excellence guidelines (NICE 2014) and the National Service Framework for LTCs (DOH 2004) both highlight the importance of self-management to encourage engagement in physical activity. Health professionals, therefore, need to find ways of supporting people to change

their behaviour so that they can become more physically active. For people with MS, the behaviour change needs to be workable (The Health Foundation 2015) so that people can adopt healthier behaviours to avoid ill health as they age (Kings Fund 2008). This may include encouraging an individual to start thinking about changes that could be made to become more physically active, setting goals and making an action plan to support them to get started (The Health Foundation 2015).

Chapter 3 Literature review

This literature review was undertaken to gain an understanding of what is known about the benefits of physical activity for people with MS and the reasons why people with MS engage in lower levels of activity. A key aim was to present the current evidence about physical activity and exercise interventions in people with MS. This includes how physiotherapists can support people with MS to adopt healthier behaviours and use behaviour change techniques to cope with the barriers and setbacks they encounter. In recent years active gaming and virtual reality (VR) have become part of exercise interventions in a wide range of conditions as a means to overcome barriers and increase adherence. The evidence for the effectiveness of these technologies for people with MS is presented and gaps in the evidence identified.

The purpose for the literature review was to answer the following questions:-

1. What is the evidence for the benefits of physical activity for people with MS
2. Is exercise safe for people with MS
3. How do the physical activity levels of people with MS compare to those of the general population and those with LTCs
4. What are the barriers and enablers of physical activity for people with MS
5. What is the evidence for the effectiveness of active gaming to support people with MS to become more physically active
6. How may physiotherapists use behaviour change techniques to support people with MS to participate in physical activity

Initially many of the databases were searched through the EBSCO federated search engine for Bournemouth University, mySearch. Using mySearch as a starting point, it was possible to compile possible search terms to find additional relevant articles in other databases not covered by mySearch. Using the terms given in Table 3-1, and combining them using Boolean operators, it was possible to combine the search terms to answer the questions above. More than one search was required to find relevant articles, for example combining the terms for physical activity AND Multiple Sclerosis to answer questions one, two and three. A limiter for article type to be review articles only was used for questions one and six. To answer question five, search terms one and three were used initially

to provide an overview of the evidence for active gaming as a tool for increasing activity levels. As the focus for this thesis is people with MS search terms one, two and three were then used to search for evidence for the effectiveness of active gaming for increasing activity levels for people with MS. Finally, search terms one, two and four were used to search for evidence to answer question six of the literature review.

Table 3-1: Search strategies

Search terms/key words	Alternate search terms
Search term 1: Physical activity	Physical activit* OR exercise* OR physical exercise* OR rehabilitat* OR physiotherapy
Search term 2: MS	MS OR Multiple Sclerosis
Search term 3: Active gaming	Wii OR exergam* OR active gaming OR Virtual Reality
Search term 4 Behaviour change techniques	Behavi*r change technique* OR BCT* OR behavi*r change model* OR behave*r change theor* OR health promotion OR self-management model* OR Behavi*r modification* OR “health behavi*r change*”

*(asterisk) represents any string of characters, i.e. for word truncation or to search for alternative spellings of words (English and American)

To reduce the references to a smaller more controllable number of results the filters of: academic journal articles, English language and the date range 2006 – 2018 were used as limiters. The search was between 2006 and 2018 which represented the period of time when active gaming began to be used as a tool to increase physical activity levels. As mySearch searched so many databases simultaneously, the individual online scientific databases of Academic Search Complete, CINAHL, Complementary Index, Medline Complete, SPORTDiscus, Science Direct, PsycINFO and Web of Science were searched so that a more manageable number were viewed at any one time. The abstracts were scanned and the full papers read for those that appeared to address the research questions. From the articles found the references from the key articles were hand searched for additional references.

3.1 Benefits of physical activity in people with MS

For people with MS participating in physical activity can potentially delay the progression of the disease (Heesen et al. 2006; Dalgas and Stenager 2012) and help with symptom management, e.g. fatigue (Pilutti et al. 2013) and balance (Gunn et al. 2015). Therefore participation in physical activity is very important for people with MS for numerous reasons relating to both MS and general health (Snook and Motl 2009; Latimer-Cheung et al. 2013a; Platta et al. 2016). Since the first published RCT of exercise and MS (Petajan et al. 1996), many trials have evaluated the benefits of physical activity for people with MS and there is now evidence from reviews that engaging in physical activity is beneficial to people with MS. These reviews also highlight some of the methodological issues raised when researching this population (e.g. the methods for assessing outcomes, the ways that adherence may be affected).

There is strong evidence from systematic reviews that participation in physical activity provides many benefits for people with MS (Rietberg et al. 2004; Snook and Motl 2009; Latimer-Cheung et al. 2013a; Platta et al. 2016). A Cochrane review assessed the effectiveness of exercise therapy for people with MS in nine RCTs (n=260) (Rietberg et al. 2004). The interventions in the studies included exercises for strengthening, general aerobic exercises, stretching and functional activities in either in-patient, outpatient or home settings. The intervention periods ranged from four weeks to six months with six trials using a no exercise therapy comparator and three an active exercise comparator. A range of outcome measures were used to evaluate the effectiveness of the interventions for strength, physical fitness, balance, walking speed and quality of life. The authors concluded that there was strong evidence for the effectiveness of exercise therapy for people with MS in the domains of muscle strength, aerobic fitness and mobility and no adverse effects. This is particularly relevant given that people with MS have reductions in both muscle strength and aerobic capacity (Dalgas and Stenager 2012). Improvements in muscle strength and aerobic capacity can translate into improvements in functional activities and quality of life (Motl and Gosney 2008). What remained unclear from the review was which specific interventions and dose (intensity, frequency and duration) were the most effective for achieving these changes. This was due to the fact that intensity was often inadequately described and there was diversity in the trials included in the review concerning the duration and frequency of the training sessions All studies in the review were RCTs and categorised as high methodological approaches even

though only one study in the review reporting concealment of allocation, blinding of assessors and inclusion in the data analysis of all randomised participants. For two of the studies reviewed the methodological quality scores were based on information provided by the first author as only abstracts were available, which may have biased the review. The studies in the review included small sample sizes and the lack of statistical power which may have introduced type-II-error. Future RCTs, therefore, need to ensure that adequate methodological approaches (concealment of allocation, adequate blinding of assessors and that all randomised participants are included in the analysis) are used and reported.

A later meta-analysis included 22 trials (n=600) to establish the effect of interventions to improve walking mobility in people with moderate MS (Snook and Motl 2009). The exercise training interventions took place in either a gym, an outpatient environment (cycling and treadmill activities) or in people's homes (resistance exercises). Mobility outcomes were used to measure walking mobility and meta-analysis was undertaken. Exercise training was associated with a small improvement in walking mobility (Hedge's $g=0.19$ (CI 0.09-0.28)). The effect of exercise training was statistically significant when the exercise training took place in a supervised environment such as a gym or outpatient rehabilitation setting. In contrast, the effect was non-significant for unsupervised interventions in the home or in settings that combined supervised and unsupervised training (e.g. exercise facility plus home-based practice). This may have been due to less supervision and therefore a possible lack of confidence with doing the exercise, which may have reduced adherence. Whilst home-based interventions may be more convenient for people who have mobility impairments, it is important to consider ways of increasing adherence by offering support and guidance so that people can have confidence to exercise at home. Interventions that were fewer than three months in duration had a statistically significant effect on walking ability whilst those that were longer than three months had a non-significant effect. It may be that there was an initial enthusiasm for the intervention followed by a loss of interest which affected adherence and resulted in the minimal overall benefit. Testing the efficacy of home-based exercise interventions that use techniques to improve compliance is therefore an important area for future research.

Latimer-Cheung et al. (2013a) conducted a systematic review of the effectiveness of exercise training for people with mild to moderate disability due to MS. The review

specifically focused on the effects of exercise on mobility, fatigue, physical fitness and quality of life. This included studies (n=54) that encompassed a range of physical training programmes (resistance training, walking, instructional exercises from a video, physiotherapist prescribed exercise programme, static cycling, yoga, treadmill walking, core stability exercises). Due to the study heterogeneity (variation in outcome measures, intervention and participant characteristics) a descriptive synthesis was undertaken and not a meta-analysis and therefore effect sizes could not be analysed. There was evidence to conclude that home based resistance training (completed two-three times a week) significantly increases muscle strength following an intervention period of between eight-20 weeks. Nine of the studies in the review reported strong evidence to support the effectiveness of aerobic training two-three times a week for 30-60 minutes. These results are promising given that stronger muscle and aerobic capacity may lead to improved balance and mobility in people with MS. However, there was insufficient evidence to conclude that exercise training improves quality of life due to the multi-factorial nature of quality of life and difficulties in assessing this outcome. The results from this systematic review have informed the development of guidelines for physical activity for adults with minimal or moderate disability due to RRMS, PPMS and SPMS (Latimer-Cheung et al. 2013b). The guidelines recommend 30 minutes of moderate intensity aerobic activity and strength training for major muscle groups twice a week. Suggestions for how to achieve these recommendations include walking, aquatic therapy and resistance exercises with weights or resistance bands. This systematic review and the subsequent development of guidelines offers helpful insights but there is still a need for robust RCTs that investigate more diverse types of exercise training for people with MS. There is a need for future research to explore ways to develop interventions that facilitate people with MS to continue to engage in physical activity and overcome the barriers they experience.

There is evidence from RCTs regarding the physical benefits of exercise training for people with MS. These include improvements in both leg and arm strength (DeBolt and McCubbin 2004; Taylor et al. 2006; Miller et al. 2011) spasticity in the leg muscles (Motl et al. 2007); walking speed (Van den Berg et al. 2006; Snook and Motl 2009) and endurance and aerobic capacity (Mostert and Kesselring 2002; Kileff and Ashburn 2005; Van den Berg et al. 2006). In some of these studies, the period of intervention was short; e.g. eight weeks (Miller et al. 2011) or ten weeks (Taylor et

al. 2006). Another limitation of these studies is the lack of long-term follow-up to assess if improvements are maintained and if participants continue to adhere to the exercise regime.

As well as evidence for physical benefits, there is also evidence to support secondary benefits of exercise in people with MS. Results from meta-analyses have shown improvements in quality of life (Motl and Gosney 2008) and depression (Ensari et al. 2014). Motl and Gosney's meta-analysis (2008) reported that exercise training was associated with small but statistically significant improvements in quality of life ($g=0.23$, 95% CI:0.15-0.31) comparable in size to the effects of disease modifying medications for people with MS. The meta-analysis by Ensari et al. (2014) reported that for people with mild to moderate RRMS, there were small but statistically significant effects of exercise training on depression.

A further potential benefit of engagement in physical activity is that it may reduce the progression of MS. Whether physical activity has a disease-modifying effect is a complex issue. A literature review was conducted to find the literature linking physical activity (or exercise) and MS disease progression (Dalgas and Stenager 2012). Data from studies measuring MS progression with clinical measures (e.g. the Expanded Disability Status Scale (EDSS)) did not support the disease-modifying effect of exercise. However, a small number of studies using MRI data and patient reported measures did suggest a disease modifying effect of exercise. This suggests that there may be some link that exercise may have some neuro-protective function on the CNS in people with MS. However, the evidence is poor due to methodological weakness of the studies (e.g. small sample sizes, the difficulty of measuring disease severity) therefore limited conclusions can be made.

Learnmonth and Motl (2015) conducted a systematic review of qualitative research of the perceived determinants and consequences of physical activity and exercise in people with MS. In the 19 studies reported, 17 used a qualitative methodology and two mixed methods (representing 235 people with MS). They found that the most commonly reported barriers to physical activity and exercise were environmental (e.g. inadequate facilities or lack of appropriate advice and support) and individual factors such as fatigue or apprehension. The most commonly perceived facilitators were related to the type of exercise (appropriate to physical abilities), presence of peer support and a sense of accomplishment. The most commonly perceived benefits

of physical activity and exercise were maintaining physical functioning, increased social participation and feelings of control and self-management.

In summary, there is evidence of a range of health benefits from exercise and physical activity (Rietberg et al. 2004; Snook and Motl 2009; Latimer-Cheung et al. 2013a; Platta et al. 2016). Exercise is well tolerated by people with MS (Motl et al. 2005; Heesen et al. 2006; Dalgas et al. 2008; Latimer-Cheung et al. 2013a). A limitation of many RCTs is a lack of long-term follow-up to assess if the improvements are maintained. Ongoing engagement with physical activity or exercise is required to maintain the achieved benefits (Latimer-Cheung et al. 2013a) and therefore ways to achieve this need to be considered.

3.2 Safety of exercise for people with MS

Despite the evidence supporting the benefits of physical activity for people with MS, there has been debate in the literature regarding the safety and appropriateness of physical activity (Betts 2008; Tallner et al. 2012). People with MS have previously been advised to avoid exercise because of problems associated with increased body temperature (Petajan and White 1999; Dalgas et al. 2008). It was thought that this may slow and block the conduction of nerve impulses in demyelinated nerves, resulting in a worsening of symptoms or possible relapse (Petajan and White 1999). Avoiding exercise and conserving energy for carrying out activities of daily living was advised (McConnell 2008).

However, authors of a systematic review of relapses and other adverse events (Pilutti et al. 2014) reported in RCTs of exercise training in MS (26 RCTs, n=1295) found that exercise training was not associated with an increased risk of relapse, and risk of adverse events was not higher than in healthy populations. They concluded that exercise is safe for people with mild to moderate MS (Pilutti et al. 2014). The researchers stated that musculo-skeletal injuries were the most common adverse incidents reported. The studies in the review had insufficient reporting of the exercise interventions and variability of the exercise intensities suggesting that future studies need to clearly report exercise training protocols. The review authors noted that there were a substantial number of studies with incomplete reporting of safety information. They highlighted the need for rigorous monitoring and reporting of safety outcomes and dropout rates in both intervention and control groups in future

RCTs as this will contribute to the understanding of safe exercise for people with MS (Pilutti et al. 2014).

Similarly a two year retrospective cross-sectional questionnaire study found no association between self-reported structured exercise and clinical relapses in 632 people with MS (Tallner et al. 2012). Participants reported their participation in exercise using a questionnaire that quantified structured exercise, leisure time physical activity and work-related physical activity. The mean relapse rate within the last 2 years for the entire cohort was 1.4 (Standard Deviation (SD)=1.55). Those who reported the highest level of participation in physical activity experienced the least relapses in the last two years (<1).

3.3 Levels of activity in people with MS

Despite what is understood about safety and the potential benefits of physical activity, people with MS are often more sedentary and less physically active than the general population (Stuifbergen 1997; Motl et al. 2005, Kinnett-Hopkins et al 2017). Adherence to traditional exercise programmes has been found to be low for people with MS (Mostert and Kesselring 2002; McCullagh et al. 2008). Physical inactivity is defined as an absence of health-enhancing physical activity or not meeting physical activity guidelines. The UK physical activity guidelines ‘Start Active Stay Active’ (DOH 2011) encourage adults to engage in moderate intensity aerobic physical activity for at least 150 minutes; the activity can be spread across the week engaging in at least 30 minutes five times a week. They are for all ages and the emphasis for adults is on getting started and building more activity into daily routines.

A meta-analysis undertaken by Motl et al. (2005) synthesised the results of 13 studies (n=2369) to compare the levels of physical activity in people with MS with those with other LTCs or with no medical condition. They reported that people with MS were significantly less active than both other groups (other LTCs and no medical condition) and that those with PPMS were significantly less active than those with RRMS. They concluded that there is a need to design physical activity interventions to improve adherence and therefore support people with MS to become more active. There is a need for exploratory studies grounded in theory (e.g. social-cognitive theory) using mixed methods approaches.

Since Motl et al.'s (2005) meta-analysis, there has been a period of growth in research into physical activity with people with MS and the development of guidelines for physical activity for adults with MS (see Section 3.1) (Latimer-Cheung et al. 2013b). Kinnett-Hopkins et al. (2017) recently updated Motl et al's (2005) meta-analysis synthesising data from 21 studies and 5303 people with MS. They reached a similar conclusion that people with MS currently still engage in lower levels of physical activity in comparison with those that do not have MS. While the original meta-analysis reported that clinical populations engaged in slightly more physical activity than those with MS, the updated analysis indicated that physical activity levels of other chronic conditions were more similar to those with MS. This suggests that the presence of a chronic LTC presents a barrier to physical activity. Future research is needed to gain further insights as to why people with MS do not seem to be becoming more active despite increased awareness and evidence of the benefits of physical activity and exercise and to find ways to increase participation in physical activity in this population.

3.4 Causes of low activity levels in people with MS

A range of physical barriers affect people's decisions and choices regarding engagement in physical activity. These include pain, fatigue, mobility limitations and overheating (Stroud et al. 2009; Kayes et al. 2011). A review of the barriers to physical activity for people with a LTC (with a high representation from people with MS) reported that functional and physiological impairments result in people feeling less confident about being physically active and less in control (Mulligan et al. 2012).

Physical inactivity leads to deconditioning which can contribute to fatigue, general poor health and lower quality of life (Ellis and Motl 2013). A further consequence of this deconditioning and sedentary behaviour may be increased health risks such as cardiovascular disease, diabetes and obesity (Motl and Goldman 2011). This downward spiral of deconditioning is frequently seen in people with MS which, together with the degenerative disease process, can lead to disability and loss of independence (Ellis and Motl 2013). The psychosocial repercussions include reduced leisure, social contacts, role fulfilment and engagement in activities of daily living; all-important for self-esteem, self-efficacy and psychological well-being (Aaron et al. 2009). This highly complex and variable nature of MS means that people face difficult and individual choices regarding whether or not to engage in physical

activity (Kayes et al. 2011). A range of psychological barriers including fear, embarrassment, lack of confidence and motivation, low mood, boredom and health beliefs may also be barriers to exercise (Vanner et al. 2008; Stroud et al. 2009). There are also social and environmental barriers such as having no one to exercise with, a lack of support, not knowing how to exercise, lack of appropriate or accessible facilities and cost (Borkoles et al. 2008).

The most common perceived barrier to engaging in physical activity for people with MS is not having safe access to facilities or equipment for participating in exercise (Mulligan et al. 2012; Learmonth and Motl 2015). Fatigue is also often cited as a barrier, as well as fear and apprehension (Learmonth and Motl 2015). Ploughman (2017) conducted a narrative review of the evidence examining barriers to physical activity. The review included 12 quantitative studies ($n=2627$) and nine qualitative studies ($n=97$). Ploughman (2017) categorised barriers into five domains: (1) MS-related impairment and disability, (2) attitude and outlook, (3) fatigue, (4) knowledge/perceived benefits of exercise, and (5) logistical factors: finances, support, and accessibility. A person centred approach using education, Motivational Interviewing (MI), exercise practice and problem solving was cited as a way of addressing these barriers.

In summary, people with MS face many barriers to participating in physical activity and adherence to home-based programmes is poor. Given the stark health risks associated with inactivity, the considerable barriers faced by people with MS and poor adherence to interventions, developing innovative and convenient ways to motivate people to participate in physical activity is important. The literature highlights the importance of emphasising the benefits of physical activity for people with MS. This may be achieved with the provision of detailed guidance, monitoring, and support may also improve adherence (McAuley et al. 2007).

3.5 The rationale for Virtual Reality and active gaming

Everyone faces challenges with continuing with exercise programmes and it is potentially harder for people with LTCs such as MS because of the barriers encountered. The concept of ‘environmental enrichment’ makes exercise more fun and engaging (Reid et al. 2016) which may lead to higher adherence (McAuley et al. 2007). The term refers to a structured motivating environment (not dependent on a therapist), possibly with the use of equipment to facilitate activity. Scoping reviews

have reported how active gaming is used in rehabilitation as a potential tool for increasing physical activity (Taylor et al. 2011; Ravenek et al. 2016). It has been shown that long-term adherence in physical activity is enhanced by an individualised approach that supports activity choice over time (Hale et al. 2012; Mulligan et al. 2013). The use of virtual reality (VR) and active gaming technology could provide a more stimulating environment for exercise for people with a LTC (Laver et al. 2015).

Active gaming technologies have developed since the 1980s. The term ‘Virtual Reality’ (VR) also started in the 1980s when three-dimensional technologies emerged. Software creates a computer-generated simulation of a real or imaginary virtual environment (e.g. space, underwater, a specific location). The user is provided with visual information viewed via a computer, television or viewing goggles. Users interact and engage in the virtual environment via a mouse, keyboard or joystick or via more complex motion capture or haptic devices which provide tactile feedback.

Active gaming (also known as gaming technology or ‘exergaming’) is a technology tool that combines the use of commercial video gaming with exercise as a means to increase physical activity (Warburton 2013). Commercial video gaming has previously been a means of entertainment for the younger generation and has raised concerns that it may result in increased sedentary behaviour (Warburton 2013). However, commercially available active gaming systems can be used to promote activity and have been increasingly used in rehabilitation settings (Taylor et al. 2011).

Commercially available active gaming technologies have been available for over two decades. The Sony Play Station video game console was first introduced in 1994 and is a two-dimensional motion capture technology. The Eye Toy can be played on a Sony PlayStation2 and uses camera technology and hand-held wands which detect movements of the arm (Taylor et al. 2011). Microsoft’s Xbox 360 video game console was first released in 2005 and has been redesigned over the last eight years with the Xbox One, released in May 2013. The Nintendo Wii™ is a three-dimensional motion-controlled video game system that became available in 2006. The Dance Dance Revolution video game is available for use on video consoles in

combination with a dance mat and facilitates the user to move in time to music beats while standing on a mat.

There is evidence that active gaming can increase activity levels in a wide range of conditions. Scoping reviews have reported on the use of active gaming in rehabilitation (Taylor et al. 2011; Ravenek et al. 2016). The Nintendo Wii™ has been frequently used by physiotherapists across a range of settings (in-patients, outpatients, residential facilities and home-based) and with neurological conditions (MS, Parkinson's disease and traumatic brain injury) and non-neurological conditions (Ravenek et al. 2016). A review reported the evidence for energy expenditure when using the Nintendo Wii™, Sony Eye Toy, Dance Dance Revolution and Xbox Connect (Taylor et al. 2011). The authors concluded that both the Nintendo Wii™ and the Dance Dance Revolution gaming systems may encourage activity and increase energy expenditure.

A systematic review of the use of video games in rehabilitation comparing 126 studies (n=4240) reported that 79% of the studies used the Nintendo Wii™ (Bonnechère et al. 2016). The majority of participants had neurological conditions (cerebral palsy, stroke and Parkinson's disease). Generally, the results suggested that using active gaming in rehabilitation with people is as beneficial as conventional therapy.

A systematic review of VR and gaming systems used by older people (over 45 years) at home (residential or in retirement home) provides insight into how VR has been evaluated in non-hospital settings (Miller et al. 2014). Fourteen studies were included in the review, the majority of which were case studies and two were RCTs. The Nintendo Wii™ was the most frequently used gaming system. Balance and mobility were measured but the findings from this review are weak due to the lack of RCTs.

These reviews illustrate how the Nintendo Wii™ has generated considerable interest among clinicians and researchers and has widely been used in clinical practice to encourage movement, balance and co-ordination. This may have been because it was marketed to promote physical fitness. The Xbox Kinect™ and Sony Play Station do not appear to have attracted the same amount of interest and feature much less in reviews (Taylor et al. 2011, Ravenek et al. 2016).

3.6 Rationale for the Nintendo Wii™ as a tool to increase physical activity

The Nintendo Wii™ is a game console designed to get people moving by playing games and pilot studies suggest that it may improve adherence for people with MS (Taylor and Griffin 2015). The Wii Fit Plus™ software is one of the most frequently sold video console software (Goble et al. 2014) which includes over 60 strength training, aerobic, yoga and balance activities.

The Wii™ has the potential to overcome some of the barriers to participation in physical activity that people with a LTC may experience. The Wii™ can be used in a wide range of settings (e.g. homes, schools, specialist centres, rehabilitation departments) and its use can be adapted for a wide range of physical and mental abilities (Warburton 2013). This may be a potential value for people with MS, given the wide range of symptoms they experience and the fluctuating nature of the condition. It offers an exercise environment in which people with disabilities can feel comfortable in their own home to play games with their family and friends with a pleasant non-threatening atmosphere (Petajan and White 1999; McAuley et al. 2007).

Adherence may also be enhanced as the Wii™ games provide prompts and feedback about progress and performance and are engaging and fun (Thornton et al. 2005). Interventions that give feedback on a person's performance have been shown to enhance self-efficacy (Ashford et al. 2010). The Wii™ offers opportunities for socialisation across the lifespan (Farrell 2009) which is relevant to people with MS given they may be diagnosed early in life. It also offers the ability to participate in semi-immersive VR activities that might otherwise be challenging for people with MS due to physical impairments (e.g. tennis and golf). It has been suggested that these VR features may be an alternative to traditional balance and postural training for people with MS and something they can use when they do not have access to physiotherapy (Massetti et al. 2016). The Wii Fit Plus™ software offers interesting features as a means of assessing balance ability (Body Test and Wii Fit™ Age) which may appeal to users with balance impairment. The Wii Sports™ games (tennis, golf, baseball, bowling and boxing) use significantly more energy than sedentary activities (Lanningham-Foster et al. 2009), but not as much as playing the actual sport (Graves et al. 2007).

Holding the Wii™ remote and pressing buttons to navigate through the on-screen commands to select games requires hand and arm dexterity, co-ordination and strength. The nunchuk offers a facility for playing games that requires both arms and also has motion-sensing technology. These hand controllers offer a way to track even subtle body movements accurately and provide feedback (like a therapist giving feedback or a virtual personal trainer). When a person stands on the Wii™ balance board, side-to-side and anterior-posterior movements are detected (Goble et al. 2014). Visual feedback is also given via an avatar known as a ‘Mii’ which is an on-screen representation of the user (Taylor et al. 2011). This provides opportunities for users to learn about their centre of balance, body mass index and can give feedback. In the Wii Fit Plus™ software a virtual on-screen trainer leads users through yoga and muscle strengthening poses giving feedback. It has been proposed that games that offer this feedback may be helpful for improving balance and core strength (Nitz et al. 2010). This feedback has the potential to support people with MS to learn about and become more aware of their movements. This has the potential to support self-management by facilitating people to take responsibility as they become more aware of their movements (Morgan et al. 2017).

The wide range of software available to use with the Nintendo Wii™ console allows for a breadth of different games to be available. The user is offered feedback on the accuracy of their movements and the difficulty of the movements can be progressed (Taylor et al. 2011). This range of games offers variety so that different activities can be done each day. Even if the same activities are repeated from day to day, new levels can be unlocked as users progress. This assortment of games may prevent some of the boredom associated with more traditional exercise interventions and may increase adherence (Deutsch et al. 2008). Within the Wii Fit Plus™ there are aerobic exercises and tasks to keep people mentally engaged (e.g. catching Hula Hoops, performing simple arithmetic while exercising). This allows for mind/body co-ordination, balance and memory. Given the range of symptoms experienced by people with MS (McConnell 2008) this may be a beneficial feature. Features such as the pleasing graphics and audio feedback promote an enjoyable experience. Wii™ games can be played for brief periods at the individual’s convenience. Daily activity levels can be accumulated in short bouts of ten minutes or more throughout the day which is thought to be as effective as doing it all in one go (DOH 2004; Wen et al. 2011). It is possible that by offering choice and flexibility to people with a

neurological condition, the Wii™ may prevent boredom and therefore support people to remain engaged.

Positive feedback provided by games is designed to enhance motivation, e.g. cheering from ‘virtual’ spectators in the stands, playing pleasing music when a game is won, the showering of ribbons (Deutsch et al. 2011). The graphics add an element of fun, particularly the ability to create a ‘Mii’ (a personalised representation of one’s self) which could enhance self-efficacy and motivation (Kerrigan et al. 2009). Interestingly, Jin (2010) found that game players who created a ‘Mii’, reflecting an ideal self, felt greater self-avatar connection than those who had created an actual self. Games in the Wii Fit Plus™ software offer the ability to monitor the accumulative time spent playing games via an on-screen timer (called the ‘Fit-Piggy’) and to achieve rewards (bronze, silver and gold). These features may be a way for people to monitor their activity and could be motivational.

The immersive aspect of using the Wii™ has been noted as an advantage as has the individualised approach that is offered (Laver et al. 2015). This aspect also offers a motivating environment to support physical activity known as ‘environmental enrichment’ (Reid et al. 2016). A sense of presence is also an advantage and relates to immersion (when users perceive that they are in the virtual world or environment (Laver et al. 2015). It has been suggested that active gaming can produce physiological and psychological benefits and that participation in active gaming is more enjoyable than traditional rehabilitation programmes (Warburton 2013). In addition, active gaming offers a wide range of intensities enabling a person to choose the type and frequency of the activity (Warburton 2013).

The concept of *flow* is experienced by high levels of performance and enjoyment (Mellecker et al. 2013). *Flow* is described as an intrinsically motivating optimal state which acts to encourage on-going activity and therefore has the potential to improve engagement in physical exercise. The Wii™ has the potential to do this because of the immersive nature of the games, whereby people may lose track of time because they are immersed in the game. This immersive aspect may be supported by the options available to progress which adds variety and allows for new and different goals to be set. The graphics and audio feedback may also enhance this immersive aspect.

3.7 Evidence for the Nintendo Wii™ as a tool for increasing physical activity for people with a long-term condition

Given an increased interest in the use of the Wii™ in research studies exploring its potential to increase levels of physical activity it is important to appraise the evidence and identify gaps and limitations in order to inform future research. In recent years, systematic reviews have been conducted on the use of the Wii™ for participants with neurological disease which include people with MS. Goble et al.'s (2014) review specifically focuses on the Wii Fit™ software as a tool for training and measuring balance ability in healthy adults (11 studies) and clinical populations (8 studies). Despite the range of studies, sample sizes were small and only three studies were RCTs. A range of outcome measures were used, including those that are easy to administer in clinical practice (Timed Up and Go (TUG) and Berg Balance Scale) and more complex assessments to assess limits of stability using balance systems. There were no negative effects of Wii Fit™ training and, in six studies, the results indicated some quantitative or qualitative improvements. The Wii Fit™ software has attracted interest in rehabilitation, possibly because of the features that may enhance adherence (e.g. the balance metrics, the virtual personal trainer and the feedback). Despite this, more research is required to determine if long-term changes can be made, particularly for people with a LTC.

A Cochrane review of active gaming in stroke rehabilitation reviewed 37 studies (n=1019) (Laver et al. 2015). Four studies used the Wii™ in the intervention in non-acute settings (but not home-based). All four studies were small (maximum 22 participants) and the intervention periods were also short (maximum 5 weeks). In two studies, the Wii™ was used as an adjunct to conventional therapy. One of the conclusions from the review was that active gaming may help with the neuro-plastic changes important in early stroke rehabilitation (Laver et al. 2015). However, this field of rehabilitation is still evolving and evidence limited suggesting the need for more robust research to measure effectiveness.

The majority of studies in the Laver et al. (2015) review were delivered in an outpatient setting to participants six-months post stroke. One study used the Nintendo Wii™ in a hospital setting (Saposnik et al. 2010) and other gaming systems were evaluated in the other studies. Adverse events were monitored and reported in eight studies (e.g. headaches, dizziness and treatment associated pain)

with six studies reporting no significant adverse effects. Most of the studies were too small to draw conclusions. The authors recommend that future Wii™ research should include the use of pilot studies as part of a process of developing and defining an intervention. Another recommendation was that future studies should measure the long-term effect of the intervention as well as assessing issues of engagement, motivation and enjoyment levels.

A systematic review and meta-analysis of six studies (n=166) investigated the effectiveness of the Wii™ in rehabilitation interventions with independently mobile people one year or more post stroke (Cheok et al. 2015). Comparisons were made between an intervention with the Wii™ to standard stroke rehabilitation care or other exercise interventions. The interventions used the Wii Fit Plus™ or Wii Sports™ software which offered opportunities for a range of activities. The intervention periods were short in duration (maximum of 12 weeks) and participants were asked to exercise for 60-90 minutes per week. The results showed that there was a small but significant improvement in the TUG test for those that received the Wii™ intervention compared to standard care. However, there were no reported improvements in balance but this may have been due to the fact that most participants were one year or more post stroke and were independently mobile.

The multi-centre TWIST trial (n=240) was the first of its kind to investigate the effectiveness of the Wii Sports™ as a home-based tool for improving arm strength following stroke (Adie et al. 2014). The Wii Sports™ software was used to motivate and facilitate people within six months of stroke to participate in repetitive, task-specific training at home. A research therapist installed the equipment in people's homes and instructed participants how to do warm up exercises and then to choose and use any of the Wii Sports™ games (bowling, tennis, golf and baseball) in a seated position for 45 minutes. Written instructions and a diary were left with participants and the equipment was loaned to them for the six-week intervention period. The control group were instructed to complete 45 minutes of seated graded repetitive arm exercises. The primary outcome measure was the Action Research Arm Test (ARAT) assessed at six weeks and six months. There was no significant difference in arm function measured by ARAT between the intervention and control group at six weeks or six months but in both groups there were improvements. The results of the TWIST trial (Adie et al. 2017) showed that the Wii™ was well tolerated and safe but the authors referred to the novelty factor of the Wii™ and

suggest that therapists may have needed reassurance that it worked and noted the need to explore therapists' attitudes to novel interventions (Adie et al. 2017).

Barry et al. (2014) conducted a systematic review of the evidence from seven studies that used active gaming technology in interventions for people with Parkinson's disease (PD). Six studies used commercial WiiTM games (Wii Fit PlusTM and Wii SportsTM) and one study developed a game designed for PD using the Sony Playstation EyeTM camera. With the exception of one study (where the WiiTM intervention took place at home (Esculier et al. 2012) all took place in the clinic setting. Participants had PD for between three and nine years with a Hoehn and Yahr stage of 1 or 2 indicating mild unilateral symptoms. The studies included in the review used a range of outcomes for mobility and function (TUG, 10 metre walk tests), balance (functional reach, Berg Balance Scale), Quality of life (PDQ39) and hand dexterity Nine Hole Peg Test (NHPT). Improvements were seen in balance assessments, motor function and disease severity in all six studies using the WiiTM, and in two of them this was maintained after the intervention ceased for two months. The use of the WiiTM in research studies with people with mild PD is limited to small studies with poor designs.

The only RCT included in the Barry et al.'s (2014) review explored the effects of the Nintendo Wii FitTM on activities of daily living in 32 adults with PD (Pompeu et al. 2012). Participants were randomised to either an intervention consisting of 10 Wii FitTM balance games or to traditional balance exercises that had been matched for the motor demands and duration of the Wii FitTM training regime but without the provision of the external cues, feedback and cognitive stimulation provided by a physiotherapist. The Wii FitTM programme consisted of 14 twice-weekly one-to-one training sessions, plus a follow-up session 60 days after the end of the programme. All sessions were held at the Parkinson's Association Centre. While both types of training led to statistically significant improvements in performance of activities of daily living, balance and cognition, the researchers speculated that a training programme using the WiiTM might be more likely to lead to better adherence in the longer term. However, the follow-up period of this study meant that longer term adherence could not be explored. A further limitation of this study was that the randomisation process was poorly described.

The one home based intervention using the Nintendo Wii™ for balance training for people with PD was a small pilot study (n=10) (Esculier et al. 2012). The balance training involved a specific programme undertaken in the home for 40 minutes, three times a week over a six-week period. The programme included 30 minutes using the Wii Fit Plus™, the balance board (the games were Hula Hooping, Table Tilt, Ski Slalom, Balance Bubble, Ski Jump, Penguin Slide and Deep Breathing) and for 10 minutes using Wii Sports™ (either golf or bowling). Participants were telephoned once a week to enhance motivation. Comparisons were made with healthy age-matched participants (n=8). The first training session was completed with supervision for safety reasons with no adverse events reported. The small sample was not powered to detect significant improvements but the results showed changes in some assessments (e.g. TUG and walking tests) at the end of the six weeks.

Logbooks were used to assess participant satisfaction of the intervention with 50% (n=5) reporting liking the programme very much and no participants disliking it. The small sample, absence of follow-up data, the lack of a control group, and the non-blinding of assessors were limitations of this study. The study was small and not powered to test effectiveness. However the home based Nintendo Wii™ intervention offered a safe and acceptable way to exercise at home for people in the early stages of PD.

The positive benefits reported in these reviews are encouraging and suggest that the Nintendo Wii™ could be a useful tool to motivate people with LTCs to participate in exercise programmes supported by a physiotherapist. However, all the studies were small and not designed to determine if long term changes can be made. This suggests that interventions using the Wii™ need to be developed and designed and then tested in large scale trials to produce stronger evidence for the effectiveness of interventions using the Wii™ in neuro rehabilitation.

3.8 Safety considerations and appropriateness of the Wii™

The Nintendo Wii™ was developed for use in a healthy population and therefore the risks for people with a LTC warrant careful consideration. The user manual provided with the Nintendo Wii™ gives information on how to use the Wii™ safely. Whilst using the Wii™, on-screen prompts about resting and taking a drink of water are provided. Despite this, injury, discomfort or increased symptoms have been reported following using the Wii™ (Cowley and Minnaar 2008; Gil-Gómez et al. 2011; Sparks et al. 2011).

Many of the injuries reported from Wii™ use have been due to people exercising beyond their limitations and without resting adequately. This may be due to the vigorous and repetitive movements and the fun, immersive nature of the games (Taylor et al. 2011), which possibly causes users to be excessively enthusiastic initially rather than starting with small periods of use and gradually increasing the time. Repetitive movements and overuse of the Wii™ has led to injuries (Sparks et al. 2011). Other reported injuries relating to gaming consoles include ‘Wii Shoulder’ (Cowley and Minnaar 2008), thumb fracture (Galanopoulos et al. 2012), ‘Wii Knee’ (Almedghio et al. 2009) and ‘Nin-tendinitis’ (Asian News International 2009). Falls have been reported when completing balance exercises with Wii Fit™ (Nilsagård et al. 2013). In a non-randomised pilot study involving 30 people with MS, a repetitive knee injury from aerobic stepping was reported and nine participants in the intervention group reported an increase in symptoms which stopped them using the Wii™ for at least one week (Plow and Finlayson 2011). Injuries may also be due to playing too much, or a poor technique, suggesting the need to provide adequate instruction and support as well as a risk assessment (Ravenek et al. 2016).

A particular concern is that some of the feedback provided by the Wii™ may not be acceptable for people with MS who are starting to exercise or who are newly diagnosed with MS. For example, feedback such as ‘unbalanced’ or ‘couch potato’ may be inappropriate or be a little disheartening and demoralising for people who have balance or mobility issues or who are just starting to engage in more physical activity.

3.9 What is the evidence base for using the Wii™ to increase physical activity levels for people with MS?

Three pilot studies and four RCTs using the Wii™ with people with MS were found in the literature review. Often research projects proceed rapidly to a full scale RCT overlooking vital preparatory stages (Craig et al. 2008). This can result in a resource intensive and costly analysis of a conceptually or clinically flawed intervention. Pilot studies are therefore essential pre-requisites to assess feasibility for a large scale study because they provide important information for informing future RCTs (Thabane et al. 2010). Pilot studies are designed to test the methodology and procedures to inform a future trial. Feasibility studies are designed to estimate the parameters that are needed to design a main study. Both pilot studies and feasibility

studies differ from powered studies which are designed to test effectiveness using adequately powered sample sizes. Studies in health research are often underpowered with no sample size calculation.

A critical review of the studies evaluating the efficacy and effectiveness of Wii™ based interventions for people with MS was undertaken (Table 3-2). The study methodologies were critiqued using guidance from the Cochrane Collaboration (2011). The study interventions were critiqued using the (TIDieR) checklist to assess if the materials used in the delivery of the intervention were clearly specified as well as the mode of delivery and location (Hoffmann et al. 2014) (Table 3-3).

3.9.1 Randomised controlled trials

To date there has been one multi-centre trial (Nilsagård et al. 2013) carried out in Sweden which specifically investigated the effects of the Wii Fit Plus™ software package on balance and mobility. This was the first study to report feedback from both participants and physiotherapists giving a dual perspective of the use of the Wii™ for improving balance (Forsberg et al. 2015). Participants (n=84) with MS, who could walk at least 100 metres without rest and who reported balance impairments, were randomised to receive either a Wii Fit Plus™ balance intervention in the hospital setting or no exercise. Twelve 30 minute balance intervention sessions were delivered over six to seven weeks with physiotherapist supervision (Nilsagård et al. 2013). In order to standardise the intervention, the games in the software were ranked by the researchers. Participants started using the games deemed to be ranked as easy (e.g. Penguin Slide, Perfect 10, Soccer Heading). Physiotherapists supported participants to progress to games that had been ranked as more difficult (e.g. Balance Bubble, Tilt Table, Snowboard Slalom). The researchers report that the physiotherapists were ‘in charge’ of the remote control and that they recorded the games played, rests required and feedback regarding progressions of games. This suggests that the physiotherapist support was directive and possibly offered extrinsic motivation to participants (Table 3-3).

The primary outcome measure was the TUG and other measures were cognitive TUG, Four Square Step Test, 25 Foot Walk test, Timed Chair Stand test and self-reported assessments (Dynamic Gait Index, 12-item MS Walking Scale and Activities-Specific Balance Confidence Scale). In the exercise group, the cognitive TUG, TUG and Dynamic Gait Index produced moderate effect sizes in the direction

of benefit, but there were no statistically significant improvements in the primary outcome measure (TUG). Moderate effect sizes in the TUG and cognitive TUG in the intervention group may be due to an increased confidence in walking as a result of the balance training. Some of the games that participants would have used in the intervention do involve cognition (e.g. Perfect 10 involves adding numbers) which may also account for the moderate effect in the cognitive TUG. The sample size was based on TUG (potential SD four seconds) however the sample was more varied than expected with a SD of six seconds giving rise to a reduced power to detect a true difference.

Nilsagård et al. (2013) reported no serious adverse events. However, participants in the intervention group reported 10 falls during the study period compared to 14 in the control group. Although none of these occurred during the intervention or assessments (maybe because participants were supervised). This does seem to be a high number of falls in a short period of time, even for people with balance problems. The definition used for falls is not stated and therefore it is not clear if the fall incidents were near falls, slips, trips or falls to the ground.

Fifty-six mobile (with or without a walking stick) adults with MS were randomised into three groups (balance training using the WiiTM, traditional balance training and a control group) (Robinson et al. 2015). Participants in the WiiTM balance training group undertook the balance, aerobic and muscle workout games in standing and those in the traditional balance training group were asked to complete balance, aerobic and strengthening excises that mirrored those in the Wii FitTM software. After the four-week programme all participants were reassessed using balance, gait and *flow* experience (an intrinsically motivating optimal state) outcomes. Those using the Wii FitTM demonstrated significantly higher post intervention *flow* scores suggesting that exergaming may be more intrinsically motivating than traditional balance training. Scores on the *flow* state scale questionnaire were statistically higher in the Wii FitTM group for five out of the nine domains on the questionnaire. This suggests that participants using the WiiTM achieved higher levels of involvement in the game and an altered perception of time.

3.9.2 Pilot studies

Prosperini et al. (2013) conducted a 24-week pilot randomised crossover trial of home-based Nintendo WiiTM training. In this study 36 people with MS with impaired

balance and an EDSS score ≤ 5.5 were randomised to receive either home-based training using Wii Fit Plus™ and the balance board followed by no intervention or the reverse. This design meant that the 36 participants in the study served as their own control which reduces between subject variability (Table 3-2). Initially the games in the intervention were at a basic level in sitting (Zazen) or standing (Table Tilt and Ski Slalom). Later more advanced games were included (Penguin Slide, Tightrope Walk, Soccer Heading and Balance Bubble) and participants were advised to choose the games they most enjoyed. A trained physiotherapist installed the Wii™ in participants' homes and supervised the first training session. During the 12-week intervention period participants were asked to undertake 30 minute sessions daily using the balance board. They were allowed to miss one session during the week and not to undertake sessions at the weekend. Therefore each participant were asked to complete 48 sessions. All participants were given a logbook giving details of the training programme and any safety considerations. They were asked to record in the logbook daily the type of game played and the duration of play. Occurrences of any adverse events were also recorded during the 24-week study period. Thereafter, face-to-face supervision was provided on a monthly basis and telephone monitoring on a weekly basis (Table 3-3). A repeated measures analysis of variance showed treatment effects for static and dynamic balance and MS-specific quality of life. Five adverse events were reported (e.g. knee, neck and back pain) with one participant having to withdraw from the study due to an event related to the balance board.

In a pilot RCT by Brichetto et al. (2013) 26 adults with MS in an outpatient setting, who had fallen at least once in the last year and had an EDSS score ≤ 6 , were randomised to either 12 one hour sessions 3 times a week of either Wii™ exercises (one hour of supervised Wii Fit™ session using the balance games randomly ordered) or traditional balance exercises (Table 3-3). The specific aim of the study was to assess if balance exercises that offer visual feedback are beneficial. The intervention was one hour of specific games in the Wii Fit™ software (Soccer Heading, Slalom Skiing, Table Tilt, Snow Boarding, Tightrope Walking and Zazen) which were supervised. The control group included a variety of balance exercises with or without a balance board (single leg stance, half-kneeling). Adherence in both groups was high but that may have been because the exercises were supervised and in both groups there seemed to be sufficient variation of exercises for the 12 sessions. The Wii™ group showed an increase on the Berg Balance Scale and some

of the static posturography outcomes compared to the traditional rehabilitation group. However, the study was not powered to detect statistically significant changes and therefore no conclusions can be made about the effectiveness of the intervention from this pilot study,

These results contrast with Nilsagård et al.'s (2013) multi-centre trial which concluded that a programme of Wii Fit Plus™ exercises compared to no intervention (Table 3-2) showed no statistically significant differences. The outcome balance measures used in Nilsagård et al.'s study (2013) were measures of dynamic standing balance (e.g. TUG, Four Square Step, Timed Chair Stands) whereas in Brichetto et al.'s RCT (2013) more static balance measures were used (Berg Balance Scale and posturography). Another reason for the different conclusion may have been the longer treatment sessions, 180 minutes a week (Brichetto et al. 2013) compared to 60 minutes a week (Nilsagård et al. 2013).

A pilot RCT by Guidi et al. (2013) showed similar results to Brichetto et al.'s RCT (2013). Participants with MS and balance disorders (n= 17) were randomised to receive either ten 45 minute twice weekly sessions of Physiofun Balance Training (WiiWare™) or recommendations about strategies for behaviour and environment aimed at reducing the risk of falls. Physiofun is a progressive sequence of six balance exercises, both static and dynamic all performed on one leg (Table 3-3). While those in the Physiofun Balance Training group demonstrated some improvements on the Berg Balance Score than those in the non-exercise group the study was not powered to detect statistical significance and therefore no conclusions be made about the effectiveness of the Physiofun Balance Training intervention. Both pilot studies (Brichetto et al. 2013 and Guidi et al. 2013) had small sample sizes and no longer term follow-up.

Findings from a non-randomised pilot study conducted in the USA suggested that people with relapsing-remitting MS (RRMS) with mild balance and mobility impairment can use the Wii Fit Plus™ safely at home (Plow and Finlayson 2011). Although non-randomised, it did have a controlled element as it incorporated a repeated measures design using a baseline control period (Table 3-2). This design uses the same participants in each group of the research which controls for factors that cause variability between subjects and also allows for repeated measures to be collected over a period of time. The advantage of this design is that fewer

participants can be used to detect a desired effect size. In this study, 30 adults with RRMS were prescribed a 14-week programme of Wii Fit™ exercises (yoga, balance, muscle strengthening and aerobic training) three times a week with weekly monitoring calls during the first seven weeks (Table 3-3). At seven weeks, there were improvements in balance and strength. However, by the end of the 14 weeks Wii™ use had returned to baseline levels. The researchers suggested that participants had not internalised the Wii Fit™ goals and may have only been motivated to achieve their goals when held accountable to the researchers.

3.9.3 Qualitative findings

As part of a pilot study of a 14-week Wii Fit™ home exercise programme, Plow and Finlayson (2014) conducted interviews to explore the usability of the Wii™. Findings suggest that the Wii™ provides an enjoyable way to become more active. Frequent uses of the Wii™ described the experience of gaming as effortless and fun and had a perception that time went quickly. The idea that the Wii™ is like having a personal trainer in the house was also noted as motivational. This helped participants to achieve goals for becoming more active and continuing to remain more active once the study was completed. They found that many of the barriers and facilitators were similar to those for traditional exercise programmes; these were time, a lack of motivation, holidays and boredom. The home environment was perceived as convenient to some participants while for others there were distractions.

The perceptions of participants and physiotherapists in Nilsagård et al.'s (2013) multicentre trial were reported (Forsberg et al. 2015). Participants also described that the time passed quickly during the training sessions and that the games were a fun way to exercise. Similarly, physiotherapists valued the competitive nature of the games and explained how participants pushed themselves and therefore compliance was good. Good adherence may also have been due to the physiotherapist supervision and encouragement offered to participants in sessions. Many participants also spoke about continuing to play with the Wii™ at home as a fun way to exercise. The Wii™ could also provide an alternative way to exercise during the winter when the weather could be a barrier to outdoor exercise. Participants also felt that the training was gentle and therefore could be done when they were not feeling well. These experiences of fun, immersion, ongoing challenges and not getting bored are described in a narrative review of exergames (Mellecker et al. 2013). The review links these narratives to the concept of “flow”.

Table 3-2: Quality review of studies using the Wii™ with people with MS

Authors	Study methodology	Participants	Intervention	Control group	Outcome measures	Summary
Plow and Finlayson (2011)	Pilot study Repeated-measures design Baseline control period N=30	People with RRMS able to walk 25 feet Patients with severe fatigue excluded Convenience sample via advertising	No randomisation No training manual but some description of intervention reported including how games were selected and progressed Adverse events reported	Baseline control period, no control group	Range of valid and reliable outcome measures administered according to a protocol. Due to concerns about a ceiling effect the second and third assessments were modified Post test data missing for four participants	No control group Patients with moderate and severe MS excluded due to unsupervised use of Wii™ at home this limits the generalisability of the results
Prosperini et al. 2013	Randomised crossover pilot study N=36	RRMS or SPMS EDSS≤5.5 with impaired balance Participants with severe cognitive impairment excluded Recruited from hospital based MS centre	Randomisation via computer generated random numbers performed by someone not involved with the assessments Training protocol and log book provided for participants Adverse events reported	Control group 12 week period without any intervention Participants in the study served as own control	Two non-blinded assessors involved in the assessments Assessors unaware of the training order allocation Valid/reliable balance measures used and self-administered questionnaire. Self-reported falls reported retrospectively Missing data for two participants	Possible reliability issues as no standard operating procedure reported Possible carry over effect from crossover design trial
Nilsagård et al. 2013	Multi-centre (four centres), single blind RCT N=84	MS in accordance with the McDonald criteria with impaired balance and able to walk 100 metres	Randomisation Physiotherapists trained to deliver the intervention	Control group no exercise Non-exercise group began exercising	Computerised random allocation sequence with a varied block sizes generated via a statistician not connected with the study Concealment achieved using sealed envelopes so that assessors could not foresee group allocation Reliable and valid self-administered assessor administered outcomes used. TUG Primary outcome measure	Low risk of selection bias Possible contamination effect from the control group No pilot feasibility work reported prior to the multi-centre trial Reduced power to detect true difference due to more heterogeneous sample than expected

Authors	Study methodology	Participants	Intervention	Control group	Outcome measures	Summary
Guidi et al. 2013	Pilot, Single blind RCT N=17	People with MS for more than 3 years, EDSS 0-3.5 and impaired balance	No details of randomisation provided No training manual	Control group received advice for environmental adaptations and behaviour strategies aimed to prevent falls	Blinding stated but details not provided Two reliable balance outcome measures used	Not able to assess if selection bias is high or low due to insufficient reporting Small sample size, no longer term follow up
Brichetto et al.2013	Pilot RCT N=36	MS defined by Mc Donald criteria, fear of falling, EDSS≤6 Participants selected from rehabilitation centre	Adaptive biased coin randomisation procedure used Training sessions with physiotherapist – No details of training manual reported	Control group received progressive static and dynamic exercises with varying base of support	Assessor blinded Researchers own static posturography equipment used dynamic balance and Berg balance for static balance Poor reporting for how adherence was measured	Low risk of selection bias Recruitment via a rehabilitation centre which limits generalisability of results
Kramer et al. 2014	Matched controlled trial N=70	MS EDSS score ≤6, impaired balance	Group matching performed according to age and performance on balance and gait assessments causing a	Control group conventional balance training	Six static balance tests on a force plate, 4 balance tests on an unstable surface and two gait analysis	High risk of selection bias Potential recall bias due to low return rates for weekly data for amount of balance training performed and falls
Robinson et al. 2015	Prospective randomised control three-arm trial design 1. Balance training using Wi Fit™ 2. Traditional balance training 3. No intervention N=56	MS, EDSS =6, able to walk 100 metres No sample size calculation	Intervention fully supervised by the researcher	Control group undertook traditional balance exercises that mimicked the Wii Fit™ balance exercises	Assessor not blinded to participant allocation Stratified randomisation by gender and block sizes of 6 using an online computer generated sequence created prior to recruitment Primary outcome measure identified as postural sway measured with force plate	High risk of assessor bias Low risk of selection bias

Table 3-3: Summary of interventions using the Wii™ for MS in studies summarised using TIDieR components

Authors	Description	Aim	Materials provided	Processes and procedures used	Delivered by/ mode of delivery	Participants	When and how much	Tailoring	Modifications	Adherence
Plow and Finlayson (2011)	Home-based Wii Fit™ exercise programme	To increase physical activity with the Wii Fit™	WiiFit™software which includes onscreen instructions	Prescribed Yoga, balance, strength and aerobic training	Four telephone calls for monitoring, goal setting, progressing exercises and overcoming barriers	RRMS able to walk 25 feet	3-5 times a week for 20-30 minutes 14 weeks	Wii™ playing minutes based on rate of perceived exertion	None noted	Wii Fit™ playing time recorded
Prosperini et al. 2013	Home-based Wii Fit Plus™ balance programme	To use the Wii Fit Plus™ and balance board to improve balance	Wii Fit Plus™ software and training protocol with rules and levels	Prescribed progressive balance training with games from Wii Fit Plus™ with the balance board	Physiotherapist supervision at first training session, then contact every four weeks and telephone contact every week	RRMS or SPMS EDSS ≤ 5.5 with impaired balance	Daily (5 times a week) for 30 minutes 12 weeks (48 sessions in total)	Allowed to miss maximum of one session a week	Action taken in response to adverse events for 5 participants (e.g. suspension or reduction of programme)	Logbook to record time and type of game played)
Nilsagård et al. 2013	Hospital based Wii Fit™ balance games	To improve balance and mobility	Wii Fit Plus™ software and Wii™ balance board	Balance exercises with the Wii Fit Plus™	Physiotherapist trained to deliver intervention and supervised all sessions	MS in accordance with the McDonald criteria with impaired balance and able to walk 100 metres	2 times a week for 30 minutes 6-7 weeks (12 sessions in total)	Participants offered choice of games they enjoyed	None noted	Physiotherapists recorded game playing time, rest periods and progressions

Authors	Description	Aim	Materials provided	Processes and procedures used	Delivered by/ mode of delivery	Participants	When and how much	Tailoring	Modifications	Adherence
Guidi et al. 2013	Hospital setting	To improve balance	Balance exercises with PhysioMode of Physiofun Balance Training of Nintendo (WiiWare™)	Progressive sequence of 6 static and dynamic exercises on 1 leg	Individual physiotherapist supervised exercises	People with MS for more than 3 years, EDSS 0-3.5 and impaired balance	2 times a week for 45 minutes, 5 weeks	None noted	None noted	Data not provided Balance was measured as key outcome measure
Brichetto et al. 2013	Outpatient	To improve balance in fallers	Specific balance exercises from the Wii Fit™ with the balance board (soccer heading, slalom skiing, table tilt, snowboarding, tightrope walking and zen)	Training sessions	Each session wholly supervised by a physiotherapist	MS defined by McDonald criteria, fear of falling, EDSS≤6 and mobile	3 times a week for 60 minutes 4 weeks (total 12 sessions)	Games randomly presented to participants at each session	None noted	Data not provided Balance was measured as key outcome measure
Kramer et al. 2014	Out-patient rehabilitation	To improve adherence to dual task balance training	Games that require arm movements from Wii Sports™ Table Tennis, Tennis and Tilt city Wii Sports Resort™ Wii Fit™ While standing on an unstable surface – Posturomed	Initial training session	Supervised sessions	MS, EDSS score ≤6, impaired balance	9 30 minute supervised sessions 3 weeks	None noted	None noted	Participants completed weekly prospective diaries for the amount and type of balance training
Robinson et al. 2015	Rehabilitation and MS centres	To improve balance and gait	Ranked Wii Fit™ exercises (balance, aerobic and muscle workouts) all undertaken in standing	4 week programme	Each session wholly supervised by a researcher (a physiotherapist)	MS, EDSS =6, able to walk 100 metres	2 weekly 40-60 minutes 4 weeks. Games repeated a standardised time per session	Participants began at normal level and increased to advanced on request	None noted	Sessions supervised by physiotherapists- record of session intensity not reported

3.10 Behaviour change techniques to support physical activity

The literature review has shown the potential for the use of the Nintendo Wii™ to facilitate people with MS to become more active (Taylor and Griffin 2015). Some of the games can be used without supervision so that users participate more in their programmes without needing someone present. This links with the concept of self-management and the need to support people to change their behaviour in order to become more physically active (Kings Fund 2008; The Health Foundation 2015). Interventions that incorporate the Wii™ need to use behavioural change techniques to encourage intrinsic motivation to address the limitations of other studies (Table 3-3). These will promote safe and ongoing engagement in the intervention.

Physiotherapists and other health care providers are trained to treat symptoms and care for people with health conditions. Historically, this has been a directive approach in which healthcare professionals offered information and professional expertise (McGrane et al. 2014). There has been a paradigm shift away from prescriptive and supervised approaches to the use of behavioural interventions to encompass lifestyle changes for the promotion of physical activity (Motl 2014). The promotion of health behaviours in order to prevent long-term health conditions has become a priority in recent years, yet despite this health professionals may not have the necessary skills to promote healthy behaviours (Van Achterberg et al. 2011).

Most of the studies reviewed that used the Nintendo Wii™ as part of an intervention had physiotherapists who supervised or facilitated the sessions and none of the interventions used behaviour change techniques (Table 3-3). Therefore, in order to be able to influence physical activity behaviour, physiotherapists need to consider theories of behaviour change and behaviour change techniques (McGrane et al. 2014).

It is often challenging to change behaviours even with behaviour change techniques (NICE 2014). For example, participation in physical activity has many health benefits (Wen et al. 2011). However, for health to improve participation in physical activity needs to become a usual and regular part of the person's life. The more physical activity a person does the better the outcome is likely to be, but this involves ongoing participation and a change of behaviour from a less sedentary to a more active lifestyle.

It is important that interventions are theoretically underpinned (Craig et al. 2008). There are many considerations to take into account when deciding an appropriate theoretical underpinning including a review of the previous literature and speaking with service users. In the light of the conclusions from previous pilot studies, it is very important to consider lifestyle changes which can be promoted in people with MS. Physiotherapists play a key role in influencing these lifestyle changes and promoting adherence (McGrane et al. 2014). A review of motivational strategies for physiotherapists used to promote behaviour change strategies identified four key psychological theories that can be applied to interventions to promote physical activity (McGrane et al. 2014). These four theories will be outlined.

3.10.1 Social Cognitive Theory

It is essential to consider the individual needs of people with MS when promoting exercise and researchers need to ensure that interventions are theory-based and incorporate appropriate behavioural change components (Learmonth and Motl 2015). This would seem to be pertinent, bearing in mind the fluctuating nature of MS and the range of symptoms (McConnell 2008) as well as the barriers to exercise experienced by people with MS.

Social cognitive theory (Bandura 1997) is a framework used for understanding health behaviours and physical activity and can influence adherence (Bassett 2003). The theory is relevant to health education programmes (McGrane et al. 2014) and has formed the basis for chronic disease self-management programmes (Jones 2006). According to social cognitive theory the key factors for learning new behaviour are a person's cognition, the environment and behaviour (Bandura 1997) and that people learn from observing others (vicarious learning). Self-efficacy and outcome expectations are described as the concepts of social cognitive theory. Self-efficacy refers to a person's perception of their capabilities within specific situations or activities (Bandura 1997) and a belief in the ability to succeed. Self-efficacy is more than a conviction about a successful outcome, but refers to an opinion regarding the ability to carry out skills required for a specific behaviour (Jones 2006). Outcome expectations refer to a person's belief about the behaviour leading to a specific outcome.

Social cognitive theory has been identified as a useful theoretical framework for physical activity interventions (Young et al. 2014). There is evidence from this

review to support that behaviour change strategies aimed to strengthen self-efficacy (e.g. planning, self-monitoring and goal setting) in physical activity interventions are beneficial. Improving self-efficacy has been shown to be linked to improved well-being and physical ability in people following stroke (Jones and Riazi 2011) and people with MS (Motl et al. 2013).

There are a number of ways of enhancing self-efficacy beliefs including mastery experience, vicarious experience and feedback (Jones 2006). Mastery experiences refer to performance. For example, a person may initially start with undertaking a small amount of physical activity and achieving this forms the basis for doing more in the future. This can be influenced by the inclusion of specific action plans for future activity. Vicarious experience refers to the provision of support and information from peers who have overcome similar barriers. This is important as social cognitive theory suggests that learning from others is important (McGrane et al. 2014). For example, stories of people with MS describing how they have become more active may enhance self-efficacy beliefs. Feedback regarding an activity that a person has completed is also an important behaviour change technique. Specific feedback regarding symptoms (e.g. ache in limbs following exercise) is important and can help a person gain understanding about exercise and know what to expect and to develop problem solving techniques (McGrane et al. 2014).

Decisions to set graded goals and actions are behavioural change techniques associated with social cognitive theory. Most human behaviour and activity is goal-directed, therefore goal setting is widely used in rehabilitation (Leach et al. 2010). The successful achievement of goals is determined by the person's skills in regulating cognition, emotions and behaviour (Siegert et al. 2004). Achieving goals can be compromised by many factors, including the presence of neurological pathology and fatigue (Levack et al. 2006). However, often the best intentions to do something do not translate into the desired action. This is known as the 'intention-behaviour gap' (Snijehotta et al. 2005). It is quite common that people do not behave in accordance with their intentions. For example, unforeseen barriers emerge and people give in to temptations.

3.10.2 The Health Action Process Approach

The Health Action Process Approach (HAPA) is a behavioural change process model that is based on social cognitive theory and attempts to bridge the 'intention-

behaviour gap' (Schwarzer et al. 2011). It identifies psychosocial influences on intention formation and the translation of intentions into behaviours. HAPA has been used as a motivational model for physical activity self-management for people with MS (Chiu et al. 2011). HAPA has two phases: motivational and volitional.

People who have not made a goal are in the motivational phase. In this phase, the goal for an intervention is to support people to develop an intention for behaviour change. The motivational phase involves health self-efficacy, outcome expectations and risk perception. A good understanding of the risk of inactivity and the benefits of physical activity correlates with higher outcome expectancy (Chiu et al. 2011).

People in the motivational phase therefore need to consider the pros and cons of making behavioural changes so that they can be satisfied with the associated costs and benefits.

Once an intention for behaviour change has been formed people are in the volitional phase. In this phase, the goal for an intervention is to support people to plan, initiate and maintain the behaviour. The volitional phase includes planning, action and maintenance behaviours, with perceived self-efficacy and other cognitions playing an important part in these behaviours. This includes the cognitive processes that enable a person to self-regulate and monitor their intentions and actions. Coping planning includes the anticipation of barriers and the identification of other actions to achieve the goal despite the difficulty (Chui et al. 2011).

Planning actions require 'implementation intentions' which are specific and structured plans for when, where and how to exercise in order to achieve intended goals (Webb and Sheeran 2008). An 'implementation intention' states the behaviour required to achieve a set goal and the situational context to perform the required behaviour (Webb and Sheeran 2007, 2008). These are known as 'If-then' plans as they link situational cues with responses that are effective in attaining goals and enabling people to overcome barriers (Gollwitzer and Brandstätter 1997). These plans are intended to give mental awareness and deliberative processes to bridge the 'intention-behaviour gap'. 'If-then' plans, when used in rehabilitation with people with MS and stroke, were found to be acceptable and feasible (Kersten et al. 2015).

Action (when, where and how to act) and coping planning (how to deal with anticipated barriers) have been found to be effective in closing the intention behaviour gap (Snijehotta et al. 2006). These plans focus on initiating behaviour and

learning how to control that behaviour so that adaptations to the plans can be made if symptoms or circumstances change. Coping planning is a technique that offers an opportunity for problem solving when a person experiences physiological changes associated with exercise (e.g. fatigue, pain) (Jones 2006). Coping planning aims to support the person to think about possible barriers and how they might be overcome. This approach to physical activity programmes, building in flexibility and planning for barriers, might increase adherence (Chiu et al. 2011). Action plans therefore need to be specific and individual to take into account beliefs and perceptions about exercise (Kayes et al. 2011). For people with MS action plans need to be flexible given the variable, fluctuating and unpredictable nature of MS.

An intervention designed to encourage cardiac patients to engage in regular activity tested the effectiveness of action and coping planning (Sniehotta et al. 2006). Participants were allocated to an action and coping planning group, an action planning group or a control group. Participants in the two intervention groups were given planning sheets and asked to make precise and concrete plans. They were also asked to memorise and visualise the plans to help them to make a definite commitment. Participants in the combined action and coping planning group took part in significantly more physical activity post-discharge compared with those in the other groups.

3.10.3 Motivational interviewing (MI)

MI was developed in 1983 as a technique to strengthen motivation (Miller and Rollnick 2013). It originates from the field of addiction counselling and can be helpful in working with a range of clients for many behavioural changes, including increasing physical activity for people with MS (Mulligan et al. 2012) and ABI (Medley and Powell 2010). MI is a style of conversation that aims to strengthen a person's motivation and commitment to change using four processes; engaging, focusing, evoking and planning (Miller and Rollnick 2013). Engaging refers to the collaboration between the health professional and person, focusing refers to the direction of the conversation with an aim to identify goals, evoking refers to promoting motivations for change so that eventually a plan can be identified.

Ploughman's (2017) review of the evidence exploring the barriers to physical activity for people with MS described that the barriers can be addressed by the use of home exercise programmes that use an individual approach and MI. An example of

this is The Blue Prescription approach which supported people to take responsibility to increase their participation in community-based physical activity (Mulligan et al. 2013). A range of activities were chosen by the 27 participants, e.g. cycling, Pilates, Tai Chi, walking, attending the gym. Qualitative findings suggest that the Blue Prescription approach offered participants freedom, flexibility and choice and that most required minimal physiotherapist contact (Mulligan et al. 2013). The role of the physiotherapist using MI was to support people to choose something that they would enjoy and succeed in doing. Participants acknowledged that respect for their personal requirements and aims supported them and differed from previous approaches. This approach differs from the traditional ‘hands on’ approach that physiotherapists are more familiar with and involves the need for training in MI (Ploughman 2017).

Authors of a systematic review and meta-analysis concluded that MI is more effective than conventional advice giving, for a wide range of diseases and behavioural problems (Rubak et al. 2005). The review discusses how the guiding style of MI can be used to enhance intrinsic motivation to change. This is endorsed by another review (O’Halloran et al. 2014) which suggests that using MI with a person with a chronic health condition may lead to modest improvements in physical activity. The literature supports the capacity for the use of MI to increase people’s intrinsic motivation to change rather than imposing extrinsic factors (Rubak et al. 2005; Medley and Powell 2010).

MI is specifically aimed towards preparing people for change by embracing a person-centred approach with open questions and reflective listening (Miller and Rollnick 2013). This approach invites a person to discuss the positive and negative factors associated with behaviour change that helps to reach a decision to change. The use of a Decisional Balance Sheet can be a helpful tool that can be used to allow people to consider and discuss the outcome of exercise in terms of losses and gains (pros and cons). The use of a Decisional Balance Sheet has been shown to influence the person’s ability to form intentions and to have a significant benefit on fitness (Prestwich et al. 2003).

3.10.4 Self-Determination Theory

Self-determination theory refers to the process for initiating and continuing with a new health-related behaviour over a period of time (Ryan and Deci 2000). This is of importance for people with MS who need to make long-term lifestyle changes and

who need to foster intrinsic motivation. Self-determination theory focuses on fostering autonomous behaviour to support people to make choices based on information they have been given (Mulligan et al. 2012). This involves respecting people's individual choices and adopting a patient-centred focus (McGrane et al. 2014). The development of autonomy requires satisfaction and achievement. With reference to physical activity this refers to the enjoyment in an activity and success at completing an activity which then supports intrinsic motivation. Adherence can be increased by making exercise for people with MS a pleasant experience and having an environment where people feel comfortable (Petajan and White 1999). Physical activity for the 'purposes of pleasure' and those activities that include social interaction and a pleasant environment are important for increasing adherence.

Competence refers to people having confidence to achieve outcomes and is linked with self-efficacy (Jones 2006). Relatedness refers to people being heard and understood which also relates to MI and self-management. Ryan and Deci (2000) suggest that autonomy and self-regulation are linked to enjoyment and fulfilment and that these are linked to the environment and social support.

In summary, physical activity is multi-faceted and psychological factors play a crucial role in its initiation and maintenance. Adopting approaches that empower people to feel more confident about managing their condition are more likely to lead to sustained behaviour change (De Silva 2011). People may agree that there are health benefits to doing exercise but may not perceive that they will be successful in doing exercise. Adherence starts with a decision to change a health behaviour, which involves considering patient choices (Heesen et al. 2014).

3.11 Future research/need for this study

The attributes of active gaming might be helpful in enhancing adherence, however future research into the use of the Wii™ for people with MS needs to incorporate behavioural change strategies to promote use and reduce usability barriers.

Behaviour change strategies that influence physical activity behaviour need to be identified and considered for inclusion in the development of an intervention using the Wii™.

The use of interactive video games is expanding within rehabilitation but the evidence base remains limited. Reviews of active gaming have identified the need for pilot studies to run a miniature version of a trial (Laver et al. 2015) and

subsequent RCTs for testing effectiveness (Taylor et al. 2011). There have been RCTs and pilot studies with people with MS using Wii™ interventions over short periods of time. The limitations of most of the studies included a small sample size, no or poor blinding (Table 3-2), limited description of the intervention and short follow up periods (Table 3-3) Future larger and well-designed trials evaluating the effectiveness of using the Wii™ therefore needed (Guidi et al. 2013).

To date, no definitive RCT of Wii™ based exercise in people with MS has been carried out in the UK and the long-term benefits of using the Wii™ are unknown. Future research for people with MS needs to include multi-disciplinary perspectives and draw upon behaviour change theories to facilitate engagement and long-term adherence. It will also be important to explore whether there are characteristics that make a person either more or less likely to engage in this type of physical activity. This will help clinicians to decide which patients may benefit the most from such interventions. Strategies for the self-management of fatigue and other symptoms need to be incorporated into these interventions.

Interventions using the Wii™ also need to include the careful monitoring of participants, particularly in the initial stages of a home-based intervention, as well as ongoing supervision (Prosperini et al. 2013). Further research needs to assess longer term use of the Wii™ and explore strategies to maintain ongoing use and facilitate intrinsic motivation (Plow and Finlayson 2014). A more patient-centred approach might help to facilitate the internalisation of goals relating to playing Wii Fit™. Strategies such as MI and building skills relating to problem solving and decision making should be explored in future studies.

Embedding qualitative methods within trials (mixed methods) can provide deeper insights into why people continue or stop using the Wii™ and those factors that promote longer term engagement with and adherence to physical activity programmes (Plow and Finlayson 2011). Most studies to date have only incorporated a short-term follow-up and it is often unclear whether participants are adhering to the intervention because of their own internalised motivation and goals or because they feel accountable to the research team (Brichetto et al. 2013; Nilsagård et al. 2013). When developing new physical activity interventions it is important to draw upon behaviour change principles and techniques to increase the likelihood that participants engage fully with the intervention and develop intrinsic motivation to

continue beyond the timeframe of the study. It is important that there is pilot and feasibility work prior to conducting full scale properly powered studies and that future RCTs incorporate long-term follow-up into their designs. There is a need for high quality RCTs to contribute to the evidence base for regular exercise and physical activity prescription for people with MS (Asano et al. 2009).

This chapter reviewed the existing literature around the benefits of exercise for people with MS and the role of VR as a tool for overcoming barriers to exercise. It highlighted the limited literature surrounding long term ongoing use of the Wii™ for people with MS and the inclusion of behaviour change techniques in interventions.

3.12 Research Questions

The main research question to be answered in this thesis is:

Can a home-based intervention, using the Nintendo Wii™ increase physical activity for people with MS (Mii-vitaliSe) (based on psychological theories, behaviour change techniques and service user involvement), be developed?

Is it feasible to run a future large RCT to assess the effectiveness of the Mii-vitaliSe intervention?

3.13 Research aims

In order to answer the research question posed above the aims and objectives of this thesis are as follows:

1. Develop the Mii-vitaliSe intervention and associated materials using service user and health professional involvement.
2. Use Mii-vitaliSe in a pilot RCT to assess the feasibility of conducting a full scale trial with the following objectives:

Objectives

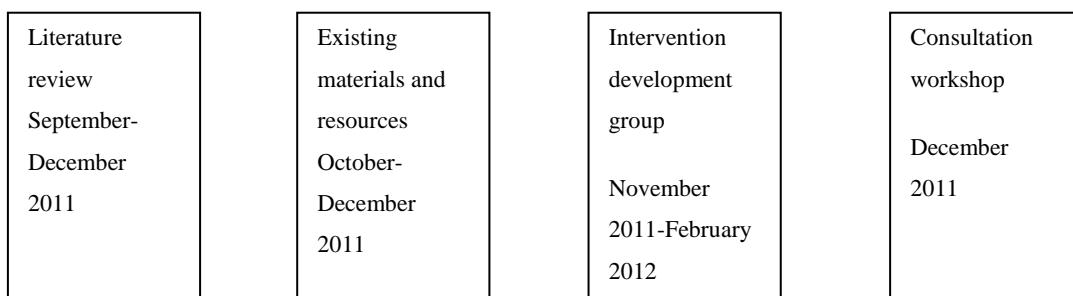
1. To test procedures, estimate recruitment and retention rates and refine the selection of outcome measures in preparation for a future full trial.
2. To calculate preliminary estimates of effect size and of standard deviation to inform a sample size for a future full trial.
3. To determine participants' views on taking part in the pilot study and receiving the Mii-vitaliSe intervention.
4. To gather feedback from physiotherapists about their experiences of delivering the Mii-vitaliSe intervention.

Chapter 4 Development of the Mii-vitaliSe resource materials

The overall aim of this phase was to refine and optimise the home-based physiotherapist-supported intervention package (that uses a commercial off-the-shelf console (Nintendo Wii™) with people with MS incorporating behaviour change techniques) for the subsequent pilot study. This chapter presents the four strands that led to the development of the resource materials for the Mii-vitaliSe intervention and aspects of study design (Figure 4-1).

The process for developing the Mii-vitaliSe intervention package was iterative involving consideration of the recent literature, a review of existing resources for using the Wii™, alongside service user involvement.

Figure 4-1: Strands leading to development of Mii-vitaliSe intervention package



4.1 Literature review

The grant application for the Mii-vitaliSe funded study was submitted to the MS Society in 2010 and the funded study commenced in September 2011. During this time the use of the Wii™ in rehabilitation was becoming popular and researchers were questioning its safety and effectiveness. Therefore as these resources were developed the more recent evidence needed to be considered.

A review of the literature presented in chapter three highlighted the need for a more person-centred approach (Hale et al. 2012; Mulligan et al. 2013), the incorporation of behaviour change techniques (e.g. motivational interviewing and problem solving) to sustain longer term use of the Wii™ and foster intrinsic motivation (Plow and Finlayson 2011; Laver et. al. 2011) and increase adherence (McAuley et al. 2007). Qualitative work undertaken in the United States suggests that people with MS

would like to be given more information about the benefits of exercise from healthcare providers and materials to support home-based exercise and behaviour change strategies (Learmonth and Motl 2015).

4.2 Existing materials and resources

Existing guidance on using the Wii™ was identified in a number of ways including searching the internet and drawing upon knowledge of those in the Intervention Development Group. The following information sources and resources informed development of the Mii-vitaliSe materials.

4.2.1 Wii-habilitation resources

Wii-habilitation is a website for those who are interested in using or already using the Nintendo Wii™ or Kinect as part of therapy or rehabilitation (Wii-habilitation.co.uk). The website was created by Rebecca Scott, a Senior Physiotherapist at the National Star College, Cheltenham, which cares for young disabled adults predominantly with cerebral palsy and ABI. Rebecca Scott was a member of the Intervention Development Group. At the National Star College, specific gaming exercises are incorporated into patients' therapy routines. The Wii-habilitation website provides resources regarding how the console can be used for general fitness as well as condition specific advice (MS, stroke, cerebral palsy, amputees) for its use in rehabilitation.

4.2.2 The Chartered Society of Physiotherapy

A protocol and advisory document for recreational or rehabilitative use of the Nintendo Wii Fit™ for people with a lower limb prosthetic was produced by a specialist physiotherapist and two prosthetists in collaboration with the British Association of Chartered Physiotherapists in Amputee Rehabilitation (2010). The protocol gives specific guidance for patients regarding how to safely use the Wii™ balance board in the physiotherapy department with supervision. The resource provides information to guide patients and therapists. A games risk framework suggests risks and solutions for preventing injuries for people that use a variety of prosthetics enabling people to make choices informed by the risk and guidance. The protocol also offers tailored advice to patients with two levels of amputation (transfemoral and transtibial).

In January 2008, the Chartered Society of Physiotherapy (CSP) provided tips for warming up and getting the most out of using the Wii™ games for physical activity

(CSP 2008). Five top tips are suggested for neck, shoulders, back, wrist and digital dexterity. The top tips included advice for warming up and cooling down and for what to do if a person experiences pain or discomfort. These were compiled by Sammy Margo (Margo 2008) and circulated via the CSP website (CSP 2008).

4.2.3 Nintendo Wii™ guidance

The guidance provided by Nintendo includes comprehensive safety advice (e.g. taking regular breaks, keeping a safe distance from the television, wearing the safety wrist strap). Nintendo Wii™ in collaboration with the physiotherapists who developed the advice above produced guidance for use of the Wii™ balance board for use in physiotherapy departments for people rehabilitating using a prosthetic following a lower limb amputation (Hirons 2009).

4.2.4 Exercise pamphlets

A colourful booklet called ‘Physical Activity For Neurological Conditions-how to get the maximum benefits from exercise’, produced by researchers at Oxford Brooks University (2010), offers advice for people with a neurological condition about the potential benefits of physical activity and how to engage in physical activity safely. The development of the second edition of the handbook was sponsored by the MS Society because people with MS had found the advice helpful. It gives practical tips using text and photographs in an easy to read format. The booklet covers many different aspects of exercising with the aim to support people to overcome barriers and support sustained participation in physical activity.

4.2.5 Guidance from Multiple Sclerosis Societies

Existing guidance for participation in physical activity and exercise from a variety of MS societies was considered:

The National US MS Society has produced an illustrated manual with an emphasis on moving and staying well (National MS Society 2016). The manual contains examples of specific exercises for head and neck, shoulder, hand and wrist etc., which were presented with simple instructions and diagrams.

The MS Society of Canada (Alberta division) provides a variety of resources on its website. These include a resource for health professionals that provides detailed and comprehensive evidence-based guidance for exercise and MS (MS Society of Canada 2007). The MS ‘ActiveNow activating your life’ resources for people with

MS includes workout journals and training logs as resources to support people to keep an exercise log as a means to monitor and structure exercise participation (MS Society of Canada 2007).

MS Australia (2009) provides resources on its website for strength and cardiorespiratory exercise. This detailed resource is supported by relevant research evidence and provides detailed information regarding different ways to exercise and includes a section on starting to exercise soon after diagnosis.

4.2.6 Games Analysis

The software available for use with the Wii™ console offers a range of games for players to choose from. Choosing which games to play may require guidance, particularly if people have disabilities. Deutsch et al. (2011) produced a game analysis of Wii Sports™ and Wii Fit™ for use in stroke rehabilitation. The analysis was completed by a team of game players and raters. The team included therapists with clinical experience and post graduate training in motor learning. They familiarised themselves with the games, noting challenges and considered how to adapt the games for use in rehabilitation. The goal for the game, the context of the environment and the actions were considered. From the analysis, tables with descriptors were created. The descriptors gave suggestions for which games might be beneficial for specific impairments, e.g. balance, strength, coordination and endurance. The aim was to create descriptions and categorisation of the Wii Sports™ and Wii Fit™ games that could be used by clinicians to guide game selection and delivery aspects in the context of rehabilitation post stroke.

From these resources, ideas for the presentation of the resource materials as well as the content emerged. It was important to make the Mii-vitaliSe resources appropriate for people with MS both in terms of content and structure. Therefore the content and structure of booklets for use with people with LTC were looked at to consider ideas for presenting the resource materials. These ideas were discussed with the Intervention Development Group.

4.3 Intervention Development Group

This group comprised physiotherapists, a psychologist, a neurologist, a medical scientist, a Wii-habilitation expert and service users. Members of this group provided feedback about the proposed key components of the intervention package. During the development stage there were regular discussions regarding the format and

content of the resource materials. These discussions included how the intervention could be personalised, how ongoing physiotherapist support would be incorporated and delivered, the potential support needs of people when selecting which games to play, how best to support people to set goals and overcome barriers.

The plans for PPI involvement were discussed with the Intervention Development Group between September and November 2011. The key messages that emerged from the workshop were discussed with the Intervention Development Group in January 2012 and a brief summary was produced.

4.4 Patient and Public Involvement (PPI)

It is important for health and social care researchers in the UK to involve patients and the public actively as equal partners in research (DOH 2006). This is known as ‘patient and public involvement (PPI)’ (DOH 2009) and this collaboration is an essential part of the research process. The NIHR has set strategic goals for 2025, identifying that public involvement is a required part of high quality research and that the experience of service users is an appreciated and necessary source of knowledge (NIHR 2015).

Service user involvement can influence and improve the quality of research (Morrow et al. 2010) and also has the potential to improve therapeutic outcomes (Baxter et al. 2001). Service users are patients or clients who are current users of a service. They can influence research through their experiences of the service, rather than professional or academic experience and training (Baxter et al. 2001). In the current study a PPI consultation in the form of a workshop was undertaken. Consultation is frequently used in PPI and offers opportunities for patients and members of the public to discuss issues of interest with researchers (Nierse et al. 2012). The workshop format offered an opportunity for service users to meet together with some members of the Mii-vitaliSe research team to share experiences and ideas.

4.4.1 Consultation workshop

The aims of the consultation workshop were:-

- To gather the views and experiences of service users who had ‘experiential’ knowledge of using the Wii™ to refine and optimise the Mii-vitaliSe intervention package

- To gather feedback on two versions of the draft play log for measuring adherence
- To discuss ways that service users could be involved in the Mii-vitaliSe research study

In accordance with the National Research Ethics Service (NRES) guidance, ethical approval was not required for this PPI consultation event (Morrow et al. 2010). INVOLVE is a national advisory group that are part of and funded by the NIHR. It works to support active patient and public involvement in NHS, public health and social care research. It defines public involvement in research as work carried out ‘with’ or ‘by’ patients and the public rather than ‘to’, ‘about’ or ‘for’ them (Hayes et al. 2012). Members of the public are therefore acting as advisors rather than research participants.

Service users of the Dorset MS service with some experience of using the Wii™ were invited to a workshop. They were approached by the physiotherapists in the Dorset MS team and asked if they were interested in being involved in a workshop to inform the development of the Mii-vitaliSe intervention package. It was important to approach service users who had direct experience of the issues under consideration. Details were provided about the venue, date and time of the workshop. Those who expressed an interest in attending the consultation workshop were asked to email or telephone the study co-ordinator to find out more and ask any questions.

During this preliminary informal phone conversation or email interaction, the service users were asked a few questions regarding their use of the Wii™, current mobility level (Adapted Patient Determined Disease Steps Scale (APDDS) (Orme et al. 2007), length of time with MS and type of MS. It was important to ask about current levels of mobility so that the service users consulted would be similar in terms of mobility to the proposed inclusion criteria for the feasibility study (i.e. ambulatory without walking aids for approximately 100 metres equivalent to an APDDS score of > 1 or ≤ 5).

The key points identified from eight pre-workshop telephone conversations were:

- Some Wii Fit™ games (e.g. Soccer Heading and Ski Jump) incorporate exercises requiring core stability similar to those in a Pilates MS class and enhance body awareness.

- The Wii™ can help an individual think about what is happening to their ‘MS body’ and how their muscles are working.
- The Wii™ can help with balance, stability, hand/eye co-ordination and stretches. There are health and safety issues and a risk of falling when an individual has balance limitations Concentration is needed to stay balanced and safe.
- The yoga positions in the Wii Fit™ are very difficult. It might be advisable to avoid the difficult yoga exercises.
- Using the Wii™ daily is fun, helps with feeling stronger physically and mentally.
- The Wii™ can be used sitting down.
- The Wii™ can be used with others at the local MS centre.
- Being able to exercise in the home can mean feeling less self-conscious.
- The software, such as the Wii™ Active, does not require the Wii™ balance board.

These preliminary discussions provided an opportunity to develop an informal and approachable relationship with service users (Hanley 2000). Arrangements were made for transport if required and dietary requirements noted. Following the initial telephone call an email was sent confirming the details for the workshop.

In advance of the workshop, attendees were sent a list of possible areas for discussion and a brief description of the proposed Mii-vitaliSe intervention. They were reminded that the workshop would be audio-recorded and that they could have an individual interview if they preferred. As recommended by INVOLVE taxis were organised or travel costs were reimbursed (Hanley 2000).

During the workshop a general discussion guide was used with prompts to ensure that important issues from the literature and pre-workshop telephone conversations were not missed. The issues discussed included:-

- Patterns of usage of the Wii™; safety aspects, benefits/drawbacks, problems identified and how they could be overcome.
- Factors contributing to longer term use, setting goals, overcoming barriers to exercise using the Wii™.

- Practical difficulties with using the Wii™, e.g. setting up, putting in batteries, charging handsets.
- Injuries, discomfort and worsening of symptoms.
- Motivation for using the Wii™; what attendees found helpful when first using the Wii™, what advice they would give to people with MS who are starting to use the Wii™.
- Feedback about the Wii Sports™, Wii Sports Resort™ and Wii Fit Plus™ software.
- The main benefits and drawbacks of the Wii™ for people with MS.

The workshop was held on 09/12/11 in the morning when levels of fatigue are often lower for people with MS (Feys et al. 2012). The workshop was held in a hotel; a neutral venue with excellent accessibility. Previous research with a similar sample from the Dorset MS Service had found service users preferred this setting to a hospital, church hall, or local MS centre (Thomas et al. 2010). Given that fatigue and other symptoms are a major problem for the majority of people with MS, refreshment and rest breaks were incorporated into the workshop schedule and it was made clear that people could take breaks at any time during the workshop. Lunch was provided at the end of the workshop.

Ten service users were invited. Eight made contact with the researcher before the workshop to discuss the workshop and confirm attendance. Two were unable to attend on the day. The characteristics of the service users who attended the workshop are presented in Table 4-1. They all used or had used the Wii™ regularly (weekly or more) and had some experience of using either Wii Sports™, Wii Sports Resort™ and Wii Fit Plus™. The workshop was also attended by the two physiotherapists from the Dorset MS service and a research psychologist (the Chief Investigator of the Mii-vitaliSe study).

Table 4-1: Characteristics of the service users at the workshop

Age	Gender	Approximate time since MS diagnosis (years)	Type of MS	Wii™ at home?	Wii™ balance board at home?	Familiar with Wii Sports™?	Familiar Wii™ Fit /Plus™	Wii™ frequency of use	Mostly uses Wii™ alone/with others/both	APDDS score /Mobility
50-59	M	1	Not known	Yes	Yes	Yes	Yes	Alternate days	Alone	(3) No limitations in walking, daily activities limited
50-59	M	24	SPMS	No	No	Yes	No	Once a week	With others at MS centre	(5) Functional electrical stimulation and crutches
50-59	M	Less than a year	Not known	Yes	Yes	No	Yes	Daily	Alone	(4) Independent in and outdoors
40-49	F	6	RRMS	Yes	Yes	Yes	Yes	Daily	Both alone and with others	(4) Often uses one stick
50-59	F	Over 20	SPMS	Yes	Yes	Yes	Yes	Weekly	Alone	(5) Uses stick outdoors
40-49	M	3	PPMS	Yes	Yes	Yes	Yes	Weekly	Alone	(5) Uses stick outdoors
40-49	M	Over 20	SPMS	Yes	Yes	Yes	Yes	Infrequently now	Alone	(5) Uses crutches when outdoors
30-39	F	Less than a year	PPMS	Yes	Yes	Yes	Yes	Not currently but was using	With children	(3) No problems with walking

The first aim of the workshop was to gather the views and experiences of service users regarding their experience of using the Wii™. The workshop was informal in style giving the opportunity for stories to be told to capture important aspects of individuals' experiences of using the Wii™. All attendees gave permission at the start of the session for the discussion to be digitally audio-recorded. Consent was gained from the attendees to use anonymised feedback and quotations generated from the workshop in the materials developed for the Mii-vitaliSe intervention and in reports and publications.

The second aim of the workshop was to gather feedback on two draft versions of a play log. The play log had a dual purpose to measure adherence and to form part of the intervention as a self-monitoring tool. One version of the log required detailed entries to be made at regular intervals throughout the day and the other had a much simpler format only requiring tick box response. The workshop attendees were asked for feedback on the content, ease of use and layout of both draft versions.

The third aim of the workshop was to discuss ways that service users could be involved in the Mii-vitaliSe research study. INVOLVE recommends active and ongoing collaboration in research between researchers and service users so that service users can continue to influence decisions made throughout the research process (Hanley 2000). Potential forms of involvement in the Mii-vitaliSe study included reviewing and commenting on draft documents and being a member of the study steering group. Discussions continued informally over lunch. Following the workshop, three information booklets from INVOLVE were sent to the attendees describing different possibilities for continued involvement throughout the research process.

Immediately after the workshop there was discussion between and reflection by the health professionals who had attended about the consultation process and some of the key issues raised. Notes reflecting these discussions were made. Both the study Chief Investigator and I listened to the audio-recordings and made notes. The information collected was not subjected to a rigorous qualitative analysis process as the purpose of the workshop was service user consultation and not to conduct qualitative research (Gooberman-Hill et al. 2013). While the aim of qualitative research is to produce generalisable new knowledge, the purpose of the workshop was specifically to inform the development of the Mii-vitaliSe intervention package

ensuring it was appropriate for people with MS. A summary of the key messages emanating from the workshop was produced. The aim of the workshop was to gather feedback from a range of people and not to achieve saturation as would sometimes be the aim in qualitative research (Gooberman-Hill et al. 2013).

The eight service users who had attended were sent this four page summary of the workshop discussions and the key topics and messages that had emerged. Providing service users with feedback and offering an opportunity for reflection is important (Baxter et al. 2001) and conveys an appreciation of their time and valuable insights.

4.5 Key messages from the service user consultation

In order to refine and optimise the Mii-vitaliSe intervention package the key messages from the workshop were summarised. They together with the critical analysis of the literature presented in chapter 3 informed the final Mii-vitaliSe intervention (resource pack and support given by the physiotherapists).

4.5.1 Patterns of use

Patterns of use varied between individuals and people liked the flexibility of being able to use the Wii™ at home for short periods of time. Some noted that the gym could be daunting and found the possibility of exercising at home convenient and appealing.

“It’s less scary to fail at home than at the gym. Also at home you can sit down for 10 minutes and then go back again. I wouldn’t do that in the gym. You can do it in stages.”

“You’re in your comfort zone. You’re in your own house and you’ve got nobody watching over you. You enjoy it much more because you’ve got things there.”

“It’s difficult with an illness like MS where a lot of symptoms are invisible. Sometimes instructors tend to push you too hard.”

Given the fluctuating nature of MS, people liked the flexibility of being able to schedule Wii™ use at times that suited their lifestyle and symptoms.

“I have to do it straight away when I get up or after I’ve had a 20 or 30 minute rest.”

“For me it’s at weekends as I’m at work in the week and really don’t feel like doing anything when I get home in the evenings.”

“I find I’m more alert at night between 6 and 10pm.”

Workshop attendees were positive about the variety of activities available for the Wii™ platform. This was beneficial as after an exacerbation of symptoms it was easy to adjust and modify aspects of their Wii™ routine.

“Start with easy exercises that you can do, then try out others when you are used to the system and work out what’s good for you.”

“Do more on the good days and on the days you don’t feel so good modify what you do and don’t expect to achieve too much.”

Workshop attendees described noticing links between the Wii™ activities and their physiotherapy and/or Pilates sessions. This aspect was also mentioned during the telephone /email pre-workshop conversations. In particular, they noted that the red dot on the screen (indicating centre of balance) shown during the body tests in the Wii Fit Plus™ provided helpful feedback about posture and balance. It was suggested that Wii Fit Plus™ was something an individual could use at times when they were not accessing physiotherapy.

“And with that there is a real connection with some of the things that they tell you in physio. When I go for my physio appointments down at the hospital rather than the actual physio classes XX (names the physiotherapist) is always telling me “right well you’ve got to adjust your leg, you’ve got to walk like this in this particular way” and it’s about shifting the whole of my gait to an unnatural position and certainly the red dot and the centre of gravity thing.....it’s what she says to me at times.”

“Sometimes you’ve got like quite large times when you’re not necessarily seeing a physio whereas if you’re doing something where you can actively do it yourself and it’s teaching yourself then you can do this without a physio then that might be helpful mightn’t it?”

4.5.2 Safety

There was general agreement that the default Nintendo Wii™ safety information offers sound advice and that a long health and safety list could be off-putting.

"It does give you quite a lot of tips though on how to do things safely and it says hold on to things if you need to and that sort of thing so I think it is quite good for that."

"That's what's going to be hard coz you're trying to adapt a game to specific disabilities but you don't want a massive great speech at the front about all the things that could go wrong, coz it could go wrong anyway I think."

Every home environment is different and there was agreement that an individual safety assessment as part of a screening process was important. The quotation below illustrates risks identified by one workshop attendee with the Ski Jump Game (Wii Fit Plus™) and potential solutions, but also reinforces the need for an individual safety assessment:

"The ski jump one is a bit...if you go for a push to get off the thing I tend to fall backwards

I tend to put a soft chair behind me

Coz you could go either way with that one because you're actually having to do a very, very sharp jerky movement. You're doing, again it's a physio move you're doing a squat or a semi squat which is good and you can feel all of your... that the right muscles are working but then when you've suddenly got to go like that it's not natural and for the likes of us that is a very, very unnatural move and we might exit stage left right backwards or forwards..."

Workshop attendees were asked if there were specific warming up and cooling down exercises they completed when using the Wii™. People reported that while they did not have a specific warm up they did tend to start off with a low intensity game.

"I personally have never carried out any warming up exercises I don't find the Wii™ that particularly strenuous that you just naturally work your way in."

"It may be that the type of games I've been using...mainly stretching and balance and so they don't tend to be too strenuous, why would you need to; the way I look at it why would you need a warm up exercise to do a stretch?"

4.5.3 Commitment and goal setting

Workshop attendees about a sense of responsibility to making time to do their Wii™ exercises These quotations illustrate how they felt about making a commitment to exercise:-

“Again it’s about making a physical commitment to it and you’re actually doing something, whether it’s on a piece of paper you’re actually marking it so it’s coming from here and it’s suddenly going down there. You’ve let it go you’ve made a commitment.”

“The important thing is to make a psychological commitment to what you are doing whether the achievement is small or whether it’s big; whether there are two achievements or whether there are 20. It’s about thinking about it, writing it down and then doing it, in three stages and making them achievable things for you as an individual; not as a group of people coz we’re all different. But recognising what you can and what you can’t do. That was my idea anyway.”

Setting goals was identified by workshop attendees as being important. However, with a fluctuating condition like MS goals may need to be more flexible and this was seen as an important consideration in the context of setting goals:-

“It’s alright saying breaking things down to weekly and monthly but I think the problem you may have then is you miss a Monday all of a sudden Tuesday’s rota is longer and if you have a bad three days all of a sudden you’re wait a minute I’ve missed the Wii™ and before you know it it’s I can’t do this week. That’s where you make a commitment to your flexibility about how you work it out.”

4.5.4 Benefits and drawbacks

There was a consensus from the workshop attendees that receiving negative feedback (e.g., the Wii Fit™ feedback includes ‘unbalanced’ and ‘coach potato’) or obtaining low scores on completion of the games in Wii Fit Plus™ can be demotivating. There was a discussion about the scores and agreement that doing some activity is more important than achieving a high score or receiving positive feedback. However, some workshop attendees noted that everyone, regardless of whether they have MS, have good and not so good days.

“Don’t expect to improve each time; don’t take it to heart: we all fluctuate with good and not so good days. It’s important to do a game rather than get through all levels-focus on the positive effects of feeling stronger and get a sense of achievement and feeling of well-being from attempting the game.”

“I think generally most people MS or no MS, know what they can do and adapt what they do accordingly. There are things I wouldn’t even attempt to do on the board for balance.”

There was general agreement that the Wii™ is fun and enjoyable to use. It was noted that setting up a ‘Mii’ character can be fun. Benefits of exercising with the Wii™ that were noted included improvements in balance, core and general strength, increases in aerobic and cardiac activity as well as general well-being.

“There’s a ‘feel-good’ associated with this type of activity. You’re basically you’re encouraging someone to improve their self-esteem by small targets, not big targets, not half an hour maybe 5 minutes then reward yourself then next week ten minutes and it’s just building up self-esteem so there is a feel-good factor to it as well.”

There was a discussion about how the Nintendo Wii™ software could be adapted to make it more suitable for a progressive chronic condition. One person suggested having an option to turn off the default feedback would be helpful.

“Do you think it would be possible to get them to turn that bit off so it’s an option you actually turn off that bit because if it’s a deterrent to people so they look at it they think I got 50 last time and I’ve only got 45 today you’re despondent.”

However, part of the overall appeal of the Wii™ is the fact that it is not specifically adapted for people with MS, it’s an off-the-shelf product which people felt normalised their MS. Also they were able to manage the demands of the Wii™ instructions and reflected that doing something in their own individual way was important:

“You’ve got to prepare yourself before you even set foot on it and say well, this is what I’m going to achieve today for me. My MS is different from

anybody else's if the Wii™ gives me negative feedback; I just think it doesn't know my world. Prepare yourself for what you want to achieve - your world is different to everyone else's."

Another noted benefit was the social aspect of the Wii™ - the fact that it is an off-the-shelf activity that can be undertaken with family and friends:-

"And the social side comes in, it brings families together who can all do the same thing whatever ability level they are."

"There's so much stuff you are restricted from doing with the kids; this is something that most people can do."

"That's the thing, it's nice that the children get involved that you say look I'm doing these exercises to help daddy withto improve my strength and stability and this that and the other. They still want to get involved and they still want to be better than me. Before you've even stood on the board, you're better than me alright! But they do, but it's nice - because it becomes a joint activity it normalises my problems."

4.5.5 Problems identified and solutions for overcoming them

While the default feedback provided by the Wii Fit Plus™ can be demotivating and seem overly harsh, the workshop attendees noted that anyone could feel disheartened regardless of whether or not they have MS. They noted that inevitably on some days one's scores, feedback, and the Wii Fit™ Age are worse than on others.

"You might have a good day. You might just happen to get on that machine on a very good day where you feel good and you record high scores. The next week you may not achieve those scores so you again you may feel that you're just not achieving."

It was noted that navigating the Wii™ menu can be time-consuming and somewhat repetitive and laborious. There were no specific problems described with using the equipment (e.g. charging batteries, connecting the nunchuk). The need to recalibrate Wii™ remotes sometimes was deemed frustrating but not a major problem. The fact that the Wii™ requires the use of a television was mentioned as a possible problem if family members were already watching the television connected to the Wii™ console.

“You know when I come back from work and pick the children up and then you get, have the trouble because the television which has got the space to actually do it with the Wii™ next to it is the main telly so the children don’t ... want the telly sorry so I’ve got to say no I’ve got to do this first and then so that’s the trouble and then as soon as I’m on it they wanna play their games as well so there are problems like that.”

4.5.6 Factors that contributed to ongoing use of the Wii™

For people with MS, becoming more physically active can be a challenge but here the fun element of setting up the Wii™ was noted as being a facilitator to get started:-

“Setting up and making the ‘Mii’ is fun - the outfits that the ‘Mii’ characters wear for the games (e.g. ski jacket in the ski jump) are very funny. The ‘Mii’ characters you create of family and friends are involved in some activities and can be spotted on the screen which adds to the fun.”

The service users explained that the flexibility of using the Wii™ at home at a convenient time was something that helped them to continue to exercise. They also suggested that support from a professional or a ‘peer’ buddy could help to maintain motivation. The wide range of available games/activities was considered preferable to a list of traditional physiotherapy exercises and less likely to lead to boredom.

The fluctuating nature of MS was a recurring topic in the workshop discussions. Exercising for a few minutes with the Wii™ was considered to be achievable and preferable to doing nothing at all, particularly on the ‘not so good’ days. One person suggested setting up three separate ‘Mii’ characters for ‘good’, ‘not so good’ and ‘bad’ MS days. This would mean that lower scores would be less demoralising and the differences less marked which might help with motivation.

“Again it’s a mind-set thing, isn’t it? You’ve got to prepare yourself before you even set foot on it to say well, this is what I’m going to achieve today for me. My MS is different from anybody else, whatever Wii™ character is giving me this negative feedback, good for them they don’t know, they don’t live in my world and I don’t live in theirs and it’s sort of getting in to that place psychologically before you have even started it. But that it’s quite difficult as we know.”

“You can have the different levels and you can think this is how I feel when I’m on a really bad day and I’m going to go and use that character from when I was last on a really bad day and see...”

Motivation for getting started was identified as a problem, particularly if an individual had already received negative feedback and had obtained a high Wii Fit™ Age when using the Wii Fit Plus™. A Wii Fit™ Age is calculated based on chronological age, performance on the Body Test (measures body mass index, centre of balance and performance on two randomly selected balance or ‘body control’ tests out of five possible activities). Basic balance, agility, walking, steadiness and single leg stance are part of the Wii Fit Plus™ Body Test. The game software randomly selects two out of the five activities to be completed per Body Test. Some balance activities within the Body Tests are harder than others (e.g. one requires a single leg stance) and therefore there will be differences in the Wii Fit™ Age depending on the combination of tests given.

“It throws you different exercises though doesn’t it? That’s one of the problems with the age test one. If you get that dodgy exercise where you know it asks you to stand on one leg you know you are finished and you’re gonna get a Wii Fit™ age of about 85 and the next day it gives you one of your preferred exercises and you end up ...

Many of the service users had developed strategies for motivating themselves in spite of low scores, a high Wii Fit™ Age or negative feedback. One suggested strategy entailed focusing on doing the activity and rewarding oneself for having exercised for a certain amount of time rather than being concerned with performance.

4.5.7 Software

There was agreement that using Wii Sports™ and Wii Fit Plus™ is enjoyable. It was noted that sometimes the games in Wii Sports™ can be difficult for people with optic neuritis (an eye problem associated with MS) or co-ordination difficulties. Playing the Wii Sports™ games was thought to be particularly helpful for strengthening arms and it was noted that the games could be played from a seated position and so are safe if people have balance problems. There was a feeling that the Wii Fit Plus™ is most suitable for those who are relatively mobile and is good for strengthening the legs and the core.

“When I try Wii Sports™ I find I can’t do a lot of it anymore because optic neuritis has meant that my hand-eye coordination is totally shot which is a shame because I used to love that but I can see for those MSers who are sitting most of the time Wii Sports™ is quite good for a lot of arm exercise and upper body whereas Wii Fit™ and the balance board and this that and the other concentrates more on the core and the lower body.”

Service users in the workshop were shown the risk assessment document for children with disabilities developed by Rebecca Scott (www.wiihabilitation.com). The risk assessment provides information about the potential risks involved in playing Wii Sports™ and Wii Fit™ games and how these can be minimised. There is also a rating of how easy and difficult the games are. The possibility of having something similar for MS with a traffic light type system was discussed. It was suggested that ranking games in terms of difficulty could be useful to help people decide which games to play.

4.5.8 Feedback on draft play logs for recording time spent on the Wii™

There was general agreement that this should be kept as simple as possible with a tickbox response format preferred.

“That’s what I was thinking...it’s nice to tick or circle something rather than writing something else.”

4.6 Summary of key messages to emerge from consultation workshop

Feedback from the workshop shaped the development and content of the Mii-vitaliSe resource materials and direct quotations from the workshop discussion were incorporated into the resource materials. The key messages from the workshop were as follows:

- An agreement that the safety aspects of using the Wii™ at home needed to be included in the guidance materials
- However, it was felt that the Wii™ already provides quite comprehensive information about general safety and that a long list of additional safety tips would be off-putting
- The Wii™ is convenient and fun to use and agreement that patterns of use are individual and variable

These messages, together with the key conclusions from the literature review were presented to and discussed by the intervention development group in order to inform the ongoing development of the resources and the support given by the physiotherapists.

4.7 Development of the resource materials

This section will define how PPI and the literature review contributed to the intervention development.

4.7.1 Mii-vitaliSe orientation sessions

The Mii-vitaliSe intervention package was described in the grant application as consisting of two orientation sessions in the hospital with a Mii-vitaliSe physiotherapist to get people used to using the Wii™ (weeks 1 and 2), followed by a session to set up the Wii™ at home (week 3) and thereafter ongoing independent use of the Wii™ at home with physiotherapist support and advice. The way that the PPI and literature review informed the content for these sessions will now be presented.

In chapter three evidence from systematic reviews was presented illustrating that participation in physical activity provides a wide range of benefits for people with MS (Rietberg et al. 2004; Snook and Motl 2009; Latimer-Cheung et al. 2013a; Platta et al. 2016). Service users at the workshop talked about the importance of conveying the benefits of exercise and described the trust they had in health professionals to offer appropriate advice about what type of exercise to do. Therefore, in the orientation sessions (weeks 1 and 2) the physiotherapist covered the benefits of doing regular physical exercise and there was an opportunity to discuss what games participants may wish to start to use. The PPI consultation also highlighted the need to be supported to exercise safely which was also a key theme from the literature review (Borkoles et al. 2008 ; Ravenek et al. 2016). The orientation session therefore included a practical demonstration of how to use the equipment safely (the Wii™ remote, nunchuk and balance board) and a demonstration of how to navigate through the menus. A selection of games from the Wii Sports™, Wii Sports Resort™ and Wii Fit Plus™ software was demonstrated and participants tried out some games supervised by the physiotherapist. Participants were encouraged to think about goals related to the use of the Wii™ to become more active and ways they may achieve their individual goals (Ploughman 2017). Participants were shown how to create a ‘Mii’ (an on-screen personalised representation of oneself) and its importance for

motivation and fun (as noted by service users) when using the Wii™ was explained. In the literature it was suggested that this feature has the potential to enhance self-efficacy and motivation (Kerrigan et al. 2009) and therefore support ongoing engagement.

4.7.2 Mii-vitaliSe resource materials

The protocol for the funded study stated that the Mii-vitaliSe resource materials would be used at the orientation sessions and to support ongoing use at home. The suggested topics for the guidance and resource pack were safety issues, warming up and cooling down, a guide for starting to exercise and goal setting. The consultation workshop and discussions with the Intervention Development Group confirmed that these topics would be an important part of the resource materials for participants and physiotherapists to refer to when starting to exercise. The consultation workshop affirmed that people with MS find the Wii™ fun and convenient to use and feedback from the workshop highlighted that the way it is used is highly variable and individual. Making sure that people exercise safely was a focus for the existing resources relating to participating in physical exercise and in using the Wii™. The service users felt that while safety was an important issue the default information provided by the Wii™ was quite comprehensive and they felt a long list of safety information was unnecessary. However, evidence from a review of gaming in rehabilitation suggests the need to provide adequate information and support so that people use appropriate techniques and take regular rest periods in order to prevent injury (Ravenek et al. 2016). This was therefore a key focus for the first orientation session and throughout the intervention.

The resource materials were paper documents developed for use throughout the Mii-vitaliSe intervention from the initial hospital-based orientation sessions through to supporting participants with continued use of the Wii™ in the home. Based on conclusions from recent research studies (Plow and Finlayson 2011; 2014) these resources adopted a person-centred approach and incorporated behavioural change techniques to encourage continued independent use of the Wii™. Within this individualised approach, taking into account beliefs and perceptions about exercise and expectations for health improvements was important (Plow et al. 2009; Hale et al. 2012).

The Mii-vitaliSe resources comprised:

- Guidance Book
- Personal Activity Workbook
- Games Descriptors (Wii Sports™ , Wii Sports Resort™ and Wii Fit Plus™)

Samples of each of the Mii-vitaliSe materials are included in Appendix 1.

The aim of the intervention was to encourage the internalisation of goals and long-term use of the Wii™ by providing people with confidence, skills and strategies as well as support to overcome barriers they encounter. This links with the principles of self-management (Morgan et al. 2017) outlined in chapter two as well as the views of service users who felt that the Wii™ is a convenient tool that can be used when a person is not accessing physiotherapy. As presented in the literature review in order to achieve the internalisation of goals and long-term use of the Wii™ behaviour change techniques (e.g. self-monitoring and goal setting) need to be included in interventions (Abraham et al. 2015). The section that follows describes the development and contents of the Mii-vitaliSe materials and explains how they were informed by existing resources, the service user consultation, relevant theory and evidence.

4.7.2.1 Guidance Book

The aim of the Guidance Book was to offer an information resource that people could refer to. This provision of information regarding health benefits and risks has been shown to be an important behaviour change technique and important aspect of interventions (Abraham and Michie 2008; Abraham et al. 2015). Information provision enables people to make informed choices and therefore setting the scene with the provision of general information was important. People at the workshop talked about a sense of personal achievement after doing some activity on the Wii™. Similarly, researchers in MS have also described the challenges that people with MS face when exercising and the sense of achievement they experience when they succeed (Stroud et al. 2009). Information about the many positive benefits of exercise was therefore outlined in the Guidance Book including guidance from the CSP and quotations from research relating to exercise for people with MS (Motl et al. 2005).

One of the eligibility criteria for the feasibility study was being currently inactive, defined as not meeting UK exercise recommendations (DOH 2011). Therefore the Guidance Book included a guide for starting to exercise. This included practical information about preparing to increase physical activity levels and ways to do so using the Wii™. Discussions at the workshop highlighted the fact that everyone is different and there is a need to find out what works best for each person. Quotations by workshop attendees about preferred times to use the Wii™ were included to illustrate the fact that it is very individual. Provision and support from peers (vicarious experience, Jones 2006) links with Social Cognitive Theory (Bandura 1997) and has the potential to support people to overcome barriers. A section on ‘Getting Started’ described how people could set up their own ‘Mii’ to use whenever they used the Wii™ as a tool to enhance self-efficacy and motivation (Kerrigan et al. 2009, Jin 2010). Service users in the workshop noted that using a ‘Mii’ makes exercising a more immersive, fun, personal, and motivating experience.

Goal setting was identified by workshop attendees as important and setting individual goals and action plans for people with a LTC is an important part of the process for becoming more active (The Health Foundation 2015). However, with a fluctuating condition like MS, goals need to be flexible. A section on goal setting drawing upon feedback from the service user consultation was included in the Guidance Book to encourage the person to set goals. There were also some ‘Mii-vitaliSe tips’ which were quotations from workshop attendees giving general advice about exercising with the Wii™ (vicarious experiences). Some quotations described the benefits of using the Wii™ at home and others conveyed the fun and ‘feel-good’ aspects encouraging people to adopt healthier behaviours (Kings Fund 2008; The Health Foundation 2015).

Service users at the workshop felt that safety and technical information, while relevant, should not be overly long and that guidance on warm up and cool down exercises were also relevant to them. However, the literature review highlighted that many of the reported injuries were due to people exercising beyond their limitations due to the repetitive movements and immersive nature of the games (Taylor et al. 2011). The default health and safety advice provided in the Nintendo Wii™ manual was reproduced and a list of references and other resources was also included.

The workshop discussion about patterns of use illustrated the range of options for using the Wii™ at home to exercise. The option of doing Wii™ activities with friends and family was perceived to be important by the service users but some people also particularly liked to exercise on their own. Statements from the workshop were used in the Guidance Book to offer support and motivation from others with similar challenges (Mulligan et al. 2013) and to make the materials more compelling and relevant for people with MS. A note of caution was also given explaining that sometimes children (and partners) have a habit of monopolising the Wii™. Therefore people were encouraged to plan some ‘Mii-time’.

As there are many known barriers to exercise for people with MS (Stroud et al. 2009; Mulligan et al. 2012) the more positive and fun elements of exercise were highlighted in the Guidance Book. One of the advantages of the Wii™ software is the wide range of games available offering different ways to exercise at varying intensities (Petajan and White 1999; McAuley et al. 2007). The software was discussed in the workshop and service users described which games they had found beneficial for certain aspects. For example, Wii Sports™ games were noted to be helpful for strengthening arms. One of the drawbacks of having a wide range of games to choose from could be that people might feel overwhelmed and unsure about which ones to use. For this reason the Guidance Book included a section on types of exercises (flexibility, strengthening, aerobic/endurance, balance and co-ordination and relaxation/cool down).

An important message from the workshop that ties in with UK guidelines for physical activity (Department of Health 2011) and evidence (Wen et al. 2011) was that a small amount of exercise is better than none. Service users at the workshop described successes at completing small bouts of exercise using the Wii™ and not being worried about the score or feedback as doing some exercise was better than no exercise. The workshop attendees therefore endorsed the importance of conveying the message that achieving a small amount of physical activity is better than none. They explained that at home you can sit down and take a break and that you can also do the exercises in stages and they can be progressed over time. However, for people with a LTC there is a concern that that performance deteriorates over time (Deutsch et al. 2011). There was a clear message from people with MS at the consultation workshop that if ten minutes are achieved, this is worthwhile and can be progressed

over time. This was, therefore, an important message ('Every ten minutes counts') in the section of the Guidance Book on starting to exercise.

The feedback and scores provided by the WiiTM were discussed at the workshop. This is a key issue as people might be demoralised and discouraged by the feedback provided by the WiiTM software which was designed with the healthy population in mind (Deutsch et al.2011). Using the principles of vicarious experiences (Jones 2006) quotations from the workshop were used to remind participants not to be overly harsh on themselves and to bear in mind that the WiiTM was not originally designed for people with MS. The importance of not being overly focused on 'points/scores' or one's 'Wii-FitTM age' was therefore clearly conveyed in the Guidance Book.

4.7.2.2 Personal Activity Workbook

The Personal Activity Workbook was designed to be used alongside the Guidance Book and orientation sessions. Making the process of continuing to exercise an active collaboration with the physiotherapist and having personal accountability was discussed at the workshop. The Personal Activity Workbook was designed to provide opportunities for participants to engage fully in the orientation sessions by encouraging them to make notes, reflect on discussions and complete tasks. The rationale being that this will increase participants' active engagement with the sessions as a means for them to learn about their individual body and the best way to become more active. The evidence suggests that personalised written information and booklets are more effective than standard printed materials for improving self-management (De Silva 2011; Mulligan et al. 2013; Morgan et al. 2017).

In the Personal Activity Workbook people had an opportunity to consider their current level of physical activity (linked to the guidelines and evidence presented in the Guidance Book). This included an opportunity to weigh up the pros and cons of becoming more active using the WiiTM as a means to bridge the 'intention-behaviour' gap (Schwarzer et al. 2011; Chiu et al. 2011). In the volitional phase of the HAPA behavioural change process model the aim is for a person to initiate, plan and subsequently maintain a behaviour (Schwarzer et al. 2011). The activities in the Personal Activity Workbook were designed to support a person to self-regulate and monitor their intentions and actions in order to maintain regular WiiTM use.

Action planning (Gollwitzer and Brandstätter 1997) and coping planning (Gollwitzer 1999) have been found to be effective in closing the intention-behaviour' gap (Sniehotta et al. 2006) and service users' feedback at the workshop suggested that they would find personalised plans helpful. The Personal Activity Workbook therefore supported participants to use these behaviour change strategies. In the workshop, service users highlighted the importance of thinking about when and where to use the Wii™ (action planning). The Personal Activity Workbook encouraged the individual to think through how using the Wii™ could be incorporated into their lifestyle routines and to think about how to warm up (action planning).

However, as noted by service users in the workshop, the fluctuating nature of MS and debilitating symptoms such as fatigue mean that often well-planned actions cannot be achieved. Coping plans using 'if-then' statements can help people to build flexibility into their plans and think through how they might overcome barriers they encounter (Gollwitzer 1999). Getting people to think about possible strategies for overcoming obstacles and how to reframe setbacks as learning opportunities were therefore important components of the Mii-vitaliSe resource materials. Examples of possible barriers that participants might encounter and possible ways they could be overcome were presented in tables (based on the service user consultation). An example coping planner was also provided and blank tables for participants to complete their own individual coping plans.

4.7.2.3 Games Descriptors

Wii Sports™, Wii Sports Resort™ and Wii Fit Plus™ software was provided for use with the Mii-vitaliSe intervention, offering a selection of almost 80 different games. Participants could select from a range of activities depending on their current preferences and symptoms. Games Descriptors were written for each game to assist participants to select games to play from the available range. The purpose of the descriptors was to provide information specifically aimed at people with MS to support them when going through the process of selecting games to decide which game to play and provide tips and guidance for safe use.

In order to write the detailed games descriptors there was a need to become conversant with the games. Personal experience of learning to use the Wii™, as well as experience as a physiotherapist working with people with long-term neurological

conditions, informed the development of the Games Descriptors. A key consideration during this process was the potential benefits of the games to people with MS, along with any risks and adaptations. Rebecca Scott's games risk assessment (www.wiihabilitation.co.uk) informed the writing of the Games Descriptors. In the context of stroke rehabilitation Deutsch et al. (2011) developed games descriptors for Wii Sports™ and Wii Fit Plus™ based on a detailed game analysis for use by clinicians. In the current study the games descriptors were developed so that people with MS could use them to support their game choices. Descriptors were developed based on feedback from the service user workshop, my personal experience of playing the games and knowledge of the principles of rehabilitation.

The Games Descriptors are grouped as a function of software (Wii Sports™, Wii Sports Resort™ and Wii Fit Plus™). At the start of each section there is a general overview of the software, e.g. how many games there are and what equipment is required. This is followed by a description of each game. Each descriptor provides details of a game's overall aim, its potential benefits, how to play it, safety tips, information about scoring and progression and game duration. Each game descriptor includes space for the physiotherapist and/or participant to write notes. An example Games Descriptor is provided in Appendix 1.

4.7.3 Support given by physiotherapists

The literature identified that the effectiveness of behavioural change strategies can be strengthened using MI principles (Smith and Porter 2007; Smith et al. 2012). The core principles of MI are a person-centred approach, developing a collaborative relationship to support intrinsic motivation and to explore and negotiate ambivalence. The physiotherapists delivering Mii-vitaliSe drew upon MI principles to support people to engage with Mii-vitaliSe and sustain engagement in the longer term. I attended the formal MI training at BU and offered support and guidance to the physiotherapists. Providing guidance on getting started with exercise and offering meaningful support can help people to tailor and individualise their own exercise programme and develop strategies for long-term engagement with exercise (Mulligan et al. 2013).

The physiotherapist supported participants with their ongoing use of the Wii™ via scheduled follow-up telephone contact and home visits. These offered an opportunity

to provide advice and encouragement as well as to support participants to identify barriers promptly and consider ways to overcome them (coping planning). To help to structure these contacts and enhance participant engagement, contact forms were included in the Personal Activity Workbook so that participants could note down in advance any issues they wished to discuss. The physiotherapist could also note down advice and suggested modifications or progressions to routines.

4.8 Ongoing service user involvement

Service user involvement in research is about co-working with researchers (Gooberman-Hill 2013) and is not limited to the initial formative stages of research but should be ongoing. At the workshop the different ways that service users could continue to be involved in the Mii-vitaliSe research study were discussed. From this discussion four service users continued to be involved contributing to the project steering group, piloting the outcome measures used in the RCT, trying out and giving feedback on some of the draft Mii-vitaliSe resources and commenting on the participant information sheets. In addition, on completion of the funded research, a further service user Wii U™ consultation group (chapter seven) involved several people who had participated in the Mii-vitaliSe pilot study. The dissemination plan for this PhD includes an output on service user involvement in collaboration with a service user.

Workshop

Following the consultation workshop, one of the service user attendees contacted the research team with further feedback and was invited for an informal discussion with two members of the research team at the university. The aim of this informal meeting was to discuss their additional feedback and to reflect on how the person's experience informed the research. The original workshop discussion guide was used as a starting point for the discussion. The researchers responded to the direction the conversation took rather than using a rigid pre-determined schedule. This discussion was not recorded but general notes were made and specific comments and feedback captured for possible use in the Mii-vitaliSe resource package. The notes were typed up immediately afterwards by the two researchers and then combined to form a summary. This was emailed to the service user within a week of the meeting and feedback or comments invited. The service user was satisfied with the summary of the discussions. This service user became a member of the project steering group and the additional information gained reinforced the importance of the fun element of the

‘Mii’ character for enhancing self-efficacy and motivation. The follow up meeting with an individual also offered an opportunity to reflect on the workshop and share reflections on the process.

The involvement of service users at the workshop and this subsequent meeting demonstrates how members of the public were actively involved in the development of Mii-vitaliSe. This is in accordance with the INVOLVE definition of patient and public involvement (www.invo.org.uk).

Protocol for hospital based assessments

A service user was consulted to gain feedback on the procedures for carrying out the assessments, to measure the time taken to complete them, to consider the order of the assessments and to gather feedback regarding the perceived participant burden. In March 2012, four months after the workshop, one of the service users who had attended the workshop was invited to undertake a range of assessments to measure gait, balance and dexterity administered by two members of the research team.

This consultation with a service user enabled the research team to agree an order and procedure for completing these assessments in the subsequent feasibility study. In order to avoid fatigue the hierarchical component of the steady stance balance tests was considered and a decision was made to start with the hardest test first (single leg stance). If the participant was successful with this test it was not necessary to complete the other steady stance tests. The time taken to complete the battery of assessments exceeded an hour therefore a decision was made to make a change to the protocol so that participants were randomly allocated to complete either the gait stride rhythmicity test or the two- minute walk test (2MWT). The protocol is provided in Appendix 6.

Ethics application

In preparation for submitting the feasibility study to the South Central Southampton-B National Research Ethics Service (NRES) for approval all the service users consulted were invited to give feedback on the draft Participant Information Sheet (PIS). The purpose was to ensure that the PIS were presented and written in a way that potential participants would find helpful, that no jargon was used and that sufficient information was provided to allow people to make a decision about involvement in the study. An email was sent to the service users (n=8) inviting feedback on the content and presentation of the PIS in March 2012. The following

feedback was received from a service user regarding the PIS and was also included in the NRES application.

"I looked through the proposed leaflet and the INVOLVE guidelines and my view is that it is an excellent leaflet in all aspects. The language is simple and easy to understand (it must be if I followed it!!!!) The content explains very concisely what the project is about, how it will work, what the timescale is and how a participant would be involved if they so wish .The presentation is excellent with easy to follow steps, easy to take in, with each section clearly defined. I hope this is useful and I will help whenever I can."

As positive feedback was gained no changes to the PIS were deemed necessary.

Mii-vitaliSe materials

Once the Mii-vitaliSe resource materials had been drafted, service users were invited to provide feedback on the documents in order to see whether they were easy to understand and relevant and if they reflected the feedback provided at the workshop. One service user, who was regularly using the Wii Fit Plus™, volunteered and was provided the draft resource materials for use and to give feedback. I visited her at home to gather feedback about her experiences of using the resources. Specific feedback was given about the Games Descriptors particularly highlighting games that had been challenging as they involved considerable co-ordination and levels of concentration. Feedback was also given about games that had been particularly enjoyable.

"Found a nice selection of exercises for mind and lower body but would have liked a few more upper body/arm exercises. I discovered my balance is very bad so although I struggled I feel this could improve with practice. My main struggle was co-ordination, anything that involved a rhythm that wasn't basic. Very interesting to see which exercises work for different people/types of MS and symptoms."

As a result of this feedback additional details were added to the games descriptors in relation to the balance, co-ordination and rhythm demands and potential challenges. Games involving the upper limbs were identified more clearly.

The games descriptors included a section to describe possible benefits. The service user provided helpful insights which led to some modifications of the games descriptors as follows:-

Soccer Heading

“This is one of the hardest for me! By the time my brain gets message to body to move it’s too late! Found myself trying to move whole body and getting frustrated.”

Change to the descriptor:-the fast pace of this game was emphasised in the descriptor as well as the need for concentration.

Tightrope Walk

“Literally gave up on this one.”

Change to the descriptor:-more attention was given to the need to have good core stability and balance.

Balance Bubble

“So hard! My balance was terrible, my body does not have the same timings as my brain.”

Change to the descriptor:-added a warning that the user might become frustrated with this game.

Ski Slalom

“Discouraged after several attempts to just steer and turn back by bending knees rather than whole body, which was a lot of pressure on my legs and quite painful.”

Change to the descriptor:-now mentions that this game involves a considerable amount of leg work.

Ski Jump

“One of the easier balance games for me. Am able to just do one balance to jump but when it involves a lot of co-ordination I failed.”

Change to the descriptor:-the descriptor states that the user must not be too hard on themselves.

Snow Board Slalom

“Pretty much the same as the ski slalom, I found this one very hard.”

Change to the descriptor:-the descriptor was amended to state that the user needs to start gently and practise control of the snowboard initially ignoring the timing and score on the first attempts.

Perfect 10

“Didn’t have any issues with moving hips to smash the mushrooms –just couldn’t calculate the maths at the same time.”

Change to the descriptor:-the descriptor was amended to state that the user needs initially enjoy the movement and not worry about the score.

Island Cycling

“Enjoyed this like the jogging. Just enough pressure on legs in short burst. Not too much to concentrate on other than the exercise.”

Change to the descriptor:-the descriptor was amended to state that this is a gentle aerobic exercise.

Driving Range

“Really loved this one. A little bit of balance required but nice, gentle upper arm workout.”

Change to the descriptor:-the descriptor was amended to state that this gives a gentle upper body work out.

Segway Circuit

“Not sure about popping beach balls. It was enough effort to get moving!! I found I had to really lean forwards to move which meant the pain in my lower leg was too much to think about steering as well.”

Change to the descriptor:-the descriptor was amended to state that the user needs quite strong legs to get the Segway moving.

Birds Eye Bulls Eye

“So much fun to do with a very hard arm workout. Enjoyed this as a change to work arms and tend to struggle more with legs-pain!”

Change to the descriptor:-the descriptor was amended to state that this is an enjoyable workout for arms and core.

Obstacle Course

“Love, love, love this!! Was hard to always co-ordinate the exact timings but for some reason, this one made me really determined. Although it involves a lot of leg strength because of the constant changing it was never unbearable pain as relief on changes.”

Change to the descriptor:-the descriptor was amended to state that the user needs strength, endurance and concentration.

Tilt City

“A little bit tricky to get used to with the co-ordination but actually enjoyed it. Not too strenuous but works the brain.”

Change to the descriptor:-the descriptor was amended to state that the user needs to stay focussed on the technique and the balance and to emphasise the enjoyable nature of this game.

Skate Board Arena

“Great fun! Bit of pressure in legs but not unbearable. Co-ordination was fine. Really enjoyed it.”

Jogging Plus

“Enjoyed this! Felt like I was really exercising my legs but because it was a short burst, wasn’t too strenuous for me, able to go at my own pace.”

Change to the descriptor:-the descriptor was amended to emphasise that this was a short and not too strenuous exercise.

Hula Hoop

“Enjoyed this one, lot of pressure on my legs.”

Change to the descriptor:-the descriptor was amended to state that the user needs leg strength.

Basic Step, Free Step and Advanced Step

“This step was great. Perfect rhythm and pressure for my legs, really enjoyed it.”

Steering group membership

The steering group met three times a year throughout the duration of the pilot study. Two service users who had attended the workshop were members of the steering group. This provided an opportunity for service users to continue to contribute to the development of the Mii-vitaliSe resource materials throughout the study and not just at the initial stage. They also commented on the study processes and materials as well as issues that arose during the course of the study.

4.9 Summary formative/development stage

The Mii-vitaliSe resource materials were developed and the protocol for the physical assessments (Appendix 6) was finalised in this formative phase of the research.

Table 4-2 summarises the key components of the Mii-vitaliSe and how these were informed. The service user consultation process was an instrumental phase, providing invaluable insights into use of the Wii™ and informed the development of the Mii-vitaliSe materials, aspects of the study protocol and participant information materials. Two service users from the workshop joined the research team as service users' partners in this phase.

It is recommended that interventions are reported more transparently, vigorously and thoroughly (Hoffmann et al. 2014). The Template for Intervention Description and Replication (TIDieR) checklist is a tool to support researchers to achieve this recommendation. It states that information materials used in the delivery of the intervention are clearly specified as well as the mode of delivery and location (Hoffmann et al. 2014). This is important so that future research can replicate or build on the findings. This is particularly important for non-pharmacological interventions which are complex, multi-faceted and often described inadequately.

Table 4-2: Summary for how Mii-vitaliSe was developed

Development strand	Aims	Findings	How informed the Mii-vitaliSe intervention
Literature review	What is the evidence for the benefits of physical activity in people with MS	Participation in physical activity provides a range of health benefits for people with MS	Inclusion of evidence based information regarding the health benefits of exercise for people with MS in resource materials
		Developing interventions that promote ongoing engagement in physical activity is a priority	The use of a Personal Activity Workbook to support ongoing engagement with physical activity
	Is exercise safe for people with MS	Exercise does not cause exacerbations or relapses	Provision of information for the safe use of the Wii™ equipment, physiotherapist support for use of correct technique when exercising and for tailoring during a relapse
		Poor reporting of adverse incidents, relapses and adherence	Play log and calendar used to monitor adherence Supervision and training offered to Mii-vitaliSe facilitators for reporting adverse incidents
	Establish the current guidance for levels of physical activity for people with MS	People with MS are engaging in insufficient levels of physical activity	Provision of information (Guidance Book and orientation sessions) for starting to exercise and progressions
		People with MS need to adopt and maintain exercise behaviours	Personal Activity Workbook provides strategies to support people with MS to overcome barriers and maintain exercise behaviours
	What is the evidence for the effectiveness of active gaming to support people with MS to become more physically active	Interventions need careful monitoring (especially in the early stages) and ongoing support	Provision of guidance in the early stages and ongoing support via phone or email
		Ways to foster intrinsic motivation are needed to increase adherence	Personal Activity Workbook includes activities to support planning, self-regulation and monitoring
		Many injuries are due to repetitive movements and the immersive nature of the games	Guidance Book includes information for preparing to exercise, frequency and intensity

Development strand	Aims	Findings	How informed the Mii-vitaliSe intervention
Literature review	What strategies can be used to support ongoing engagement in physical activity for people with MS	Interventions need to include self-management and behaviour change strategies	Mii-vitaliSe includes tools for self-monitoring, planning actions and goals and overcoming barriers Mii-vitaliSe provides supportive information from peers with similar barriers
Review of existing materials and resources	Review existing resources for how the Wii™ can be used for physical activity	Ideas for content and presentation of resource materials	Use of pictures and large font Use of quotations and examples from users
	Review the existing resources for people with MS and other LTCs	Safety guidance	Guidance Book includes quotations from the CSP, MS Society of Canada and Nintendo Wii™
		Analysis of Wii Fit™ games	Development of Games Descriptors tailored for people with MS
Intervention development group	Inform a draft intervention package	Safety aspects are important Ideas for how to personalise the intervention with support for people to select which games to play, set goals and overcome barriers Ideas for how physiotherapist support would be included	Health and safety advice developed Mii-vitaliSe provides information specific for people with MS to support choose of games, goal setting and ways to overcome barriers Training resources provided for physiotherapists during delivery of Mii-vitaliSe

Development strand	Aims	Findings	How informed the Mii-vitaliSe intervention
Consultation workshop PPI	Gather views and experiences of service users of using the Wii™	<p>Key messages from the consultation workshop</p> <ul style="list-style-type: none"> • Patterns of use and the ongoing use of the Wii™ • The importance of safety • Commitment and goal setting • Benefits and drawbacks • Overcoming problems • How people used the software 	<p>Key messages discussed with Mii-vitaliSe facilitators</p> <p>Key messages formed the basis for the resource materials</p> <p>Quotations used from workshop attendees were included in the resource materials regarding</p> <ul style="list-style-type: none"> • Preferred times to use the Wii™ • The importance of personalised Wii™ time • Tips for Wii™ use • Setting individual goal <p>To state that the yoga exercises are difficult</p> <p>To make the materials relevant to people with MS</p> <p>To take into account the fluctuating nature of MS</p>
	Gather feedback on versions of the play log	Needs to be simple	Tickbox format was included
	Discuss how to involve service users throughout the study	Four service users from the workshop continued to be involved in the study	Contribution to project steering group, piloting the outcome measures, giving feedback on draft resources and participant information sheet.

Table 4-3: TIDieR template for intervention description and replication

1. Brief name or phrase that describes the intervention	Mii-vitaliSe: a home-based physiotherapist supported Wii™ intervention for people with MS that uses commercial software.
2. Rationale, theory or goal of elements of the intervention	The aim of the intervention is to increase physical activity levels in people with MS. The intervention draws on relevant psychological and physiotherapy theory and models of care:- <ul style="list-style-type: none">• Motivational Interviewing• Social Cognitive Theory and Health Action Process Approach (HAPA)• Self-Determination Theory• Self-management The intervention incorporates behaviour change techniques.
3. What materials were provided to participants and used in the intervention delivery?	Nintendo Wii™ console. Two Wii™ remotes and two nunchucks, balance board, non-slip cover, Wii™ remote charging cradle, rechargeable batteries and battery charger. Wii Fit Plus™. Wii Sports™ and Wii Sports Resort™ software. Two orientation sessions and ongoing support and monitoring Guidance Book Personal Activity Book Games Descriptors Daily Play Log
4. What processes and procedures were used in the intervention?	Orientation sessions weeks 1 and 2 face-to-face in the hospital Wii™ installed at home week 3 Ongoing support weeks 5 and 12 via telephone or email Home review visits weeks 7 and 16 face-to-face at home Thereafter ongoing monitoring, support and encouragement via monthly contact (telephone or email) from the physiotherapist
5. Who delivered the intervention?	Mii-vitaliSe physiotherapists - senior specialist physiotherapists from the Dorset MS service and the research co-ordinator. They were trained and supported by the Mii-vitaliSe research co-ordinator.
6. What mode of delivery was used?	Wii™ used at home with a mixture of face-to-face and telephone physiotherapist support.
7. Where were participants that used the intervention recruited from?	The Dorset MS service at Poole Hospital Foundation Trust.
8. When and how much - describe the number of times the intervention was delivered and over what period of time	Over a period of approximately 12 months (immediate group) and 6 months (delayed group) Duration of each hospital-based orientation sessions were typically 90 minutes. Duration of home-based follow-up sessions were approximately 60 minutes.
9. Tailoring	The intervention was tailored so that participants had individual goals and action plans. Each participant had their own Personal Activity Workbook to complete. Additional visits were occasionally required if there were technical problems or specific barriers that people encountered that needed to be resolved.
10. Modifications	There were no modifications to the intervention during the course of the pilot study.
11. Adherence	Adherence was measured by self-reported play logs.

Chapter 5 Methods

This chapter describes how the Mii-vitaliSe intervention was tested in a pilot study. In preparation for a future RCT, a pilot study allows procedures to be tested to see if they are feasible for using in a larger study. The aim of this pilot study was to run a miniature version of the trial and to test processes such as recruitment, data collection, randomisation and data analysis. An additional aim was to test the safety, feasibility and acceptability of delivering the Mii-vitaliSe intervention in the home. The Medical Research Council (MRC) guidelines (Craig et al. 2008) suggest that feasibility or pilot studies should be conducted prior to any large-scale trial that evaluates an intervention. The MRC guidelines define complex interventions as those that have several interacting components (Bond et al. 2010). As physical activity is a multi-faceted phenomenon (McAuley et al. 2007) and Mii-vitaliSe incorporates both physiotherapy and psychological theory, it is a complex intervention.

The current pilot study uses mixed methods whereby qualitative data are gathered to augment and qualify the quantitative data (Thabane et al. 2010). In this approach both types of data are collected, analysed and integrated in a single study (Creswell 2013) utilising the strengths of both qualitative and quantitative research. Mixed methodology sits well within this two-phase model of the development and evaluation of a complex intervention (Craig et al. 2008). The use of mixed methodology in this study expands the scope and range of the study and increases confidence in the conclusions reached (Greene 2010).

The 2008 MRC guidance recommends the use of process evaluations alongside outcome evaluations - “process evaluation nested within a trial can also be used to assess fidelity and quality of implementation, clarify causal mechanisms and identify contextual factors associated with variation in outcomes” (page 12). However, it provides little detail about how to conduct a process evaluation. Since then new MRC guidance for process evaluations has been produced (Moore et al. 2015). In the context of a pilot study a process evaluation can provide insights into the feasibility and acceptability of the intervention, explore possible mechanisms of impact and barriers and facilitators to implementation, and optimise aspects of design and evaluation. In order to design and conduct a study that combines a process evaluation

a mixed methods approach is required. Quantitative methods are used to measure and test key processes and qualitative methods are required to capture participants' experiences of the intervention and any unexpected outcomes (Moore et al. 2015). In order to design and conduct a study that combines a process evaluation a mixed method approach is required. Quantitative methods are used to measure and test key processes and qualitative methods are required to capture participants' experiences of the intervention and any unexpected outcomes (Moore et al. 2015).

The objectives for this pilot study were:

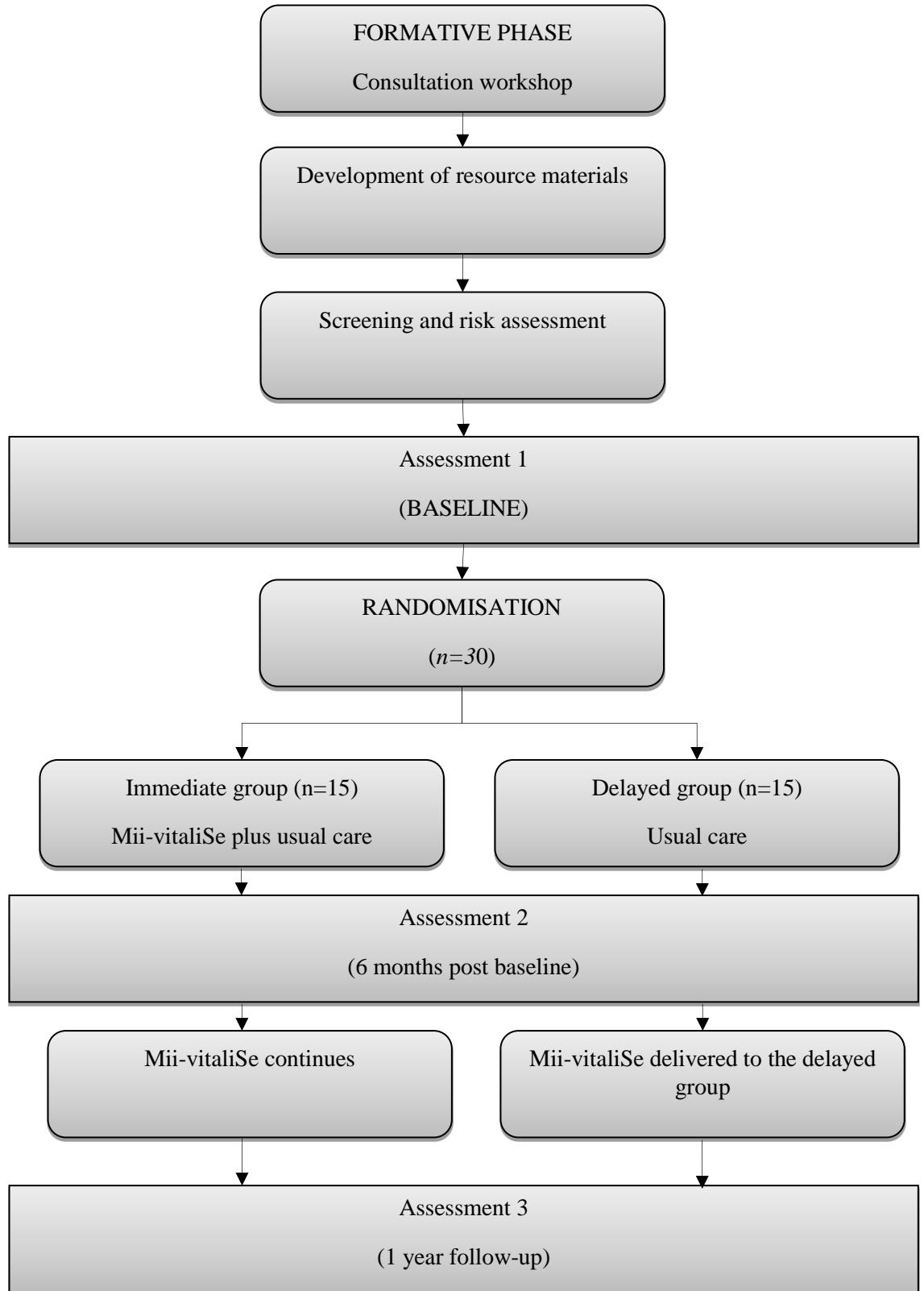
1. To test procedures, estimate recruitment and retention rates and refine the selection of outcome measures in preparation for a future full trial.
2. To calculate preliminary estimates of effect size and of standard deviation to inform a sample size for a future full trial.
3. To determine participants' views on taking part in the pilot study and receiving the Mii-vitaliSe intervention.
4. To gather feedback from physiotherapists about their experiences of delivering the Mii-vitaliSe intervention.

5.1 Design

A single centre wait-list randomised controlled pilot study of Mii-vitaliSe plus usual care versus usual care alone (See Figure 5-1). Participants were randomised to receive Mii-vitaliSe either immediately ('immediate group') or after a six-month delay ('delayed' group). During this period, the *delayed* group were asked to continue their usual routines, refrain from using the WiiTM and acted as controls for the *immediate* group. At six months the *delayed* group received the Mii-vitaliSe intervention and the *immediate* group continued with Mii-vitaliSe. Outcomes were assessed at six months and one year post-baseline for all participants. This design was chosen as it minimises the impact of disappointment that those allocated to a non-intervention group might experience, while ensuring those in the delayed group received the full intervention. It was reasoned that delivering the intervention to those in the delayed group may increase compliance with refraining from use for a six-month period. This design also permitted a preliminary consideration of long term (one year) follow-up (immediate group only). The randomised controlled component allowed for testing of procedures, design, etc. in preparation for a

subsequent full scale trial. Follow-up periods were deemed sufficient for novelty value to diminish and patterns of use to be established.

Figure 5-1: Mii-vitaliSe study flow chart



5.2 Ethics and governance

A research protocol and ethics application was submitted to the South Central Southampton B National Research Ethics Service (NRES) via the Integrated Research Application System (IRAS) on 05/07/12 and was reviewed on the 25/07/12. I attended the Research Ethics Committee meeting with the Chief Investigator and answered queries related to the following issues:

- The amount of physical activity expected of participants.
- The procedure for participants who may be anxious or depressed and require referral to psychology/counselling services.
- Transparency on the participant information sheets (PIS) that the Wii™ equipment would be provided to participants for use with their own television.
- The potential participant burden of including a decline form should they not wish to participate.

Favourable opinion was granted subject to minor amendments. These amendments were re-submitted on 10/08/12 together with an amended PIS Version 002 and protocol Version 002. Full favourable approval was granted in a letter dated 20/08/12.

A substantial amendment was submitted to the South Central Southampton B NRES on 29/11/12 to request permission to modify the location for the storage of data from Poole Hospital NHS Foundation Trust to the BUCRU. The amendment application was submitted with amended documents (protocol version 003, PIS version 003 (Appendix 2) and participant consent form version 002 (Appendix 3)) on 29/11/12. Approval was granted in a letter dated 20/12/12 (Appendix 4).

The sponsor was Poole Hospital NHS Foundation Trust. The project was reviewed by the Research and Development (R & D) Department at Poole Hospital NHS Foundation Trust and granted approval on 11/10/12. Following the substantial amendment approval was also granted on 28/02/13.

An electronic site file was set up in accordance with a Poole R & D Department template. There were regular site monitoring visits from the R & D Department

during the course of the study to examine the site file, consent forms and the storage of the data.

Ethics permission was also sought from and granted by the School of Health and Social Care (now the Faculty of Health and Social Sciences) at BU.

Mii-vitaliSe was registered on the UK Clinical Research Network Study Portfolio (Study ID 13130) and was assigned ISRCTN49286846.

5.3 Sample/participants

A formal power calculation based on testing whether the Mii-vitaliSe intervention is clinically effective was not undertaken. This was because this was a pilot study which was designed to test the methodology and procedures to inform a future trial. A ‘rule of thumb’ of 30 is common for pilot studies (Lancaster et al. 2004). A sample size of 30 (15 in the immediate and 15 in the delayed arms) was considered to be adequate given the specific quantitative aims of this pilot.

5.3.1 Sample size

A sample size of 30 allowed for the three aims of the pilot study to be met. The recruitment rate was estimated with a precision of $\pm 11\%$ (i.e. width of 95% confidence interval). This assumed a recruitment rate of approximately 40% which is based on a previous trial with people with MS carried out in BUCRU (Thomas et al. 2010). To estimate the SD of potential primary outcome measures, assuming they have been standardised ($SD=1$), the precision summarised by the standard error will be $+\/- 0.13$. To estimate the degree of participant adherence to the intervention (as measured by the proportion of days used), the potential range is 0-1, and thus the SD is likely to be around 0.17 (i.e. assumes range covers $+\/- 3$ SDs). With a sample size of 30, average adherence was estimated with a precision of ± 0.06 (i.e. width of 95% CI).

5.3.2 Participants

Inclusion criteria:-

- Confirmed clinical diagnosis of MS.
- Has moderate symptoms (equivalent to an Adapted Patient Determined Disease Steps Scale (APDDS) score of more than 1 and EDSS score of less than 6).
- Aged 18 or over.
- Lives in the Bournemouth or Poole area and on Dorset MS service database (Poole Hospital NHS Foundation Trust).
- Fulfil a risk assessment (Appendix 5) carried out by the study researcher at home (see below).
- Currently not active, i.e. physically active on fewer than five days a week for at least 30 minutes or more.
- Not a regular (weekly or more) WiiTM user.
- Own a suitable television.

Exclusion criteria:-

- MS relapse within past 3 months requiring corticosteroids.
- Already participating in exercise/rehabilitation research.
- Any medical condition placing individual at risk from exercise participation /using the WiiTM.
- Unwilling/unable to comply with protocol.

5.4 Recruitment

Thirty currently ‘inactive’ (see inclusion criteria) people with MS aged 18 or over were recruited from the Dorset MS service between February 2013 and June 2013. Potential participants were identified by members of the Dorset MS team (includes neurologists, physiotherapists, occupational therapists, and MS specialist nurses). They were sent or given information packs which included a letter of invitation from the study Chief Investigator and Consultant Neurologist/Head of Dorset MS Service, a simple one page ‘Key Facts’ summary, a set of participant information sheets (version 3), a question about current levels of physical activity, the Adapted Patient Determined Disease Steps Scale (Orme et al. 2007) and a Reply Slip with a prepaid envelope to return to the study researcher at BU. Regular contact was made with the

Dorset MS team throughout the recruitment period to monitor recruitment and discuss any issues that arose.

Individuals were asked to return the reply slip in a pre-paid envelope (with information about current activity levels and a completed APDDS scale) if they wished to find out more about the study. A follow-up reminder letter with another copy of the information pack was sent if a reply slip was not received within two weeks.

5.5 Screening

Those who returned a reply slip were telephoned by the study researcher who described the study in more detail, answered any questions and went through the remaining screening criteria. During this conversation it was important to ask questions regarding previous use of the Wii™ (for those individuals who owned one). If they were using it regularly (weekly or more) they did not fulfil the inclusion criteria. Those who were not eligible were informed over the telephone. Those who fulfilled the study criteria were visited at home for a risk and home suitability assessment.

5.5.1 Risk and home suitability assessment

A proposed risk assessment described in the original grant application was reviewed and refined based on the discussions at the workshop and my personal experiences of learning to use the Wii™. This was then used to structure an assessment related to the individual's balance on the Wii™ balance board and the suitability of the home environment where Mii-vitaliSe would be delivered (Appendix 5).

The first part of the assessment involved taking a subjective history of postural instability, discussing falls, near falls and gait disturbance. I was able to draw on previous research of falls and postural instability when taking this subjective assessment (Stack and Ashburn 1999) and my previous experience of screening people with Parkinson's disease for falls and near falls (Ashburn et al. 2007). In the second part of the assessment, the potential participant's balance when getting on and off the Wii™ balance board and while moving on the board was assessed. This assessment included the range of movements identified as pre-requisites for safe participation in the study.

Participants were considered eligible if:

- They were able to maintain independent static standing balance with eyes open for one minute.
- They demonstrated to the physiotherapist adequate balance reactions while on the Wii™ balance board.
- They demonstrated an ability to step on and off the Wii™ balance board safely forwards, backwards and sideways.
- Their home environment was suitable for using the Wii™ to exercise regularly (with minor modifications, if appropriate and possible).

The assessment also considered the suitability of the environment and of the television for Wii™ use, noting potential hazards and set-up issues. Any concerns identified at the risk assessment were discussed with the PhD supervisors. At the end of the risk assessment modifications or recommendations were noted to ensure that such risks were minimised. A copy of this risk assessment was given to the physiotherapists delivering Mii-vitaliSe for reference when setting up the Wii™ equipment in participants' homes.

On satisfactory completion of the risk assessment informed consent (Appendix 3) was taken in accordance with Good Clinical Practice guidance. A letter was sent to participants' general practitioners (GPs) advising them of their patient's participation in the study along with copies of the PIS (Appendix 2). Following consent, an appointment date and time for the participant to attend Poole Hospital NHS Foundation Trust for baseline assessments was given. The baseline questionnaire booklet with accompanying letter and activPAL3™ accelerometer plus instructions for use were given to the participant. The participant was instructed to bring their completed questionnaire booklet and the activPAL3™ device with them to their baseline assessment appointment (which was at least a week later). One copy of the consent form was given to participants, a second was stored at BU and a third was filed in participants' MS case notes in the Dorset MS service at Poole Hospital.

5.5.2 Randomisation

A randomisation schedule was discussed and agreed with the study statistician in February 2013. Participants were randomised between two groups with a 1:1 ratio using random permuted blocks of size two or four. Block sizes of two or four were

randomly chosen to help maintain allocation concealment. Blocking was used to ensure approximately equal numbers in the two groups. To ensure good allocation concealment, random allocation was email-based and administered by the study statistician. Randomisation utilised a computer-based random sequence generator. No stratification was used.

Participants allocated to the immediate group were informed of their allocation by letter or email. The contact details for participants in this group, together with their completed home risk assessment, were given to the physiotherapists at the Dorset MS Service so that arrangements could be made to commence the intervention. Participants allocated to the delayed group were informed of their allocation by letter or email and advised to continue with their usual routines and activities.

5.6 Outcome measures

5.6.1 Demographic and descriptive data

At baseline, demographic and clinical descriptors were collected for age, sex, education, employment, marital status, ethnicity, household composition, time since diagnosis, disease course, relapse history, medication, co-morbidities, and familiarity with technology.

As this was pilot work, a broad range of outcomes were included but none was defined as the primary outcome measure. All outcome measures were assessed at baseline (0 months), six months and 12 months (see Figure 5-1). This allowed for a parallel randomised controlled comparison at 6 months (immediate vs. delayed group), pre and post comparisons for the immediate (0 vs. 6 months) and delayed groups (6 vs. 12 months) and a consideration of the long-term follow-up in the immediate group (12 months).

The outcomes used in the study included hospital-based assessments and self-reported questionnaires. The hospital-based assessments included performance measures of aspects of balance, gait and dexterity. I administered these assessments with a clinical scientist. They were administered at similar times of the day to reduce the confounding effects of fatigue. The self-reported questionnaires included measures for leisure time physical activity (Godin Leisure-Time Exercise Questionnaire (Godin and Shephard 1985), self-efficacy

(for MS and physical activity and exercise), quality of life, fatigue, mood, impact of MS and health utilisation. These self-reported questionnaires were presented in a booklet using a large font and either given or sent to participants for completion at home at their own convenience and pace prior to the hospital-based assessments.

Self-reported questionnaires were completed by participants in their homes and collected when the physical assessments were completed.

5.6.2 Adverse events

An adverse event was defined as any undesirable outcome, such as injury, falls, discomfort, pain, and relapse. Adverse events for all participants, and their possible relation to the Mii-vitaliSe intervention were closely monitored, documented and reported to a Safety Monitoring Committee. Adverse events data were gathered via multiple sources. Participants were asked to report all adverse events related to use of the WiiTM using the play log. They were instructed to record any adverse events (including pain, tenderness, soreness, fatigue, dizziness, headaches, aching, stiffness, nausea, falls or near falls). Data were also gathered from the Dorset MS team, at the hospital-based assessments, from the Mii-vitaliSe physiotherapists via face-to-face or telephone contacts with participants. During the semi-structured interviews participants were also asked about any adverse events experienced. All these data were collated throughout the study and reviewed by the Safety Monitoring Committee which comprised a neurologist and a neuro-physiotherapist. The Chief Investigator assessed each adverse event to establish if it should be classified as a Serious Adverse Event (in terms of seriousness, relatedness and unexpectedness) according to the NRES. A key aim of this study was to test the safety and feasibility of the intervention and therefore details about minor adverse events linked to WiiTM use were collected (e.g. discomfort and muscle ache), even if these were expected.

5.6.3 Adherence

Measuring adherence is challenging and while some data can be captured by the WiiTM console this approach is problematic (e.g. other family members could use a participant's 'Mii'). In this study, adherence was originally defined as the total number of days on which activities are performed by an individual divided by the number of days agreed with the physiotherapist in their action plan. However, with the variability of the MS and frequent need for physiotherapists to modify participants' goals this definition was not practical.

Adherence was measured using a play log that participants were asked to complete on a daily basis. This had a dual purpose of providing a means for participants to self-monitor their Wii™ use as well as providing the research team with insights into levels and patterns of use. This included the following fields; date, whether the Wii™ was played, adverse events (e.g. pain, fatigue, falls or near falls), games played, total duration and number of bouts of activity, intensity, enjoyment and fatigue rating (on a scale of 1-10), reasons for non-use and free text comments. This log was provided in the form of a booklet for the initial six-month intervention period (months 0-6 immediate group and months 6-12 delayed group). The booklet included a page for each day with tick boxes to complete and space for comments. Play logs were collected from participants in the immediate group at the end of six months and at the end of 12 months from the delayed group.

The research team had some concerns that asking people to complete a daily log may be overly burdensome. A briefer log in the form of a calendar was therefore used for those in the immediate group for months 6-12. This calendar consisted of a page for each month with a box to tick for each day. Participants were asked to either put a cross on the date to indicate non-use or to write down the duration played if they had used the Wii™.

5.6.4 ActivPAL3™ tri-axial accelerometer

Participants were asked to wear an activPAL3™ [http://www.paltechnologies.com] accelerometer for seven days following the risk assessment. This is a small, unobtrusive, lightweight device can be attached to the midline of the thigh using a sticky gel attachment pad ('PAL Stickies'™) plus medical tape if needed. The activPAL3™ measures the periods of time an individual spends sitting, standing and walking along with sit-to-stand transitions and step counts.

Participants were given a demonstration of how to affix the activPAL3™ and a contact number for the research co-ordinator was provided so that any questions or concerns regarding the activPAL3™ could be resolved promptly. Participants were given a letter specifying dates for the start and end period for wearing the activPAL3™, detailed instructions (including explanatory illustrations) along with three additional PAL Stickies™ and ten strips of medical tape. The default activPAL3™ settings were used and the activPAL3™ accelerometers were administered with instructions to wear the device for 24 hours a day for seven

consecutive days including at night but to remove during water-based activities (showering, bathing, swimming, etc.)

The recorded data were downloaded from the activPAL3™ using version 7.1.18 (Research Edition) of the activPAL3™ software from Paltechnologies. This produced a visual representation ('activity summary') displaying periods spent sitting, standing and walking and the number of steps and sit-to-stand episodes. As the main interest in the pilot study was in the feasibility of collecting the activPAL3™ data the number of valid wear days for the seven day administration period was estimated for each participant via the activity summary.

The activPAL3™ has been found to have criterion validity for measuring steps taken, duration of walking and duration of standing for people with moderate MS (EDSS 4-6.5) (Coutler et al. 2017). In order to be eligible for the current study participants had moderate MS (EDSS score less than 6) which is similar to the population assessed by Coutler et al. (2017). Inter-rater reliability was excellent for steps taken ($ICC=0.995$, 95% CI 0.992, 0.997), walking duration ($ICC=0.999$, 95% CI 0.998, 0.999) and standing duration ($ICC=0.999$. 95% CI 0.998, 0.999) when raters assessed video recordings of a 20-30 metre walk. The confidence intervals are very narrow demonstrating low variability. In participants with a slower walking speed the activPAL3™ underestimated the number of steps taken by 8.7% possibly due to the slower movement of the thigh (where the device is attached) during the swing phase of gait. The use of the ActivPAL3™ for participants with an EDSS of 5-6 who may have short, slow steps may need to be considered due to the ActivPAL3™ underestimating the number of steps which may not be an accurate representation of their physical activity. As the inclusion criteria for this sample is an EDSS of less than 6 the underestimation of steps may impact on a small proportion of participants in the study.

5.6.5 Hospital assessments

Participants attended Poole Hospital NHS Foundation Trust for the hospital assessments. I carried out the assessments with Dr Steve Perring (registered clinical scientist) in the Medical Physics department. A protocol that had been piloted and agreed in phase 1 was followed (Appendix 6). Taxis were organised for participants if required or reimbursement for travel expenses including parking was offered. The nature of the intervention meant that participant blinding was not possible and

participants were not asked to conceal their allocation when they attended for the hospital assessments. I was not blinded to participant allocation but the clinical scientist was unaware of which group participants had been allocated to (unless participants referred to the intervention during the assessment). Participants were offered refreshments and rest periods during the assessment. The hospital assessment sessions lasted one hour.

5.6.5.1 Step test

The step test is a test of standing balance which incorporates dynamic single leg stance (Hill et al.1996). The test involves stepping one foot fully onto and then off a step as quickly as possible in 15 seconds. The step test has been shown to be reliable in healthy older adults and stroke patients for measuring balance performance over time with an excellent test-retest reliability ICC between 0.88 and 0.97 (Hill et al.1996). A strong and significant correlation has been reported between the step test and measures of gait (speed and stride) supporting the validity of the step test (Hill et al.1996).

The steps used were the Wii™ balance board (7.5 cm height) and an aerobic step (15 cm height). The procedure used was as described by Hill et al. (1996) and both legs were tested. The test requires the ability to transfer weight to the stance leg as well as strength, co-ordination and sensation for the stepping leg. As well as requiring stability and strength in the lower limbs, the step test also requires strength and stability in the trunk, i.e. core stability. Many of the exercises in Wii Fit™ require stepping on and off the balance board; therefore, it would seem a valid measure to detect changes in participants' standing balance as well as leg strength and core stability. In a recent pilot study with people with MS, researchers found improvements in a 3-minute stepping test following a 14-week Wii Fit™ home intervention (Plow and Finlayson 2011).

5.6.5.2 Steady Stance tests

Postural stability was tested using the steady stance tests, which assess ability to maintain a steady stance for a 60-second period in a series of five pre-determined stances with eyes open and without support:

1. Feet 10 cm apart.
2. Feet together with medial borders of feet touching.

3. Stride stance with feet 10cm apart and toes of rear foot in line with heel of front foot. Completed with right foot in front of left foot and with left foot in front of right foot.
4. Tandem stance with one foot in front of the other and the heel of the front foot in contact with the toes of the other foot. Completed with the right foot in front of left foot and with left foot in front of right foot.
5. Single leg stance completed on each leg (i.e. left and right leg).

The test was completed using the procedures originally described by Goldie et al. (1990) and Smithson et al. (1998). The most difficult stance position was tested first (single leg stance) and if this was completed the other tests were not tested. For each of the tests assessed, the participant was asked to hold the position for 60 seconds.

These tests have been found to be useful for assessing balance in patients with Parkinson's disease. However, a ceiling effect was found when testing for 30 seconds (Smithson et al. 1998) but patients with moderate MS did not reach this ceiling (Frzoviv et al. 2000). The tandem stance and single leg stance were shown to be sensitive to change in a study of 14 mobile participants with MS (Frzoviv et al. 2000) and also to discriminate between fallers and non-fallers with Parkinson's disease in a small study (Smithson et al. 1998). These tests are widely used by physiotherapists in clinical practice because the five positions are similar to those required for functional activities, e.g. walking (Goldie et al. 1990).

No significant difference was found between people with MS and control subjects for feet apart and feet together for 30 seconds (Frzoviv et al. 2000). Significant differences were found between people with MS and healthy subjects for stance and tandem positions suggesting discriminative validity of the test for with people with mild to moderate MS (Frzoviv et al. 2000). Test -retest reliability has been shown to be high ($ICC=0.85-0.94$) within sessions in patients following stroke (Goldie et al. 1990)

5.6.5.3 Nine hole peg test (NHPT)

The NHPT is an established outcome measure that assesses the ability to perform fine dexterous manual movements and is a measure of hand or finger dexterity (Mathiowetz et al. 1985). Its limitation is that it does not assess other important upper limb functions such as reaching, lifting and grasping objects. The NHPT is an acceptable fast screening tool despite the fact that there is no outcome measure

available to measure the entire range of upper limb impairments (Lamers and Feys 2014).

In a group of people (n=32) with moderate MS (mean EDSS score 4.5) good test-retest reliability was found across six tests administered on the same day (Solari et al. 2005). In a study of people (n=68) with moderate MS (mean EDSS 4.73) a moderate correlation (-0.7) was found with the Box and Blocks test (a measure of manual dexterity) suggesting concurrent validity in this sample (Goodkin et al. 1988).

The NHPT assesses grasping, releasing and dexterity. The test is timed and requires participants to place nine pegs into nine holes in a shallow board and then remove them as quickly as possible trying not to drop any. The test was completed using instructions provided by Mathiowetz et al. (1985). Participants were asked to complete it using their dominant hand first followed by the non-dominant hand.

5.6.5.4 Instrumented Timed Up and Go (i-TUG)

The TUG is used to assess functional mobility which is a term used to describe the balance and gait movements used in everyday life (Shunway-Cook et al. 2007) and muscle function (Paul et al. 2014). It is a timed test and requires the individual to stand up from a seated position, walk three metres, turn, walk back and sit down (Cattaneo et al. 2006).

The TUG has been found to be valid for use with people with MS with moderate balance problems (Cattaneo et al. 2006). Nilsagård et al (2007) found high concurrent validity ($ICC=0.81$) between the TUG and 10 metre walk test and TUG and 30 metre walk test ($ICC=0.85$) in people with MS.

Recently, researchers have improved the sensitivity of the TUG by administering it in an instrumented format using accelerometers attached to the participant's back with a waist strap connected to a recorder (Weiss et al. 2011). The iTUG captures the time to execute the movement, the number of steps taken and the time taken for the standing and sitting phases. The test was repeated twice and the average time of the two tests reported.

5.6.5.5 Measurements of the limits of sway

This test was performed using equipment that measures movement of an individual's centre of gravity (Static Posturography System) via an ultrasound transmitter when

standing under five conditions. The Static Posturography system has been found to be an objective and sensitive method for measuring balance in patients with neurological problems (Perring and Jepson 2001). The test gives an objective measure of stability based on the participant's movements when standing during a series of standardised conditions.

Two ultrasound transmitters were mounted on the participant's waist, one facing forward and one to the participant's left side. The time-of-flight for the ultrasound pulse to reach wall-mounted ultrasound receivers facing those transmitters was used to calculate anterior/posterior (AP) and lateral movement of the participant's centre of gravity in real-time. Assessments of the participant's limits of sway (LOS) was obtained by measuring the furthest they could lean forwards and backwards with a straight stance bending only from the ankles without losing balance. Then motion of the participant's centre of gravity (COG) was recorded for 20 second assessment periods when the participant was encouraged to stand as still as possible. The participant's stability under these circumstances was measured by the Equilibrium Quotient (EQ).

$$EQ = \frac{100 * (AP \text{ forwards} - AP \text{ backwards})}{LOS \text{ forwards} - LOS \text{ backwards}}$$

Where:

AP forwards = maximum forward extent of COG AP movement during the 20 second assessment period.

AP backwards = maximum backward extent of COG AP movement during the 20 second assessment period.

LOS forwards = Maximum forward limit of sway.

LOS backwards = Maximum backward limit of sway.

Thus an EQ score of 100% represents no AP movement (i.e. perfect stillness). An EQ score of 0% was assigned if the participant's AP position fell outside the LOS and loss of balance was observed, corrected by the participant stepping to steady themselves or requiring support from the assessors. The higher the EQ score the more stable the participant was during the 20 second assessment period. The measurement was performed for three time periods of 20 seconds each and the

average EQ score recorded. EQ assessment was performed for the following conditions:

- Eyes open, solid surface.
- Eyes closed, solid surface.
- Eyes open, solid surface with three distractions
- Eyes open, soft surface.
- Eyes closed, soft surface.

There were three distraction tasks which included mental arithmetic, naming sports and naming places in Dorset. Each participant completed the same three distraction tasks for each 20 second measurement period. The soft surface was a hardboard disc resting on a motorcycle inner tube inflated to 180mm Hg (Perring and Jepson 2001). At all times the participants were closely supervised by the researcher and clinical scientist to ensure that there was no risk of falling.

5.6.5.6 Two-minute walk test (2MWT)

The 2MWT is a measurement of endurance by assessing walking distance in two minutes. The test has been shown to have concurrent validity when correlated with the Rivermead Mobility Index and 10 metre walking test in people with a range of neurological conditions including MS (Rossier and Wade 2001). The test is a less demanding version of the widely used six minute walking test (6MWT) that has been used in clinical trials with people with MS (Motl et al. 2012). Both the 2MWT and the 6MWT measure the time taken to walk a relatively long walk (Feys et al. 2012).

The 2MWT is a symptom-limited exercise test, so in the current study participants were permitted to stop if necessary, although they were instructed to resume walking as soon as possible. The number of rest periods was recorded. The 2MWT was conducted using the standard protocol described by Rossier and Wade (2001). The test was conducted in the corridor in the Medical Physics Department at Poole Hospital using a 12 metre lap and the distance walked calculated by counting the number of whole laps completed and any additional ground covered. The use of walking aids and orthotics was permitted if required.

5.6.5.7 Gait stride-time rhythmicity

Gait rhythmicity measurement assesses gait outside the laboratory for a period of three to five minutes. This was measured using a portable recorder connected to flat

in-shoe heel impact sensors as described by Perring and Summers (2007). Participants were asked to walk unaccompanied (but with minimal supervision) on an extended walk along a covered and flat route (typically between 200-250 steps per foot). They were instructed to walk at their normal pace without interruption and could use their normal orthotic or walking aid. They walked for three to five minutes along a straight corridor in the hospital, turned and returned to the Medical Physics department. The stride time between adjacent heel strikes was recorded for each foot separately and the mean and standard deviation stride times were calculated. This test has been found to be effective at measuring treatment response in a small study of patients with vestibular symptoms (Perring and Summers 2007).

5.6.5.8 Randomisation for two-minute walk test and gait stride rhythmicity

As described in Section 4.8 the hospital assessments described above were tested on a person with MS so that a protocol for the procedure for these assessments could be developed (Appendix 6). The conclusion from the testing was that the whole battery of assessments took over an hour to complete. This was considered to be too long in view of the fact that people with MS often experience severe fatigue. As both the 2MWT and gait stride-time rhythmicity tests assess aspects of walking performance, half the sample were randomly allocated to complete the 2MWT and the other half the gait stride-time rhythmicity test. Randomisation was administered by the study statistician. On the day of the assessment, the researcher opened an envelope that contained the participant's test allocation.

5.6.5.9 Data collection and storage

Data collected for the assessments were recorded on a case report form with an ID number for each participant. On completion of the hospital assessments, the researcher collected the completed questionnaire booklet from participants checking that all questions had been completed and ensuring there was an ID number and no personal details. The case report forms and questionnaire booklets were stored in a locked filing cabinet at BU. The activPAL3™ was collected from participants and the data downloaded using activPAL3™ software version 7.1.18 (Research Edition) and stored in a password protected electronic file on a BU computer.

All study documents (both paper and electronic) were retained in a secure location at BU during and after the trial in accordance with the Data Protection Act 1998. Only

authorised members of the research team had access to these data. The documents will be retained for a period of five years following the end of the study.

Following the baseline assessments, participants were informed by letter of their allocation to either the immediate or the delayed group.

5.6.6 Data analysis

Data were inputted into SPSS Version 21. Data that were assumed to be interval scaled were reviewed to assess whether they were normally distributed. The data analysis was mainly descriptive in line with the feasibility aims of the pilot study. Estimates of recruitment and retention rates and SDs of outcome measures for the hospital-based assessments are presented with 95% confidence intervals. Mean differences in outcomes between study arms and between assessments (within group) were calculated with 95% confidence intervals. Participants were analysed in the group they were randomised to (immediate and delayed).

The analysis of the quantitative data from the hospital-based assessments was descriptive and presented in graphs and tables to illustrate the changes in means and confidence intervals for both groups at each of the three assessments. The formula for calculating error bars depends on variability in the outcome measure and on the sample size. The higher variability between people and smaller sample sizes will lead to large error bars.

Cohen's d is a measure that can be used to measure the effect sizes between the immediate and delayed groups of the trial by measuring the mean outcomes in the two groups (Cohen 1962). This allows data to be compared across outcomes and the ability to categorise the magnitude of difference (small $d=0.20$, medium $d=0.50$, large $d= 0.8$).

Standardised effects sizes (Cohen's d) were calculated to compare the results across outcome measures and to categorise the magnitude of difference. Cohen's d was calculated by dividing effect sizes by pooled baseline standard deviation using these equations:

$$\text{Cohen's } d = (\text{mean}_2 - \text{mean}_1) / \text{SD pooled}$$

$$\text{SD pooled} =$$

$$\text{Square Root SQRT}((\text{SD}_1^2 + \text{SD}_2^2)/2)$$

There are several ways to calculate Cohen's d . The formula used assumes that the two groups are roughly the same size and that the sample is small. In order to standardise the effect size calculations the following process was adhered to:

- Mean at six months subtracted from mean at baseline
- Mean at one year subtracted from mean at six months
- Immediate group subtracted from the delayed group

Thus when high values of outcome measure are of benefit to the participant, a positive standardised effect size indicates an effect in the direction of benefit. Therefore when high values of outcome measure are detrimental to the participant, a positive standardised effect size indicates an effect not in the direction of benefit.

Adherence rates were estimated via the play log data. Use was measured in terms of percentage of days used, number of 10 minute sessions per day, mean number of days used, when used and if used alone or with others. Descriptive statistics were used to summarise participants' use of the WiiTM to include games used.

The visual output provided by the activPAL3TM was looked at to provide an estimate of the number of days data for each participant for each 7-day administration period.

5.7 Intervention

Table 5-1 provides a summary of the Mii-vitaliSe intervention.

Table 5-1: Summary of the components of the Mii-vitaliSe intervention

Components of the Mii-vitaliSe intervention	Summary of each component
Orientation sessions with physiotherapist (weeks 1 and 2) Face-to-face, individual or in pairs	Two orientation sessions in the hospital with the physiotherapist for familiarisation with the Wii™
Provision of Mii-vitaliSe resource materials	Resource materials provided to support ongoing use: Guidance Book, Personal Activity Book, Games Descriptors, Daily Play Log
Provision of Nintendo Wii™ equipment and software for use at home (week 3)	Wii™ equipment provided and set up at home with Wii™ balance board and Wii Sports™, Wii Sports Resort™ and Wii Fit Plus™ software
Physiotherapist guidance Face-to-face (weeks 7 and 16) Telephone or email (weeks 5 and 12)	Ongoing support and monitoring by physiotherapist (face-to-face, email and telephone)

The initial orientation (sessions 1 and 2) of the intervention took place in the neuro-gym in the physiotherapy department at Poole Hospital. There was already a Wii™ set up there that could be booked. Session 3 took place in participants' homes. Two senior physiotherapists from the Dorset MS Service and I delivered Mii-vitaliSe. All three physiotherapists were experienced neuro-physiotherapists who had been practising in the NHS for several years since graduation. The majority of participants were seen by the two physiotherapists from the Dorset Multiple Sclerosis Service. I delivered the Mii-vitaliSe intervention to two participants (one in the immediate group and one in the delayed group). These two participants were in full-time employment /education and their Mii-vitaliSe sessions were delivered outside usual working hours.

5.7.1 Orientation session 1 (week 1)

Participants were given the Mii-vitaliSe resources, Guidance Book and the Personal Activity Workbook. Session 1 focused on getting ready for change, i.e. moving from being inactive to becoming more active. This involved a discussion with participants regarding the benefits of physical activity for people with MS. They were asked to consider their present level of physical activity and then to weigh up the pros and cons of using the Wii™ to become more physically active. A decisional balance pros and cons table in the Personal Activity Workbook was used to help participants reflect on becoming more active and as a motivational tool.

During the session the physiotherapist gave a demonstration of using the Wii™ equipment and the Games Descriptors were shown. Games from each category of the Wii Fit Plus™ were demonstrated (balance, aerobic, yoga, muscle strengthening and training plus). This illustrated the wide range of games offered by the Wii™ software that was provided as part of the Mii-vitaliSe intervention package. Safety issues were highlighted and participants were directed to relevant sections of the Guidance Book giving general health and safety advice. Participants were given an opportunity to try out the Wii™ remote, nunchuk and the balance board. They were also shown how to create a ‘Mii’.

At the end of the session participants were asked to reflect on what had been discussed and shown in the session and to start to think about games they might like to try when using the Wii™. They were encouraged to read through the Guidance Book and to write down potential goals to be discussed with the physiotherapist at the next session based on the games that had been demonstrated and those that appealed to them.

5.7.2 Training and individualised assessment Session 2 (week 2)

In the second hospital orientation session, participants were guided through warm up and cool down exercises and given an opportunity to try out activities with supervision. Their personal preferences for games were explored and discussed with the physiotherapist. Personal goals and a plan for achieving these goals were discussed and noted.

By the end of the second session, participants had an appreciation of the range of games available to them and had identified personal goals and an action plan in preparation for starting to exercise once the Wii™ was set up in their home.

Refreshments were provided at both hospital orientation sessions and taxi transport was provided if needed. Travel or parking/ expenses incurred were reimbursed.

5.7.3 Session 3 (week 3)

After the two hospital orientation sessions, the Wii™ equipment was installed in participants' homes by the physiotherapist. Safety advice was reiterated and carefully considered when setting up the equipment. Participants were supported to create a 'Mii' character and were instructed to use their own 'Mii' whenever they used the Wii™. In this session, working closely with the participant, the physiotherapist reviewed the goals they had created in the second hospital orientation session and together they agreed a personal exercise programme/action plan. The physiotherapist also provided guidance on completing a play log each day detailing use/non-use of the Wii™ and reasons for not using the Wii™.

Participants were then encouraged to start using the Wii™ independently for regular exercise according to their personal exercise programme/action plan. The physiotherapist provided continued personalised support via home visits (weeks 7 and 16) and monthly telephone support. The telephone support offered troubleshooting advice, support to help people find ways to overcome barriers encountered or identify facilitators and encouragement. At the home visits, the physiotherapist undertook a review and offered advice on progressing or modifying the personal exercise programme. If any difficulties occurred between scheduled contact times, participants were encouraged to contact the physiotherapist or study researcher.

5.7.4 Follow-up support

Following the three orientation sessions, participants continued with independent home use of the Wii™ using the Mii-vitaliSe resource materials provided. Participants were given a contact number for their Mii-vitaliSe physiotherapist for clinical issues and the study researcher for any issues relating to the research. The Dorset MS service also offered a routine telephone support service. Participants were advised to report any adverse incidents immediately.

At week 5, telephone support was offered to identify and resolve any early difficulties encountered. This telephone call offered an opportunity for monitoring which included offering feedback and support as well as reviewing goals and action

plans. Similarly, at week 12, telephone support was provided to encourage progress and support people to overcome any barriers.

At weeks 7 and 16 a review visit was scheduled so that the physiotherapist could reassess and review participants at home. This visit also offered opportunities for providing support and advice to progress or modify the individualised programme of activities. This session also sought to support participants to problem solve and self-manage their exercise schedules. This included encouraging participants to use the Mii-vitaliSe resources to review their barriers and facilitators for exercise. From this, review action plans could be revised to incorporate coping planning ('if-then' plans).

Following week 16, the physiotherapist contacted participants monthly via telephone or email to provide feedback and encouragement to maintain continued self-monitoring, goal setting and problem-solving.

Table 5-2 presents a summary of the format and content of the Mii-vitaliSe intervention.

Table 5-2: Format and content of the Mii-vitaliSe intervention

Week	Session	Content of session and activities completed
Week 1	Orientation to Wii™ using Mii-vitaliSe resources	The evidence for the benefits of physical activity Consider present levels of physical activity Complete a decisional balance - pros and cons of increasing physical activity with the Wii™ versus not increasing physical activity Physiotherapist demonstration of using Wii™ equipment highlighting safety Creating a ‘Mii’ Familiarisation with the controls
Week 2	Orientation to Wii™; training and individual assessment	Guided through warm up and cool down exercises With supervision, try out exercises Discuss personal preferences for games Set goals and actions plans
Week 3	Installation of equipment and commencement of individual programme at home	Equipment set up by physiotherapist Revision of safety advice Support to create a ‘Mii’ Goal setting and action planning supported by physiotherapist Guidance on keeping the daily play log and on setting/recording goals
Week 5	Follow-up	To identify and resolve any early difficulties encountered Review and adapt goals Offer feedback Support self-management
Week 7	Review visit	Reassess providing individualised support Offer advice and encouragement Discussing possible progression/modification of the activities
Week 12	Follow-up	Continued self-monitoring, goal setting Feedback ‘If-then’ plans, action planning, coping planning including a review of individual barriers and facilitators Problem-solving
Week 16	Review visit	Reassess and provide support, advice and encouragement Discussing possible progression/modification of the activities Continued self-monitoring, goal setting, feedback; ‘if-then’ plans, action planning, coping planning; problem-solving
Weeks 20 onwards	Ongoing support	Monitoring, providing support and individualised advice, encouraging accountability and providing encouragement Continued self-monitoring, goal setting, feedback; problem-solving

5.7.5 Usual care

Both groups received usual care and the Mii-vitaliSe intervention was delivered in addition to usual care. The TIDieR checklist recommends that the term ‘usual care’ is not a sufficient description (Hoffmann et al. 2014). However, producing a detailed account of usual care using the TIDieR checklist can be challenging if usual care is highly variable. The multi-disciplinary Dorset MS service provides ongoing support for patients in their care which includes all the participants in this study. Within this team, patients are reviewed annually either at an outpatient appointment at Poole Hospital NHS Trust or at home. Following this review, any referrals are made for medical or therapy treatments as necessary. There is an option for patients to self-refer if their symptoms deteriorate before the review appointment is due. This is done via a telephone service where designated times are available for patients to speak to a member of the team.

5.8 Qualitative data collected from semi-structured interviews

The MRC guidance states that a systematic approach is recommended for conducting process evaluations on complex interventions (Moore et al. 2015). A process evaluation can help to understand more about how an intervention is implemented (how delivery is achieved and what is delivered). This offers insights to how an intervention works in practice. This process evaluation aims to acquire information regarding if the intervention was delivered as intended (fidelity) and the dose delivered (Moore et al. 2015). The evaluation also identifies any changes that may need to be made to the intervention in the future.

A qualitative component formed part of the mixed methods feasibility study and was carried out to gain feedback from participants and physiotherapists. The aim for this approach was to understand the process (the delivery of Mii-vitaliSe) and the perceptions of the participants who were involved. This qualitative component formed part of the process evaluation to provide a more detailed understanding about the implementation of the Mii-vitaliSe intervention (resources and processes through which the intervention was delivered) and the impact of Mii-vitaliSe (how participants interacted with the activities in the intervention and how changes were, or were not, made). A generic qualitative research methodology was used which is an approach that is not based on established philosophical assumptions (Caeli et al 2003). The rationale for using this methodology is that it focusses on understanding an experience which in this study was the participants’ involvement in the study. In

generic qualitative research data analysis generates patterns and themes that offer insights and understanding.

The framework approach to data analysis was used. This approach is popular for healthcare research as it is a method for systematically managing the data and uses a clear audit trial which enhances the rigour of the analysis (Smith and Firth 2011). In the framework approach there are clear aims and objectives and a structured interview guide to focus the collection of the qualitative data. A key aim of the qualitative component was to gain insights into how and why the Mii-vitaliSe intervention did or did not increase activity levels in people with MS. This was achieved by developing an understanding of participants' patterns of use of the Wii™ and barriers and facilitators they had encountered. The semi-structured interviews also explored participants' experiences of participating in the Mii-vitaliSe study.

Interviews were undertaken with the Mii-vitaliSe physiotherapists to gain insights into whether the intervention was delivered as intended and learn about any challenges they encountered when delivering it. It was also important to explore the physiotherapists' views about the extent to which Mii-vitaliSe could be implemented in clinical practice and in other settings.

The key objectives were as follows:-

- To determine the acceptability of using the Wii™ at home supported by physiotherapists and the Mii-vitaliSe intervention
- To obtain information about patterns of use and barriers and facilitators
- To gain insights into how and why the Mii-vitaliSe intervention did or did not increase activity levels in people with MS
- To gather feedback from the physiotherapists about their experiences of delivering the Mii-vitaliSe intervention

Semi-structured interviews were undertaken using a pre-determined topic guide (Appendix 7). The topic guide used open-ended questions which enabled participants to talk about their experience of participating in the study and of using the Mii-vitaliSe package. Topics discussed included participants' experiences of taking part

in the Mii-vitaliSe study, experiences of receiving the Mii-vitaliSe intervention, barriers and facilitators of using the Wii™ at home with physiotherapist support, default feedback provided by the Wii™ software and the content and use of the Mii-vitaliSe resources. The topic guide was used flexibly to guide the discussions and facilitate participants to describe their experiences of taking part. An iterative process is recommended in the MRC guidance (Moore et al. 2015) so that themes noted in the initial interviews can be explored further with participants in later interviews. Participants' daily play logs were referred to during the interviews to prompt participants to consider their patterns of Wii™ use.

Participants from the pilot study were purposefully selected to be interviewed from a sub-set of participants from the pilot study. This involved selecting participants with specific characteristics with the aim of obtaining relevant and diverse data to answer the research questions (Tong et al. 2007). The purposive selection aimed for diversity in age, type of MS, previous experience using the Wii™, employment status, children at home and self-reported disability (tables 5-3 and 5-4). There were three men in the pilot study and all three were interviewed. The aim was to interview 50% of participants from each group (immediate and delayed) after the 6-month follow-up assessments and 50% in both groups following the one-year assessments. Twenty-three interviews were conducted in participants' homes and one in the Medical Physics Department at Poole Hospital. Participants who had been purposively selected were contacted to arrange an appointment for a face-to-face interview in their home.

The physiotherapists were interviewed at Poole Hospital NHS Trust. A pre-determined topic guide was used (Appendix 7). During the interviews the physiotherapists referred to the Mii-vitaliSe resources and their participant records as they described their experiences of facilitating people with MS to exercise at home

Table 5-3: Purposive sample from the delayed group.

Interviewed	Date of baseline assessment	Date of 6 month follow-up	Gender	Age (Years)	No. of children in household	Employment status	Previous Wii™ use	Self-reported type of MS	APDSS score	Exercises to a sweat 1=often, 2=some, 3=never
One year	14/02/13	29/08/13	Female	40-49	1	Not working	None	RRMS	5	3
Six-months	26/02/13	29/08/13	Female	50-59	0	Not working	None	RRMS	5	1
Not interviewed	06/03/13	06/09/13	Female	40-49	0	Part-time	None	RRMS	4	3
Both six-months and one year	06/03/13	06/09/13	Female	50-59	0	Part-time	None	SPMS	5	3
Both six-months and one year	21/03/13	21/09/13	Female	40-49	0	Full-time	None	RRMS	3	2
Not interviewed	10/04/13	10/10/13	Female	40-49	1	Part-time	None	RRMS	5	3
Not interviewed	18/04/13	18/10/13	Female	50-59	0	Not working	None	Not known	5	3
Six-months	18/04/13	18/10/13	Female	30-39	1	Not working	None	SPMS	5	3
Six-months	20/05/13	20/11/13	Female	60-69	0	Not working	None	PPMS	5	3
Not interviewed	20/05/13	20/11/13	Female	60-69	0	Retired	None	RRMS	5	3
Not interviewed	28/05/13	28/11/13	Female	50-59	0	Part-time	None	RRMS	2	3
Both six-months and one year	25/06/13	25/12/13	Male	30-39	0	Full-time	Has but not used since diagnosis	RRMS	5	3
One year	19/06/13	19/12/13	Female	30-39	0	Full-time	Has Wii™-not using	RRMS	5	1
One year	19/06/13	19/12/13	Male	40-49	1	Full-time	None	Benign	4	3
One year	19/06/13	19/12/13	Female	40-49	2	Part-time	Has Wii™ not using	Not known	2	3

Table 5-4: Purposive sample from the immediate group.

Interview	Date of baseline assessment	Date of 6 month follow-up	Gender	Age (Years)	Children in household	Employment status	Previous Wii™ use	Self-reported type of MS	APDSS score	Exercises to a sweat 1=often, 2=some, 3=never
Both six-months and one year	20/03/13	20/09/13	Male	40-49	1	Not working	None	RRMS	6	3
Not interviewed	26/02/13	29/08/13	Female	40-49	2	Part-time	Yes	RRMS	4	3
Six-months	27/02/13	29/02/13	Female	40-49	0	Full-time	Yes	SPMS	4	2
Not interviewed	07/03/13	07/09/13	Female	60-69	0	Retired	None	SPMS	5	2
Both six-months and one year	21/03/13	21/09/13	Female	40-49	1	Part-time	None	RRMS	5	3
Not interviewed	19/04/13	19/10/13	Female	40-49	1	Full-time	None	RRMS	2	3
Not interviewed	08/05/13	08/11/13	Female	50-59	0	Full-time	None	RRMS	4	3
Both six-months and one year	19/04/13	19/10/13	Female	50-59	0	Full-time	None	RRMS	5	3
Not interviewed	20/05/13	20/11/13	Female	40-49	0	Full-time	None	RRMS	2	3
Both six-months and one year	28/05/13	28/11/13	Female	60-69	0	Retired	None	RRMS	2	3
Six-months	28/05/13	28/11/13	Female	60-69	0	Not working	None	RRMS	5	3
One year	03/07/13	03/01/14	Female	50-59	0	Full-time	Has Wii™ but doesn't use	RRMS	4	3
One year	19/06/13	19/12/13	Female	50-59	0	Not working	None	RRMS	5	2
One year	12/06/13	12/12/13	Female	40-49	0	Part-time	None	RRMS	5	3

5.8.1 Data analysis

A thematic analysis was carried out on the interview data using a framework method (Gale et al. 2013). This method is appropriate for using in multi-disciplinary health research teams as a way of organising and describing data while reflecting on the study aims and objectives. The framework method is commonly used for the thematic analysis of semi-structured interview transcripts. Data analysis involved a consideration of the *a priori* themes from the original interview guide as well as emergent concepts generated inductively from the data. The primary aim for data analysis was to answer specific questions rather than to generate new theory (Ward et al. 2013). A thematic analysis can provide insights into the questions asked which in this study involved using Mii-vitaliSe and participating in the study. An advantage of organising data is that the opinions of each participant remain connected to aspects of their narrative to preserve the context of these ideas. Therefore both a theme-based and case-based analysis can be performed (Gale et al. 2013; Ward et al. 2013).

Overview of the stages of data analysis (Ward et al. 2013):-

- Familiarisation.
- Identification of recurrent and important themes.
- Indexing and charting.
- Summarising data.
- Reporting and interpreting.

5.8.1.1 Familiarisation with the data

Preliminary analysis took place while the data were being collected by reflecting on the content of the interviews in order to shape the interview guide and subsequent interviews. All interviews were audio recorded digitally, downloaded and saved on a password protected networked drive. The recordings were transcribed verbatim. I checked and corrected the transcriptions by listening to the original recording and simultaneously reading the transcript. This ensured the transcript remained ‘true’ to the original interview. The transcripts were then bound in three volumes (participant interviews at six and 12 months and physiotherapist interviews) in preparation for analysis.

The first stage of data analysis involved listening to interview recordings while reading through the transcripts to become familiar with and immersed in the data. This led to becoming familiar with the breadth and content of the data, to identifying particular events, key words and processes throughout the transcripts.

Prior to reading the entire set of transcripts, the overall aim of the research study and specific aims for the qualitative component were reviewed so that these could be carefully considered throughout the analysis. The TIDieR template describing Mii-vitaliSe (Table 4-3) was also reviewed so that the components of the intervention could also be considered. The entire set of transcripts was read while listening to the recordings from the beginning in order to become familiar with the data (Smith and Firth 2011). This was time consuming because of the volume of data (approximately 21 hours of recorded interviews) but valuable and formed the foundation for analysis that followed. Initial notes were made as ideas and thoughts emerged from the transcripts. The transcripts were also marked with key words in the margins and different colours were used to highlight common points made by participants in order to start to identify key emerging themes.

5.8.1.2 Generating initial codes

During the process of reading the data, line by line initial notes were made in the margins of the transcripts. These notes related to the content of the data and what was relevant to the research question, aims and objectives. Many of the codes used at this stage related to specific questions as there had been a structured interview guide; e.g. patterns of Wii™ use, barriers to using the Wii™. This coding process was performed manually using ‘post-it’ notes to identify segments of data. The ‘post-it’ notes were colour-coded to identify which interviews the code related to i.e. six months, one year or physiotherapist interviews. The ID number and group allocation was also recorded on the ‘post-it’ note and, if there was a specific quotation from the text, the page number was noted to allow this part of the text to be easily found at a later date. This allowed for the comparison and contrasting of data across cases as well as within individual cases (Gale et al. 2013) and the selection of significant sections from the data. This process is known as coding and is a way of assigning units of meaning to descriptive information.

The entire data set was then worked through systematically by taking the ‘post-it’ notes from the transcripts and sticking them onto a whiteboard in order to sort the codes and identify potential themes, patterns and events. This noting of themes using

‘post-it’ notes was a technique for organising the data, which allowed flexibility as the ‘post-it’ notes could be moved around when thinking about themes (Ward et al. 2013). This could also have been done using computer software which allows for the data to be organised and sorted (Ward et al. 2013). This process allowed for the range and diversity of the themes to be noted while identifying associations between them so that the ‘whole picture’ emerges (Smith and Firth 2011).

5.8.1.3 Searching for themes

The recurring themes from the coded, segmented data were added to a chart. This allowed for the data to be analysed in a systematic and organised way. This again can be done using computer software but in this case paper charts were used. This can be more time consuming but was useful as it allowed all the data to be seen at once as the charts were displayed across walls in a room (Ward et al. 2013). This process also allowed for continued immersion in the data and the ability to refer back to the transcripts. The themes that emerged linked with the specific areas of interest of the project and also the components of both the intervention and the pilot study. Despite this deductive approach to the analysis, it was important to have a thorough approach to identifying themes so that notable emergent views were not missed (Gale et al. 2013).

Whilst it is important to stay closely immersed in the data it is also necessary to discuss emerging themes with other researchers. Framework analysis is used in multi-disciplinary research and it is recommended that at least two researchers identify themes from the data (Gale et al. 2013). Following my initial analysis the Chief Investigator viewed the findings. This led to important discussions from which different perspectives were gained which informed the analysis (Gale et al. 2013; Ward et al. 2013). Using participants’ own words key phrases were summarised to create ‘in-vivo’ themes. Initial thoughts then developed into more formal ideas so that themes could be generated.

5.8.1.4 Indexing and charting

Once the themes had emerged the next stage involved summarising the data. This can be a challenge as it is important to stay true to the unique meaning and context of the data while condensing it so that it can be reported (Gale et al. 2013). This stage, therefore, involved identifying quotations from the data so that summaries of what was said by participants could be presented. Several tables were made using participants’ own comments to present the themes generated from the interviews.

These tables allowed the summarised data to stay within the context of the case providing full description and showing the multifaceted nature of the data (Gale et al. 2013).

5.8.1.5 Interpretation of themes

It is important that the themes that emerged from the data analysis linked to the research aims and objectives. The themes were therefore aspects of the data that were important in relation to the research question and aims. The process of interpretation involved moving beyond the codes and themes and checking back against the written transcripts. The interpretation process also referred back to the intervention description and underpinning theory as detailed in the TIDieR template (section 4-3). This was important so that generalizable knowledge regarding the implementation and mechanisms of the intervention could be better understood.

5.8.1.6 Reflexivity

When interpreting the themes it is also important for the researcher to consider their role and how this may have affected what participants said at the interviews. In the feasibility stage of developing an intervention it is appropriate for the researcher to have an active role. An active role is defined as being close enough to the intervention to note any problems and interpret why they occur, yet sufficiently independent to report them to the research team and supervisors (Moore et al. 2015). The researcher was the research co-ordinator and had screened and recruited participants to the trial as well as trained and supported the Mii-vitaliSe facilitators. This would imply that an active role was taken and therefore the influence of the researcher needs to be considered. The research was overseen by a Chief Investigator and a project steering committee and the data analysis was discussed with the team.

In qualitative research it is important to be aware of and report the engagement with participants that the researcher has so that potential sources of bias can be recognised and documented (Tong et al. 2007). In order to identify sources of bias field notes in the form of a researcher's diary were made. This diary captured the researcher's thoughts and feelings regarding the information gathered from the interviews and identified issues that could be discussed in supervision meetings.

5.8.1.7 Reporting

It is recommended that qualitative data in a process evaluation are collected at several time points so that changes to the intervention can be described over time

(Moore et al. 2015). In this study qualitative data were collected at two time points. The Consolidated criteria for reporting qualitative research (COREQ) is a 32 item checklist to guide the reporting of in-depth interviews and focus groups (Tong et al. 2007). It recommends that when participant quotations are presented to illustrate themes the participant is identified. When reporting the qualitative data in chapter six the participant will be identified by group allocation (immediate or delayed) and by the timing of the interview (six months or one year).

As well as reporting themes, sub-themes and quotations tables generated from the framework analysis will also be reported in the results chapter. Tables using participants' own comments illustrating a between- case framework analysis will present themes generated from the interviews.

Chapter 6 Results

In this chapter, quantitative and qualitative findings from the pilot evaluation are presented in two parts and in sections that relate to each of the study aims and objectives described in chapter 3 (Section 3.11). In the first part quantitative results presented focus on objectives one and two which relate to the study procedures; recruitment, retention and assessment processes.

Objectives 1 and 2

1. To test procedures, estimate recruitment and retention rates and refine the selection of outcome measures in preparation for a future full trial.
2. To calculate preliminary estimates of effect size and of standard deviation to inform a sample size for a future full trial.

Descriptive results for the hospital-based assessments are presented with preliminary estimates of effect sizes and standard deviation as well as data on the return rates for the questionnaires and adherence.

In the second part of the chapter the qualitative findings presented focus on the intervention and how objectives three and four were met.

Objectives 3 and 4

3. To determine participants' views on taking part in the pilot study and receiving the Mii-vitaliSe intervention.
4. To gather feedback from physiotherapists about their experiences of delivering the Mii-vitaliSe intervention.

Participant feedback about completing the assessments, wearing the activPAL3™, being randomised and taking part in the intervention is presented. This includes any problems encountered with using the equipment, facilitators and barriers to engaging with the intervention and the ways that participants used the Wii™. This section also presents the findings from the interviews with the physiotherapists who delivered the intervention. This includes experiences of delivering the intervention, any difficulties encountered and suggestions for the potential refinements of the Mii-vitaliSe intervention looking ahead to a future trial. Following the presentation of the results an overall chapter summary is given.

Part 1: Quantitative results

6.1 Procedures (Objective 1)

The first objective was to test the procedures, estimate recruitment and retention rates and refine the selection of outcome measures in preparation for a future full trial. The procedures include screening, recruitment and retention and the assessment procedures for the hospital based assessments.

6.1.1 Screening processes

The telephone screening questionnaire was administered to 34 people and of those 30 were eligible to participate. When completing the Godin Leisure Time Exercise Questionnaire (GLTEQ) both at screening and during data collection participants sometimes left blank spaces on the form rather than putting zeros. During screening, the questions needed to be checked by speaking to the person to determine and understand their current level of activity in more detail. This was important, as it was an inclusion criterion.

As part of the screening process 31 risk assessments were conducted in people's homes between February 2012 and June 2012. The risk assessment offered an opportunity to assess the person's safety when stepping on and off the Wii™ balance board and moving on the board. It also provided a chance to look at the type and set up of an individual's television; in particular the AV1 and AV2 sockets for insertion of the yellow, red and white leads from the Wii™ console. On some televisions, these sockets were not available because they were already in use for other equipment (DVD and/or video). In this instance, a component lead was required to set up the Wii™ console. This was discovered during the initial processes of setting up the equipment for participants. As a result the risk assessment was slightly modified so that the availability of the AV1 and AV2 sockets could be checked and, if required, a component lead would be taken to the set-up appointment.

6.1.2 Recruitment

The recruitment target of 30 participants was achieved. Recruitment information packs were sent in small batches between November 2012 and May 2013. Table 6.1 shows the pattern of recruitment during the nine month recruitment phase. In total, 98 information packs were given out by the Dorset MS Service, the majority were sent in the post and some were given out face-to-face. Potential participants were identified from discussions in meetings with the Dorset MS service and from the

database. There was a slow build up time at the start of the recruitment phase (December 2012) as strategies were developed for identifying potential participants and giving out recruitment packs. Similarly, at the end of the recruitment phase (June 2013) there was a gradual slowing down of the rate recruitment packs were given out. This was to prevent over-recruitment to the study and minimise potential disappointment. In the period between December 2012 and June 2013, larger batches of recruitment packs were given out, except for March 2013, when only one recruitment pack was sent. This was due to annual leave during the Easter period for the staff in the Dorset MS Service involved with recruitment.

During March 2013, there was an opportunity to look at the initial recruitment rate and consider strategies for continued recruitment. At this point in recruitment, the majority of the interest had been expressed by females and therefore strategies for targeting more eligible males to participate in the study were considered. This included highlighting this need to the team and looking at the database to identify male participants who fulfilled the screening criteria. During the four months when recruitment activity was at its peak, the average number of packs sent out per month was 23 and the average return rate was 10 packs per month. The average monthly recruitment rate was 3.3 participants over nine months. Table 6-1 shows the pattern of recruitment to the study. Of those who were sent or given information about the study there was a response rate of 44% of whom 31% consented.

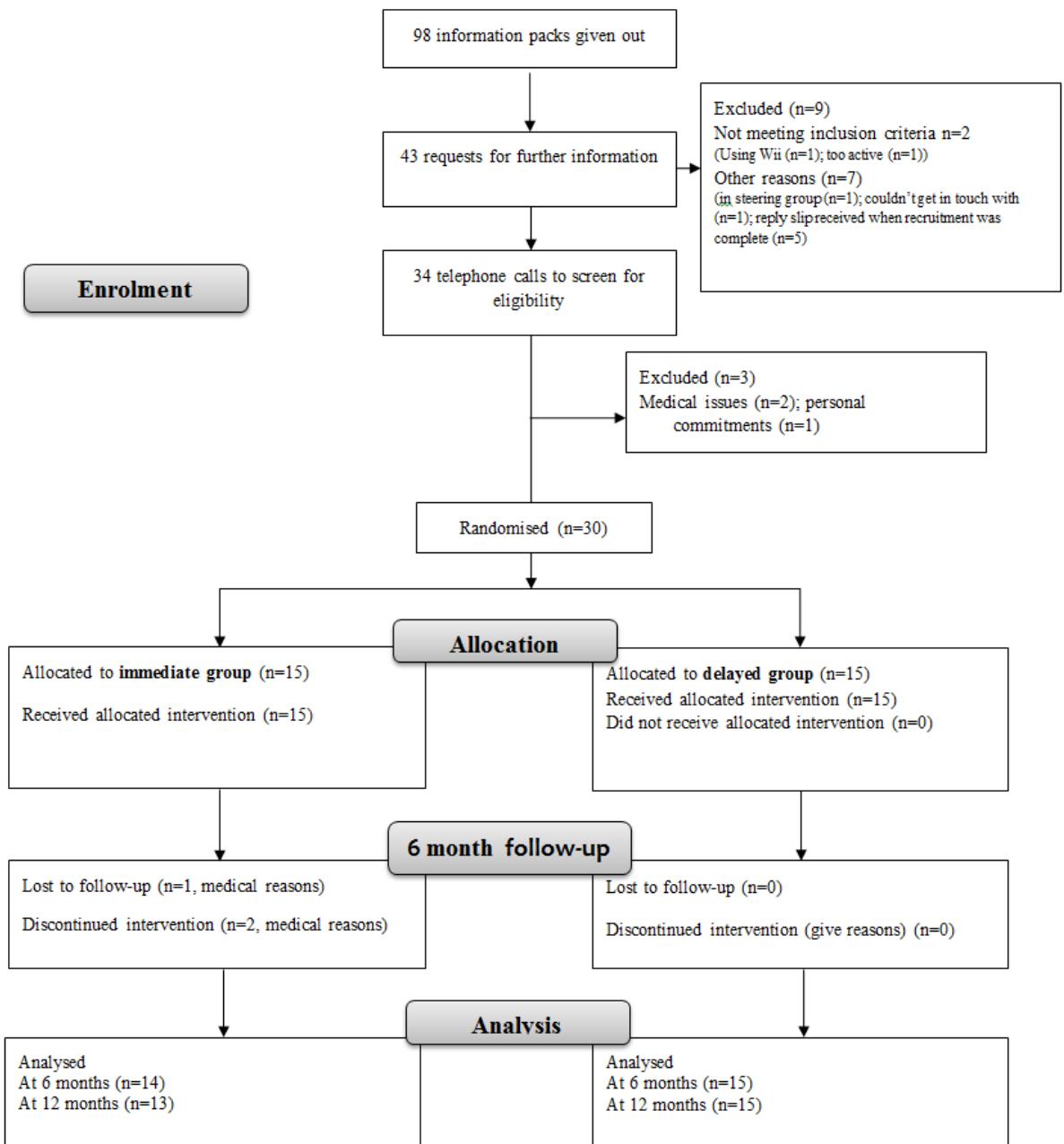
Table 6-1: Monthly recruitment patterns from the Dorset MS Service to the feasibility study between November 2012 to July 2013.

	Nov 2012	Dec 2012	Jan 2013	Feb 2013	March 2013	April 2013	May 2013	June 2013	July 2013	Total
Recruitment packs given out	1	3	26	19	1	34	14	0		98
Reminder letters sent	0	0	11	4	15	6	22	0		58
Reply forms returned	0	0	7	13	5	3	13	2		43
Reply forms returned after recruitment complete							3	2		5
Telephone screens	0	0	5	9	8	1	11	0		34
Risk assessments completed	0	0	0	9	5	3	10	4		31
Number Recruited	0	0	0	9	5	3	9	4	1	30

6.1.3 Retention

The processes for recruitment and subsequent randomisation, assessment and analysis are detailed in the Consort diagram (Figure 6-1). The reasons for not responding to the invitation to participate are unknown, as the NHS ethics committee did not permit the use of a decline slip. The withdrawal rate from the study was low (7%) and reasons for and timings of withdrawals once recruited are presented in Figure 6-1. Outcome data were available for 29 (97%) participants at six months and 28 (93%) participants at 12 months. The two participants who were lost to follow-up or withdrew from the intervention chose to keep the Wii™ equipment; however, it is not known if they continued to use it.

Figure 6-1: Consort diagram



6.1.4 Data collection procedures

In this section the processes for the collection of the hospital based outcome measures are presented. The hospital-based assessments were completed in the medical physics department at Poole Hospital between February 2013 and August 2014. The pattern for completion of the assessments mirrored the recruitment rate with a slow build up initially and gradual decrease towards the end. During the four months when the assessment rates were steady, on average between five and six assessments were completed each month (see Table 6-2).

At the hospital assessment visit, participants returned their completed questionnaire booklets and daily play logs and participants were given the activPAL3™ device and instructions. The hospital visit took an hour, including a rest break. Appointments for the hospital visits were booked in blocks of two or three participants. The six-month and one year follow-up assessment visits were booked within a two-week time window of the original baseline assessment visit date if possible. At some visits (particularly the earlier visits), there were problems with the equipment used for the iTUG and the static posturography and therefore there were missing data. Details regarding levels of missing data for specific tests will be provided in later sections of this chapter when the test results are reported. Table 6-2 shows the reasons why some participants were not assessed within the two-week time window. At the six-month follow-up, one participant withdrew and had no assessments and two participants had moved house and therefore had assessments outside of the 2-week time window. At the 12-month follow-up, another participant had withdrawn and had no assessments and nine participants had assessments completed outside of the two-week time window. Most of these were due to holidays as the assessments were scheduled in the spring and summer months.

Table 6-2: Monthly patterns for number of participants attending hospital-based assessments

Dates	Number of completed baseline assessments	Number of completed six-month assessments	Reasons why assessments were not completed within 2 week period	Number of 12 month assessments completed	Reasons why assessments were not completed within 2 week period
Feb 2013	4				
March 2013	7				
April 2013	5				
May 2013	7				
June 2013	6				
July 2013	1				
August 2013		3	moved house (n=1)		
September 2013		6	withdrew (n=1)		
October 2013		6			
November 2013		6			
December 2013		5			
January 2014		2			
February 2014		1	moved house (n=1)	3	
March 2014				3	
April 2014				5	withdrew (n=1) on holiday (n=1)
May 2014				3	
June 2014				8	on holiday (n=4)
July 2014				4	on holiday and illness (n=3)
August 2014				2	work/study commitments (n=1)

Tables 6-3 and 6-4 give details of participants' characteristics at the first baseline assessment. All participants were white, the majority (90%) being white British. The majority (90%) of participants were female and 87% reported 'rarely' or 'never' taking part in physical activity long enough to work up a sweat.

Table 6-3: Baseline characteristics of participants in pilot study recruited from the Dorset MS service 2013-14

	Immediate group (n=15)	Delayed group (n=15)	Total (n=30)
Gender n (%)			
Female	14 (93%)	13 (87%)	27 (90%)
Male	1 (7%)	2 (13%)	3 (10%)
Age (years)			
Mean (Standard deviation)	50.90 (8.08)	47.60 (9.26)	49.30 (8.70)
Range	37-63	33-65	33-65
Current marital status n (%)			
Married/cohabiting	11 (73%)	10 (67%)	21 (70%)
Living alone (single/widowed/divorced)	4 (27%)	4 (33%)	9 (30%)
Children living at home n (%)			
None	12 (86%)	10 (67%)	22 (73%)
One or two	2 (14%)	5 (33%)	7 (27%)
Highest level of qualification achieved n (%)			
No qualifications	2 (13%)	0 (0%)	2 (7%)
School qualifications	3 (20%)	6 (40%)	9 (30%)
University /professional qualifications	4 (27%)	5 (33%)	9 (30%)
Other qualifications (e.g. NVQ/BTEC)	6 (40%)	4 (27%)	10 (33%)
Employment status n (%)			
Full or part time paid employment	10 (67%)	9 (60%)	19 (63%)
Not in paid employment (e.g. retired)	5 (33%)	6 (40%)	11 (37%)
Prior to study previous experience of using home gaming system n (%)			
Not used	10 (67%)	8 (53%)	18 (60%)
Previous/occasional use	5 (33%)	7 (47%)	12 (40%)
Self-reported participation in regular activity long enough to work up a sweat n (%)			
Often	0 (0%)	1 (7%)	1 (3%)
Sometimes	3 (20%)	0 (0%)	3 (10%)
Never/rarely	12 (80%)	14 (93%)	26 (87%)

Table 6-4: Baseline characteristics of participants in pilot study recruited from the Dorset MS service 2013-14

	Immediate group (n=15)	Delayed group (n=15)	Total (n=30)
Self- reported type of MS			
Benign	0 (0%)	1 (7%)	1 (3%)
Relapsing-remitting	12 (80%)	9 (60%)	21 (70%)
Secondary progressive	3 (20%)	2 (13%)	5 (17%)
Primary progressive	0 (0%)	1 (7%)	1 (3%)
Participant stated “didn’t know”	0 (0%)	2 (13%)	2 (7%)
Years since MS diagnosis n (%)			
Less than one year	1 (7%)	2 (13%)	3 (10%)
1-5 years	7 (47%)	4 (27%)	11 (37%)
6-10 years	3 (20%)	4 (27%)	7 (23%)
11-15 years	2 (13%)	1 (7%)	3 (10%)
16 or more years	2 (13%)	4 (27%)	6 (20%)
Self-reported Adapted Patient Determined Disease Steps (Scores 2-6)			
Noticeable symptoms but mild (2)	3 (20%)	2 (13%)	5 (17%)
Limitations with ADL * (3)	0 (0%)	1 (7%)	1 (3%)
Walking affected, can walk 300-500 m (4)	5 (33%)	1 (3%)	7 (23%)
Can walk 100-200 m (often with a stick) (5)	6 (40%)	10 (67%)	16 (53%)
Requires a walking aid (6)	1 (7%)	0 (0%)	1 (3%)

*ADL Activities of Daily Living

6.2 Objective 2

The main focus of the study was to consider the feasibility and practicalities of completing these assessments and to present preliminary estimates of effect size to inform the selection of a primary outcome measure for a later trial. Effect sizes provide statistics regarding the size of an effect in order to inform the selection of outcomes (Table 6-15). Cohen quantified effect sizes as small ($d=0.2$), medium ($d=0.5$) and large ($d=0.8$) (Sullivan and Feinn 2012).

Since participants were allocated to the two groups using randomisation it is likely that any observed differences in means at baseline are due to chance. The graphs show the error bars (95% confidence intervals) for each estimate of mean. It is known that MS is a highly variable condition and Tables 6-4 and 6-5 illustrate that in this sample participants had range of MS type, years with MS and APDDS scores. This would indicate a wide range of symptoms in this sample and higher variability between people. The sample size is the main reason for the wide confidence intervals. Since the vertical scale for the graphs presented in this chapter do not start at zero the error bars seem wider than they otherwise might be.

6.2.1 Balance tests

The balance tests comprise the 7.5cm and 15cm step tests, static posturography and stance tests.

7.5cm and 15cm step tests

The results of the step tests are presented for both the 7.5 cm and 15 cm tests showing the number of steps combined for right and left leg as well as the individual leg. The test for stepping with the right leg is assessing standing balance on the left leg as well as the ability to move the right leg to clear the step (and vice versa for the test for stepping with the left leg). The number of steps completed is presented, the higher the number, the better the performance. The number of steps completed was similar for each leg in both groups for the 7.5 cm and 15 cm step test. There were missing data for the two participants who withdrew from the study but otherwise all the step tests were completed. (Figures 6-2 to 6-4 and Table 6-5).

Figure 6-2: 7.5 cm and 15 cm steps test - mean number of steps completed (95% Confidence Intervals (CIs)) with right and left leg combined scores

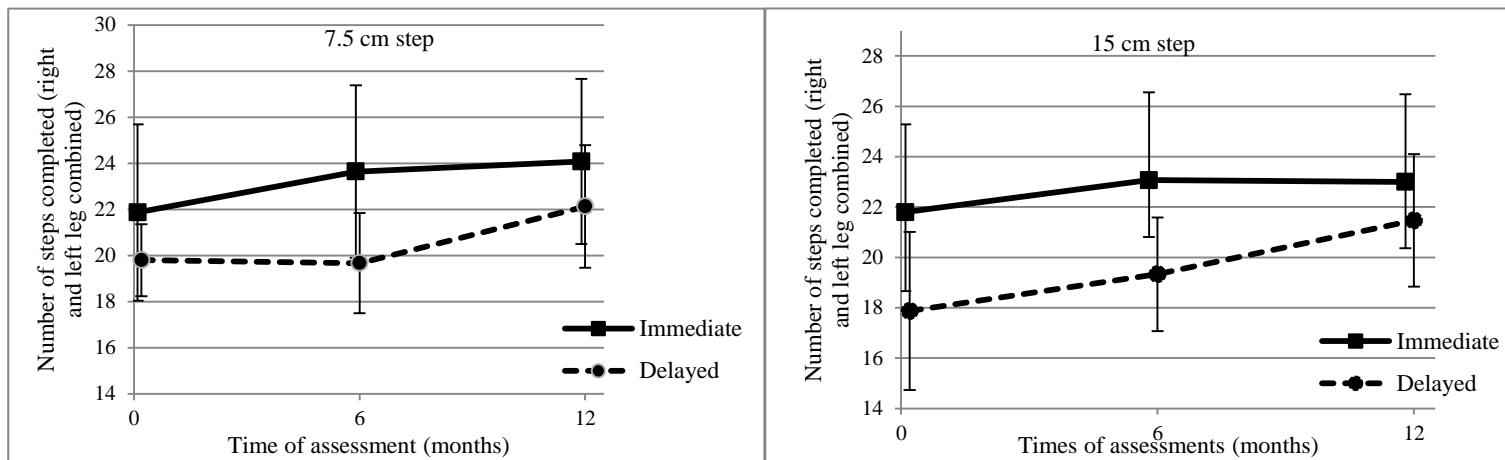
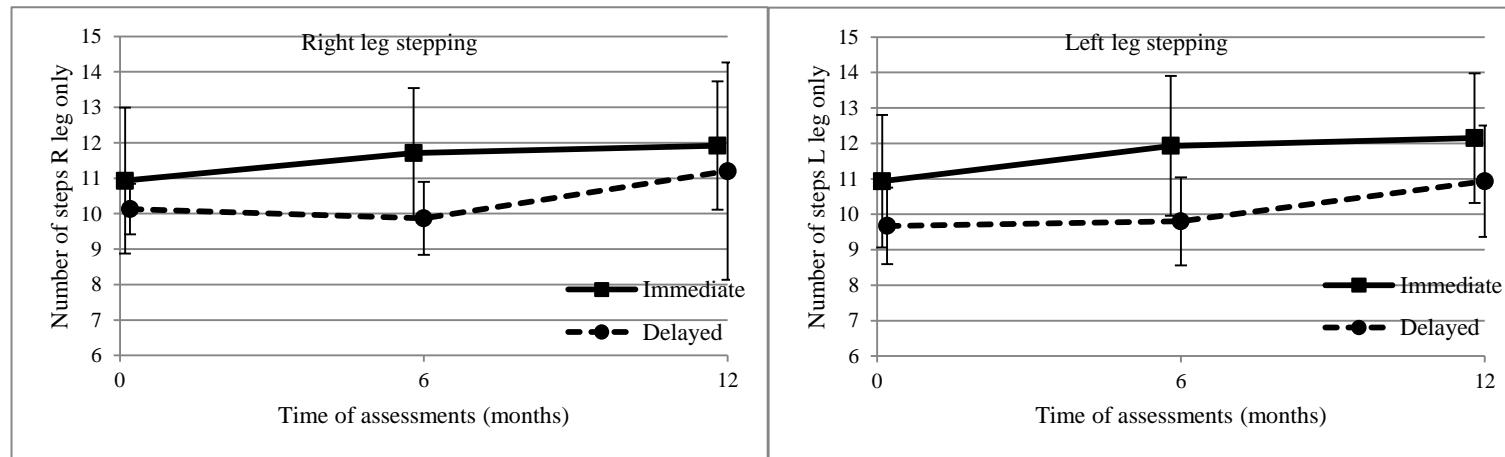
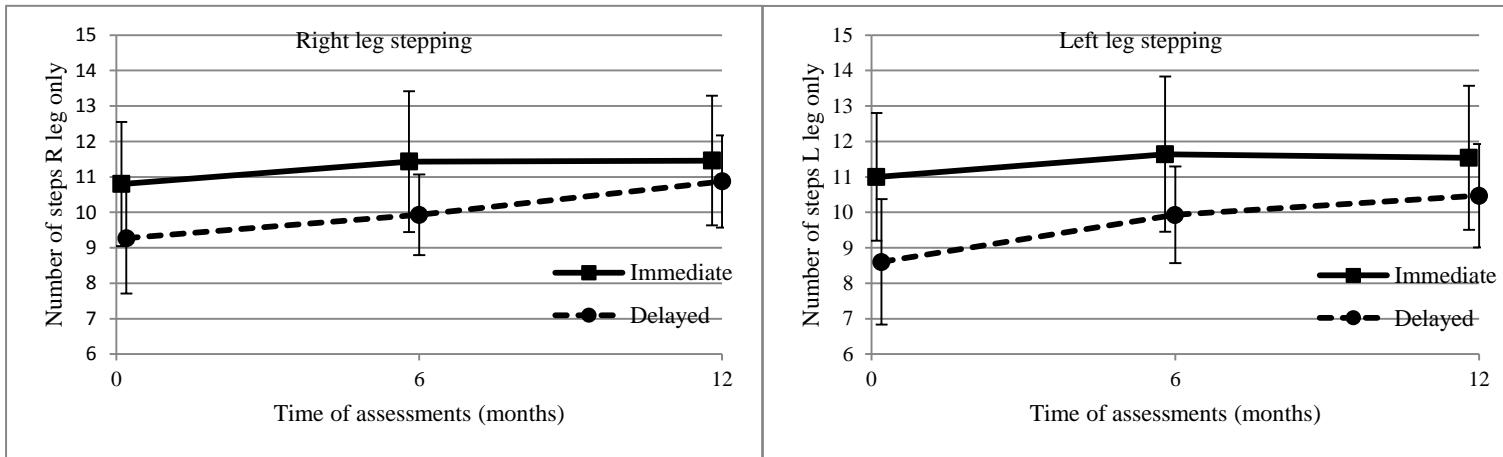


Figure 6-3: 7.5 cm step test mean number of steps completed (95% Confidence Interval)



Baseline assessment n=30, 6 month assessment n=29, 12 month assessment n=28

Figure 6-4: 15 cm step test - mean number of steps completed (95% Confidence Interval)



Baseline assessment n=30, 6 month assessment n=29, 12 month assessment n=28

Table 6-5: 7.5 cm and 15 cm step test means and standard deviations

	Baseline assessment n=30	6 month assessment n=29	12 month assessment n=28
7.5 cm step test combined score both legs			
Immediate group	21.87 (7.56)	23.64 (7.14)	24.08 (6.59)
Delayed group	19.80 (3.09)	19.67 (4.29)	22.13 (5.26)
7.5 cm step test right leg stepping			
Immediate group	10.93 (4.08)	11.71 (3.50)	11.92 (3.33)
Delayed group	10.13 (1.41)	9.87 (2.03)	11.20 (2.46)
7.5 cm step test left leg stepping			
Immediate group	10.93 (3.69)	11.93 (3.75)	12.15 (3.15)
Delayed group	9.67 (2.13)	9.80 (2.46)	10.93 (3.11)
15 cm step test combined score both legs			
Immediate group	21.80 (6.87)	23.07 (7.76)	23.00 (6.94)
Delayed group	17.87 (6.20)	19.33 (4.47)	21.47 (5.19)
15 cm step test right leg stepping			
Immediate group	10.80 (3.45)	11.43 (3.80)	11.46 (3.36)
Delayed group	9.27 (3.08)	9.93 (2.25)	10.87 (2.56)
15 cm step test left leg stepping			
Immediate group	11.00 (3.55)	11.64 (4.18)	11.54 (3.73)
Delayed group	8.60 (3.50)	9.93 (2.69)	10.47 (2.88)

Static posturography tests

The results for the five static posturography tests are presented in a series of line graphs (Figures 6-5 and 6-6) and summary table (Table 6-6) showing the different conditions of testing and presenting the mean and confidence intervals for both groups. The unit of measure shown on the graphs is a percentage of perfect stillness. The figure out of 100 as a percentage of the limits of sway (anterior-posterior movement) outside of which the participant would lose balance. So, if the participant stood perfectly still and did not sway at all, they would score 100% and if they lost balance would score 0%. The higher score therefore indicates the better performance. The order of the tests presented in Figures 6-5 and 6-6 mirror the order these tests were carried out namely, the easiest first (eyes open solid surface) and the hardest last (eyes closed unstable surface). There were missing data for two participants in the immediate group who discontinued the intervention.

Figure 6-5: Three conditions of testing on the solid surface - mean % of stillness and 95% Confidence interval

Baseline assessment n=30, 6 month assessment n=29, 12 month assessment n=28

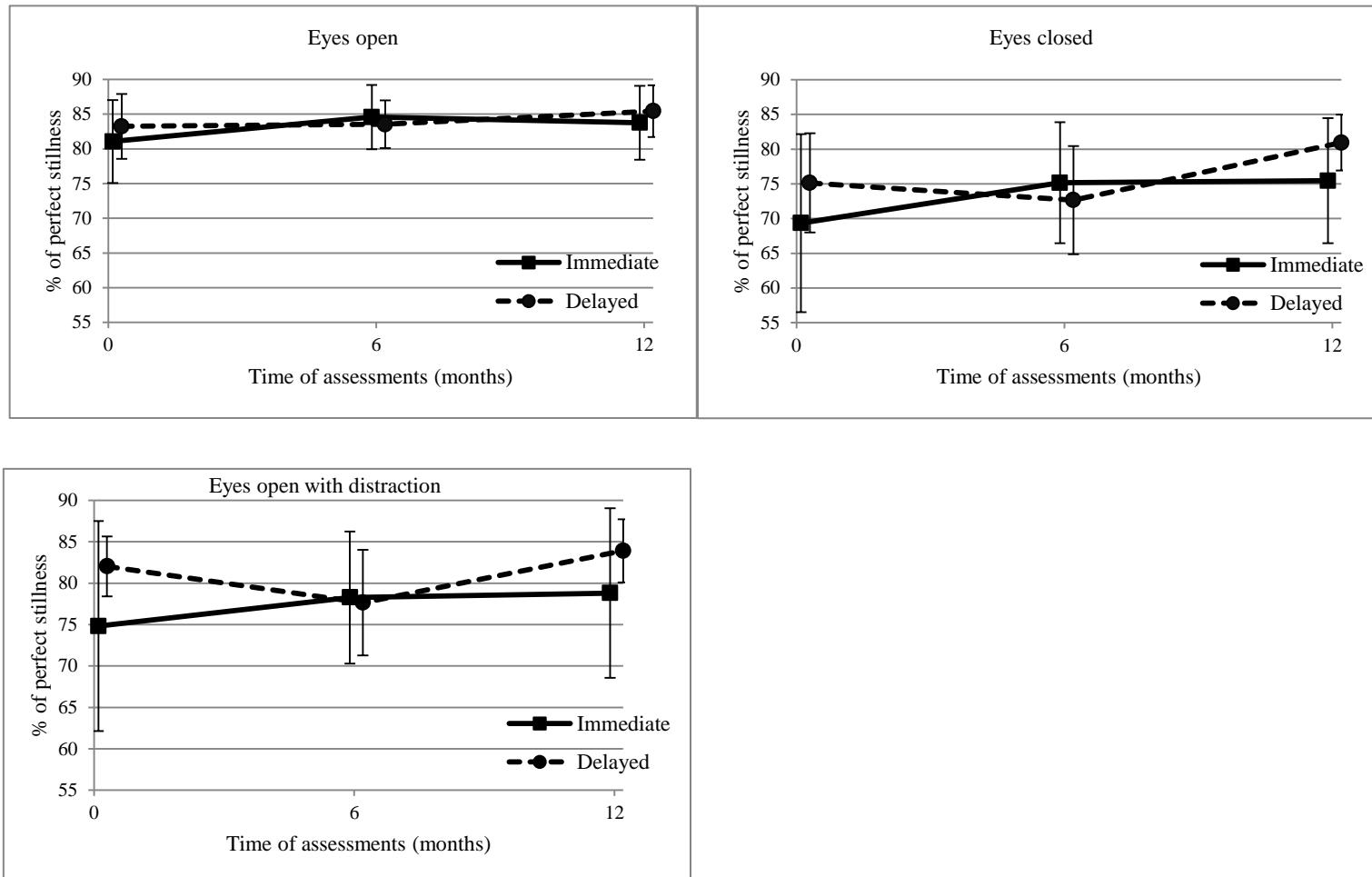


Figure 6-6: Two conditions of testing on the unstable surface - mean % of stillness and 95% Confidence interval

Baseline assessment n=30, 6 month assessment n=29, 12 month assessment n=28

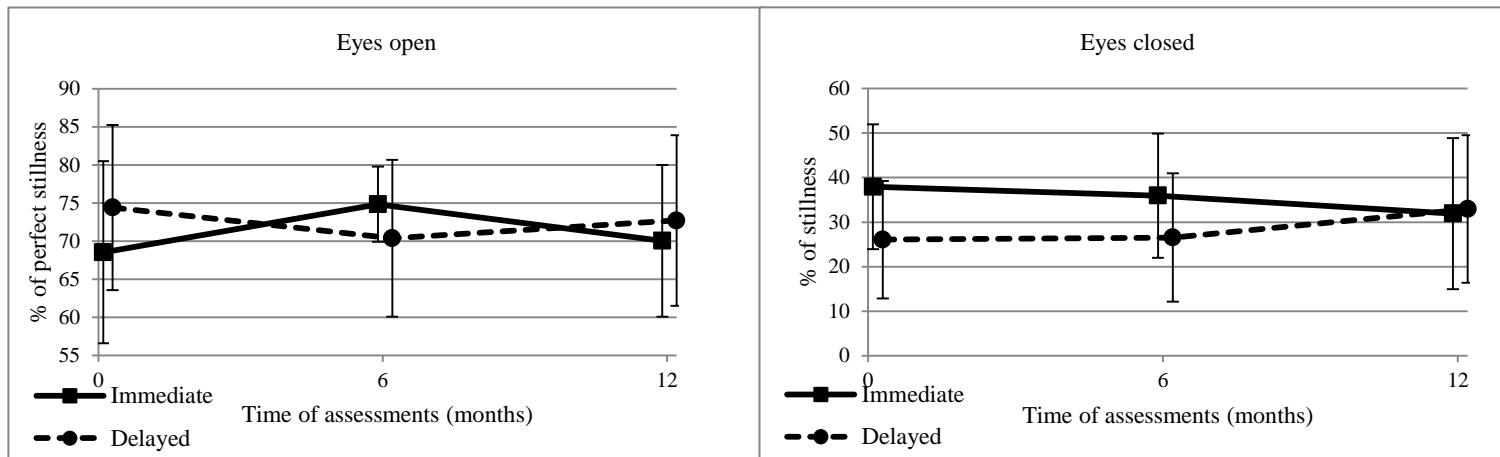


Table 6-6: Static posturography tests means and standard deviations

	Baseline assessment n=30	6 month assessment n=29	12 month assessment n=28
Solid surface: eyes open			
Immediate group	81.06 (11.40)	84.58 (8.82)	83.77 (9.79)
Delayed group	83.24 (9.45)	83.54 (6.79)	85.44 (7.36)
Solid surface: eyes closed			
Immediate group	69.34 (24.50)	75.16 (16.62)	75.44 (16.57)
Delayed group	75.14 (14.10)	72.65 (15.39)	80.94 (7.92)
Solid surface: eyes open with distraction			
Immediate group	74.82 (24.20)	78.27 (15.20)	78.80 (18.32)
Delayed group	82.03 (7.15)	77.65 (12.60)	83.91 (7.53)
Unstable surface: eyes open			
Immediate group	68.54 (22.80)	74.84 (9.41)	70.05 (18.32)
Delayed group	74.41 (21.43)	70.39 (20.33)	72.71 (22.09)
Unstable surface: eyes closed			
Immediate group	37.94 (26.72)	35.94 (25.60)	31.92 (31.17)
Delayed group	26.07 (26.04)	26.55 (28.42)	32.94 (31.62)

Stance tests

The results of the seven stance tests are shown in Table 6-7 which presents the percentages and number of participants able to complete the test for 60 seconds. Completion of the test means that the participant was able to hold the position without assistance for the 60 seconds. The test results for both legs for the stance and tandem tests are presented. In addition, if the test was not completed the number of participants who did not complete the test in each group is reported and the mean time achieved in each test. The reason for presenting the detail of these stance results in Table 6-7 is to illustrate the floor and ceiling effects of this test and to help identify the most relevant stance test in this sample as a means to refine the selection of outcome measures.

The feet together stance was the easiest test and one participant in each group was unable to complete this test (the time achieved for these two participants was almost the full 60 seconds). For all the other tests (apart from the stride standing left in front of right) the mean time (if participants were not able to complete the full 60 seconds) was less than 30 seconds.

The delayed group's performance on the feet together, stride standing, tandem-standing subsets of these stance tests improved from the first to the second assessment. As the sample size was small this may have been chance or could have

been due to a practice effect given that participants knew what to expect in the second assessment at 6 months. There are missing data for the two participants who withdrew from the study.

Figure 6-7 illustrates the percentage of participants who reached the respective sub-tests in the hierarchy of difficulty. Figure 6-8 illustrates the changes in the ability to complete the stance tests between baseline and six-months for the immediate group and between six-months and one year for the delayed group.

Figure 6-7: The percentage of people that reached sub-tests for stance tests in hierarchy of difficulty

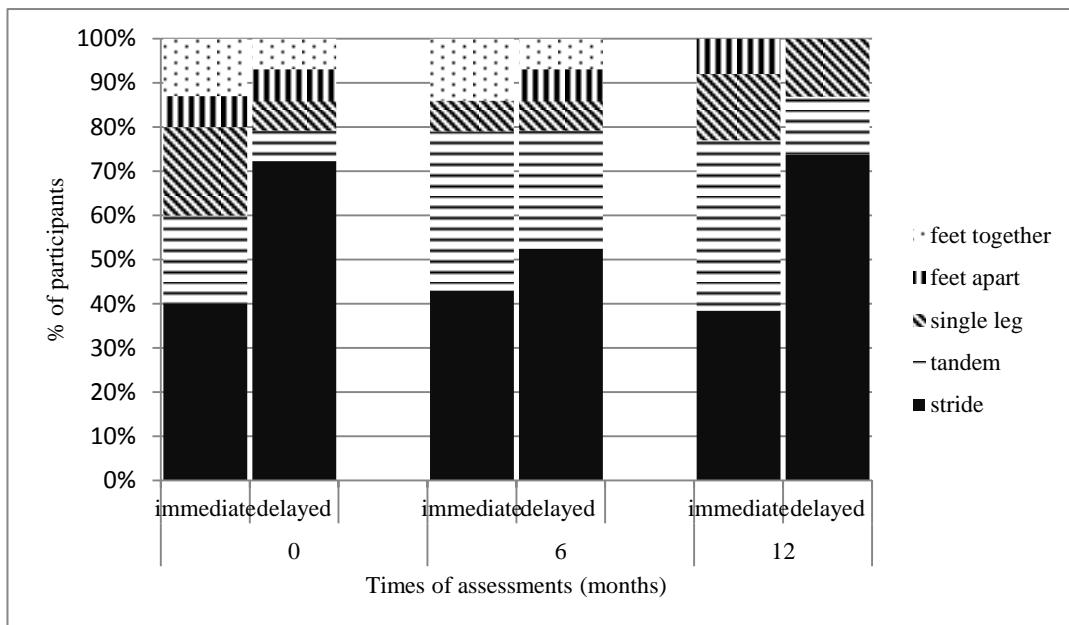


Figure 6-8: Changes in ability to complete stance tests following intervention (0-6 months)

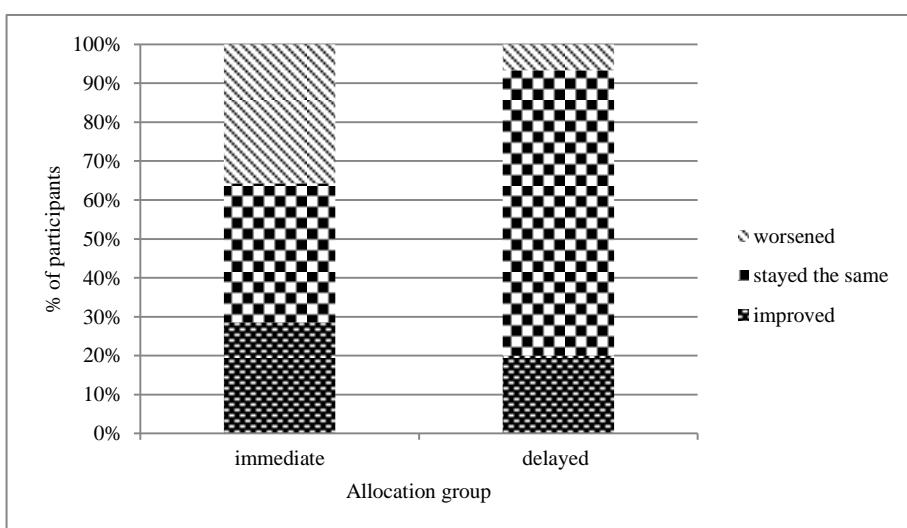


Table 6-7: Results of stance tests showing % for each test completed and mean times if tests were not completed

Test	Baseline assessment		6 month assessment		12 month assessment	
	Completed 60 seconds	Mean time if didn't complete 60 seconds	Completed 60 seconds	Mean time if didn't complete 60 seconds	Completed 60 seconds	Mean time if didn't complete 60 seconds
Feet together	14/15 (93%)	Immediate (n=1) 10.97	14/14 (100%)	Immediate (n=0)	13/13 (100%)	Immediate (n=0)
	14/15 (93%)	Delayed (n=1) 58.22	14/15 (93%)	Delayed (n=1) 44.80	14/15 (93%)	Delayed (n=1) 30.00
Stride standing – right foot in front of left foot	13/15 (87%)	Immediate (n=2) 16.39	13/14 (93%)	Immediate (n=1) 18.10	13/13 (100%)	Immediate (n=0)
	14/15 (93%)	Delayed (n=1) 26.00	13/15 (87%)	Delayed (n=2) 19.79	14/15 (93%)	Delayed (n=1) 15.00
Stride standing –left foot in front of right foot	12/15 (80%)	Immediate (n=3) 28.99	13/14 (93%)	Immediate (n=1) 13.84	13/13 (100%)	Immediate (n=0)
	13/15 (87%)	Delayed (n=2) 48.53	15/15 (100%)	Delayed (n=0)	14/15 (93%)	Delayed (n=1) 24.00
Tandem standing-right foot in front of left foot	6/15 (40%)	Immediate(n=9) 18.79	7/14 (50%)	Immediate (n=7) 14.18	8/13(62%)	Immediate (n=5) 7.21
	4/15 (27%)	Delayed (n=11) 23.11	6/15 (40%)	Delayed (n=9) 15.58	4/15(27%)	Delayed (n=11) 11.94
Tandem standing-left foot in front of right foot 16/30 (53%)	8/15 (53%)	Immediate (n=7) 9.26	8/14 (57%)	Immediate (n=6) 24.06	7/13 (54%)	Immediate (n=6) 14.01
	8/15 (53%)	Delayed (n=7) 9.93	7/15 (47%)	Delayed (n=8) 13.57	5/15 (33%)	Delayed (n=10) 8.02
Standing on right leg	3/15 (20%)	Immediate (n=12) 8.83	3/14 (21%)	Immediate (n=11) 17.45	4/13 (31%)	Immediate (n=9) 12.52
	3/15 (20%)	Delayed (n=12) 11.17	5/15 (33%)	Delayed (n=10) 13.58	3/15 (20%)	Delayed (n=12) 8.25
Standing on left leg	3/15 (20%)	Immediate (n=12) 13.58	3/14 (21%)	Immediate (n=11) 22.87	3/13 (20%)	Immediate (n=10) 16.55
	2/15 (13%)	Delayed (n=13) 16.32	2/15 (13%)	Delayed (n=13) 12.17	3/15 (20%)	Delayed (n=12) 14.42

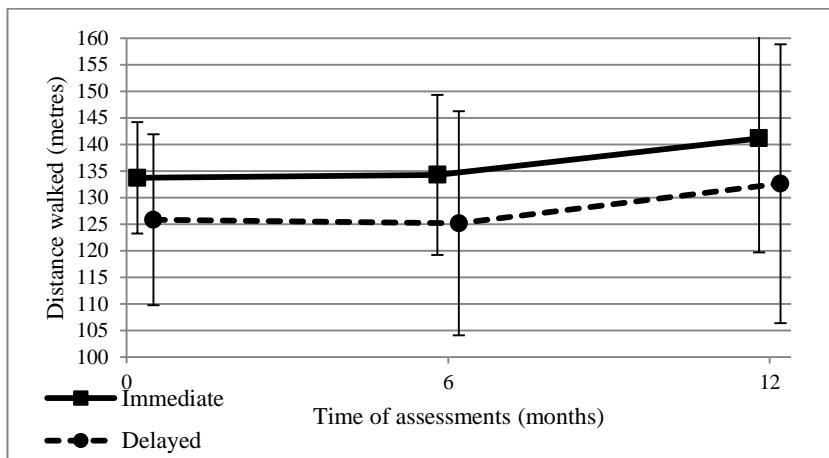
6.2.2 Gait tests

The three gait tests are the two-minute walk, iTUG and the gait cadence test. Due to concerns about participant burden, half the participants were randomly assigned to undertake the two minute walk test and half the gait cadence test. All participants completed the iTUG.

6.2.2.1 Two minute walk test

The distance walked in laps over 2 minutes is presented in metres, with higher scores indicating better performance. There are missing data for the two participants who withdrew from the study.

Figure 6-9: Distance (metres) walked in two minutes



Baseline assessment n=15, 6 month assessment n=14, 12 month assessment n=13

Table 6-8: Distance (metres) walked in two minutes

	Baseline assessment (0 months) Mean (SD) n=15	6 month assessment Mean (SD) n=14	12 month assessment Mean (SD) n=13
Two minute walk test			
Immediate group	133.73 (14.17)	134.29 (20.32)	141.15 (26.82)
Delayed group	125.82 (23.19)	125.18 (30.39)	132.63 (35.40)

6.2.2.2 Instrumented Timed up and go

At each assessment visit, the instrumented iTUG was completed twice and Figure 6-10 presents data for each test. A faster time represents a better performance. In both the immediate and delayed groups, participants performed better on the second test, which could be due to chance or the likely practice effects. There were technical problems with the equipment at one of the initial assessment visits and therefore there is one set of missing data at baseline for participant 04. Other missing data are due to two participants that withdrew from the study.

Table 6-9: **Instrumented timed up and go test (seconds).**

	Baseline assessment (0 months) Mean (SD) n=30	6 month assessment Mean (SD) n=29	12 month assessment Mean (SD) n=28
Timed up and go test			
Immediate group	10.72 (3.11)	10.19 (2.40)	10.17 (2.57)
Delayed group	11.06 (1.79)	11.59 (2.98)	11.05 (2.78)

Figure 6-10: Instrumented timed up and go; differences between first (baseline) and second tests (6 months)

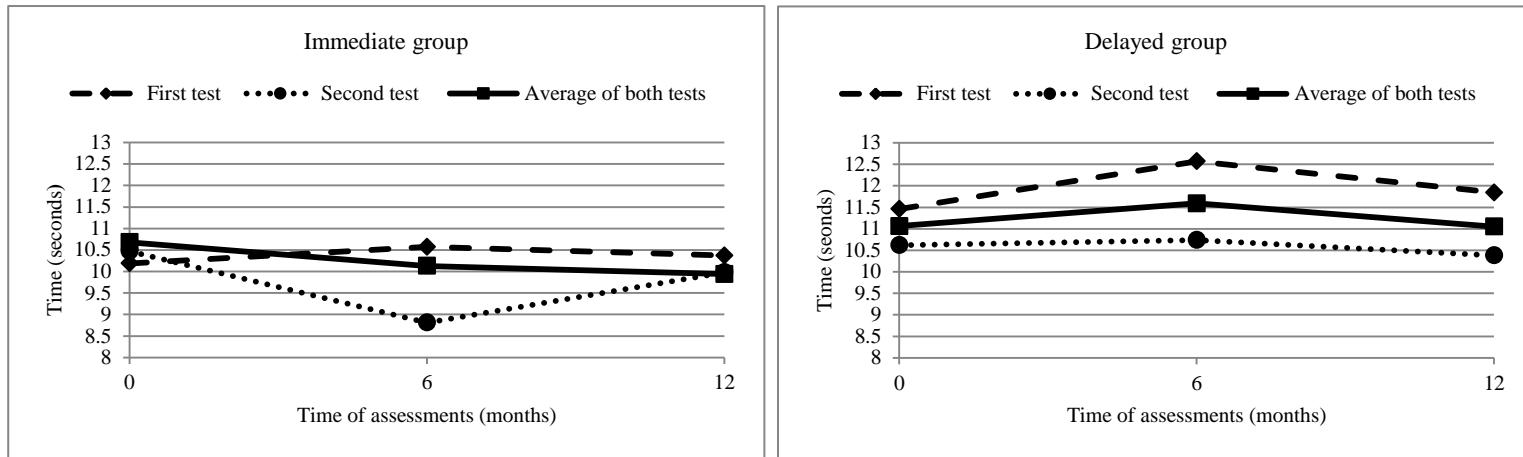
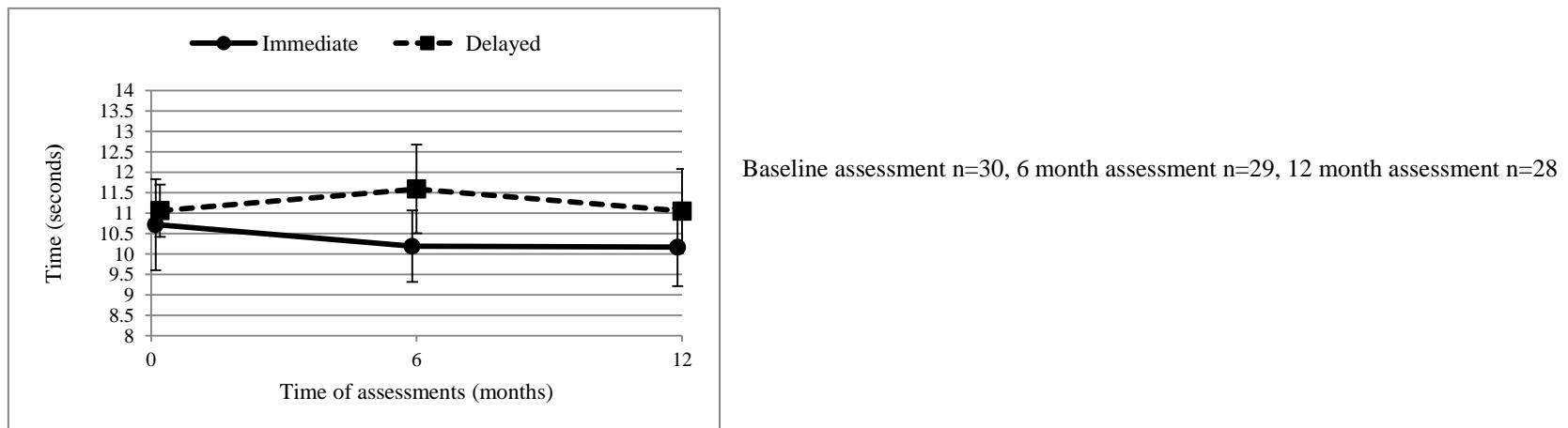


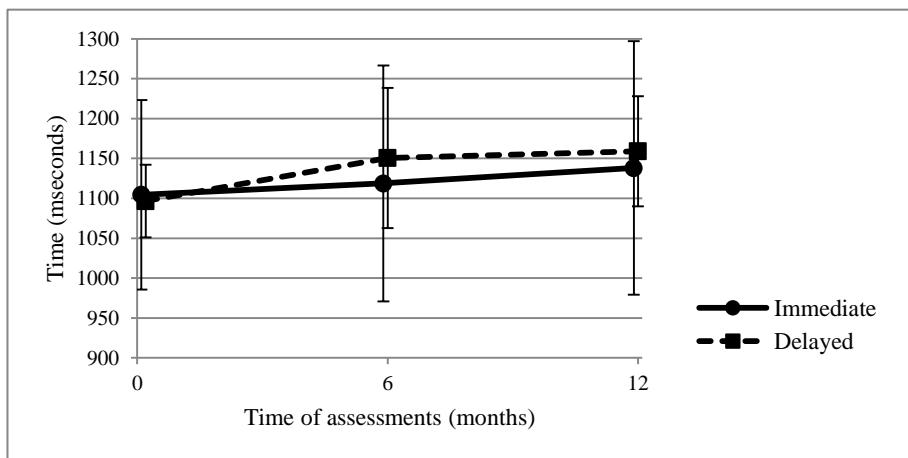
Figure 6-11: TUG mean time for first and second tests



6.2.2.3 Gait cadence test

These tests were performed on half the sample. The results in Figure 6-12 show walking speed outside of the laboratory setting for up to 256 steps.

Figure 6-12: Mean performance (mseconds) gait cadence test



Baseline assessment n=15, 6 month assessment n=14, 12 month assessment n=13

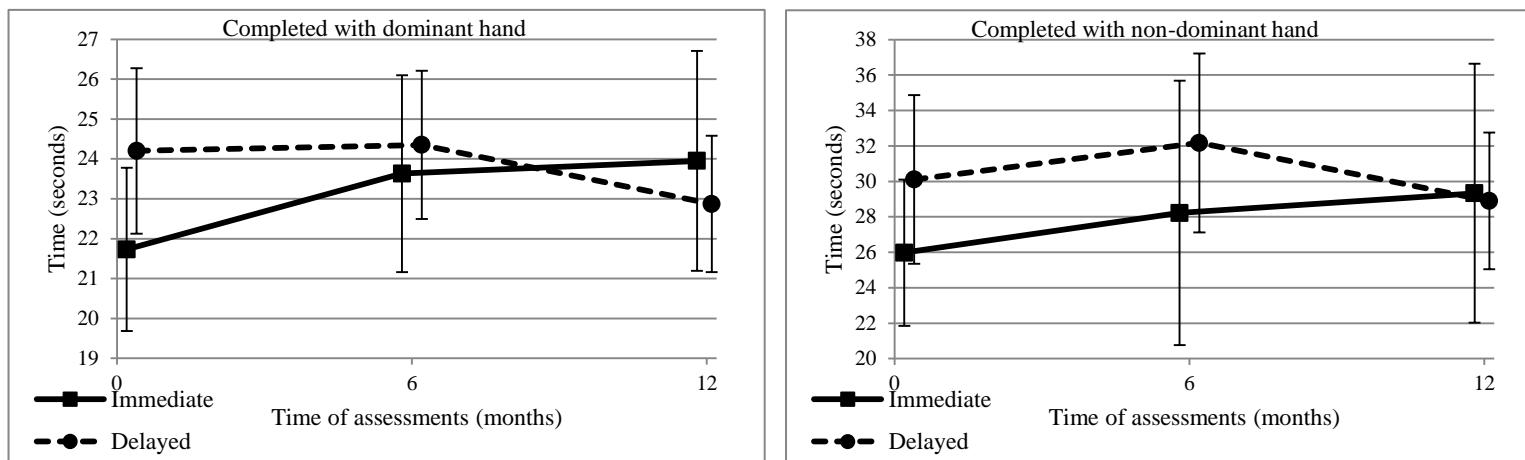
Table 6-10: Mean performance and SD (seconds) on the gait test

	Baseline assessment 0 months Mean (SD) n=15	6 month assessment Mean (SD) n=14	12 month assessment Mean (SD) n=13
Gait cadence test			
Immediate group	1108.43 (171.60)	1118.69 (199.65)	1138.02 (214.44)
Delayed group	1096.61 (61.61)	1150.64 (118.73)	1158.99 (92.93)

6.2.3 Dexterity test: Nine hole peg test

Descriptive statistics are reported for the NHPT in terms of the mean time to complete the test for dominant and non-dominant hands and the associated CI. A faster time indicates better performance (Figure 6-13 and Tables 6-11 to 6-14).

Figure 6-13: Mean performance (seconds) on the Nine Hole Peg Test



Baseline assessment n=30, 6 month assessment n=29, 12 month assessment n=28

Table 6-11: Mean (SD) performance (seconds) on the Nine Hole Peg Test

	Baseline assessment (0 months) Mean (SD) n=30	6 month assessment Mean (SD) n=29	12 month assessment Mean SD n=28
Dominant hand			
Immediate group	21.73 (4.04)	23.63 (4.71)	23.93 (5.07)
Delayed group	24.20 (4.10)	24.35 (3.67)	22.87 (3.48)
Non-dominant hand			
Immediate group	25.98 (8.15)	28.22 (14.23)	29.33 (13.43)
Delayed group	30.11 (9.40)	32.17 (9.78)	28.90 (7.63)
Participants that dropped one or more pegs			
Immediate group	10	2	6
Delayed group	10	9	9

The Nine Hole Peg Test is a measure of hand dexterity, co-ordination and grip strength. Therefore, as well as assessing the time to complete the assessment the number of pegs dropped during the assessment was recorded. Tables 6-12 to 6-14 present the results for the number of pegs dropped.

Table 6-12: Nine hole peg test: Pegs dropped with dominant and non-dominant hand

Number of pegs dropped	Completing nine hole peg test using dominant hand						Completing nine hole peg test using non-dominant hand					
	Number of participants at baseline assessment		Number of participants at 6 months assessment		Number of participants at 12 months assessment		Number of participants at baseline assessment		Number of participants at 6 month assessment		Number of participants at 12 month assessment	
	Immediate	Delayed	Immediate	Delayed	Immediate	Delayed	Immediate	Delayed	Immediate	Delayed	Immediate	Delayed
0	9	9	12	10	8	10	7	10	1	10	9	11
1	3	5	2	4	4	4	7	3	13	4	3	2
2	1	0	0	1	0	1	0	2	0	0	0	1
3 or more	2	1	0	0	1	0	1	0	0	1	1	1

Table 6-13: Nine hole peg test: Number of pegs dropped (combined scores)

Number of pegs dropped	Combined number of pegs dropped from tests with dominant and non-dominant hand					
	Number of participants at baseline assessment		Number of participants at 6 months assessment		Number of participants at 12 months assessment	
	Immediate	Delayed	Immediate	Delayed	Immediate	Delayed
0	5	5	12	6	7	7
1	5	5	1	6	3	5
2	2	3	1	1	1	1
3 or more	3	2	0	2	2	3

Table 6-14: Nine hole peg test: Change in number of pegs dropped

Combined number of pegs dropped (dominant and non-dominant hand)	Number of participants between baseline and 6 month assessments		Number of participants between 6 months and 12 month assessments	
	Immediate	Delayed	Immediate	Delayed
Fewer pegs dropped	7	7	1	5
No change in number of pegs dropped	7	3	6	6
More pegs dropped	0	3	6	4

6.2.4 Estimates of effect size

In order to meet the second objective for the study preliminary estimates of effect sizes were calculated. Standard effect sizes (Cohen's d) were calculated and the effect sizes and description for the size and direction of the effect for the outcome measures are reported in Table 6-15. The trends for the estimates of effect size were in the direction of benefit for all the outcome measures with the exception of the NHPT. The effect sizes in the direction of benefit were small with the exception of the step test and the iTUG.

Table 6-15: Standard effect size calculations (Cohen's *d*)

Outcome measure	Group	Time of assessments	Cohen's <i>d</i>
iTUG	Immediate *	Between baseline and 6 months	$d=-0.19$ (small effect size in the direction of benefit)
		Between baseline and one year **	$d=-0.19$ (small effect size in the direction of benefit)
	Delayed	Between baseline and 6 months	$d=0.22$ (small effect size not in the direction of benefit)
		Between 6 months and one year	$d=-0.19$ (small effect size in the direction of benefit)
Difference in changes scores	Immediate and delayed	Between baseline and 6 months	$d=-0.41$ (almost medium effect in the direction of benefit)
NHPT Dominant hand	Immediate	Between baseline and 6 months	$d=0.43$ (almost medium effect not in the direction of benefit)
		Between baseline and one year	$d=0.48$ (almost medium effect not in the direction of benefit)
	Delayed	Between baseline and 6 months	$d=0.04$ (small effect size not in the direction of benefit)
		Between 6 months and one year	$d=-0.41$ (almost medium effect in the direction of benefit)
Difference in changes scores	Immediate and delayed ***	Between baseline and 6 months	$d=0.39$ (small effect size not in the direction of benefit)
NHPT Non dominant hand	Immediate	Between baseline and 6 months	$d=0.19$ (small effect size not in the direction of benefit)
		Between baseline and one year	$d=0.30$ (small effect size not in the direction of benefit)
	Delayed	Between baseline and 6 months	$d=0.21$ (small effect size not in the direction of benefit)
		Between 6 months and one year	$d=-0.37$ (small effect size in the direction of benefit)
Difference in changes scores	Immediate and delayed	Between baseline and 6 months	$d=-0.02$ (small effect size in the direction of benefit)
7.5 cm step test both legs	Immediate	Between baseline and 6 months	$d=0.24$ (small effect size in the direction of benefit)
		Between baseline and one year	$d=0.31$ (small effect size in the direction of benefit)
	Delayed	Between baseline and 6 months	$d=-0.04$ (small effect size not in the direction of benefit)
		Between 6 months and one year	$d=0.51$ (medium effect size in the direction of benefit)
Difference in changes scores	Immediate and delayed	Between baseline and 6 months	$d=-0.28$ (small effect size in the direction of benefit)
15 cm step test both legs	Immediate	Between baseline and 6 months	$d=0.17$ (small effect size in the direction of benefit)
		Between baseline and one year	$d=0.17$ (small effect size not in the direction of benefit)
	Delayed	Between baseline and 6 months	$d=0.27$ (small effect size in the direction of benefit)
		Between 6 months and one year	$d=0.62$ (medium effect size in the direction of benefit)
Difference in changes scores	Immediate and delayed	Between baseline and 6 months	$d=-0.1$ (small effect size not in the direction of benefit)
In order to standardise the effect size calculations the following process was adhered to :* 6 months subtracted from baseline, **One year subtracted from 6 months, ***Immediate subtracted from delayed			

6.2.5 Activ PAL3™ data

For 14 (47%) participants, activPAL3™ data was collected for at least seven days at all the assessments (Table 6-16). ActivPAL3 data were missing for two participants at baseline either due to technical issues or user error with the set up. At the six-month assessment, one participant had withdrawn and was not assessed. There were missing data for two participants again either due to technical issues or user error with set up. At the 12-month assessment, three participants had missing data. Two had withdrawn from the study and the third was due to an error with the activPAL3™. Again, the reason for this error is unknown. At the 12-month assessment, two participants were reissued with a replacement activPAL3™ (due to either losing the initial activPAL3™ and ill health).

Table 6-16: Completeness of activPAL3™ data

Number of days with complete data	Baseline assessment	6 month assessment	One year assessment	At all assessments
7 days % (n)	60% (18)	80% (24)	77% (23)	73% (65)
6 days % (n)	33% (10)	13% (4)	13% (4)	20% (18)
5 days % (n)	0% (0)	3% (1)	0% (0)	1% (1)
No data % (n)	7% (2)	10% (1)	10% (3)	7% (6)
Total % (n)	100% (30)	100% (30)	100% (30)	100% (90)
Participants with 7 days' data at all three assessments				47% (14)

6.2.6 Patterns of play and adherence

The play logs indicated that participants tended to exercise mostly alone in the morning and afternoon (Table 6-17). The most commonly used activities/games were the balance exercises, yoga and the aerobics in the Wii Fit Plus™ (Table 6-18). Not enough time, feeling too tired or feeling unwell were the most frequent reasons documented in the play log for not exercising (Table 6-19).

Table 6-17: Patterns of use data from the play logs

	During first 6 months of using Wii™			6-12 months of using Wii™
	Participants in the immediate group	Participants in the delayed group	All participants	Immediate group only
Total number of days in study	100% (1962)	100% (2379)	100% (4341)	100% (2566)
Number of days used % of total days	31% (618)	28% (656)	29% (1274)	19%(490)
Min number of 10 min sessions per day	1	1	1	
Max number of 10 min sessions per day	6	9	9	
Mean number of sessions /day when used	1.29 (0.63)	1.50 (1.15)	1.41 (0.95)	
When used *				
Morning	39 % (223)	44% (270)	42% (493)	
Afternoon	41% (231)	38% (228)	39% (459)	
Evening	23% (133)	22% (132)	23% (265)	
How used				
Alone	81% (435)	90% (534)	86% (969)	
With others	18% (94)	9% (52)	13% (146)	
Alone and with others	1% (8)	1% (7)	1% (15)	

Footnote:*participants used on multiple occasions in the day and therefore the % add to more than 100

Table 6-18: Wii™ games recorded as used in play logs in 6 months

	Immediate % (n) sessions	Delayed % (n) sessions	All participants % (n) sessions
Games /activities More than one answer possible.			
Tennis	7% (40)	6% (40)	6% (80)
Bowling	11% (66)	4% (27)	7% (93)
Baseball	1% (5)	3% (22)	2% (27)
Golf	2% (13)	3% (19)	3% (32)
Boxing	1% (9)	4% (27)	3% (36)
Swordplay	3% (18)	17% (108)	10% (126)
Wakeboarding	2% (12)	4% (28)	3% (40)
Frisbee	1% (5)	11% (71)	6% (76)
Archery	4% (27)	6% (38)	5% (65)
Basketball	1% (6)	10% (62)	5% (68)
Table Tennis	5% (29)	14% (88)	9% (117)
Golf Sports Resort™	1% (6)	3% (17)	2% (23)
Bowling Sports Resort™	3% (20)	14% (93)	9% (113)
Powercruising	0% (1)	3% (21)	2% (22)
Canoe	3% (16)	10% (63)	6% (79)
Cycling	5% (28)	7% (43)	6% (71)
Airsports	0% (1)	3% (17)	1% (18)
Wii Fit Plus™			
Body/Balance Test	28% (170)	27% (179)	28% (349)
Yoga	37% (225)	19% (123)	28% (348)
Strength	5% (28)	15% (99)	10% (127)
Aerobics	33% (202)	56% (362)	45% (564)
Balance	48% (288)	64% (419)	56% (707)
Training Plus	-	42% (272)	22% (272)
Other	24% (147)	22% (142)	23% (289)
No. days no answer	13	5	18

Table 6-19: Barriers (% n) recorded in play log for 6 months of intervention (more than one answer possible for any day)

	Immediate group	Delayed group	Combined group
Not Scheduled	20% (188)	28% (360)	24% (548)
Forgot	2% (19)	2% (27)	2% (46)
MS Relapse	3% (28)	1% (7)	2% (35)
Unwell	13% (124)	14% (175)	13% (299)
No Time	25% (239)	28% (355)	27% (594)
Too Tired	19% (183)	14% (181)	16% (364)
Others Using	0% (4)	3% (33)	2% (37)
Other	33% (311)	17% (215)	23% (526)
No. of Days with an Answer	952	1289	2241

6.3 Part 2: Qualitative findings (Objectives 3 and 4)

This part of the chapter presents the findings of the qualitative part of the mixed methods study and relates to study objectives three and four. Participant feedback regarding Mii-vitaliSe and the ways that participants engaged with the multiple interacting components of the intervention are key aspects of the process evaluation (Moore et al. 2015). The qualitative findings presented are based on the data from 25 face-to-face semi-structured interviews (refer to Section 5-8). Thirteen interviews were undertaken at six months and 12 at one year. One participant was unable to participate due to having moved away from the area. The mean interview duration was 38.71 minutes with a range of 19-61 minutes. The semi-structured interviews aimed to explore participants' views of taking part in the pilot study and the Mii-vitaliSe intervention and gain feedback from the physiotherapists about their experiences of delivering Mii-vitaliSe.

6.4 Objective 3

A purposive sample was recruited for interview selecting participants from the sample in the pilot study. Table 6-20 provides details for the characteristics of the sample. Data were analysed using Framework Analysis encompassing the five stages as presented in Section 5.8.1. The initial stage of framework analysis is familiarisation. Figure 6-14 shows how the codes fit together within the initial themes for a section of the data during the process of familiarisation. Subsequent stages of the framework analysis involved linking codes together to identify themes and sub-themes which are illustrated in Figures 6-14 and 6-15. The findings are presented by describing the themes generated by the data and sub-themes within each theme and providing illustrative quotations.

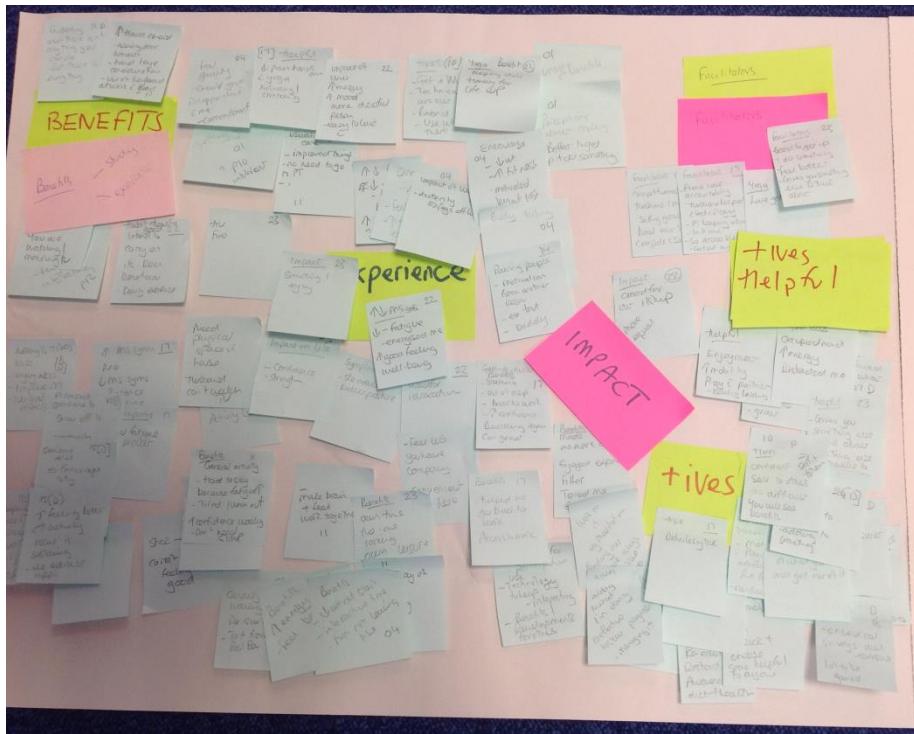
Table 6-20: Baseline characteristics of participants in interviews

	Interviews at six months	Interviews at twelve months	Interviews at both six and twelve months
Number of participants (n)	13	12	5
Allocation group (n)			
Immediate	7	6	3
Delayed	6	6	2
Gender n (%)			
Female	11 (85%)	10 (83%)	4 (80%)
Male	2 (15%)	2 (17%)	1 (20%)
Age (years)			
Mean (Standard deviation)	49.38 (9.22)	49.75 (10.15)	50.40 (10.46)
Range	36-63	33-65	36-65
Current marital status n (%)			
Married/cohabiting	10 (77%)	10 (83%)	4 (80%)
Living alone (single/widowed/divorced)	3 (23%)	2 (17%)	1 (20%)
Children living at home n (%)			
None	10 (77%)	10 (83%)	5 (100%)
One or two	3 (23%)	2 (17%)	0 (0%)
Paid employment status n (%)			
Full or part-time paid employment	6 (46%)	6 (50%)	2 (40%)
Not in paid employment (e.g. retired)	3 (54%)	6 (50%)	3 (60%)
Self-reported type of MS			
Not known	0 (0%)	1 (8%)	0 (0%)
Benign	0 (0%)	1 (8%)	0 (0%)
Relapsing remitting	10 (77%)	9 (76%)	4 (80%)
Primary progressive	1 (8%)	0 (0%)	0 (0%)
Secondary progressive	2 (15%)	1 (8%)	1 (20%)
Years since MS diagnosis n (%)			
Less than one year	2(15%)	2 (17%)	1(20%)
1-5 years	4 (31%)	5 (42%)	3 (60%)
6-10 years	3 (23%)	2 (17%)	0 (0%)
11-15 years	1 (8%)	1 (8%)	0 (0%)
More than 16 years	3 (23%)	2 (17%)	1 (20%)
Prior to study previous experience of using home gaming system n (%)			
Not used	9 (70%)	6 (50%)	4 (80 %)
Previous/occasional use	4 (30%)	6 (50%)	1 (20 %)

Figure 6-14: Framework analysis on data to identify themes



Figure 6-15: Framework analysis on section of data to identifying sub-themes



6.4.1 Participants' views about taking part in the pilot study

One of the study aims was to assess the feasibility of conducting a full scale trial. The interview questions were designed to reflect this aim and therefore the themes presented closely relate to the interview guide (Table 6-21).

Table 6-21: Themes and sub themes for participants' views on taking part in the pilot study

Theme	Sub-themes
Acceptability of study processes (includes:-recruitment, screening, risk assessment)	Confidence Uncertainty
Acceptability of data collection processes (includes : -hospital-based assessments, self-reported questionnaires, wearing the activPAL3™)	Commitment and interest Challenges Factors to consider in a future trial
Acceptability of trial design (includes randomisation, control group)	Disappointment and frustration Benefits

6.4.1.1 Theme 1-Acceptability of study processes

This theme highlights participants' perceptions of the acceptability of the study processes which include the recruitment and screening processes. Two sub-themes illustrate the confidence described by participants and some of the perceived uncertainties.

Confidence

There seemed to be a sense of confidence that participants described in the study team and with the research processes. Despite being a little apprehensive at the beginning participants were pleased to get involved and generally positive about taking part. In the semi-structured interviews, participants also described the factors that motivated them to participate in the study. These included a sense of wanting to help people with MS, a commitment to the Dorset MS service and an interest in the technical aspects of the study.

"No I think um when (states Consultant's name) put it forward to me because it came from him I knew that it would have been looked into properly and I had

confidence in him and everybody that I've met whilst doing the study have explained everything well to me so I think it's been worthwhile taking part."

(12-month interview, immediate group)

The process of completing the risk assessment with supervision at home also offered participants confidence, particularly if they were not familiar with the Wii™ or if they had concerns about their balance, using the technology or the space at home. Some participants had specific concerns and perceptions about 'risky' movements. For example, about stepping onto the balance board while looking at the screen and therefore not thinking about their feet. Another concern was about stepping sideways on and off the board as is required for some games. Those participants who had concerns were pleased to go through the risk assessment with supervision and felt the assessment alleviated the concerns they had. One person was concerned that they might 'fail' the home risk assessment, as they were worried about their environment.

"I suppose my only concern was that you were going to say the roof was too low or something so I was pleased to get through it but in terms of actually doing it, it wasn't a difficult task or anything complicated or confusing."

(6-month interview, delayed group)

Uncertainty

Participants described a sense of uncertainty in relation to some of the screening questions. Some participants described difficulty with completing the APDDS questionnaire as they found categorising their mobility difficult because it varied from day to day. They also explained that with the APDDS questionnaire, some of the categories seemed to overlap and therefore it was confusing to select one category when completing this questionnaire.

"About how you categorise perhaps your mobility, it just seemed a little bit, not confusing but seemed to overlap and I think I struggled possibly both times really to understand how to categorise myself as somebody that obviously isn't really badly affected mobility wise but that does use a stick and perhaps is still learning about what their abilities are."

(6-month interview, delayed group)

6.4.1.2 Theme 2-Acceptability of data collection processes

The semi-structured interview guide included several questions regarding the data collection processes and the second theme concerns the acceptability of these. Questions about the relevance and ease of completion of the hospital-based assessments and questionnaires were included, as well as questions relating to wearing the activPAL3™. These findings will be presented in three sections relating to the sub-themes.

Commitment and interest

Participants described a sense of commitment to and interest in the study. Referring to the hospital based assessments they enjoyed seeing improvements and being measured and pushed themselves to improve and perform well in the tests. The hospital-based assessments were perceived as fun, enjoyable and easy to complete. Regarding the timing of appointments, participants who were working appreciated the flexibility offered, however they often needed to take a half-day's annual leave to attend appointments.

There was feedback that the assessments were perceived as relevant as they measured important physical domains such as balance and walking. An example of a relevant assessment was the test with eyes closed with the distraction test (during the static posturography tests) as these activities required cognition (as did some activities in the intervention). Participants reflected that they were measuring things not usually measured, but also there was a link with the assessments conducted by the physiotherapists as part of routine care.

Participants described how they were committed to the process for completing the questionnaires. The process was described as straightforward and not onerous. The content of the questionnaires was described as relevant, not too intrusive and easy to follow. Participants described the ways they had completed the questionnaires. For example, many completed them in small sections over two or three days or in several short periods of time.

Participants explained that completing the questionnaires offered useful insights into what they can and cannot do which enhanced their awareness of their MS and impairments. The mood-related questionnaires were considered to be thorough and very relevant as it was perceived that exercise does impact positively on mood.

"I can remember thinking when I first did the mood-related questionnaire over a year ago now, but I can remember thinking then that it was kind of thorough and the best type of that questionnaire that I'd done to assess mood with MS, which is obviously something that's quite commonly assessed but I remember thinking it was good and so that presumably means that it all seemed very relevant to me. It didn't take too long and the exercise did impact positively on my mood so I think that was, that was and my feeling about my own abilities physically with the MS so all that seemed very relevant."

(12-month interview, delayed group)

There was feedback about how the variability of MS affected the way the questionnaires were completed and how this sometimes posed challenges. Some participants described how their answers varied depending on a variety of factors (such as physical feelings, mood and the effect the hot weather can have on MS symptoms). With this variability, they were concerned about their own consistency for filling out the questionnaires.

"Because I don't know if I was putting myself too high or underplaying it and therefore whatever results you get may not be exactly what you were expecting. I suppose from my perspective whether it would have been easier to have that discussion with you to say this is how I am generally, how do you think that fits I, perhaps that would give you the option to say, yeah sure what we're looking for or not."

(6-month interview, delayed group)

Participants described a sense of accountability to the research team. This referred to the commitment to completing the daily play logs or calendars. This raises an interesting issue about the dual role of the play logs as part of the intervention for self-monitoring (and an important part of facilitating participants to continue with the intervention) as well as a measure of adherence as a research outcome.

Challenges

Participants described the challenges encountered when completing the assessments and questionnaires and explained how they had overcome them. Referring to the hospital-based assessments some described the first one as hard, the second better (participants

described feeling less tired) and the third a lot easier as they knew what to expect. The challenges were perceived as positive with some participants reporting that they had performed better than they had expected. Participants referred to challenges inherent in specific tests. For example, a participant noted that by the end of the two-minute walk test their weaker leg was dragging; something that was not noted in the measurements but that is a relevant outcome to participants.

Some of the challenges of the assessments related to fatigue and drained feelings that participants described experiencing following the hospital assessment appointment. These challenges led to feelings of anxiety which were also related to the uncertainty of not knowing what to expect at the first assessment visit to the hospital. They explained that this anxiety seemed to stem from their desire to achieve good scores in the assessment and the frustration experienced if they were unable to do so because they were not in good form on the day of the assessments. They explained that these anxieties were easily dispelled once they knew what to expect.

The test that many participants found challenging was the standing on one leg balance assessment (one subtest of the hierarchical stance tests). Here is an example of how a participant described this subtest:

"It shocked me the other day that I couldn't stand on one leg at all for more than about three seconds."

(6-month interview, delayed group)

Participants also described anxiety about being unable to pick up pegs in the NHPT due to poor hand sensation and difficulty with the arithmetic task in the distraction condition of the static posturography test.

"I can remember the embarrassment of not being able to count back, that was awful. I was stood I think on the wobble board or I was stood, I had to count back in three or something and made an absolute pigs' ear of that I thought for goodness sake! That was embarrassing but no the assessments were fine and obviously at those times it shows exactly how limited you are particularly those

horrible pegs in that dish ‘cos they’re so slimy, well not slimy but you’ve got no sense of touch in your fingers it’s a pain.”

(12-month interview, delayed group)

Participants with cognitive and memory problems explained that they needed to be reminded to complete the questionnaires and those with visual problems appreciated the large font. Some participants remarked that completing the questionnaires brought their MS to the fore and others said they found it best not to reflect too deeply over each question.

Some participants described feeling anxious about the possibility of losing the activPAL3™ device as they perceived it to be costly to replace. One participant, who had lost and subsequently found the device, continued to feel anxious that it might fall off again and may get lost. There was feedback from some participants that the PAL Stickies™ did not work well and that the medical tape was more effective. This was individual and depended on type of clothes and skin. The PAL Stickies™ caused minor skin irritation in one participant.

Factors to consider in a future trial

Participants had ideas for a future trial. There was a suggestion that other relevant assessments could include rhythm, speed and strength-related tests; one participant noted that their rhythm had improved since starting the intervention. Participants described that they expected to feel tired and wiped out the evening after the assessments and feel physically and mentally tired the following day. It was suggested that participants should be advised to plan not to do too much before and following the assessments in order to manage this fatigue.

Referring to the potential of the activPAL3™ to fall off there was a suggestion that wearing it on the ankle may be more secure. This, however, would not work and therefore the reason for wearing the device on the thigh may need to be made clearer in a future trial. There was feedback about the instructions and materials provided for applying the activPAL3™. There was a suggestion to refer to the ‘Pad of Jelly’ in the instructions in order to clarify what the PAL Stickies™ are. If the activPAL3™ tended to fall off while undressing or did not adhere well because of leg hair people used the medical tape in addition to the PAL Stickies™. There was a recommendation to include

information or a warning about this in the instructions and guidance for when wearing different types of clothing (for when wearing shorts or skirts).

Two participants said that they purchased extra tape (masking tape or sellotape) which they carried with them in case the activPAL3™ fell off. This suggests the need to supply more medical tape for applying the activPAL3™.

“And this was most unfortunate because I was in the shopping centre and so then I sort of rushed in, I was sort of holding it there cos I’d pulled it completely off and went to get some masking tape. Anyway so what I would say is carry some masking tape round or sellotape or something just in case.

(6-month interview, immediate group)

6.4.1.3 Theme 3-Acceptability of trial design

Participants were asked for their views concerning the study design and randomisation to an immediate or delayed group. This theme explains their perceptions of the study design within two sub-themes.

Disappointment and frustration

Some participants randomised to the delayed group described feelings of disappointment when they found out they would have to wait for six months to start the intervention. This initial disappointment related to an excitement and readiness for starting to exercise. Linked to this disappointment was also a feeling of frustration for some participants in that they were keen to do something that could be potentially beneficial for their mobility and MS in general. For one participant, there was a perception that getting started earlier might have prevented a relapse:

“The other side as well is that because I have this question mark under the relapse, certainly an increase in the symptoms, that prompted me to seek the physio. The question mark is would it have helped me to have the.... Be in the first group. Obviously that’s out of your control, that’s just the nature of it but I suppose it was just frustration, like damn I’ve got to wait 6 months I was really interested and just wanted to get on with it really.”

(6-month interview, delayed group)

Despite the disappointment randomisation was perceived as being an integral part of being involved in a research study. Once the initial sense of disappointment was over, six months went by quickly and participants explained that they tended not to think about it.

For three participants, being allocated to the delayed group fitted in well with work and personal commitments which they saw as a benefit. Another participant described that they preferred being delayed for six months as it meant they would start the intervention during the winter, which was seen as preferable. For these participants there was sense of relief.

Participants were asked about the acceptability of a trial design incorporating a one-year delay. Overall, it was felt that this was a long time to wait and that an individual's MS and other circumstances may have changed in this time frame. There were concerns that a longer delay might affect recruitment rates and outcomes of the study as people would find other ways to exercise. There would need to be a careful explanation for a year's delay so that participants fully understood the rationale. This quotation illustrates how waiting longer for an intervention may affect an individual's motivation to participate:-

"I just wonder whether it needs to be clearer as to exactly what you plan to achieve with that, that delay just in case there is somebody that perhaps ... what's the point, are we going to do this and then I'm not going to know anything about it for 12 months, my life might have changed so much that I can't participate in that time frame."

(6-month interview, immediate group)

Benefits

Participants were asked about the acceptability of a care-as-usual control group design for a future trial. On the whole, participants said that they would be willing to be involved in such a study given the benefit of additional monitoring and contact with healthcare professionals. There was an altruistic view that by being involved in a study there would be benefits to others in the future, even though the immediate benefit to them may be minimal. Having a care-as-usual group was compared to being involved in a drug trial and perceived as part of the process of taking part in research and a chance that you have to decide whether to take. On the whole, there was a sense of being

pleased to be invited to be involved in a study with the possibility of receiving the Wii™ intervention and an acceptance of taking the chance.

6.4.2 Participant feedback about receiving Mii-vitaliSe

This section presents participant feedback regarding how Mii-vitaliSe was delivered explaining the perceived challenges and offering suggestions for future tailoring. The themes (Table 6-22) refer to participants' experiences of the various components of Mii-vitaliSe and the ways that the intervention affected levels of physical activity.

Table 6-22: Themes and subthemes for participant feedback about receiving Mii-vitaliSe

Themes	Sub-themes
Delivery of Mii-vitaliSe (refers to the equipment, the resource pack, the orientation sessions and physiotherapist support)	Participant engagement Overcoming barriers and challenges Physiotherapist support Adaptations
Factors that contributed to increased physical activity	Convenience and fun Motivators Facilitators and benefits

6.4.2.1 Theme 1-Delivery of Mii-vitaliSe

The four sub-themes illustrate how people used the various components of Mii-vitaliSe, the strategies and adaptations made. In the interviews participants referred to the components of the intervention described in Tables 5-1 and 5-2.

Participant engagement

Generally, the equipment was described as user-friendly and in the majority of interviews no problems were reported by participants. Having equipment available to charge the batteries and getting into a routine of keeping the Wii™ remote handsets fully charged made it easier for participants to use the Wii™ regularly. There was a perception that the balance board was good for balance. Participants described that regular use of and practice with the balance board improved their technique.

Conversely, if participants did not use it regularly they tended to experience more difficulty stepping on and off the board and placing their feet on the board.

“I notice now that if I don’t play for a couple of weeks I have trouble, much more trouble balancing and staying on yeh, but that’s just more reason for me to play more often. It’s more likely that I would step off the board where as if I’m playing regularly that’s not an issue.”

(12-month interview, delayed group)

With reference to the Wii™ remote practising moving the cursor around and pressing the A and B buttons was perceived to be a way of helping with hand coordination. One participant described how she had made some notes (about how to use the Wii™ remote) as a prompt, she described this as her own ‘idiot’s guide for how to use the Wii™ remote’.

Having access to a range of sources and modes for accessing information (Resource Book, Wii™ on-screen information and the physiotherapist) was perceived as positive. Participants described the Mii-vitaliSe Resource Book as a helpful resource and prompt, particularly when getting started. Some participants explained that once they had got started they felt they no longer needed to refer back to the Resource Book. Others described scanning through it initially to get an overview or going through it with the physiotherapist. Sometimes it was read for specific reasons, e.g. to find out how to do some warming up exercises or to know which discs to use and how to use them. Others talked about using it as a means to re-focus and described how the physiotherapist referred and re-directed them back to the resources to find relevant information

The Personal Activity Workbook helped participants to formalise their goals and set action plans. Here is an example of how a participant set an action plan to achieve their goals:-

“I’m going to set my goal that I use it four times a week, that’s my goal. Which I will because on one morning I help at a charity shop now so I’ve got that one sorted, so Monday, Tuesday, Thursday, Friday I will y’know, I will, that’s my plan. I don’t plan to do it at the weekends as such as we are busy, husband’s around and things like that. But no I think four times a week is a good, is a good thing to have. And because I enjoy it I’ve missed not doing it.”

(12-month interview, delayed group)

Participants described a variety of goals they had set. For example: to beat previous scores, to achieve specific levels or scores in the named games, to exercise three times a week, to achieve increased fitness and balance, to lose weight, to exercise for 10-15 minutes, to do a specific type of exercise (aerobic, balance, cardiovascular).

Here is an example of a participant with a flexible approach to their goals:-

“...and I've been able to set goals one week at a time, but not always having to improve, ‘cos I have to keep telling myself ‘cos I do, I am one of these people who likes to improve. But I've found it's given me a very positive attitude um, and my advice to anybody would be to find what works for you. I think that's important and physical activity is important for everyday life, for anyone actually. And focus on what you can do, y'know not on what you can't do, ‘cos loads of things, well loads of people can't do as well. And be flexible, adjust, I've put life is unpredictable, modify goals to accommodate events, unexpected, for example certain symptoms OK, I'm really aching now I'm not going to do that I'm going to listen to some music.”

(12-month interview, immediate group)

The interviews yielded rich data, describing a variety of ways that participants had set action plans and the strategies they used for coping (coping plans). Table 6-23 details these descriptions in a case based framework chart.

Table 6-23: Case based framework chart illustrating participants' descriptions of how they engaged with Mii-vitaliSe

Action plans	Used alone or with others	Software used and games played	Processes of use described by participants -examples of coping plans	Suggestions for other coping strategies
Planned to use at start, middle and end of week (three times) Mostly in the afternoon	Mostly alone Sometimes with step daughter	Tennis Sword Fighting Balance games- (Balance Bubble, Soccer Heading) Zen Golf	Trial and error to get familiar with games Played the games that I knew and preferred Tried some at the hospital but if didn't like it dismissed it Do the Wii™ or chill after work and dog walking Liked golf pre MS so tried that game	Do it with someone then you don't give up so easily
Morning as less fatigue	Mainly on own but sometimes with daughter	Wake Boarding Tennis, Boxing, Table Tennis Wii Fit Plus™ Juggling Wii Sports Resort™ and Wii Sports™	Do what like and do best e.g. the juggling Motivated by improvement in fitness and scores Fitted in with work and more livelier in the morning Some games are harder and if you are not good at them you tend not to do them More fun when played with daughter –otherwise got a bit bored doing alone Texted friend to see what score she got in the obstacle course	Buddy system via text would be helpful Did some games in sitting e.g. Boxing
For 45 minutes in the afternoons four times each week (not at week-end)	Alone	Balance Bubble Training plus-enjoyed Yoga Wii Sports Resort™ Wii Fit Plus™	Motivated to get to the end of the balance bubble Try to prevent the 'Wii' women telling me off Connected with another person via Facebook TV in bedroom too small therefore tend to do the exercises when the family are not in so can use the larger screen TV in lounge Got more out of Wii Sports Resort™ - found going through the menu in Wii Fit Plus™ time consuming and not necessary and wasn't interested in body test and losing/monitoring weight	Wear sunglasses because bright light affects eyes Walking and stepping activities sometimes difficult in standing and so adapted some games e.g. running used arms
In afternoon or early evening (cooler) On days off from work	On own mainly - With husband once Taught the kids	Steps, Hula Hoop, Balance Bubble, Snow Boarding Tilt Table, Table Tennis, Snowball fight, Archery, Ten-Pin Bowls, Rhythm Parade, Cycling and Island Cycling	Technology can be challenging therefore need to start gently and persist, then built up to more exercise and progress targets If you keep practicing it helps to find solutions Do in underwear to keep cool Made own 'Idiots guide' to using the handset Had a rest after work and then woke up to do it-intended to do it straight after work but didn't achieve this Snow ball good for co-ordination	To help with motivation would be good to pair people up

Action plans	Used alone or with others	Software used and games played	Processes of use described by participants -examples of coping plans	Suggestions for other coping strategies
Morning before work	Alone	Wii Fit Plus™, Wii Sports™ Jogging, Balance, Stepping, Hula Hoop, Penguin slide, Cycling and Canoeing	Choose the games with a timer to see exactly how much done Get hot and therefore need to shower afterwards before work At the end of the day after work too exhausted so had to do it in the morning Enjoy canoeing in real life so did that Found out more about where limits of activity were The 10 minutes of physical exercise also takes mental energy	Length of time not recorded on Wii Sports™ so need to time yourself- it's quicker to have the on-screen timer as finding a way to time takes longer if you are in a hurry When you hit a mental barrier pair up with another person to help with motivation
Small amounts-15 minutes am and pm- Before work or occasionally after	Mainly alone Sometimes with husband	Yoga-first 5 on screen Aerobics-running, strengthening Balance Bubble, Segway, Ski slalom Hula Hoop	Fitted well with everything else done for the MS - difficult at first but OK once got going and got into a routine Getting good scores and mastering yoga technique Easier to let slip in the second 6 months Need physical space in house - husband cannot watch TV. Lot of equipment to set up –need to move table and then tidy away or just leave out and set up	Another face-to-face /refresher when things were not going well as needed to be pushed Concerned about being ill when I exercise so would be nice to have someone else here for support
After lunch in the afternoons	Always alone	Perfect 10, Obstacle, Tight Rope, Ski-jump, Stepping, Cycling	Used a chair for support Got a lot of pleasure out of it, Challenge self in own time, increased confidence to do more Choose good day for hard game, e.g. cycling for 1-1 ½ hours Aim to increase the on-screen score with stepping and cycling Can lose myself for 1-1.5 hours Good for using in winter Step game has benefitted me the most - increased heart rate with cycling, sword play, stepping Tended to focus on one disc rather than swop-disc chosen depended on mood and what else done	Ski jump technique required bending knees-needed more information regarding technique Keen to do with a friend
Variable routine Try to do 3-4 times a week Sometimes up to six days a week in the winter	Mainly alone Occasionally with a friend		Yoga very positive, physical relaxation and own personal space Can pick and choose games to do at home, but with some company A distraction like music and art – gives a feeling of well-being Good for my relationship with my husband - more equal Do in sitting room, no need to dress and no hassle of getting to a class Easy to modify motivated because it makes me feel well Got into the habit, it's been beneficial so motivated to carry on want to keep fit for as long as possible	Don't like the body test Unsure if technique is correct Initially cautious about nunchuk Am retired but still difficult to fit in Small environment –need to compromise with husband as only TV in lounge

Action plans	Used alone or with others	Software used and games played	Processes of use described by participants - examples of coping plans	Suggestions for other coping strategies
Afternoons or evenings	On own or with partner	Archery, Jogging, Golf, bowling	Fits with toning tables Makes you concentrate	Go out more when weather is warm therefore use Wii™ less
3-4 times a week On alternate days In the afternoons or lunch time, rarely the evenings	Alone	Wii Fit Plus™, Wii Sports™ occasionally	Played Wii Sports™ sitting on a perching tool Fits well with other care Occupied the mind and distracted me Achieved moderate level activity (slightly increased pulse) Wii™ self-monitoring balance	Don't overdo it in the golf Weather –too warm –didn't help fatigue Do body test as a way of deciding which game to do as gives an indicator of type of day
Use 5 times a week for 45 mins before everyone comes home	Alone	Do Wii Fit Plus™ Hula Hoop, Step, Boxing, Rhythm Parade, Obstacle course, Tilt Table, Penguin Slide, Step game	Always tried to do 10 minutes on the Fit-Piggy - progressed from bronze to gold Step ups while watching TV Tend to do later in the day otherwise ruins rest of the day Found the games that suited me and were enjoyable Tended to do games for arms, legs and balance – stuck with them and tried to progress Need to exercise on your own at home after being shown at the sessions Need to focus on pressing the arrow on the handset Filling in the calendar helped with motivation	Would be helpful to know what levels there are on the games so that you can advance through the levels- otherwise you wonder if you are stuck because of ability or due to there not being another level
Early evenings 5.30 Before or after lunch if doing alone	With daughter and her friend	Birds Eye, Balance Bubble, Perfect 10, Skate Boarding, Cycling, Running, Ski-jump/Slalom, Penguin Slide	Competition with each other Some games are too easy not enough challenge Started off using the stick when getting on and off the board	Do with others to develop a competitive spirit Doing with friends is fun
Afternoons, on days off 70-80 minutes	Alone	Tried them all but stuck with main ones: Balance games, Wii Sports Resort™- Table-Tennis and Sword Play	Records time and calories Do similar games each time and follow a pattern Beating own scores-trying to get to top score on the leader board Getting familiar with games	
Mainly in the mornings and on a day off	Alone mainly, sometimes with the family	Moderate running, aerobic, Hula Hoop, yoga	Use when weather bad Enjoyable and fun as family time Useful BMI and scales	Mild MS so maybe be more suitable for people more disabled

Several participants used the Games Descriptors and described how they had found them useful to read and to learn about the various games available. They described using them as a guide to decide which games to try, explaining how they had marked those they wanted to try. Sometimes they initially read through them with the physiotherapist who helped them to find appropriate games. The Games Descriptors were also used to support participants to adapt games to their individual needs, e.g. after an ankle problem. They were perceived to be helpful to illustrate the different game levels available to provide variety and opportunities for progression. The Games Descriptors were also perceived as helpful for those participants with coordination problems who could use them to select games on the basis of whether they required the use of arms and /or legs.

“The bit that interests me were the different parts of the body or the different functions of the body that each game is aimed at.”

(6-month interview, immediate group)

Generally the play log was considered to be well laid out and easy to complete.

“I thought they were really well laid out, they were quite easy to fill in and I quite like that, yes. I liked all the boxes. Some ah, in the unwell box I thought that maybe, ‘cos there’s unwell and there’s unwell to do with MS and I felt that maybe that could be well there’s no MS relapse there, I don’t know, I always like to put in what I was ill with just as a record for me as well because it could be unwell due to medication or unwell unwell, or MS unwell.”

(12-month interview, delayed group)

Strategies people used to remind themselves to complete the log included leaving it somewhere visible or putting it in a drawer along with the Wii™ remote control.

Another strategy used was to record their Wii™ use on a calendar and to transfer the information at the end of each week or to fill it in retrospectively every so often.

“What I tended to do was rather than get out the book I wrote it on my calendar and then filled in the book once a week, because I put the calendar away. If there had been somewhere to leave it hanging up I probably would have had it hanging up and wrote it straight on to that but the same with the second one

I tended to tick the days I'd done it on my calendar and then filled it afterwards, this might not have been the right way to do it but it worked for me."

(12-month interview, immediate group)

Two of the initial orientation sessions were conducted with two participants at the same time, rather than in a one-to-one format. These had mixed success. One participant felt this did not work well as the person they were paired with was perceived to have differing needs.

"The other lady and I felt she needed more time than what I needed because her disability is more than mine. I felt she needed a little bit more time and I know it's hard to try and put people with people, you can put people in the same area don't you, whereas I think, I grasped a lot quicker and also physically quicker, so."

(6-month interview, immediate group)

However, another participant felt that meeting the other person was beneficial and enhanced motivation and following the orientation session they encouraged one another by linking up on Facebook.

Overcoming barriers and challenges

This sub-theme describes some of the barriers participants described when using the WiiTM and ways in which they had overcome them. Getting the discs out of the packaging and the box was perceived as a challenge for one participant who had difficulties with hand function and dexterity. A few participants described themselves as 'not technical' and needed assistance with the equipment from family members. Even when participants were familiar with using a computer and had previous experience of using a home gaming system, using the WiiTM was perceived as a different challenge. Orientating or aiming the cursor on the screen when using the WiiTM remote was one of the main challenges described by participants.

Some participants described challenges associated with playing games that required the WiiTM balance board. Some of these were related to stepping on and off the board safely and also playing the game. Those who did use the balance board described a need to

focus and concentrate particularly when doing the more complex activities, e.g. when stepping on and off, moving from side to side and changing direction.

“Just occasionally, I think maybe once or twice I’ve sort of hesitated, where I got from side to side with the stepping. But it’s more, it’s a concentration thing, ‘cos if you get too involved you’re not concentrating quite so much.”

(6-month interview, immediate group)

Some of the barriers seemed to be connected with balance and a concern about near falls or the risk of catching a toe in the balance board and then feeling unstable. Pain and fatigue were also barriers; some of which were associated with injuries that pre-dated Wii™ use. This quotation refers to pain experienced by a participant when using the balance board:-

“It’s like a constant toothache, that’s how I can describe it and if I do too much, I was getting a lot of pain in the underneath but now I’m just getting like a constant toothache all the way up my leg.

Standing on the Wii™ balance board used to really aggravate it and the, you know the leaning forward on the Segway. I just couldn’t, I did tell the physio at the hospital because I had to sit down afterwards”.

(6-month interview, immediate group)

Some participants chose not to use the balance board as they had concerns that it may be unsafe for them to do so because they had difficulty stepping onto steps. A technical challenge reported by three participants was synchronising the balance board to the handset as both needed to be synchronised before use. If the handset and balance board were not synchronised they could not be used.

“As soon as I tried to sync it to the hand unit, if you got the hand unit to sync then you, the balance board went out of sync, the actual syncing of one seemed to unsynch the other.”

(12-month interview, immediate group)

The nunchuk requires hand dexterity to connect to the Wii™ remote. Sometimes participants needed to stop in order to focus to connect it to the Wii™ remote. Some

participants did not use the nunchuk and others were confused or unsure about how to use it so had avoided games that required it. However, participants who had initially been cautious described how they had managed to overcome their initial reticence.

“Sometimes dexterity wise it’s a bit fiddly and I couldn’t get it in and so but as long as I just stopped and concentrated on it rather than trying to get it y’know ‘cos I go into a game and I go I haven’t put it in where’s the nunchuk oh, and then trying to do it quickly and then no just slow down, take your time.”

(12-month interview, delayed group)

Charging the Wii™ remote was challenging for some participants. For example, some found it difficult to place the Wii™ remote into the charging cradle. Changing the batteries and remembering to charge the Wii™ remote were also described as challenging.

“Occasionally like putting it in the charger sort of taking off the sleeve, making sure the strap, cos if you, I used to find where the click is on the strap sometimes trying to take it out, if you hadn’t shut that it’s awkward to get through and so y’know it was just having to remember y’know it’s fine once you’ve got it like that but y’know and then you’re taking it off if you’ve left it open that ends up down there and then you’re trying and it gets a bit fiddly, so making sure that it’s closed, it makes it easier to take out.”

(12-month interview, delayed group)

With reference to the Wii™ remote perseverance and practice with the cursor for a few weeks was sometimes required to keep the arm steady and the cursor in the right place to prevent the juddery on-screen arrow that participants described. As well as talking about the Wii™ remote participants also mentioned the television remote control which needs to be used to switch the screen to the correct channel when using the Wii™. Some participants described the challenges of the small buttons on the television remote control and subsequent difficulty with switching the screen to use the Wii™.

Participants with memory issues and cognitive fatigue explained that they tended to forget to refer to and use the resource materials unless they were prompted by the physiotherapist to do so. Participants also described some of the challenges and

problems with completing the play log. Those with memory problems and cognitive fatigue explained that they needed reminders to complete the log. Sometimes participants forgot and missed a few days and then had to complete the log retrospectively. It could be challenging to recall what games they had played and rate their fatigue and enjoyment levels.

“The process of completing them. When you can remember to do it, you know at the same time, it was quite easy to do it but it was, cos I’ve got a terrible memory. And you know so sometimes I’ve got a week and thought ‘oh flippin heck’ and then have to sit down and remember and that’s not good.”

(6-month interview, immediate group)

The barriers recorded in the play log are presented in Table 6-19 and a summary of barriers described by participants are described in Table 6-24. There were a variety of barriers that encompassed physical (MS and non-MS related), psychological, cognitive, and environmental aspects as well as Wii™ related ones. Non-MS related barriers included previous injuries and the onset of infections and need for antibiotics causing participants to feel unwell and not able to exercise. Only one of the participants interviewed mentioned boredom but this related to doing the exercises alone and not been able to link with other participants.

Injuries were carefully monitored throughout the trial. Participants were also asked in the interviews to describe any injuries, occurrences of pain, instability or symptom changes. These are presented in Appendix 8.

Table 6-24: Summary of participants' perceptions of barriers to using Mii-vitaliSe

Physical barriers	
General	Variable pattern of MS, MS relapse, fatigue, bringing awareness of MS to the forefront, eye problems (need to wear sunglasses), shortness of breath, urinary tract infections, needing to be pushed
Leg	Leg pain when standing on the balance board and leaning forwards, limitations of weaker side, foot caught on edge of board (near fall) , knee pain/discomfort/soreness (from aerobic, tilt table, stepping or golf activities), foot stiffness (from jogging), muscle spasm, heavy/tired legs, twinges in back, leg injuries, broke toe
Arm	Aching in right arm, pins and needles in arms and shoulder pain (with some yoga exercises)
Co-ordination	Using both arms and legs together is risky, difficulty with co-ordination with Wii Sports™
Balance	Fall (when doing step ups and Balance Bubble). Near fall (due to concentration). Lost balance (doing Perfect 10) Not possible to do sideways steps so made adjustments by using a chair at the right side
Pain	Pain (neck, back and from previous injury)
Psychological barriers	Mood, motivation, mental strength, anxiety about exercising. Felt guilty and disappointed with myself that 'should be' doing more. Pressures in life, no perceived benefits, Wii™ became a major mental block
Cognitive	Remembering to do it, cognitive fatigue
Environmental barriers	Need to shower afterwards before going to work (need to allow time), hot summer (want to be out in the fresh air doing exercise, do other things, get more fatigued in the heat), feel self-conscious (complaints of noise from neighbours from jumping and aerobics), small environment, TV connected to Wii™ not always available (husband /children want to watch it or use the Wii™), a lot of equipment –need to move table and then tidy away, cautious initially about using nunchuk, being away from home
Wii™ related barriers	Using the Wii™ alone, not being able to link with another person on the Internet, need to be cautious when doing games using balance board, length of time not recorded on Wii Sports™ (so need to time yourself), body test-unsure if technique is correct, demotivating to be told you are 85 years old, buttons too small on the TV remote therefore difficulty pressing to get channel for using Wii™, games do not appeal (some too easy, some not challenging enough, didn't enjoy Wii Sports™), occasional difficulty with synching the balance board and the handset, the language used in the yoga exercises is unfamiliar, experienced a lag with the steps when playing Kung Fu game
External	Time/too busy (work, family, dogs, days out at weekends), work issues, home issues, holiday

Physiotherapist support

This sub-theme referred to participants' perceptions regarding the support and amount of contact time they had with the physiotherapists at the orientation sessions, home visits and via the telephone calls. Participants described how they enjoyed the hospital-based orientation sessions, the physiotherapist home visits and telephone calls. There was a sense that you could feel overwhelmed by information and that it was helpful to have the physiotherapist to guide you. There was generally a feeling that these sessions were well planned, important and offered valued encouragement.

The initial contact at the orientation session was considered to be particularly relevant and helpful for those with no previous experience of using the Wii™. These participants described the process as hard initially when getting started but the physiotherapist orientated them to the Wii™ slowly and in stages. The orientation sessions were described as an interesting way to find out what was expected of you. Participants seemed to feel that these sessions offered a good introduction and that it was helpful to have the physiotherapist present initially when starting to use the equipment. Most participants felt that the duration of the orientation sessions (60-90 minutes) was appropriate. The physiotherapists were perceived to be supportive, encouraging and available if advice was needed. Participants described how the physiotherapists offered guidance for setting goals, suggesting a variety of exercises as well as providing general support.

"I think it was the right length of time between her first visit here and the second visit here. Because issues that did arise while I was using it after the first visit I was able to raise and it was only a couple of weeks. And I think I might have telephoned her, I think during that time to raise a particular question but it meant I wasn't left for a long time not knowing what I was doing."

(6-month interview, immediate group)

At times participants asked the physiotherapist to demonstrate how to play specific games, as they were concerned they were not using an appropriate technique and required reassurance. They felt it was beneficial to see the correct technique, i.e. see someone doing it rather than a picture.

“The obstacle course, that’s right, that one I found quite difficult and again it was the same with the tightrope walking, I found the standing on the board and then having your knees bent and then straightening them, that was still a challenge. And I don’t think that was particularly well illustrated in the instructions.”

For those participants who were not used to using technology, the Wii™ was described as causing worry at the start and therefore there was a suggestion for more contact to alleviate this anxiety. The initial stages seemed to be when participants felt least confident and needed support, but as they became familiar with the technology and intervention, they gained confidence. There was a suggestion by one participant that older people may need more contact, as there is a lot of information to take in.

“Otherwise it’s too much to take in and you go home and you’ve forgotten it all, so that it was done in three stages or two stages, that was easier to take in to get used, because I’ve never used a Wii™ before in my life, nothing like that ever, so it was totally new for me to pick it up. I don’t know whether it would be a good thing for older people, whether they would, I don’t know whether my mum would be able to get on with it or not, I don’t think it would be something for her maybe, she’s 66 my Mum, I don’t know how older people would get on with it but I think my sort of age and below would be good.”

(6-month interview, immediate group)

Two participants felt that more face-to-face contact would have been beneficial especially when they were experiencing barriers to using the Wii™. They identified a need for this support towards the end of the intervention period (12 months for those in the immediate group and 6 months in the delayed group) when support was less. This could keep someone motivated by offering an additional session for support to overcome barriers.

For two participants extra sessions were offered to address specific requirements. One was put in place for a participant with memory problems and another for a participant who wanted the equipment set up in the bedroom. For those participants who had previously used the Wii™ prior to having MS, there was a suggestion that

one orientation session instead of two would be sufficient. This one session would be a refresher and act as a reminder of how to use the Wii™ but not include the basics of getting started. There was, therefore, a suggestion to ask about prior Wii™ use first and then the orientation sessions could be adapted for individual need. One longer hospital session (to fit in with work) and a longer set up session at home worked well for a participant who had previous experience of using the Wii™ and who had limited availability for daytime orientation sessions due to work commitments.

The telephone calls offered an opportunity for informal conversation and were perceived to be a supportive back up and useful for staying in touch, answering questions and discussing any challenges encountered when using the Wii™. The telephone calls were also described as encouraging and a means to give advice and support participants to ensure they were using good techniques when playing the Wii™ games. Participants perceived that there was always advice on hand with the ongoing email and/or telephone contact and felt reassured that if a problem arose they could contact someone. They stated that this worked well and that the amount of contact and advice provided was enough to support behaviour change. Several participants perceived the telephone calls to be an extrinsic motivator due to feeling guilty if they had not used the Wii™.

"I think that's good in that even a phone call I suppose because you think oh XXX (names physiotherapist) going to be ringing up so I must have something to tell her, I must do something. So you kind of get a little bit of guilt in there, so you think oh I must do something."

(6-month interview, immediate group)

The monthly physiotherapist telephone calls were generally found to be helpful in terms of suggesting ways to incorporate Wii™ time into lifestyles and to allay guilt that some participants felt if they had not achieved their goals.

"Yes because as I say there were a couple of times when I felt I wasn't doing as much as I should be doing and XX (names the physiotherapist) was able to ease my mind about that and you know to say to me well don't feel guilty, don't beat yourself up about it, try and put a little bit more in later in the

week, you know. She was able to sort of suggest things to me that maybe I wouldn't have thought about, like oh well if you don't do it on a Saturday and Sunday to make up for those two days, doing like that. As time went on you kind of got more used to doing what you should be doing."

(6-month interview, immediate group)

Adaptations

This sub theme relates to how participants suggested the intervention could be refined and developed in the future. Participants had the following suggestions for other helpful content to be added to the resources:-

- A section on how to practise the body tests, then you can gauge what sort of a day you are having and this would enable you to plan which games/activities to do that day.
- A simple 'How To' section as this may prevent barriers early on, e.g. how to synchronise the Wii™ remote.
- Information about the relevance of the types of games for people with MS and what other people with MS have found to be useful.

One participant found having a perching stool nearby while on the balance board was helpful to assist balance and gave confidence when stepping on and off the board. Others described how they adapted the way they did the games involving stepping to be safe so they did not need to change direction or step sideways as this was perceived to be risky. The Step Plus game was described by one participant as very risky because of the need to turn and step. Therefore this participant continued to play the Basic Step test game and did not progress to the more complex and challenging Step Plus:-

"Yeh but the other one it turns you, it turns you, you go on and on like that and then you step off facing forwards left and right but then you turn your whole body to go on with your left foot and then come off and go with your right foot, and that's a bit of a ...but I still can't master that one."

(12-month interview, immediate group)

6.4.3 Theme 2: Factors that contributed to increased physical activity

In this theme participants refer to the aspects of the intervention that supported them to become more physically active.

Convenience and fun

This sub-theme refers to participants' perceptions concerning the convenience and fun elements of the intervention.

One of the main benefits of the Wii™ from participants' perspectives was that it is a fun and convenient way to participate in physical activity and do physiotherapy. This enjoyment was also a motivation to use the Wii™:

"Well I'd say it's made me feel fitter and my balance has got better and gives you a good positive look about exercise because you're not, I've never been one for doing exercise, it's not the thing I do or I don't go out to do it. If a walk I walk, so exercise in itself I did join a doctor's programme for 6 months and went up to Stokewood, I don't like gyms, dreadful places. I don't know why people like them. Doing it with your friends at home it's fun, your're not with people who think look how wonderful I am. Yeh I know your wonderful, I'm not deal with it!"

(12-month interview, immediate group)

In terms of enjoyment this related to the fun nature of the games and the fact that you can participate in virtual reality activities that might in real life, be challenging due to physical limitations, or require further unrealistic adaptation to enable participation (e.g. ten-pin bowling, golf, archery). Enjoyment was also gained by the on-screen 'Mii' character which participants were encouraged to set up and use at the orientation sessions. Participants described this 'Mii' character as a factor that contributed to the enjoyment of using the Wii™.

"Because it's realistic, when you see, you know, you're playing it on the screen and that and it is, it's realistic. You believe, so, I mean, I know damn well if I went to a bowling alley I'd never be, cos you know I haven't got the strength. It's great."

(6-month interview, immediate group)

The fact that the Wii™ was in the home and you can use it for brief periods of time (just 10 minutes) were important aspects in terms of its convenience. In addition, the fact that you do not need a partner to play table tennis nor a physiotherapist to work on balance and be given feedback were also of importance to participants. The variety offered by the games was a factor that prevented boredom as illustrated by this quotation referring to the obstacle course:

"I yeh I think I've never, I've never really been into playing games since I was a child, and I've always rather frowned upon it and I've really enjoyed just the game element of it, and I've realised I'm very competitive, and I just had so much fun, and so it's made me very happy and I've really enjoyed it so it's been a really good kind of quality time just with myself and XX and with my mum. And yeh especially during the winter that was really, really good stress relief because it kept me going because it gave me this window where I was just physically exerting myself and just enjoying myself."

(12-month interview, delayed group)

With reference to convenience participants seemed to appreciate being able to exercise for 10 minutes (which could be recorded on the Fit-Piggy).

"I knew that I could give 10 minutes every day and sometimes I did 10 minutes on my own in the morning and then I'd go on it in the afternoon with my husband or something. But I just made sure that I'd be able to say to myself each day look you can spare 10 minutes, so that's why I'd kept it short and sweet."

(12-month interview, immediate group)

Motivators

A key aim for this intervention was to foster intrinsic motivation to increase levels of physical activity. Support from the physiotherapist and other Mii-vitaliSe resources to establish routines also played an important part to encourage ongoing use.

"we had a little thing going where we were trying to beat each other as well, so that was quite fun y'know I'd do it and then I'd come home from work and he'd been on it and he'd say right I've beaten your score so that I'd next day

go on it and say right now I've got to beat your score and that was fun, I enjoyed that so to be able to do that would be good."

(12-month interview, immediate group)

Some participants described the play log as a good motivator as it served as a reminder or prompt to use the Wii™. Some explained that while it could be frustrating to complete the play log every day, the process became a motivator. They described how it enabled them to self-monitor their performances over time, which was helpful and encouraging. In the process of self-monitoring, participants described that while completing the play log sometimes provoked guilt it could also help to allay that guilt by reminding them of some of the reasons why they had not achieved their goals as this quotation illustrates:

"The daily record, weekly record, for me was a good thing, because I think, it's almost in the back of your, oh you need to do that, it kind of keeps you on task or on occasions I'd think oh goodness I haven't done it for a couple of days and sometimes I've written in there, I don't know it might have been mum, it might have been visitors for the weekend, I needed to do that because I, on occasions was thinking I feel guilty because I haven't done it, and then I think well why didn't you do it, well mum wasn't well or you have people come over or whatever so I think that for me just made me focus on why I didn't do it."

(12-month interview, delayed group)

After the first six months of the intervention, for those in the immediate group the daily play log was replaced with a simple version in the form of a calendar. While two participants preferred the briefer calendar, others noted that they had missed recording the more detailed information previously required, e.g. reasons for not playing. One participant explained that they liked to use the log as a sort of diary to record MS symptoms and they missed keeping this record

Examples of ways that people were motivated were the encouragement from the virtual companion that is present with you when you jog, the music that is played

when you have exercised for 30 minutes and the feedback provided of minutes spent exercising stored in the ‘Fit Piggy’ or calories burnt.

“Also the visual and sort of sound effects, so like if you go for a jog, you go for a jog outside but it’s raining or cold or you think oh I don’t want the neighbours to see me this is so embarrassing and all this, but just jogging on the spot’s a bit dull but when you’ve got a little man jogging with you, and it’s the sounds as well, with the jogging that ‘tu tu tu’ or saying ‘slow down’ or ‘speed up’ you felt like you had some, you were jogging with some company almost y’know and you were moving along y’know as well.”

(12-month interview, delayed group)

Participants described their experiences of setting and writing down their goals in the Personal Activity Workbook as a means to motivate themselves to exercise. Some participants commented that it was helpful to set goals and action plans and that writing these down served as a helpful reminder, as this quotation illustrates:

“Yes, I’ve put all those in. I think I did most of those. I think that was quite good because sometimes you think what did I intend to do, what did I want to get out of this and what should I be getting out of it, so then you can look back and think oh yeah.”

(6-month interview, immediate group)

Facilitators and benefits

Participants described a range of both physical and psychological health benefits and also examples of how these translated into their everyday activities. These are summarised in this section and further details are presented in Appendix 9.

Some of the physical health benefits related to general fitness and participants described that their stamina had improved and that they were able to do more exercise and sleep better. Improved balance was also a benefit which participants had noticed in everyday activities such as walking, cooking, gardening and going up and down stairs. Moving better and feeling stronger with improvements in co-ordination, rhythm, posture and core strength were also noted to be benefits.

Participants described how they used the Wii™ as a health monitor or assessment

tool for weight, BMI, centre of gravity and distribution of weight in their legs. Participants noted less fatigue and pain and less deterioration and deconditioning when using the Wii™ regularly.

"It would be physical, can I just say that? It would be physical and it would be walking related, dexterity related I think. That's the main thing, I mean all the, I see it quite holistically, but the physical would be the, yeh."

(12-month interview, delayed group)

"Not particularly I don't know whether my balance has got slightly better whether the results from the test will show that. I don't know but I think that I haven't got any worse, and for me that's the main thing, 'cos I know last year the Consultant when I saw him in December said I was de-conditioned, and so that I was just trying to get myself back on an even level that I wasn't getting any worse again."

(12-month interview, delayed group)

Improved psychological benefits included feeling more confident, feeling more supported, providing a distraction from MS and increased self-efficacy. Additional benefits included the Wii™ being a stress reliever and the perception that you have company (in a virtual sense) for supporting your exercise programme. Participants described a sense of achievement from improving scores, getting onto the leader board, increasing time played or competing with others.

"I think mentally I have felt better about myself. I think 'cos probably I'd, I wouldn't say I was in a rut 'cos I did do various other things but physically I would say oh I can't go walking anymore, I can't cycle anymore, so I think mentally I felt better 'cos I was actually achieving something on this so yeh definitely a mental benefit for me."

(12-month interview, delayed group)

6.5 Objective 4

The interviews with the two physiotherapists were conducted at Poole Hospital NHS Foundation Trust and were conducted over two days. Each interview took two and a

half hours (conducted in two sessions of 90 minutes and 60 minutes). The physiotherapists talked about the delivery of the Mii-vitaliSe intervention referring to how they had used the resource materials and the challenges they faced.

6.5.1 Usability

The Mii-vitaliSe resource materials were described by the physiotherapists as useful. The Games Descriptors were liked and particularly helpful if participants had a particular goal in mind. The headings section (coloured labels with headings at the beginning of the Mii-vitaliSe resource book) was thought to be very good and user-friendly. The physiotherapists felt that the Mii-vitaliSe Guidance Book and Personal Activity Workbook could be combined to prevent the need to switch between the two documents in the orientation sessions. The section on barriers and facilitators to exercise was described as ‘used when needed’ rather than used routinely and could have been utilised more. The quotations from people with MS in the Guidance Book were referred to by the physiotherapists. Additionally the physiotherapists described how they had also drawn upon their own experiences and examples.

The physiotherapists described the orientation sessions 1 and 2 at the hospital as an interesting way of working and felt that both sessions were needed. They explained that with practice their delivery of these two sessions became ‘quicker and slicker’. The location (hospital physiotherapy neuro-gymnasium) was described as convenient although it was necessary to move some gym equipment to provide adequate space for the Wii™ equipment.

The physiotherapists felt that the two follow-up home visits flowed well. These sessions provided an opportunity to demonstrate and try out new games, suggest different games to accommodate changes in symptoms, look at and correct techniques/posture, review goals and encourage, reassure and motivate. They found that participants were sometimes over-ambitious and in these instances they needed to support and guide them during the follow-up home visit to adjust their plans and goals so they were more realistic and achievable or even sometimes start from the beginning again. The follow-up sessions provided an opportunity for trouble shooting if there were equipment problems, e.g. with the chargers. The physiotherapists observed that participants often managed to do more on the balance board in the familiar surroundings of their own home than in the hospital setting.

This was sometimes surprising to the physiotherapists and this finding will be discussed in more detail in the discussion chapter.

The physiotherapists described how some participants found that the ongoing telephone calls were encouraging and a way of keeping on track with the exercises. However, the feeling of being ‘checked up on’ led some people to feel guilty if they had not used the Wii™. The telephone calls offered opportunities for discussion and reflection so that participants could work out the reasons why they had not used the Wii™ and consider solutions. For some there were particular reasons why they may not have been able to achieve the activity goals they had set (e.g. starting a new job, walking to work). In these instances the physiotherapist provided reassurance to allay their guilt. For others it was about providing reassurance that it is challenging to sustain changes in physical activity and to work through ways of overcoming identified barriers.

For those participants who were motivated and continuing to use the Wii™, the physiotherapists encouraged and supported progression of their activities. For those who were less motivated and engaged finding ways to motivate participants with the telephone contact was deemed to be a challenge and ‘out of their comfort zone.’ If the physiotherapist already knew the participant prior to the research study the telephone calls were described as less challenging and more likely to flow, as there was already a rapport. It was therefore noted that it was important to establish a rapport with those participants they did not know so well.

Enjoyment and the fact that participants felt that their scores were improving (which they identified as an achievement) were identified by the physiotherapists as key facilitators. If participants were able to improve their previous scores and were enjoying the process then they were motivated to continue. With those participants who were particularly focused on beating previous scores, the physiotherapists described concerns that they might overdo the exercises causing discomfort or injury. However, despite warnings and advice to warm up before starting participants sometimes still overdid some of the activities. If participants were finding it difficult to keep to their agreed action plan then they discussed why this was the case and made suggestions for ways to overcome identified barriers or make adjustments to the plan as this quotation illustrates:-

“And so it was looking at other ways that she, obviously that was still working towards the activity guidelines, but it was almost a compromise, that we obviously wanted her to be able to benefit. And she really enjoyed it up to then, but her, things in her life had changed. So we tried to look at alternative ways that she could still benefit from the Wii™ but not necessarily looking at it from an activity point of view but as de-stressing, but she was still getting active.”

(Physiotherapist interview - B)

6.5.2 Challenges

Referring to the use of the Mii-vitaliSe resource materials the physiotherapists reported that they initially found it difficult navigating from one section to another but became more adept with time and practice. The physiotherapists did not complete a detailed physiotherapy assessment with participants in the initial orientation sessions and without this background information, goal setting was perceived to be challenging. However, they described how in the initial orientation session they got people standing on the Wii™ balance board to weight transfer and would provide feedback about their centre of gravity, posture and technique. The balance board was used in this way as part of an objective balance assessment, e.g. illustration of lateral weight shift on the balance board while playing the Snow Ball Fight game. It was helpful to demonstrate how to use the Wii™ in the orientation sessions and to get people involved and trying it out at the start.

“And as a general rule I, within the sessions where we had the first session of getting the board. I would always get them on and show them the deep breathing. That is because it shows the board as a whole and shows where the centre of gravity is. So they, and I would say, right we’re going to ignore the score completely and what I would like you to do is move your weight from side to side. So they got the feeling of standing on the board and seeing how the cursor moved for them, forwards and backwards, so they, and then centring it. So they actually got the idea of how the board was actually working.”

(Physiotherapist interview - B)

On two occasions, the two orientation sessions were completed with two participants at the same time. For some participants this seemed to be enjoyable and was seen as an opportunity to get to know someone else with MS. One participant felt that they had been paired with someone who had differing needs from them. From the physiotherapists' perspectives, the group session could raise more challenges. These challenges related to building a rapport, working at a different pace, requiring different levels of support or of time.

The third home visit session (when the Wii™ equipment was set up) was described by the physiotherapists as challenging and sometimes stressful. The challenges described include technical issues (getting things connected, charged and synchronised, finding the right channel, Sky boxes and multiple remotes in use), physical (moving and handling the Wii™ equipment from the hospital to the home) and safety (overloaded sockets and unsteady participants trying to help, moving expensive TV equipment). Some practical suggestions were made, including having a pair of scissors in the set up kit as well as Wii™ component cables. There was one broken handset but otherwise all the equipment worked well. Towards the end of the trial, there was less charge in the rechargeable batteries as they had been stored for longer. The lead on the Wii™ remotes needs to be pulled forwards to ensure there is contact with the charging station; it was suggested that this information needs to be included in the Mii-vitaliSe resources.

The physiotherapists advised that the third home visit session required two hours and could take longer if there were technical difficulties when setting up the equipment. On two occasions, there were technical difficulties and a second visit was required. Sometimes partners/family members either assisted with or undertook the setting up process - especially if the television was complex and other equipment connected to it. The physiotherapists noted that at this home visit some participants found the equipment rather overwhelming.

The physiotherapists spoke about their experiences of the follow-up telephone calls. They often initially engaged in general conversation with participants to establish a rapport before discussing progress (or otherwise) with the Wii™. The discussion then evolved to explore any issues and consider ways to overcome identified barriers. The physiotherapists described challenges encountered in providing support

and motivating people via telephone calls and felt that sometimes these calls were perceived by participants to be a form of ‘checking up’ on them. This felt somewhat uncomfortable. The physiotherapists described that there were practical and logistical challenges with the telephone calls and that it was difficult to reach some people by telephone.

The physiotherapists gave examples of the types of barriers that got in the way of regular Wii™ use and the strategies they had used to support participants to overcome some of these. These barriers included limited time, medical and social issues. The physiotherapists commented that during the study they had been able to draw upon their wide ranging clinical experience of supporting people to manage LTCs but also that learning and experiences from involvement in the study were feeding into their everyday practice:-

“I think we learnt a lot about people, when, as physios, when you give them exercises and they stop doing them. So you found out, you know, they’d come back in and they weren’t doing their exercises and you’d find out what goes on in people’s lives, behind life. Like elderly parents becoming unwell and stress related to other family members. So obviously people take on board. One lady, she, she found that she, she found that she really started to struggle because she had a lot going wrong with her mother and, who was becoming unwell and they were doing regular long trips to go and see her and looking at going to nursing homes and it was all very stressful. She got to the point where, initially she was really quite motivated and using the Wii™. But it got to the point where it just became effortful. So we would talk about how we were going to, what the best things were. And eventually we, she concluded that actually she would use it as a stress relief.”

(Physiotherapist interview - B)

For those participants with cognitive fatigue and impairments, setting goals was challenging and required guidance to break the goals into small stages. The written activities in the Personal Activity Workbook were perceived by the physiotherapists to be helpful. However, some participants found completing sections in the Personal Activity Workbook (e.g. setting and writing down goals and completing the

decisional balance grid) challenging. In these instances the physiotherapists provided additional support. There was a perception that there was a lot of information for participants to take in and the resource materials were sometimes daunting. To support participants, the physiotherapists would summarise the resource materials or introduce specific sections when they were required, e.g. the barriers and facilitators section. The physiotherapists reported that they did not use some of the resources initially until they had become more familiar with them but it was felt that the Mii-vitaliSe resources should be used as fully as possible.

“So yes, they were definitely helpful resources and generally, really encouraged goal setting and I think that is really something you can carry forward as well. But just the odd person struggled with the boxes, the pros and cons or the positives and negatives of you know the exercising with the Wii™ versus not the exercising. They struggled, but then I think, you’d find that in the general public and you know, cognitive awareness in some people.”

(Physiotherapist interview - A)

6.6 Interface between physiotherapist and participant interviews

Drawing together the participant and physiotherapist interviews yielded descriptions regarding the practical processes of both receiving and delivering the Mii-vitaliSe intervention. Insights were gained in terms of the usability and reasons why engagement could be challenging. Considering both perspectives offered insights into practical recommendations for how the intervention could be improved and modified in the future.

The importance of advice from the physiotherapists about using the correct technique and avoiding damage or harm featured in both participant and physiotherapist feedback. Participants made links between using the Wii™ and physiotherapy, noting that while it could be used at home without the physiotherapist they needed advice about their technique. This point was raised with a participant in the delayed group prior to starting the Mii-vitaliSe intervention:-

“I think at the back of my mind is how much it’s going to feed back to me and say yes you’re in the right position, you’re not in the right position, I guess

it's a question of will I do too much or do it wrong, I'm likely to injure myself somehow or other and just flailing my arms and hitting something, if depending on what exercises are, if I don't do that right, is it going to cause me more problems. That's the only real thing that sort of, one is the commitment of time but that would be for any exercise you asked me to do, I'd probably come with some excuse for that but then the other one is just I think one to one, always has to be the ultimate answer doesn't it but I know it's not a solution really, it's not something that going to be available. You know it's a negative in the system we have."

(6-month interview, delayed group)

The physiotherapists also highlighted the importance of ensuring that participants used the correct muscles and movement patterns:-

"Obviously you're looking at normal movement and trying to ensure they don't establish poor movement patterns and actually they're using the right muscles when on the board. I saw, I think I mentioned to you, I saw a lady in the study who was compensating very, very badly and rotating her trunk and hyper extending her knees too, so it can show that without guidance of normal movement and actually using the Wii™ properly, people can use it and actually possibly hurt themselves, or cause problems to themselves or not gain any benefit from compensating."

(Physiotherapist interview - B)

The issue of using the correct technique seemed particularly pertinent to those games that required the balance board as here there were issues about safety and concern about falls and near falls. These quotations illustrate the Perfect 10 game from both participant and physiotherapist perspectives, suggesting that instruction is needed to get the most from playing this game:

"I was doing the kicking your bottom from side to side and backwards and forwards and things like that, trying sort of like move my, and a few times I did it with the (name of physiotherapist) and she noticed that I wasn't, I was putting too much, cos I wasn't very good at hitting the balloon with my left

and she was noticing the way I was standing wasn't quite right and she adjusted me and I did better on that."

(12-month interview, immediate group)

The physiotherapist also describes this same game explaining that caution is needed and advice on the technique. This was in relation to the Perfect 10 game referred to by the participant in the quotation given above:-

"But that's one that I'd be careful, like really encourage people to be very careful of their movements, cos it's quite easy to get carried away and then hurt your hips. So we had to look very much at weight transference."

(Physiotherapist interview - B)

Data from the participant and physiotherapist interviews illustrate the challenges of the monthly telephone calls. Physiotherapists found these telephone calls difficult at times particularly when the participants had not been using the Wii™.

"I think across the telephone it comes as me, I'm, I'm, what's the word, I'm trying to dictate."

(Physiotherapist interview - A)

"Yes because as I say there were a couple of times when I felt I wasn't doing as much as I should be doing and (names the physiotherapist) was able to ease my mind about that and you know to say to me well don't feel guilty, don't beat yourself up about it, try and put a little bit more in later in the week, you know."

(6-month interview, immediate group)

Participants described using the Personal Activity Workbook for setting personalised goals initially but then often did not refer back to it in future sessions. There was little mention in the interviews of how the section for overcoming barriers was used although both the physiotherapists and participants mentioned barriers.

One of the barriers that participants described was cognitive fatigue and the challenges of remembering to do the intervention. This was also described by the physiotherapists, particularly in relation to creating goals.

“Cognitively and to write it down. And I used to find that I would end up within my chatting to them and working out their assessments they required lots of guidance to come up with their rules, their independent goals. I think it was a way of thinking that as professionals we do a lot and somebody who worked in the health profession picked it up straight away, who’s a nurse understood it straight away. And some people who I think perhaps worked, I think one of my ladies in IT, she picked it up quite quickly. But other people didn’t really, they used to stand with their pen poised while I dictated to them”

(Physiotherapist interview - B)

“It’s a lot of information to take on. So I do find myself summarising and also asking people to look at it. But people didn’t look at it. So I would find myself then, at future sessions, referring them back when they’re trying to, when they are saying one thing and I said, well let’s refer to this. Just trying to bring lots together...

.... I think it’s probably daunting some of the paperwork.”

(Physiotherapist interview - A)

6.7 Overall chapter summary

In the first part of this chapter, findings related to recruitment, screening and data collection in the Mii-vitaliSe study were described. Descriptive statistics for the hospital-based balance, gait and dexterity assessments were presented showing the means, confidence intervals and changes between each assessment for the immediate and delayed groups. As this is a pilot evaluation the practicality of administration, completeness of data and perceived acceptability to participants has been considered. The design aspects of the study regarding the acceptability of randomisation, the waiting list control design and the processes for data collection were also considered.

In the second part the findings from the semi-structured interviews undertaken with a sub-sample of participants and the two Mii-vitaliSe physiotherapist facilitators were presented. Themes and sub themes were described and presented with quotations from the interviews. It was not possible to interview the people who stopped the intervention and not all participants were interviewed. However, the rich data yielded from the participant and physiotherapist interviews provides useful insights in terms of refining and optimising aspects of the Mii-vitaliSe intervention looking ahead to a future trial.

Chapter 7 The Wii U™

Technology moves at a swift pace. Novel technologies such as the Wii™ come and go. One of the challenges to researchers using off-the-shelf technology is the risk that this will be superseded. Since this study has been completed, the Wii™ has been replaced by the Wii U™. Following the Mii-vitaliSe pilot study, a Wii U™ usability workshop was held at BU using Seedcorn funding awarded by the Faculty of Health and Social Sciences.

7.1 The Wii U™

The Wii U™ has a touch screen game pad which is used to navigate through the menus instead of the Wii™ remote. Navigation around the game pad can be by touch screen using a finger or stylus or by pressing buttons for those who do not like touch screens. Using the Wii U™ gamepad means that games can be played without a television. One of the main differences from the Wii™ is that the Wii U™ has the facility to connect with other players online. A community can be created so people who join the group can look at games other people have played and the scores achieved. Comments can be posted to offer support and encouragement to people in the group. Crowns can be awarded to the person who has achieved the highest score therefore offering competition.

The Wii U™ equipment also includes a pedometer (Wii™ Fit Meter) meaning that steps, calories burnt and altitude can be logged. These data can be uploaded and displayed on the gamepad or TV as charts and graphs. There are additional games in the Wii U™, which include dance and additional balance, aerobic and muscle strengthening games. An additional function of the Wii U™ is the facility to make a personalised exercise programme or routine.

7.2 The workshop

The purpose of the workshop was to demonstrate the features of the Wii U™ to people with MS, to ask them to use the Wii U™ and offer feedback.

7.2.1 Methods

Five participants from the Mii-vitaliSe study were invited to a workshop in August 2015. Four attended the workshop, which lasted for two hours. During the workshop,

there was a demonstration of some of the new games available on the Wii U™. There was also a demonstration of the Wii U™ gamepad, its Internet functions, the pedometer and the way that exercise routines can be tailored to suit individual preferences. Following these demonstrations, those attending the workshop were invited to try out some of the Wii U™ games.

7.2.2 Findings

The Wii U™ received encouraging feedback from those at the workshop. Attendees liked the fact that it had more functions than the Wii™. Those at the workshop had been using the Wii™ in the study (some for one year), and so the new games were welcomed and there was an eagerness to try them as they offered additional variety. The Wii U™ gamepad was also liked and it was noted that there was less getting on and off the board when using the gamepad. This may mean that people who have anxieties about their balance feel more confident to attempt the games.

People at the Wii U™ workshop found the gamepad light to hold. For those familiar with using an iPad navigating round the gamepad seemed straightforward, but for others it took a little practice to become proficient. In particular, there was initial anxiety and a fear of dropping the gamepad; as one hand held it while the other was needed for the touch screen.

People at the workshop were positive about the pedometer and felt that it was beneficial and motivational. The ability to take the pedometer on holiday or when away from home to record activity was liked. Similarly, without the need for a television the portability of the Wii U™ was also deemed to be an advantage.

People at the workshop liked the option for being part of an MS community via the Wii U™. This would allow for ideas and hints for use to be shared and would prevent feeling isolated. All four people at the workshop had reservations about sharing their scores with others but recognised that this may appeal to other younger people who are more used to sharing information via social media.

Regarding setting up personalised exercise routines on the Wii U™, people liked this option and again confirmed that this was something they would use. For example, on some days they might choose to do the muscle strengthening exercise and on other

days the balance. A feature where three separate routines could be set up within the Wii U™ was therefore well received.

7.2.3 Conclusion

The workshop achieved its aim of gaining feedback on the features of the Wii U™. The Wii U™ ceased production in 2016. However, the findings from the workshop contributed to understanding the features of interventions that are important to people with MS. These features will be considered in the discussion chapter.

Chapter 8 Discussion

8.1 Introduction

This chapter focuses on the discussion related to the two parts of the study and results presented in chapter six. The aim is to discuss the development of Mii-vitaliSe (chapter four) and the processes of the pilot study (chapter five). The discussion will be presented as a review of the study aims and objectives.

8.2 Development of the Mii-vitaliSe resource materials

The first aim of this PhD was to develop the Mii-vitaliSe intervention and associated materials with service user and health professional involvement. A strength of this study was the rigorous way in which Mii-vitaliSe was developed in line with MRC guidance (Craig et al. 2008) for the development of complex interventions and drawing upon the existing evidence base. Tickle-Degnen notes that ‘planning intervention research takes creativity and innovation’ (2013, p.171). This doctoral study allowed the time to fully engage with all processes of the research including learning how to use the Wii™ myself, attending training in MI, supporting the physiotherapists to use it and incorporate MI and also delivering the Mii-vitaliSe intervention.

The consultation workshop formed an important part of the development of the Mii-vitaliSe intervention and influenced the research (Baxter et al. 2001). The consultation workshop involved careful planning and preparation which, as Gooberman-Hill et al. (2013) states, takes time. Investing this time was effective and resulted in developing a meaningful relationship with service users that enriched the consultation workshop and the subsequent pilot study (Nierse et. al. 2012). It provided opportunities for attendees from the workshop to be approached on other occasions. The service users who attended the workshop had prior experience of using the Wii™. This therefore provided perspectives from those individuals with some familiarity with the equipment which may have been a weakness. Seeking the views of individuals with no experience would more clearly represent the eligibility criteria for the pilot study and thus offer further insights.

Process evaluation is a crucial part of developing and piloting a complex intervention (Moore et al. 2015). The MRC process evaluation guidance advocates that good working relationships are required with stakeholders (Moore et al. 2015). In the Mii-vitaliSe study relationships were developed with the workshop attendees and during the development of the intervention and these continued during the pilot study. Two of the workshop attendees joined a project steering group ensuring that service users could continue to influence the study at all stages (Hanley 2000).

Quotations from the service user consultation workshop were included in the Mii-vitaliSe resources allowing participants in the study to gain insights from others. Learning from others (vicarious experience) has been noted to be important for enhancing self-efficacy (McGrane et al. 2014). The Mii-vitaliSe physiotherapists noted in the interviews that when they were delivering Mii-vitaliSe they drew upon these quotations as well as their own experiences.

Technology moves at a fast pace and the Wii™ is no longer in use and has been superseded by the Wii U™. The Wii U™ workshop (chapter seven) offered an opportunity for some participants to make comparisons with the Wii™ and the Wii U™ which was used in the workshop. This suggests that as technology continues to move at a rapid pace continued consultation and collaboration with people with MS will be important to inform future research.

Promoting fidelity (the extent to which the intervention was delivered as intended) in the developmental phase of the current study involved creating the detailed Mii-vitaliSe resource materials and schedules for the orientation sessions. One of the aims of these resources was to standardise the delivery of the intervention. Service users from the Mii-vitaliSe steering group helped to refine the materials and a service user from the consultation workshop tested the materials prior to the pilot study. These processes improved the clarity and detail of the resources.

Guidance for process evaluations recommends documenting the intervention to produce a full and complete representation (MRC 1998) so that the intervention can be replicated. In the pilot study the Mii-vitaliSe intervention has been reported (Table 4-2) using the TIDieR checklist (Hoffmann et al. 2014). The MRC guidance suggest that a logic model can be helpful to report ideas about how the intervention

works and represent the structures put in place to deliver the intervention (Moore et al. 2015). A logic model includes details regarding who the intervention is targeted for and the content of the intervention which can be documented using the TIDieR checklist. A logic model also documents the target population, the intervention outcomes, mechanisms of change and impact (Wolpert et al. 2016). In this study the intervention mechanisms relate to getting fitter by participating in physical activity which may also have an impact on how a person manages their MS. The mechanisms also relate to the behavioural aspects of Mii-vitaliSe (e.g. the factors that support individuals to engage with physical activity). In this study a logic model was not used but many of the components of the logic model were carefully considered during the developmental phase. In a future study the use of a logic model would be an advantage to document what is expected to be achieved and how the intervention will lead to the expected outcome, (Moore et al. 2015). Therefore a logic model has now been developed for Mii-vitaliSe illustrating the target population, mechanisms of change and impact (Table 8.1).

The use of a logic model allows for consideration of how the intervention will lead to the expected outcomes. In this doctoral thesis consideration of the academic literature identified the importance of supporting self-management and the inclusion of behavioural change techniques to facilitate engagement and long term adherence in interventions that use the WiiTM. Reviewing the literature also identified key uncertainties e.g. barriers to exercise for people with MS, injuries with using the WiiTM and guidance on activity levels for people with MS.

Table 8-1: Mii-vitaliSe logic model

Problem	Evidence base	Resources	Pilot study outcomes	Full trial outcomes
People with MS are engaging in insufficient levels of physical activity	Preliminary evidence suggests that active gaming can help people with MS to become more active Ways to foster intrinsic motivation are needed	Mii-vitaliSe intervention:- Resource materials Orientation sessions Physiotherapist support Behaviour change techniques	Increased use of Nintendo Wii™ Increased levels of physical activity Improvements in measures of walking endurance, gait, static and dynamic balance Mii-vitaliSe successfully piloted to assess feasibility for a future RCT	Increases in levels of physical activity Increases in confidence to do physical activity

Guidance for using a logic model suggests the need for a theoretical framework as the basis for an intervention. However, interventions that incorporate behaviour change techniques have been criticised for not identifying a theoretical framework (Howlett et al. 2017). In order to support researchers to design behaviour change interventions in a more systematic manner Michie et al. (2014) developed a Behaviour Change Wheel. The COM-B model of behaviour is a key element of the Behaviour Change Wheel and represents capability, opportunity and motivation as drivers to influence levels of physical activity (Cane et al. 2012). The capability construct refers to aspects of gaining knowledge and regulating behaviour which can be supported with the provision of activity guidelines, action planning and self-monitoring. The opportunity construct refers to the social and environmental influences which include support for exercise behaviour and overcoming barriers. The motivation construct refers to a person's belief about their capabilities (self-efficacy) and beliefs about the consequences (goal setting and action planning). Although the COM-B model of behaviour did not inform the development of Mii-vitaliSe its three components are consistent with the drivers identified from the literature review.

8.3 Assess the feasibility of conducting a future trial

The second aim of this PhD study was to assess the feasibility of conducting a future definitive trial. This section discusses how this was achieved referring to the four objectives within this aim (Section 3-12) and considers the design and conduct of a future trial.

8.3.1 Objective1

Screening procedures

Developing thorough screening processes is an important aspect of pilot studies (Tickle-Degnan 2013). The self-reported APDDS scale (Orme et al. 2007) was used as part of screening in this study to assess mobility levels. The EDSS is a neurologist administered assessment which is much broader than the APDDS as it incorporates functional systems (such as visual, sensory and pyramidal) (Kurtzke 1983).

Although this has the potential to be more objective (because it is completed by a trained clinician rather than self-reported) there would be cost implications for the study and this could potentially be a slower screening method. The EDSS has been used as a screening tool in other studies using the Wii™ balance games for people with MS (Nilsagård et al. 2013; Prosperini et al. 2013). Nilsagård et al. (2013) report that EDSS scores were not available for some participants in their study suggesting that this may be a potential barrier. Since the start of this study a nurse-led assessment of EDSS via telephone has become available and been found to be accurate within half a point of a physician face to face EDSS assessment (Huda et al. 2016). Any health care professional can complete the online training and therefore the EDSS no longer requires completion by a neurologist. This would be a recommendation for a future study.

In the APDDS scale scores above three refer to levels of mobility but in this study participants reported difficulties in completing the items on the APDDS which related to mobility. This study has shown the limitations of completing the self-administered questionnaires at home due to the need for supporting potential participants with the completion of the questions so that they can understand the questions and accurately answer them (Tickle-Degnan 2013). However, administrating questions via an interviewer raises other issues about assessor bias.

The inclusion and exclusion criteria form an important part of the screening process and it is key to consider if they are too broad or restrictive (Tickle-Degnan 2013). In this study, the fact that cognitive impairment was not an exclusion criterion meant that the eligibility criterion were inclusive. Qualitative feedback from people with MS and physiotherapists described how some of the Wii Fit™ balance games are both cognitively and physically demanding (Forsberg et al. 2015). People with MS with severe cognitive impairment were excluded in another study using gaming technologies (Brichetto et al. 2013). Including individuals with cognitive impairments in clinical trials is important so that consideration of the cognitive impairments that prevent full participation in an intervention can be understood. By including some participants with mild cognitive impairment in this study insights into the challenges of completing the research and participating in the intervention have been gained (e.g. additional support might be needed).

In summary the difficulties described by participants regarding the completion of the ADSS need to be considered for a future trial. The strategies to assist people with cognitive impairments will need to be included in the Mii-vitaliSe intervention. Health care professionals can be trained to complete online training for the EDSS and this could then be used as an outcome measure for disease severity.

Recruitment and retention

In this study the aim to recruit 30 participants was achieved by having regular contact with the Dorset MS Service. This raised awareness of the study and allowed for the identification of potential participants who could then be sent an invitation letter. Similarly, attendance by researchers at physiotherapy clinics (Carter et al. 2015) and support groups (Plow and Finlayson 2011) has been shown to be an effective recruitment strategy in studies involving exercise for people with MS.

A personal invitation letter from a consultant neurologist was used to invite people to participate as this is known to play an important part in patients' decision-making about involvement in research studies (Lindbald et al. 2011). A response rate of 44% was achieved and a sub-theme that emerged from the qualitative data analysis described the sense of confidence participants had in the research team. Nilsagård et al. (2013) conducted a multi-centre trial that invited people with MS to participate in

a programme of balance exercises using the Wii™. Participants were identified via the national MS register and four participating centres in Sweden and sent an invitation letter. This approach targeted a breadth of people with MS in Sweden yielding a response rate of 47%.

Not all UK hospital trusts have consultant-led multi-disciplinary MS service and therefore other recruitment strategies will be necessary in a future RCT. These may be via MS (Prosperini et al. 2013) or outpatient centres (Brichetto et al. 2013) and via national MS registers (Plow and Finlayson 2011; Nilsagård et al. 2013).

Recruiting from a national MS register may not be feasible due to the wide geographical area covered. These routes are less personal than the personal invitation letter but may be necessary for recruiting from non-consultant-led multi-disciplinary service and will need to be taken into account when considering centres for a future trial.

The option of using the Wii™ as part of an intervention may be attractive to participants and may account for the recruitment rates in studies using the Wii™ with people with MS (Nilsagård et al. 2013; Prosperini et al. 2013). In the current study there was a slow start to recruitment in the first three months (Table 6-2). However, during both February 2013 and May 2013 nine participants were recruited to the study. Nilsagård et al. (2012) recruited 84 participants from four centres during an 11 month recruitment period (average seven per month). During a five month recruitment period Prosperini et al. (2013) recruited 45 participants (average nine per month). In the current study, fewer participants were recruited during public holidays (Christmas, New Year and Easter). Any recruitment strategy will be limited by public holidays and other factors. The recruitment rates from the current study suggest that it was possible to recruit at a rate similar to other researchers in the field. The recruitment rate of nine participants per month from one recruitment centre can be used to estimate the length of time needed to recruit participants for a future trial.

A limitation of the sample in the current study was that all participants were white reflecting local demographics and mostly female (80%). The predominantly female sample reflects the fact that MS is more common in females than males (Mackenzie et al. 2014). Other researchers testing interventions for increasing activity in people with MS have also had predominately female samples (Stroud et al. 2009; Plow and

Finlayson 2011; Paul et al. 2014; Carter et al. 2015). In the current study, strategies for targeting males were considered during recruitment. These included purposely trying to identify and sample males who were eligible to participate in the study by discussions with the MS team. This occurred after the first few months of recruitment once it had been noted that the sample was predominately female.

Despite this, only three (10%) were recruited. Recruitment strategies for attracting a higher percentage of males into a future study will need to be considered and could involve consulting with service users and further discussion with the multi-disciplinary team.

Plow and Finlayson (2011) report that five participants with MS commenced other activities (e.g. an exercise class) after participating in the Wii™ intervention. Data from the interviews in the current study suggest that the Wii™ intervention did provide this ‘gateway’ to people with MS. This message, that an intervention using the Wii™ can be a ‘gateway’ to other physical activities would need to be clearly emphasised in a PIS for a future study, to ensure that participants are recruited with this in mind.

The ability to recruit people to research is also dependent on ensuring the recruitment criteria are feasible. The qualitative data from this study illustrate some of the barriers to using the Wii™ and some of these relate to the complex and variable nature of MS (McConnell 2008). These barriers did not suggest that adjustments needed to be made to the inclusion criteria during the recruitment phase. However, they do illustrate the factors that need to be considered when facilitating people with MS to exercise with the Wii™.

It is important to consider if people who consented to participate in this study were different from those who did not and therefore establish if there is any recruitment bias. The presence of any factors that affected recruitment must also be considered and the potential bias produced. The reasons for participating in a study may be related to an individual’s personality, their interests and availability. In the current study the reasons for consenting to participate could have been due to wanting to please the Dorset MS team. The team identified eligible people and gave them information about the study and then it was up to the individuals to make a decision

about whether to find out more by contacting myself. This separation between the clinical team and the research team was intentional to minimise any bias.

In summary, study recruitment was successful and provided a potential recruitment rate for a future study. Retention to the study was good and participants found both the hospital-based assessments and the self-administered questionnaires relevant and completion rates were high.

Data collection processes

Objective one was also to refine the selection of outcome measures in preparation for a future trial. Developing rigorous processes for data collection are an important aim for feasibility studies. Tickle-Degnen (2013) suggests the need to reflect on data collection procedures which in this study included the administration of questionnaires and hospital-based assessments.

The factors that contributed to participants completing the assessments included accountability and the opportunity to be monitored and assessed. Monitoring is an important aspect in the management of LTCs (Plow and Finlayson 2011). In this study participants were accountable to the research co-ordinator so that they could be clearly informed about the processes for the study and timely completion of questionnaires and assessments. The times for the hospital-based assessments were carefully planned to minimise variability. However, participants chose when they completed the self-administered questionnaires and the actual time for completion was not recorded and many completed them over several days to take into account MS symptoms such as fatigue. In a future trial a more standardised approach could be adopted although this may result in poorer completion.

The gait cadence and two minute walk test were conducted on half of the sample due to issues of participant burden identified when the protocol for the physical assessments was compiled. There were no issues with the processes for conducting these tests. The use of the activPAL3™ to measure activity worked well providing activity data over seven days for the majority of participants. The instructions would need to be amended based on the feedback provided by participants. The activPAL3™ could be administrated by post.

Adherence

The MRC process evaluation guidance advocates that the quantity of an intervention implemented (the dose) is assessed (Moore et al. 2015). The Mii-vitaliSe intervention encouraged people to exercise using the Wii™ in small blocks of 10 minutes aiming to work up to three 20 or 30 minute blocks a week or more. The play logs indicated that participants recorded a minimum of one and a maximum of nine 10 minute blocks with the Wii™ per day. These results are encouraging given that there is evidence to support that one of the barriers to exercise for people with MS is time due to other commitments including work (Stroud et al. 2009).

The play logs yielded quantitative data on patterns of play and the data from the interviews complemented and qualified these data. These data provide insights into the context and processes of use of the Wii™. An RCT using Wii Fit Plus™ with people with MS successfully used a logbook for recording Wii™ use and adverse events for a 12-week intervention (Prosperini et al. 2013). In the current study completing a play log daily for one year could have been thought to be burdensome and for this reason it was completed in a simpler form in the second six months. The qualitative data suggests that while some participants in the immediate group really missed the play log when it was replaced by a simpler diary, others preferred the simpler version. Asking people to self-monitor their behaviour by logging use or non-use of the Wii™ in the play log seemed an important means to keep people engaged with the intervention.

The play logs therefore played an important part in the assessment of adherence to the intervention. As already discussed participants invested effort into completing the play logs and there was a high response rate which yielded valuable data. Participants recorded goals in the Activity Workbook but a limitation of this study was that these data were not collected for the research. However, these aspects were explored in the interviews. In summary, the use of the Wii™ came close to the recommended activity guidelines for people with MS (Latimer-Cheung et al. 2013).

Risk assessment and safety

The need for a risk assessment when using active gaming in rehabilitation has been highlighted (Ravenek et al. 2016). Nilsagård et al. (2013) gave participants an

opportunity to become familiar with the Wii™ balance board but did not complete a detailed risk assessment, possibly because the intervention was fully supervised. An APDDS score of 5 implies the ability to walk 100-200 metres often with a stick or some form of support implying that participants in the study with a score of 5 would have balance problems. The home risk assessment was undertaken because Mii-vitaliSe was a home-based intervention that involved the unsupervised use of the Wii™, and also to provide information about the feasibility of installing the equipment in people's homes as recommended by Plow and Finlayson 2014.

The initial risk assessment was adapted (by including information about participants' televisions) after the first eight participants had been recruited in response to feedback from the physiotherapists. This ensured that an appropriate cable was taken to the Wii™ set-up home visit. This risk assessment will be a valuable tool for a future study as well as a resource for therapists to use when considering the suitability of the Wii™ for people with MS.

Findings from other research using the Wii Fit™ balance games reported that participants perceived the pace of some games to be challenging (Forsberg et al. 2015) and the board too small (Plow and Finlayson 2014). Plow and Finlayson (2011) reported that the most popular exercises used by participants in their study were the balance exercises using the Wii™ balance board. In the current study the balance exercises were also widely used which supports the need for a risk assessment to be undertaken and for physiotherapist support when undertaking challenging balance activities.

Injuries using the Wii™ are usually as a result of too much gameplay (Taylor et al. 2011) and the authors of a systematic review regarding the safety of exercise for people with mild to moderate MS advise that researchers monitor and report adverse events (Pilutti et al. 2014). The current study carefully monitored adverse events and the amount of gameplay. None of the adverse events was serious and most were similar to those reported by other researchers e.g. knee or low back pain (Prosperini et al. 2013; Plow and Finlayson 2011). This contributes to the understanding of safe exercise for people with MS using the Wii™ and also illustrates that the thorough process in place to monitor and report on adverse events in this study worked well. This was important in this study from a feasibility and safety aspect but in a future

trial adverse event reporting would more likely be focussed on reporting serious adverse events.

Plow and Finlayson (2011) reported that participants in their study found adaptations to support safe use of the Wii™ (e.g. placing a chair in front of the board while playing challenging games or modifying yoga poses that require standing on one leg by placing the other leg on the floor next to the balance board). One of the sub-themes that emerged from the analysis of data in the interviews describe adaptations for making games safer. This indicates that therapists can tailor the Wii Fit™ exercise programmes to meet the individual needs of people with MS to minimise risks. Examples of how therapists can achieve this could be included in the Mii-vitaliSe resource materials based on the qualitative data from this study.

In summary, safety was paramount in this study and is an important aspect in the development of a complex intervention (Craig et al. 2008). The design of the Mii-vitaliSe intervention and study processes reflected this emphasis on safety with eligibility limited to those who were ambulatory, an initial risk assessment undertaken, the inclusion of orientation sessions held at the hospital and the provision of ongoing physiotherapist support. This study has shown that using a detailed and thorough risk assessment has allowed for people with MS (some of whom with balance problems) to exercise safely in their home using the Wii™ balance board.

Issues that limit scaling up to a definitive trial

This was a single centre study and therefore the practicalities for the co-ordination of a multi-centre definitive RCT with usual care comparator need to be considered. There would be a range of models of care in different centres and therefore mechanisms for control for the differences in normal care across the participating centres would need to be considered. When selecting participating centres using some with the same model of care as this study would be beneficial if possible.

The key messages to consider for a future study would be the aspect of accountability to a research co-ordinator which seemed important to participants but also to achieving the administrative processes of the research study. The implications for a scaled up RCT are that it would be very important to have a blinded assessor to

reduce bias and to be able to control for the differences in usual care across different participating centres. The completeness of the data suggests that the data collection processes in this study were successful and transferable to a future trial. With a larger sample size and multiple centres the practicalities of study co-ordination would need to be considered to ensure that the administration is carried out according to the protocol and standard operating procedures.

8.3.2 Objective 2

The second objective was to calculate preliminary effect sizes and estimates of SDs to inform the sample size for future trial.

Hospital based assessments

In order to measure the effectiveness of an intervention outcome measures that are able to detect clinically meaningful changes are required. The descriptive statistics from the broad range of outcomes collected and qualitative feedback will be discussed and recommendations made for outcome measures for a future trial.

In this study the iTUG was used which despite some initial technical equipment problems this was an easy test to perform. The standardised effect size for the iTUG was 0.41 in the direction of benefit for the immediate group at 6 months. This was the largest standard effect size for the hospital-based assessments at 6 months. The aim of the study was not to show effectiveness but to calculate preliminary estimates of effect size. The iTUG involves a combined knee and hip movement together with turns that challenge balance. The data collected from the play logs showed that many of the games frequently used involve movements that incorporate combined knee and hip movements with balance. Participants in the interviews reported physical benefits, including having more confidence when walking, improved stamina and generally feeling that they could move better.

The TUG was used as a primary outcome measure in a multi-centre trial evaluating the effects of a balance programme using the Wii Fit™ in people with MS (Nilsagård et al. 2013). In comparison to a control (non-exercise group) the TUG produced a moderate effect size (0.35) in the direction of benefit. The Cognitive TUG, which asks the person to perform the TUG while subtracting three from a number chosen at random, was also used by Nilsagård et al. (2013) producing a

moderate effect size. Plow and Finlayson (2011) used the standard TUG and TUG with three variations (head turns, stepping over boxes and dual tasks) in a pilot study to evaluate the benefits of the Wii Fit™ balance games in people with MS. The rationale for using the TUG variations was due to the fact that the games in the Wii Fit™ intervention require well-timed reactions and dual tasks. The results of their pilot study suggest a positive effect in the direction of benefit following the intervention.

Standing on one leg is an advanced balance activity, and standing for 60 seconds is part of the steady stance tests that assess postural stability. In the current study participants were required to hold these stance positions for 60 seconds but an assessment of 30 seconds could also have been considered (Smithson et al. 1998). The results of these tests shown in Table 6-8 illustrate that feet together stance was the easiest test and for all the other tests (apart from the stride standing left in front of right) the mean time (if participants were not able to complete the full 60 seconds) was less than 30 seconds. This suggests that 30 seconds may be a preferred time for testing the stance tests and that ‘feet together’ may not be a relevant test in this sample as a ceiling effect was achieved. Many of the games in the intervention (e.g. the yoga) did involve challenging balance exercises with a varying base of support and therefore these stance tests replicated the intervention demands.

In the current study balance was also measured using posturography equipment to measure static balance and limits of sway. Other researchers (Prosperini et al. 2013; Brichetto et al. 2013) have used force platform-based measure of static standing balance similar to the posturography tests used in the current study. Prosperini et al. (2013) reported a significant improvement in centre of pressure force plate measures following a 12 week home-based balance intervention using the Wii Fit™ balance games. Similarly, Brichetto et al. (2013) reported a significant improvement in postural assessments (limits of sway with eyes open and eyes closed) using a stabilometric platform following 12 sessions using balance exercises from the Wii Fit Plus™. The advantage of posturography tests is that they may be more sensitive to small changes in balance and therefore reduce the variability of assessments. However, the disadvantage is that they require hospital-based equipment and may require two assessors which is time consuming and has cost implications.

Normative data for the NHPT states that most individuals complete the test in 18 seconds (Mathiowetz et al. 1985). In this study, the mean time taken to complete the NHPT was greater than 18 seconds at all three tests in both groups suggesting that participants in the current study did have some dexterity problems. The purpose of the Mii-vitaliSe intervention was to improve general whole body activity and it so it was not an upper limb specific intervention. The Wii™ remote is sometimes used to mimic actions (such as swinging a tennis racquet or baseball bat) requiring movement of the upper limb through a larger range of movement and co-ordination. The standardised effect size for the NHPT was not in the direction of benefit in the current study even though participants were using the Wii™ remote which involves dexterous co-ordinated hand and arm movements. However, identifying objective measures that are sensitive to capture changes in upper limb function over a large range of symptoms in a complex disease like MS remains a challenge.

The Action Research Arm Test (ARAT) was used in the TWIST trial (Adie et al. 2017) to assess the ability to handle objects and test grasp, grip, pinch, and gross movement of the elbow and shoulder on the weaker or affected side. The advantage of this test is its ability to assess gross movements of the arm similar to those played in the Wii™. The disadvantage is that it takes longer to complete and requires training for the assessors. The ARAT test has been used in studies with people with MS where most participants in the study had a score of 53/57 reaching the ceiling for this outcome (Lamers et al. 2015). This suggests that it is not a very satisfactory outcome

Since the protocol for the feasibility study was designed (Thomas et al 2014) guidelines have been published for core outcomes to include in exercise trials for people with MS (Paul et al. 2014). The TUG and six-metre walk test are recommended both requiring assessor administration. Ideally in a future trial avoiding or reducing the requirement for people to attend the hospital for assessments would be preferable. This would reduce the inconvenience and fatigue that participants talked about in the interviews relating to the hospital-based assessments. In a RCT with a usual care comparator it would be challenging to undertake the TUG or a timed walking test blinded in the home, as the Wii™ equipment might be visible in the homes of those allocated to the Mii-vitaliSe group.

In summary, all the balance and gait outcome measures were able to be completed according to the protocol except when there were problems with the equipment used at the hospital-based assessments. The iTUG produced the largest standardised effect size and considering the nature of the intervention, and previous research could potentially be a primary outcome measure for a future trial. The iTUG could be administered at home which would avoid the need for participants to attend the hospital for assessments. The use of the activPAL3™ to measure activity worked well and participants provided feedback regarding how the instructions could be improved.

8.3.3 Objective3 (pilot study)

Objective three was to determine participants' views on taking part in the pilot study to explore the acceptability of the study design. The qualitative data from this study suggested that participants tended to accept allocation to the delayed group and saw it as being part of the research process. Nilsagård et al. (2013) reported that several participants in their multi-centre trial were disappointed when allocated to a non-exercise control group. This disappointment led them to start exercising independently.

Participants in the current study generally had an altruistic view of being involved in research with a view to helping other people with MS. They stated that they would be willing to be involved in a pragmatic study design with usual care comparator. One option may be to offer group sessions for the control group at the end of the intervention period so those randomised to usual care are given a Wii™ taster session. This may however mean that if long term follow-up data is collected participants would have to wait at least 12 months for the taster session.

Forty per cent of participants in the study were in paid employment and therefore the feedback about the venue and times for assessment and orientation sessions needs to be noted. The convenience of the Wii™ may appeal to those currently working as it offers flexible options for exercise at home. In the current study, some participants took annual leave so that they could attend appointments underlining the importance of offering appointments at a range of times. This may have resource implications and also may affect the assessments as participants may be more fatigued if assessed after work. It is important that the designs of future active gaming trials do not

preclude the participation of those in employment. The completion of assessments in the home environment could be an option but this would impose challenges for blinding the assessors, as the Wii™ is likely to be visible. Limiting outcome measures to self-reported ones would mean that people do not have to attend the hospital for appointments.

In summary, the design of the pilot study was perceived as acceptable to participants despite some reporting initial disappointment when allocated to the delayed group. A usual care comparator was thought to be acceptable for a future trial.

8.3.4 Objective 3 (feasibility and acceptability of Mii-vitaliSe)

Objective three was also to gather participants' feedback about the Mii-vitaliSe intervention. In-depth qualitative data can provide insights regarding how the intervention ran in the pilot study and helps to identify issues that may need to be addressed for scale up to a definitive trial (Moore et al. 2015). The use of qualitative methods to capture participants' experiences of the intervention at two time points (six months and one year) was useful to offer insights into the longer term use of the Mii-vitaliSe (Moore et al. 2015). The ways that the Mii-vitaliSe intervention sought to engage and motivate people with MS and to improve adherence will be discussed and recommendations made for the future refinement of Mii-vitaliSe.

Plow and Finlayson (2011) suggested the need to incorporate behavioural change strategies for encouraging habitual use in future research with the Wii™. This fits with a framework the Behaviour Change Wheel for characterising and designing interventions. The COM-B framework sits at the hub of the Behaviour Change Wheel (Cane et al. 2012). The COM-B framework suggests that there are three drivers that influence behaviours (capability, opportunity and motivation). A retrospective consideration of these drivers enables reflection of their influence on physical activity when reviewing Mii-vitaliSe.

Fidelity is the extent to which an intervention was delivered as intended (Moore et al. 2015). The qualitative interviews with the participants and physiotherapists provided indications as to whether the intervention was delivered as intended and if it was acceptable both from the perspective of people with MS and the facilitators. Quantitative data from the play logs also provided indications regarding if the dose

of the intervention was as intended. All the Mii-vitaliSe sessions were delivered as planned and the physiotherapists completed work sampling forms (Thomas et al. 2017). Having someone who knows how to deliver the intervention in the way it was intended is also important. In this study I had been involved in the development of the intervention and also the delivery. Fidelity was also addressed by having a manualised intervention with detailed resource materials. A checklist could have been developed for facilitators to complete. This was not done in the current study because the intervention was manualised and the physiotherapists were completing work sampling forms. Some of the sessions could have been recorded and but this would have resource implications.

This next section will discuss the components of the intervention as described in the TIDieR template Table 4-2 in the context of the participants' views of the acceptability of the Mii-vitaliSe intervention.

Rationale of Mii-vitaliSe

Mii-vitaliSe draws upon psychological and physiotherapy theory and incorporates behavioural change and self-management techniques. Some participants in the current study talked about how they had kept practising and worked out for themselves ways to solve the problems they had encountered, suggesting that they were using problem solving skills. This suggests that they had taken responsibility which is an important aspect of self-management (Morgan et al. 2017). The capability component of the COM-B model describes that acquiring physical skills and ability may influence participation in physical activity (Howlett et al. 2017).

Supporting self-efficacy was a key aspect of the intervention and links to the motivation component of the COM-B model (Howlett et al. 2017). One source of self-efficacy is linked to the mastery of daily experiences. Participants in the interviews described how benefits from using the WiiTM had transferred into their daily lives and a sense of achievement when they were able to do things independently. The ability to problem solve and to find solutions to barriers was also noted by participants as well as the ways in which they had gained confidence. They talked about a sense of satisfaction with their achievements and the confidence to attempt further challenges. These examples suggest that self-efficacy was

strengthened in some participants and that supporting people with MS to gain confidence is important (Learnmonth and Motl 2015).

Mii-vitaliSe resource materials

This section includes a discussion regarding the Mii-vitaliSe materials provided to participants (Wii™ equipment and the resource materials) in the context of the results.

Wii™ equipment

Peer support and a person with MS as a role model have been identified as key facilitators for physical activity in MS (Learnmonth and Motl 2015; Ploughman 2017, Howlett et al. 2017). Several participants in the current study stated in the interviews that contacting others for peer support and encouragement would have been helpful to them. But this was a limitation of the Wii™ equipment used in Mii-vitaliSe. People at the Wii U™ workshop (chapter seven) liked the option of being part of an online community for peer support with others with MS. Therefore bringing in opportunities for peer-to-peer support and opportunities for linking with others would be a choice for people to have. This would enable those who wish to establish links to be able to do so while those who prefer to exercise on their own without these links could also continue to do so.

The data also provide insights into how people mastered using the Wii™ remote and nunchuk and the support and guidance they required to do so. Plow and Finlayson (2014) found that people with MS expressed concerns about learning to use the technology, but this related generally to the equipment and not specifically to the Wii™ remote and nunchuk. The data from the interviews in the current study suggest that generally when there were problems participants were able to overcome these by seeking help from either family members or the Mii-vitaliSe physiotherapists.

Bilateral exercises using the Wii™ software require both the Wii™ remote and nunchuk (e.g. archery, canoeing, cycling). Encouraging purposeful and meaningful bilateral activities is an important aspect of neurorehabilitation (Kleim 2011). The quantitative data from the play logs shows that games requiring the nunchuk were

not widely used by participants. The reason for this may be that participants perceived connecting the nunchuk as a challenge and therefore avoided the games that required it. This also has implications for training as more information regarding connecting and using the nunchuk needs to be included in the orientation sessions and Mii-vitaliSe resources. People would then have more confidence and support to engage in the games that require both the nunchuk and the Wii™ remote.

Making exercise fun and convenient has been identified as an important facilitator for physical activity (McAuley et al. 2007; Plow and Finlayson 2014). Findings from the current study support the previous evidence that the Wii™ is a fun and convenient way to exercise at home (Forsberg et al. 2015). For example, people can play ten-pin bowling with their family, which normalises life for them. The elements of immersion (Mellecker et al. 2013) link with the dimension of ‘entertainment’ offered by the Wii™. Immersion could be another reason why the use of the Wii™ for exercise is perceived as enjoyable as it offers an element of escapism and can act as a stress reliever. The detailed accounts from the qualitative interviews in the current study suggest that the fun aspects of the Wii™ are the features that provide feedback and encouragement, e.g. the Fit Piggy timer with its awards. These aspects of the intervention led to high levels of enjoyment and an altered perception of time (Robinson et al. 2015) which prevents boredom.

When exercising alone the haptic feedback and sound effects provided by the Wii™ provide an immersive experience. The importance of these extrinsic effects have also been noted when using Wii Sports™ in the context of home-based rehabilitation for people following stroke (Wingham et al. 2015). Other MS researchers have noted that the most highly rated perceived benefits were those related to improvements in physical health (Stroud et al. 2009; Learmonth and Motl 2015). This sense of personal accomplishment was noted by participants in the current study when they beat their previous scores or felt a sense of mastery from their achievements in using the equipment or playing games.

The aerobic exercises were frequently used in the current study and were also described as enjoyable by participants in the interviews. A Cochrane review suggests that aerobic exercise can be beneficial for people with MS (Rietberg et al. 2004).

Finding ways for people with MS to participate more regularly in aerobic exercise is, therefore, an important outcome.

The games that involve the balance board provide an interesting alternative to traditional balance exercises and incorporate built-in progressions, thereby reducing monotony. A systematic review of the effectiveness of balance and falls prevention interventions in people with MS suggests that effective interventions need to provide both variety, interest and sufficient challenge (Gunn et al. 2015) to prevent boredom and maintain adherence. The balance games in Plow and Finlayson's (2011) pilot study were reported to be the most frequently played games. In the current study, although some participants described concerns with using the Wii™ balance board the games were well used.

Resource materials

Prosperini et al. (2013) provided participants with a training protocol, which included precautions for using the Wii Fit Plus™ and the Wii™ balance board in their 12-week intervention. The Mii-vitaliSe resource materials offered a greater breadth of support, information and advice than their training protocol. The data show that participants used the Mii-vitaliSe resources in a variety of ways supporting the need to have a range of resources available to allow for an individualised approach.

In this study, the provision of advice via both the orientation sessions and resource materials was seen to be of value by participants and facilitators. Advice in the Guidance Book about how to start engaging in physical activity and encouraging the accumulation of activity in short bouts of time (DOH 2011) made targets more achievable. The interview data illustrate that some participants achieved 10 minutes each day. Since the Mii-vitaliSe resource materials have been developed, guidelines for physical activity for people with MS have been published and recommend 30 minutes of moderate activity twice a week and two sets of 10-15 repetitions of strength training twice a week (Latimer-Cheung et al. 2014b). These more specific recommendations for people with MS need to be included in the Mii-vitaliSe resource materials.

The provision of information regarding how an individual can make lifestyle changes is an important behaviour change technique in interventions that can potentially influence physical activity (McGrane et al. 2014). In the context of behaviour change and physical activity in MS, Learmonth and Motl (2015) note that people with MS want information from a variety of sources, e.g. a focus on the knowledge and benefits of exercise, types of exercise and success stories. The Mii-vitaliSe intervention did offer variety with both hard copy and the on-screen information provided by the Wii™ software and a breadth of information about exercising with the Wii™. The brief quotations from the consultation workshop provided examples and tips from people with MS.

The qualitative data suggest that using the Personal Activity Workbook to support goal setting was deemed helpful by participants. Plow and Finlayson (2014) reported that goals set in the context of using the Wii™ were both general (e.g. improving health and staying more active) and related to future aspirations (e.g. returning to the gym or dance class). In the current study, participants also described very specific short-term goals relating to the number of sessions a week and scores to achieve in specific games. The knowledge gained from these data will help to refine the Mii-vitaliSe resource materials as examples of goals from participants can be included.

The purpose of the Games Descriptors in the current study was to highlight to participants the therapeutic reasons for choosing the game and to indicate potential risks and limitations. In contrast Prosperini et al. (2013) used a system to rank games so that participants could start at a basic level and progress to an advanced level after four weeks. Data from the interviews suggests that the Games Descriptors achieved the aim for some participants, but there was also a sense that for some a demonstration was preferable to the description. A demonstration of some games was given at the orientation sessions, then participants found new games to try so they would refer to the Games Descriptors or the on-screen instructions. Elsworth et al. (2009) conducted focus groups with people with neurological conditions and reported that people with MS expressed ‘a fear of not performing the exercise correctly’ (page 19). This has also been noted by patients following a stroke (Jones et al. 2017). This concern may be linked with a fear of causing a worsening of physical symptoms if an exercise is perceived to be performed incorrectly. This

raises an interesting point that perhaps written guidance cannot replace a demonstration. This also supports the need for guidance from facilitators delivering the intervention as well as the written materials and the potential for video recordings to become part of the Mii-vitaliSe resources.

A particular surprise from the qualitative analysis was the fact that some participants had used the yoga games in the Wii Fit Plus™. Based on what was said at the consultation workshop there was a perception that these yoga games in the Wii Fit Plus™ were challenging. Furthermore, my personal perception was that the yoga games may be too difficult for the population in this study. For this reason the games descriptors indicated that these exercises required the user to have strength and balance and suggested that they were suited to people who regularly practise yoga. Despite this, a few participants seemed to find this set of exercises both feasible and enjoyable and therefore regularly used them as part of their routine. No serious adverse events were reported as a result of doing the yoga exercises. This suggests that the Mii-vitaliSe resources need to include a more positive focus for these exercises.

Mii-vitaliSe processes and procedures

This section refers to the orientation sessions and the ongoing physiotherapist contact and support. Home-based activities overcome some of the barriers that people with MS have to exercise. This was one of the drivers for the Mii-vitaliSe funded study and therefore if the Wii™ is safe to be used at home, it offers potential for doing activity at home providing people have been given the appropriate information and demonstration. Plow and Finlayson (2014) explored usability issues and reported that for some participants there were concerns about using active gaming technology. The Mii-vitaliSe orientation sessions were designed to alleviate such anxieties and provide an opportunity for people to try out and become familiar with the technology with physiotherapist support. Sixty per cent of participants in the current study had not previously used active gaming technology. People who are less familiar with this technology may need longer orientation sessions at the start and people with previous experience of using technology may need a shorter refresher session rather than starting from basics. This suggests the need to ask people about their previous experience of using technology to ensure that the appropriate level of

support can be offered. It is also important to note that new generations are likely to be increasingly more comfortable with technology.

Mii-vitaliSe mode of delivery

This section discusses the role of the Mii-vitaliSe physiotherapists. The findings from the current study suggest the need for more formal training in using the Wii™ so that the facilitators feel confident about setting up the equipment efficiently and about troubleshooting problems as they arise. The barriers associated with the usability of the Wii™ and the lack of familiarity of the therapists with the equipment were also noted by Forsberg et al. (2015). There are however cost implications for training NHS band six and seven specialist physiotherapists in setting up the equipment. Therefore when this study is scaled up it could be more cost effective to train NHS band three or four rehabilitation assistants in these set up procedures.

The qualitative data suggest that most participants were satisfied with the time they had with the physiotherapist. There is preliminary evidence suggesting benefits from the provision of regular physiotherapist supervision and monitoring (face-to-face and telephone) for people with MS when starting to use the Wii™ and when exercises are progressed (Prosperini et al. 2013). Provision of such support was a key aim of the Mii-vitaliSe intervention and findings from the current study suggest advice, support and monitoring of progress was helpful. There were no serious adverse events and the contact was valued by the participants.

Ongoing advice, support and monthly monitoring were offered by physiotherapists during the telephone calls. This was less frequent than in other studies using the Wii Fit™ balance intervention for people with MS in which participants were offered weekly telephone calls to encourage progression of exercises for 12 weeks (Prosperini et al. 2013) or seven weeks (Plow and Finlayson 2011). In the current study participants had first undergone the two orientation sessions and had the Mii-vitaliSe resources to refer to. The physiotherapist telephone calls offered individualised advice, encouragement and support for overcoming barriers. This monitoring encouraged accountability and supported participants to develop problem-solving skills.

The support offered by the physiotherapists received positive feedback but would be relatively costly to implement and therefore more cost effective ways to deliver this intervention need to be considered. These may include conducting initial orientation sessions in groups and using rehabilitation assistants (NHS band three-four).

Alternatively specialist physiotherapists could film the orientation sessions and these could be watched by participants. A section on frequently asked questions could be included based on the interview data. This could include aspects relating to the equipment e.g. connecting the nunchuk and also aspects relating to behaviour change e.g. how to overcome barriers, how to complete the Personal Activity Workbook.

An important motivation for continued use of the Wii™ that emerged from the interviews was a sense of accountability. This accountability could be to the Wii™, to the physiotherapists, to the research study, to oneself or a combination. For some participants external motivation became internalised over the course of the study. For example, initially they might have been motivated by wanting to please the physiotherapist but gradually over time, they started to use the Wii™ because they were enjoying it and it made them feel good. However, some participants described a sense of guilt or pressure if they had not been able to do what they had planned to. In such instances, the physiotherapists needed to provide reassurance. There was a fine line between accountability being a motivator and becoming an unhelpful pressure. In the future if the Mii-vitaliSe intervention becomes part of clinical practice in the NHS then people would no longer be accountable to a study team. Therefore, it is important to consider internal motivation and how to maximise the impact of behaviour change techniques in clinical practice.

Mii-vitaliSe participants

This was a novel intervention package which incorporated behaviour change techniques and the principles of MI as well as the balance and other exercises. Participants therefore had not previously been exposed to the treatment in this study even though some already had owned a Wii™ and had used it prior to their MS diagnosis. This suggests that the sample were treatment naïve and the physiotherapists noted in the interviews that facilitating Mii-vitaliSe was different from their usual practice.

One of the physiotherapists described how a participant became an expert in one of the Wii™ activities suggesting that they had practised for long enough to become very knowledgeable and experienced. This observation suggests that people with MS who become proficient in using the Wii™ may be able to offer peer support to others with MS or be filmed and the recordings made be included in the resource materials. This raises an important issue to consider, as the Mii-vitaliSe intervention is refined for future testing. It may not be possible for staff who facilitate the intervention to be ‘experts’ in all the Wii™ games and be aware of all the levels, but they will need the skills to motivate people to exercise and develop autonomy and internal motivation.

Mii-vitaliSe delivery time period

Mii-vitaliSe was delivered over approximately 12 months to the immediate group and six months to the delayed group. The Mii-vitaliSe physiotherapists completed forms indicating the duration of each of the sessions (both hospital based and follow-up sessions). These have not been presented in this thesis but can be found in Table S9 online web supplement 2 (Thomas et al. 2017). The mean contact time per person was 699.6 (158.16) minutes which means that an estimated cost of the intervention per participant was calculated to be £384 for physiotherapy time.

Tailoring

The intervention was tailored so that participants created individual action plans and goals and could select games to play from the wide range available. This individualised support and advice offered by physiotherapists encouraged accountability and provided opportunities to co-develop strategies for ongoing Wii™ use.

The hot British summers in 2013 and 2014 were cited as issues during the study. This links to the advice that people with MS need to be cautious about overheating, as heat can worsen some MS symptoms, such as fatigue. Plow and Finlayson (2014) note that participants in their study described using the Wii Fit™ as effortless and easy. This suggests that people were exercising at a low intensity and not working up sweat. The use of the Wii™ for low intensity exercise when the weather is hot may need to be promoted more and included in the training sessions and guidance resources to support users to overcome fatigue as a barrier to exercise.

Wii Sports™ and Wii Sports Resort™ formed part of the Mii-vitaliSe intervention package in addition to Wii Fit Plus™ rather than specifically focussing solely on the Wii Fit Plus™ (Plow and Finlayson 2011; Nilsagård et al. 2013; Brichetto et al. 2013; Prosperini et al. 2013). This offered a wider variety of ways for people to participate in physical activity enabling a person-centred approach to accommodate individual preferences. From the interviews an understanding of how people selected and used the software and games has been gained and also why some were preferable to others. Participants with cognitive impairments required additional contact and support suggesting that the intervention needs to be tailored to support those with memory impairments.

Adherence

Adherence was measured by the play logs. The mean use of the Wii™ approached guidance levels for physical activity for people with MS (Latimer-Cheung 2013b). Findings from the current study suggest that the Wii™ may play an important part in the process of self-monitoring and the daily play log assisted with these processes. In the current study, the play log formed a key part of the intervention helping people to self-monitor their use of the Wii™. The current study showed that the play log helped participants to identify the reasons why they were not exercising. This was an important component in overcoming barriers to exercise. The play log therefore had a dual purpose as a measure of adherence for the research and a way to facilitate self-monitoring. For those participants with memory problems it would be important to provide extra support and prompts for completing the play log.

In summary the Mii-vitaliSe resource materials gave a breadth of information to participants including health education, skills development and practice, goal setting and action planning; as well as details about exercising and safety precautions. This multi-faceted approach with physiotherapist support helped to increase people's confidence and autonomy in using the Wii™. The specific physical activity recommendations for people with MS (Latimer-Cheung et al. 2014b) need to be included in the Mii-vitaliSe resource materials.

The demonstrations of how to use the equipment and play the games in the orientation sessions by the physiotherapist were cited as particularly helpful. This

meant that participants did not have to read through all the instructions and could ask questions if they needed. The third home based session was challenging and therefore providing training for set up and ongoing technical advice would be recommended.

8.3.5 Objective 4

Objective four was to gather feedback from the physiotherapists about their experiences of delivering Mii-vitaliSe. The physiotherapists observed that most people performed better on the Wii™ in their home environment than in the orientation sessions at the hospital. This raises an interesting point regarding the venue for assessments in a future trial. The home may be the preferred option for convenience and also to ensure that participants are assessed in the environment where they engage with the intervention. However, it would be challenging to undertake assessments blinded in the home as the Wii™ equipment might be visible to those allocated to the Mii-vitaliSe arm of the trial.

Conducting orientation sessions in groups is more cost effective for clinical time. However, the qualitative data suggest that sessions with more than one person posed challenges for both participants and the Mii-vitaliSe physiotherapists. This was only tried out with two sets of participants and therefore it is difficult to draw conclusions from this. The potential for conducting orientation sessions with more than one person but would be worth discussing with service users.

In the current study, feedback from the Mii-vitaliSe physiotherapists suggested that the third home visit session (when the Wii™ equipment was set-up) was challenging and time consuming. This was to be expected initially until they became more experienced in the set-up of the Wii™, which improved as they conducted more visits. Forsberg et al. (2015) noted that physiotherapists supporting people to use Wii Fit™ balance games felt unsure about the technology. This suggests that it is important for facilitators to become familiar with the technology (both setting up and using the games). The lessons learnt from these set-up sessions provide information regarding developing training sessions for facilitators to set up the Wii™ in the future.

The physiotherapists mentioned that the telephone calls were easy and brief if participants were getting on well. It was important to reassure people if they were feeling guilty while still encouraging accountability. This is a difficult balance as noted with reference to the Blue Prescription programme (Mulligan et al. 2013), where meaningful support (which participants noted differed from other approaches) supported people with MS to take responsibility to increase their participation in community-based physical activity. An interesting point made by the Mii-vitaliSe physiotherapists is that they noted that the approach used differed from their usual practice.

In this study, the physiotherapists explained that developing a rapport and supportive relationship with participants was an important basis for motivating them to make plans to become more physically active. Ambivalence is a normal part of this partnership and the interviews gave insights into the reasons why participants were sometimes ambivalent. These included struggling due to other life events, or the fact that the Wii™ just did not suit them. In these situations skills for directing and guiding were used to support a person to make decisions, set goals and to support autonomy. The underpinning use of MI enabled participants to take a more active role in their rehabilitation and the physiotherapists to be less directive. There was also a sense from the participant and physiotherapist interviews that an individualised patient-centred approach underpinned the support offered.

Using MI skills alongside the Mii-vitaliSe resources offered support for participants to problem solve. For example, if someone was to say they were finding it hard to walk to the shops then the physiotherapist might link that to the Wii™ in terms of building up stamina. Sometimes it was necessary to be creative and to find out what works for people and their lifestyle (e.g. looking at the Wii™ as a tool for de-stressing rather than as a way of doing activity).

While the principles of MI informed the Mii-vitaliSe intervention, only one of the physiotherapists (me) had received formal training in the approach. Attending the MI course helped me to understand the ethos of MI and orientate the two Mii-vitaliSe physiotherapists to use the technique in the intervention. Feedback from the two physiotherapists suggested that formal training in MI should be incorporated into a future trial for all those delivering Mii-vitaliSe. The insights gained from the

interviews regarding how participants made the most of the guidance from the physiotherapists offers valuable insights into how people with MS and other LTC can be motivated to participate in physical activity interventions.

In summary, the physiotherapist support and use of MI and behavioural change techniques worked well. In the future formal MI training would be needed for facilitators.

8.4 Reflexivity

Reflexivity is the awareness of the researcher on their effect on the research processes. According to Forbes (2008) doctoral learning provides opportunities for reflexivity. This section discusses the influence that I as the researcher may have had in this study. My role as the Mii-vitaliSe research co-ordinator and dual role as researcher and Mii-vitaliSe physiotherapist may have had an influence on the research process.

The researcher needs to be aware of their influence on the study participants during the research processes and to take into account their involvement to prevent potential bias. The researcher also needs to be aware about their influence on the collection, analysis and interpretation of data. As an experienced physiotherapist I already held views and assumptions about physical activity for people with MS. I am an able bodied person and do not have a LTC, therefore my barriers to participating in physical activity differ to those of the participants in this study. In order to prevent these views being a potential source of bias an awareness of these assumptions was required. This occurred by questioning myself regarding my previous way of thinking, knowledge and experiences. For this reason a reflexive diary was used to note problems with the study processes and the intervention and potential reasons why they had occurred. The use of this diary then enabled me to maintain awareness and objectively and critically report issues at regular meetings with research supervisors and the Mii-vitaliSe steering group. This process allowed me as the researcher to be close enough to the study but also to be able to freely report to the wider research team.

Reflexivity also concerns how the research has influenced me. The process of carrying out this research as a doctoral student and the multi-faceted nature of my

involvement with the study has impacted my thinking about behaviour change and intervention development. The study has challenged my thinking around physical activity and the role of the physiotherapist and also the use of technology in supporting people with MS to become more active. In addition I have gained insight in intervention development, process evaluation and PPI.

The opportunity to work in BUCRU with an experienced research team during this doctoral study has offered a variety of learning opportunities. The particular learning points for me have been an opportunity to enhance my research skills and develop skills in clinical trial management and intervention development. The ability to draw from a range of disciplines and to attend training in MI and utilise this new skill in supporting the Mii-vitaliSe facilitators and carrying out the intervention has also offered a depth of learning.

8.5 Summary

In summary, the Mii-vitaliSe intervention package enabled participants to feel confident about using the Wii™ technology so that they could engage in independent home-based use. In general, participants gave positive feedback about the Mii-vitaliSe resource materials as well as offering helpful suggestions for improvements. The physiotherapists noted that there were differences between the delivery of Mii-vitaliSe and their usual physiotherapy practice. This was anticipated, given that Mii-vitaliSe was a novel intervention that incorporated behavioural change techniques and MI. Similarly, this is the first time that a Wii™-based intervention has been developed and tested in the UK so the detailed physiotherapist feedback is very useful.

Participant feedback is of value to gain understanding of how people engaged with the intervention to inform the ongoing development for a future trial. From this study, these are the factors that will need to be considered to refine the Mii-vitaliSe intervention.

The results of this study show that a randomised trial is feasible. The results of the pilot testing shows medium preliminary estimates of standardised effect sizes for the gait and balance measures in the direction of benefit for the immediate group at six months. This pilot study provides important information in relation to the feasibility

of a home-based exercise programme using the Nintendo Wii™ and appropriateness of the outcomes used.

Table 8-2: Summary of how the qualitative findings will inform the development of the Mii-vitaliSe intervention

- A longer orientation session initially for those less familiar with technology
- The use of the risk assessment by facilitators in the orientation sessions
- A refresher course at the start for those familiar with technology
- Include opportunities for peer support
- Include the guidelines for physical activity for people with mild/moderate MS (Latimer-Cheung et al. 2013b) in the resource materials
- Include more detailed information to support the use of the nunchuk for bilateral activities in the resource materials and orientation sessions
- Include information regarding the use of the Wii™ for low intensity exercise during hot weather
- Include more detailed stories from people with MS regarding their patterns of use and processes of use in the resource materials

8.6 Strengths and Limitations of this study

Strengths

1. A strength of this pilot study is the rigorous intervention development phase underpinned by the MRC guidance for the development of complex interventions (Craig et al. 2008) and the use of a pragmatic randomised controlled design with high external validity.
2. The intervention was developed in the context of the current evidence, drew upon the views of service users and incorporated behavioural change techniques. This approach has not been reported previously in the literature regarding the development of an exercise intervention for people with MS using the Wii™.
3. The consultation workshop was conducted in a systematic and rigorous way. Workshop discussions considered and informed aspects of the trial design and the Mii-vitaliSe intervention (e.g. the equipment, the supporting

materials, the role of the physiotherapist as facilitator). Obtaining the views of people with MS who were using the Wii™ helped to refine and optimise the intervention package.

4. Health-care is complex and acknowledges the need for different perspectives to build a whole picture. This randomised controlled pilot study incorporated a qualitative component and patient and public involvement throughout. A mixed methods approach enables quantitative findings to be qualified by qualitative data, giving a depth of understanding to the ways in which participants used the Wii™ and the barriers they encountered.
5. Findings from the workshop ensured that safety and practical issues related to the study and the Mii-vitaliSe intervention were considered from both clinical and service user perspectives. This has addressed a gap in the literature.
6. The MRC framework (Craig et al. 2008) advocates the need to use a strong theoretical basis for the intervention. The theoretical frameworks drawn upon were MI, social cognitive theory, cognitive behavioural and self-determination theory (Bandura 1997; Ryan and Deci 2000; Schwarzer et al. 2011; Miller and Rollnick 2013). This addressed the limitations of a previous pilot study (Plow and Finlayson 2011). The intervention was personalised with the Personal Activity Workbook offering a means to support people to structure and plan their exercise using the when, where and how of participation as outlined in the HAPA framework (Schwarzer et al. 2011). Findings from this pilot study have provided insights into using the Wii™ based intervention for this population and gathered estimates of the amount of physiotherapy support provided and the costs of delivering Mii-vitaliSe. These results will be vital in supporting future implementation of the Wii™ in interventions for people with MS. This study adds new knowledge to the current research in exercise for people with MS.

Limitations

1. A limitation of this sample was that all participants were white and mostly female. Recruitment strategies for attracting a higher percentage of males into a future study will need to be considered.
2. The study took place in one centre within a multi-disciplinary MS team, which is not typical of services available to patients across the UK.
3. This study was a small pilot study and therefore was not powered to test for effectiveness. Future research needs to be powered to detect a change in the primary outcome measure. This will mean that future studies need to utilise the recruitment strategies discussed earlier in this chapter based on the lessons learnt from recruiting to this study.
4. There was blinding of one assessor but both were not blinded to participant allocation.
5. Two of the outcome measures, the 2MWT and gait cadence test were not completed on all participants due to participant burden and therefore confidence intervals are particularly wide for these two tests.
6. The qualitative data do not include feedback from caregivers. Participants sometimes referred to their carers in the interviews, describing the competitions had and the impact that the Wii™ had on others.
7. Participants commented on encountering difficulties when completing the self-reported APDDS scale to rate their mobility. This may have led to errors and a lack of parity as some participants spoke to the research co-ordinator but not all of them. The most accurate way to do this would be by neurologist assessment but this would be time consuming, costly and not practicable.
8. The action and coping plans made in the Personal Activity workbook were not collected from participants. In the interviews with both participants and physiotherapist, these were noted but reviewing what they had recorded would have provided useful data.

Chapter 9 Conclusion

Table 9-1: Summary of key conclusions

Key conclusions:

- The Mii-vitaliSe intervention and the associated resource materials have been developed and successfully piloted to assess feasibility for a future RCT to assess the benefits of using VR interventions with people with MS.
- Mii-vitaliSe offers an acceptable, fun and convenient way for people with MS to increase physical activity.
- Mii-vitaliSe requires further evaluation with a larger sample size.

This research has achieved the aim of developing the Mii-vitaliSe intervention and the associated resource materials, with extensive service user and multi-disciplinary health professional involvement. Mii-vitaliSe is a unique intervention which supplements existing commercially available software (allowing people to choose which games they would like to do; strengthening, balance, aerobic and recreational) with physiotherapist support. The inclusion of behaviour change techniques and physiotherapist support using MI to foster ongoing engagement addressed some of the limitations of previous published pilot studies using the Wii™ with people with MS. This approach included the principles of self-management to support people to live well with their long-term condition by engaging in more regular physical activity.

This research has successfully piloted the Mii-vitaliSe intervention to assess feasibility for a future RCT. The pilot study has shown that the Wii™ is safe to use with people with MS. This thesis has presented data that will inform the conduct and design of any future study.

The current study has shown that the recruitment strategies used within the multi-disciplinary MS service were successful, except for the recruitment of males. The home risk assessment used at screening provided an opportunity to assess potential participants while at the same time offering reassurance to individuals about embarking on exercise. This was key, as safety was paramount given that participants would be using the Wii™ unsupervised at home. Retention in the study

was good, but this may have been connected to being provided with the Wii™ equipment at no cost to participants.

The processes for the collection of the questionnaire data and protocol for the administration of the hospital-based assessments worked well. There were minor issues with the equipment at the hospital-based assessments, with the collection of activity data using the activPAL3™ and with participants' interpretation of the mobility questions in the APDDS. Otherwise, there were no issues with data collection procedures and rates of missing data were low. The use of the Wii™ was good and produced increases in physical activity with some participants still using it at 12 months and others finding the confidence to do other physical activities.

In this study, adverse incidents were thoroughly monitored in a variety of ways. There were no serious adverse events and none of the recorded events was thought to be a major concern. The qualitative data regarding injuries and discomfort experienced by participants provide insights that will contribute to how physiotherapists support people with MS to use the Wii™.

All the hospital-based assessments, with the exception of the NHPT, produced a preliminary standardised effect sizes in the direction of benefit. The largest standardised effect size was achieved with the iTUG, which could potentially be a primary outcome measure for a future trial. Confidence intervals were wide due to the small sample size. This was a pilot/ feasibility study and therefore no conclusion about the effectiveness of the intervention can be made.

The feedback from participants regarding the study design and procedures suggest that these were considered to be acceptable. Randomisation to a delayed group was perceived as initially disappointing but at the same time acknowledged as acceptable. Participants generally had an altruistic view of being involved in research with a view to helping other people with MS. Most of those interviewed said they would be willing to be involved in a study with a usual care comparator. Participants found the hospital-based assessments acceptable and expressed interest in them. Some found them tiring and those in full-time employment noted they were inconvenient. The qualitative data suggests that the instructions securing the ActivPAL3™ could be clearer.

Participant feedback in this study provided insights into how the Mii-vitaliSe intervention was used. They valued the orientation sessions and found them helpful. The majority of participants engaged with the intervention and participant feedback concerning the resource materials was that they were well written, relevant and useful in the early stages when initially starting to use the Wii™. The Guidance Book was used as a resource, the Personal Activity Book for setting and adapting goals and the Games Descriptors to select games. Participants also gave suggestions for additional content they felt would be relevant to include in the resource materials. The play log was perceived as motivational and formed an important part of the intervention. The telephone calls were perceived as supportive, but participants valued the face-to-face support and contact with the physiotherapists.

Participants talked about some problems with the equipment (e.g. caution with the balance board and occasional difficulty with the nunchuk) but these were minor and could be resolved. Some participants suggested that contacting others to share experiences and offer support would be useful. The Nintendo Wii™ did not offer this facility but technology continues to move at a rapid pace it is important to consider innovative ways of doing so.

Participants in the study reported how they had engaged with the intervention giving examples of plans they had set, games they had played and the process for using the Wii™. A wide range of physical and psychological benefits were described as well as attributes of the Wii™ that enhanced adherence and motivation. Some barriers associated with the Wii™ equipment were described. These qualitative findings give insights into the ways people engaged with this novel intervention. As VR and active gaming technologies continue to be used in rehabilitation these insights can be applied.

Feedback from the physiotherapists delivering Mii-vitaliSe was that they liked the novel approach of the Mii-vitaliSe intervention. Based on the feedback from participants and the Mii-vitaliSe physiotherapists the hospital orientation sessions worked well and they had a preference for individual 1:1 sessions. As part of the first orientation, they used some of the screening risk assessment so that they could assess the safety of the person on the balance board. They found some of the home visits challenging and time consuming, particularly if there were technical difficulties.

They also found some of the follow-up telephone calls challenging but this related to the practicalities of contacting people within NHS working hours. They suggested that there was scope to simplify and possibly combine the resource materials to make them easier to use in the orientation sessions. They felt that the Wii™ provides opportunities for therapists to tailor Wii™ exercises to meet individual needs, goals and circumstances. The study shows that the Mii-vitaliSe intervention package appears promising for people with mild to moderate MS symptoms and that future research is warranted.

9.1 Contribution to science

The main research question stated in this thesis in Section 2.11 has been answered. A novel home-based intervention for people with MS using the Wii™ that incorporates physiotherapy and psychological approaches has been developed. The two aims presented in Section 2.11 have also been met. The Mii-vitaliSe intervention and its associated resource materials were developed using a rigorous approach, which included service user input and the MRC framework for complex interventions. Once evaluated in a full-scale trial, the intervention could make a contribution to the management of patients with MS. This development work was essential preparation for achieving the second aim which was to pilot the Mii-vitaliSe intervention to assess feasibility for conducting a full-scale trial. The study protocol has been published in BMJ Open (Open Access) (Thomas et al. 2014) and cited in a review of gaming technology in the Multiple Sclerosis Journal (Taylor and Griffin 2015). This could impact the design of future research in this field; the knowledge arising from this feasibility work will help inform the design and conduct of similar feasibility studies and full-scale trials.

Through being involved in this study, I have gained experience in developing and piloting an intervention and in MS research. I have received training in MI and gained experience of using it with participants in the trial and supporting two physiotherapists to use it as part of the Mii-vitaliSe intervention. The combination of motivational strategies with active gaming technology in the Mii-vitaliSe intervention has contributed to my experience as a physiotherapist and will enhance my professional practice and teaching to undergraduate physiotherapy students.

9.2 Recommendations for future research

As a result of this study, further areas have been highlighted for future research. The results suggest that a full scale RCT would be feasible, although active gaming technology has now moved on (but the Wii™ can still be purchased). The results and approach used will be applicable to other active gaming technologies and VR as it continues to evolve.

Based on the qualitative findings the Mii-vitaliSe resource materials could be simplified. More cost effective ways to deliver the intervention also need to be considered. This could be by using band 3 or 4 rehabilitation assistants with physiotherapist supervision. The first orientation session could be conducted as a group intervention offering the facility for people to find a buddy or form a community for peer support and motivation. A Mii-vitaliSe website would also offer opportunities for peer support, encouragement or asking questions.

Regarding the design of a future trial, an appropriate control group is required. The 6-month delay was deemed to be acceptable but a longer delay less so which limits the possibilities for measurement of long-term outcomes. As the intervention has a monetary value, being randomised to usual care may lead to disappointment and affect recruitment. An option may be to offer group sessions for the control group at the end of the intervention period so that they are given a taster of the Wii™.

For a future trial there needs to be a primary outcome measure. A variety of physical and psychological benefits were reported by participants in this study which means that finding a primary outcome measure is complex. The iTUG produced the largest preliminary standardised effect size of all the hospital-based outcome measures, is clinically meaningful and easy to conduct in the home. The use of the activPAL3™ to measure activity worked well, providing activity data over seven days for the majority of participants. The instructions would need to be amended based on the feedback provided by participants. This would avoid the need for participants to attend the hospital for assessments.

9.3 Conclusion

1. Recommendations for clinical practice:- Mii-vitaliSe intervention has promise in helping physiotherapists to deliver care, and in helping people with MS manage their condition.
2. Recommendations for future research:- it is feasible to proceed to a main RCT with modifications to the protocol and intervention based on these results. This vital preparatory work has paved the way for achieving the best possible design for a future study. References

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Appendices

Appendix 1: Samples from the Mii-vitaliSe resource materials

From the Guidance Book

5. A guide for starting to exercise

An activity guide for Wii Sports™, Wii Sports Resort™ and Wii Fit Plus™

You'll be given Wii Sports™, Wii Sports Resort™ and Wii Fit Plus™ software games. These are discs that you insert into the Wii™ console.

Wii Sports™ includes:

- Tennis
- Baseball
- Bowling
- Golf
- Boxing

Wii Sports Resort™ consists of:

- Sword play
- Wakeboarding
- Frisbee
- Archery
- Basketball
- Table tennis
- Golf
- Bowling
- Power cruising
- Canoeing
- Cycling
- Air sports

Wii Fit Plus™ uses the balance board and consists of:

- 9 balance games
- 9 aerobic exercises
- Training plus - 15 activities for improving balance, strength or aerobic capacity
- Yoga exercises - for stretching and strengthening
- Strength training exercises

You'll have an opportunity to discuss with the physiotherapist which games you'd like to practise regularly. This will be based on the activities you tried out with the physiotherapist at the hospital orientation session and your own goals and preferences.

The physiotherapist will give you some **Games Tables** that contain descriptions of all the games and how to play them along with possible benefits and safety advice. It's important to read the description for the game you'd like to try (see **Games Tables**) before you attempt the game. There is space so that you can jot down anything you need to bear in mind when doing the activity, problems you encounter, things you are unsure about etc.

Preparation for exercise

- Wear clothing that doesn't restrict movement and is comfortable. Layers can be helpful as you can remove them as you get warmer.
- Exercise in a comfortably cool room. Remember to drink water before, during, and after exercise.
- Don't exercise when you have just eaten a big meal and try not to exercise when you are hungry. It's best to leave at least an hour after a meal before exercising.

- If you find that fatigue is particularly troublesome by the end of the day then you may find it better to exercise in the morning when energy levels are higher.
- If you work then it may be best to exercise on your days off or in the evenings after having a rest after work. You may need to experiment with different times/routines until you find one that suits you.
- If your fatigue is never the same from one day to the next you might need to be quite flexible with your routines.

We asked some people with MS what would be the best times to use the Wii™. As you can see everyone is different, but most avoided afternoons. It's about finding out what works best for you.

Well for me it would be using it in the morning when the kids are at school.

I find I'm more alert at night between 6 & 10pm.

From a fatigue point of view my best time would be midday-ish or late morning as towards the end of the afternoon the fatigue really kicks in.

For me it would be weekends as I'm at work all week and don't really feel like doing anything when I get home in the evenings.

I have to do it straight away when I get up or after I've had a 20 or 30 minute rest.

I go regularly to the local MS centre and do physiotherapy and Pilates. I find that if I'm feeling quite fit after I've done that then I'll do the Wii™ at home.

In the evenings I find I am too tired. I use it during the day when I'm fresher.

From the Personal Activity Workbook

Session 2: Having a go on the Wii™ with support

Training/individual assessment at hospital

Warm up and cool down exercises

Section 5 in the **Mii-vitaliSe Guidance Book** (page 9) is a guide for starting to exercise and provides some guidance on warming up and cooling down.

The physiotherapist will discuss with you how to get started with your exercises. Make a note of any specific warm up/cool down activities that you need to do.

My warm up and cool down exercises for shoulders, neck, back, wrists and hands:

Individual orientation session with the physiotherapist

It's important that the exercises you start off with are right for you and your abilities as well as your personal preferences. In this session you'll have a chance to try out some games and exercises with support and guidance from the physiotherapist.

Make a note here of the ones you enjoyed and would like to practise again.

Games/exercises I have tried today and enjoyed are:

An example of a Games Descriptor

Wii Fit Plus™ Games Descriptions

NAME OF GAME	DESCRIPTION	NOTES (participant or physiotherapist)
Balance Bubble	<p>Aim Safely navigate your <u>Mii</u> down a river in a bubble, avoiding being 'popped' by river edge, rocks, walls, stinging bees.</p> <p>Benefits Improved balance and coordination, reactions, concentration and leg strength. You'll also make the small muscles in your feet and ankles work hard which can help your balance and walking.</p> <p>How to play Move your <u>Mii</u> gently down the river by moving in all four directions on the balance board. Lean forward (weight towards toes), backward (weight towards heels), left (weight towards left leg) and right (weight towards right leg). Speed increases by time spent in a shifted position. Lean back to slow down your <u>Mii</u>. Keep movements small and controlled. If you hit anything the game is stopped and you can try again.</p> <p>Safety tip Requires small movements in all directions to move your <u>Mii</u>. If necessary hold onto a stable object (or relative/friend) for support. Take care when leaning backwards, ensure there are no sharp objects nearby (preferably a sofa behind for a soft landing). Try not to get too frustrated if you hit the rocks or river edge or if the bee stings you. Remember you are exercising by moving your <u>Mii</u> even if you don't feel you are moving far. Working on the slow movements can be really beneficial even if you don't make it to the end of the course.</p> <p>Scoring Based on time to complete activity. You are given 90 seconds to complete the river course. If your bubble is popped your score will be given in yards. If you complete the course your score will be given in time.</p> <p>Game duration: Up to 90 seconds</p> <p>Progression: Unlock advanced level by completing beginner level.</p>	

Appendix 2: Participant Information Sheet HEADED NOTEBOOK

Information about the Research

Mii-vitaliSe Feasibility Study: Testing the safety and feasibility of using the Nintendo Wii™ home gaming system to increase activity levels, vitality, and well-being in people with multiple sclerosis: a pilot randomised controlled study.

Chief Investigator: Dr Sarah Thomas

Study Physician: Dr Charles Hillier

Study Statistician: Professor Peter Thomas

Study Researcher/Coordinator: Louise Fazakarley

We are inviting you to help us with our research. Before you decide whether or not you would like to join our pilot study, we would like to explain why we are doing this research and what we would be asking you to do.

These information sheets are yours to keep. Please take time to read them carefully, and talk to others about the study if you wish. If there is anything that is not clear, or if you would like to find out more, you can contact the study researcher, Louise Fazakarley. Take time to decide whether or not you would like to be involved. If you do not wish to take part this will not affect your NHS care.

Part 1 tells you the purpose of this study and what will happen to you if you take part. **Part 2** gives you more detailed additional information about the study.

PART 1

Why are you asking me?

You have been invited to join this study because you have multiple sclerosis (MS) and have reported to the Dorset MS service that you are currently not exercising regularly.

What is the purpose of the study?

It can sometimes be difficult for people affected by MS to keep active due to factors such as fatigue, lack of confidence, transport and lack of suitable facilities. It can often be difficult to begin and stick with exercise programmes at home.

We are interested in exploring whether the Nintendo Wii™ home gaming system with physiotherapist support (Mii-vitaliSe) offers a safe and acceptable way for people with MS to become more active at home.

What is the intervention you will test?

Mii-VitaliSe intervention

This is a recently developed home-based programme designed to support people with MS to use the Nintendo Wii™ at home.

The Wii™ equipment (including balance board and remote controls) and software will be provided at no cost to participants for the duration of the study.

It consists of:

Session 1: Orientation to the Nintendo Wii™ at the Poole Hospital

In this first session the physiotherapist will give a practical demonstration of the Wii™, Wii Sports™ and Wii Fit Plus™ and you will have a chance to become familiar with the controls. You will be given a Guidance and Resource pack and individual activity workbook.

Session 2: Training and Individual assessment

You will be shown how to do warm up and cool down exercises and will have a chance to try out activities under supervision. The physiotherapist will devise an individualised activity plan with you.

Session 3:

The researcher will install a Wii™ in your home and will go through an individualised programme of activity with you.

You will then be encouraged to continue to use the Wii™ independently at home with physiotherapy support (home

To find out whether the Mii-vitaliSe intervention could be a beneficial addition to the usual care that people with MS receive, we would need to carry out a much larger study called a randomised controlled trial (RCT). However, before we can be sure that such a trial is possible we need to carry out a much smaller study called a feasibility study. This is what we are inviting you to take part in.

Will everyone who joins the study receive the Mii-vitaliSe intervention?

Yes, everyone will receive the Mii-vitaliSe intervention.

However, half those who take part will receive the Mii-vitaliSe intervention as soon as the study starts (IMMEDIATE Mii-vitaliSe) while the other half will receive it after a period of 6 months (DELAYED Mii-vitaliSe).

Those assigned to the DELAYED Mii-vitaliSe group will be asked to continue their usual lifestyle, health, and exercise routines and refrain from using the WiiTM for 6 months.

Allocation to these two groups will be decided by a computer that has no information about those enrolled in the study. It is the computer equivalent of tossing a coin and there is an equal chance of being allocated to either group.

This means that if you are eligible for the study and decide to take part you will not know which group you have been assigned to until after you have decided to join the study.

Who is this study suitable for?

You must be at least 18 years old, have a suitable television in your home, have a diagnosis of MS and currently be doing less than five bouts of 30 minutes of physical activity per week. You must be able to walk 100 metres without mobility aids or rest, and be able to read and understand English.

Is this study suitable for everyone who has MS?

There are some people for whom it might not be appropriate; for example, if

- you have had an MS relapse within the past 3 months requiring corticosteroids
- you are already participating in exercise/rehabilitation research
- you have a medical condition that means that exercise using the WiiTM is not appropriate (for example problems with your heart and/or lungs)
- you already use a WiiTM regularly (weekly or more)

Will my decision whether to participate or not have any impact on my treatment or care?

If you decide you do not wish to take part this will not affect your normal medical care, nor influence your chance to participate in any other research study.

Do I have to take part?

No. It is up to you to decide whether to take part. We ask you to take your time to think about what you'd like to do. If you decide you would like to find out more please complete the questions enclosed relating to your mobility and activity levels and return these with the enclosed Reply Slip within two weeks. The Study Researcher/Coordinator (Louise Fazakarley) will contact those who have expressed an interest in participating to discuss the study in more detail and answer any questions. If, for any reason, or at any time, you decide you no longer wish to be involved in this study you are free to withdraw without needing to give a reason. This would not affect the standard of the care you receive.

If I volunteer what will happen next?

Assessment of suitability

If you are interested in participating in this research we will telephone you to discuss the study and give you a chance to ask any questions that you have. We will ask you several questions to help us to decide whether it is appropriate for you to take part in the study.

If you are eligible and are still interested in participating, we will make an appointment to visit you at home to do a safety and suitability assessment. This is to assess whether the Mii-vitaliSe intervention is appropriate for you and whether the layout of your home is suitable for the Wii™ equipment.

Consent

Providing that the physiotherapist considers it is appropriate for you to take part, and if you still wish to participate, we will ask you to sign a consent form that says you agree to be assigned to either of the two groups ('immediate' or 'delayed' Mii-vitaliSe).



You will then be enrolled into the study. You will be sent a signed copy of your consent form to keep.

What would taking part involve?

Assessment 1 (start of study, after joining the study)

The first assessment will take place after you have given consent but before you are randomised and will consist of the following:

1. QUESTIONNAIRE BOOKLET (HOME)	2. ActivPAL™ ACTIVITY MONITOR (HOME)	3.PHYSICAL ASSESSMENT (HOSPITAL)
	 	

1. Completing a questionnaire booklet

We will give you a questionnaire booklet to fill in. It will contain questions about your activity levels and attitudes towards physical activity, your mood, confidence, your general well-being and use of health services. It will take approximately 40 minutes to complete and you can complete it at home at your own pace and bring it with you to the hospital assessment.

2. Wear an ActivPAL™ Physical Activity Logger for 7 days.

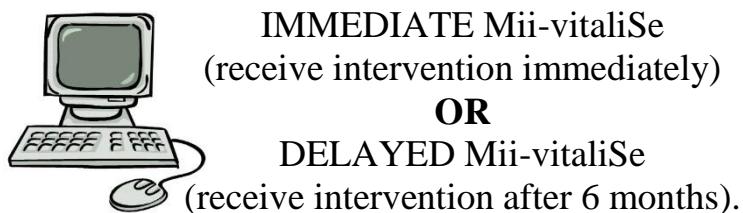
This is a small lightweight device worn on the thigh that records physical activity. We will give this to you and ask you to wear it for 7 days. It records your activity levels and if you are sitting, lying or standing and walking. We will ask you to bring it with you when you come for your hospital assessment visit.

3. Assessment of walking, balance, & hand function (at Poole Hospital).

This will involve undertaking some tasks to assess your walking, balance and hand function. A senior physiotherapist and senior medical scientist will do these assessments. Your visit will take approximately 1 hour and light refreshments will be provided. Transport (taxi) to and from the hospital will be provided (or a reimbursement for mileage if you prefer).

Randomisation

You will be randomly allocated (randomised) via a computer that is independent from us to either:



We will write to you to let you know which group you have been allocated to (see page 3 for description of the two groups).

Assessment 2 (6 months after start of study)

These will take the same format as Assessment 1 (Questionnaire booklet at home, ActivPAL™ activity monitor at home, physical assessments at hospital).

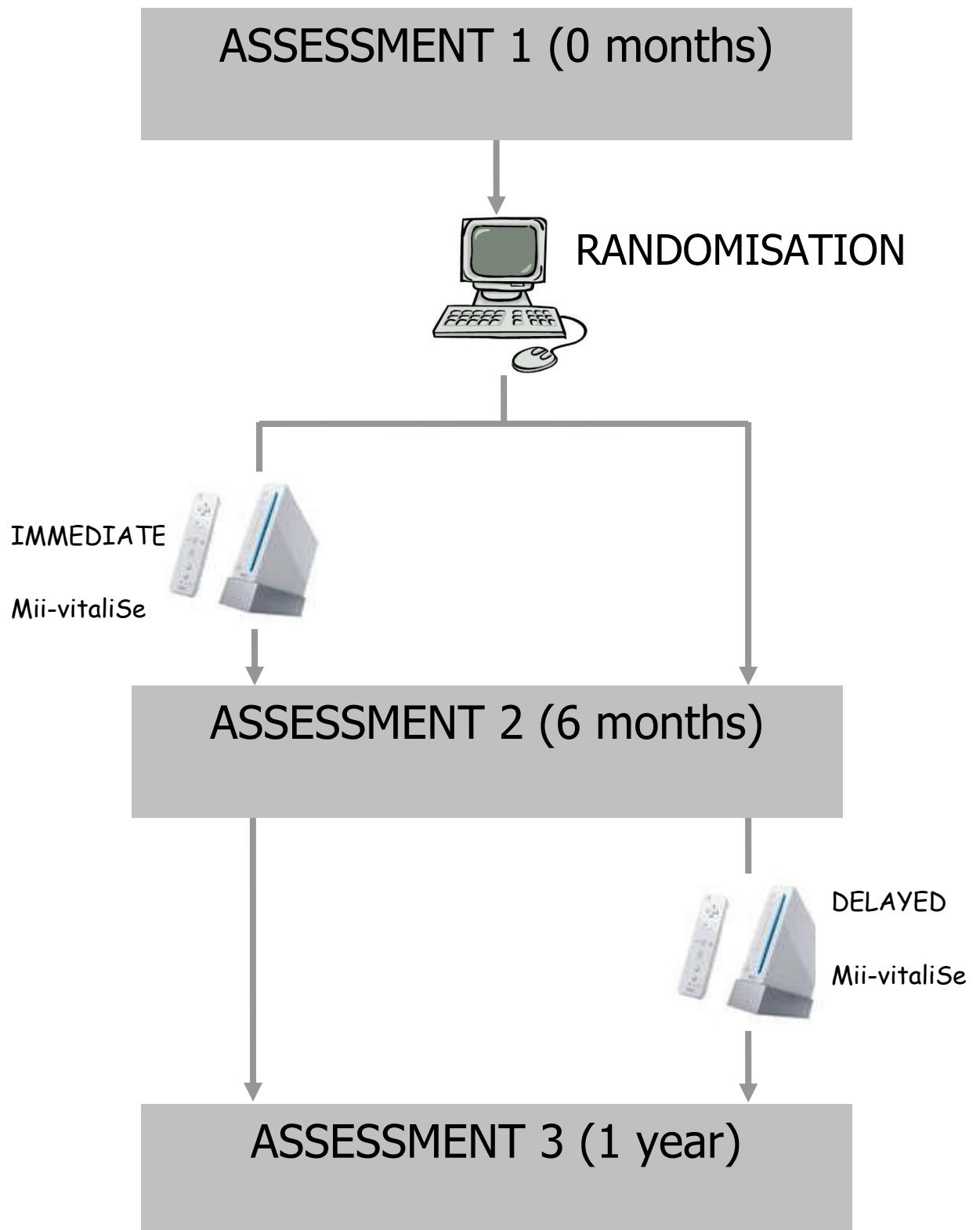
Assessment 3 (12 months after start of study)

These will take the same format as Assessments 1 and 2 (Questionnaire booklet at home, ActivPAL™ activity monitor at home, physical assessments at hospital).

Interviews

At the end of this study, 15 people who have taken part will be selected to be interviewed by the study researcher to get a range of perspectives about experiences of taking part. These interviews will last no longer than 60 minutes and will be arranged at a mutually convenient time. Interviews will take place either face-to-face in the home or over the telephone depending on individual preferences. The interviewer will be a member of the research team who is not involved in your usual care. Interviews will be audio recorded so that no information is missed.

Study summary



Travel arrangements

Taking part in this project will involve some trips to the hospital. Travel to and from the hospital will be provided.

What are the possible disadvantages of taking part?

Taking part in this research will involve a commitment to using the Wii™ at home on a regular basis and also keeping a brief daily diary to record Wii™ use.

As with any physical activity there is a small risk of injury from using the Wii™. However, the physiotherapist will give participants detailed guidance about how to use the Wii™ safely to minimise this risk.

Telephone support will be provided on a monthly basis to monitor progress and offer advice about any difficulties encountered.

Participants may experience some mild muscle ache and fatigue initially which is normal when introducing a new physical activity into daily life. The physiotherapist will give participants advice on pacing activity and review individuals' programmes so that they can continue safely and with minimal discomfort.

Participants may also experience increased fatigue initially; however, in the longer term being more active can help reduce the impact of fatigue and other MS symptoms.

Some of the automated feedback provided by the Wii™ may be distressing for some participants. As the Wii™ was originally designed with a healthy population in mind, one of the aims of this study is to explore whether people with MS find this feedback appropriate and acceptable.

What are the possible benefits of taking part?

Taking part in this study may help participants to become more active but we cannot guarantee this. Individuals may find exercising using the Wii™ more interesting than traditional exercise routines. This pilot study will help us to find out whether the Wii™ can be used safely by people with MS and is an acceptable way to increase activity levels. This study may lead to a larger trial that would enable us find out whether using the Wii™ can be beneficial for people with MS. Even if being involved in the research does not benefit participants directly now, it may provide benefit to participants and others with MS in the future.

What if something goes wrong?

Any complaint about the way you have been dealt with during the study will be addressed. Detailed information on this is given in Part 2.

Will my taking part be kept confidential?

Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

What next?

If you feel that you may be able to help us with this research, you can find out more about the study by returning the enclosed **Reply slip** along with your answers to the two questions asking about your activity levels and mobility.

Please do not hesitate to get in touch if you wish to discuss any aspect of this study, before you decide whether to volunteer or not.

Do not worry if you are not able or do not wish to volunteer to help with this study as we realise that it may not be convenient for everyone. If you do not wish to volunteer please complete and return the decline slip to let us know that you do not wish us to contact you about the study again.

If you would like to find out more about what taking part in research studies involves from a local source you can contact the

Health Information & Resource Centre, Poole Hospital NHS Foundation Trust

http://www.poole.nhs.uk/health_information_and_resource_centre/index.asp

Tel no.: 01202 448003 or drop-in facility Monday to Friday, 9.30 a.m. - 4.p.m.

Patient Advice and Liaison Service (PALS), Poole Hospital NHS Foundation Trust

http://www.poole.nhs.uk/contact_us/pals.asp

Telephone: 01202 448499 with confidential answer phone;

email:pals@poole.nhs.uk

This completes Part 1 of the information about the research. Thank you for taking the time to read about this project. If the information in Part 1 has interested you and you are considering participation, please continue to read the additional information in Part 2 before making any decision.

PART 2

What if relevant new information becomes available?

Sometimes during the course of a research project new information becomes available about the treatment that is being studied. If this happens, a member of the research team will tell you about it and discuss whether you would like to or should continue to take part in the study. If you decide not to carry on, the usual care you receive from the Dorset MS service will continue. If you decide to continue in the study you will be asked to sign an updated consent form. Occasionally, on receiving new information the research team may consider it to be in your best interests to withdraw you from the study. They will explain the reasons and your usual care with the Dorset MS service will continue. If the study is stopped for any other reason, you will be told why and your care will continue as usual.

What will happen if I don't want to carry on with the study?

If, for any reason, or at any time, you decide that you no longer wish to be involved in this study you are free to withdraw without needing to give a reason. Deciding to withdraw from the study will not affect your usual NHS medical care at all. If you were to withdraw from the study we would use the data collected up to your withdrawal with your permission.

What if there is a problem?

If you have a concern about any aspect of this study you should ask to speak with the researchers who will do their best to answer your questions. Please call 01202 448617 at Poole Hospital Foundation Trust. If there is no-one available to talk to you when you call, please leave a message and someone will call you back as soon as possible. If you remain unhappy and wish to complain formally you can do this through the NHS Complaints Procedure (or Private Institution).

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 be able to take legal action, but you may have to pay your legal costs. The normal National Health Service complaints system will still be available to you (if appropriate). You can access this by contacting the Patient Advice and Liaison Service (PALS) on 01202 448499.

Will my taking part in this trial be kept confidential?

All information that is collected about you during the course of the trial will be kept strictly confidential within the study's research and clinical team. No questionnaire will contain your name or any identifying details, only a trial number. This means that only the authorised members of the

research team will know which information is yours. Questionnaires will be sent out by, and returned to, Louise Fazakarley the Study Researcher/Coordinator who is based at Bournemouth University but has an honorary contract at Poole Hospital. All completed questionnaires will be stored at Bournemouth University in a secure locked cabinet for a period of 5 years after the end of the trial and then destroyed.

All electronic data will be kept on a secure computer and access to the data will be secured by use of specific passwords known only to authorised persons within the research team. We will ensure that you are not named in any publications that may result from this research.

If you agree to participate we will write to your GP to let him/her know that you are taking part in this study.

Sections of your medical notes may be looked at by authorised members of the research team where it is relevant to your taking part in this research project.

What will happen to the results of the trial?

At the end of the study the results will be reported on the Bournemouth University Clinical Research Unit website:

<http://blogs.bournemouth.ac.uk/bucru>

We will send you a copy of the final report if you would like us to. You will not be identified in any reports or publications.

Who is organising and funding the research?

This study has been funded by a project grant from the Multiple Sclerosis Society. This funding helps pay the salaries of some of the researchers involved; whether or not you agree to participate will not affect how much the researchers are paid. Nobody gets paid a fee for signing you up to this study.

Who has reviewed the trial?

To protect your safety, rights, well-being and dignity all research in the NHS is looked at by an independent group of people, called a Research Ethics Committee. This trial has been reviewed and given a favourable opinion by the South Central- Southampton B Research Ethics Committee.

Further information and contact details

You can contact the study researcher/coordinator for more information about this trial or to discuss being involved in the study.

Louise Fazakarley
Study Researcher/ Coordinator
Poole Hospital NHS Foundation Trust
Longfleet Road
Shaftesbury House
Poole
BH15 2JB
Direct Line: 01202 448617

You may also find the following websites helpful:

- The National Research Register - UK database of research projects
<http://www.nihr.ac.uk/Pages/NRRArchive.aspx>
- INVOLVE - Promotes public involvement in the NHS.
<http://www.invo.org.uk/>
- MRC Clinical Trials Unit - Advice for potential participants including lists of trials and questions that people may wish to ask researchers.
http://www.ctu.mrc.ac.uk/about_clinical_trials/taking_part_in_a_trial.aspx
- Current Controlled Trials - Information about ongoing international randomised controlled trials.
<http://www.controlled-trials.com>

Who is involved in the research?

The researcher team includes the following:

Dr Sarah Thomas (Chief Investigator)

Senior Research Fellow, Clinical Research Unit, Bournemouth University.

Professor Peter Thomas (Study Statistician and Methodologist)

Professor of Health Care Statistics and Epidemiology, Clinical Research Unit, Bournemouth University.

Louise Fazakarley (Study Researcher/coordinator)

Physiotherapy lecturer, Bournemouth University

Sarah Collyer (Mii-vitaliSe Physiotherapist)

Senior Physiotherapist specialising in MS, Dorset MS Service, Poole Hospital NHS Foundation Trust

Sarah Brenton (Mii-vitaliSe Physiotherapist)

Senior Physiotherapist specialising in MS, Dorset MS Service, Poole Hospital NHS Foundation Trust

Dr Charles Hillier (Study Physician)

Consultant Neurologist and lead clinician for Dorset MS Services, Poole Hospital NHS Foundation Trust

Dr Steve Perring (Performance-based assessments)

Registered Clinical Scientist, Poole Hospital NHS Foundation Trust

Professor Kate Galvin (Study qualitative adviser)

Professor of Health Research, School of Health and Social Care, Bournemouth University

Rebecca Scott (Wii™ expert)

Physiotherapist and creator of Wiihabilitation website

<http://wiihabilitation.co.uk/>

Service users

Two people with multiple sclerosis and experience of using the Wii™

**Thank you for taking the time to read these Participant
Information Sheets**

Appendix 3: Consent Form



Bournemouth
University

Mii-vitaliSe Feasibility Study: CONSENT FORM

Participant ID number:

STUDY RESEARCHER: Louise Fazakarley

1. I confirm that I have read and understood the information sheet dated 23/11/12 [Version 003] for the above study and have had the opportunity to ask questions.
2. 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.
3. I understand that sections of any of my medical notes may be looked at by authorised clinical members of the research team from Poole Hospital NHS Foundation Trust where it is relevant to my taking part in research. I give permission for these individuals to have access to my records.
4. I am aware that my GP will be informed about my participation in this study.
5. I understand that the researchers will hold my name and address at Poole Hospital and Bournemouth University for the purposes of sending me questionnaires and contacting me for study-related purposes.
6. I understand that if I am interviewed as part of this project it will be audio-recorded.
7. I understand that direct quotations from interviews may be included in publications provided that anonymity is preserved.
8. I agree to take part in the above study.

Name of Participant

Date

Signature

Name of Person taking consent
[if different from researcher]

Date

Signature

Name of Researcher

1 for participant; 1 for researcher; 1 to be kept with Dorset MS Service notes

Date

Signature

Appendix 4: Ethics Committee Approval letters



NRES Committee South Central - Southampton B

Bristol REC Centre
Level 3, Block B
Whitefriars
Lewins Mead
Bristol
BS1 2NT
Tel: 0117 342 1384
Fax: 0117 342 0446

20 December 2012

Dr Sarah Thomas
Senior Research Fellow
Poole Hospital NHS Foundation Trust
Bournemouth University Clinical Research Unit
School of Health and Social Care
Bournemouth University
BH13LT

Dear Dr Thomas

Study title: Mii-vitaliSe: a pilot randomised controlled trial of a home gaming system (Nintendo Wii™) to increase activity levels, vitality and well-being in people with MS.
REC reference: 12/SC/0420
Amendment number: 1
Amendment date: 29 November 2012
IRAS project ID: 1369

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Participant Consent Form	002	23 November 2012
Participant Information Sheet	003	23 November 2012
Protocol	003	23 November 2012
Notice of Substantial Amendment (non-CTIMPs)		05 December 2012
Covering Letter		29 November 2012

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

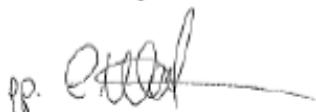
The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

12/SC/0420:

Please quote this number on all correspondence

Yours sincerely



Professor Ron King
Chair

E-mail: nrescommittee.southcentral-southamptonb@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Mrs Sarah Chessell, Poole Hospital NHS Foundation Trust*

NRES Committee South Central - Southampton B

Attendance at Sub-Committee of the REC meeting by correspondence

Name	Profession	Capacity
Professor Ron King - Chair	Mathematician (Retired)	Lay
Mr Alan Smith	Barrister's Clerk (Retired)	Lay Plus

Appendix 5: Risk assessment

Mii-vitaliSe risk assessment

Name	
Date of home visit	
Subjective assessment	
History of instability	
History of near falls	
History of falls	
History of gait instability	
Vertigo/dizzy feelings/low BP	
Visual problems ? bifocals	
Sensory disturbance -feet	
Ataxia	
Medications for heart, BP, tranquillisers or sedatives	
Taking 4 or more meds	
Other comments	

Objective assessment	
Ability to stand unsupported	
Ability to maintain independent static standing balance with eyes open for a minute	
Demonstrate adequate balance reactions while on Wii™ balance board	
Weight transfer forwards and backwards and sideways	
Movement of upper limbs while maintaining balance	
Ability to step off safely	
Step off forwards	
Step off backwards	
Step off sideways Left Right	
Comments /risks	

Home environment	
Position of TV	
Space for Wii Balance board	
Hazards with furniture, lights etc	
Pets /children	
Adequate light	
Temperature of room	
Suggested environmental modifications	
Analysis	
Actions	

Appendix 6: Protocol for Hospital Based Assessments

Mii-vitaliSe balance and gait assessments

Since the assessments involve provoking instability in participants, this method is likely to induce overbalance in some patients. Care should be taken to ensure patient safety at all times:

- Tests carried out in medical physics department at Poole Hospital
- Ensure that the area surrounding the patient is free of sharp items that may cause injury if the patient falls.
- Ensure that a chair or low couch is close by in case the patient faints or becomes excessively tired.
- Reassure the patient that stepping forwards or backwards to correct overbalance is perfectly acceptable.
- Ensure that two staff members are present at all times; one operating the equipment and one ready to provide support if the patient overbalances.
- Assess the stability of the patient prior to the investigation to plan the degree of support required beforehand.
- Continue to communicate with the patient all through the investigation so as to assess their state of alertness. If they are becoming tired then sit them down rapidly to allow them to recover.
- For all tests participants are instructed to wear comfortable non-restrictive clothing and flat comfortable shoes.

The following equipment is required:-

- PC equipped with the Sway Monitor interface, 9 Pin serial connector and software
- 2 ultrasound receiver units, R1 and R2, connected to the interface board by coaxial cable with BNC plugs either end
- Remote transmitter unit with Velcro belt attachment communicated with the interface board via an infra-red pulse.
- Soft surface. This is a circular board, on which a Honda Melody inner tyre has been mounted. It is connected to a sphygmomanometer and bulb for inflation to a standard pressure of 180 mmHg.
- Equipment to ensure that the transmitter unit is held level when attached to the patients waist.
- Visual acuity test board
- Stopwatch
- Marked-out track for gait assessment
- Poole Hospital Gait Cadence Measurement System
- PC with gait cadence analysis software and suitable serial port lead to attach to the unit.
- TUG equipment (patient wearable accelerometer box and radio interface bonded to the accelerometer box) and PC with TUG software installed.
- 9 hole peg test and non slip mat
- Two blocks/steps 41 cm wide by 30 cm deep one 7.5 cm high the second 15cm high

- Record sheet for stance tests, step test, 9 hole peg test and 2 minute walk test
- Record sheet for factors affecting physical performance
- Removable coloured footprint templates
- Refreshments for participants

1. Balance tests in steady standing

Performance in five stance positions without hand support.

- Single leg stance; standing on one foot with the opposite knee held at 45 degrees of flexion.
- Tandem stance with one foot directly in front of the other foot and with the toes of the rear foot contacting the heel of the front foot
- Stride stance with feet placed 10cm apart and the heel of the front foot in line with the toes of the rear foot
- Feet together
- Feet 10cm apart (this is measured in the limits of sway test-see section 4)

Preparation

In order to standardise foot placement footprint templates for aligning the feet in parallel, step, and tandem stance are marked on the floor using removable coloured contact footprint images. A chair positioned in front of the participant for safety and the researcher on one side.

Procedure

Researcher carefully positions participants' feet on the template for each position. Green contact paper for the right foot and red for the left foot. Participants instructed to look straight ahead and keep arms by side during the testing time. The testing time for each stance position is 60 seconds measured with a stop watch and time recorded in seconds to two decimal places. Stride and tandem stances are tested twice; once with right leg in front and once with left leg in front in each position. Single leg stance also measured twice; once standing on the right leg and once standing on the left leg. Tests completed in the order given assessing the most difficult stance position first.

The researcher demonstrates and describes each test. Participant is wearing normal footwear.

Instructions

"The purpose of these 5 short tests is to see if you can maintain the 5 positions with your eyes open and without hand support. The goal for each test is to keep your balance

for 60 seconds in each position. Look straight ahead and keep your arms by your side. If you are unable to maintain the position for 60 seconds or if I am required to offer you support then the test is stopped and you will be given another chance. I will help you to position your feet on the contact footprints for each position. I will say “go” at the start of the timing and “stop” on completion of the test. You will have time to sit down and rest in between each test if you need to. The tests get progressively easier so if you are able to complete the first one you will not need to do all the others.

Based on guidelines and evidence from:-

Dragana, F., Meg, E. Morris, and Lindsay, V., 2000. Clinical tests of standing balance: Performance of persons with multiple sclerosis. *Archives of Physical Medicine and Rehabilitation*, 81, 215-221.

Goldie, P, A., Matyas, T.,A., Spencer, K., I.,1990. Postural control in standing following stroke: test-retest reliability of some quantativie clinical tools. *Physical therapy*, 70, 4, 234-243.

Smithson, F., Meg, E. Morris, and Iansek, R., 1998. Performance in clincial tests of balance in Parkinson’s disease. . *Physical therapy*, 78, 6, 577-592.

2. Step test

A clinically useful balance test incorporating single leg stance

Subjects supported with feet parallel and the block 5 cm directly in front of them. The therapist stands to one side and places one foot on the side of the block to steady it in case it is knocked during the stepping procedure. Two blocks 41cm wide by 30 cm deep are used, one 7.5 cm high and the other 15 cm high. Participants stand with feet 10 cm apart, with a block positioned 5 cm in front of their toes.

Subjects are advised which leg is the stepping leg and instructed to place the whole foot onto the block, then return it fully back down to the floor, repeating as fast as possible for the test duration. They are also instructed not to move the opposite (supporting foot) during the test period. One completed step comprises placing the foot fully up onto the step then down off the block. In addition to the verbal explanation the researcher demonstrates the task while the participant sits on a chair and observes.

Instructions

“When I say “Go” step your foot onto then off the step as many times as you can until I say stop. Make sure all of your foot contacts the step each time. The number of times you place your foot on the step in the 15 seconds is recorded. Then the same procedure is repeated with the other leg.”

Practice test first with each foot followed by actual test.

The researcher supervises the person being tested but does not provide hands on support unless the subject needed steadyng if balance is lost during the test. If this occurs counting stops at the number of completed steps and the score is recorded.

Dragana, F., Meg, E. M., and Lindsay, V., 2000. Clinical tests of standing balance: Performance of persons with multiple sclerosis. *Archives of Physical Medicine and Rehabilitation*, 81, 215-221.

Goldman, M. D., Marrie, R. A., and Cohen, J. A., 2008. Evaluation of the six-minute walk in multiple sclerosis subjects and healthy controls. *Multiple Sclerosis* (13524585), 14 (3), 383-390

3. Instrumented Timed Up and Go (TUG) Test

Introduction

The TUG is a well established simple measure of mobility and fall risk. It is a simple test, but performing the investigation requires a number of complex mobility tasks (standing, turning sitting etc) that together make the technique powerful for assessing general mobility (J American Geriatric Soc 1991;39: 142-148). Recently other groups have found improved sensitivity of the technique by attaching accelerometers to the patient to record the movement of the patient during the TUG manoeuvre.

Measurement

Attach the accelerometer recording device to the patient’s back with the waist strap and turn on the recorder. Connect the telemetry receiver to the computer and run the TUG recording software on the computer. Enter the patient information and ensure that connection has been made to the recorder. Ensure that the patient is sitting in the appropriate chair (with arms) opposite the wall (not the cupboard). Explain the

procedure: “sit with your back against the chair and your arms on the armrests. When I say “go”, get up, walk to the opposite wall so that you touch it, turn round, walk back and sit down. I will be timing, but this is not a race; you should move at a pace that is comfortable and safe for you”. Have any walking aid or orthotic they use within easy reach.

If the patient is able to, they should perform the procedure 3 times. The first is a practice run. Use the opportunity to ensure full compliance on the next 2 runs, which should be measured. Start recording on the software and get them to perform the 2 recorded TUG runs, recording the time taken to perform each run on a stopwatch.

Analysis

Record the fastest performance of the TUG by stopwatch measure for reporting. Review the recording of the procedure and establish the time of the TUG performance from the accelerometer data. Further analysis will become available in time.

4. Measurement of the Limits of Sway (LoS)

The test must be performed in a suitable room. A corner of the room must be clear of all other equipment. The receiver devices R1 and R2 must be fitted by Velcro to the walls in the corner, approximately 1 metre from the corner and at a height of approximately 1 metre from the floor. R1 should be on the wall which the patient will face. R2 should be on the wall to the patient’s left. Ensure that the cabling does not interfere with the patient, securing it to the floor if necessary. Ensure that the computer is placed a suitable distance away from the patient location. The patient location should be marked on the floor by two parallel lines, 10cm apart.

Ensure that the patient is fully reassured and adequately briefed as to what is required. First results indicate that a number of factors e.g. tiredness, state of agitation and some conditions such as hay fever significantly affect the results of sway assessment. Try to ensure as much consistency in the test conditions as possible and record any factors that may be relevant e.g. excessive tiredness, the patient having been on a course of therapy since the last measurement, the presence of peripheral neuropathy or limb injury.

It is very helpful to observe the patient as they move to the clinical room and sit down. If they are not aware of being observed they are often more natural in their movements and give a good indication of their balance state.

Assembly

Ensure that the equipment is set up as described above.

Patient Preparation

The patient should be put at ease as much as possible. Explain the procedure clearly. Establish the context of the test and check for any factors that may influence the result. Consider the risk of the patient falling and take steps to avoid this situation.

Ask the patient to take off their shoes. If they are wearing any upper garments that may interfere with the line-of-sight between transmitter T2 and receiver R2, ask the patient to remove or tuck in the item of clothing.

Setting up

Initiate the Sway Monitor Program Version 4.0. Select “Enter New Test” and enter the patient demographic data as required. Do not change the Centre of Gravity height measure. Select “OK” to return to the main screen.

Ask the patient to stand with their feet 10cm apart, facing receiver R1 and with their front waist level with R2 on the patient’s left. Use the floor markers for guidance. Place the transmitter unit on the patient’s waistband and adjust the angle of the transmitter and the heights of the receivers on the wall so that the transmitters and receivers are directly facing each other. Poor alignment will result in unreliable measures of patient location.

Explain to the patient the procedure carefully. Ensure that the patient does not bend at the waist during this test or any subsequent tests. Select the option “Measure LoS” from the main screen. With the patient upright and stable select “Start”. If the patient location appears to be unrealistically unstable then check the alignment of the transducers.

Otherwise request the patient to lean forward from the ankle with their back and waist straight until they reach a point where any further leaning would result in them losing their balance. The operator’s assistant must be in such a position as to prevent the patient falling if they overbalance. By standing slightly in front of the patient and to the patient’s right hand side it is possible to provide such reassurance and support if required without interfering with the line-of-sight between the transmitters and the receivers. The maximum unsupported forward movement may then be marked on the screen where the motion is displayed by placing the mouse arrow at the maximum forward movement displayed and pressing the left hand mouse button. The process is

then repeated for the maximum backwards motion, the patient being supported at their back if required. Select “OK” to continue

Measurement of Sway

For each of 4 measurement conditions the following procedure is followed:

1. Select the appropriate test condition button.

1 = Eyes open, solid surface (floor)

2 = Eyes closed, solid surface

3 = Eyes open, distraction mental task

4 = Eyes open, soft surface

5 = Eyes closed, soft surface

2. Explain the conditions to the patient

3. For each of 3 runs of 20 seconds each, ensure that the patient is upright and steady.

4. Press “Start” to initiate each acquisition.

When the condition involves closing the eyes, ensure that the eyes are closed moments after the recording is initiated so that the patient starts from a position of relative stability. Ensure that the patient is not in danger of overbalancing, or be prepared to offer physical support if required. If the 20 second trace appears to be valid then press “Accept”, otherwise reject the trace and repeat. Allow recovery time if the patient has become excessively tired. If the patient overbalances then offer sufficient support to maintain the patient’s posture sufficiently to finish the present 20 second run. If the patient is clearly unable to continue then save the present run and stop the test.

5. The run should be rejected if the transducers fell out of alignment giving artefactual movement indications or when the patient appears to fall outside of the LoS lines without actually appearing to lose stability.

6. For the tests on the soft surface, the tyre should be inflated to a pressure of 180mmHg while the patient is standing on the board.

Reporting

Reporting should be performed using the sway reporting program SWAY_RES.EXE. If there is no access to a printer on the clinical machine, copy the directory containing the patient data to a floppy disk and run the reporting software on another PC connected to a printer. Run the program, select the patient directory and print out the results page.

5. Nine-hole peg test protocol

Preparation

The participant is seated with a table in front. The pegboard (square board with 9 holes, each hole spaced 3.2 cm apart and each hole is 1.3cm deep) in the centre of the table in front of the participant. The pegboard has a non-slip mat to prevent slippage during the test. The 9 wooden pegs (0.64 cm in diameter and 3.2 cm long) are placed in a plywood container (13cm X 13 cm) *ours is 26cm X13cm*. The container of pegs is placed on the side of the participant's dominant hand side.

The activity is first demonstrated to the participant by the researcher.

The participant's dominant hand is tested first. The first test is a practice/familiarisation test.

Instructions

1. "Pick up the pegs one at a time, using your right (or left) hand only and put them into the holes in any order until the holes are all filled."
2. Then remove the pegs one at a time and return them to the container.
3. Stabilise the peg board with your left (or right) hand.
4. See how fast you can put all the pegs in and take them out again.
5. Are you ready? Go. On "go" as the participant touches the first peg researcher starts the stop watch. The stop watch is stopped as the last peg hits the container.
6. On completion of the practice test the participant has a rest and opportunity to check the instructions and ask questions.
7. When the participant is ready to proceed with the test the researcher instructs "This will be the actual test. The instructions are the same. Work as quickly as you can. Are you ready? Go (stop watch started when first peg touched)."
8. When the participant places the last peg on the board instruct "out again.... Faster"

9. When the last peg hits the container the researcher stops the stop watch and records the time in seconds to the nearest 0.01 seconds.

The peg container is moved to the opposite side of the participant. The test is repeated with the non-dominant hand and the score recorded.

If a participant drops a peg on the table the patient would pick up the peg and continue, if dropped on the floor the researcher picks up the peg and the patient continues.

Based on instructions from Mathiowetz 1985 and www.rehabmeasures.org

6. Two minute walk test

1. The walk test is set up in a 175 foot hallway with markers at each end to show the point to pivot/turn. The participant to sit at rest in a chair at the starting position while the researcher explains the test.
2. The participant instructed as follows:-

The object of the test is to walk as far as possible for 2 minutes. A walking aid or any orthotic (AFO, FES) may used if required. You will walk back and forth in the corridor outside this room “at a comfortable pace”. Walk continuously if possible but do not be concerned if you need to slow down or stop to rest. The goal is to feel at the end of the test that more ground could not have been covered in the 2 minutes. You will be walking back and forth around the cones. You should pivot briskly around the cones and continue back the other way without hesitation. Now I’m going to show you. Please watch the way I complete this test”.
3. DEMONSTRATION - show a few laps with turns/pivot around the cones.
4. “I’m going to count the number of laps you complete. I will mark on my sheet each time you turn around at this starting line. I will tell you when you are half way through after the first minute saying “You have one minute to go”. At the end of the 2 minutes I will say “stop” so please stop where you are and I will bring the chair so you can sit down”.
5. “Are you ready to do that?”
6. When the participant is ready, instruct them to stand at the starting line.

“Remember that the object is walk as far as possible for 2 minutes but do not run or jog. I am going to press the stop watch to time the 2 minutes and you can start walking when I say go”.

7. Stop watch started and at same time participant instructed to “go”.
8. Each time the participant returns to the starting line a record is made that a lap has been completed. If the participant stops for a rest during the walk reassure

- them “you are doing well keep walking if you feel able” but do not stop the timer.
9. After one minute say “You have one minute to go”
 10. After two minutes say “stop” take the chair to the participant and allow them to sit down. Mark the spot where they stopped on the floor with tape.
 11. If the participant stops before the 2 minutes are up and refuses to continue (or it is decided that they should not continue) take the chair to the participant to sit on, discontinue the walk and note the distance walked, the time stopped and the reason for stopping prematurely.

Instructions based on the American Thoracic Society guidelines for the six minute walking test and modified instructions (Goldman et al. 2008). The modified instructions focus on maximising effort by emphasising speed and omitting instructions for permitted rest in the 2 minutes.

Goldman, M. D., Marrie, R. A., and Cohen, J. A., 2008. Evaluation of the six-minute walk in multiple sclerosis subjects and healthy controls. *Multiple Sclerosis* (13524585), 14 (3), 383-390.

7. Method - Laboratory-Free Gait Cadence Assessment

Introduction

The aim of this procedure is to assess the walking pattern of the patient in as near to normal conditions as is possible. This includes walking a significant distance, typically for about 3 to 5 minutes; either unaccompanied or accompanied by a partner if this is a normal arrangement. Crucially the experimenter should not accompany the patient. Also the walk should be as close to unobstructed as possible. The patient should walk purposely along the described route at their natural pace without stopping.

Measurement

The patient should remove their shoes. Flat pressure switches are then taped carefully onto the inside of the sole of the shoe under the heel and the shoes put back on. The patient should then stand up and the wire from the heel switches is taped to the leg and waist so as to offer no obstruction to movement. The wires are then connected to the Poole Hospital Gait Cadence Assessment Unit as appropriate. This unit should be switched on and set to record so that the red LED on the side is on. Get the patient to start walking with the unit in their hand. Adjust the trigger threshold until the green LED's come on and off with every step. This may take a little while to establish a stable pattern. Use this time to get to a point where there are no barriers to walking e.g. to the

dome. Confirm the protocol and the route with the patient then reset the recorder, place the unit in a carry case to avoid the patient looking at it, and send the patient on their way. The normal route is to the payment machines at the car park and back along the covered walkway.

On return the record button is turned off, the unit disconnected from the switches and the data downloaded. The patient removes the switches from their shoes.

Analysis

On download of the footfall patterns of the 2 feet, the data is checked and any clearly erroneous and unrepresentative data removed. There is normally a discontinuity at the time when the patient turns round. The results are then printed off.

Reporting

A report pro-forma can be generated from the IRIS Patient Activity Database program. In this should be included all the results from observational studies, quantitative studies and the patient self-reporting on their questionnaires. Patient history and any comments can be included.

A copy of this as well as a copy of the static posturography graphs should be sent to the referring clinician.

The patient data must not be kept on any PC not registered for the data protection act

Record of activity tests

Assessor initials		Participant ID		Date:-
				Time:-
	Type of assistive device /orthotic used	Number of rests required	Number of whole laps completed	Total distance in 2 mins in cms
Practice 2 minute walk test				
Actual 2 minute walk test				
Length of rest if required				
Stance tests	Able to complete 60 secs	Not able to complete 60 secs	No of secs completed if less than 60	Comments/reason for loss of balance
Feet apart (LOS)				
Feet together				
Stride stance right foot in front of left				
Stride stance left foot in front of right				
Tandem stance right foot in front of left				
Tandem stance left foot in				

front of right				
Single leg stance right leg				
Single leg stance left leg				
Length of rest if required				
9 hole peg test	Time in seconds	No of pegs dropped	Comments e.g. spasticity, ataxia, dropping pegs, not following instructions	
Dominant hand				
Practice dominant hand				
Actual test dominant hand				
Actual test non dominant hand				
Length of rest if required				
Step test	Orthotic worn? AFO/FES	No of steps in 15 secs		Observations/comments
		7 .5 cm	15 cm	
Right foot practice test				
Right foot actual test				
Left foot practice test				
Left foot actual test				

Appendix 7: Interview Guides

Mii-vitaliSe Interview schedule (delayed group)

Reminder about recording interview and how the information will be used

As you know from the information sheet I am interested in hearing your feedback about taking part in the Mii-vitaliSe feasibility study

How have you found the experience of participating in the Mii-vitaliSe trial so far?

- Completing the questionnaires (recently and 6 months ago)
- The walking and balance assessments in medical physics
- Wearing the activPAL3™ for 7 days,
- Completing the risk assessment at home
- Being in a delayed group and waiting 6 months before starting the Mii-vitaliSe intervention

What are the positive and negative aspects of taking part?

What would you say to someone else about getting involved in this study? Would you be happy to consent to this trial if you didn't get any Wii™ intervention? How would you feel if the control was "usual care" instead of a delayed offer of the Wii™ ie you would be randomised to either the Wii™ or your usual MS care

What if you were asked to delay for longer than the 6 months i.e. 1 year?

Do you think the NHS should provide people with a Wii™?

Any other comments you would like to add about your participation in the study?

Mii-vitaliSe Interview schedule (Immediate group)

Reminder about recording and how information will be used

As you know from the information sheet I am interested in hearing your feedback about taking part in the Mii-vitaliSe feasibility study

How have you found the experience of participating in the Mii-vitaliSe trial so far?

- Completing the questionnaires-ease of completion, content, relevance
- The physical assessments in medical physics-ease of completion, relevance
- Wearing the activPAL3™ for 7 days,
- Completing the risk assessment at home
- Completing the daily play log-ease of completion

How have you found the experience of taking part in the Mii-vitaliSe intervention in the last 6 months?

Getting started with using the Wii™?

- What did you think about the Mii-vitaliSe Resource Book and the Personal Activity Workbook you were given? Was there any information not included in the workbook that would have been helpful? What did you think about the games descriptors you were given? How have you used the Mii-vitaliSe resources (Resource Book and Personal Activity Workbook) in the last 6 months
- What do you think in terms of the amount of contact you had with the physiotherapist at the hospital and home appointments? Do you feel it was too little or too much? Would you have preferred more face to face contact?

Using the Wii™

- How did you find using the remote control? Did you experience any difficulties controlling the onscreen pointer or pressing the buttons?
- What have you found helpful and unhelpful using about the Wii™?
- Did you tend to use the Wii™ alone or with others?
- What times of the day did you use the Wii™? What did you play more – Wii Fit Plus™ or Sports™? Did you use other games? Which ones?
- How does the Mii-vitaliSe intervention fit in with your usual MS care and current goals eg Physiotherapy /OT
- How does the Mii-vitaliSe intervention fit in with your other activities eg Pilates, gym sessions

Injuries/problems/barriers/facilitators

- Did you suffer any injuries or discomfort from using the Wii™. Did you fall while using the Wii™?
- Did you notice any increase or decrease of MS symptoms while using the Wii™?
- Did you find the feedback acceptable? Do you think some people affected by MS might find it upsetting?
- What problems did you encounter when using the Wii™?
- What stopped you from using the Wii™? What barriers did you encounter?
- What encouraged you or helped you to use the Wii™?
- Did anyone else encourage you?
- Did you find setting goals on the Wii Fit Plus™ helped you to stay motivated? Did you find setting goals in your personal activity book helped you to stay motivated? Did you achieve the goals that you set?
- If you used the Wii Fit Plus™ or other games using the balance board did you encounter any difficulties in stepping on or off the balance board. Did you use support?
- It has been a very hot summer. How has this impacted on you using the Wii™?

Perceived benefits

- Do you feel using the Wii™ has impacted on other areas of your life - such as general activity levels, mood? Overall was it a positive, negative, or neutral experience? Primary outcome measure?
- Would you recommend the Wii™ to others affected by MS?
- Should the NHS provide the Wii™ for patients with MS?

Participation in study

- How have you found the experience of participating in this study? What would you say to someone else who is thinking about whether to be involved? What have been the positive and negative aspects of taking part in this study?
- Would you have been happy to have delayed using the Wii™ for 12 months? (to gauge acceptability of randomisation for a RCT). How would you feel if the control was “usual care” instead of a delayed offer of the Wii ie you would be randomised to either the Wii or your usual MS care?

On-going use

- What are your plans now for using the Wii™ and the Mii-vitaliSe resources you have been given.

Are there any other comments you would like to add?

Physiotherapist interview schedule July/August 2014

Explain processes and need for digital recording

Take Mii-vitlaiSe case notes/SOAP notes so these can be referred to during interviews

Take consent

The purpose of this interview is to gather feedback about your experiences of delivering the Mii-vitlaiSe intervention.

The orientation sessions –getting started with using the Wii™

- How did you get on with conducting the two Mii-vitaliSe hospital orientation sessions? (prompts: timing, content of sessions, process of delivery, venue, amount of contact time, delivery format (hospital-based; group versus 1:1, engagement /participation of participants etc.)

The home-based sessions (week 3, week 7 and week 16)

- How did you find the first home-based session (week 3) when you set up the Wii™ in people's homes? How long did this take on average? Did you encounter any challenges setting up the equipment? Did you feel you had adequate experience to set up the Wii™? Any suggestions for improvements?
- What about the two follow-up home visits (weeks 7 and 16)? Can you say how you found these? (the timing, length of time, setting goals, content etc.). Can you comment on the number of face-to-face contacts with participants –was this not enough/too much or just about right?

The follow-up phone calls

- How did you find the follow-up monthly phone calls? Was it easy to contact people each month? What were your experiences of encouraging people over the telephone in this way? What were the pros and cons? Did it offer an appropriate way of reviewing progress, setting goals, overcoming barriers? Were you able to stick to the 15 mins? How long did the conversations take on average? What challenges did you encounter? Were there differences between your experiences with clients you already knew versus ones that were new to you? Did you use email at all with any participants for the monthly follow-up? If so how this work as a strategy for supporting people to continue with their Mii-vitaliSe exercise plans?

Contact time - overall

- Overall what did you feel about the Mii-vitaliSe intervention package in terms of the overall length of the intervention and the contact time (including the two appointments at the hospital, the home visits and the ongoing telephone support)? Do you feel the contact time was the right amount and format?
- Was there any information not included in the resources that would have been helpful?

The Mii-vitaliSe intervention materials

- The Mii-vitaliSe intervention package included various materials including

a resource book, activity log and games descriptors. Did you use these? For those that you used how did you find using them? Can you give examples of how you used them? Are there ways the materials could have been improved? Can you comment on what information was useful/not useful for the participants?

Goal setting

- How did you facilitate participants to make action plans and set goals? Can you give examples? What were the facilitators and barriers to supporting participants to do this?
- What factors prevented participants from completing their action plan /achieving goals? Can you give examples?
- How did you facilitate/encourage participants to overcome these barriers?
- Was there anything else that could have helped them to overcome these barriers-other resources/support/strategies/?
- For those participants that were successful in completing their actions plans what supported them to do this? What can we learn from this for the future application of the Mii-vitaliSe intervention?

Using the Wii™

- What do you see as being the pros and cons of using the Wii™ in this way with pwMS?
- Did participants experience or report any difficulties with using the Wii remote / controlling the onscreen pointer / pressing the buttons, stepping on and off the balance board, using the software?
- Mii-vitaliSe included Wii Sports™, Wii Fit Plus™ and Wii Sports Resort™. Did you use these equally or were some used more than others? Did everyone use the balance board or did some not use it? If so why was that? How did support participants to choose games to play? Were there any games that seemed better suited to this client group or less well suited? Were there certain games that were best to start off with? Can you comment on how you progressed people through the games?
- Did you get a sense of patterns of play; how were people using the Wii when they were setting their goals? Alone/with others?; in short bursts?; longer bursts? etc. Weekends; weekdays, summer /winter?

Injuries/problems/barriers/facilitators

- Did participants experience any injuries/ discomfort/falls related to using the Wii™?
- Did you notice or did they report any increase or decrease of their MS symptoms while using the Wii™?
- Did any of the participants you facilitated comment on the Wii™ feedback/Wii Fit™ age /did they find it acceptable/how did they react to it?
- Did setting goals on the Wii Fit Plus™ /in the activity workbook help participants to stay motivated? Did they achieve the goals that they set?
- What got in the way of people achieving their goals?
- How has the warmer summer climate impacted people using the Wii™?

Perceived benefits

- Do you feel using the Wii™ impacted on other areas of participants' lives? If so, how? – eg ADL, general activity levels, mood, social aspects, fitness, weight loss, fatigue, MS symptoms, sleep, general well-being, (need to consider primary outcome measure for future trial)

Patient group

- Was it delivered to an appropriate patient group?
- Were there any characteristics that you can identify that made people more likely to persist or succeed/ more likely to give up? For those people who encountered barriers and subsequently overcame them can you identify any characteristics that made that more likely?

Delivery model and future trial

- What barriers and facilitators did you encounter in delivering the Mii-vitalise?
- Was there adequate training? Did you feel you had the skillset to deliver Mii-vitaliSe? What support needs would physiotherapists delivering this in clinical practice require? What banding/experience/expertise do you think would be required to deliver it? Would it have to be delivered by a MS specialist physiotherapist?
- What do you think about the amount of physiotherapist support provided? About right? Too little? Too much? What about the balance of face-to-face versus telephone support and the timing of that support?
- What did you think about the choice of the Nintendo Wii™? Would this be a suitable intervention for the subsequent trial?
- What is the feasibility of delivering Mii-vitaliSe in clinical practice? How, when and for whom do you think it could be used? What aspects do you think would work well in clinical practice and what wouldn't work so well? Do you feel there are aspects that could be changed that would make it easier to deliver?
- What about the design of the Mii-vitaliSe study-did participants in the delayed group comment on being delayed for six months, did participants in the immediate group have a different approach to the intervention as they were involved in it for longer? If so what was the difference? What do you feel would be an appropriate choice of control group for a trial (usual MS service care, waiting list control(as we did in the pilot study, other physio intervention (eg list of similar balance/strengthening exercise or DVD but not gaming technology etc)
- Are there issues you can think of that should be borne in mind when looking ahead to the future trial? A future trial would involve different physiotherapists and different services, potentially with different models.
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Any other comments/thoughts or examples from cases you have seen in the pilot intervention?

Appendix 8: Case based framework chart

Appendix 8: Case based framework chart illustrating participants' perceptions of the facilitators for using the Wii™ and the subsequent perceived benefits

Facilitators/motivators to use	Perceived physical benefits	Perceived psychological benefits
There's no harm in using it Do not need to leave the house Fun and interactive time Do those that you can do and enjoy Observing weight loss Seeing improvements in scores	Better to get up and do something Improved fitness and energy Initially lost weight Improved balance and co ordination	Gives interest and variety to the day Feel better Wii™ feels supportive for the MS
Enjoy competing with myself and aim to beat previous scores Very enjoyable The exercises are good and links with core and balance exercises	Seem able to walk further every day Stronger core strength Feel better	Feel better mentally A good addition to my life
It helps to keep practicing and to solve the problems encountered Fun way to do Physiotherapy but without one Can wear your underwear to keep cool A partner not needed for the table tennis Found the Hula Hoop game very enjoyable Convenient	Improved balance; noticed when cooking and picking things up Improved dexterity and co-ordination e.g. when getting the pegs off the line (drop less) Improved hand-eye co-ordination; the brain and feet work better together Increased confidence when walking so don't need the strap on the foot to hold the toes up No trips/falls for a year as brain and feet link Makes the muscles work properly	Feel more positive Feel clever - can do it and show the children how to do it
Do more exercise than I would normally do	Games with nunchuck help arm co-ordination	Important to achieve goals and targets set Positive feeling that you are helping someone with research Find out more about yourself and what your limits are - i.e. more insight
Getting a routine that fits in with everything else Getting good scores and mastering the yoga technique Being competitive with myself and my husband Being monitored by face-to-face and phone contact helps to increase confidence in what you are doing	Lost a bit of weight Balance and posture improving Moving better and improved stamina Less pain in hands in the morning due to using handset and stretching in yoga Helped fatigue Achieved moderate/vigorous levels of activity, e.g. do jogging and feel a bit out of breath Can carry things up and down stairs without holding on	Returned to work Increased confidence so can go out again and feel more confident and steadier Feel better in self Feel less mental fatigue, perkier Know it does me good Wii™ stress relief

Facilitators/motivators to use	Perceived physical benefits	Perceived psychological benefits
Competing with husband Enjoyment and motivation to increase scores and win, e.g. on balance bubble and slalom More enjoyable way of doing exercise than at the gym.	Can still be active in the winter/bad weather Less pain in back and shoulders, moving more, better core strength, Confidence to walk outside without a stick - for over a year have not used stick while out Balance better –people keep telling me Noticed I could do things I couldn't do a year ago - e.g. stepping in and out of shower independently Managing the fatigue	Feel confident Understand the reasons for doing the games and exercises Feels positive about being involved with the research
Enjoyed the whole thing - got a lot of pleasure out of it Fun, challenging and nice to be able to challenge yourself	Step game has benefited me most - got improved scores Get increased heart rate with cycling, sword play, stepping	Increased my confidence to do more
Given me a sort of exercise ethic Good healthy habit to get into exercise You can pick and choose what you do	Made me more active, fitter and more toned up Feel less tired as it has energised me	Occupied my mind and given a focus Sort of distracted me Increased feeling of well-being Gives you a good mood-more cheerful person
Enjoyment Not able to bowl in real life but can with Wii™ Convenient - do when you want No one looking Effortless	Legs feel stronger - don't need a stick as much Less pain when walking and quality of walking better Makes you more body aware otherwise just sit and do nothing increased confidence	Makes you concentrate Enjoyment Gives you something else worthwhile to think about and enjoy
Convenient fits in well with other care Interested in numbers so like Perfect 10 -try to improve scores as this is encouraging Committed to it by signing up to do the research-feel a duty to do it	Increased heart rate - can increase even when sitting on perching stool Slightly increased pulse Can get further along balance bubble Feels standing balance, stamina and weakness have improved Haven't deteriorated	Quality of life improved Enjoyable Feel I am contributing to something and helping –feel positive Occupied mind (helped me to focus) and distracted me A means to self-monitor
Wii Fit Plus™ user friendly and interactive Keeping Wii™ has motivated me to continue to use it Motivating by fit piggy-got gold (40 hours) Always aim to get 10 minutes on fit piggy Gives you a nice welcome when you turn it on	Beneficial as wasn't doing any exercise at all Can do more now than when started so improved fitness –initially 10 minutes then progressed to 40 minutes More aware of centre of gravity and weight distribution Improved co-ordination – e.g. can march and do something with hands	Feel motivated to the beat scores to increase fitness See the improvements in score and this becomes self-motivating

Facilitators/motivators to use	Perceived physical benefits	Perceived psychological benefits
<p>Main exercise in the winter</p> <p>Flexible</p> <p>Enjoyable</p> <p>Light-hearted and not serious</p> <p>Can set realistic targets</p> <p>Some games are addictive, e.g. balance and training plus</p> <p>Often work at home so the Wii™ is there</p> <p>Yoga and balance exercises are good for monitoring the centre of gravity</p>	<p>Feel better for moving in a variety of ways</p> <p>Increased aerobic tolerance and level of activity</p> <p>Able to dance keeping in time after 3 months of using Wii™</p> <p>Improved leg strength and core strength</p> <p>Muscle tone in legs improved and can go without wearing the splint in summer</p> <p>Impacted mobility, balance, co-ordination , ability to move, rhythm, hand dexterity and bilateral activities</p> <p>Also uses the brain</p> <p>If feel a bit fatigued it can sometimes help</p>	<p>Stress relief</p> <p>Sleep better</p> <p>Enjoyment of exercise</p> <p>Seeing improvements is motivational</p> <p>Hugely positive being involved in the trial</p>
<p>Fun and competitive with others</p> <p>Able to do when weather not good</p> <p>Fun seeing your Mii and how funny you look</p> <p>30 mins reward with music</p> <p>Motivated to lose weight and to do with others</p> <p>There is a huge choice of things to do</p> <p>Wii Fit™ stands for ‘we wanted to get fit’</p>	<p>Achieved vigorous level activity and feel better</p> <p>Feel like actually doing some exercise when doing the games that make you do more, and some involve doing mental arithmetic</p> <p>Better balance-noticed when standing on a step</p> <p>pruning, shopping and getting things out of the kiln</p> <p>Improved leg strength-the muscles have built up the legs which feel less “wobbly”</p> <p>Better stomach control</p> <p>No relapses - maybe being more active made a difference</p> <p>Less fatigue</p>	<p>Increased confidence</p> <p>Positive view of exercise</p> <p>Feeling healthier and more positive</p>
<p>Usually start with the ‘header’ exercise then follow a pattern for 20 minutes</p> <p>Motivated to get on the leader board and then to beat scores each time</p> <p>Played an extra 10 minutes to either improve the top score or reach it each time</p>	<p>Felt healthier</p> <p>Balance on the Wii™ board is quite good –but not when on uneven ground</p>	<p>More alert</p> <p>Feel that it might help someone else 20 years down the line even if doesn’t help me</p>
<p>Fun and enjoyable -100 pin bowling a bit of a novelty</p> <p>Use in bad weather - can have family time</p> <p>Useful for BMI and scales-visual line/graph and virtual body changes, also gives feedback about balance</p> <p>Sound effects egg little man jogging with you and visual prompts</p> <p>Went for smaller ambitions about doing cardiovascular and balance activities</p>	<p>Achieve light to moderate level exercise</p> <p>Better stomach control - toned up and fitter</p> <p>Hula Hoop quite good for trimming waist</p> <p>Balance a bit better-get correction and feedback so know how to do it properly</p> <p>Weight loss</p>	<p>Feel better and more awake immediately</p> <p>Hasn’t done any harm and has been very interesting</p> <p>Had enjoyable family times doing the Wii™</p>

Appendix 9: Case based framework chart

Appendix 9: Case based framework chart illustrating injuries /discomfort and falls described by participants in the interviews

Injury /discomfort/fall/near fall described	Perceived cause of injury/discomfort described	Perceived solution /preventative strategy described
Discomfort like being fatigued Sometimes cramp at the end of the day	Fatigue is part of a normal day	
No fall/near fall		Haven't looked up if did would fall back
Leg pain, a constant ache (like toothache) all the way through the leg	Standing on balance board –if did too much (first time at hospital session) Weight transfer (leaning forwards) when doing Segway Circuit	Had to sit down Took a while for leg to recover Stopped standing on the board and did exercises sitting Referred to MS nurse for medication management
Pain in torso	Day after Hula Hoop exercise –(got carried away) thought it was a pulled muscle/pulled scar tissue	Saw GP, neurologist and MS nurse - maybe the MS and not connected to the exercise
Near fall	Lost footing doing Rhythm Parade	Gave up as too difficult to concentrate on hands doing one thing and feet doing another
Fall off the balance board onto the floor	First time did the Balance Bubble as it is very fast and you move in all directions	Need to take it slowly and be careful
Stiffness in legs	First and second time of jogging	Gradually eased off
Pulled muscle in back doing jack knife exercise (yoga)	Got high scores so maybe technique was incorrect	Stopped doing the jack knife exercise as it is really difficult
Discomfort and pins and needles in hands got worse, arm would start to shake	Yoga-Warrior Pose	Spoke to Physio and amended technique
Felt nausea/felt sick/dizzy	Yoga –at time starting to come down with chest infection and ears were blocked	Sat down and had a drink of water
Knee problem-aggravated a previous injury	Aerobic exercise-jogging	
Near fall/trip	Got too adventurous when steeping on and off the balance board sideways	
Shoulder pain	Suddenly came back when did certain exercises	Was a long-standing problem - had taken medication for it
Knee discomfort on weaker side	Aggravated by Tilt Table and stepping motion.	Aggravated the discomfort in weaker knee Not possible to do sideways step - so needed to make adjustments-used chair at right side
Right arm discomfort	Table tennis or basketball - quite intense	Had also lifted wheelchair into the car.
Fall	Reaching too far	
Arms, hands and fingers felt stiff/heavy and discomfort usually later in the day	Repetitive movements in table tennis make arms feel even more stiff - may not be MS related	May not be the MS
Right knee pain? pulled ligament	Started when going up stairs	Saw Dr, given gel, had to limit what doing

Injury /discomfort/fall/near fall described	Perceived cause of injury/discomfort described	Perceived solution /preventative strategy described
Near fall/miss	Hesitated when stepping on and off balance board. Going side to side when stepping	Loss of concentration because you get so involved in what you are doing
Near fall onto sofa Pain in leg	Lost balance doing Perfect 10 Playing golf -got carried away and instead of doing 3 holes kept going and did 9 holes	Had perching stool nearby Don't get carried away and stay with doing 3 holes in the future
Tired/heavy legs	Did too much early in day so affected the day	Tend to do exercises later in day so tired legs don't affect the day
Tone increases in left leg and left side of body especially if get hot	Get hot when doing the obstacle course or aerobic activity	Tend to do aerobic activity and then a more calmer one to let the muscle tone relax
Overstretched muscles	Doing Hula Hoop and Half-Moon pose in yoga	Not to be concerned as just feel a normal stretch
Shortness of breath		Didn't do the right exercise in the first place as warm up
Near fall/miss	Step Plus-because it gets faster and faster	Managed to stop the fall
Near miss/fall	Trying to step on and off board. Caught foot as couldn't feel it - trying to do rapid movements to get on and off - poor co-ordination	Put off doing stepping so did yoga where you stay on the board and don't need to get on and off

