PROTOCOL

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

The TwoCan Project

Protocol Version	Version 1.9, 12/09/2019
Chief Investigator:	Dr Anna Basu Clinical Senior Lecturer (Newcastle University) and Honorary Consultant Paediatric Neurologist (Newcastle upon Tyne Hospitals NHS Foundation Trust)
Sponsor:	Newcastle upon Tyne Hospitals NHS Foundation Trust
REC Reference:	19/LO/1319
R+D Reference:	9038
Funder's reference:	GN2707 (Action Medical Research)
IRAS project ID:	254853
Internal BH reference:	BH180673

1 CONTENTS

2 STUDY SUMMARY

Background: Hemiplegic Cerebral Palsy (HCP) causes lifelong weakness and stiffness of one side of the body, impacting everyday functioning. Most affected children do not have access to effective intensive upper limb therapy.

Aim: To determine whether a wrist-worn device and software (including a smartphone application), incorporating positive feedback and peer support, can encourage increased use of the affected arm and hand during everyday activities.

Study design: Proof of concept study

Methods:

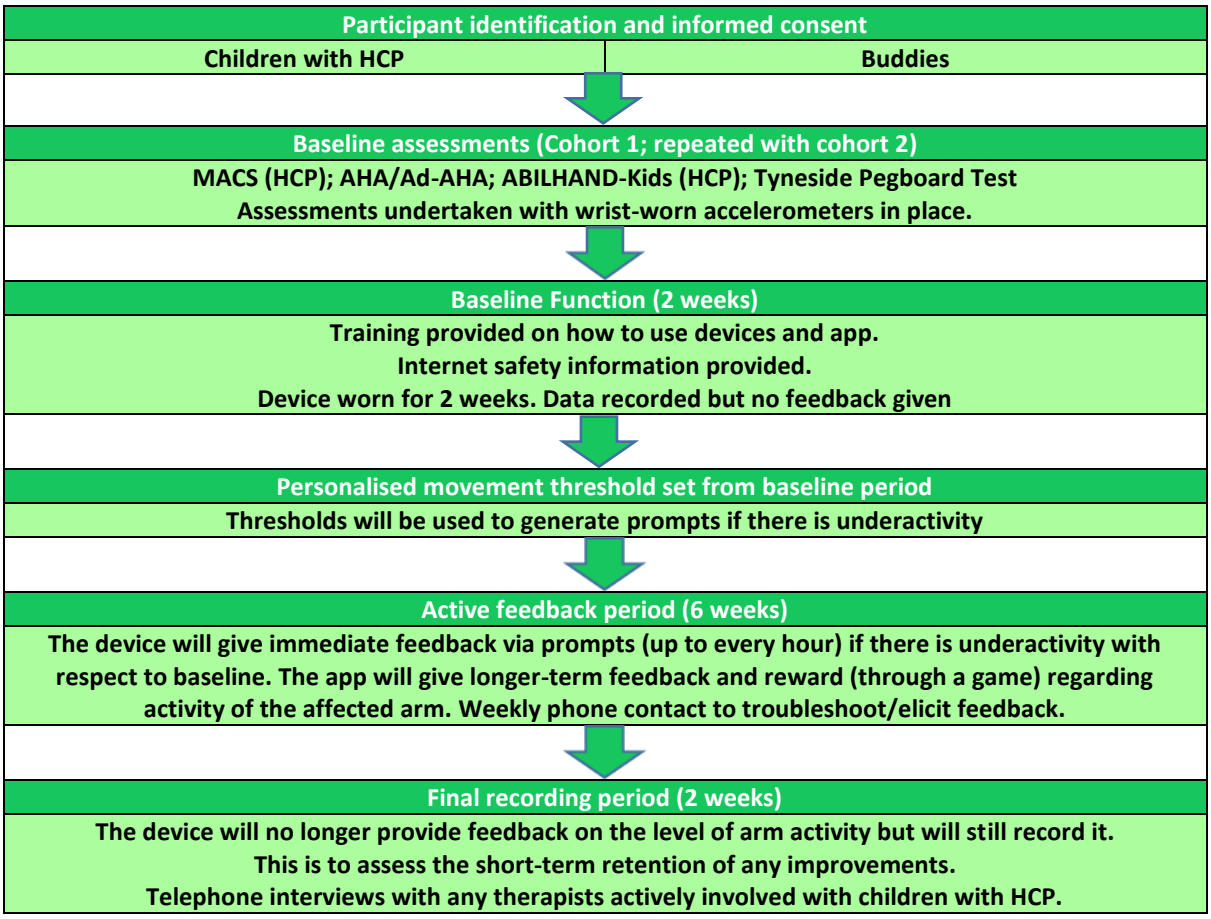
Participants: 20 children aged 8-18 years with HCP, their age-matched controls ("Buddies"), therapists and family members. The children with HCP will be recruited by clinicians at Newcastle upon Tyne Hospitals Trust and at the Evelina London Children's Hospital and through local self-help groups. The children will each nominate and approach their potential "buddy", who will then decide with their family whether they wish to learn more about the study and contact the research team if this is the case.

Intervention: *Baseline (2 weeks):* the device records arm activity without giving feedback. *Active feedback (6 weeks):* the device records and gives feedback (through the app) as well as personalised prompts during the day based on encouraging arm activity if this falls below a pre-set personalised threshold. *Final (2 week) period:* as for baseline.

Assessment:
At the start of the study the children will take part in a range of standardised hand and arm assessments conducted by an experienced occupational therapist. This will include the Assisting Hand Assessment (AHA) or equivalent Ad-AHA (age 13 years+), the Tyneside Pegboard Test (manual dexterity) and the ABILHAND-Kids questionnaire. Proof of concept assessment will be quantitative, produced by the data collected from the accelerometer with regards to the level of arm activity. In addition, there will be a qualitative component, via weekly meeting by phone/Skype/face to face. This will help to understand the acceptability and feasibility of implementation of the device and help with troubleshooting.

Analysis: We will assess feasibility and, through discussion with families, "Buddies" and therapists, acceptability. Hand function will be assessed at baseline. Changes in arm activity (derived from accelerometer data in the devices) will be analysed using single case experimental design for proof of concept that the approach can increase use of the affected upper limb.

3 FLOW DIAGRAM



4 BACKGROUND

Background: Hemiplegic Cerebral Palsy (HCP) affects around 39 000 people in the UK. HCP causes weakness and stiffness of one side of the body, impacting on activities of daily living [1, 2], peer relationships [3], quality of life and self-esteem [4], with long-term consequences for independent living and employment [5, 6]. Intensive therapy interventions improve upper limb function in children with HCP compared with usual (low-frequency, low-intensity) care [7], Intensive interventions require high levels of resources (e.g. 1:1 staffing levels, 8 hours/day in 2-week blocks) and are unavailable to most children. Approaches such as constraint therapy (in which the less-affected arm is restrained) are somewhat intrusive, and still require intensive therapy to promote use of the affected arm [8-10]. Fitting therapy around the home and school routine is challenging and requires motivation, patience and understanding: children with HCP require more practice than their typically developing peers to learn motor tasks [11]. It is hard to achieve adequate practice throughout the day without “nagging”.

Use of wearable technology to monitor activity levels [12] has the potential for marked behaviour change [13, 14]. Smartphone apps promoting self-monitoring and self-management are becoming popular for young people with chronic health problems e.g. diabetes and epilepsy [15, 16]. Through a collaboration between the Institute of Neuroscience and Open Lab (both at Newcastle University), funded by the Stroke Association, wrist-worn devices, and a software interface for providing feedback on use of the affected arm, were developed for adults with hemiplegia. The device contained an accelerometer to monitor arm activity;

it also reminded them to use the affected arm by vibrating discreetly if activity during the previous hour fell below a personalised, agreed threshold [17]. In a pilot trial there was a 16% increase in arm activity (counts per minute) in the hour after a prompt, compared with the preceding hour.

This approach is a promising real-world solution for children with HCP, empowering them to take control of their own improvements using technology with which they are familiar and comfortable. Children are comfortable with the use of smartphone applications, and therefore in this project they receive feedback through a smartphone app rather than a software interface on a personal computer. The app provides feedback and motivation. We will also collect normative data from a "Buddy" for each young person with HCP, to capture the variation in activity (and between limbs) in typically developing peers in the same settings.

5 AIMS

1) To test the feasibility and acceptability of a smartphone application and wrist-worn devices for children with HCP, providing performance-related feedback to reinforce and reward activity of the affected upper limb in everyday life.
2) To assess proof of concept that this approach can increase activity of the affected upper limb.

6 METHODS

6.1 Design: Proof of concept mixed methods study

6.1.1 Inclusion Criteria

A) Children/young people with HCP who are:

1) 8-18 years old
2) Manual Ability Classification (MACS) level I-III. MACS is a 5-point classification scheme for the children's ability to handle objects. Those at MACS IV-V struggle significantly more to undertake daily activities independently, which would affect the use of the wrist-worn device and the smartphone [18].
3) Fully informed signed parental consent and assent from parents

B) Typically developing controls:

Each of the children/young people will select a "buddy" who is a typically developing peer (sibling/school friend) within the same age range 8-18 years, (same age or in the same school year) who will act as a control to collect a comparative/normative dataset. These children/young people will have normal hand function. Again, fully informed consent (parental for children)/assent (child) will be obtained.

C) Therapists of children with HCP:

Following consent from the parents of the children/young people with HCP, we will ask their therapists to take part in providing feedback. These will be either physiotherapists or occupational therapists and are eligible if they are providing input related to upper limb function.

For all of the above, adequate command of the English language and fully informed consent (and for children, assent).

6.1.2 Exclusion Criteria

A) Registered blind or partially sighted, as they will not be able to see the visual (LED) cues or app feedback.

B) Unable to detect vibratory cues to wrist from the device.
C) Significant cognitive and/or language deficit precluding ability to use the device and application.
D) Current involvement in another research study likely to interfere with the conduct of this study.

6.1.3 Sample Size
20 children/young people with HCP and a "buddy" (typically developing) for each child will participate in the study. This sample size is expected to be sufficient for qualitative data saturation [19], permitting a range of scenarios in regards to demographics (across two sites) and functional ability to illustrate proof of concept. We will also recruit the therapists of the children/young people with HCP. The quantitative analysis will be on a single case experimental design basis.

6.1.4 Intervention
All children/young people taking part in the study will wear a device on each wrist, containing an accelerometer and sending data through Bluetooth linking to a smartphone application which can derive information on the activity of each arm. The devices are similar to a Fitbit and are CE tested activity trackers.

The children/young people will also borrow a smartphone for the course of the study if they do not already have one. If they do have a smartphone which is of adequate specification, the app will be downloaded on to their smartphone.

We will make sure the children/young people and families are provided with information/education about safe internet use as part of the project. Currently available suitable sources of information include the Safer Internet Centre (www.saferinternet.org.uk/advice-centre/young-people/resources-11-19s) which has suitable resources; and the Online Safety Guide from Internet Matters: https://www.internetmatters.org/advice/online-safety-guide.

The children/young people and families will be provided with instructions regarding the use of the app and phone, as well as on charging the devices. These instructions will be finalised at the end of the current development phase of the research. We will check that they understand the instructions and can carry them out. We will also provide them with contact details in case they have any questions or difficulties.

The children/young people will wear the wristbands all day each day for the 10 week period, one on each wrist. They will be removed at night, and for charging, and for activities which might be detrimental to the devices such as swimming, washing etc.

During the first 2 weeks, the devices will record arm activity but will not provide any hourly prompts to move. There will also not be any personalised feedback through the app. The aim of the first 2 weeks is to obtain baseline data on activity levels for each young person.

Personalised thresholds for activity levels will then be set, based on this baseline data and after negotiation with the children/young people and families. In a previous study in adults with hemiplegia, most chose to aim for a 10% increase in activity of the affected arm with respect to baseline. For those without hemiplegia, the prompts will be simply based on baseline data.

Activity levels will by necessity vary during the day and be different for school days and weekends. However, the ratio of the activity of the affected versus unaffected arm provides a method of modulating the prompts in a responsive manner for those with hemiplegia.

During the next 6 weeks, the personalised thresholds will be used to set prompts (visual and/or vibratory cues) through the wristbands for the children/young people to use their arm and hand if activity falls below the set threshold. It will be possible for a researcher to adjust the thresholds for prompts, through a web-based login, if necessary.

At the end of the day the children/young people will be encouraged to view the app to gain information regarding how much they managed to improve the activity of the affected arm. To provide motivation, this improvement will also be translated into reward points to use in a simple game they can play on the app.

During the final 2 weeks of the study the children/young people will not be given prompts or feedback: this will allow us to see if the increased level of activity can be maintained without this information.

The children/young people and families will have weekly contact with a member of the research team over the phone, via Skype or if needed face to face to troubleshoot and obtain feedback.

6.1.5 Control Group: Buddies

The role of the "buddies" is to obtain normative data to compare to each of the young people with HCP, and to capture the variation in the level of activity and between limbs in typically developing peers within the same situation, throughout a similar day. Buddies will therefore also wear the two wristbands and have access to the app for a 10 week period.

6.1.6 Assessments and Outcome Measures

The children/young people will take part in assessments at baseline to test upper limb function, undertaken by an occupational therapist. Children/young people will wear the wrist-worn devices during the assessments – this will allow us to obtain additional data regarding movements, pairing video data, accelerometry data and comparing with the clinical scores. During the assessments, the accelerometers will be set to sample at high frequency (e.g. 100 Hz) to capture the movement data at high resolution. The devices are lightweight (similar to Fitbits) and will not interfere with performance.

6.1.6.2 Manual Ability Classification System (MACS) [18] – children with UCP only

MACS is a validated 5 point classification system describing how those with CP use their hands in everyday activities. MACS I represents the highest level of self-initiated hand use. Parents, or the children/young people themselves, can complete the assessment by following the simple questions on the flow chart. The MACS is stable over time.

6.1.6.2 Assisting Hand Assessment (AHA) or equivalent Adolescent-AHA (age 13y+) – children with UCP only [20, 21]

AHA is a standardised evaluation of hand and arm baseline function. It is a measure of how efficiently people who suffer from conditions such as HCP spontaneously use their affected arm and hand in bimanual tasks. The children/young people will take part in a semi-structured 'play' session that uses a specific testing kit of toys and lasts 10 to 15 minutes. This session is recorded and reviewed based upon 22 items. Each of these items relates to a different action during the test: these actions are rated on a 4-point scale with higher scores representing better function. The AHA test is valid for children between the ages of 2 years to 12 years old. The test is fully validated and has excellent psychometric properties. There is an equivalent adolescent-AHA (Ad-AHA) for children ages 13-18 years. Ad-AHA was developed due to those over the age of 12 finding the AHA 'play session' unappealing due to its 'childish' nature. The raw scores for these assessments are converted through Rasch analysis to a '0-100 unit' logit-based AHA score. The Ad-AHA can

be scored exactly as the AHA: the two assessments can be considered as equivalent. We will collect this data from all children and young people taking part, to gather baseline information about arm movements.

6.1.6.3 ABILHAND-Kids Questionnaire - children with UCP only [22]
The ABILHAND-Kids questionnaire is used to gauge manual ability whilst performing daily tasks. The questionnaire is completed by the parents (taking around 5 minutes) and is based upon their perception of their child's manual ability (regardless of which hand is used). The assessment has been validated and is suitable for children aged 6-15 years. Each item is rated on a 3-point scale as to whether the child would find that task impossible, difficult or easy. The questionnaire scoring system is Rasch-based and is completed online. For those aged 16 and over, the ABILHAND questionnaire will be used instead.

6.1.6.4 Question regarding Cognitive Performance at School – all children/young people
We will ask parents about their child's performance at school, and if they require(d) additional support.

6.1.6.5 Accelerometry Data – all children/young people
The children/young people with HCP and their buddies will be wearing wrist-worn devices on both of their wrists during the day to collect data regarding arm movements, for a period of 10 weeks. Accelerometers within these devices provide information in relation to the arm activity that they perform during this period. The data over the 10-week period will be exported with 1-minute resolution, except for specified periods e.g. during specific assessments, during which higher resolution (e.g. 100 Hz) data will be collected. This data will allow calculation of the signal vector magnitude for each arm, and a comparison of each, over time.

6.1.6.7 Tyneside pegboard test – all children/young people [23]
This assessment was developed at Newcastle, to assess and compare unimanual and bimanual function. The pegboards are adapted to be accessible by people with conditions such as HCP. The assessment can be completed in around 15 minutes and simply involves removing and replacing pegs from a board.

6.1.6.7 Qualitative Study – all families
Throughout the study the children/young people and their buddies (and parents of both as appropriate) will take part in a weekly overview with a member of the research team. This will be done via phone/Skype or if needed face to face to gather information on acceptability of the device and the app as well as to undertake any troubleshooting. The families will be asked about the effect of using the device on social contact, activities and participation, and if the children suffer from any discomfort/fatigue (which is unlikely). The children/young people will be able to comment on any difference the device has made to their lives and if they think that the device has had a perceived effect on their ability to concentrate on other tasks (e.g. lessons). The sessions will be audio recorded and transcribed (anonymised) prior to subsequent analysis (see below).

6.1.6.8 Information on healthcare resource use
This will be collected initially before the study starts and will be reviewed during the weekly discussions throughout the study. This will concern if the child/young person has seen their occupational/physiotherapist and if so, the nature of any input/advice.

6.1.6.9 Information from therapists
Telephone interviews with therapists undertaken at the end of the limb movement data collection period will explore their views on the approach.

6.2 Study Conduct

6.2.1 Approach to participants

Children/young people with HCP who are eligible to take part in the study will be identified by clinicians at the Newcastle upon Tyne Hospitals NHS Foundation Trust, and by clinicians at the Evelina Children's Hospital in London. These children/young people will then be referred through their regional clinics once a member of the team has had a discussion with them and their families about the research project. We will also advertise the project through local self-help groups for families with children/young people with hemiplegia (former HemiHelp groups) in the Newcastle and London regions.

Once these children/young people have been referred, the families and children/young people will be given more information about the study and will be provided with an information sheet. An age-appropriate information sheet will be given. They will then be given time to go away and consider their participation in the study and at any point will be able to ask a member of the team any questions they might have. If the children/young people and their parents decide they want to take part, they will be asked to identify a potential "buddy" to take part too. They will be given a flyer to provide to the buddy and family, who will be encouraged to get in touch and provide their contact details so that they can discuss the study in detail with a researcher. They can then decide whether they wish to take part. Likewise, the families of the young people will contact any physiotherapist or occupational therapist who is providing input regarding upper limb function, so that they can also be approached regarding their decision to take part in the study.

The children/young people with HCP, their families and their buddy and their families will be made aware that they are free to drop out of the study at any time even after signing a consent form, without having to provide a reason.

6.2.2 Recruitment and Consent

The families will have adequate time since being initially approached about the study to consider if they wish to take part. They will be able to contact one of the research team and if they do want to continue they will be able to attend a meeting so that we can go through the information sheet with them to ensure that they fully understand the study and to answer any further questions. They will be informed that if they decide to not take part in the study that their children and their clinical care will not be adversely affected in any way.

Parents will sign consent forms on behalf of their children, who will also provide assent. Those aged 16 years and over will provide their own consent.

Therapists will provide written informed consent to be approached for telephone interviews (providing the parents of children with hemiplegia consent for the therapists to be approached).

The researcher providing the children with information will have experience with research involving minors so that they can assess whether they think that the child has fully understood and that they have enough information to make an informed decision.

6.2.3 Action in event of poor recruitment rate

We will monitor the rate of recruitment between the Newcastle upon Tyne Hospitals Foundation Trust and the Evelina Children's Hospital. We will raise awareness of the study at both sites through local talks. If the level of recruitment remains low we may consider involving other sites/PICS.

6.2.4 Schedule of assessments

6.2.4.1 Children/young people with hemiplegia

		Baseline function data collection		Active feedback period						Final recording period	
Assessment	**Baseline**	**1W**	**2W**	**3W**	**4W**	**5W**	**6W**	**7W**	**8W**	**9W**	**10W**
Manual Ability Classification System (MACS)	**X**										
Assisting Hand Assessment (AHA)/ Adolescence-AHA	**X**										
ABILHAND-Kids (or ABILHAND if aged 16 years and over)	**X**										
Ask about school inc. performance/support at school	**X**										
Accelerometry Data (from wristworn devices)	**X**	**x**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Tyneside Pegboard Test	**X**										
Telephone interviews		**x**	**x**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

6.2.4.2 Typically developing buddies

Assessment	Baseline	1W	2W	3W	4W	5W	6W	7W	8W	9W	10W
Manual Ability Classification System (MACS)											
Assisting Hand Assessment (AHA)/ Adolescence-AHA	**x**										
ABILHAND-Kids											
Ask about school incl. performance/support	**X**										
Accelerometry Data	**X**		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**
Tyneside Pegboard Test	**X**										
Telephone interviews		**x**		**X**	**X**	**X**	**X**	**X**	**X**	**X**	**X**

6.2.5 Digital Recordings

The data recorded by the accelerometer will be stored and used for analysis. In addition the therapist interviews will be audio recorded so analysis can be conducted at a later date, as will telephone interviews with families. These interviews will be sent for transcription to UK based services with strict data privacy policies, which comply with GDPR; and who have ISO 27001 certification. This data will be stored on a secure server at Newcastle University, which only members of the Limb Buddies research team will be able to access. This activity data will be coded via a study ID and assessment number: no names of participants will be used though pseudonyms will be used in the telephone transcripts.

Videoed assessments will be labelled by study number (not name), and transferred electronically using Newcastle University File Transfer system to a secure server at Newcastle University, downloaded and anonymised prior to analysis of limb movement in relation to limb accelerometry data. Anonymisation will be done using Adobe Premier Pro video editing software (or similar) to blur out faces and any other identifying information.

6.2.6 Data analysis

Qualitative data: Analysis of the telephone interviews throughout the study will provide a large dataset in regards to the acceptability and the feasibility of the device and the app during the children's everyday life. The qualitative analysis will be conducted according to the standard procedures [24] including open and focused coding, constant comparisons and memoing [25], deviant case analysis [26], and mapping [27]. When analysing this data we will specifically explore the issue in regard to age and gender on the acceptability of the device/app, ease of use, fidelity and the perceived benefits of use.

Quantitative data: The data recorded from the accelerometer will be analysed to see if the prompts to increase arm activity were effective. The change in arm activity will be measured by a signal vector magnitude of overall arm movement for pre-specified periods of time including the hour before a prompt and the hour following a prompt. This data once analysed can be further categorised in terms of the level of arm use (e.g. if movements are light, moderate or vigorous) in comparison to the child's baseline threshold.

The level of change in arm activity is judged from the extent to which baseline measures do not overlap with those in the intervention phase (percentage of non-overlapping date) [28]. From the data collected from each of the participants a 10% increase in the relative arm use in the active monitoring period compared with baseline function will be considered a proof of principle that the approach can increase arm use in daily activities.

In addition to this the relationship between baseline AHA/Ad-AHA, ABILHAND-Kids and Tyneside Pegboard test scores and improvement in arm use will be explored.

6.2.7 End of study

The end of the study (excluding analysis/writeup period) is defined as the point in time at which the last data item has been collected from the last participant.

6.3 Dissemination and Publication

Once the all of the data has been analysed and a conclusion has been drawn, the findings of the study will be disseminated to the children with HCP who took part in our study, along with their families and their buddies and therapists as a summary/leaflet. If the paper is published the children and their families will also be informed and once published they will be able to get a copy of this paper. We also intend for the results to be presented at a national or international conference. None of the participants of the study will be identifiable in the summary, the published paper or when the findings of the study are presented.

7 ETHICS

The study protocol and all of the required documentation will be submitted to the NHS Research Ethics Committee (REC). All other research approvals will be obtained before the study begins.

7.1 Ethical Considerations

Due to the study involving children who are under the age of 16 years there are ethical issues around consent, confidentiality and power relations. These will be handled sensitively. However, we believe that it is appropriate to undertake this research in children, because this is the only way to find out whether this

approach could benefit them in future. The approach has been specifically designed with this age group in mind, to be appealing and to help them develop independence in managing their own healthcare. Similar approaches (without the app) have been used in adults after stroke but this does not mean we can infer they are acceptable or likely to work in HCP.

7.1.1 The research team

Anna Basu is a Clinical Senior Lecturer at Newcastle University (Institute of Health and Society) and Honorary Consultant Paediatric Neurologist at Newcastle upon Tyne Hospitals NHS Foundation Trust. She is a clinical academic with expertise in the development and evaluation of interventions to improve upper limb function in infants and children with, or at risk of developing, hemiplegic cerebral palsy. She is CI for the project and will take overall responsibility for it.

Chris Price is Stroke Association HRH Princess Margaret Senior Reader in Stroke Medicine at Newcastle University (Institute of Neuroscience). He is a clinical academic working with multidisciplinary research teams to improve physical recovery following stroke, funded by NIHR and the Stroke Association. This has included development and demonstration of the clinical feasibility of live feedback from wrist-worn accelerometers to encourage upper limb activity. He will be an advisor to the project.

Janice Pearse is a research paediatric occupational therapist at Newcastle upon Tyne Hospitals NHS Foundation Trust, who has worked together with Dr Basu on a number of research projects. She has expertise in assessment and intervention for the upper limb in cerebral palsy. She will undertake and score clinical assessments and weekly contacts with families.

Ruth da Silva is an occupational therapist affiliated to the Stroke Research Group at the Institute of Neuroscience, Newcastle upon Tyne. For her PHD, she worked on a Stroke Association funded study: Wristband Accelerometers with Vibrating alert to prompt Exercise after Stroke (WAVES). She will be an advisor to the project.

Yu Guan is a lecturer in data science at Open Lab, Newcastle upon Tyne and leads the Machine Learning research group. He has collaborated with Dr Basu on a previous project detecting movement abnormalities in infants with perinatal stroke. He will lead the Open Lab team working on the project including any machine learning aspects of data analysis.

Tom Nappey is a research associate at Open Lab, Newcastle upon Tyne and has experience with industrial design. He was involved in the design phase of the app and will contribute to evaluation of feasibility and acceptability.

Dan Jackson is a senior research associate at Open Lab, Newcastle upon Tyne. His research is in the areas of ubiquitous computing and technologies that support health and wellbeing. He helped establish the Open Movement platform (www.openmovement.co.uk), whose *AX3* device has been widely used in movement research and population studies. This has underpinned his recent work focussed on movement sensing with wearable computing, including projects supporting people with conditions such as Parkinson's and stroke. He developed the algorithms required to analyse the data from the wrist-worn devices and will contribute to analysis of the movement data collected.

Karim Ladha is a research hardware engineer at Open Lab who developed the hardware and who will advise and assist with troubleshooting.

Tim Rapley is a medical sociologist at Northumbria University and Newcastle University with expertise in qualitative research in relation to medical contexts. He will advise on the qualitative research analysis components of the project.

Grace Edmonds is an internship student at Newcastle University who assisted with the development stage of the project and with preparation of documents for research governance and who will continue to be involved with the project from a learning and development point of view.

Jill Cadwgan is a consultant in paediatric neurodisability with a predominant interest in motor disorders and cerebral palsy. Her clinical interest includes management of children with cerebral palsy and other complex medical or developmental disorders, with a focus on improving function to facilitate participation. She will be the PI at the Evelina/GSTT site.

Anne Gordon is a consultant level occupational therapist with over 20 years clinical experience in paediatric neuroscience. She runs a tertiary level clinical intervention service for children with hemiplegia and has a strong post-doctoral publication track record in the field of paediatric brain injury. She will assist with patient identification at the Evelina/GSTT site and oversee the therapist activities at that site.

Patrick Olivier is an internationally recognised expert in the design of pervasive and ubiquitous computing systems, including wearable computing. He originated and led the Open Movement open source activity sensing initiative, which produced the AX3 physical activity monitor. The AX3 was recently used in UK Biobank's survey of 7-day physical activity in 103K participants - the largest study of physical activity ever conducted. He has since moved to Monash but will continue to be a collaborator and source of advice regarding the study.

7.1.2 Risks

When taking part in the study there is a risk that the children may experience fatigue and/or discomfort due to the increased level of activity of their affected arm when trying to reach their personalised threshold of movement. If this is the case we will set the child a lower threshold of activity to achieve if they choose to continue taking part in the study.

The wrist-worn devices are safe and should not pose any risk to the children. However there may be a risk that the children will find them uncomfortable, if they do find them uncomfortable we can try loosening the devices or changing the strap.

There are risks to children when using smartphones and having access to the internet. Parental safeguards/controls can be put in place, including on phones borrowed for use in this study. We will offer guidance into this including links to further information/advice on internet safety.

We will replace lost phones/devices within reasonable limits.

We will be open to recognise potential child safeguarding issues and follow them up as the law requires. Staff will have DBS checks in place. Dr Basu and Dr Cadwgan are paediatricians.

We recognise that taking part in the study involves significant time and commitment but our long term goal is to allow the children to be able to incorporate the approach into their daily lives with minimum disruption.

There is no financial incentive for taking part in the research project, though children will receive a small gift voucher as a token of appreciation for their participation. Any travel costs incurred will be reimbursed to the families.

7.1.3 Systems for monitoring and reporting of adverse events

General definitions:

- Adverse event: This is any untoward medical occurrence – there does not need to be a causal relationship between the occurrence and the study or any treatments administered.
- Serious adverse event: Any adverse event that
  - results in death
  - is life-threatening
  - requires hospitalisation or prolongation of existing hospitalisation
  - results in persistent or significant disability or incapacity
  - Consists of a congenital anomaly or birth defect.

7.1.3.1 Reporting an adverse event

Adverse/reportable events that occur have to be reported to the sponsor of the study under EU law.

7.1.3.2 Timeline of Reporting

The Chief Investigator will report:

- Immediately and no later than 2 calendar days after awareness of a SAE which indicates an imminent risk of death, serious illness and that requires prompt action for other patients / subjects, users or other persons;
- Immediately, but no later than 2 calendar days after awareness of a new reportable event or of new information in relation with an already reported event.
- Immediately, but not later than 7 calendar days following the awareness of any other reportable events or a new finding / update to a new reportable event or one which is already known.

7.1.4 Withdrawal from the study

If the parent(s) or the child decide that they no longer want to participate in the study they are free to withdraw at any time without having to provide a reason. This will not affect their normal NHS care or treatment. The data that will be collected from the participant up until this point will be retained and may still be used.

If one of the "buddy pair" drops out of the study, the other member of the pair can still remain in the study.

7.1.5 Informed consent

Fully informed written parental consent and assent from the young person will be obtained prior to participation. Therapists will also provide informed consent prior to any discussions (and following consent from the parents to approach the therapists). All parties will be given sufficient time to discuss the study, read the information sheets, ask questions and think about whether they want to take part, and will be made aware that they can change their mind at any time without any adverse consequences.

7.1.6 Funding and Sponsorships

The study is funded through Action Medical Research. The intended sponsor of the study is the Newcastle upon Tyne NHS Foundation Trust.

7.1.7 Indemnity and insurance

In the event of personal injury occurring on NHS premises or due to NHS treatment or negligence, professional and NHS insurance provides indemnity cover. In the event of injury occurring due to conduct of the research study, the Newcastle upon Tyne Hospitals NHS Foundation Trust provides indemnity cover. Newcastle University provides indemnity for the study design.

7.1.8 Anonymisation and data storage

All the data collected during the study will be stored on secure servers which are password protected. We will store patient identifiable information on Trust servers and use a patient study number to link this data to study data stored on secure university systems. In addition a hard copy will also be kept securely in a locked filing cabinet situated on Trust premises in a secure-access building. This is so that participants can be contacted in regards to follow up appointments/assessments. Personal data for participants who are not patients will be stored on secure university systems. Only appropriate members of the research team will have access to the files. The research data that is kept (both that on the computer and the hard copies) will be stored with a unique identification code. The Chief Investigator will maintain all of the stored data: this will include keeping documents updated and making any amendments necessary.

Any audio recordings that are collected during the study will be transcribed as soon as reasonably possible after the workshop. The originals will be destroyed once the project is completed for reference.

All data and audio recordings will be stored in accordance with the Data Protection Act 2018 and registered through the GDPR registrar.

7.1.9 General Data Protection Regulation (GDPR) Policy and Action in Event of a Breach

In the unlikely event of a breach in GDPR the relevant supervisory authorities will be made aware of the breach within 72 hours, where feasible. If the breach is likely to affect an individual personally, that individual will be informed without undue delay. If they feel it appropriate, they will be able to make a formal complaint through the NHS Complaints Procedure. If the breach is a result of negligence then participants may have grounds for compensation against Newcastle upon Tyne Hospitals NHS Foundation Trust, or the Evelina Children's Hospital.

References

1. Skold, A., S. Josephsson, and A.C. Eliasson, *Performing bimanual activities: The experiences of young persons with hemiplegic cerebral palsy.* American Journal of Occupational Therapy, 2004. **58**(4): p. 416-425.
2. A, J., *Prevalence and characteristics of children with cerebral palsy in Europe.* Developmental Medicine & Child Neurology, 2002. **44**(9): p. 633-640.
3. Goodman, R., *Psychological aspects of hemiplegia.* Archives of Disease in Childhood, 1997. **76**(3): p. 177-178.
4. Russo, R.N., et al., *Self-Esteem, Self-Concept, and Quality of Life in Children with Hemiplegic Cerebral Palsy.* Journal of Pediatrics, 2008. **153**(4): p. 473-477.
5. Beecham, J., T. O'Neill, and R. Goodman, *Supporting young adults with hemiplegia: services and costs.* Health & Social Care in the Community, 2001. **9**(1): p. 51-59.
6. van der Slot, W.M.A., et al., *Everyday physical activity and community participation of adults with hemiplegic cerebral palsy.* Disability and Rehabilitation, 2007. **29**(3): p. 179-189.
7. Sakzewski, L., A. Gordon, and A.C. Eliasson, *The State of the Evidence for Intensive Upper Limb Therapy Approaches for Children With Unilateral Cerebral Palsy.* Journal of Child Neurology, 2014. **29**(8): p. 1077-1090.
8. Page, S.J., et al., *Stroke patients' and therapists' opinions of constraint-induced movement therapy.* Clinical Rehabilitation, 2002. **16**(1): p. 55-60.
9. Wallen, M., et al., *Modified constraint-induced therapy for children with hemiplegic cerebral palsy: a randomized trial.* Developmental Medicine and Child Neurology, 2011. **53**(12): p. 1091-1099.

10. McConnell, K., L. Johnston, and C. Kerr, *Efficacy and Acceptability of Reduced Intensity Constraint-Induced Movement Therapy for Children Aged 9-11 years with Hemiplegic Cerebral Palsy: A Pilot Study.* Physical & Occupational Therapy in Pediatrics, 2014. **34**(3): p. 245-259.
11. Hung, Y.C. and A.M. Gordon, *Motor learning of a bimanual task in children with unilateral cerebral palsy.* Research in Developmental Disabilities, 2013. **34**(6): p. 1891-1896.
12. Research, W., *Smart Wearables for Sports and Fitness: Market Shares, Market Strategies, and Market Forecast, 2015 to 2021.* 2015.
13. Harris, T., et al., *Effect of a Primary Care Walking Intervention with and without Nurse Support on Physical Activity Levels in 45-to 75-Year-Olds: The Pedometer And Consultation Evaluation (PACE-UP) Cluster Randomised Clinical Trial.* Plos Medicine, 2017. **14**(1).
14. Lyons, E.J., et al., *Behavior Change Techniques Implemented in Electronic Lifestyle Activity Monitors: A Systematic Content Analysis.* Journal of Medical Internet Research, 2014. **16**(8).
15. J, J.R.C.L.H.S.A.E.P., *Apps and online resources for young people with diabetes: the facts.* Journal of Diabetes, 2013. **17**: p. 20-26.
16. Murray, E., et al., *Interactive Health Communication Applications for people with chronic disease.* Cochrane Database of Systematic Reviews, 2005(4).
17. al, D.S.R.M.S.J.D.J.D.B.M.B.K.e., *Wrist worn accelerometers with vibrating-alert to prompt exercises after stroke (WAVES).* European Stroke Journal, 2016. **1**(S1): p. 531.
18. Eliasson, A.C., et al., *The Manual Ability Classification System (MACS) for children with cerebral palsy: scale development and evidence of validity and reliability.* Developmental Medicine and Child Neurology, 2006. **48**(7): p. 549-554.
19. Francis, J.J., et al., *What is an adequate sample size? Operationalising data saturation for theory-based interview studies.* Psychology & Health, 2010. **25**(10): p. 1229-1245.
20. Krumlinde-Sundholm, L., et al., *The assisting hand assessment: current evidence of validity, reliability, and responsiveness to change.* Developmental Medicine and Child Neurology, 2007. **49**(4): p. 259-264.
21. Louwers, A., et al., *Development of the Assisting Hand Assessment for adolescents (Ad-AHA) and validation of the AHA from 18 months to 18 years.* Developmental Medicine and Child Neurology, 2016. **58**(12): p. 1303-1309.
22. Arnould, C., et al., *ABILHAND-Kids - A measure of manual ability in children with cerebral palsy.* Neurology, 2004. **63**(6): p. 1045-1052.
23. Basu, A.P., et al., *The Tyneside Pegboard Test: development, validation, and observations in unilateral cerebral palsy.* Developmental Medicine and Child Neurology, 2018. **60**(3): p. 314-321.
24. T, R., *Some Pragmatics of Data Analysis. Qualitative Research: Theory, Mehtod & Practice.* SAGE Publications, 2016. **30**: p. 273-290.
25. Glaser, B.G., *The Constant Comparative Method of Qualitative Analysis.* Social Problems, 1965. **12**(4): p. 436-445.
26. C, S., *The Quality of Quantative Research* SAGE Publications, 1999.
27. Clarke, A.E., *Situational analyses: Grounded theory mapping after the postmodern turn.* Symbolic Interaction, 2003. **26**(4): p. 553-576.
28. Remschmidt, H., *SINGLE CASE EXPERIMENTAL-DESIGNS - STRATEGIES FOR STUDYING BEHAVIOR-CHANGE - BARLOW,DH, HERSEN,M.* Zeitschrift Fur Kinder-Und Jugendpsychiatrie Und Psychotherapie, 1986. **14**(3): p. 270-270.
29. Diekema, D.S., *Ethical Issues in Research Involving Infants.* Seminars in Perinatology, 2009. **33**(6): p. 364-371.