ISRCTN49286846 https://doi.org/10.1186/ISRCTN49286846

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

Registration date
18/10/2012

Overall study status
Completed

Last Edited
04/10/2018

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 measure
Demographic/descriptor variables measured at baseline and 6 months

Secondary outcome measures
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

Overall study start date
01/11/2012

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 30

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
England

United Kingdom

Study participating centre
Bournemouth University
Bournemouth
United Kingdom
BH1 3LT

Sponsor information

Organisation
Poole Hospital NHS Foundation Trust (UK)

Sponsor details
Dorset Research and Development Support Unit
Cornelia House
Longfleet Road
Poole
England
United Kingdom
BH15 2JB

Sponsor type
Hospital/treatment centre

Website
http://www.poole.nhs.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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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