P14

Post Market Surveillance Case Study Protocol: Dynamic postural management with Aergo PS

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Summary

Aergo PS is a novel, patent-filed and CE-marked, innovative postural support device designed to assist paediatric neuromuscular diseases (NMDs). A post-market surveillance study demonstrated Aergo PS was safe for use at home, and that children with NMDs had positive experiences of comfort, posture, independence from carer support, and usability.

Aims and Objectives

Aim:

To verify Aergo PS's responsive air supports are effective in improving comfort and independence for children living with Neuromuscular diseases (NMDs), and to assess usability and safety of the device in a home setting.

Objectives:

1. Evaluate the impact on independence and comfort of Aergo PS' automated postural management feature during prolonged sitting.
2. Record adverse events to assess safety.
3. Evaluate children's ability to control Aergo PS device for optimal postural support with the remote control.
4. Examine the views and experiences of patients using the Aergo PS device to identify and address the feasibility and usability of implementing the Aergo PS device in the home setting.

▲ *Aergo PS V1 interfaced on manual and electric wheelbases for PMS Case Study.*

Background

Children born with neuromuscular diseases (NMDs) rely heavily on specialist seating to prevent spinal deformities and organ compression. Existing solutions are superior in maintaining optimal sitting alignment, but as children moves throughout the day, the prescribed position can often be lost and require carers and clinicians to conduct frequent adjustment. To address this, we have developed a responsive postural support seating system, Aergo PS. It uses a network of pressure sensitive air cells to monitors user's sitting position and automatically adjust support levels as the user moves; keeping them in an optimal sitting position. A remote control is also introduced for users to self-initiate minor adjustments for improved comfort. We have CE-marked Aergo PS as a class 1 medical device and present initial findings of our post market surveillance (PMS) study.

Technique

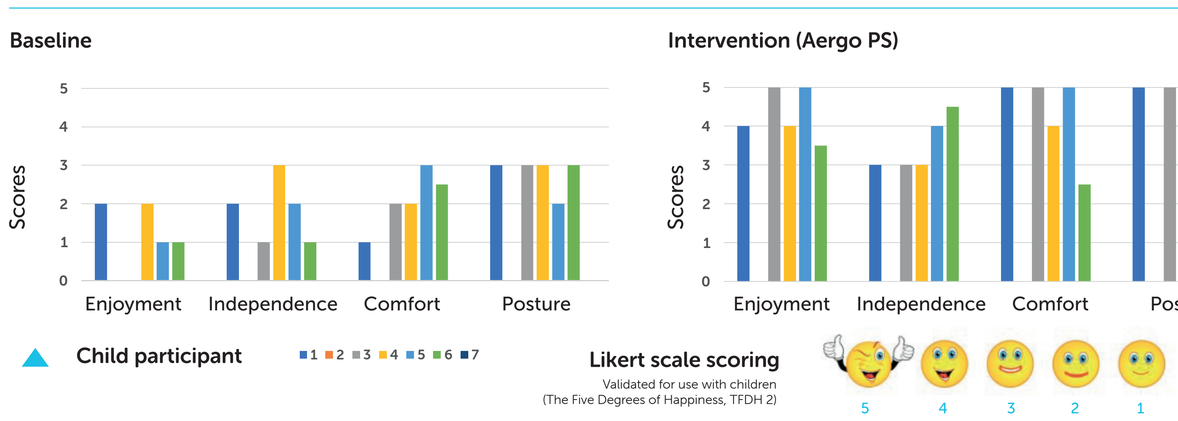
A PMS case study was carried out with seven children with neuromuscular conditions using Aergo PS and their parents within the home-based setting for 8 weeks. Children were asked to use Aergo PS fitted to their wheelchair during their waking hours. Safety was monitored throughout, including adverse events (AE), serious adverse events (SAE). A Likert scale, validated for use with children (the Five Degrees of Happiness, TFDH 2) was administered to children after one week of using Aergo PS. Here, children rated their enjoyment, independence, comfort, and postural support, and were given an additional opportunity for open feedback. Barriers to adherence were assessed with the Problematic Experiences of Therapy Scale (PETS ref) and parent feedback was collected through usability and safety feedback diaries at bi-weekly intervals (ref).

Clinical Details

Inclusion criteria included clinical diagnosis of a child with a neuromuscular disorder, children aged 5-16 yrs, child able to give informed consent, and cognitively able to use Aergo PS. Users were required to be medically stable and have a parent or carer willing and able to assist with use of Aergo PS as required. Exclusion Criteria included uncontrolled epilepsy/seizures, active pressure ulcer/open wound, severe loss of sensation, loss of bowel and bladder control. Here, users were aged between 9 and 16 years old and had been diagnosed with the following paediatric neuromuscular conditions: LMNA (n=1), DMD (n=3), CP (n=2), and undiagnosed neuromuscular condition (n=1).

Results

Four children and six parents reported on their experiences using Aergo PS. Descriptive mean reported values by children for enjoyment (5/5), independence (4/5), comfort (4.25/5), and posture (4.25/5). Comfort was the most frequently reported benefit (n=3) followed by adaptability of posture (n=1). Parents reported improvements in their child's independence (n=4), postural management (n=4), comfort (n=5), and usability (n=3). The greatest benefits of Aergo PS were comfort (n=3), postural management (n=2) and adaptability (n=1). One parent reported no benefit due to their child having too high functional ability. Reported challenges were size of components (n=3) (none =1) (transfers n=1) (sensory feedback n=1). No AEs or SAEs were reported by any users for the duration of use. The PETS demonstrated a minimal barriers to adherence of using Aergo PS in the home based setting.



Qualitative feedback from parents:

"Main benefit using the Aergo seat was being able to adjust it when she was uncomfortable or pain in her legs so having the ability to do this really quickly and easily was a huge benefit."

Parent of child with LGMD

"When sitting he is more mindful of his seating position. He will adjust cells in aergo to assist better seating"

Parent of child with MD

Discussion

Preliminary data from the PMS case study has shown that Aergo PS has improved independence and comfort significantly for children living with NMD. The device is also proven to be safe for use in the home-based environment. Users with complex need for postural control may have limited benefit, and the level of sensory feedback needs to be assessed for potential users. However, the benefits focused on improved postural management, comfort and independence compared to using their standard seating systems.

The PMS result also suggests the benefit of including digital tools to postural management practices. For example, young wheelchair users found the Aergo PS' remote control to have improved their independence, and the responsive features of the air cells have enhanced comfort during prolonged sitting. This opens up future potential for Aergo to introduce more digital features to enhance postural care provision. Further development will explore a digital postural management platform for clinicians to access Aergo PS remotely to prescribe and adjust postural support settings. Clinical studies will be conducted to verify positive long-term health impact of Aergo PS on its users.

Update: Since this study was published, Aergo Health has implemented the digital postural management tools: a User App Control and Clinician Web Portal.

Standards/Guidelines

MHRA Medical Device Guidelines for safety reporting of medical devices.

References

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