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Standing Frames in Cerebral Palsy

Submission date 05/10/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 16/10/2015	**Overall study status** Completed	
Last Edited 21/12/2020	**Condition category** Nervous System Diseases	

Plain English summary of protocol

Background and study aims

One in 400 UK children has cerebral palsy, leading to difficulty with movement, coordination and muscle tightness. Children with severe cerebral palsy may be unable to walk and have associated learning or communication difficulties. Cerebral palsy is caused by damage to the brain while it is rapidly developing, before birth or in the first year of life. Although the brain damage does not worsen, effects on the body such as pain, spasms, limb and joint deformity do. These children need physiotherapy, including management of posture. One aspect of this is the use of a Standing Frame, a rigid frame with a wide base. A child is positioned in the frame with fastenings to enable him/her to be vertical, yet free to use his/her arms and hands. There is much variation in type of frame and how long children are positioned in them. Standing frames have many proposed benefits such as improvement in limb movement, bone strength, bladder and bowel control, breathing and participation in activities as well as the prevention of hip dislocation. There is little evidence to support such benefits. Frames also have disadvantages such as taking up space, being uncomfortable, needing time to position children in them, cost, and therapist time to monitor use. In order to assess the usefulness of standing frames, we would ideally carry out a trial in which children were assigned by chance to having treatment with a frame or not. However, withholding treatment with a frame may not be acceptable to some children, parents and healthcare providers who have firm views that they are helpful. So, before designing a trial, we must find out:

1. Current practice: How are frames used? How long are children being asked to stand in them? What are the difficulties with using frames?
2. Attitudes: What do users think about frames? Why do they think they are useful? Are trials needed? What are the pros and cons of frame use?
3. Thoughts on proposed trial designs: Would users be prepared to change the time spent in a frame each day? Would users be prepared to stop using a frame, or be allocated by chance to different treatments in a research trial?

Here, two surveys will be carried out and discussions held with children, parents and healthcare providers to prepare for a trial or trials of the effectiveness of standing frames to help children with cerebral palsy.

Who can participate?

Parents of young children using standing frames for cerebral palsy, healthcare and educational professionals working with children who use standing frames and children and young people (aged 8-18) that have cerebral palsy and use standing frames.

What does the study involve?
The study involves three steps. The first is a survey asking professionals and parents about how standing frames are currently used. The second step involves discussions using focus groups with parents and healthcare staff and one to one interviews with children using the frames in order to understand attitudes to standing frame use and how acceptable they would consider a trial. The third step involves a second survey to bring together the findings from the first two steps and ask for opinions on potential trial designs. Both surveys are sent via internet or post to parents and health and named education staff, with questions adjusted for each group. This will help in designing future trials to assess the benefits of standing frames.

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

Where is the study run from?
Newcastle University, Great North Children's Hospital, Robert Jones and Agnes Hunt Hospital (Oswestry) and Chailey Heritage Clinical Services (UK)

When is the study starting and how long is it expected to run for?
October 2015 to July 2017

Who is funding the study?
National Institute for Health Research (UK)

Who is the main contact?
Dr Jill Kisler

Contact information

Type(s)
Scientific

Contact name
Dr Jill Kisler

Contact details
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
HTA 13/144/01

Study information

Scientific Title
Standing Frames as part of Postural Management for Children with spasticity. What is the acceptability of a trial to determine the efficacy of standing frames.

Study objectives
The aim is to answer the question: What is the likely acceptability of a future trial to determine the efficacy of standing frames? We plan to undertake two surveys and qualitative research to assess the feasibility and inform the design of a trial (or trials) of standing frame use for children with cerebral palsy (CP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
East Midlands - Nottingham 1 Research Ethics Committee, 07/12/2015, ref: 15/EM/0495

Study design
Sequential, mixed-methods (quantitative and qualitative) studies

Primary study design
Observational

Secondary study design
Sequential, mixed-methods (quantitative and qualitative) studies

Study setting(s)
Other

Study type(s)
Other

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

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

Interventions
Participants will be completing surveys and there will be focus groups of parents and professionals and in-depth interviews with young people. Steps include:

1. Survey 1: Professionals (health and education staff) and parents: to identify current use of standing frames.
2. Qualitative research: focus group work with parents and professionals; in-depth interviews

with children to understand attitudes to standing frame use and acceptability of a trial.
3. Synthesis of findings from survey 1 and qualitative research, and development of potential trial designs with appropriate comparators and outcome measures.
4. Survey 2: Professionals and parents: regarding acceptability and feasibility of potential trial designs, including willingness to recruit (professionals), to have their child randomized (parents), comparators and outcome measures.
5. Propose a design for a substantive trial or trials.

Intervention Type
Other

Primary outcome measure
1. Description of current standing frame use for children with CP (including treatment indications, treatment goals, types of frame, durations of intended and actual use; perceptions and practicalities of standing frame use)
2. A proposed design (Population- Intervention-Control/comparator-outcome(s) – Timeframe formulation and trial design) for a clinical trial(s) of effectiveness of frames in children with CP, GMFCS levels IV or V

Secondary outcome measures
N/A

Overall study start date
01/10/2015

Completion date
31/07/2017

Eligibility

Key inclusion criteria
1. Parents of young children using standing frames for cerebral palsy
2. Healthcare professionals working with children who use standing frames
3. Education professionals and other carers working with children who use standing frames
4. Children and young people age 8-18 years who have cerebral palsy GMFCS IV or V and use standing frames

Participant type(s)
Mixed

Age group
Mixed

Sex
Both

Target number of participants
Surveys: 450-500 parents and professionals; focus groups: 48 parents and professionals. interviews 12-15 young people aged 8-18years.

Key exclusion criteria
Severe cognitive impairment and/or significant communication difficulties resulting in inability to be able to make simple choices or communicate “yes” vs. “no” responses.

Date of first enrolment
01/01/2016

Date of final enrolment
30/04/2017

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Newcastle University
United Kingdom
NE14LP

Study participating centre
Great North Children's Hospital
Newcastle upon Tyne NHS Foundation Trust
Newcastle
United Kingdom
NE1 4LP

Study participating centre
Robert Jones and Agnes Hunt Hospital
Oswestry
Shropshire
United Kingdom
SY10 7AG

Study participating centre
Chailey Heritage Clinical Services
Beggar's Wood Rd
Lewes
East Sussex
United Kingdom
BN8 4JN

Sponsor information

Organisation
Newcastle Upon Tyne NHS Foundation Trust

Sponsor details
Royal Victoria Infirmary
Queen Victoria Road
Newcastle
England
United Kingdom
NE1 4LP

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05p40t847

Funder(s)

Funder type
Not defined

Funder Name
National Institute for Health Research

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan

Dissemination will take place during the study, not just at its end. We want young people, parents/carers and professionals to be aware of this work at an early stage so that they feel their reactions and suggestions are contributing to it and anticipate the results with interest. We will consult with parents who participate in Survey 1 about additional ways to disseminate information, but will include:
1. Information for newsletters and web sites of Cerebra, SCOPE, Contact-a-family, Council for Disabled Children.
2. Information to children and families through leaflets, parent/carer forums and internet social sites such as website/facebook page and Twitter.
3. During the project, presentation at Annual Conferences of:
3.1. European Academy of Childhood Disability
3.2. Royal College of Paediatrics and Child Health
3.3. British Society for Children's Orthopaedic Surgery
3.4. Association of Paediatric Chartered Physiotherapists
4. Open access publication in peer reviewed journals at the end of the project:
4.1. Results of Survey 1 of current use of standing frames in the UK.
4.2. The qualitative work on feasibility and acceptability of a trial into the use of standing frames for children with CP with a proposed study protocol (which if funded in the future, will be published in the Trials Journal).

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Data sharing statement to be made available at a later date

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			28/06/2023	No	No