Effectiveness of gait trainers (support walkers) for children with cerebral palsy

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Introduction

This document contains a brief overview of information regarding the effectiveness of gait trainers or support walkers for children with cerebral palsy (CP) and other complex developmental disabilities that have a similar presentation.

How was the literature review completed?

An electronic search was performed in November 2014 of the following databases: CINAHL, Medline, EBM reviews and Embase. Keywords used in the search included: 'walker', 'walking', 'David Hart walker' and 'children.' The American Academy for Cerebral Palsy and Developmental Medicine (AACPDM) Levels of Evidence[1] (Appendix 1 and 2) were assigned to relevant studies with consensus scores from two raters reported throughout the document (see Table 1). The Assessment of Multiple Systematic Reviews (AMSTAR)[2] (Appendix 3) was used to rate the quality of the systematic review (see Table 2) and the AACPDM scale[1] (Appendix 4 and 5) was used to rate quality of individual included studies achieving levels I-III evidence (see Table 2). The International Classification for Functioning, Disability and Health (ICF) was used to describe study outcomes.[3] Finally the Traffic Light Classification Scale[4] (Appendix 6) was used to classify outcomes as either green (go: strong evidence supports the effectiveness of this intervention), yellow (measure: evidence level/quality is weak) or red (stop: there is strong evidence that this intervention is ineffective or harmful).

What is a gait trainer intervention?

The term **gait trainer** comes from US Medicare codes and is widely used in the literature to describe walking devices that provide trunk and pelvic support. They are also known as posture support walkers, body-weight support walkers or **support walkers**. Examples include the Rifton Pacer™, Ormesa Grillo™, Prime Engineering KidWalk™, Snug Seat Pony™ or Mustang™, Mulholland Walkabout™ and Meywalk™ among others. Gait trainers are not always used to 'train gait' or to develop unsupported walking although this is an option. Gait trainers are commonly used to facilitate independent mobility, exploration and participation for children who are unable to use more basic hand-held walkers.

Studies using gait trainer or support walker interventions sometimes describe this intervention as **overground walking**, in order to distinguish it from partial body-weight support treadmill training where the child walks in place on a treadmill with or without facilitation of stepping from therapists. In this paper, we will be discussing research pertaining to the use of gait trainers in overground walking; gait trainers that can be used in typical home, school or community settings. We will not be discussing interventions that use robotic or powered stepping e.g. Lokomat™, treadmills, parallel bars or large institutional types of gait trainers e.g. LiteGait™.

Some gait trainers are set up with the supports in front of the child and are known as **anterior gait trainers** e.g. Meywalk or Pony. Others have all the supports attached behind and are known as **posterior gait trainers** e.g. KidWalk. Some gait trainers can be set up in either configuration e.g. Rifton Pacer, Mustang or Grillo. Some gait trainers are referred to as **hands-free walkers** and are usually posterior gait trainers that do not typically provide upper limb supports e.g. KidWalk or Walkabout. Gait trainers may be available with a number of the following features:

- Rigid or flexible 'seat' or pelvic support with or without lateral guides
- Anterior, posterior and/or lateral trunk supports
- Systems to limit adduction (scissoring) at the hips and/or ankles

- Arm gutters or tray (anterior gait trainers)
- Head supports (posterior gait trainers)

Gait trainers are also available in two distinct frame types – four swivelling caster systems or two fixed wheel and two swivelling caster systems. Fixed wheels or casters are most efficient for speed of walking in a straight line or over a treadmill whereas at least two swivel casters are needed to allow manoeuvring without lifting and placing the walker. Most gait trainers allow swivel casters to be locked to go straight, or unlocked to swivel freely. Four free swivelling casters allow the most manoeuvrability but may make it difficult to walk forward in a straight line and tend to 'crab creep' or slide laterally to turn rather than rotating. Clinically, the most common set-up for four caster systems is fixed rear wheels or casters and swivelling front casters. Many gait trainers are available with wheel locks, ability to increase resistance on wheels and/or anti-roll back mechanisms.

What else is important to know about setting up a child to use a gait trainer?

Gait trainers or support walkers include a 'seat' or pelvic support, however sitting is not its intended use. As much as possible, weight that is not borne through the feet should be supported by the trunk and pelvis - but not the groin area. As the child's skills and speed increase, the weight taken by the legs should be gradually increased to full weight bearing if possible.

When selecting a gait trainer, therapists should consider the type of transfer required. Posterior gait trainers are behind the child who faces the adult during transfers. With anterior gait trainers, the child faces the device and some children can transfer forward from a wheelchair, whereas pivoting around into a posterior gait trainer may be challenging. Many children in GMFCS IV and V need to be lifted and a mechanical lift may be helpful to assist with transfers.

What do therapists report about gait trainers?

A survey of 513 paediatric physical therapists in the United States[5] suggests that therapists prescribe gait trainers hoping to influence a number of Body Structure and Function outcomes (e.g. hip development, cardio-respiratory function and bone mineral density). However, these outcomes should be measured, as there is currently very limited research evidence to support them. Therapists also often prescribe gait trainers to improve gait, mobility, participation at school and interaction with peers. More research on these participation benefits would be beneficial. Most therapists report trialling a gait trainer for at least a month prior to prescription and suggest that nine sessions with the therapist will be required to prepare the child to use a gait trainer in school.

Which children with cerebral palsy use gait trainer interventions?

Children at GMFCS level III typically walk with hand held walkers but may benefit from using gait trainers in early childhood to establish upright posture and walking. Adolescents at GMFCS level III may also use gait trainers to help maintain walking abilities as these may decline through the teenage years.[6] Children at GMFCS levels IV and V primarily use wheeled mobility but may walk with gait trainers. Children at GMFCS level V will typically require gait trainers that provide full upper body support, while children at GMFCS level IV should be encouraged to maximize their own body-weight support if possible.

Can gait trainer interventions be recommended for children with cerebral palsy?

One high quality systematic review[7] including 16 individual studies[8–23] involving 181 children with CP was used as the basis for this evidence summary. Although a high quality level II group study[21] was included, statistically significant results were found only in moderate quality level III studies[10,19] and descriptive studies. As a result, evidence supporting gait trainer interventions merits an overall traffic lighting code of Yellow or 'measure' – due to insufficient high quality evidence. Therapists should use

sensitive, reliable outcome measures to evaluate outcomes for individual children. No negative outcomes were identified in either the review or the individual studies, although authors of individual studies did not state specifically that they looked for negative outcomes.

The following outcomes have been measured in gait trainer interventions:

Body Structure and Function outcomes

- Statistically significant improvement in bowel function (measured using a diary) was found following use of a gait trainer when compared with static standing.[10] (Level III evidence)
- There was a trend towards increased bone mineral density in children who spent more time in either a stander or gait trainer in the same level III evidence study.[10]
- Children with profound intellectual disabilities demonstrated increased motivation and emotional function when stimulating feedback, such as music or vibration, was added to their gait trainer to encourage stepping.[12–17] (Level IV evidence)

Activity outcomes

- Children with profound intellectual disabilities demonstrated large (2-3 times) increases in the number of steps taken during intervention phases when motivating feedback was added to their gait trainer. The number of steps dropped back towards baseline during withdrawal phases.[12–17] (Level IV evidence)
- A trend towards increased walking speed as measured by the 10 meter walk test[24] was found in the overground (gait trainer) walking group when compared to the children walking on a treadmill with partial body-weight support.[21] (Level II evidence)
- Increased walking speed and distance measured using a tape measure and stop watch was found in level III[10] and IV[22] group studies as well as level V case studies.[9,11]
- Use of a specific hands-free walker with lower limb orthotics improved directional control while walking[22,23] (Level IV evidence)
- Improved transfers and self-care abilities were measured using the Physical Abilities and Mobility Scale in a single case study.[11] (Level V evidence)
- Statistically significant improvement in Pediatric Evaluation of Disability Inventory (PEDI)[25] mobility subscale scores were found in one level III group study[10] following 6 months of hands-free walker use. While scores improved when using the walker, as compared to not using the walker, they did not continue to progress over time in a level IV three-year longitudinal study.[22,23]
- Increased scores on the Gross Motor Function Measure (GMFM)[26] stand and walk domains were observed in a level V case study[11] and a significant increase in the walk domain was observed following 12 months use in a level IV group study.[22]
- Increased PEDI [25] self-care subscale scores were measured following 24 months use of a hands-free gait trainer.[23] (Level IV evidence)

Participation outcomes

- Increased PEDI[25] social function subscale scores were found following 24 months use of a hands-free gait trainer.[23] (Level IV evidence)
- Parents reported increased independence, communication and participation in children using a hands-free gait trainer over a three-year period.[18] (Qualitative evidence)

Summary

Although evidence supporting gait trainer interventions is primarily descriptive rather than experimental, outcomes appear positive for children with CP and no evidence of harm has been found. This intervention merits a traffic lighting code of Yellow or 'measure' – because of insufficient high quality evidence. It is recommended that clinicians measure meaningful client and family outcomes when using gait trainer interventions.

Insufficient

The author would like to acknowledge Lynore McLean BSc PT for providing an independent AMSTAR rating for the systematic review, Janice Evans BSc PT for her feedback on this manuscript and Ginny Paleg DSc PT for providing consensus scores on level and quality of evidence for the original studies.

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Table 1: Assigned Levels of Evidence and Quality Consensus Scores

Reference	Study Design	AACPDM Level of Evidence[1]	AMSTAR[2]	AACPDM[1]		Unique Sample	Participant Age and Diagnosis
				Group Design	SSRD		
Paleg 2015.[7]	SR	II	**9/11 - High**	NA	NA	Includes all listed below	182 children aged 2 – 18 yrs, predominantly diagnosed with CP
Barnes[8]	SSRD - MBD	III	NA	NA	**10/14 - Medium**	Y	N=3 CP; 3 yrs, 4 yrs and 9 yrs
Broadbent[9]	Case studies	V	NA	NA	NA	Y	N=4 CP; 8 yrs, 8 yrs, 9 yrs, 14 yrs
Eisenberg[10]	Non-random 2 group study	III	NA	**5/7 - Medium**	NA	Y	N = 22 CP; 3.5-10 yrs
Farrell[11]	Case study	V	NA	NA	NA	Y	N = 1; CP; 10 yrs
Lancioni 2005 [12]	SSRD - ABAB	IV	NA	NA	NA	Y	N = 1 PID;13 yrs
Lancioni 2007a [13]	SSRD - ABAB	IV	NA	NA	NA	Y	N=2 PID; 10 yrs, 8 yrs
Lancioni 2007b [14]	SSRD - ABAB	IV	NA	NA	NA	Y	N = 2 PID; 6 yrs, 8 yrs
Lancioni 2008 [15]	SSRD - ABAB	IV	NA	NA	NA	Y	N = 2 PID; 3 yrs 12 yrs
Lancioni 2010 [16]	SSRD - ABAB	IV	NA	NA	NA	Y	N = 5 PID; 5 yrs, 6 yrs, 7 yrs, 10 yrs, 11yrs
Lancioni 2013 [17]	SSRD - ABAB	IV	NA	NA	NA	Y	N = 2 PID; 10 yrs, 12 yrs
McKeever [18]	Qualitative	Q	NA	NA	NA	Same as Wright	N = 19 CP; 9-15 yrs
Van der Putten [19]	Non random 2 group study	III	NA	**5/7 - Medium**	NA	Y	N = 44 PID; 2-16 yrs
Whinnery [20]	Case study	V	NA	NA	NA	Y	N = 1; CP; 3 yrs
Willoughby [21]	RCT	II	NA	**6/7 - Strong**	NA	Y	N = 34; CP; 5-18 yrs
Wright 1999 [22]	Pre-test, post-test one group study	IV	NA	NA	NA	Y	N = 20 CP; 4-12 yrs
Wright 2006 [23]	Follow up study	IV	NA	NA	NA	Same as Wright	N = 19 CP; 9-15 yrs

AACPDM: American Academy for Cerebral Palsy and Developmental Medicine; MBD = Multiple Baseline Design; N = number; NA = not appropriate; PID = Profound Intellectual Disability; RCT: Randomized Controlled Trial; SR: Systematic Review SSRD: Single Subject Research Design; AACPDM Quality rating appropriate for evidence levels I through III only.

Table 2: Level of Evidence for ICF Outcomes

	Positive Outcomes						No Change					
Evidence Level	**I**	**II**	**III**	**IV**	**V**	**Q**	**I**	**II**	**III**	**IV**	**V**	**Q**
	Body Structure and Function											
Improved bowel function measured by parents using a diary			**Eisenberg** [10]									
Improved bone mineral density			Eisenberg [10]									
Increased motivation and emotional function – video scoring				Lancioni [11-16]								
	Activity and Participation											
Increased # of steps		Barnes [8]		**Lancioni** [12–17]	Whinnery [20]							
Increased walking speed and distance			Eisenberg [10]	**Wright 1999** [22]	Broadbent Farrell [11]					Wright 2006 [23]		
GMFM [26] – Stand and Walk subscales				**Wright 1999** [22]	Farrell [11]					Wright 2006 [23]		
Walking speed measured using the 10 meter walk test [24]		Willoughby [21]										
Ability to manoeuvre a walking aid measured using the Directional Mobility Assessment [22]				**Wright 1999** [22] **Wright 2006** [23]								
PEDI [25] mobility subscale			**Eisenberg** [10]	**Wright 1999** [22]						Wright 2006 [23]		
PEDI [25] self-care subscale				Wright 1999 [22] Wright 2006 [23]								
PEDI [25] social function subscale				Wright 1999 [22] Wright 2006 [23]								
Transfers and self-care abilities measured using Physical Abilities and Mobility Scale [11]					Farrell [11]							
Independence in functional mobility skills measured using Top Down Motor Milestone Test [27]			**Van der Putten** [19]									
Parent perception of increased independence, communication and participation						McKeever [18]						

[a]Statistically significant results are indicated in **bold.**

ICF: International Classification of Functioning, Disability and Health. GMFM = Gross Motor Function Measure; PEDI = Pediatric Evaluation of Disability Inventory; Q= Qualitative

Appendix 1: AACPDM - Levels of Evidence for Group Intervention Studies (December 2008)[1]

Level	Group Intervention Studies
I	Systematic review of randomized controlled trials (RCTs)
	Large RCT (with narrow confidence intervals) (n>100)
II	Smaller RCTs (with wider confidence intervals) (n<100)
	Systematic reviews of cohort studies
	"Outcomes research" (very large ecologic studies)
III	Cohort studies (must have concurrent control group)
	Systematic reviews of case control studies
IV	Case series
	Cohort study without concurrent control group (e.g. with historical control group)
	Case-control study
V	Expert opinion
	Case study or report
	Bench research
	Expert opinion based on theory or physiologic research
	Common sense/anecdotes

AACPDM: American Academy for Cerebral Palsy and Developmental Medicine.

Appendix 2: AACPDM - Levels of Evidence for Single Subject Research Designs (December 2008)[1]

Level	Single Subject Research Designs (SSRD)
I	Randomized controlled N-of-1 (RCT) Alternating treatment design (ATD) Concurrent or non-concurrent multiple baseline design (MBDs) (generalizability if the ATD is replicated across three or more subjects and the MBD consists of a minimum of three subjects, behaviours, or settings. These designs can provide causal inferences)
II	Non-randomized, controlled, concurrent MBD; (generalizability if design consists of a minimum of three subjects, behaviours, or settings. Limited causal inferences)
III	Non-randomized, non-concurrent, controlled MBD; (generalizability if design consists of a minimum of three subjects, behaviours or settings. Limited causal inferences)
IV	Non-randomized, controlled SSRDs with at least three phases (ABA, ABAB, BAB, etc.); (generalizability if replicated across three or more different subjects. Only hints at causal inferences)
V	Non-randomized controlled AB SSRD; (generalizability if replicated across three or more different subjects. Suggests causal inferences allowing for testing of ideas)

AACPDM: American Academy for Cerebral Palsy and Developmental Medicine.

Appendix 3: AMSTAR Conduct Rating)[2]

Systematic Review Being Appraised:	Paleg 2015[7]
1. Was an 'a priori' design provided? The research question and inclusion criteria should be established before the conduct of the review.	Yes
2. Was there duplicate study selection and data extraction? There should be at least two independent data extractors and a consensus procedure for disagreements should be in place.	Yes
3. Was a comprehensive literature search performed? At least two electronic sources should be searched. The report must include years and databases used (e.g. Central, EMBASE, and MEDLINE). Key words and/or MESH terms must be stated and where feasible the search strategy should be provided. All searches should be supplemented by consulting current contents, reviews, textbooks, specialized registers, or experts in the particular field of study, and by reviewing the references in the studies found.	Yes
4. Was the status of publication (i.e. grey literature) used as an inclusion criterion? The authors should state that they searched for reports regardless of their publication type. The authors should state whether or not they excluded any reports (from the systematic review), based on their publication status, language etc.	Yes
5. Was a list of studies (included and excluded) provided? A list of included and excluded studies should be provided.	Yes
6. Were the characteristics of the included studies provided? In an aggregated form such as a table, data from the original studies should be provided on the participants, interventions and outcomes. The ranges of characteristics in all the studies analyzed e.g. age, race, sex, relevant socioeconomic data, disease status, duration, severity, or other diseases should be reported.	Yes
7. Was the scientific quality of the included studies assessed and documented? 'A priori' methods of assessment should be provided (e.g., for effectiveness studies if the author(s) chose to include only randomized, double-blind, placebo controlled studies, or allocation concealment as inclusion criteria); for other types of studies alternative items will be relevant.	Yes
8. Was the scientific quality of the included studies used appropriately in formulating conclusions? The results of the methodological rigor and scientific quality should be considered in the analysis and the conclusions of the review, and explicitly stated in formulating recommendations.	Yes
9. Were the methods used to combine the findings of studies appropriate? For the pooled results, a test should be done to ensure the studies were combinable, to assess their homogeneity (i.e. Chi-squared test for homogeneity, I^2). If heterogeneity exists a random effects model should be used and/or the clinical appropriateness of combining should be taken into consideration (i.e. is it sensible to combine?).	Not applicable
10. Was the likelihood of publication bias assessed? An assessment of publication bias should include a combination of graphical aids (e.g., funnel plot, other available tests) and/or statistical tests (e.g., Egger regression test).	No
11. Was the conflict of interest stated? Potential sources of support should be clearly acknowledged in both the systematic review and the included studies.	Yes
Total Score (1 for each 'yes' rating):	9/11 – High Quality

Quality Rating[5]

High Quality:	8 to 11
Moderate Quality:	4 to 7
Low Quality:	0 to 3

Appendix 4: AACPDM Conduct Questions for Group Design [1]

		Eisenberg et al.[10]	Van der Putten et al.[19]	Willoughby et al.[21]
1.	Were inclusion and exclusion criteria of the study population well described and followed?	Yes	Yes	Yes
2.	Was the intervention well described and was there adherence to the intervention assignment? (for 2-group designs, was the control exposure also well described?) Both parts of the question need to be met to score 'yes'.	Yes	Yes	Yes
3.	Were the measures used clearly described, valid and reliable for measuring the outcomes of interest?	Yes	Yes	Yes
4.	Was the outcome assessor unaware of the intervention status of the participants (i.e., were the assessors masked)?	No	No	Yes
5.	Did the authors conduct and report appropriate statistical evaluation including power calculations? Both parts of the question need to be met to score 'yes'.	No	No	Yes
6.	Were dropout/loss to follow-up reported and less than 20%? For 2-group designs, was dropout balanced?	Yes	Yes	No
7.	Considering the potential within the study design, were appropriate methods for controlling confounding variables and limiting potential biases used?	Yes	Yes	Yes
Total Score		5 - Moderate	5 - Moderate	6 - Strong

AACPDM: American Academy for Cerebral Palsy and Developmental Medicine.

Quality Rating for AACPDM levels of evidence I through III.[1]

Strong (well conducted): 6 to 7
Moderate (fairly conducted): 4 to 5
Weak (poorly conducted): 0 to 3

Appendix 5: AACPDM Conduct Questions for Single Subject Design Studies[1]

	Barnes & Whinnery[8]
1. Was/were the participant(s) sufficiently well described to allow comparison with other studies or with the reader's own patient population?	Yes
2. Were the independent variables operationally defined to allow replication?	Yes
3. Were intervention conditions operationally defined to allow replication?	Yes
4. Were the dependent variables operationally defined as dependent measures?	Yes
5. Was inter-rater or intra-rater reliability of the dependent measures assessed before and during each phase of the study?	Yes
6. Was the outcome assessor unaware of the phase of the study (intervention vs. control) in which the participant was involved?	No
7. Was stability of the data demonstrated in baseline, namely lack of variability or a trend opposite to the direction one would expect after application of the intervention?	Yes
8. Was the type of SSRD clearly and correctly stated, for example, A-B, multiple baseline across subjects?	Yes
9. Were there an adequate number of data points in each phase (minimum of five) for each participant?	No
10. Were the effects of the intervention replicated across three or more subjects?	Yes
11. Did the authors conduct and report appropriate visual analysis, for example, level, trend and variability?	Yes
12. Did the graphs used for visual analysis follow standard conventions, for example x- and y- axes labelled clearly and logically,	Yes
13. Did the authors report tests of statistical analysis, for example celeration line approach, two-standard deviation band method, C statistic, or other?	No
14. Were all criteria met for the statistical analyses used?	No
Total Score	10 - Moderate

Quality Rating[1]

Strong (well conducted):	11 to 14
Moderate (fairly conducted):	7 to 10
Weak (poorly conducted):	Less than 7

Appendix 6: Traffic Light Classification Scale [4]

Colour Code	Criteria	State of the Evidence
	Group design Level I or II evidence of good* quality demonstrating negative outcomes (e.g. absence of change compared to no treatment)	**Proven Ineffective**
	• Group design Level I or II evidence of poor∞ quality, regardless of outcome • Group design Level III-V evidence of any quality, regardless of outcome • Single study research design Level I-V of any quality, regardless of outcome • Inconclusive results	**Insufficient Evidence**
	No evidence about the intervention's effectiveness	**No Evidence**
	Group design of either Level I or II evidence, where both studies of the same level of evidence show conflicting results	**Conflicting Evidence**
	Group design Level I or II evidence of good* quality, demonstrating statistically significant positive outcomes	**Proven Effective**

*Moderate or Strong quality (Group Design AACPDM Conduct Rating Scale[2] score of 4-7 or AMSTAR score of 4-11)
∞Weak (Group Design AACPDM Conduct Rating Scale[2] or AMSTAR score of 1-3)