

Five-days of intensive hands-on therapy improves functional outcomes in children with CP living in a rural African setting: a randomized controlled trial



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(A non-profit organization offering innovative solutions to improve the quality of life of children with Cerebral Palsy and their caregivers in rural resource-constrained settings)

BACKGROUND

Ethical considerations of withholding therapy make it difficult to establish evidence for "hands-on" functional therapeutic handling for children with Cerebral Palsy (CP). Resource-constrained settings offer an opportunity to address this dilemma as the ratio of therapists to children is low and intervention typically involves passive movements together general advice to caregivers as opposed to active and functional therapeutic handling.



AIM

To establish whether direct therapeutic handling conferred any advantage on the functional performance of children with CP living in a low-resourced rural South African district. This study sought to:

- compare three different once-off intervention strategies on the functional performance of children with CP and
- establish whether hands-on Bobath-based therapy conferred any specific advantage.



METHOD

Children aged 1 to 17 years across all Gross Motor Function Classification levels attending a rural CP Clinic were randomized into one of three study arms based on geographical clustering:

- a once off two hour caregiver training session (no intervention group);
- a daily three hour caregiver training workshop over five days (caregiver training group) or
- a daily two hour caregiver training workshop plus 75 minutes of daily hands-on therapy for five days (therapy group)

All children were given equipment and continued with their monthly therapy appointments.

Child and caregiver related outcomes were assessed at baseline, immediately pre- and post-intervention, and eight weeks later using both child-related and caregiver-related outcome tools.

For the children:

- Gross Motor Function Measure (GMFM)
- Modified version of the Pediatric Evaluation of Disability Inventory (PEDI);

For the caregivers:

- Personal Quality of Life (PQOL)



RESULTS

- Seventy-three children were enrolled, as follows.

Study Details: Gender and Age (n=73)

	Caregiver training (n=27)	Usual care (n=20)	Hands on therapy group (n=26)
Males	15 (56%)	11 (55%)	11 (42%)
Females	12 (44%)	9 (40%)	15 (58%)
Mean age (months)	5.9 yrs	5.8 yrs	4.8 yrs

Study Details: GMFCS Level (n=73)

GMFCS Level	Caregiver training (n=27)	Usual care (n=20)	Hands on therapy (n=26)
GMFCS Level 1	3 (11%)	1 (5%)	1 (3%)
GMFCS Level 2	3 (11%)	2 (10%)	1 (3%)
GMFCS Level 3	3 (11%)	5 (25%)	3 (11%)
GMFCS Level 4	3 (11%)	4 (20%)	8 (31%)
GMFCS Level 5	15 (56%)	8 (40%)	13 (50%)

Study Details: CP Subtypes (n=73)

CP Subtype	Caregiver training (n=27)	Usual care (n=20)	Hands on therapy (n=26)
Spastic quad	13 (48%)	8 (45%)	16 (62%)
Spastic hemi	3 (11%)	2 (10%)	0 (0%)
Spastic di	3 (11%)	2 (10%)	1 (4%)
Dystonic	6 (22%)	2 (10%)	5 (19%)
Choreoathetoid	0 (0%)	0 (0%)	1 (4%)
Ataxic	0 (0%)	2 (10%)	0 (0%)
Mixed	2 (7%)	3 (15%)	3 (12%)

RESULTS

- At 8 week follow-up, *GMFM scores were significantly better for the therapy group* compared to the other two groups.

GMFM Score Comparisons (n=73)

	Caregiver training (n=27)	Usual care (n=20)	Hands on therapy (n=26)
GMFM-66 baseline	34.91	33.68	25.15
GMFM-66 post-intervention	34.27	34.44	27.06
Mean difference	-0.64	0.76	1.91
95% Confidence interval	(-2.9 - 1.64)	(-1.3 - 2.8)	(0.05 - 3.75)
Significance	0.57	0.45	0.04

- Modified PEDI scores increased significantly in the therapy group* (3.92 [95% CI -0.29 - 8.12]) compared to the other groups.

PEDI Score Comparisons (n=73)

	Caregiver training (n=27)	Usual care (n=20)	Hands on therapy (n=26)
Modified PEDI pre-intervention	25.52	20.43	17.25
Modified PEDI follow-up	24.26	21.86	21.17
Mean difference	-1.26	1.43	3.92
Significance	0.092	0.260	0.004



RESULTS

- In contrast, caregiver related changes were greatest in the caregiver training group, although these changes did not reach significance.

Caregivers Personal Quality of Life Results

	Caregiver training (n=27)	Usual care (n=20)	Hands on therapy (n=26)
PQOL pre-intervention	63.00	75.10	74.74
PQOL post-intervention	69.88	75.45	73.58
Mean difference	6.88	-0.35	-1.16
	(SD = 18.14; 95% CI: -0.44 - 14.21)	(SD = 12.13; 95% CI: -5.33 - 6.03)	(SD = 11.33; 95% CI: -6.00 - 3.15)
PQOL follow-up	69.08	71.95	77.00
Mean difference	6.08	-3.15	2.26
	(SD = 15.94; 95% CI: -03.62 - 12.52)	(SD = 14.91 95% CI: 10.13 - 3.83)	(SD = 12.74; 95% CI: -2.78 - 7.30)
Significance	0.063	0.357	0.366



CONCLUSIONS

- A five day intensive course of hands-on therapy significantly improved functional outcomes in children with CP living in low-resourced settings, immediately following therapy and for eight weeks thereafter.
- Maximum gains can best be achieved through a combination of caregiver training and hands-on therapy.



IMPLICATIONS

- The study provides strong evidence for the role of hands-on Bobath-based therapy in improving functional outcomes and clinically meaningful changes in children with CP living in low-resourced settings. However, any therapeutic strategy in these settings also needs to address the well-being of caregivers.



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