

Title of study: The effects of night positioning on sleep, postural deformity and pain in children and young people with cerebral palsy - an exploratory study

Study start date: 1st November 2011
End date: 31st October 2014

Funding: NIHR - Research for Patient Benefit

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Background to research:

Many children with cerebral palsy (CP) experience sleep disturbance, pain and postural deformity. Poor sleep, pain and postural problems significantly affect the quality of life of the child and also impact on their parents/carers. Night time positioning has become a popular part of 24 hour postural management programmes for posture and comfort. However there is very limited evidence of the effect of night positioning using sleep systems on postural deformity and sleep and the effect on pain has not been investigated.

Aim:

This was an exploratory study to test a study design for a randomised controlled trial (RCT) including recruitment strategy, appropriateness and feasibility of outcome measures, length of intervention period, sample size and adherence to using sleep systems.

Methods:

The target for recruitment to the study was 50 children/young people with CP, aged 2-16 years and at GMFCS levels IV to V. For each participant a baseline assessment was undertaken to collect information on sleep quality, pain and musculoskeletal deformity. Children were then randomly allocated into one of two groups with allocation concealed from the local researcher (LR) until consent had been recorded:

- Intervention group – 12 months using a sleep system
- Control group - standard care (i.e. without provision of a sleep system)

A choice of three commercial sleep systems was offered. All three systems provided similar postural support (i.e. 30° of abduction at the hips). Training was provided to all LRs by the

research team to set up, adjust and monitor the sleep system and train the participant's family/carers in the use of the sleep system.

Outcome measures collected were based on oximetry, actigraphy, sleep diaries, Chailey Sleep Questionnaire, pain profiles, range of movements and hip x-rays. Measures were recorded at baseline and repeated after 6 and 12 months.

Results:

The most significant issue encountered was recruitment. Of the 26 sites that expressed an interest only 3 sites proceeded to recruiting participants.

Reasons for teams declining to take part were:

- Sleep systems established as part of service postural management pathway therefore they were reluctant to not provide this equipment if the child were allocated to the control group
- Teams were interested but had low numbers of possible participants as they were already providing sleep systems; had difficulty accessing information on numbers of eligible children with CP; or potential participants did not have a definite diagnosis of CP.
- Some sites declared an interest at a senior staff level, but frontline staff proved difficult to engage
- Staffing issues affected some sites (organisational restructuring, no cover for maternity leave)
- Some therapists, although acknowledging there was a need for evidence, felt the 1-2 year intervention too long to agree to the RCT protocol

For sites which progressed past the local R&D approval stage, recruitment was more difficult and slower than anticipated. Reasons identified were:

- Parents were cautious - not wanting to do anything which might adversely affect sleep patterns
- Parents did not want a sleep system, or were already acquiring one.
- Information systems / paper records were unhelpful in identifying whether the child already had a sleep system
- Parent's preference was to co-sleep with their child
- The child was used to sleeping on their side
- Parents felt a change of position if needed during the night was more easily achieved using pillows
- Parents had anxiety about the child lying supine due to potential seizures or breathing difficulties.

Of the 50 anticipated participants, 22 were recruited to the study but 6 withdrew prior to allocation (2 as the site withdrew; 2 due to hip surgery, 1 not wishing to be in the control group; and 1 due to a change in the child's diagnosis).

Of the remaining 16 participants:

- 7 were in the intervention group and 9 in the control group
- 9 participants were male and 7 female
- Age range: 2.9 – 15.5 years. Average age: 7.7 years

For those in the intervention group, important information was gained on how participants and their families felt about using sleep systems. For instance, how sleep systems were introduced to the child and constantly monitored were important factors in adherence in the use of equipment.

Practical issues associated with the outcome measures were also identified. Most notably there were difficulties in the home use of oximetry with issues including:

- sensors fell off in the night
- parents found the machines noisy and disturbed the child
- problems in the reliability of the devices
- parents easily put off using them

Conclusion:

This study identified a number of areas for further consideration. Rich data was gathered on the challenges establishing an evidence base for interventions which are already being used in clinical practice and the practical challenges to running a trial in community therapy services.

Changes could be made to enhance recruitment such as greater support for local researchers and frontline therapists to encourage engagement in research. The mapping of service provision where sleep systems are and are not provided could also prove useful as clinical teams were reluctant to take part where sleep systems are routinely used

The provision of sleep positioning systems is a complex intervention that merits greater evaluation to understand not only effectiveness but also the context of clinical decision making and prescription as part of postural management.