Research Paper

# Add-on Home-Centred Activity-Based Therapy vs Conventional Physiotherapy in Improving Walking Ability at 6-Months in Children with Diplegic Cerebral Palsy: *A Randomized Controlled Trial*

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**ABSTRACT**

**Background:** Institutional physiotherapy as a standard of care for management of cerebral palsy (CP) has certain shortcomings, especially in resource-constrained settings. This is a proof-of-concept trial to evaluate the efficacy of individualized home-centered activity-based therapy in children with spastic diplegic CP. **Design:** Randomized controlled trial (open-label). **Settings:** Tertiary-care hospital with pediatric neurology services (July 2014 to July 2016). **Participants:** Consecutive sample of 59 children (5-12yrs) with spastic diplegic CP (Gross Motor Function Classification System scores II - III) without fixed lower-limb contractures, illnesses impeding physiotherapy or history of recent botulinum toxin injection/surgery were recruited. **Procedure:** Children were randomized to Intervention or Control arms. Their 6-minute-walk Test (6MWT) scoring and clinical examination were performed at baseline, 3 and 6 months. Children in Intervention Arm (*n*=30) were prescribed parent-supervised home-centered activity-based therapy (walking, standing, squatting, climbing up/downstairs, kicking a ball, dancing, riding a tricycle/bicycle) in addition to their institutional physiotherapy. Children in Control Arm (*n*=29) were prescribed ongoing institutional physiotherapy alone. Logbooks, home videos and telephonic follow-ups were used to ensure compliance. **Main outcome measures:** Comparison of the mean change in 6MWT scores at 6 months (from baseline) between the two groups. **Results:** Median (IQR) change in 6MWT scores at 6 months (from baseline) in the Intervention and Control arms were 3.5 (-5.3, 9) m and 3 (-7.8, 6.3) m **Conclusions:** Adjunct home-centered activity-based therapy was safe and feasible, but did not result in appreciable gains over 6 months.

**Keywords:** *Neurorehabilitation, Play therapy, Brain injury, Perinatal brain injury, resource-limited*

**Clinical Trial Registration No:** NCT02412007

Physical therapy is the cornerstone in the management of cerebral palsy (CP). Various targets of physical therapy include spasticity-reduction, functional mobility optimization and prevention of secondary musculoskeletal complications [1]. Numerous schools of physical therapy are based on different principles, and have their own pros and cons [2]. Existence of a multitude of physical therapy techniques indicates that a singularly effective regime for children with CP is yet to be formulated. Apart from physical therapy, holistic rehabilitative practices aim to improve affected individuals' functional capabilities so that they may gainfully participate in day-to-day activities [3].

Activity-based therapy is generating interest as an alternative mode of CP rehabilitation [4]. The philosophy behind this modality is functional improvement through repetitive performance of activity-based training, lifestyle modifications, and mobility-enhancing devices rather than traditional passive physiotherapy protocols. Activity-based rehabilitative regimes that have been scientifically evaluated and found effective include Constraint-Induced Movement Therapy (CIMT) (for hemiparetic CP rehabilitation), treadmill therapy (for gait disorders) and Robotic arm technique. For conventional physical therapy, the deficiency of physiotherapists, equipment and rehabilitation centers are limiting factors in resource-limited settings [6]. A simple home-based regime empowers parents and truncates expenses of institutional care [7]. The role of home-centered, activity-based therapy in children with diplegic CP has not been evaluated till date. Our study was designed as a proof-of-concept trial to look into the efficacy of home-centered activity-based therapy in children with spastic diplegic CP in resource-limited settings.

## METHODS

This randomized controlled trial (RCT) was conducted in a tertiary-level pediatric teaching hospital and its associated rehabilitation centre from July, 2014 to July, 2016 after obtaining approval from the institutional ethics committee.

Children between 5 and 12 years of age, clinically diagnosed with spastic diplegic CP with Gross Motor Function Classification System (GMFCS) Score II/ III were eligible. Spastic diplegic CP was defined as 'CP with predominant bilateral lower limb involvement with hyperreflexia, spasticity and relative non-involvement of upper limbs'. Enrolled children required a minimum visual acuity of 6/60 and the ability to follow single-step commands. They were enrolled if their parents/primary caregivers were willing and capable of following instructions and maintaining an activity log. Informed consent from the parent(s)/primary caregiver(s) and assent (as and when applicable, from a child) were obtained before enrolment. Children with fixed lower-limb contractures or deformities affecting stance and gait, chronic systemic/acute illnesses interfering with physiotherapy and children who received botulinum toxin injection or underwent corrective orthopedic surgery up to one year prior to the day of screening were excluded.

A detailed general and systemic examination of every child was performed and findings recorded on proforma. Each child was scored for 6-minute-walk-test (6MWT) (in meters), 10-metre-fast-walk-test (10MFWT)(in seconds), modified Ashworth scale (MAS), modified Tardieu scale (MTS), Gross Motor Function Classification System (GMFCS), Gross Motor Function Measure-88 (GMFM-88) (D & E) and Cerebral Palsy Quality of Life (CP-QoL) (Primary-caregiver).

Randomization was done by another person who was otherwise not involved in any other aspect of the trial. Block randomization of varying sizes was prepared with an open access randomization software (*www.randomizer.org*). Allocation concealment was achieved using sealed opaque envelopes. Envelopes were kept in custody of a person not involved in the study.

*Scoring for 6MWT*: Test arena comprised of a marked, flat, non-slippery, rectangular cemented area with a perimeter of 34 meters. Children were made to walk along the outer boundary of the area after an initial demonstration. If at any point, the child had difficulty walking (due to any reason) or did not want to walk, he or she could stop. In that case, the test would be postponed to a later date. Practice trial immediately preceding test was avoided to reduce fatigue [8]. The parents/primary caregivers were instructed to encourage the child throughout the process. In case a child needed one-hand support, the parent/primary caregiver walked alongside the child holding his/her hand. Distance covered in 6 minutes was recorded in meters (up to nearest centimeter). The test was videographed for future reference.

*Scoring for 10MFWT*: Test area comprised of a cemented, flat, non-slippery, rectangular floor. Start and finish lines were marked with parallel white lines 10m apart. An explanation and demonstration preceded the test. To start, the child was made to stand with toes touching the start-line. On being told to start, the child had to start walking. The stop command was given after the child had walked 5m past the finish line so that he/she may not decelerate until after reaching the 10 m mark [9]. Time to walk 10m was recorded with a stopwatch with the least count of 0.01 seconds. The test was video graphed for future reference.

Eight activities were recommended in the 'Intervention Arm,' viz., walking on plain surface, standing from squatting position and squatting from standing position on level floor, climbing up and down a flight of stairs, kicking a football while standing, dancing on level floor, riding a tricycle/bicycle (with additional support wheels) depending on child's age and functional capability. Every child was expected to perform at least seven out of eight activities (exception being cycling) to the best of his/her ability. Parents/primary caregivers were given a brief overview of the interventions in the language they understood. They were taught how to keep the activities interesting by incorporating them within play activities. Activities were tailored according to the age and functional capacity of the child and modified periodically to avoid monotony. Strict compliance was emphasized upon. At the outset, videographic demonstrations of the activities were displayed to the parents. Videos were prepared in the same centre previously and approved by all the researchers involved in the study. The parents/primary caregivers were asked to make their children perform the activities under the researcher's supervision. Doubts were clarified and modifications suggested. A logbook was issued to each parent/primary caregiver with simple instructions written in English and Hindi and sketches depicting the activities. The logbook had an earmarked space for every day ,in which the parent/primary caregiver was instructed to record whether the pre-assigned activity was performed as advised or not. There was a 'remarks' column for noting any deviations.The logbook was designed to serve as the main mechanism to ensure compliance. At the completion of the study, percentage compliance was calculated from the entries in the logbooks. In addition, home videos taken by parents acted as a reinforcement of compliance. The activities were designed to be repeated three times per session, with three sessions per day for five days per week. In case of any acute illness, pain, injury, compelling domestic issues or in the case of a child strongly resenting therapy, a break could be allowed but the parent/primary caregiver was supposed to record it in the logbook. These activities were in addition to activities that were already being performed as a part of an ongoing physiotherapy program. Parents/primary caregivers of children in the Control arm were advised to continue ongoing physiotherapy i.e. certain sets of active and passive exercises that were administered by certified physiotherapists after individualized assessment as per guidelines. Three physiotherapists offered conventional physiotherapy in the study centre. These manoeuvres were tailored to the needs of a child with periodic reassessment and modification as per the disability, tolerability of intervention and clinical response (spasticity, stability of gait, etc). Techniques of conventional physiotherapy are described in **Web Box I**.

Besides filling the logbook, the parents/ primary caregivers also made intervention home videos periodically, which were perused by one investigator at follow-up. Telephonic follow-up was done at 2 weeks of enrolment. The telephone number of the primary investigator was shared with parents/primary caregivers for addressing queries. In addition, parents who expressed difficulty in understanding the procedures were contacted telephonically to reinforce the prescribed procedures. Follow-up visits were planned at 3 months (+ 1 week), 6 months and (+ 2 weeks) after enrolment. Doses of drugs (such as baclofen or antiepileptics) were not modified for study purposes. If any child developed seizures during the course of study, he/she was managed as per standard protocol.

The primary study outcome was change in 6 MWT score at 6 months. The secondary outcomes included change in 10MFWT score (in s) ,MAS, MTS, GMFM-88 (D & E) ,CP-QoL (Primary caregiver version) scores at 3 and 6 months, and change in 6MWT score at 3 months. A single investigator assessed all the outcomes.

For sample size calculation, it was assumed that the intervention would result in 60 m change in distance covered in 6MWT. This value of 60 m was an extrapolation from the study by Fitzgerald, et al. [10] in children with CP (GMFCS II) wherein, the standard deviation was 77. Keeping $\alpha$ as 0.05 and power of study as 80%, a sample size of 27 in each group was required . Assuming a 10% loss to follow-up, the targeted sample size was 59 (minimum 30 children per group).

*Statistical analyses*: Data were recorded on a Microsoft Excel spreadsheet. Statistical analysis was performed using the statistical software SPSS (IBM Corp), Version 20. Student t-test was used to compare the difference in the means between the two groups for parametric variables, while non-parametric variables were expressed as median (IQR) and compared using Mann-Whitney U test

## RESULTS

Two hundred and sixty-two children with CP were screened ,among whom 169 met inclusion criteria and fifty-nine were enrolled (**Fig. 1**). Thirty children were randomized to the Intervention arm and twenty-nine to the Control arm. One child allocated to the control arm withdrew from the study.

The mean (SD) ages of children in the study was was 115 (23.1) months. Anthropometric and clinical characteristics of the two groups were comparable at baseline (**table I**). Five children (intervention arm: 3, control arm: 2) had fresh onset seizures during the study period in all of which oral sodium valproate was initiated. Good seizure control was achieved in four of them with monotherapy of sodium valproate (dose range 15-40mg/kg/day) while one child (intervention arm) required additional therapy with oral clobazam. Except for a brief interruption of their respective intervention schedules, there was no long-term interruption of the rehabilitation program in any of these children. The majority of children in both groups achieved a compliance rate of 80-100%, There were no differences in the compliance rates between the children in the two groups, as derived from logbooks filled by the primary caregivers, with 93.3% and 93.1% children in intervention and control group, respectively having rates >60%.

The difference in mean 6 MWT between baseline and 6 months was 3.5m and 3m in the Intervention and Control Arm, respectively (**table II**). There was no significant change in any of the secondary outcome variables (**supp. table I**).

## DISCUSSION

The study is a proof of concept trial to evaluate the efficacy of a home-centered activity-based rehabilitation program for children with diplegic CP. Childrn with diplegia constitute a major subset of CP [11]. It is probable that children younger than 5 years would probably have responded better owing to their neuroplasticity. However, they were excluded from the study due to issues in eliciting cooperation, validity of 6MWT in toddlers, and because activity regime would have required significant modification in younger children.

Common interventions for physiotherapy in CP children include strength and functional training; weight supported treadmill training (WBSTT), and neuro-developmental treatment (NDT) [2]. None of these techniques are universally applicable. Children in this study followed a standardized institutional physiotherapy regime comprising of passive joint mobility and assisted gait training as outlined in methodology. Activity-based therapy refers to a regime of age-appropriate motor activities such as walking, for example, which involves multiple repetitions of coordinated, reciprocal limb activities [12]. CIMT is a popular and effective example of upper limb activity-based therapy [13-15]. Activity-based therapy for lower limbs may include day-to-day activities like climbing stairs, walking, and sit-to-stand. Intense activity-based training, lifestyle modifications, and mobility-enhancing devices are hypothesized to increase motor activity leading to better physical and mental health cognitive performance in people with motor impairments [12]. The neurophysiological basis of improvement rests on the principles of neuroplasticity [4,16,17]. There is a scientific basis to the assumption that regular activities performed by a child with CP would lead to alteration in the representation of the motor cortex with corresponding motor improvement. Intensive upper limb rehabilitation has been seen to be associated with enhanced motor area activation and size in children with CP [18]. Brains of individuals with CP have been noted to display adaptation in the motor areas subsequent to rehabilitation and activity [19]. Hence, the hypothesis of the index study appears biologically plausible. In order to explore neuroplastic modeling, researchers have attempted integrated neurorehabilitation using combined modalities of physical therapy, magnetic stimulation and nutraceuticals [20].

Simple, interesting, age-appropriate, safe, economically feasible and objectively assessable activities within the ambit of day-to-day functioning were incorporated in the study. Walking was a key component. Maher, et al. [21] studied a walk-based model of rehabilitation in children with CP between 8-17 years of age the Step Up study. Azizi S, et al. [22] demonstrated that anti-gravity treadmill therapy is effective in improving gait in CP. Squatting and standing are additional tasks included in the activity schedule meant to increase the strength of lower limb musculature and to promote functional mobility. Contemporary systematic review has quoted Level II (b) evidence in support of sit-to-stand training for improvement of balance [23]. Climbing up and down stairs is intended to improve functional mobility. Kicking a football has not been reported as a specific therapeutic modality for rehabilitation in CP. It is anticipated to increase lower limb strength, balance, and coordination while sustaining the child’s interest. Cycling was chosen to improve lower limb strength and joint mobility, reduce spasticity and to make the program joyful for the children. However, this was reserved as an optional activity depending on the child’s ability, interest and availability of cycle. The cycles used were either tricycles or bicycles with two accessory balancing wheels. The utility of different types of cycling in neurorehabilitation has been previously reported [24,25]. Dancing has been included in order to promote joint mobility and balance while maintaining the child’s interest in the program, as previously reported [26,27]. However, in the present study, the dancing activity was an unstructured one. In the present study, activity-based interventions were chosen so that the children could perform them either independently or with minimal assistance. So children with functional levels of GMFCS IV-V were excluded from our study.

The role of task-directed rehabilitation is evident from contemporary upper limb rehabilitation programs [29]. There is a growing body of evidence of molecular plasticity and functional recovery secondary to CIMT [30]. The test-test reliability and validity of 6MWT in children and adolescents with CP has been previously demonstrated [31,32]. A timeline of 6 months for measuring the primary outcome was adopted in our study arbitrarily as it was anticipated that there would be some change in the functional status of the children by that period without suffering significant attrition. Home-based rehabilitation is exalted in view of benefits such as better compliance, involvement and empowerment of parents, economical and feasible [33]. The greatest strength of the study is that it highlights the feasibility of a home-based rehabilitation program in resource-constrained settings. This family-based model simplistic model is appealing because it is economically viable and suits the needs of resource-constrained settings. However, the comparable difference in 6MWT at 6 months (from baseline) in the two groups indicates the fact that adjunctive home-centered activity-based therapy does not improve the outcome associated with regular institutional physiotherapy. The initial 3-month decline and the latter 3-month improvement noted in the study were higher in the Control arm. This phenomenon may be probably due to fewer fluctuations in 6MWT in children receiving both home-based and institutional therapy due to a stable trajectory. It is unlikely that compliance issues could explain the differential trends because compliance was stable across the study in both groups. Satisfactory adherence was maintained throughout the study indicating that, if applied in the community, this model is likely to be well accepted. There was no intervention-related adverse effects eliciting the safe nature of the regime.

The results do not show a significant difference between the two groups probably because of certain limitations in the study design such as brief follow-up period, low intensity of interventions, Parent/primary caregiver report-based compliance assessment and varied etiologies of CP. There was no mechanism in the study, which could ensure absolute uniformity in the administration of interventions and live monitoring of the same. A feasible approach to compliance monitoring was adopted at the cost of increasing bias. Despite concealed group allocation, follow-up and evaluation were open-label with the potential risk of bias. The novelty of the study lies in its practical model whereby a simplistic home-centered program, with day-to-day activities, have been analyzed in children with diplegic CP. Hence no analytical comparison to other similar studies could be drawn.

Our study revealed that home-centred activity-based therapy is a feasible and practical modality of CP rehabilitation; however, significant benefits were not appreciable over a 6-month period, therefore, reinforcing need for intense institutional-based therapy. We suggest a larger study size with more intensive intervention strategy, prolonged follow-up interval and more stringent compliance monitoring be conducted in order to effectively evaluate the efficacy of home-centered activity-based programme in children with CP.

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*Contributors*: JNG: patient management, data collection, literature review, and preparation of the draft manuscript; NS: Protocol development, supervision of the study, interpretation of results, editing and final approval of the manuscript. PS: Concept and design of the study, supervising conduct of the study, interpretation of results, clinician-in-charge of patient management, final approval of the manuscript, will act as the guarantor of the study.

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**WHAT IS ALREADY KNOWN?**

- Physiotherapy plays a major role in the management of children with cerebral palsy.

**WHAT THIS STUDY ADDS?**

- Adjunctive home-centred activity-based therapy does not improve the functional outcomes of children with CP as measured by 6-Minute-Walk-Test scores at 6 months when compared with those receiving institutional physiotherapy alone.

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**Table I Baseline Characteristics of Children with Diplegic Cerebral Palsy in the Intervention and Control Arms**

| *Characteristic* | *Intervention arm (n=30)* | *Control arm (n=29)* |
|---|---|---|
| Age, mo[a] | 73(65-89) | 71(63-79) |
| Males | 19 (32) | 24 (41) |
| *Functional status* | | |
| GMFCS II | 16 (53) | 11 (40) |
| GMFCS III | 14 (47) | 18 (60) |
| *Assistive devices* | | |
| Ankle-foot-orthosis | 10 (33) | 14 (48) |
| Knee-ankle-foot-orthosis | 2 (7) | 2 (7) |
| Epilepsy | 8 (27) | 8 (28) |
| Refractive error | 8 (27) | 6 (21) |
| Receiving baclofen | 17 (57) | 20 (69) |

*All values in no. (%) or [a]mdian (IQR). GMFCS: Gross motor functional classification scale.*

**Table II Change in 6-Minute Walk Test (6MWT) Scores in Children With Spastic Diplegia in the Two Groups**

| | *Intervention arm (n=30)* | *Control arm (n=29)* |
|---|---|---|
| Baseline | 227.5 (168.8,340) | 243.0 (142.5,350) |
| 3 mo | 225.5 (165.5,343.3) | 230.0 (134.5,336) |
| 6 mo | 229.0 (165.3,340.8) | 246.0 (141,336) |
| 0-6 mo[a] | 3.5 (-5.3,9.0)] | 3.0 (-7.8,6.3) |

*All values in median (IQR):* Difference between scores at baseline and at 6 months;P>0.05 for all comparisons.*

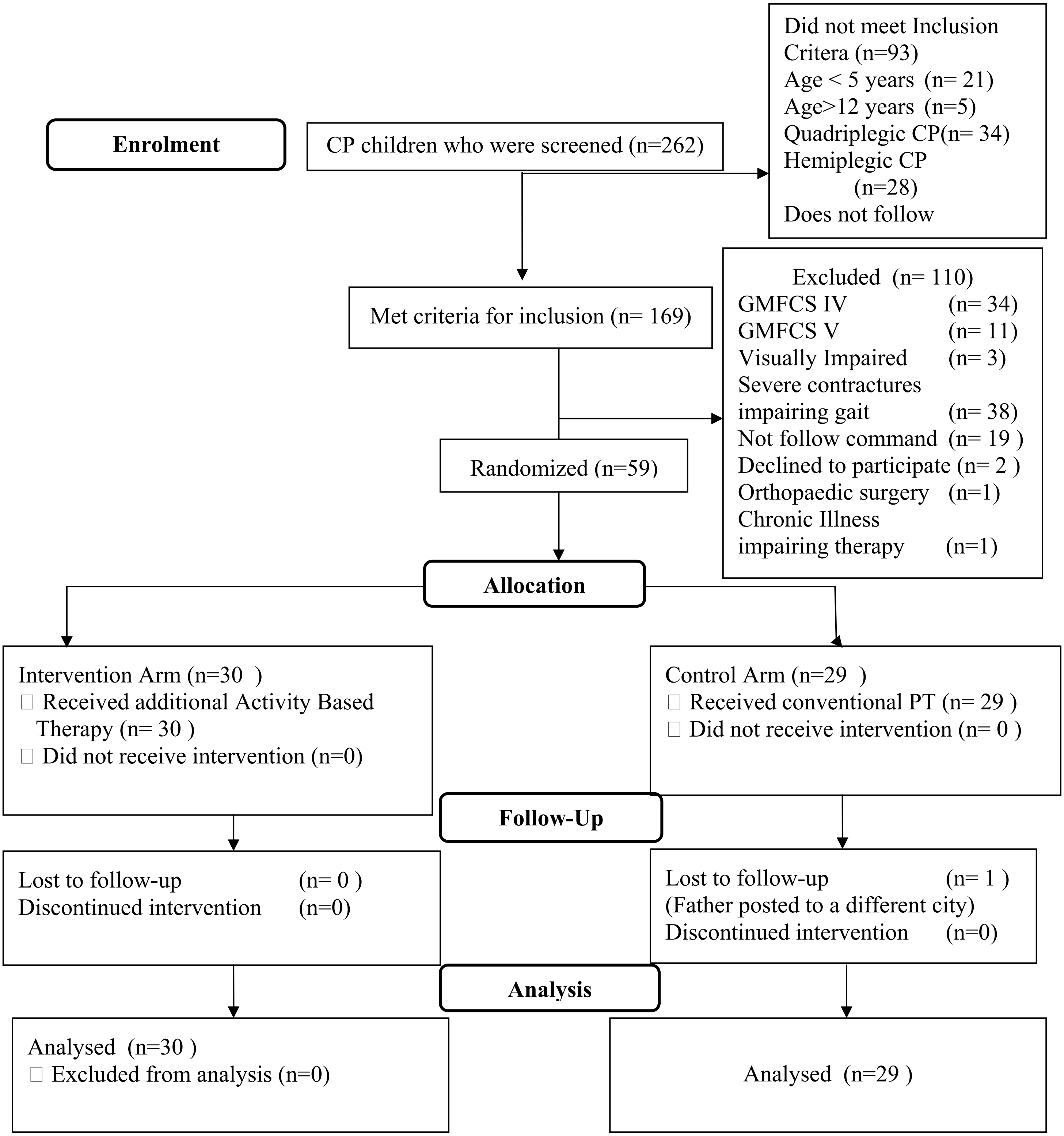


**Fig. 1** CONSORT flow diagram for the study.

**Supplementary Table I Secondary Outcome Variables Among the Two Groups**

| | *Intervention arm (n=30)* | *Control arm (n=29)* | *P value* |
|---|---|---|---|
| *10 Minute Fast Walk Test (10MFWT) Scores (in seconds)* | | | |
| Baseline | 9 [6.6,14.1] | 8.4 [6.9,13.1] | 0.62 |
| 0-3 mo[a] | 0.4[(-) 0.1, 1.2] | 0.2 [(-) 0.6, 0.7] | 0.55 |
| 0-6 mo[b] | (-) 0.2[(-)1.4, 0.8] | (-) 0.2[(-)0.9, 0.6] | 0.61 |
| *Modified Ashworth scale (MAS)* | | | |
| Baseline | 15.5[13.8,18] | 15.5[12.8,19] | 0.90 |
| 0-3 mo[a] | 0.4 [0,0] | 0.2 [0,0] | 0.05 |
| 0-6 mo[b] | (-) 0.2[0,0] | (-) 0.2[0,0] | 0.83 |
| *Modified Tardieu scale (MTS)* | | | |
| Baseline | 86.5 [65.8,101.3] | 88 [56,123.5] | 0.74 |
| 0-3 mo[a] | (-) 1.0[(-)10.5 ,3] | (-) 4.0[(-)14.5,2] | 0.64 |
| 0-6 mo[b] | 2.5 [(-)3.3,18.5] | 0[(-)11.5,16] | 0.82 |
| *Gross Motor Function Measure -88 (GMFM-88) (D & E)* | | | |
| Baseline | 50.9[41.2,68.5] | 51.5[42.1,70.2] | 0.70 |
| 0-3 mo[a] | 0[0,0.7] | 0[0,0.9] | 0.99 |
| 0-6 mo[b] | 0[0,4.6] | 0[0,8.3] | 0.30 |
| *Cerebral palsy-quality of life (CP-QoL): Primary caregiver version* | | | |
| Baseline | 303[285.5,322.5] | 297 (254.0,328.5) | 0.80 |
| 0-3 mo[a] | 2.5[(-)1.3, 8.5] | 0[(-)4.5, 5.5] | 0.20 |
| 0-6 mo[b] | 3.5 [0,8.8] | 3[(-)5.5,2] | 0.70 |
| *6 Minute walk test (6MWT) Scores (m)* | | | |
| 0-3 mo[a] | 3.0[-6,6] | -6.0 [-12.5,0.25] | 0.70 |

*Values in median (IQR). Total scores are depicted for all the scales used. [a]Difference between score at baseline and at 3 mo; [b]Difference between score at baseline and at 6 mo.*

**SUPPLEMENTARY BOX I Techniques of conventional physiotherapy**

(*a*) Passive manual muscle stretching of involved muscle (commonly thigh adductors, tendo-achilles, and hamstrings). Stretches were performed using gradual manual pressure. Each stretch was initially performed up to five times. In subsequent sessions, the number of repetitions was gradually increased to a maximum of fifteen per circuit, with repetitions up to 3 sets per muscle group per session. Sessions were prescribed five days per week.

(*b*) Gait training was administered as per protocol. Assistance was provided, if required, by an attendant. Sessions were performed once daily and difficulty level increased as per child's response by increasing distance, duration and incline of the walking platform. Climbing steps was the next goal.