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Research Protocol

Community Section

Effectiveness of the PACT Protocol for Caregivers of Children with Cerebral Palsy: A Research Protocol for Randomised Controlled Trial

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ABSTRACT

Introduction: Cerebral Palsy (CP) is a lifelong condition that affects a person's movement, posture, and ability to perform daily self-care tasks, often making them dependent on caregivers. The newly developed PACT is a structured caregiver training protocol designed to support families by improving caregiving skills, encouraging greater independence in self-care, and enhancing overall care for individuals with CP in community settings.

Need of the study: Families often experience considerable emotional stress, social isolation, and physical fatigue while caring for individuals with CP. Therefore, there is a need for a structured caregiving protocol that can help reduce caregiver burden and improve their overall mental wellbeing.

Aim: To evaluate the effectiveness of a structured training programme, the Parent/Caregiver-Assisted Care and Training (PACT) protocol, in improving Activities of Daily Living (ADL) among caregivers of children with CP.

Materials and Methods: This randomised controlled trial will be conducted from June 2025 to September 2026 in selected community areas of Wardha district, Maharashtra, India. Caregivers of children with a confirmed CP diagnosis will be enrolled with Group A (control) receiving routine care, while Group B (intervention) will undergo a four-session evidence-based PACT programme focusing on daily care, home exercises, safe drug administration, communication, and stress management. Baseline and two-month postintervention assessments will be conducted using the Paediatric Evaluation of Disability Inventory (PEDI) and the Gross Motor Function Measure (GMFM). Data will be analysed using descriptive statistics, paired t-tests/Wilcoxon signed-rank tests for within-group changes, independent t-tests/Mann-Whitney U tests for between-group differences, and ANCOVA for adjusted comparisons, with significance at p-value <0.05.

Keywords: Community health services, Parent training, Rehabilitation

INTRODUCTION

CP is among the most common causes of motor disability in children. It is currently defined as a group of permanent disorders affecting the development of movement and posture, leading to activity limitations, and resulting from non progressive disturbances in the developing foetal or infant brain. Over time, this definition has evolved, reflecting the fact that CP is a highly heterogeneous condition in both its causes and clinical presentation [1].

The CP occurs in approximately 2–3 per 1,000 live births and results from various causes that lead to brain injury affecting movement, posture, and balance. Its movement disorders are classified into spasticity, dyskinesia, ataxia, or mixed types, with spasticity being the most common, present in nearly 80% of cases. These primary motor impairments often lead to secondary complications such as hip pain or dislocation, balance difficulties, hand dysfunction, and equinus deformity, all of which can significantly affect functional abilities and quality of life [2].

Prematurity, low birthweight, maternal infections, and multiple gestations increase CP risk, with most brain injuries occurring early in foetal development. Diagnosis is mainly clinical, aided by neuromotor assessments and Magnetic Resonance Imaging (MRI), and management requires a multidisciplinary approach to address associated conditions, enabling many affected children to lead productive lives [3].

Caregivers of children with CP face heavy physical, emotional, financial, and social burdens, worsened by limited family support, stigma, poverty, and inadequate public resources in low- and middle-income settings [4]. Caring for children with CP involves managing complex disabilities and long-term dependence, posing physical and psychological challenges for parents. Understanding caregiver health requires a multidimensional approach that examines both direct and indirect factors affecting wellbeing [5].

Social support, such as information support, emotional counseling, and community-based programme, combined with positive coping strategies like mindfulness, meditation, and stretching, can realistically improve caregivers' parenting efficacy by addressing their deficiencies in care knowledge and negative perceptions of illness. These approaches can also effectively alleviate psychological stress by altering thought patterns and helping caregivers recognise their own and their child's strengths. Strengthened caregiving skills and reduced stress in turn support better rehabilitation engagement and improved functional outcomes for children with CP [6].

REVIEW OF LITERATURE

Studies assessed community-based intervention package of primary caregivers of children with CP. Postintervention, caregivers showed significant improvements in knowledge, attitude, and home-care skills, indicating Community-Based Intervention Packages (CBIPs) effectiveness in community-based CP care [7]. Another study evaluated a family-professional collaboration model involving children with CP, their caregivers, and physical therapists. Therapists in the experimental group were trained to integrate collaboration into sessions. Caregiver burden was significantly lower in the experimental group, suggesting that family-professional

collaboration can help sustain functional achievements and reduce caregiver burden [8].

Self-help strategies in CP focus on building functional independence in ADLs such as feeding, dressing, toileting, and mobility, which reduces physical strain and time demands on caregivers.

In infants at risk of CP, interventions that are task-specific, intensive, and child-initiated (e.g., directed play-based therapies) have shown promise in enhancing motor skills like sitting, which supports functional independence [9].

While home-based and parent-delivered programme have been shown to enhance children's participation and motor outcomes when they are well-structured, goal-directed, and provided at an adequate intensity and duration [10]. Many conventional caregiver education approaches lack standardised content, coaching, and fidelity monitoring. A recent study demonstrated that structured protocols, including telerehabilitation-supported home programme, significantly outperform usual care in improving motor function, activity, participation, and goal attainment [11]. Similarly, community-based caregiver training interventions like the Getting to know CP programme have shown measurable improvements in both child outcomes and caregiver wellbeing in Low- and Middle-Income Countries (LMIC) settings [12].

Despite this evidence, there remains a critical gap in comparative studies assessing structured caregiver protocols against conventional approaches, particularly in resource-limited community settings. The newly developed PACT protocol aims to fill this gap by providing caregivers with structured, goal-directed modules, monitoring tools, and guided support to enhance self-help skills in children and improve caregiver competence and confidence. Evaluating the comparative efficacy of PACT against conventional methods will generate actionable evidence to inform scalable, community-based rehabilitation strategies that align with global best practices [11,13].

Null Hypothesis (H_0): There is no significant difference in caregiver outcomes (e.g., PEDI scores, caregiver competence, quality of life, or other study outcomes) between caregivers receiving the PACT protocol and those receiving standard care.

Alternative Hypothesis (H_1): There is a significant difference in caregiver outcomes between caregivers receiving the PACT protocol and those receiving standard care.

This study aims to evaluate the comparative efficacy of a newly developed PACT (structured protocol) versus conventional methods in improving self-help abilities and caregiving practices among caregivers of children with cerebral palsy in a community setting.

Primary objective: To evaluate the effectiveness of the structured training programme in improving the Activities of Daily Living (ADL) among caregivers of children with cerebral palsy in the experimental group.

Secondary objectives: To assess the existing Activities of Daily Living (ADL) among caregivers of children with cerebral palsy in both experimental and control groups.

To compare the post-intervention improvement in ADL between caregivers in the experimental and control groups.

MATERIALS AND METHODS

The present randomised controlled trial study will adopt an interventional approach to evaluate the effectiveness of a structured training programme. The study will be conducted in selected community areas, Devali, Seloo, Wardha, of the Wardha district for the time period of June 2025 to September 2026, and the population will consist of caregivers (mother, father, siblings, or primary caregivers) of children with CP of any age group. The study has obtained approval from the Institutional Ethical Committee (Ref. No. DMIHER(DU)/IEC/2023/04) and was registered with the Clinical Trials Registry of India (CTRI Reg. No. CTRI/2025/06/089063). Caregivers who are willing to participate and meet the inclusion criteria will be enrolled.

Inclusion criteria: Caregivers of children with a confirmed diagnosis of CP, availability for the entire duration of the intervention and evaluation phases, and willingness to provide informed consent and caregivers aged between 18–60 years will be included in the study.

Exclusion criteria: Caregivers who are not directly involved in the daily care of the child or those with medical or psychological conditions preventing participation in the training sessions will be excluded from the study.

Sample size: The sample size was estimated using Cohen's effect size (d) for comparison of two independent means of PEDI scores, as advised by the study statistician. Cohen's effect size was calculated as:

$$\mu_2\text{-}\mu_1$$

Considering large effect size difference=0.8 (Medium effect size)

$$\text{Sample size } N = \left(\frac{1+r}{r}\right)\frac{(Z_{1-\alpha/2}+Z_{1-\beta})^2}{d^2} + \frac{Z^2_{1-\alpha/2}}{2\,(1+r)}$$

$Z_{1\text{-}a/2}$ at 5 % level of significance=1.96 at 95 % Power = 1.64

$$\text{Sample size } n = \left(\frac{1+1}{1}\right)\frac{(1.96+1.64)^2}{0.8^2} + \frac{(1.96)^2}{2\,(1+1)} = 42 \text{ per group.}$$

Total 42 samples required per group.

Group A (control group) will include participants receiving routine care as per standard need-based practice, while Group B (intervention group) will receive the PACT protocol intervention.

Randomisation will be done using the opaque sealed envelope method. Eligible participants will be randomly allocated into Group A and Group B using sequentially numbered, opaque, sealed envelopes to ensure allocation concealment. The evidence-based educational programme will be given to the caregivers for motivating the self-help. The programme will be emphasised on practical skills and emotional support. It should cover training in daily care activities such as feeding, hygiene, toileting, mobility, and safe positioning. Caregivers should be taught simple physiotherapy and home-based exercises to improve the child's motor skills, along with basic communication techniques and behaviour management strategies. Guidance on safe drug administration, recognising warning signs, and accessing healthcare services is essential. The programme will include stress management techniques, self-care practices, and information on available community and financial support. Regular monitoring and feedback sessions can help caregivers build confidence, improve skills, and enhance the child's functional independence.

Baseline (pretest) data will be collected at home or the community centre by a trained assessor blinded to group allocation, using a structured Knowledge Questionnaire on CP care (feeding, hygiene, mobility/positioning, home exercises, drug administration, red-flags),

Following baseline, the experimental group will receive the 4-session PACT programme; the control group continues usual care. Post-test assessments will repeat the same tools at 2 months (±1 week) by the same blinded assessor. Data quality will be ensured via standardised SOPs, inter-rater calibration ($\kappa \geq 0.70$), and real-time logic checks. Data will be captured on paper forms and REDCap/excel with double entry, encrypted storage, and coded IDs to maintain confidentiality. Missed items will be minimised through on-site review; remaining missingness will be handled using predefined rules (e.g., person-mean imputation for ≤10% item gaps) and intention-to-treat analysis with last observation carried forward for attrition. Session attendance and fidelity checklists will be recorded to verify intervention delivery dose and adherence.

PEDI [14]

The PEDI evaluates functional skills, caregiver assistance, and environmental modifications. Functional skills are scored as 0 (unable) or 1 (capable), while caregiver assistance is scored from 0 (total assistance) to 5 (independent). These raw scores are converted into a scaled score from 0 to 100, where higher scores indicate greater functional independence and reduced caregiver dependency in self-care, mobility, and social functions.

Gross Motor Function Measure (GMFM) [15]

The GMFM is scored across five domains- lying and rolling, sitting, crawling and kneeling, standing, and walking/running/jumping- using a 4-point scale where 0 indicates no initiation of the task and 3 indicates full completion. The scores from each domain are summed and converted into a percentage, with higher percentages reflecting better gross motor abilities. In the GMFM-66 version, scores are processed using the Gross Motor Ability Estimator (GMAE) software, providing a 0-100 score for precise tracking of motor improvements.

STATISTICAL ANALYSIS

Data will be analysed using both descriptive and inferential statistics. Descriptive statistics, including mean, standard deviation, frequency, and percentage, for baseline demographic and clinical characteristics of caregivers and children in both groups. For within-group comparisons of pre- and postintervention scores of PEDI and GMFM, paired t-tests will be used for normally distributed data and Wilcoxon signed-rank tests for non parametric data. Between-group comparisons of change scores (post-pre) will be analysed using independent t-tests or Mann-Whitney U tests, depending on the distribution of the data. To control for baseline differences and improve precision, ANCOVA will be applied with baseline scores as covariates, and adjusted mean differences with 95% confidence intervals will be reported. Statistical significance was set at p-value <0.05. Effect sizes, such as Cohen's d for continuous outcomes, will also be calculated to assess the magnitude of the intervention effect. All analyses will be conducted using intention-to-treat principles, with last observation carried forward for participants lost to follow-up, ensuring robust estimation of intervention effects.

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