# **RESEARCH ARTICLE**



WILEY

Check for updates

# The 'heROIC' trial: Does the use of a robotic rehabilitation trainer change quality of life, range of movement and function in children with cerebral palsy?

Clare Grodon | Paul Bassett | Harriet Shannon 3

# Correspondence

Clare Grodon, Whittington Health NHS Trust, London, UK.

Email: clare.grodon@nhs.net

# **Funding information**

This study was sponsored by Whittington Health NHS Trust. No funding was received for this study.

# **Abstract**

Background: Children with severe cerebral palsy (CP) (GMFCS IV/V) can find it difficult to access equipment that allows them to exercise effectively, potentially impacting their quality of life. Physiotherapists working within special schools are well placed to facilitate increased physical activity as part of the school day. This study explored whether the Innowalk Pro, a robotic rehabilitation trainer, could influence quality of life (measured by the CPCHILD questionnaire), in children with CP, alongside, joint range of movement, spasticity and functional goals of the lower limbs, measured by goniometry, modified Tardieu scale and goal attainment scoring, GAS, respectively.

**Methods:** A prospective single-arm, pre-post trial was undertaken. The Innowalk Pro was used four times a week for 30 min alongside usual physiotherapy care in a school setting over a 6-week period. Outcomes were evaluated immediately pre/post intervention and at 6 weeks and 3 months post intervention. Analysis also explored differences between primary and secondary age participants.

Results: Twenty-seven participants aged 5–18 years with a diagnosis of CP GMFCS IV/V (10 female, 17 male, mean age 12 years) were included from a convenience sample in a special school. Quality of life improved in 36% of participants, the majority of these being secondary aged. Knee extension reduced significantly 3 months post intervention. There were no meaningful changes in spasticity. GAS goals improved in 88% of participants after using the Innowalk Pro. GAS goals tended to decline after a break from using the equipment, with 21% declining by two or more units at 3 months post intervention.

Conclusion: A 6-week course of the Innowalk Pro can improve quality of life and functional goals for children with CP aged 5–18 years. After a break of 6–12 weeks, functional goals tend to return to baseline. Further research is needed to explore different prescriptions of the Innowalk Pro, to see if increasing the time used/increasing the frequency or number of weeks it is used for can provide longer lasting benefits.

# KEYWORDS

cerebral palsy, functional limitations, paediatric, physical activity, quality of life, school

This is an open access article under the terms of the Creative Commons Attribution License, which permits use, distribution and reproduction in any medium, provided the original work is properly cited.

© 2023 The Authors. Child: Care, Health and Development published by John Wiley & Sons Ltd.

<sup>&</sup>lt;sup>1</sup>Whittington Health NHS Trust, London, UK

<sup>&</sup>lt;sup>2</sup>Statsconsultancy Ltd, Amersham, UK

<sup>&</sup>lt;sup>3</sup>UCL Great Ormond Street Institute of Child Health, London, UK

elibrary.wiley.com/doi/10.1111/cch.13101 by University College London UCL Library Ser

# 1 | INTRODUCTION

An active lifestyle with spontaneous and organised physical leisure activities is recommended for children with cerebral palsy (CP) (Carlon et al., 2013) and is likely to improve their health outcomes, physical function and human metabolism, ultimately improving quality of life (QoL) (Lauruschkus et al., 2017). Equipment accessibility can be challenging for children with CP GMFCS level IV/V who are unable to stand, transfer or walk unaided (Maltais et al., 2014), often leading to reduced activity levels and subsequent negative health outcomes (Verschuren et al., 2016). There are strong associations between poorer parent-reported QoL and higher severity of motor impairments in the domains of physical wellbeing for children with CP (Arnaud et al., 2008).

Children with significant physical impairments related to CP often have additional issues with pain and physical wellbeing (Houlihan et al., 2004). Physiotherapy management of children with CP focuses on improving/maintaining gross motor function, activities of daily living and preventing secondary complications such as contractures and deformities (Maher et al., 2016; Patel et al., 2020). For children with CP, an increase in repetition, motivation and intensity of therapy, defined as more than three times a week, could increase rehabilitation potential (Arpino et al., 2010; Meyer-Heim & van Hedel, 2013).

The Innowalk Pro (IP) is a robotic rehabilitation trainer that provides assisted, guided and repetitive movements, close to normal gait, allowing for mobilisation with high intensity, to children with physical disabilities, in a weight-bearing position (AS, M, 2018). The IP comprises of a motor-driven gait orthosis for legs, a weight support system, head rest, shoulder straps and side-support with a belt. It has additional accessories, such as a tray, neck support, shoulder straps and handles to encourage arm movement with supports to reduce overstretching, which can be added/removed as needed. Robot-assisted therapies, such as the IP, have evolved over the last 15 years and are improving equity of access to therapy, since they include adjustable settings for differences in children's range of movement (ROM), tone and functional ability. Emerging evidence suggests improvements in QoL reported by parents and children from using robot assisted devices (Balcı, 2016). Th IP is easily transportable between different spaces, such as classrooms within the school setting, allowing it to be more versatile than other such robotic rehabilitation trainers, increasing accessibility for it to be shared between students throughout the school day. The fact that it is tethered within the setting means that once the child is in the device and safe, carers can support other students within the classroom that they would not be able to do if the equipment was mobile.

A systematic review based on nine studies reported that the IP can improve passive ROM, muscle tone and general well-being associated with physical exercise (Schmidt-Lucke et al., 2019). All studies were case series that lack wider generalisability and recommend further, more robust research into the IP. The current study's aim was to explore effects of the IP on QoL, as reported by parents, with secondary outcomes assessing ROM and spasticity of the lower limbs, and

# Key messages

- Adding the Innowalk Pro to routine care for children with cerebral palsy GMFCS IV-V four times a week for 30 min over 6 weeks has the potential to improve their quality of life and functional goals.
- Having a break of 6-12 weeks from using the Innowalk Pro sees a drop in functional goals.
- Larger more meaningful changes in QOL results were found in secondary aged students (11–18), and therefore, more research into the effects of the Innowalk Pro for adolescents and adults with cerebral palsy is advised.
- Given the known benefits of exercise, further suggestions to research how the Innowalk Pro could impact earlier in life on complications secondary to disability such as pain, weight gain and gastro-intestinal function is also advised.

students' functional goals. Further analysis reviewed the differences between primary and secondary age students.

# 1.1 | Patients and methods

A single-centre, single-arm prospective pre-post study was conducted at a special school (with primary and secondary provision) in London, UK. Ethical approval was granted by the London-Camden and Kings Cross Research Ethics Committee, REC reference: 19/LO/1721. The IP was used in adjunction with usual physiotherapy care over a 6-week period. Usual physiotherapy care in school consists of students accessing static standing frames/walkers up to three times a week, PE once a week, and a physiotherapy programme including a range of functional activities, ability dependent. Outcomes were measured prior to and immediately following the 6 weeks of intervention and at 6 weeks and 3 months post intervention.

A convenience sample of students was recruited from a special school of 90 students with complex physical and/or learning needs. Children (aged 5–18 years) were eligible for recruitment if they attended the school and had a diagnosis of CP level IV/V. Exclusion criteria are outlined in Figure 1. Written, informed consent was obtained from all parent/guardians of participants who met the inclusion criteria, along with verbal assent/consultee declaration, depending on the age and capacity of the participant.

The IP is listed as Grade 1 classification on the Medical Device Directive registered with notified body of conformity through assessment with NEMKO AS Identification No. 0470. A risk assessment suggested that the IP was no higher risk than standard physiotherapy. NHS employed physiotherapists work on-site full-time and were available during each session to resolve any concerns. For the IP intervention, a team of trained staff supported the participants in and out of

FIGURE 1 Summary of exclusion criteria for the heROIC study.

# **Exclusion Criteria**

Any child/young person who:

- had undergone orthopaedic surgery to their lower limbs within one year prior of the trial
- had botulinum toxin injections in their lower limbs within 3 months of the trial
- was younger than 5 years or older than 18 years
- had contractures that did not allow access to the IP
- had any orthopaedic/medical advice not to stand
- had any fixed flexion deformity of the hip >40 degrees or knee >50 degrees
- Has ankle contractures meaning they are unable to stand with an AFO (ankle-foot orthoses)
- had severe scoliosis, windswept deformity, contractures, or other deformities that would interfere with positioning in the IP
- had epilepsy not controlled by medication
- had a lack of independent head control which is not possible to support in the IP
- had skin lesion/pressure areas in the contract areas of the padding/contact with the device
- had osteoporosis with previous or suspected spontaneous fractures of the lower extremities
- had alack of compliance of acceptance of dynamic standing
- had intolerance, pain or not able to cooperate or be positioned adequately within the IP.

the device and recognised any signs of discomfort or contraindications to its use. The team consisted of three physiotherapists, two physiotherapy assistants, two teachers and 15 teaching assistants across the site. All staff were known to the participants, and had indepth understanding of their individual needs. Participants were accurately measured for the IP by a physiotherapist before the trial began. Participants participated in 30 min of IP per day, four times a week for 6 weeks. If 30 min using the IP was not reached, a reason for this was recorded. If a student felt any discomfort and/or pain, the session was stopped immediately and reviewed by a physiotherapist who decided whether they continued.

#### 1.2 Outcome measures

The study used a range of outcome measures to reflect the complexity of measuring change in this population. CPCHILD is a paper-based survey that measures QoL. It has demonstrated good reliability and

.wiley.com/doi/10.1111/cch.13101 by University College London UCL Library Services

, Wiley Online Library on [03/07/2023]. See the

validity in this population (Carlon et al., 2010; Narayanan et al., 2006, 2011). It was completed independently by participants' parents at each time point.

ROM/Spasticity measurements were taken in accordance with the CPIP-UK standardised assessment protocol (CPIP Cerebral Palsy Integrated Pathway, 2017). Measurements were completed by two trained members of the physiotherapy team at school. These were bilateral measurement of hip extension of each participant using a goniometer in a prone position and bilateral measurement of popliteal angle, knee extension and dorsiflexion with knee flexed and knee extended of each participant using a goniometer in supine. The Modified Tardieu Scale (MTS) measured spasticity in the hamstrings, gastrocnemius and soleus bilaterally in a supine position and rectus femoris bilaterally in prone.

Individualised goals were set in collaboration with the participant, parents, physiotherapist and teacher using the Goal Attainment Scale (GAS).

Measures of QoL, ROM, spasticity and function were taken at four timepoints. These were before treatment (usually on the day of the IP, except for the GAS and CPCHILD which were completed up to 5 days prior to the first IP session), immediately post the 6-week intervention and at 6 weeks (±3 days) and 3 months (±3 days) after the final treatment session. The study was single blinded, so outcomes were measured by the paediatric physiotherapy team blinded as to whether the participant was starting or had finished the intervention stage. The first author was principal investigator (PI), overseeing the safe running of the trial, and ensuring the timely completion of the questionnaires and collating all the data throughout the trial.

If a participant was not in school for a prolonged period (more than 5 days) during the intervention or they missed the follow-up window at 6 weeks (±3 days) and 3 months (±3 days) data from that point forward was removed. Retention strategies included direct reminder messages to parents about assessments and communication about absences. Home visits were carried out to complete assessments when necessary.

#### 1.3 **Analysis**

Analysis was undertaken in Stata (version 15.1). Data were scrutinised for normality, and presented as mean (SD). To allow for the repeated measurements from the same subjects over time, analysis was performed using two-way analysis of variance (ANOVA). The two factors in the analysis were participant number and timepoint. Participant number was included to allow for the repeat measurements from the same subjects, with the differences between timepoints of primary interest.

Differences in outcomes between groups of primary versus secondary were analysed using the unpaired t test. Level of significance was set at P < 0.05. Data for the CPCHILD is presented in relation to the minimal clinical importance difference set at six units (Narayanan, 2022, see Appendix A.2).

#### 2 | **RESULTS**

From October 2019 to June 2020, 34 students were identified as eligible for recruitment. Two families declined consent, and one student was COVID-19 shielding. A further four students were excluded as they required surgery before the intervention. Twenty-seven participants were successfully recruited. Of these, two did not complete the first phase of the intervention due to absence from school (social reasons and illness). One child was unable to complete the two follow-up assessments due to illness. Baseline characteristics are summarised in Table 1.

#### **QoL** measured by the CPCHILD 2.1

Immediately post intervention, there was a statistically significant improvement in the CPCHILD score of 3.2 units (Table 2 and Figure A2). This improved further 6 weeks post intervention, and the score was maintained above pre-intervention levels after 3 months. Of the 25 participants in whom CPCHILD was recorded, nine (36%) increased scores between timepoints 1 and 2 by at least six units. Eight of these participants were secondary age and one primary age.

Further analysis focused on the subcomponents of the CPCHILD. Components 2 (positioning transferring and mobility) and 3 (comfort and emotions) showed statistically significant improvements immediately post intervention. The largest clinically important change was for component 3, with a mean increase of 9.4 units between timepoints, and 5.5 units for component 2 (Table 3). Twelve participants (48%) had an improvement of six units or more in component 2, and 10 participants (41.6%) improved by six units or more in component 3, with an equal spread between primary and secondary age participants. Two participants decreased scores by at least six units, both of whom were primary aged children. There were no significant changes in any other components between timepoints.

#### 2.2 Changes in joint ROM and spasticity

Although some statistically significant changes were seen in ROM and spasticity at different time points, these were not clinically

TABLE 1 Demographic summary of patient group.

Variable	n	Category	Summary
Gender	27	Female	10 (37%)
		Male	17 (63%)
Age	27	-	12.7 ± 4.0
School phase	27	Primary	11 (41%)
		Secondary	16 (59%)
GMFCS	27	IV	15 (56%)
		V	12 (44%)

Note: Baseline characteristics for participant. Summary statistics are number (percentage) or mean ± standard deviation.

**TABLE 2** Changes in CPCHILD, GAS, ROM, and spasticity pre and post Innowalk Intervention.

	Timepoint 1 Pre intervention (n = 27)	Timepoint 2 Immediately post intervention $(n = 25)$	Timepoint 3 Six weeks post intervention (n = 24)	Timepoint 4 Three months post intervention $(n = 24)$	P value (overall)
CPCHILD	60.4 (13.6)	63.5 (12.3)*	66.0 (12.5)*	64.8 (11.7)*	0.004
GAS score	-2.0 (0.0)	1.0 (1.2)**	0.2 (1.2)**	-0.3 (1.3)**	<0.001
Left hip extension (median)	15	15	15.5	11.5	0.02
Right hip extension (median)	13	14	14	11	0.05
Left knee extension (median)	-5	-5	-10	-12	0.02
Right knee extension (median)	-9	-10	-9	-14.5	0.17
Left ankle extended (median)	0	-2	-5	3	0.02
Right ankle extended (median)	-5	0	-5.5	1.75	0.03
Left ankle flexed (median)	16	13	10	15	0.004
Right ankle flexed (median)	15	12	9.5	13	0.08
Left gastrocnemius spasticity (median)	-12	-10	-15.5	-8	0.02
Right gastrocnemius spasticity (median)	-13	-12	-10	<b>−7.5</b>	0.27
Left soleus spasticity (median)	0	0	-3	0.75	0.25
Right soleus spasticity (median)	0	0	4	4	0.19

*Note*: Measurements were taken pre and post the 6-week intervention (timepoints 1 and 2), 6 weeks post intervention (timepoint 3) and 3 months post intervention (timepoint 4). ROM was measured in degrees. Spasticity of rectus femoris, hamstrings, were also measured and found to be non-significant. Full assessment details are available from the author.

P < 0.05.



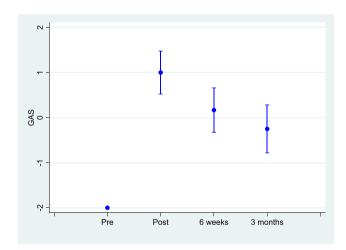
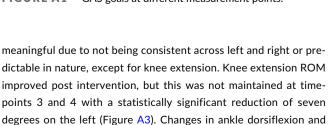


FIGURE A1 GAS goals at different measurement points.



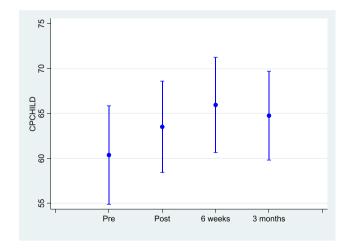


FIGURE A2 CPCHILD score at different measurement points.

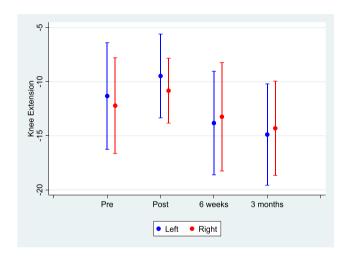
left hip extension ROM were not maintained post intervention (Table 2).

Spasticity of the left gastrocnemius showed a statistically significant increase between timepoints, with a mean increase of 7.6 degrees at timepoint 3 when compared with the post-intervention measurement.

# 2.3 | Functional outcomes, measured using the GAS

There was a statistically significant improvement of 3.0 units in GAS scores immediately post intervention; 88% (n=22) of the participants met or exceeded their functional goals set pre intervention with a change of two or more units (Table 2 and Figure A1). GAS scores slightly decreased between timepoints, from a mean of 1.0 at post-intervention to a mean of 0.2 at timepoint 3, and then significantly declined between timepoints 2 and 4 by 1.7 units (Table 2). A change of two units is seen to be clinically important (King et al., 2000). Some participants' functional goals declined by two units or more after ceasing to use the IP, with two participants (8.3%) deteriorating at timepoint 3, and a further five participants (21%) deteriorating at timepoint 4.

GAS goals were all set individually. One example was for a participant to sit straighter in his chair. Pre-intervention he leaned to the left 100% of the time, and by the end of the intervention, he maintained



**FIGURE A3** Knee extension (degrees) at different measurement points.

an upright posture. This was not maintained, dropping to maintaining an upright posture approximately 75% of the time at timepoint 3 and to 25% of the time after timepoint 4 (Appendix A.1 details a full list of GAS goals).

# 2.4 | Primary versus secondary

Further analysis compared changes in QoL between participants of primary and secondary school age. The results indicated a statistically significant difference for CPCHILD score in secondary age participants compared with primary. There was a mean increase in CPCHILD scores of 6.5 units for secondary participants while there was a decrease of 0.8 for primary children. For the full set of analyses comparing all data between primary and secondary age children, please contact the author.

# 3 | DISCUSSION

This study demonstrated a statistically significant improvement in QoL using the IP. The change was clinically important for up to 12 participants in different components of the CPCHILD and at different timepoints. The biggest changes were in components 2 and 3; both could have been influenced by increased activity levels. A diagnosis of CP GMFCS level IV/V affects mobility and will therefore generally result in lower scores for health-related QoL measures that include items of self-care and mobility, with secondary consequences such as pain and gastro-intestinal problems (Jarl et al., 2019). A rapid review in 2022 informed the Department of Health (DoH) guidelines for physical activity for general health benefits in disabled children and young people. It concluded that evidence shows a likely relationship between engaging in physical activity and positive health outcomes for this population (Smith et al., 2022). This study extends the body of evidence showing that adding the IP four times a week for 30 min

**TABLE 3** Changes in CPCHILD subcomponents.

Variable	Timepoint 1 (n = 27)	Timepoint 2 $(n = 25)$	Timepoint 3 (n = 24)	Timepoint 4 (n = 24)	P value (overall)
Component 1 personal care/ADL	40.1 ± 13.1	42.8 ± 13.4	43.9 ± 12.6	43.1 ± 15.0	0.32
Component 2, positioning, transferring and mobility	38.5 ± 13.2*	44.0 ± 13.2	44.1 ± 12.8	44.4 ± 14.5	0.006
Component 3, comfort and emotions	73.7 ± 21.6*	83.1 ± 12.7	82.7 ± 18.7	81.3 ± 18.9	0.006
Component 4, communication and social interaction	57.1 ± 20.1	57.6 ± 19.9	60.7 ± 19.8	59.8 ± 17.8	0.77
Component 5, health	65.1 ± 16.7	69.3 ± 19.0	73.6 ± 14.8	69.7 ± 15.6	0.04
Component 6, overall QoL	62.3 ± 25.5	64.0 ± 21.6	72.5 ± 24.2	70.0 ± 22.1	0.06
Component 7, importance of items to QOL	83.9 ± 9.2	84.1 ± 9.7	84.4 ± 10.7	84.5 ± 11.3	0.97

P < 0.05.

<sup>\*</sup>P < 0.01.

<sup>\*\*</sup>P < 0.001.

WILEY 17

over 6 weeks to their normal physical routine potentially improves QoL for children with CP.

There were no clinically meaningful changes in ROM or spasticity of the lower limbs immediately post intervention. Previous studies using the IP have demonstrated that regular use reduces spasticity in the lower limbs immediately after use (Schmidt-Lucke et al., 2019). Research shows good inter and intra-reliability of goniometry within the same session (McWhirk & Glanzman, 2006); however, the precision of measurement decreases when measurements are undertaken by different assessors or at different sessions and group data, especially when analysed using correlational tests, may mask the absolute value of intraindividual variability of ROM measurements (Darrah et al., 2014). Reliability of ROM and spasticity measures may also vary due to factors such as pain and emotional state of the child (Graham et al., 2019). Of note there were six participants who improved their bilateral knee ranges, and four participants who improved their bilateral ankle ROM with knee flexed by five or more degrees between timepoints 1 and 2. This is in line with another study which demonstrated that regular usage of the IP in a paediatric population, PROM of joints in the lower extremities improves (Schmidt-Lucke et al., 2019). Bilateral knee ROM was not maintained 3 months postintervention, reducing up to seven degrees, suggesting that a 3-month break from using the IP could be detrimental to knee ROM.

Previous studies using the IP have demonstrated that using it regularly reduces spasticity in the lower limbs immediately after use (Schmidt-Lucke et al., 2019). This study did not find any meaningful clinical change in muscle tone in the lower limbs immediately after use and although there was some increase in spasticity in the left gastrocnemius muscle after a 6-week break from using the IP, there were no other significant changes in the other muscle groups. This could be due to multiple factors, as tone is highly variable in children at GMFCS levels IV and V (Graham et al., 2019).

Our study demonstrated that 88% (n = 22) of the participants met or exceeded their functional goals set pre-intervention using the GAS with a change of two or more units, which is statistically and clinically significant. The sensitivity to change of GAS can be assumed to be better than that of common standardized functional measures at the level of abilities and participation; however, it does have floor and ceiling effects, which could introduce a bias for the calculation of group effects (Steenbeek et al., 2007). One of the challenges of undertaking research with patients with CP is that the nature and severity of physical aspects of their condition are highly individual. Individual goals were therefore set by the physiotherapist with the caregivers and/or student prior to using the IP and had to be related to using the IP.

Some participants' functional goals declined by two units or more after ceasing to use the IP, with two participants deteriorating at timepoint 3 and five participants deteriorating at timepoint 4. This suggests the benefits of the IP are only maintained for a short period of time, and a regular course of the intervention (with no more than 6 weeks between courses) would be required to ensure deterioration does not occur over time. This 'block' type therapy allows for more students to access the equipment over the academic year. Students

should be selected with careful consideration to meet specific goals that continue to be monitored to ensure fair access, this can help to address equity to using the IP.

It is recognised that children with CPs' physical function tends to decline moving into adolescence and young adulthood, and is even more apparent in those at GMFCS levels IV/V where, according to the GMFM-66 score, gross motor function peaks at around the of age 7 to 8 years for GMFCS level IV/V (Hanna et al., 2009). Therapists therefore tend to aim for maintenance of functional skills as children with CP get older, especially at secondary age. Our study suggests that the largest changes in QoL were recorded in secondary school aged participants, who are generally more sedentary than primary aged participants (Activity Alliance, 2020). Suggestions from other studies highlight the importance of increasing opportunities for physical activities for young people with higher levels of motor impairment to potentially delay a decline in functional ability and other long-term negative health consequences related to low physical activity (Carlon et al., 2013: Reedman et al., 2020). Our study shows that the IP provides this opportunity to increase activity levels with positive results. Accessing the IP within a school setting allows the increase to these activity levels on a regular and consistent basis when therapists are not always available to achieve this.

It is important to acknowledge the following limitations. The population was a convenience sample that could have caused selection bias; however, all participants who met the inclusion criteria were given the opportunity to take part in the trial. Participants recruited were a representative range of ages and ethnicities, although generalisations should be made with caution. The study was single-blinded whereby outcomes were measured by assessors unaware of the timing of the intervention; however, this could have reduced the reliability of ROM and spasticity. These limitations highlight some of the challenges of undertaking research in this highly complex group, whose physical function can vary between days and in response to multiple factors such as stress and pain (Graham et al., 2019).

This study was conducted in a school setting, which enabled participants to be active while in the classroom with minimal disruption. Further studies within this setting could assess the use of the IP prescriptively for distinct time periods to see if they have specific effects, for example on bowel function or pain levels. As the results were also positive for secondary-school aged students, extending the study into adulthood for people with CP could be beneficial. Current feedback from schools in the United Kingdom demonstrate that they have fundraised locally for the IP's that they have on site—it is hoped that with more evidence to promote the benefits of the device that health commissioners and/or local authorities would be able to support with the funding to improve the access for these young people.

#### 3.1 Potential conflict of interest

Made for Movement provided the IP on loan for free for the purposes of the trial.

# 4 | CONCLUSION

The results of this study suggest that a 6-week course of the IP (four times a week for 30 min) can improve QoL and functional goals for children with CP aged 5–18 years, albeit with no clinically meaningful change in ROM or spasticity. It also demonstrates that after a break of 6–12 weeks of using the IP, functional goals tend to return to baseline level and knee extension range could reduce. This is the first study in the United Kingdom to demonstrate these findings within a school setting, suggesting huge potential for improving QoL and functional goals within the CP population by using the IP in addition to their normal routines. With the IP in place within school settings, improving outcomes for several students throughout the day, it allows more time for therapists to be supporting with the other increased needs of this complex population.

### **ACKNOWLEDGEMENTS**

We thanked Alesha Southby who supported the author with the initial protocol for the study and supported her from afar to continue with the trial.

# **CONFLICT OF INTEREST STATEMENT**

Made for Movement provided the Innowalk Pro on loan for free for the purposes of the trial. There are no other known potential conflicts of interest.

# DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

# ORCID

Clare Grodon https://orcid.org/0000-0002-4682-9418

# REFERENCES

- Activity Alliance. (2020). My active future: Including every child. https://www.activityalliance.org.uk/how-we-help/research/5658-my-active-future-including-every-child-march-2020
- AS, M. (2018). Articles I Made for movement. [online] Madeformovement. com. http://www.madeformovement.com/articles
- Arnaud, C., White-Koning, M., Michelsen, S., Parkes, J., Parkinson, K., Thyen, U., Beckung, E., Dickinson, H. O., Fauconnier, J., Marcelli, M., McManus, V., & Colver, A. (2008). Parent-reported quality of life of children with cerebral palsy in Europe. *Pediatrics*, 121(1), 54–64. https://doi.org/10.1542/peds.2007-0854
- Arpino, C., Vescio, M., De Luca, A., & Curatolo, P. (2010). Efficacy of intensive versus nonintensive physiotherapy in children with cerebral palsy: A meta-analysis. *International Journal of Rehabilitation Research*, 33(2), 165–171. https://doi.org/10.1097/mrr.0b013e328332f617
- Balcı, N. Ç. (2016). Current rehabilitation methods for cerebral palsy. In M. K. Gunel (Ed.), Cerebral palsy—Current steps. IntechOpen. https://doi.org/10.5772/64373
- Carlon, S., Shields, N., Yong, K., Gilmore, R., Sakzewski, L., & Boyd, R. (2010). A systematic review of the psychometric properties of quality of life measures for school aged children with cerebral palsy. BMC Pediatrics, 10(1), 81. https://doi.org/10.1186/1471-2431-10-81

- Carlon, S. L., Taylor, N. F., Dodd, K. J., & Shields, N. (2013). Differences in habitual physical activity levels of young people with cerebral palsy and their typically developing peers: A systematic review. *Disability* and Rehabilitation, 35(8), 647–655. https://doi.org/10.3109/ 09638288 2012 715721
- Cerebral palsy integrated pathway Scotland (CPIPS). (2017). [EBook]. Scotland.
- Darrah, J., Wiart, L., Gorter, J. W., & Law, M. (2014). Stability of serial range-of-motion measurements of the lower extremities in children with cerebral palsy: Can we do better? *Physical Therapy*, 94(7), 987– 995. https://doi.org/10.2522/ptj.20130378
- Graham, D., Paget, S. P., & Wimalasundera, N. (2019). Current thinking in the health care management of children with cerebral palsy. *Medical Journal of Australia*, 210(3), 129–135. https://doi.org/10.5694/mja2. 12106
- Hanna, S. E., Rosenbaum, P. L., Bartlett, D. J., Palisano, R. J., Walter, S. D., Avery, L., & Russell, D. J. (2009). Stability and decline in gross motor function among children and youth with cerebral palsy aged 2 to 21 years. Developmental Medicine and Child Neurology, 51(4), 295–302. https://doi.org/10.1111/j.1469-8749.2008.03196.x
- Houlihan, C. M., O'Donnell, M., Conaway, M., & Stevenson, R. D. (2004). Bodily pain and health-related quality of life in children with cerebral palsy. *Developmental Medicine and Child Neurology*, 46(5), 305–310. https://doi.org/10.1017/s0012162204000507 PMID: 15132260
- Jarl, J., Alriksson-Schmidt, A., & Rodby-Bousquet, E. (2019). Health-related quality of life in adults with cerebral palsy living in Sweden and relation to demographic and disability-specific factors. *Disability and Health Journal*, 12(3), 460–466. https://doi.org/10.1016/j.dhjo.2019.
- King, G. A., McDougall, J., Palisano, R. J., Gritzan, J., & Tucker, M. A. (2000). Goal attainment scaling: Its use in evaluating pediatric therapy programs. *Physical & Occupational Therapy in Pediatrics*, 19(2), 31–52. https://doi.org/10.1300/J006v19n02\_03
- Lauruschkus, K., Hallstrom, I., Westbom, L., Tornberg, A., & Nordmark, E. (2017). Participation in physical activities for children with cerebral palsy: Feasibility and effectiveness of physical activity on prescription. Archives of Physiotherapy, 7(1), 13. https://doi.org/10.1186/s40945-017-0041-9
- Maher, C. A., Toohey, M., & Ferguson, M. (2016). Physical activity predicts quality of life and happiness in children and adolescents with cerebral palsy. *Disability and Rehabilitation*, 38(9), 865–869. https://doi.org/10. 3109/09638288.2015.1066450
- Maltais, D. B., Wiart, L., Fowler, E., Verschuren, O., & Damiano, D. L. (2014). Health-related physical fitness for children with cerebral palsy. *Journal of Child Neurology*, 29(8), 1091–1100. https://doi.org/10. 1177/0883073814533152
- McWhirk, L. B., & Glanzman, A. M. (2006). Within-session inter-rater realiability of goniometric measures in patients with spastic cerebral palsy. *Pediatric Physical Therapy*, 18(4), 262–265. https://doi.org/10.1097/01.pep.0000234960.88761.97
- Meyer-Heim, A., & van Hedel, H. J. A. (2013). Robot assisted and computer-enhanced therapies for children with cerebral palsy: Current state and clinical implantation. *Semin Peiatr Neurol* 20, 139–145. https://doi.org/10.1016/j.spen.2013.06.006
- Narayanan, U. (2022). Email to Clare Dorset-Purkis, 25 January 2022. https://lab.research.sickkids.ca/pscoreprogram/
- Narayanan, U., Fehlings, D., Weir, S., Knights, S., Kiran, S., & Campbell, K. (2006). Initial development and validation of the Caregiver Priorities and Child Health Index of Life with Disabilities (CPCHILD). Developmental Medicine and Child Neurology, 48(10), 804–812. https://doi.org/10.1017/S0012162206001745
- Narayanan, U. G., Sponseller, P., Newton, P. O., & Marks, M. C. (2011). The CPCHILD questionnaire is sensitive to change following scoliosis surgery in children with cerebral palsy: PAPER# 62. In Spine journal meeting abstracts (pp. 86–87). LWW.

- Patel, D. R., Neelakantan, M., Pandher, K., & Merrick, J. (2020). Cerebral palsy in children: A clinical overview. Translational Pediatrics, 9(Suppl 1), S125-S135. https://doi.org/10.21037/tp.2020.01.01
- Reedman, S. E., Johnson, E., Sakzewski, L., Gomersall, S., Trost, S. G., & Boyd, R. N. (2020). Sedentary behavior in children with cerebral palsy between 1.5 and 12 years: A longitudinal study. Pediatric Physical Ther-32(4), 367-373. https://doi.org/10.1097/PEP. 000000000000740
- Schmidt-Lucke, C., Käferle, J., Rydh Berner, B., Ahlborg, L., Hansen, H., Skjellvik Tollefsen, U., Thon, T., Damkjær Moen, R., Pekanovic, A., Tornberg, Å. B., & Lauruschkus, K. (2019). Effect of assisted walkingmovement in patients with genetic and acquired neuromuscular disorders with the motorised Innowalk device: An international case study meta-analysis. PeerJ, 7, e7098. https://doi.org/10.7717/peerj.7098
- Smith, B., Rigby, B., Netherway, J., Wang, W., Dodd-Reynolds, C., Oliver, E., Bone, L., & Foster, C. (2022). Physical activity for general health in disabled children and disabled young people: Summary of a rapid evidence review for the UK chief medical officers' update of the physical activity guidelines (Vol. 56, pp. 588-589). London, UK.

- Steenbeek, D., Ketelaar, M., Galama, K., & Gorter, J. W. (2007). Goal attainment scaling in paediatric rehabilitation: A critical review of the literature. Developmental Medicine and Child Neurology, 49(7), 550-556. https://doi.org/10.1111/j.1469-8749.2007.00550.x
- Verschuren, O., Peterson, M., Balemans, A., & Hurvitz, E. (2016). Exercise and physical activity recommendations for people with cerebral palsy. Developmental Medicine and Child Neurology, 58(8), 798-808. https:// doi.org/10.1111/dmcn.13053

How to cite this article: Grodon, C., Bassett, P., & Shannon, H. (2023). The 'heROIC' trial: Does the use of a robotic rehabilitation trainer change quality of life, range of movement and function in children with cerebral palsy? Child: Care, Health and Development, 1-11. https://doi.org/10.1111/cch.13101

# APPENDIX A

# A.1 | GAS Goals scoring

- -2 How they are functioning now
- −1 Less than expected outcome
- **0** Expected outcome, where I want them to be at the end of therapy block
- +1 Better than expected outcome
- $+2\,\mbox{Much}$  better than expected outcome, where you want them to be in 6 month time

GAS Goals

Aim for GAS goal to achieve 0	Timepoint 1 score	Timepoint 2 score	Timepoint 3 score	Timepoint 4 score
To lift head for around 2 min to read a book while bench sitting	-2	1	0	0
To actively participate 30% during a standing transfer	-2	-2	-1	-2
To sit straight in chair 50% of the time	-2	2	1	-1
To take approx. 1.5 min to transfer into chair and support needed to relax legs	-2	2	-2	-2
To transfer from chair to floor in sling with no resistance 60% of time	-2	2	-1	-1
To be able to sit cross legged unsupported for 15 min	-2	2	1	1
To transfer into chair with two people and just verbal prompts to help relax	-2	2	1	1
To scissor legs 50% less in lying	-2	2	-2	-2
To take 4–6 purposeful steps using standing sling	-2	1	1	0
To pull self to stand using ladderback	-2	1	1	1
To only need a break from chair due to pain at 5 pm	-2	2	1	1
To stand in standing frame with gaiters on and hips flexed to 15 degrees	-2	0	0	0
To move right hip for transfers or personal care with only occasional hesitancy	-2	1	1	1
To need minimal adult support and take full weight through legs to stand up from chair to a transfer aid	-2	NC	NC	NC
NC	NC	NC	NC	NC
To stand in standing frame with gaiters on and hips flexed to 15 degrees	-2	1	1	-2
To be able to be supported on trike and tolerate using supportive gloves on handlebars	-2	1	1	0
To sit straight 50% of the time	-2	-1	-1	-2
To only need moderate adult support and take full weight through legs to stand up from chair	-2	1	1	0
To be awake but drowsy when using the Innowalk	-2	2	NC	NC
To take 60% of weight through legs during a step transfer	-2	-2	-2	-2
To stand in frame with knees flexed to 30 degrees	-2	1	0	0
To only drop head occasionally when sitting and have moderate precision with upper limbs due to truncal sway	-2	1	0	0
To get to sleep my midnight but still wake during the night	-2	1	2	2
To take 10 steps independently in walker once initiated by an adult	-2	1	-1	-1
To walk in walker with heels raised 80% of the time	-2	2	1	1
To hold head up for around 2 min for something motivating	-2	1	1	1

**To:** DORSET-PURKIS, Clare (WHITTINGTON HEALTH NHS TRUST) <clare.dorsetpurkis@

nhs.net>

Subject: RE: CPCHILD question

Dear Clare,

I apologize for the delayed response.

On your question about what is the minimal clinically important difference (MCID) for the CPCHILD, that has never been formally established. Any difference of points or less, might be attributable to chance based on our test-retest reliability studies. We believe a difference of 6 points is clinically significant (valued by parents) based on what it would take to change to generate a 6 point difference. A 10 point difference is a big change.

Since the domain scores are also standardized (1 to 100), similar differences of 6 points or over may be considered clinically important change for the individual domain scores. Once again this is based on judgement rather than formal analysis.

I hope this is helpful.

Best wishes,

Unni Narayanan

Unni G. Narayanan, MBBS, MSc, FRCS(C)

Professor, Departments of Surgery & Rehabilitation Sciences Institute

Division of Orthopaedic Surgery

University of Toronto

Senior Associate Scientist

Child Health Evaluative Sciences Program

The Hospital for Sick Children

 $Research\ Program:\ https://lab.research.sickkids.ca/pscoreprogram/$