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To evaluate increased benefits to upper limb function of home based assistive rehabilitation technology designed for children with cerebral palsy

Submission date
09/08/2013

Recruitment status
No longer recruiting

Registration date
09/08/2013

Overall study status
Completed

Last Edited
16/11/2017

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Cerebral palsy (CP) is a common cause of disability in childhood, affecting approximately 2.5 children per 1000. A large number (up to 80%) of these children have difficulty using their upper limbs. This has a major impact on children's developmental opportunities. Treatment of children with CP focuses on physiotherapy and occupational therapy, supported more recently by botulinum treatment. Therapy involves exercises and repetitive functional movements often guided by hands-on assistance, a regime not popular with the children. Botulinum is an anti-spasticity treatment that allows targeting of specific muscles, aiding improvements in the quality of therapy, but there is only a small window of opportunity before the effects wear off. It is difficult for therapists to provide timely support of sufficient quantity, given the stretched resources of NHS therapy departments. We have designed and produced a computer games system for children with cerebral palsy, played using a robotic arm (like a joystick, but with motors that provide guidance and assistance) to support and assist the children's hand directions when playing the games. The games encourage exercise while providing the extra dimension of fun. Initial studies indicated that children enjoy playing the games, and also showed that there were improvements in upper limb activity. The games are simple but children do need sufficient ability to understand the games and concept of using the joystick/robotic arm. This study aims to evaluate whether the use of a home-based computer-assisted arm rehabilitation games system has functional benefits of botulinum.

Who can participate?
The study involves children with cerebral palsy aged 5 - 12 years old who have sufficient understanding to be able to play simple computer games, who have voluntary arm movements and who have had botulinum treatment for the upper limb.

What does the study involve?
Children are randomly allocated into a control group (no computer games system) and an intervention group (receives a home-based computer games system for 6 weeks after botulinum

treatment). Both groups receive follow up support (e.g. occupational therapy, orthotic splinting etc) as normal. Before the children receive botulinum (and before their group allocation), their arm ability is assessed using two measures which are validated and reliable for use with children with cerebral palsy. They also check the quality of their hand movements (hand speed, accuracy and smoothness of movements). Between six and seven weeks after receiving botulinum treatment, and again at twelve weeks, both groups are measured in exactly the same way again. We expect all children to show an improvement because they have all received botulinum for reduction of spasticity but we will examine the measurements to see if those children who played the computer-assisted arm rehabilitation games system have improved significantly more than those who were in the control group.

What are the possible benefits and risks of participating?
There is no strong evidence that participating will benefit the children, although we hope to find that children fortunate enough to receive a games system will show greater improvements in arm activity. There is a risk that the unaccustomed arm use caused by playing the game might cause muscle aching.

Where is the study run from?
The study is being managed and conducted by researchers at the School of Medicine and the School of Mechanical Engineering at the University of Leeds, UK.

When is the study starting and how long is it expected to run for?
The study will finish recruitment in July 2014. It has been underway since June 2013.

Who is funding the study?
The study is funded by the National Institute for Health Research (NIHR) through a Clinical Doctoral Research Fellowship, UK.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
11789

Study information

Scientific Title
A randomised controlled trial to evaluate increased benefits to upper limb function of home based assistive rehabilitation technology designed for children with cerebral palsy

Study objectives
Method
Blinded assessment of children using validated measures of manual ability (ABILHAND-kids), functional performance at individualised goals (Canadian Occupational Performance Measure) and using a measure of kinematic performance of the upper limb prior to botulinum treatment and randomisation.
Randomisation (carried out using minimisation procedure):performed by remote third party using bespoke program; balances the groups according to pre-determined prognostic factors: age; gender; manual ability; regular use of commercial computer games.
Intervention group: 29 children will use hCAAR for a period of 6 weeks. Follow up by blinded researcher at 6 weeks and at 12 weeks. A visit at 3 weeks will take place to monitor and reset assistive settings and games parameters if necessary.
Control group: 29 children will receive follow-up visits as Intervention group (including at 3 weeks as an attention control).
All participants will receive their usual NHS follow-up. Families will keep diaries of any therapy and use of commercially-available computer games use.
Data analysis
Linear regression on an 'Intention to treat' basis, adjusting for child covariates (e.g. age group, gender, use of other computer games and manual ability).
Will assume that children lost to follow-up did not show any improvement.

Ethics approval required
Old ethics approval format

Ethics approval(s)
11/YH/0276

Study design
Randomised; Interventional; Design type: Treatment

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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Generic Health Relevance and Cross Cutting Themes; Subtopic: Generic Health Relevance (all Subtopics); Disease: Paediatrics

Interventions
The study is a single-blind randomised controlled trial. Children meeting inclusion criteria will be have their arm activity and kinematics evaluated using validated and reliable measures, before random allocation into either a control group or an intervention group. All children will receive exactly the same treatment and will receive follow up and medical support as usual following botulinum treatment: the only difference is that the intervention group will receive a home-based computer-assisted arm rehabilitation games system. Randomisation is by a computer-based minimisation program that balances the groups based on gender, age, arm ability and use of commercially-available computer games (e.g. Wii, XBox). Follow up assessments by researchers will take place at 6 and 12 weeks. Statistical analysis will be linear regression on an 'Intention to treat' basis, adjusting for child covariates (e.g. age group, gender, use of other computer games and manual ability) and will assume that children lost to follow-up did not show any improvement.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
ABILHAND-kids Timepoint(s): Baseline, at 6 weeks and at 12 weeks
The ABILHAND-kids is a measure of manual ability developed and validated for children with cerebral palsy aged 6 - 15 years old. The ABILHAND-kids consists of a questionnaire of 21 manual activities (e.g. 'Zipping up a jacket'), each of which is scored by parents as Impossible, Difficult or Easy. The questionnaire scores Easy as 2 points, Difficult as 1 point and 0 points for Impossible, but an important strength of the ABILHAND-kids is an on-line scoring system which transforms this ordinal outcome score to a linear interval-level score.

Secondary outcome measures
1. Canadian Occupational Performance Measure (COPM)
Timepoint(s): At baseline, at 6 weeks and at 12 weeks

Overall study start date
14/05/2012

Completion date

31/12/2014

Eligibility

Key inclusion criteria
1. Children aged 5 to 12 years with confirmed diagnosis of cerebral palsy
2. Children treated with botulinum for arm spasticity
3. Children with Manual Abilities Classification System Levels 2-4
4. Sufficient cognitive ability to be able to play simple computer games
5. Able to hold hand grip of robotic arm
6. Vision sufficient to view computer screen and follow onscreen movements.
Target Gender: Male & Female; Upper Age Limit 12 years ; Lower Age Limit 5 years

Participant type(s)
Patient

Age group
Child

Lower age limit
5 Years

Upper age limit
12 Years

Sex
Both

Target number of participants
Planned Sample Size: 58; UK Sample Size: 58; Description: Children with cerebral palsy aged 5 - 12

Key exclusion criteria
1. Children who have had upper limb surgery within the last 6 months.

Date of first enrolment
14/05/2012

Date of final enrolment
01/07/2014

Locations

Countries of recruitment
England

United Kingdom

Study participating centre

Leeds General Infirmary
Leeds
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Sponsor information

Organisation
University of Leeds (UK)

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Sponsor type
University/education

ROR
https://ror.org/024mrxd33

Funder(s)

Funder type
Government

Funder Name
NIHR Clinical Doctoral Research Fellowship, UK; Grant Codes: CDRF 2009-30

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?
Results article	results	01/10/2016		Yes	No