

# 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

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| <b>Submission date</b><br>17/10/2012   | <b>Recruitment status</b><br>No longer recruiting    | <input checked="" type="checkbox"/> Prospectively registered |
| <b>Registration date</b><br>18/10/2012 | <b>Overall study status</b><br>Completed             | <input checked="" type="checkbox"/> Protocol                 |
| <b>Last Edited</b><br>04/10/2018       | <b>Condition category</b><br>Nervous System Diseases | <input type="checkbox"/> Statistical analysis plan           |
|  |  | <input checked="" type="checkbox"/> Results                  |
|  |  | <input type="checkbox"/> Individual participant data         |

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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## Additional identifiers

### Protocol serial number

13130

## Study information

## **Scientific 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

## **Acronym**

Mii-vitaliSe

## **Study objectives**

People with MS (pwMS) often find it difficult to exercise for a variety of different reasons (physical, social, psychological, environmental). Physical activity is important in maintaining health and in pwMS can help combat fatigue. The Nintendo Wii™ is an increasingly popular gaming system that offers possibilities for increasing physical activity at home in a fun, engaging way; perhaps leading to benefits in well-being and quality of life. Using the Wii™ in conjunction with individual support from a physiotherapist will help to ensure that pwMS use it in a safe and effective long-term way.

The main aim of this project is to conduct a small pilot randomised controlled trial comparing:

1. pwMS using the Wii™ with physiotherapist support
2. pwMS not using the Wii™

We will follow up participants for up to a year and assess their use of the Wii™, their physical functioning, quality of life and general well-being. This pilot study will be a vital step in reducing uncertainties in designing and preparing for a much larger definitive study. For example, we will develop specific guidance for pwMS on using the Wii™ and test out procedures for a full-scale study.

## **Ethics approval required**

Old ethics approval format

## **Ethics approval(s)**

1. NRES South Central Southampton B Research Ethics Committee, 28/08/2012, IRAS Ref: 1369
2. NRES South Central Southampton B Research Ethics Committee, substantial amendment approval, 06/12/2012

## **Study design**

Randomised interventional trial

## **Primary study design**

Interventional

## **Study type(s)**

Treatment

## **Health condition(s) or problem(s) studied**

Nervous system disorders

## **Interventions**

Mii-vitaliSe

Week 1: Orientation to the Wii™ (hospital).

Week 2: Training and individualised assessment (hospital).

Week 3: Physiotherapist home visit; Wii™ equipment installed

Independent home use with 2 home reviews visits and regular telephone monitoring.

Participants receiving Mii-vitaliSe will continue to have access to services available as part of their usual local care.

### **Intervention Type**

Procedure/Surgery

### **Primary outcome(s)**

Demographic/descriptor variables measured at baseline and 6 months

### **Key secondary outcome(s)**

1. 2 minute timed walk measured at baseline and 6 months
2. ActivPAL accelerometer measured at baseline and 6 months
3. Adherence measured throughout study duration
4. Adverse events measured throughout study duration
5. Euroqual 5 Dimensions-5 Levels measured at baseline and 6 months
6. Fatigue Symptom Inventory measured at baseline and 6 months
7. Gait-stride time rhythmicity measured at baseline and 6 months
8. Godin Leisure Time Questionnaire measured at baseline and 6 months
9. Hospital Anxiety and Depression Scale measured at baseline and 6 months
10. Multiple Sclerosis Impact Scale measured at baseline and 6 months
11. Multiple Sclerosis Self-Efficacy Scale measured at baseline and 6 months
12. Nine hole peg test measured at baseline and 6 months
13. Semi structured interviews measured at 6 months (12 months immediate group only)
14. Static Posturography measured at baseline and 6 months
15. Steady Stance test measured at baseline and 6 months
16. Step test measured at baseline and 6 months
17. The Medical Outcomes Short-Form Survey version 2 measured at baseline and 6 months
18. The Spinal Cord Injury Exercise Self-Efficacy Scale measured at baseline and 6 months
19. Timed Up and Go measured at baseline and 6 months

### **Completion date**

01/09/2014

## **Eligibility**

### **Key inclusion criteria**

1. Clinically definite diagnosis of MS
2. Aged 18 or above
3. 'Inactive' (typically physically active for 30 mins or more on fewer than 5 days/week)
4. Living within Poole/Bournemouth conurbations
5. Fulfil risk assessment criteria - this will be undertaken by a Senior Physiotherapist in the home setting
6. Participants who can maintain independent static standing balance with eyes open for 1 minute
7. The physiotherapist clinically judges that the participant can demonstrate adequate balance reactions while on the Wii™ balance board and are able to step off safely backwards and sideways
8. The participants' home environment is suitable (with minor modifications, if appropriate and

possible) for using the Wii™ equipment safely for exercise

9. Male or female participants

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. If only have mild symptoms (equivalent to an Adapted Patient Determined Disease Steps Scale of 1 (EDDS of 1) Require at least intermittent assistance (cane, crutch or frame) to walk 100 metres with or without resting (Equivalent to an APDDS and EDSS score of 6 or more).
2. Relapse within past 3 months requiring corticosteroids
3. Already participating in exercise/rehabilitation research
4. Medical condition placing participant at risk this will be based on their neurologist's judgement
5. Owns a Wii™ and uses it regularly (weekly or more)
6. Unwilling or unable to comply with protocol
7. Not in possession of a suitable television

**Date of first enrolment**

01/11/2012

**Date of final enrolment**

01/09/2014

**Locations**

**Countries of recruitment**

United Kingdom

England

**Study participating centre**

**Bournemouth University**

Bournemouth

United Kingdom

BH1 3LT

# Sponsor information

## Organisation

Poole Hospital NHS Foundation Trust (UK)

## ROR

<https://ror.org/03kdm3q80>

# Funder(s)

## Funder type

Charity

## Funder Name

Multiple Sclerosis Society (UK)

## Alternative Name(s)

mssocietyuk, MS Society UK, Multiple Sclerosis Society UK, Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society

## Funding Body Type

Private sector organisation

## Funding Body Subtype

Associations and societies (private and public)

## Location

United Kingdom

# Results and Publications

## Individual participant data (IPD) sharing plan

## IPD sharing plan summary

Not provided at time of registration

## Study outputs

| Output type                      | Details  | Date created | Date added | Peer reviewed? | Patient-facing? |
|----------------------------------|----------|--------------|------------|----------------|-----------------|
| <a href="#">Results article</a>  | results  | 27/09/2017   |            | Yes            | No              |
| <a href="#">Protocol article</a> | protocol | 07/05/2014   |            | Yes            | No              |

