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Wii Fit and cerebral palsy feasibility study

Submission date
04/03/2015

Recruitment status
No longer recruiting

Registration date
05/03/2015

Overall study status
Completed

Last Edited
26/08/2020

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Cerebral palsy is a term that is used to describe a number of neurological conditions resulting in problems with movement and co-ordination. It is caused by damage to the part of the brain before, during or just after birth that is responsible for motor control (muscles that control movement). We want to see if a widely available home console system (the Nintendo Wii Fit) can be used to provide regular, tailored physiotherapy, or virtual reality therapy (VRT), to children with cerebral palsy.

Who can participate?
Children aged 5-16 with cerebral palsy that are able to walk and are managed by the Sussex Community NHS Trust, and their families.

What does the study involve?
The children are randomly allocated into one of two groups. Those in group 1 (the intervention group) follow a therapist prescribed schedule for 12 weeks, playing with specified Nintendo Wii Fit games for a specified amount of time per session. Each session lasts 30 minutes and take place three times a week. The games are chosen based on specific physiotherapy purposes, such as core stability or balance. During this 12 week period, the family is contacted every two weeks to see how the child is progressing, make changes to the games played as necessary and answer any questions that the family may have. Those in group 2 (control group) also play with the Nintendo Wii Fit console 3 times a week in 30 minute sessions, but they are able to choose whatever games they like. The family is not contacted at all during the 12 weeks, unless they need physiotherapy advice. All participants, including the parents, are asked to keep a simple daily diary to rate sessions. The children's balance and mobility is tested just before they start the trial, half way though and then at the end. All participants are also asked to fill in a questionnaire after the trial has ended (an exit questionnaire) in which they can report on engagement, ease of use and tiredness after sessions.

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

Where is the study run from?
Nightingale Primary Care Centre (UK)

When is the study starting and how long is it expected to run for?
February 2015 to January 2016

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr William Farr
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Contact information

Type(s)
Public

Contact name
Dr William Farr

Contact details
Nightingale Primary Care Centre
Child Development Centre
Sussex Community NHS Trust
Butlers Green Road
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
18271

Study information

Scientific Title
A feasibility study of virtual reality as a therapeutic intervention in children with ambulatory cerebral palsy

Acronym
CPWiiO

Study objectives
1. What does the current use of commercially available systems in the home look like, and therefore, how different would a prescribed programme be?

2. If virtual reality therapy (VRT) is effective, is it the amount or type of activity? A comparison of usage of home-based systems will be undertaken to question whether it is the amount of play time or scaffolded practice that contributes to therapeutic effects and whether childrens enjoyment influences engagement and participation. Amount of contact with children, families and professionals will also be logged to analyse economic impact of either wing of the study (supported, unsupported use).
3. Which tools are primary measuring devices that produce consistent and reliable results with VRT? Standardised balance and mobility measures alongside child-defined goals will consider benefits of Nintendo Wii fit on individual functionally meaningful outcomes.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Lancaster NRES committee, 02/12/2014, ref: 14/NW/1499

Study design
Randomised; Interventional; Design type: Treatment

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Home

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Cerebral Palsy

Interventions
1. Control Group:
Control participants will use the Nintendo Wii Fit for 30-minute sessions, 3 times a week, over a 12-week period. They will have free choice over which games they choose and duration each game is played within the session. Scheduled phone contact will be made every two weeks but only to oversee progress or if they need physiotherapy advice
2. Supported Group:
Supported participants will follow a therapist prescribed schedule over a 12-week period, utilising specified Nintendo Wii Fit games for designated amounts of time per session. Sessions will last 30 minutes, undertaken three times a week with games selected for specific physiotherapy purposes, such as core stability or balance. During this 12-week period, fortnightly telephone contact to families will oversee the child’s progress, update game selection and respond to any queries.

Intervention Type
Behavioural

Primary outcome measure
1. Gross Motor Function Measurement (GMFM)
2. Bruininks-Oseretsky test of motor proficiency (BOT-2)
3. Timed up and go test (TUG)
4. Goal Attainment Scale (GAS)
5. Strengths and Difficulties Questionnaire

Measurements will be taken at baseline (week 1), midway (week 6), and exit of trial period (week 12). Measurements will be taken by blinded members of the trial team.

Secondary outcome measures
N/A

Overall study start date
01/12/2014

Completion date
01/01/2017

Eligibility

Key inclusion criteria
1. Inclusion criteria for questionnaire (phase one of study):
1.1. Parents of children with cerebral palsy of any level (ie GMFCS 1-5)
1.2. Child aged 5 to 16 years old
1.3. Under management of Sussex Community NHS Trust identified from local clinical database

2. Inclusion criteria for randomised, single blind, controlled study (phase two of study):
2.1. Ambulatory Bilateral and Unilateral CP
2.2. GMFCS types I and II e.g. able to walk without a walking aid
2.3. Ability to follow simple task instruction
2.4. All school ages -from 5 up to the age of 16; primary -5 to 11 years and secondary >11 – 16 years, (Upper limit of 16 to avoid timetabling variations at 6th form programmes)
2.5. Under management of Sussex Community NHS Trust, identified from local clinical database

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
Planned Sample Size: 80; UK Sample Size: 80; Target for questionnaire stage = 50; Target for intervention stage = 30

Total final enrolment
31

Key exclusion criteria
1. Exclusion criteria for questionnaire (phase one of study):
1.1. Child aged less than 5 or over 16 years old

2. Exclusion criteria for randomised, single blind, controlled study (phase two of study):
2.1. Children who are GMFCS III, IV, V
2.2. Child/Family unable to follow simple task instructions in English
2.3. Over the age of 16, outside of school age
2.4. Child with epilepsy who is photosensitive and has had a seizure within the last year
2.5. On anticonvulsant medication

Date of first enrolment
27/07/2015

Date of final enrolment
10/05/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Nightingale Primary Care Centre
Child Development Centre
Sussex Community NHS Trust
Butlers Green Road
Haywards Heath
United Kingdom
RH16 4BE

Sponsor information

Organisation
Sussex Community NHS Trust

Sponsor details
Research and Development
Freshfield Annex
Brighton General Hospital Elm Grove

Brighton
England
United Kingdom
BN2 3EW

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04e4sh030

Funder(s)

Funder type
Government

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Dissemination to national conferences e.g. BACD, RCPCH, study applications to Journal of Developmental Medicine and Child Neurology, human computer interaction journals and conferences (e.g. TEI, CHI, UBICOMP) Publication of phase 1 date autumn 2015 phase 2 publication data to be published late 2016 Further theory papers to be written and published where the opportunity arises.

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?
Results article	results	01/01/2021	26/08/2020	Yes	No
HRA research summary			28/06/2023	No	No