

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 17/10/2012	Recruitment status No longer recruiting	☒ Prospectively registered
		☒ Protocol
Registration date 18/10/2012	Overall study status Completed	☐ Statistical analysis plan
		☒ Results
Last Edited 04/10/2018	Condition category Nervous System Diseases	☐ Individual participant data

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design

Interventional

Study design

Randomised interventional trial

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?
Results article	results	27/09/2017		Yes	No
Protocol article	protocol	07/05/2014		Yes	No

