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Can play-based therapy improve hand function in hemiplegia?

Submission date
30/11/2010

Recruitment status
No longer recruiting

Registration date
24/01/2011

Overall study status
Completed

Last Edited
13/06/2016

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.
Children with hemiplegia (muscle stiffness) often have weakness and stiffness affecting the use of one hand and arm. We want to assess the benefit of two types of play-based therapy on hand function in children with hemiplegia. There will be two groups of children one group will have play therapy A and the other will have play therapy B. By looking at differences in tests of hand function before and after therapy, we can see whether it leads to an improvement in the way children with hemiplegia can use their hands. We can also compare improvements between play therapy A and B to establish if one treatment is more effective than the other.
Using EEG to record brainwaves, we can look at brain responses when watching or making movements. This may help us to understand which children might benefit from play-based treatment.

Who can participate?
We are recruiting 70 children aged 3-10 years with a form of cerebral palsy leading to hemiplegia for this study. Children with cerebral palsy who are eligible for the study are identified by doctors and therapists in the region who have been told about the study.

What does the study involve?
If you agree for your child to take part, you would both come to the Sir James Spence Institute, Royal Victoria Infirmary for a total of four visits, as well as you or your childs daytime carer helping your child with brief (15 minutes/day) but regular play based therapy at home for a 3 month period. There are two therapies so your child will be randomly allocated to one of them and a member of our team will tell you what that will involve.
- Visit 1: baseline tests of hand function
Your child will undertake some simple tests of hand and arm function. During this time we will ask you to fill in a questionnaire (about 10 minutes) about your childs hand function. We will also demonstrate the play therapy to you and show you what you will need to do.
- Visit 2: EEG study
EEG allows us to study brain waves. We use disposable metal discs over the scalp and some paste or gel. The discs are attached by wires to a recording device and computer. Your child will need to wash his/her hair after the EEG. We will tape a small recording device (EMG) on the skin over hand muscles on both sides to record activity from those muscles.

Your child will sit in a comfortable chair in front of a computer screen showing some simple hand movements. He or she will also perform some simple hand movements. We will record the session on video. Data collection takes about half an hour but setting up takes longer so you will need to be free for a few hours.

- Home-based play therapy

When the EEG study has been completed we will give you some games and a member of our team will go over again what the play therapy your child has been allocated to involves and what you will need to do. We would like you, or your childs carer, and your child to spend 15 minutes per day, 5 times a week on the therapy for 3 months and we will provide you with a journal to record frequency and duration of these sessions.

After six weeks we will visit you at your home to see how you are getting on. We will also contact you by telephone from time to time to see how things are going. You will be free to contact us at any time if you need any advice or information.

- Visit 3: repeat tests of hand function

After three months we will invite you and your child back to the Sir James Spence Institute and repeat the assessments of hand function which were done at the first visit. This is to see if the therapy has been effective. We will ask that your child does not start any new therapies in the following three months if possible. However, if it is very important that he/she starts immediately, we understand and ask that you let us know.

- Visit 4: final tests of hand function

We will invite you for a final visit around 6 months after the start of the study, to see if there has been a lasting effect of the therapy. We will test your childs hand function as we did at visit 1.

What are the possible benefits and risks of participating?

We hope your child will find participation in our study interesting, educational and enjoyable. Unfortunately we cannot offer any financial incentive for taking part! Our aim is that this research will lead to a new approach to therapy in hemiplegia as well as improving our understanding of how the brain controls movement. However, we cannot be sure whether your child will benefit directly from the therapy - this is why we need to do the study.

EEG is non-invasive, painless and safe. It has been used in our research group for over a decade and is commonly used in many other hospitals around the world. It is very unlikely that our EEG study would detect any pattern which might represent an illness in your child that you were not aware of. In the unlikely event of our observing an EEG abnormality about which we were concerned, we could help by contacting your childs GP (with your permission) and providing a copy of the recording for review by a clinical neurophysiology department if requested.

Where is the study run from?

Newcastle upon Tyne NHS Hospitals Foundation Trust.

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

The study started in February 2011 and is expected to run until February 2014.

Who is funding the study?

Newcastle University and the WellChild Trust

Who is the main contact?

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Contact information

Type(s)
Scientific

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United Kingdom
NE1 4LP

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effect of parent-delivered action observation therapy on upper limb function in unilateral cerebral palsy: a randomised controlled trial

Study objectives
1. Home delivered play based therapy will improve hand function in hemiplegia. We plan to compare two forms of play based therapy to see if one is superior to the other
2. That EEG-based Mu (~10 Hz) wave changes will discriminate between children who do or do not improve with the intervention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Newcastle and North Tyneside 2 Research Ethics Committee, 21/02/2011, ref: 11/NE/0011

Study design
Single centre single blind (outcomes assessor) randomised interventional study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Screening

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet (once ethical approval granted)

Health condition(s) or problem(s) studied
Hemiplegic cerebral palsy

Interventions
Carer-delivered home-based play therapy which will involve practice of useful hand and arm movements. Duration: 15 min/day, 5 days/week for 3 months.

Both groups (active control and intervention group) will undertake the play based therapy, with some minor differences between the two groups in how it is delivered. Information about the differences will be made available to participants at the end of the trial, and if one method is found to be superior to another we will offer to train carers in use of this method.

Assessments of hand function will be undertaken at baseline, 3 and 6 months.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Hand function measured using the Assisting Hand Assessment (AHA) score, at baseline, 3 months and 6 months. This is a 22 item Rasch-based test designed for children ages 18m-12 years with unilateral upper limb disability such as hemiplegia and assesses performance of the hemiplegic hand during bimanual activities within a semi-structured video recorded play session lasting 10-15 minutes. All 22 items are scored from 0 (does not do) to 4 (effective use).

Secondary outcome measures
Hand function measured at baseline, 3 and 6 months using:
1. Melbourne assessment of unilateral upper limb function. This is a capacity-based test for children with cerebral palsy, measuring many aspects of unimanual reaching, grasping and manipulation. The assessment is video recorded and takes around 15 minutes, with the score

expressed as a percentage.
2. ABILHAND-Kids questionnaire. The 21 items reflect both unimanual and bimanual performance during daily activities. Completion is undertaken by the parents and takes around 10 minutes.
3. An adapted 9-hole pegboard test of manual dexterity
4. A brief test of movement planning, based on handle rotation, adapted from Mutsaarts et al. (2006)

Overall study start date
01/02/2011

Completion date
28/02/2014

Eligibility

Key inclusion criteria
Male and female children aged 3 - 10 years with hemiplegic cerebral palsy predominantly affecting arm and hand function.

Participant type(s)
Patient

Age group
Child

Lower age limit
3 Years

Upper age limit
10 Years

Sex
Both

Target number of participants
58 participants completing the study

Key exclusion criteria
1. Registered visually impaired
2. Inability or unwillingness to understand or attempt the tasks
3. No active grasp in the affected hand
4. Children who have had another intervention such as upper limb Botulinum toxin therapy or surgical intervention in the preceding 3 months and those who are planned to have such an intervention within the next 6 months and are unable to defer this until after the study

Date of first enrolment
01/08/2011

Date of final enrolment

01/09/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
United Kingdom
NE1 4LP

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
Darlington Memorial Hospital
Hollyhurst Road
Darlington
United Kingdom
DL3 6HX

Study participating centre
University Hospital of North Durham
North Road
Durham
United Kingdom
DH1 5TW

Study participating centre
North Tyneside General Hospital
Rake Lane
NE29 8NH

United Kingdom
North Shields

Study participating centre
South Tyneside District Hospital
Hospital Lane
South Shields
United Kingdom
NE34 0PL

Study participating centre
North Tees General Hospital
Hardwick Road
Stocktonon Tees
United Kingdom
TS19 8PE

Study participating centre
Chowdene Children Centre
Waverley Road
Harlow Green
Gateshead
United Kingdom
NE9 7TU

Study participating centre
James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre
Cumberland Infirmary
Newtown Road
Carlisle
United Kingdom
CA2 7HY

Sponsor information

Organisation
The Newcastle upon Tyne Hospitals NHS Foundation Trust (UK)

Sponsor details
c/o Dr Lesley Hall
Joint Research Office
Level 6, Leazes Wing
Royal Victoria Infirmary
Queen Victoria Road
Newcastle upon Tyne
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

Website
http://www.newcastle-hospitals.org.uk/

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
University/education

Funder Name
Newcastle University (UK) - Henry Miller Studentship

Funder Name
WellChild Trust (Added 24/05/2011)

Results and Publications

Publication and dissemination plan
Planned publication in a peer reviewed journal.

Intention to publish date
28/02/2015

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/10/2016		Yes	No