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

Submission date
11/11/2019

Recruitment status
No longer recruiting

Registration date
18/11/2019

Overall study status
Completed

Last Edited
06/03/2023

Condition category
Nervous System Diseases

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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?
Dr Anna Basu
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Study website
https://research.ncl.ac.uk/earlytherapy/researchstudies/twocan%20project/

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
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

Secondary study design
Qualitative/proof of concept

Study setting(s)
Home

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

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 participants 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 measure
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

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

Overall study start date
01/12/2019

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 100; UK Sample Size: 100

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
England

United Kingdom

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

Sponsor details
Newcastle Joint Research Office
Level 1, Regent Point
Regent Farm Road
Gosforth
Newcastle-Upon-Tyne
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United Kingdom
NE7 7DN
+44 (0)191 282 23070
karen.verrill@nhs.net

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Government

Funder Name
Action Medical Research; Grant Codes: GN2707

Alternative Name(s)
actionmedres, action medical research for children, AMR

Funding Body Type
Private sector organisation

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

Location
United Kingdom

Results and Publications

Publication and dissemination plan
The study protocol will be made available on request. The researchers will submit the research findings for publication in peer-reviewed scientific journals and as conference presentations. They also intend to write an article for young people with hemiplegia and their families, to disseminate through the HemiHelp group (now part of the organisation Contact).

Intention to publish date
31/08/2023

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?
Other publications	Participatory design workshops	21/12/2022	01/02/2023	Yes	No
Results article		30/01/2023	01/02/2023	Yes	No
Protocol file	version 1.9	12/09/2019	06/03/2023	No	No
HRA research summary			28/06/2023	No	No