ISRCTN14852234 https://doi.org/10.1186/ISRCTN14852234

Using the Nintendo Wii as an intervention for elderly fallers

Submission date	Recruitment status	[ ] Prospectively registered
23/02/2016	No longer recruiting	[ ] Protocol
Registration date	**Overall study status**	[ ] Statistical analysis plan
04/03/2016	Completed	[ ] Results
Last Edited	**Condition category**	[ ] Individual participant data
18/10/2017	Other	[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
There were 64,7721 A&E attendances and 20,4424 admissions to hospital for fall-related injuries in people over the age of 60 years in 2000. The cost of these falls to the NHS is approximately £980 million per year. For north Essex (the area where this study takes place) the cost of falls is approximately £5 million per year. To combat recurrent falls Colchester Hospital University Trust (CHUFT) runs a falls clinic. The training lasts for 9 weeks (1 hour session per week), it is patient specific and it aims, among other things, to improve balance. The training commonly incorporates the use of the Nintendo WiiFit™. A previous study was undertaken using the Wii as a training tool for fallers attending hospital as outpatients mainly to assess its safety. This study will test the effectiveness of the Wii in patients' homes. Undertaking supervised training in the home will reduce the burden placed upon patients by requiring them to come to the hospital for an extra training session. This will also enable to intervention to be made available to more people.

Who can participate?
Recurrent fallers aged 60 or over, assessed by physiotherapy staff as being suitable to attend the falls prevention training

What does the study involve?
Participants are randomly allocated to one of three groups. Group A is given physiotherapy falls training at the hospital. Group B is given extra Wii balance training by a physiotherapist /physiotherapist assistants. Group C is given an extension of the current hospital training with physiotherapy staff supervising, correcting and progressing patients. The extra training for groups B and C consists of 20--45 minutes supervised training twice per week in the patient's home. We compare the functional mobility and psychological wellbeing of all patients before and after training

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Colchester Hospital University Foundation Trust (UK)

When is the study starting and how long is it expected to run for?
March 2016 to March 2017

Who is funding the study?
Post Graduate Medical Charity at Colchester Hospital University NHS Foundation Trust (UK)

Who is the main contact?
Dr Murray Griffin

Contact information

Type(s)
Scientific

Contact name
Dr Murray Griffin

Contact details
University of Essex
Wivenhoe Park
Colchester
United Kingdom
CO4 3RL

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Using the Nintendo Wii as an intervention for elderly fallers: a randomised controlled trial

Study objectives
1. Wii training will reduce the incidence of falls, improve balance, functional mobility, physical activity and psychological wellbeing.
2. Using the Wii at home will improve compliance and reduce drop out rates (which have been significant) but with no compromise on the efficacy of the treatment.

Ethics approval required
Old ethics approval format

Ethics approval(s)

IRAS approved 14/EE/1182

Study design
Single-centre interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Elderly fallers

Interventions
10 week training program RCT with 30 patients randomly allocated to one of three conditions plus 3 month follow up:

Group A will be given physiotherapy falls training at the hospital (‘hospital only group’).
Group B will be given extra Wii balance training by a physiotherapist/physiotherapist assistants (‘ Wii group’).
Group C will be an extension of the current hospital training with physiotherapy staff supervising, correcting and progressing patients (‘non-Wii group’)

The extra training for groups B and C will consist of 20-45 min supervised training twice per week in the patient's home.
We will then compare functional mobility and psychological wellbeing of these patients before and after training

Intervention Type
Behavioural

Primary outcome measure
Incidence of falling

Secondary outcome measures
1. Timed get up and go test (TUG)
2. Turn 180° test
3. Functional reach test

4. Single leg balance test
5. Patients' gait will also be assessed by measuring walking speed over a 10 m course
6. Psychological wellbeing and quality of life

Overall study start date
01/03/2016

Completion date
01/03/2017

Eligibility

Key inclusion criteria
1. Potential participants will comprise recurrent fallers aged 60 + years, assessed by physiotherapy staff as being suitable to attend the falls prevention training
2. They must be able to stand/ambulate with minimal assistance (i.e., walking stick/frame)
3. They will be identified by physiotherapy staff at falls prevention training assessments and referred to the study via falls clinic at CHUFT or from the multidisciplinary falls prevention service in the community

Participant type(s)
Patient

Age group
Senior

Sex
Both

Target number of participants
30

Key exclusion criteria
1. Any patient who has a Wii at home or regularly uses the Wii
2. Patients who are unable to stand/walk without physical assistance
3. Patients who are unable to follow instructions e.g., due to dementia
4. Patients with significant visual impairment who are unable to see the TV screen
5. Patients who may feel dizzy during the Wii exercise e.g., due to vestibular problems
6. Patients with pacemakers will be excluded because even though the Wii has been reported to 'seem safe with pacemakers' (Rajani et al 2008), Nintendo state that the Wii console and Wii Remote can emit radio waves that can affect the operation of nearby electronics, including cardiac pacemakers. Therefore these patients will be excluded

Date of first enrolment
01/03/2016

Date of final enrolment
01/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Colchester Hospital University Foundation Trust
United Kingdom
CO4 5JL

Sponsor information

Organisation
University of Essex (UK)

Sponsor details
c/o Ms Sarah Manning-
Press Research and Enterprise Office
Colchester
England
United Kingdom
CO4 3SQ

Sponsor type
University/education

ROR
https://ror.org/02nkf1q06

Funder(s)

Funder type
Charity

Funder Name
Post Graduate Medical Charity at Colchester Hospital University NHS Foundation Trust (UK)

Results and Publications

Publication and dissemination plan

Intention to publish date
01/03/2018

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No