



Information Sheet for Participation in Standing Frame Research Study

Summary of standing frame study:

This national research study “Standing frames as postural management for children with spasticity, what is the acceptability of a trial to assess the efficacy of standing frames?” is being carried out by a research team led by Dr Jill Kisler from Newcastle University and is funded by the National Institute for Health Research Health Technology Assessment (NIHR HTA) programme.

The purpose of this study is to understand the current use of standing frames in children with cerebral palsy in the UK, and to consider how we may design a research trial or trials to develop clinical evidence for standing frame use.

Background:

1:400 UK children has cerebral palsy (CP). Children with CP may be unable to walk and have associated learning or communication difficulties. CP is caused by damage to the brain, before birth or in the first year of life. Although the brain damage does not change, effects on the body such as pain, limb and joint deformity do. Physiotherapy treatment may include using a Standing Frame but there is much variation in UK practise.

There is little evidence to support the proposed benefits of frames including improvement in limb movement, bone strength, bladder and bowel control, breathing, participation in activities; and prevention of hip dislocation. Frames also have disadvantages: they use space, take time and may be uncomfortable and expensive.

To assess the usefulness of standing frames, a trial is needed where children are assigned by chance to using a frame or not. However, not using a frame may not be acceptable to some children, parents and healthcare providers who think that they are helpful.

Study Plan:

This study aims to prepare for a feasible and acceptable trial to assess the effectiveness of standing frames for children with CP by:

Step 1: Survey 1 to understand current practice in the UK. How are frames used? How long do children stand in them? Are there difficulties with using frames?

Step 2: Discussions using focus groups with parents and healthcare staff and interviews with children. What do users think about frames? Why are they useful? Are trials needed? What are the pros and cons of frame use? Would users be prepared to stop using a frame, or be allocated by chance to different frame use in a trial?

Step 3: Survey 2 will summarise findings from the first two steps and seek opinion on potential trial designs.

Outcome:

The ultimate goal this study is to identify any variability in practice across the UK, then to consider how we can design trials to inform best practice, also to find out if professionals, parent/carers or children/ young people would be prepared to participate in research trials.

How can you participate?

Surveys:

You may be invited to participate via a paper or on line survey – Survey 1 and Survey 2 will be distributed amongst UK professional groups, parent-carer forums and personal contacts.

Focus Groups:

If you complete Survey 1 and express interest in participating further in the research (by providing your contact details) then you may be contacted and invited to participate in focus groups, or asked if your child wants to participate in interviews. Further information regarding each of these will be provided before participation – so that you can decide if you want to participate.

Interviews:

Young people will be identified and invited through one of 3 the clinical teams involved in the research, led by: Dr Jill Kisler at the Great North Children's Hospital: Royal Victoria Infirmary, The Newcastle upon Tyne NHS Trust, Mrs Sarah Crombie, Physiotherapist: Chailey Heritage Clinical services or Mr Andrew Roberts, Consultant Orthopaedic Surgeon: The Robert Jones and Agnes Hunt Orthopaedic Hospital.

Confidentiality:

All data produced from the study will be kept strictly confidential and anonymized according to University and Trust Guidelines.

Final Report:

If you would like to receive a copy of the final report of this study (or a summary of the findings) when it is completed, please feel free to contact us, even if you decide not to take part in the study.

Useful Contact Information:

If you have any questions or concerns regarding this study, its purpose or procedures, or if you have a research-related problem, please feel free to contact the researcher(s),

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What if I have concerns or a complaint?

If you have any concerns about this research and would like to discuss them further, please contact:

- Dr Jill Kisler via Jane Tilbrook with the above details.
- The Patient Advice and Liaison Service (PALS), Royal Victoria Infirmary, Newcastle Upon Tyne Hospitals NHS Trust, Queen Victoria Road, Newcastle, NE14LP Freephone - 08000320202
- The Dean of Clinical Research at Newcastle University: Professor John Simpson.
PA = Jill McKenna Jill.Mckenna@ncl.ac.uk - telephone -01912083889

