# 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

Submission date<br/>17/10/2012Recruitment status<br/>No longer recruiting[X] Prospectively registered<br/>[X] ProtocolRegistration date<br/>18/10/2012Overall study status<br/>Completed☐ Statistical analysis plan<br/>[X] ResultsLast EditedCondition category☐ Individual participant data

**Nervous System Diseases** 

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

04/10/2018

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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<sup>™</sup>, 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<sup>™</sup> 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 Ouestionnaire 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 particpant can demonstrate adequate balance reactions while on the Wii™ balance board and are able to step off safely backwards and sidewards
- 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 particpants

# 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)

Multiple Sclerosis Society of Great Britain and Northern Ireland, The MS Society, MS Society UK, Multiple Sclerosis Society UK, 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?
Results article	results	27/09/2017	Yes	No
Protocol article	protocol	07/05/2014	Yes	No