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Delivering affordable, functional prostheses in the NHS: a trial across two clinical sites to compare existing care with an affordable, multigrip prosthesis to increase function and choice for children and adolescents with upper limb difference

Submission date 18/01/2019	**Recruitment status** No longer recruiting	[ ] Prospectively registered [ ] Protocol
Registration date 20/03/2019	**Overall study status** Completed	[ ] Statistical analysis plan [ ] Results
Last Edited 20/03/2019	**Condition category** Other	[ ] Individual participant data [ ] Record updated in last year

Plain English summary of protocol

Background and study aims
At present via the NHS, the majority of patients with upper limb differences are either provided with a passive prosthesis (cosmetic only), or a body-powered, single grip prosthesis. This limited choice reflects the cost-effectiveness and durability of these prostheses. However, almost half of all upper limb amputees abandon their prostheses, attributed primarily to a lack of function. With recent advances in robotics, the production of multi-grip prostheses that use muscle activity (myoelectric) to create movement, have become a reality. However, with the cost of these prostheses between £25, 000 - £80, 000, they are rendered inaccessible for the majority of patients. This study looks to address this problem. The researchers have taken the first steps in completing a small scale study within a single NHS centre, which established the ability to deliver the prosthesis in an NHS care pathway. The next step is to conduct a full clinical trial that will compare the Hero Arm™, a multigrip, myoelectric prosthesis, with standard care (a single-grip myoelectric prosthesis).

Who can participate?
Patients aged 8 to 18 who are trans-radial (forearm) upper limb amputees or with congenital (from birth) limb deficiencies

What does the study involve?
Participants use both prostheses in a random order over a period of 6 months (3 months with each prosthesis) and are assessed at the start of the study and after 3 and 6 months.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
1. Bristol Centre for Enablement (UK)
2. Specialised Ability Centre Manchester, University Hospitals of Manchester (UK)

When is the study starting and how long is it expected to run for?
March 2018 to June 2020

Who is funding the study?
Innovate UK, SBRI Healthcare (UK)

Who is the main contact?
Dr Abby Tabor

Contact information

Type(s)
Scientific

Contact name
Dr Abby Tabor

Contact details
University of Bath
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Bath
United Kingdom
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
244661

Study information

Scientific Title
Affordable robotic prostheses in the NHS: a randomised controlled trial comparing the Hero Arm™ with the NHS standard upper limb myoelectric single grip prosthesis

Acronym
Affordable Prosthetics

Study objectives

The provision of an affordable, multigrip, robotic prosthesis is equal in performance, as measured through function in children and young people in comparison to standard care.

Ethics approval required
Old ethics approval format

Ethics approval(s)
London -Camberwell St Giles Research Ethics Committee, Level 3, Block B, Whitefriars, Lewins Mead, Bristol, BS1 2NT, Tel: +44 (0)20 7104 8044, 06/08/2018, REC ref: 18/LO/1228, IRAS project ID: 244661

Study design
Randomised controlled trial, crossover design, with stratified randomisation

Primary study design
Interventional

Secondary study design
Randomised cross over trial

Study setting(s)
Community

Study type(s)
Quality of life

Participant information sheet
Not available in web format

Health condition(s) or problem(s) studied
Trans-radial upper limb difference (congenital/acquired/traumatic), aged 8-18 years

Interventions
Having completed feasibility testing in a single centre, this Randomised Controlled Trial (stratified randomisation, with cross-over design) will involve recruitment from two NHS centres, comparing the Hero Arm™ with the standard care pathway currently commissioned in the NHS - a single grip myoelectric prosthesis. Specifically, the trial will engage a stratified randomisation, with participants stratified by age (8-13 years; 14-18 years) and previous prosthesis experience (novice, expert). This trial will also involve a cross-over design such that each participant tests each prosthesis sequentially for 3 months (6 months in total).

Intervention Type
Device

Primary outcome measure
Upper limb function measured using Action Research Arm Test at baseline, 3 and 6 months

Secondary outcome measures

Measured at baseline, 3 and 6 months:
1. Health-related quality of life measured using Paediatric QOL Inventory (PedsQL)
2. Self-reported function and symptoms in the upper limb measured using Disabilities of the Arm, shoulder and Hand (DASH)

Overall study start date
01/03/2018

Completion date
26/06/2020

Eligibility

Key inclusion criteria
1. Aged 8 years – 18 years
2. Trans-radial (forearm), upper limb amputee
3. Established upper limb amputees: congenital limb deficiencies and post acquired limb loss more than 1-year post amputation

Participant type(s)
Patient

Age group
Child

Lower age limit
8 Years

Upper age limit
18 Years

Sex
Both

Target number of participants
8

Key exclusion criteria
1. Incomplete wound healing at residuum
2. Uncontrolled cardiovascular or respiratory conditions
3. Current multi-grip myoelectric prosthesis user

Date of first enrolment
01/02/2019

Date of final enrolment
28/06/2019

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Bristol Centre for Enablement, North Bristol NHS Trust
Jupiter Rd, Patchway
Bristol
United Kingdom
BS34 5BW

Study participating centre
Manchester Specialised Ability Centre
Altrincham Rd, Wythenshawe
Manchester
United Kingdom
M22 4NY

Sponsor information

Organisation
The University of Bath

Sponsor details
Claverton Down Rd
Bath
England
United Kingdom
BA2 7AY

Sponsor type
University/education

Website
www.bath.ac.uk

ROR
https://ror.org/002h8g185

Funder(s)

Funder type
Other

Funder Name
SBRI Healthcare

Funder Name
Innovate UK

Alternative Name(s)
innovateuk

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
1. Peer reviewed journal, open access (protocol and results)
2. International conference presentation

Intention to publish date
26/07/2020

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Abby Tabor at the University of Bath. Once the study is closed (from June 2020) the data will be available, including quantitative and qualitative outcomes. The data will be stored for 5 years and can be accessed throughout this time. All data is anonymised, associated with a participant number. At the outset of the study, all participants are informed as part of their consent that they can access their data at the conclusion of the study. The lead researcher is able to determine the data in association with a particular participant without compromising ethical restrictions.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

HRA research summary	28/06/2023	No	No