Testing the feasibility and acceptability of using the Nintendo Wii in the home to increase activity levels, vitality and well-being in people with multiple sclerosis (Mii-vitaliSe): protocol for a pilot randomised controlled study

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ABSTRACT

Introduction: The benefits of physical activity for people with multiple sclerosis (pwMS) have been recognised. However, exercise regimens can be difficult to maintain over the longer term and pwMS may face unique barriers to physical activity engagement. Pilot research suggests the Nintendo Wii can be used safely at home by pwMS with minimal mobility/balance issues and may confer benefits. We have developed a home-based physiotherapist supported Wii intervention (‘Mii-vitaliSe’) for pwMS that uses commercial software. This is a pilot study to explore the feasibility of conducting a full scale clinical and cost-effectiveness trial of Mii-vitaliSe.

Methods and analysis: 30 ambulatory, relatively inactive pwMS will be randomised to receive Mii-vitaliSe immediately, or after 6 months. Outcomes, measured at baseline and 6 and 12 months later, will include balance, gait, mobility, hand dexterity and self-reported physical activity levels, fatigue, self-efficacy, mood and quality of life. Interviews conducted on a purposive sample of participants will explore experiences of participation in the study and barriers and facilitators to using the Wii. Mean recruitment, adherence rate and standard deviations (SDs) of potential primary outcomes for the full trial will be estimated and precision summarised using 95% confidence intervals (CIs). Interview transcripts will be thematically analysed using a generic qualitative approach.

Ethics and dissemination: National Health Service (NHS; ref 12/SC/0420) and university ethical approvals have been obtained as has NHS Research and Development permission from the relevant trust. A home risk assessment will be undertaken for all potential participants. All adverse events will be closely monitored, documented and reported to the study Safety Monitoring Committee. At least one publication in a peer reviewed journal will be produced and research findings presented at a national and international conference. With service users, we will coproduce a summary of the findings for dissemination on our research unit’s website and elsewhere.

Trial registration number: ISRCTN 49286846.

Strengths and limitations of this study

▸ This pilot study will include a long-term (1 year) follow-up to consider adherence.
▸ The intervention will incorporate individual tailoring, behaviour change strategies and home-based Wii use with physiotherapist guidance.
▸ Mixed methods will be used.
▸ Physical outcome assessments will not be blinded.

INTRODUCTION

Historically, people with multiple sclerosis (pwMS) have been advised to limit physical activity levels. However, over the last decade the salutary effects of exercise for pwMS have become evident1–5 with no deleterious effects described.6–9 Physical activity has been shown to be associated with improvements in mobility, muscle strength and physical fitness.1 9–14 In a meta-analysis, planned and structured regular exercise was associated with a small improvement in quality of life (QoL) in MS.15 Other secondary benefits might include reduced fatigue, depression and anxiety and improved sense of well-being—although more rigorous trials are needed.14 16 Early intervention may help to slow or prevent the accumulation of physical disability.17 18

However, pwMS typically engage in dramatically lower levels of physical activity than the general population.2 4 19 This can lead to a downward spiral of deconditioning, fatigue, reduced self-efficacy, increased levels of disability4 as well as increased health risks (such as cardiovascular diseases, obesity, diabetes, etc). Psychosocial repercussions include reduced leisure, social contacts, role
fulfilment and engagement in activities of daily living; all important for self-esteem and psychological well-being.

People with long-term disabling conditions such as MS face unique barriers to participation in physical activity including physical (eg, pain, fatigue, mobility limitations and overheating), psychological (eg, fear, embarrassment and lack of confidence) and environmental (transport, cost, lack of suitable facilities/trained staff) factors. While home-based activities overcome some of these, adherence to traditional exercise programmes is poor. Making exercise an enjoyable experience undertaken in a non-threatening and comfortable environment along with the provision of detailed guidance, monitoring and support may improve adherence.

The National Institute for Health and Care Excellence (NICE) guidelines, the National Service Framework for long-term conditions and the Health Foundation highlight the importance of guided tailored self-management supported by health professionals to encourage engagement in physical activity and leisure and social pursuits.

Physical activity is multifaceted and psychological factors play a crucial role in its initiation and maintenance. Adopting a multidisciplinary approach can help to support behaviour change and physical activity prescription. Social Cognitive Theory and in particular, the concept of self-efficacy has been proposed as a key mediator in the promotion and maintenance of physical activity and adherence and an important predictor of health status.

The Wii overcomes some of the barriers to participation in physical activity highlighted earlier. It is low cost, can be used at home, and has broad appeal, incorporating variables known to enhance motivation, self-efficacy and adherence (such as self-monitoring, prompts, peer comparison and feedback about progress and performance) in the context of fun purposeful tasks. It offers opportunities for socialisation across the lifespan and participation in immersive virtual reality activities that might, in real life, be challenging due to physical limitations, or require further adaptation to enable participation (eg, golf). Games such as Wii Sports use significantly more energy than sedentary activities (though not as much as playing the sport itself).

For the current study the Wii was deemed preferable over other newer more complex virtual reality platforms, such as the Xbox Kinect: it is low cost, requires less space, permits support from a therapist within the field of view and the Wii sensors are relatively ‘forgiving’ thereby facilitating use by people with impaired or compromised movement. Our findings will, nevertheless, have applicability to and relevance for other platforms and chronic conditions.

In conjunction with the Wii balance board, the Wii Fit Plus incorporates games requiring the user to shift his/her weight from side to side and forwards and back to control gameplay. A key feature of these systems is the provision of dynamic visual feedback about centre of gravity allowing training and adjustments of movement via biofeedback techniques. These recent advances in interactive gaming have created the potential for increasing physical activity and decreasing sedentary behaviour. It has been suggested that such games may be helpful for improving balance and core strength under the guidance of a qualified health/rehabilitation professional (who can advise on the selection of appropriate activities to challenge balance safely and gradually).

Wii games can be played for brief periods, at the individual’s convenience. Daily activity levels can be accumulated in short bouts of 10 min or more throughout the day (which is thought to be as effective as all in one go, at differing levels, and a range of activities can be selected, depending on current symptoms and preferences. Creating a personalised representation of oneself (a ‘Mii’) may enhance self-efficacy via a greater sense of ‘presence’ and motivation.

However, there are potential disadvantages. As with other physical activities, playing the Wii could lead to injury, discomfort or increased symptoms. Many of the reported injuries have been due to people exercising beyond their limitations and without resting adequately. The user manual provides guidance on how to use the Wii safely and onscreen prompts about resting are regularly provided. As the Wii software has been developed with a healthy population in mind, it is important to explore its acceptability to pwMS.

While applications of the Wii are diverse and preliminary findings positive, the evidence base is limited and definitive answers require well-designed randomised controlled trials (RCTs). In this pilot study, we wish to explore whether a commercially available interactive gaming system, the Nintendo Wii, offers a safe, feasible way to provide opportunities in the home for increased physical activity for pwMS (which could lead to improvements in domains such as vitality, balance, mobility, QoL and well-being). To date, Wii research with people affected by MS is mostly preliminary. Early findings are promising, however, and suggest that the Wii might be helpful for balance and fitness.

In a non-randomised pilot study Plow and Finlayson found that pwMS who have mild balance and mobility limitations can use the Wii Fit safely at home. However, they also reported that Wii use declined after 3 months. They suggested that a more person-centred approach as well as the use of behavioural change techniques (such as motivational interviewing and problem solving) might help to promote longer term Wii use and foster intrinsic motivation. In a scoping review of the exergaming literature Plow et al recommended that trials incorporate longer term follow-up periods, employ mixed methods and follow patients from the clinical setting to the home. Others have suggested that an individualised approach is essential to take into account individuals’...
beliefs, self-efficacy and perceptions about exercise and their self-identity, goals and expectations for improving health. Often research projects proceed rapidly to a full scale RCT, with vital, preparatory phases overlooked. This can result in a resource intensive and costly analysis of a conceptually or clinically flawed intervention. In this study, we have consulted with pwMS already using the Wii, and adapted existing guidance on using the Wii to develop a home-based physiotherapist supported Wii intervention for pwMS (MiivitaliSe). We will undertake a small pilot RCT of the MiivitaliSe intervention to explore the feasibility of a full-scale formal evaluation of effectiveness.

METHODS

Aim
To investigate the feasibility of conducting a multicentre definitive RCT to assess the clinical and cost-effectiveness of a home-based physiotherapist supported Wii intervention (MiivitaliSe) for pwMS.

Objectives
1. Test procedures (including administration of the self-reported outcomes and the physical assessments, delivery of the intervention, recording and monitoring of adverse events (AEs)), estimate recruitment and retention rates, and refine the selection of outcome measures in preparation for a definitive RCT to test the effectiveness of MiivitaliSe.
2. Collect data on the variability of outcome measures to inform a sample size calculation for a larger trial.
3. Estimate adherence rates via a self-reported daily play log (in terms of frequency, intensity, duration).
4. Determine the acceptability of randomisation and of the MiivitaliSe intervention to participants and obtain information about patterns of use/barriers to use.
5. Gather feedback from physiotherapists about their experiences of delivering MiivitaliSe.

Study design
A single centre wait-list controlled pilot study of MiivitaliSe plus usual care versus usual care alone (see figure 1) will be undertaken. Participants will be randomised to receive MiivitaliSe immediately or after 6 months (‘delayed’ group). The delayed group will continue their usual routines and receive the MiivitaliSe intervention after a 6-month delay. During this period, they will be asked to refrain from using the Wii and will act as controls for the immediate group.

This design has the potential to minimise the impact of disappointment that those allocated to a non-intervention group might experience, while ensuring those in the delayed group receive the full intervention with an emphasis on safety aspects. Delivering the intervention to those in the delayed group may increase compliance with refraining from use for a 6-month period. This design also permits a preliminary consideration of long-term (1 year) follow-up (immediate group only). The randomised controlled component allows testing of procedures, design, etc in preparation for a full scale trial. Follow-up periods are sufficient for novelty value to diminish and patterns of use to be established.

Service user involvement
Following INVOLVE principles, services users have been involved in all stages of the research so far, including the development of this protocol. A service user consultation was held to inform the content and format of the MiivitaliSe materials and aspects of the study design. Service users will be represented on the trial steering group and will continue to provide ongoing input into the study.

Data protection and data storage
All information collected during the course of the study will be kept strictly confidential and any information that leaves Poole Hospital/Bournemouth University will
contain no personal details. Questionnaires will be allocated a participant ID; they will not contain names or any identifying details. Only authorised members of the research team will have access to the study data.

Data will be collected and retained in accordance with the Data Protection Act 1998. Study documents (paper and electronic) will be retained in a secure location during and after the trial has finished. All source documents will be retained for a period of 5 years following the end of the study.

Compliance
The Chief Investigator will ensure that the study is conducted in compliance with the principles of the Declaration of Helsinki (1996) and in accordance with all applicable regulatory requirements including, but not limited to, the Research Governance Framework and Trust policies and any subsequent amendments.

Sample size considerations
A ‘rule of thumb’ of 30 is common for pilot studies. A sample size of 30 (15 in the immediate and 15 in the delayed arm) will be adequate given the specific quantitative aims of this pilot.

Objective 1 is to estimate the recruitment rate to help in planning recruitment for a full scale RCT. Precision of this estimate will be based on the width of the 95% CI. With a total sample size of 30 people recruited, the recruitment rate will be estimated with a precision of ±11% (assuming a recruitment rate of approximately 40% based on experiences of running a RCT of ±11% (assuming a recruitment rate of approximately 40% based on experiences of running a RCT of a fatigue management programme for pwMS).93

Objective 2 is to estimate the SD of potential primary outcome measures in preparation for a formal sample size calculation for a larger RCT. Assuming these outcomes are standardised, so that they have a SD of 1, the precision (as summarised by standard error) will be 0.13. When using this estimate for a later sample size calculation it will be inflated as suggested by Browne.94

Estimating the effect size for the Mi-vitaliSe intervention is not an aim of this pilot, but would be the aim of a later full scale RCT.

Objective 3 is to estimate the degree of adherence of participants to Mi-vitaliSe. For each individual this will be summarised as the number of days on which activities were performed divided by the number of days agreed with the physiotherapist in their action plan. The potential range is 0–1, and the SD will be at most 0.17 (NQuery Advisor). With a sample size of 30, average adherence will be estimated with precision ±0.06 (ie, width of 95% CI).

Participants
Thirty ‘inactive’ (see eligibility criteria) pwMS aged 18 or over, will be recruited from the Dorset MS Service. Individuals excluded from the research project will continue to be seen as per usual care.

Eligibility criteria
Inclusion criteria
▸ Clinically definite diagnosis of MS
▸ Aged 18 or above
▸ Fulfil home risk assessment criteria (see below)
▸ ‘Inactive’ (physically active on fewer than 5 days/week for ≥30 min)
▸ Living within Poole/Bournemouth conurbations
▸ Suitable television

Exclusion criteria
▸ Have only mild symptoms (equivalent to an Adapted Patient Determined Disease Steps (APDDS) Scale score of 6 or more)
▸ Relapse within the past 3 months requiring corticosteroids
▸ Already participating in exercise/rehabilitation research
▸ Any medical condition placing participant at risk from exercise participation/using Wii
▸ Owns a Wii and uses it regularly (weekly or more)
▸ Unwilling/unable to comply with protocol

Risk assessment
This will be undertaken at home by the study researcher (who is a senior physiotherapist) to assess balance on the Wii balance board and the suitability of the home environment for setting up the equipment and using the Wii.

Participants will be considered eligible if:
▸ They can maintain independent standing balance with eyes open for 1 min.
▸ The physiotherapist clinically judges that they demonstrate adequate balance reactions while on the Wii balance board and are able to step off safely forwards, backwards and sideways.
▸ Their home environment is suitable (with minor modifications, if appropriate and possible).

Identification and recruitment
Recruitment will be via the Dorset MS Service. Potential participants will be identified by the multidisciplinary Dorset MS team. A member of the MS team will go through a screening checklist to identify potential participants and will then either send or give them an invitation letter with a simple one-page summary (‘Key Facts’) about the study, participant information sheets, the APDDS Scale, a question about current levels of physical activity and a reply slip and pre-paid return envelope. Participants will be asked to return the reply slip and their responses if they wish to find out more about the study. A follow-up reminder letter with another copy of the information pack will be sent if a reply is not received within 2 weeks.
Screening procedure
The study researcher will telephone those who have expressed an interest in the research, describe the study in more detail, answer questions and go through the remaining screening criteria (see section ‘Exclusion criteria’) over the telephone. Those not eligible will be informed over the telephone. Individuals who fulfil the study criteria will be visited at home for the risk and home suitability assessment. Minor modifications to the home environment to facilitate the safe use of the Wii balance board will be discussed with the potential participant and documented.

Individuals not eligible to take part will continue to be seen as per usual care.

Informed consent process
Informed consent will be taken by the Good Clinical Practice (GCP) accredited study researcher in individuals’ homes, providing they satisfy the risk and home assessment criteria.

Randomisation
To ensure good allocation concealment, random allocation will be email based and administered by the study statistician. Randomisation will be carried out on a 1:1 basis and will utilise a computer-based random sequence generator. Variable-sized blocks will be used to ensure approximately equal numbers in the two trial arms. No stratification will be used.

Outcome measures
As this is feasibility work, a broad range of outcomes has been included. Participants will be requested to complete the outcomes even if they stop using the Wii. A detailed description of outcome measures is included in the web supplement.

Outcomes will be assessed at baseline and at 6 and 12 months. Physical assessments (administered at similar times of the day to reduce the confounding effect of fatigue) will be undertaken at the hospital by the study researcher and a clinical scientist. Self-reported questionnaires (presented in a large font) will be completed by participants in their homes, at their own convenience and pace.

Demographic/descriptor variables
Age, sex, education, employment, marital status, ethnicity, household composition, time since diagnosis, disease course, relapse history, medication, comorbidities.

Adverse events
Defined as any undesirable outcome, such as injury, falls, discomfort, pain, relapse. These will be recorded and reviewed by an independent Safety Monitoring Committee (comprising a neurologist and a physiotherapist).

Balance, gait mobility
- Two-minute walk test
- Step test

Physical activity
- Instrumented Timed Up and Go (ITUG)
- Gait stride-time rhythmicity
- Static posturography (Limits of Sway)

Hand dexterity/coordination
- Nine-hole peg test

Self-efficacy
- The Spinal Cord Injury Exercise Self Efficacy Scale (SCI-ESES)
- The Multiple Sclerosis Self-Efficacy (MSSE) Scale

Psychological well-being and QoL
- Hospital Anxiety and Depression Scale (HADS)
- EuroQual 5 Dimensions-5 Levels (EQ-5D-5L)
- Multiple Sclerosis Impact Scale (MSIS-29)
- The Fatigue Symptom Inventory (FSI)
- The Medical Outcomes Short-Form Survey V.2 (SF-36v2)

Adherence
Measuring adherence is challenging and while some have relied on the data captured by the Wii console, this approach is problematic (eg, other family members could use a participant’s Mii). In this study, adherence will be defined as the total number of days on which activities are performed divided by the number of days agreed with the physiotherapist in the action plan. We will also collect information related to duration and intensity, as well as the data stored on the Wii console.

Process measures
- Daily play log: date/time, whether played, AEs (eg, pain, tenderness, soreness, fatigue, dizziness, headaches, aching, stiffness, falls), activity, duration, intensity, enjoyment, fatigue, reasons for non-use, free-text comments.
- Physiotherapist feedback: Participant contacts will be recorded using a template. At the end of the intervention period the physiotherapists will be interviewed about the ease of delivering the intervention and any problems encountered.
- Semistructured interviews will be conducted (at home/ via telephone) on a purposive sample of participants selected to represent factors pertinent to expectations/experiences of participating in the study and receiving Mii-vitaliSe (such as age, gender, employment status, disease severity, prior experience of home console systems). These will comprise 50% of participants from each group at the 6-month follow-up and at the 12-month follow-up, the ‘immediate’ group only.
Health utilisation
Economic evaluation would be an important component of future research. We will pilot an existing measure of healthcare utilisation developed for a RCT of a fatigue management programme.125 We will provide participants with a resource use log to aid completion of the questionnaire.

Mii-vitaliSe intervention
Drawing upon a literature review, existing materials121–125 and our knowledge of best practice in physiotherapy and psychological interventions in MS, guidance and resource materials for using the Wii were developed. The research team worked in partnership with a service user panel (8 patients from the Dorset MS Service with experience of using the Wii and familiarity with the Wii Sports and Wii Fit Plus software). A workshop was held to discuss the Mii-vitaliSe intervention. The following aspects were discussed:

1. Safety aspects, patterns of usage, benefits/drawbacks, problems identified and whether/how they could be overcome.
2. Factors contributing to longer term use.
4. Which outcome domains are most relevant/meaningful to service users.
5. Feedback on the format and content of a draft daily play log.

After an iterative process of revision, LF and ST produced a set of materials to be used as part of a physiotherapist-supported home-based Wii intervention (Mii-vitaliSe). These include:

▸ General information about the Wii and Mii-vitaliSe;
▸ Safety and technical information;
▸ Guidance on warm up/cool down exercises;
▸ A guidance book and personal activity workbook;
▸ Games descriptors for Wii Sports, Wii Sports Resort and Wii Fit Plus;
▸ Tips on goal-setting and overcoming barriers;
▸ Signposts to useful resources (eg, websites, forums);
▸ Quotations from pwMS who attended the consultation workshop about their experiences of using the Wii.

The Mii-vitaliSe intervention is underpinned by principles of self-management, social cognitive, motivational interviewing and cognitive behavioural theories. It incorporates a workbook to enable individually tailored goal setting, monitoring and the identification of facilitators and barriers to engagement with Mii-vitaliSe.

Usual care
The Dorset MS service offers pwMS multidisciplinary support. Patients are reviewed annually by the team at an outpatient clinic or home visit appointment. This includes a medical review by a neurologist and specialist MS nurse and a therapy review by a physiotherapist and occupational therapist. On completion of the review and necessary assessments, medical and therapy treatment is modified as required. If patients experience a deterioration of their symptoms before the next review they can self-refer to the service. This may take the form of advice regarding relapse management or specific intervention.

The team operates a help-line between 9:00 and 11:00 Monday to Friday and there is an answer-phone out of hours. The team is available to discuss problems with patients and action appropriate treatments in a timely way. If therapy is required (occupational therapy/physiotherapy) this is offered by the MS specialist therapists and patients can be assessed and treated at home, as an outpatient, in work or a gym environment. Education, support and advice regarding disease modifying therapies, management of symptoms and carer support is available from the specialist nurse.

Statistical analysis
Recruitment and retention rates for the study and SDs of potential primary outcome measures will be

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**Mii-vitaliSe intervention**

**Session 1: Orientation to the Wii in the hospital setting (week 1)**

The physiotherapist goes through the guidance book with the participant to cover:

▸ The benefits of physical activity
▸ A practical demonstration of using the software (Wii Sports, Wii Sports Resort and Wii Fit Plus) safely
▸ Creating a ‘Mi’
▸ Familiarisation with the controls

**Session 2: Training and individualised assessment in the hospital setting (week 2)**

Participants will be guided through warm up/cool down exercises and given the opportunity to try out activities safely under supervision. The physiotherapist and participant will discuss appropriate activities, taking into account physical capabilities, and personal preferences.

**Session 3: Installation of Wii at home and starting individual programme (week 3)**

The physiotherapist will install the Wii equipment in participants’ homes to interface with their television. Participants will be provided with Wii Sports, Wii Sports Resort and Wii Fit Plus, asked to use their Mi when playing, and to log any other software used via the daily play log. The physiotherapist will reiterate safety advice (eg, the importance of the safety strap, taking a graded approach and frequent rests, etc). The physiotherapist will agree an individualised programme with the participant, indicate ways this could be progressed and provide guidance on keeping the daily play log and on setting/recording goals.

**Ongoing support and monitoring**

This will be followed by independent home use supported by a combination of telephone support (week 5—to identify and resolve any early difficulties encountered; week 12 to encourage progress, support people to overcome any barriers) and home review visits (weeks 7 and 16) at which the physiotherapist will reassess the individual and provide support and discuss possible progression/modification of the activities. Thereafter, ongoing monitoring, support and encouragement will be provided via monthly contact (phone/email) from the physiotherapist.
estimated, and precision summarised using 95% CIs. For each individual, adherence will be summarised ((the number of days on which activities were performed divided by the number of days recommended by the physiotherapist)×100%). These data will be collected via participant-completed daily play logs. We will estimate mean adherence (%) in the first 6 months of using the Wii by combining data from months 1–6 for the immediate group and months 7–12 for the delayed group. We will estimate adherence in the second 6 months of using the Wii using data from months 7–12 in the immediate Wii group.

We will develop and test out data analysis procedures in preparation for developing a statistical analysis plan for a later RCT. This will involve (1) capitalising on the randomised nature of the study by comparing outcomes between study arms at 6 months (in months 1–6 the immediate Wii group will have been using the Wii, and the delayed group will not have been using the Wii), (2) analysing within person change over 6 months of using the Wii (ie, months 1–6 in the immediate group and months 7–12 in the delayed group) and (3) analysing within person change over 12 months of using the Wii (ie, months 1–12 in the immediate group).

Qualitative analysis
The interviews will be recorded, transcribed and thematically analysed using a generic qualitative approach126–131 and involving inter-researcher and service user interpretation/discussion. Free-text comments in the daily play logs will be collated and summarised. Themes developed will inform the design of a future trial and the selection of outcome measures.

Participant withdrawal from study and/or from research follow-up
If a participant withdraws from the study, the study researcher will be informed and will contact the participant. Provided the participant is willing to give a reason, the study researcher will find out why he/she wishes to withdraw from the study. The study researcher will also determine whether he/she wishes to continue to be included in the research follow-up or wishes to withdraw. If the participant wishes to withdraw from the research follow-up the study researcher will determine whether he/she gives permission to retain data collected before withdrawal for use at final analysis, or whether this information should be destroyed. No data will be used in the analysis without a participant’s consent.

Adverse events
All AEs and their possible relation to the Mii-vitaliSe intervention will be closely monitored, documented and reported to the study Safety Monitoring Committee. The Safety Monitoring Committee will consider the events and offer advice to the project team. Participants will be asked to report all AEs related to use of the Wii to either the physiotherapists delivering Mii-vitaliSe or to the study researcher. These will be recorded on a case report form. In addition there will be a section on the daily play log to record AEs (including pain, tenderness, soreness, fatigue, dizziness, headaches, aching, stiffness, nausea, falls or near falls). The physiotherapists will ask participants whether they have experienced any AEs related to using the Wii in their monthly monitoring phone calls. The Dorset Multiple Sclerosis team will notify the research team of any AEs that become known to them.

The Chief Investigator will assess an AE to establish if it should be classified as a Serious Adverse Event (SAE) according to the National Research Ethics Service definition. If the AE is not defined as ‘serious’, it will be recorded in the study site file and the participant will be followed up by the research team. The AE will be documented in a participant’s MS Service notes (where appropriate). Reports of related and unexpected SAEs will be submitted to the Research Ethics Committee within 15 days of the CI becoming aware of the event, using the ‘Report of SAE form for non-CTIMPs’ (V.3, April 2007), published on the NRES website. The sponsor will be notified within 24 h.

Project management and safety monitoring
The study researcher will deal with the day-to-day management and coordination of the study and will call on other members of the project team as appropriate. The Chief Investigator will be responsible for the overall management of the project. The CI, study statistician, and study researcher will have regular meetings to discuss study progress. The study steering group will meet twice yearly to monitor progress. A Safety Monitoring Committee comprising two independent advisors (a neurologist with expertise in MS and clinical trials and a physiotherapist with expertise in risk assessment and management of service users with neurological disability) will review any AEs and make recommendations to the study steering group (eg, adapting the protocol/stopping the study, as necessary).

Monitoring and audit
The study will be monitored and audited in accordance with Poole Hospital NHS Foundation Trust (PHFT) policy. All trial related documents will be made available on request for monitoring and audit by PHFT and the Research Ethics Committee. Regular meetings will take place with the study monitor.

Ethical considerations and dissemination
The study has been reviewed and given a favourable opinion by the National Health Service (NHS) South Central Hampshire B Research Ethics Committee (ref: 12/SC/0420). Poole Hospital NHS Foundation Trust is acting as the sponsor. The study will be performed subject to Research Ethics Committee (REC) approval, including any provisions of Site Specific Assessment (SSA), and local Research and Development (R&D) approval. This study will be conducted in accordance
with the Research Governance Framework for Health and Social Care and GCP.

It is likely that majority of the participants in the study will have fatigue, and so we will try to minimise the impact that participation in the study has on their fatigue (eg, by staggering questionnaire load and providing a refreshment break during the physical assessments, offering taxi transport to the hospital).

We aim to disseminate the results of this research working closely with service user partners and the funder. It is anticipated that at least one publication in a peer reviewed journal will be produced and we intend to present the findings at a national and international conference. In collaboration with our service users we will produce a short report suitable for the general public. Further dissemination to pwMS will be via our unit’s website, the Wihabilitation website and (with their permission) MS charities and the Chartered Society of Physiotherapy. We also plan to disseminate findings via press releases and social media.

**DISCUSSION**

This pilot study will assess the acceptability and suitability of a home-based physiotherapist supported Wii intervention (Mii-vitaliSe) to increase activity levels in pwMS. Mii-vitaliSe addresses limitations highlighted in the literature by incorporating home-based activity, behavioural change principles, employing mixed methods and including a long term follow-up period. Findings from this study will establish whether a full scale RCT is feasible and, if supportive of proceeding to a full trial, will inform its design and conduct. The decision on whether to progress to a full trial will be made by the trial steering group. No specific criteria have been set. If found to be effective in a full trial, Mii-vitaliSe could increase activity levels in a group of people known to have low activity levels overall and could be readily implemented in a healthcare system such as the NHS.

Technological developments in this field are ongoing with rehabilitation software currently being developed for the Nintendo Wii and other platforms. The general principles and findings from this research will have relevance for the next generation of software and platforms and also for other chronic conditions.

**REFERENCES**


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124. Advisory document (created by Hirons C [Clinical Specialist Physiotherapist], Smith O [Clinical Specialist Prosthetics], Hirons R [Clinical Specialist Prosthetics] on the suitability of Wii™ Fit exercises for lower limb prosthetic users either as a recreation or rehabilitation tool. 2009. http://www.wiihabilitation.co.uk/files/wii_fit_bro_uk_traffic_light_version.pdf


Web supplement: Detailed description of outcome measures

Balance, gait mobility

- **Two-minute walk Test** (2MWT)
  This is a measurement of endurance by assessing timed walking distance over 2 minutes. It has been suggested that it is an acceptable alternative to the more common 6 minute walk test. The 2MWT will be conducted in a >12 metre hallway with markers at each end to show the point to turn. The individual is instructed to walk for two minutes and to cover as much ground as possible in that time. The distance covered is measured and logged. Habitual assistive devices and orthotics can be used. We will use instructions based on the American Thoracic Society guidelines for the six minute walk test and modified instructions. The modified instructions focus on maximising effort by emphasising speed and omitting instructions for permitted rest in the 2 minutes.

- **Step test**
  This is a test of dynamic standing balance. It involves recording the number of times a participant steps one foot fully on, then off a block as quickly as possible in a 15 second time period. Two block heights are used: 7.5 cm and 15 cm. Each leg is tested separately. Participants are instructed to perform this task as quickly as possible.

- **Steady Stance tests**
  Steady stance tests measure the ability of an individual to maintain a steady stance for a 60 second period in five predetermined stances without support: (1). feet apart, with feet placed 10 cm apart; (2). feet together; (3). stride stance, with feet placed 10 cm apart and with the toes of the rear foot in line with the heel of the front foot; (4) tandem stance, with one foot directly in front of the other, with the heel of the front foot in contact with the toes of the rear foot; and (5) single leg stance, with the individual standing on one leg with the opposite foot held off the floor. The tests end when an
individual either maintains steady stance for the 60 second testing duration, loses balances and takes support or alters their foot position.

- **Instrumented Timed Up and Go (ITUG)**
  This is a timed test used to examine functional mobility and requires the individual to stand up from a seated position, walk 3 metres, turn, walk back, and sit down. Recently researchers have found that an instrumented version of the TUG (ITUG) achieved using a body-fixed accelerometer to record movement during the standard TUG assessment protocol can improve its sensitivity. We will use an accelerometer to measure the initialisation and completion times of the TUG manoeuvre and its overall duration. Time for completion, number of steps and duration of standing and sitting position will be recorded.

- **Gait stride-time rhythmicity**
  This is measured in a laboratory-free setting using a portable recorder connected to flat in-shoe heel impact sensors. The extended walk of up to 256 steps per foot is not accompanied by the assessor. The participant may use a normal walking aid or orthotic. Participants are asked to walk at their natural walking speed and instructed not to stop to talk if they see people they know. The walk route is flat and covered throughout. The stride time between adjacent heel strikes is recorded for each foot separately and the mean and standard deviation stride times are calculated.

- **Static posturography** *(Limits of Sway)*
  The Poole Hospital Static Posturography System provides a method for objectively assessing balance via the tracking of limits of sway in a series of standardised conditions. It uses ultrasound time-of-flight (ToF) posturography measurements to locate an individual’s centre of gravity (CoG) in a protocol mirroring the Equitest sensory organisation test protocol. Two orthogonal 40 kHz ultrasound transmitters are mounted on the individual's waist at the height of the centre of gravity.
(CoG). Anterior/posterior and lateral motions are detected independently by measuring variations in
the ToF from the transmitters to appropriately positioned wall-mounted receivers. The motion of the
CoG is accurately tracked during the course of 20 second assessment periods as the individual
stands on either a solid or soft surface with eyes open or eyes closed or when doing a cognitive
distractor task. Measures obtained include the Equilibrium Quotient (EQ) percent score (100-
(Anterior posterior maximum sway during 20 seconds/maximum anterior posterior movement
possible without losing balance)*100) and the average speed of CoG movement during
measurement.

Physical activity

- **Godin Leisure-Time Exercise Questionnaire (GLTEQ)**\(^{11,12}\)
  This is a self-reported measure of usual physical activity that has been widely used in
epidemiologic, clinical and behavioural change studies. It consists of 2 items: the first is open
ended and measures frequency and intensity of exercise during free time in a typical week. The
weekly frequencies are multiplied by metabolic equivalents and summed to form a measure of total
leisure activity. The second question is ordinal with 3 options and measures the frequency of
engaging in any regular activity long enough to work up a sweat.

- **ActivPAL™**\(^{13}\)
  This classifies an individual's free-living activity into periods spent sitting, standing and walking
and gives the number of steps and sit-to-stand episodes. This information can be used to estimate
daily energy expenditure, and time spent resting. [http://www.paltechnologies.com]. We will ask
participants to wear an ActivPAL™ for periods of 7-days.

Motor Coordination

- **Nine-hole peg test**\(^{14}\)
This timed test assesses finger and hand dexterity in both hands. It involves placing nine pegs and then removing them from a peg board as quickly as possible.

**Self-efficacy**

- **The Spinal Cord Injury (SCI) Exercise Self Efficacy Scale (SCI-ESES)**\(^{15}\)
  
  As the name suggests, this scale was originally developed and validated in spinal cord populations. However, it has since been used with multiple sclerosis patients\(^ {16}\). It consists of 10 items with higher scores indicating higher perceived self-efficacy. It uses a 4-point Likert-type response scale.

- **The Multiple Sclerosis Self-Efficacy (MSSE) Scale**\(^ {17}\)
  
  This 22-item scale comprises two subscales: i. confidence with function and ii. confidence with ability to manage symptoms/cope with the demands of illness. The rating scale consists of 10-points where 10 is *very uncertain*, 50 is *moderately certain* and 100 is *very certain*. Higher scores indicate greater self-efficacy.

**Psychological well-being and quality of life**

- **Hospital Anxiety and Depression Scale (HADS)**\(^ {18}\)
  
  The HADS is a self-report measure consisting of an anxiety and a depression subscale. Each subscale consists of 7 items with a 4-point Likert-type response scale. Higher scores indicate worse levels of anxiety and depression.

- **EuroQual 5 Dimensions-5 Levels**\(^ {19}\)
  
  EQ-5D-5L is a standardised measure of health status developed by the EuroQoL Group. The EQ-5D consists of the EQ-5D -5L descriptive system and the EQ visual analogue scale (EQ VAS). The EQ-5D descriptive system comprises 5 dimensions: mobility, self-care, usual activities,
pain/discomfort and anxiety/depression. Each dimension has 5 levels: no problems, slight problems, moderate problems, severe problems, and extreme problems.

The EQ VAS records the respondent’s self-rated health on a 20 cm vertical, visual analogue scale with endpoints labelled ‘the best health you can imagine’ and ‘the worst health you can imagine’.

- **Multiple Sclerosis Impact Scale (MSIS-29)^20,21**

This scale measures the physical (20 items) and psychological impact (9 items) of MS on day-to-day life. It uses 5-point Likert-type scales ranging from ‘not at all’ to ‘extremely’ and is based on quality of life in the last two weeks.

- **The Fatigue Symptom Inventory (FSI)^22**

The FSI is a 14-item self-administered multi-dimensional questionnaire which measures the severity, frequency and diurnal variation of fatigue and its perceived interference on quality of life. We will use 4 items comprising the severity subscale that assess most, least, and average fatigue in the past week, as well as current fatigue.

- **The Medical Outcomes Short-Form Survey version 2 (SF-36v2)^23**

The SF-36 measures eight dimensions: physical functioning, role limitations because of physical health problems, bodily pain, general health perceptions, vitality, social functioning, role limitations because of emotional problems, and mental health. It generates scores for the eight dimensions as well as two summary measures (physical health and mental health). It uses Likert-type response scales.

**References**


