

Developing technology-based hand and arm activity tracking for children with hemiplegia

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| Submission date 11/11/2019 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 18/11/2019 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 06/03/2023 | Condition category Nervous System Diseases | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Background and study aims

Hemiplegic Cerebral Palsy (HCP) causes lifelong weakness and stiffness of one side of the body. Upper limb therapy at effective intensity is not accessible to most. The aim of this study is to determine whether wrist-worn devices and software (smartphone application) incorporating positive feedback and peer support encourages use of the affected arm and hand during everyday activities.

Who can participate?

20 children/young people aged 8-18 years old who have HCP. In addition, 20 typically developing controls or "buddies" in the same age range will also be recruited. Participants of any gender can be included in this study.

What does the study involve?

Participants, both those with HCP and typically developing controls, wear two wrist-worn devices, on one each wrist. These devices contain accelerometers and measure the participants' arm movements. They wear the devices for 10 weeks. The first two weeks involve establishing a baseline for each participant i.e. how much do they normally move their arms? In the following 6 weeks, participants with hemiplegia receive vibratory and/or auditory prompts from the device, to remind them to move their affected arm more. These prompts are based on their baseline movement and their individual personalised thresholds they have set for planned increase in movement. If they are not on target, they receive a prompt. "Buddies" do not receive any prompts. The device communicates with a mobile phone application via Bluetooth, on which participants are able to view the processed data, and play a game at the end of the day. The idea of the game is to incentivise participants to increase the movement of their affected arm, as they are rewarded for doing so by having access to an enjoyable game. Additionally, participants and their parents receive a weekly phone call/Skype call from a researcher, during which, they are asked various questions about how they are finding the project and give them a chance to express any difficulties they may have been experiencing. The phone calls are tailored to whether they are a child/young person with HCP, or a buddy. Therapists of the participants with HCP also receive a phone call, asking their opinions on the TwoCan project and about treatment for HCP in general.

What are the possible benefits and risks of participating?

Possible benefits of taking part include potential improvement of movement of the affected arm in children/young people with hemiplegia. When taking part in the study there is a risk that participants may experience fatigue and/or discomfort due to the increased level of activity of their affected arm, in an attempt to reach their threshold. If this is the case, a lower threshold will be set for this child.

Where is the study run from?

The study will be run from the participants' homes, as they will be wearing the devices in their everyday lives. However, the clinical centres will be Newcastle upon Tyne Hospitals NHS Foundation Trust and Guy's and St Thomas' NHS Foundation Trust (London) (UK)

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

December 2019 to December 2021 (updated 19/08/2021, previously: August 2021 (updated 05/08/2020, previously: September 2020))

Who is funding the study?

Action Medical Research (AMR) and the EPSRC Digital Economy Research Centre

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

Protocol serial number

CPMS: 42944

Study information

Scientific Title

Developing technology-based hand and arm activity tracking for children with hemiplegia: the TwoCan Project

Study objectives

To establish whether a wrist-worn device and software (including a smartphone application), incorporating positive feedback and peer support, will encourage increased use of the affected arm and hand, of those with hemiplegia, during everyday activities.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 25/10/2019, West Midlands – Edgbaston Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, UK; Tel: +44 (0)2071048071; Email: NRESCommittee.WestMidlands-Edgbaston@nhs.net), ref: 19/WM/0257

Study design

Observational; Design type: Qualitative/proof of concept

Primary study design

Observational

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hemiplegic cerebral palsy (HCP)

Interventions

Following baseline observational assessments of hand function, participants will wear two wrist-worn devices, on one each wrist which will measure the participants' arm movements. They will wear the devices for 10 weeks. The first two weeks will involve establishing a baseline for each participant i.e. how much do they normally move their arms? In the following six weeks, participants will receive vibratory and/or auditory prompts from the device in an attempt to remind them to move their affected arm more. These prompts will be based on their baseline movement and their individual personalised thresholds. If they are not on target, they will receive a prompt. "Buddies" will not receive any prompts. The device communicates with a mobile phone application via Bluetooth.

Participants will receive weekly telephone/skype contact for feedback and any troubleshooting. At the end of the study they will also take part in a qualitative interview about their experiences.

Intervention Type

Device

Phase

Not Applicable

Primary outcome(s)

1. Feasibility and acceptability of the approach assessed through qualitative interviews with participants at the end of the study
2. Recruitment rate recorded as the number of eligible participants who consent to participate in the study within 6 months
3. Attrition rate recorded as the number of participants who consent to participate that remain in the study until the end of follow up at 10 weeks

Key secondary outcome(s)

Arm movement measured by wrist-worn accelerometer continuously for approximately 12 hours /day for the whole 10-week period

Completion date

31/12/2021

Eligibility

Key inclusion criteria

1. Children/young people (male or female) with HCP who: are 8-18 years old, and have Manual Ability Classification (MACS) level I-III
2. Typically developing controls (male or female) who: are 8-18 years old, and have normal hand function
3. Therapists of children with HCP who: are either physiotherapists or occupational therapists, and provide input related to upper limb function
4. For all of the above, adequate command of the English language and fully informed consent are required

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Those registered blind or partially sighted
2. Those unable to detect vibratory cues to wrist from the device
3. Those with significant cognitive and/or language deficit precluding ability to use the device and application
4. Those with current involvement in another research study likely to interfere with the conduct of this study

Date of first enrolment

01/01/2020

Date of final enrolment

31/03/2021

Locations

Countries of recruitment

United Kingdom

England

Study participating centre

Great North Children's Hospital

Newcastle upon Tyne Hospitals NHS Foundation Trust

Level 3, Sir James Spence Institute

Royal Victoria Infirmary

Queen Victoria Road

Newcastle upon Tyne

United Kingdom

NE1 4LP

Study participating centre

Evelina Children's Hospital

Guy's and St Thomas' NHS Foundation Trust

Westminster Bridge Road

London

United Kingdom
SE1 7EH

Sponsor information

Organisation

The Newcastle Upon Tyne Hospitals NHS Foundation Trust

ROR

<https://ror.org/05p40t847>

Funder(s)

Funder type

Government

Funder Name

Action Medical Research; Grant Codes: GN2707

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

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analysed during this study are not expected to be made available in order to maintain patient confidentiality given the small study size and qualitative nature of much of the data.

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 | | 30/01/2023 | 01/02/2023 | Yes | No |
| HRA research summary | | | 28/06/2023 | No | No |
| Other publications | Participatory design workshops | 21/12/2022 | 01/02/2023 | Yes | No |
| Protocol file | version 1.9 | 12/09/2019 | 06/03/2023 | No | No |
| Study website | Study website | 11/11/2025 | 11/11/2025 | No | Yes |