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Brain stimulation to improve movement in children with cerebral palsy

Submission date
16/03/2020

Recruitment status
No longer recruiting

Registration date
22/12/2020

Overall study status
Completed

Last Edited
12/07/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Cerebral palsy (CP) is the most common cause of childhood physical disability. Many children with CP experience lifelong difficulties with their movement, affecting their daily activities. Transcranial direct current stimulation (TDCS) is a safe, painless and non-invasive type of brain stimulation which may increase the ability of the brain to adapt, and could be effective at improving movement and function when combined with therapy. However, no one has combined TDCS with therapy involving both the arm and leg, even though many people with CP experience difficulties with both of these limbs. This study aims to assess whether 10 sessions of TDCS over 2 weeks could be effective at improving movement and function when combined with therapy tasks for the arm and leg that are repetitive, functional and relevant. Specifically the researchers aim to assess how large the potential improvement in function is in order to plan future large-scale clinical trials, and to use brain scanning to explore who is most likely to benefit from the TDCS.

Who can participate?
Young people aged 10-16 years with CP affecting the movement of their arm and/or leg

What does the study involve?
Assessments will be at the start of the study, 1 week following the intervention, 6 weeks and 3 months later. These include assessments to measure participants ability to move their arm and leg and questionnaires about quality of life. Participants who are able and willing will also undergo one magnetic resonance imaging (MRI) brain scan at the start of the study.
The intervention consists of 10 sessions over 2 weeks, each lasting about 2 hours. Each session will involve 20 minutes of TDCS, alongside 90 minutes of physical therapy exercises for the arm and leg, in groups of up to five. This includes functional and magic tasks in a fun and engaging manner. Half the participants will receive real TDCS, the other half will receive a sham/placebo where the brain is not actually stimulated. All participants will receive physical therapy training.

What are the possible benefits and risks of participating?
Participants may experience an improvement in their movement. Possible side effects of the TDCS include an itching/tingling/prickling sensation on the scalp and some short-term redness on the skin. This is normal and typically resolves within a few minutes. Participants may also

experience a mild headache after the stimulation which should go away on its own or with over-the-counter medications such as paracetamol. Possible side effects of physical therapy training include sore or tired muscles for people who do not normally do much activity. This is normal and will go away on its own. It is a sign that they are been working their muscles.

Where is the study run from?
The study is run by the Centre for Movement, Occupational and Rehabilitation Sciences, Department of Sport & Health Sciences, Oxford Brookes University, together with the Wellcome Centre for Integrative Neuroimaging, University of Oxford and the Department of Clinical Sciences, Brunel University London (UK)

When is the study starting and how long is it expected to run for?
September 2018 to December 2023

Who is funding the study?
1. Action Medical Research UK
2. Chartered Society for Physiotherapy (UK)

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
272945

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 44942, IRAS 272945

Study information

Scientific Title
Transcranial direct current stimulation to improve motor function in children with cerebral palsy: a pilot study

Acronym
StimCP

Study objectives
1. Improvements in motor function will be greater for the active transcranial direct current stimulation (TDCS) group in comparison with sham
2. Baseline measures of corticospinal tract integrity will have a tendency to correlate with change in motor function

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 22/04/2020, West Midlands – Edgbaston REC (3rd Floor Barlow House, Minshull Street, Manchester M1 3DZ, UK; +44 (0)207 104 8019, +44 (0)207 104 8089; edgbaston.rec@hra.nhs.uk), REC ref: 20/WM/0046

Study design
Randomized; Interventional; Design type: Treatment, Imaging, Physical, Rehabilitation

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
Setting: Testing will take place in either Oxford Brookes University, University of Oxford, Brunel University (or approved research site), London or at the child's school.

Recruitment: Considering a prevalence of 0.2% of young people with CP (~250 in the stated age range in Oxfordshire Community Paediatric Physiotherapy Team caseload in schools), assuming a recruitment period of 16-18 months, and planned recruitment through paediatric clinics and the physiotherapy team, the researchers are confident 30 participants can be recruited. They will primarily recruit through NHS clinics at Oxford University Hospital (OUH), Oxford and The Royal Free (London), community therapy teams and through schools. Clinical staff, the Community Physiotherapy Team and teachers will distribute the PIS to the potential participants and their parents/carers who may be eligible and interested in taking part in the study. They will also

advertise through posters, social media and CP support groups/websites. The direct care team at OUH NHSFT (research site) will identify potential participants and pass information on to them (leaflet/PIS). Potential participants will then be asked by the direct care team to give verbal consent to be contacted by Oxford Brookes University (OBU) and University of Oxford researchers. The researchers will then contact the participants to go through the details of the study with them. It will be made clear to them that agreeing to have their contact details passed to the researchers does not oblige them to agree to take part. If they do not wish to have their contact details passed to the researchers then they may contact the researchers directly using the contact information provided on the PIS/leaflet. At the PIC sites (Oxford Health NHSFT, Royal Free London NHSFT) the direct care team will identify potential participants and pass information on to them (leaflet/PIS). Potential participants will then contact the researchers directly if they are interested in participating or have any questions.

If interested in participating in the study, the participants will be required to visit either the OBU laboratory (Oxford) or Brunel University (London) for a baseline assessment initially. Travel and time cost will be reimbursed. They will also be made aware that the study is entirely voluntary and they can opt out at any time.

Randomisation: Participants will be randomly allocated to receive active or placebo/sham TDCS, using an online minimisation programme (rando.la). The randomisation software minimises between-group differences in age and baseline function (Jebsen Taylor Test / Timed Up and Go). The participants, physiotherapist and outcome assessor will be blind to group allocation.

Measures:
Baseline assessment: age, medication and type of CP. Upper and lower limb functional assessments include:
1. The Jebson Taylor hand test
2. Timed Up and Go
3. Modified Ashworth spasticity scale
4. Gait Outcomes Assessment List (GOAL)
5. Assisting hand assessment (AHA)
6. Woods and Teuber scale for mirror movements
7. Children’s hand use experience questionnaire (CHEQ)
8. Functional mobility scale (FMC)
9. Functional assessment questionnaire (FAQ)

This will be done by the research team. Additionally, spontaneous arm use will be assessed by asking participants to wear a wrist-worn, waterproof activity monitor on one or both wrists for 1 week (optional assessment). Baseline (only) measures of brain structure and function will be collected using Magnetic Resonance Imaging (optional assessment) by the researchers at the Wellcome Centre for Integrative Neuroimaging, University of Oxford.

Outcome assessments: Following the intervention, functional assessments (as above) will be repeated at 1 week, 6 weeks at 3 months.

Intervention:
Participants will attend 10 sessions over 2 weeks, lasting approximately 2 hours each.

Training: In each session, all participants will receive 90-minutes of physical therapy in groups of five. This will include functional upper and lower limb tasks incorporating principles of the Hand Arm Bimanual Intensive Therapy (HABIT), the upper limb intensive (Magic) camp programme and

the HABIT Including Lower Extremities (HABIT-ILE). Individualised prescription/progression for both upper and lower limbs will be ensured, and activities incorporated in a fun and engaging manner.

Brain stimulation: Anodal tDCS (1 mA) will be delivered for the first 20 minutes of each training session (alongside the training). The anode electrode will be placed over the primary motor cortex on the hemisphere opposite to the more-affected upper/lower limb, using the EEG 10-20 system for localisation, as close to the midline as possible and the cathode electrode on the opposite forehead. Sham stimulation will be delivered in a standard manner; ramped up over 30 s then turned off. This sham protocol is effective for establishing the initial tingling/itching sensations induced by TDCS which then fade.

Fidelity, feasibility and acceptability of the intervention: To address the ability to recruit to the trial, the researchers will record the number of participants recruited relative to the number identified/screened, and reasons why potential participants did not enrol in the trial. To address adherence, they will record the number of sessions attended, and any reasons for non-attendance or study withdrawal if known. They will also evaluate session content, enjoyment, assessment duration and effects on sleep/fatigue (Process evaluation form: parent and child).

Any adverse effects identified will be recorded as related/unrelated and reported to the steering group.

Intervention Type
Procedure/Surgery

Primary outcome(s)
1. Hand function measured as performance time for the Jebsen Taylor hand test at baseline and 1 week post-intervention
2. Performance time for the instrumented Timed Up and Go test at baseline and 1 week post-intervention

Key secondary outcome(s))
1. Hand function measured using the Jebsen Taylor hand test (time, in seconds) at baseline, 6 weeks post-intervention and 3 months post-intervention
2. Lower limb function measured using the Timed Up and Go (time, in seconds) at baseline, 6 weeks post-intervention and 3 months post-intervention
3. Bimanual hand use measured using the Assisting Hand Assessment at baseline, 1 week, 6 weeks and 3 months post-intervention
4. Spasticity measured using the Modified Ashworth Scale at baseline and 1 week post-intervention
5. Mirror movements measured using the Woods and Teuber scale at baseline and 1 week post-intervention
6. Performance in activities of daily living assessed using the Gait outcomes assessment list at baseline, 1 week, 6 weeks and 3 months post-intervention
7. Hand use measured using the Children's hand use experience questionnaire at baseline, 1 week, 6 weeks and 3 months post-intervention

Other measures:
Corticospinal tract integrity assessed using a diffusion-weighted MRI scan at baseline, to test for correlations with change in functional measures

Completion date
31/12/2023

Eligibility

Key inclusion criteria
1. Diagnosis of cerebral palsy
2. Ages 10-16
3. Gross motor function classification score I-III
4. Manual ability classification score I-III
5. Upper and/or lower limb impairment

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Child

Lower age limit
10 years

Upper age limit
16 years

Sex
All

Key exclusion criteria
1. Contraindications to TDCS (e.g. pacemakers, metallic implants in the head or neck, pregnancy, seizures within the past 2 years)
2. Inability to understand instructions and actively participate in the motor training

Additional exclusion criteria apply for the optional MRI substudy, such as the presence of non MR-compatible metallic implants. Participants who are excluded from MRI will still be able to undergo all other aspects of the trial.

Date of first enrolment
01/01/2021

Date of final enrolment
31/03/2023

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University of Oxford
Wellcome Centre for Integrative Neuroimaging
John Radcliffe Hospital
Oxford
United Kingdom
OX3 9DU

Study participating centre
Oxford Brookes University
Centre for Movement, Occupational and Rehabilitation Sciences (MOReS)
Gipsy Lane Campus
Oxford
United Kingdom
OX3 0BP

Study participating centre
Brunel University London
Department of Clinical
Department of Clinical Sciences
Uxbridge
United Kingdom
UB8 3PH

Study participating centre
John Radcliffe Hospital
Oxford University Hospitals NHS Foundation Trust
Headley Way
Headington
Oxford
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Sponsor information

Organisation
Oxford Brookes University

ROR
https://ror.org/04v2twj65

Funder(s)

Funder type
Charity

Funder Name
Action Medical Research; Grant Codes: GN2813

Alternative Name(s)
action medical research for children, actionmedres, The National Fund for Research into Crippling Diseases, AMR

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Funder Name
Chartered Society for Physiotherapy

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during the study will be stored in a non-publicly available repository, RADAR. This will include de-identified assessment data. Data will be available following publication of the results, for a period of 20 years. Data will be shared for research purposes, following reasonable request. Consent is obtained from participants for this purpose.

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes