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Does the use of a specific cognitive intervention for children with movement disorders improve functional outcomes following deep brain stimulation?

Submission date
09/03/2016

Recruitment status
No longer recruiting

Registration date
09/03/2016

Overall study status
Completed

Last Edited
25/04/2023

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
Movement disorders are a collection of conditions which affect the speed, fluency, quality, and ease of movement. They are typically divided into two categories: hyperkinetic (disorders of excessive movement) and hypokinetic (disorders in which there is slowness or absence of movement. Hyperkinetic movement disorders (HMD) include a range of involuntary movement, including dystonia (muscle spasms which cause twisting, repetitive movements and poor posture), chorea (jerky movements which are irregular and unpredictable), athetosis (muscle contractions causing writhing movements), myoclonus (sudden contraction of a group of muscles) and tremor (uncontrolled shaking). Conditions such as these can make everyday activities such as washing and dressing very difficult, making it very hard for those affected to look after themselves, which can affect their independence later in life. Many children with HMD undergo a type of treatment called deep brain stimulation (DBS) which can help to ease the symptoms and reduce pain caused by abnormal movements. Children and young people with HMD who are able to get involved in daily activities often have difficulties doing so, even after DBS. However, very little is known about other aspects that may influence children's and young people's ability to improve their skills required for living and learning. Treatments such as occupational therapy (working with a therapist who can help to maintain, regain or improve independence using different techniques and equipment) could potential help children with HMD when offered with DBS. Cognitive orientation to occupational performance (CO-OP) is a type of occupational therapy which helps people who have difficulties performing everyday skills. The aim of this study is to find out whether the CO-OP approach can be used to treat children with HMD and if this treatment approach is acceptable to families.

Who can participate?
Patients aged between 6 and 21 who have a hyperkinetic movement disorder

What does the study involve?
Participants are randomly allocated to one of two groups. Participants in the control group

continue to receive treatment as usual for the duration of the study, which might include equipment provision, occupational therapy or physiotherapy. Participants in the intervention group are visited by an occupational therapist trained in CO- OP for up to 10 sessions, lasting for 45 minutes to one hour, once or twice a week at the child’s home. All participants are assessed at the start and end of the treatment and at 3 months follow up.

What are the possible benefits and risks of participating?
There is a possibility that participants will benefit from a reduction in the HMD symptoms. There are no notable risks involved with taking part in this study.

Where is the study run from?
Evelina Children's Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2014 to February 2017

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

Who is the main contact?
Miss Farhiya Ashoor

Contact information

Type(s)
Public

Contact name
Ms Hortensia Gimeno

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
17472

Study information

Scientific Title
Randomised controlled trial using the cognitive orientation to occupational performance (CO-OP) intervention with paediatric hyperkinetic movement disorders following deep brain stimulation (DBS): a feasibility study

Study objectives
The aim of the study is to explore whether cognitive orientation to occupational performance (CO-OP) could be used to treat children with hyperkinetic movement disorders (HMD) and whether the treatment approach would be acceptable to families.

Ethics approval required
Old ethics approval format

Ethics approval(s)
South Central - Oxford A Research Ethics Committee, 26/08/2014, ref: 14/SC/1159

Study design
Single-centre 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 available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Topic: Children, Neurological; Subtopic: Children (all Diagnoses), Neurological (all Subtopics); Disease: All Diseases, Neuro-muscular and Encephalitis

Interventions
Participants are randomly allocated to one of two groups.

Intervention group: A trained occupational therapist on cognitive orientation to daily occupational performance (CO- OP), will visit the child's home to complete the intervention. CO-OP will be implemented with the child and main carers will be asked to be present so that the strategies and general approach can be implemented on a daily basis. When necessary written instructions will be provided for the child and/or family. The CO-OP intervention will employ the treatment manual produced after the developmental phase so that if several treating therapists employed, adherence to the protocol can be ensured. There will be up to 10 CO-OP sessions, lasting for 45 minutes to one hour, delivered once or twice a week. The sessions will be

completed in the child’s natural environment (i.e., home). The sessions will be videoed and a random session chosen for scoring of therapist adherence to the protocol by a CO-OP expert.

Control group: Participants continue to receive treatment as usual for the duration of the study. This might include equipment provision, occupational therapy or physiotherapy.

Intervention Type
Other

Primary outcome measure
Quality of functional performance for chosen goals is measured using the Performance Quality Rating Scale (PQRS) at baseline, post-intervention and 3 months follow up.

Secondary outcome measures
1. Typical performance is measured using the Assessment of Motor and Process Skills (AMPS) questionnaire is measured at baseline, post intervention and 3 months follow up
2. Executive Function (Proxy reported) is measured using the Behaviour Rating Inventory of Executive Function (BRIEF) is measured at baseline, post intervention and 3 months follow up
3. Dystonia impairment is measured using the Burke-Fahn-Marsden Dystonia Rating Scale is measured at baseline, post intervention and 3 months follow up up
4. Goal acquisition (self-reported) is measured using the Canadian Occupational Performance Measure (COPM) is measured at baseline, post intervention and 3 months follow up
5. Executive function is measured using the Colour Word Interference Test is measured at baseline, post intervention and 3 months follow up
6. Executive function is measured using the Comprehensive Trail Making Test (CTMT) is measured at baseline, post intervention and 3 months follow up
7. Quality of life is measured using the EQ-5D is measured measured at baseline, post intervention and 3 months follow up
8. Goal acquisition is measured using the Goal Attainment Scale (GAS) is measured at baseline, post intervention and 3 months follow up
9. Self-care and mobility function ability (proxy reported) is measured using the Pediatric Evaluation of Disability Inventory Computerised Assessment Tool (PEDI-CAT) is measured at baseline, post intervention and 3 months follow up
10. Self efficacy (self-reported) is measured using the Self-Efficacy Gauge Measure - Paediatrics is measured at baseline, post intervention and 3 months follow up
11. Anxiety (self and proxy reported) is measured using the Spence Children's Anxiety Scale (parent and child versions) is measured at baseline, post intervention and 3 months follow up
12. Adaptive behaviour (proxy reported) is measured using the Adaptive Behavior Assessment System (ABAS) is measured at baseline, post intervention and 3 months follow up

Overall study start date
25/09/2014

Completion date
28/02/2017

Eligibility

Key inclusion criteria
1. Participants must express and evidence a willingness to participate
2. Sufficient receptive and expressive communication ability to follow simple instructions and

engagement with treatment (including adequacy of English language)
3. Diagnosis of hyperkinetic movement disorder other than neurodegenerative conditions
4. Age 6-21 years
5. Manual Ability and Classification System (17) (MACS) levels IIII
6. Emerging skills in self-care such as starting to want to get undressed, brush own teeth, self-feed
7. Ability to mobilize independently
8. Requiring adult assistance to complete age appropriate activities. e.g. eating and drinking, toothbrushing, washing and dressing, making a sandwich, making a bed, etc
9. Cognitive ability of 6 years of age and IQ above 70 as assessed using the Wechsler Intelligence Scale for Children (WISC)
10. Deep Brain Stimulation in situ and without signs of infection

Participant type(s)
Patient

Age group
Mixed

Sex
Both

Target number of participants
Planned Sample Size: 36; UK Sample Size: 36

Key exclusion criteria
1. Pure spasticity or mixed phenotype when spasticity is dominant feature;
2. Dystonia arising due to a neurodegenerative condition
3. Scheduled for surgical treatment in the study period
4. Known signs of DBS infection

Date of first enrolment
25/09/2014

Date of final enrolment
30/09/2016

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Evelina Children's Hospital
Complex Motor Disorders Service
Guy's and St. Thomas' NHS Foundation Trust
Lambeth Palace Road

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Sponsor information

Organisation
King's College London (UK)

Sponsor details
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Sponsor type
University/education

ROR
https://ror.org/0220mzb33

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 will take place during the study and not just at the end. We are planning to publish the trial protocol by May 2016. Results will be published for stage 1 first using n-of-1 trial data. Group data will be published separately. We anticipate this will be published by the end of 2016. Stage 2 will be published in 2017 after data analysis is completed. It is also hoped to present during the project duration at conferences such as:
1. British Paediatric Neurology Association (BPNA)
2. European Academy of Childhood Disability (EACD)
3,. Canadian Association of Occupational Therapists (CAOT)
4. National Children and Young People and Families Occupational Therapy Conference
Further, it is hoped to engage young people and families to help write some of the results

Intention to publish date
31/12/2017

Individual participant data (IPD) sharing plan
The data-sharing plans for the current study are unknown and will be made available at a later date

IPD sharing plan summary
Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications		25/12/2020	25/04/2023	Yes	No
Other publications		22/02/2019	25/04/2023	Yes	No
Results article		21/01/2021	25/04/2023	Yes	No
HRA research summary			26/07/2023	No	No