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CLINICAL RESEARCH- RESEARCH PROTOCOL OPEN ACCESS

PROTOCOL FOR A MULTI-CENTRE, OPEN-LABEL CONTROLLED STUDY COMPARING THE EFFICACY OF AYURVEDIC THERAPEUTIC PROCEDURES AND PHYSIOTHERAPY IN SARVANGA VATA ROGA (SPASTIC CEREBRAL PALSY)

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ABSTRACT

Background: Cerebral palsy is a group of permanent disorders of movement and posture causing activity limitation that are attributed to non-progressive disturbances in the developing fetal or infant brain.Its incidence is more common in low birth weight infants who weight less than 1000gm, 15 in 100 births.As previous study shown good results of Ayurveda with other intervention, this study is a novel to know the combined effect of Ayurveda therapeutic procedure and gold standard of cerebral palsy,physiotherapy as a multi modal approach compare with other multi modal like approach like occupational therapy,orthopedic management,Baclofen to reduce spastic condition.Cerebral palsy by its clinical features can be correlated to sarvanga vata roga of Ayurveda texts,which is caused by vata prominent, vatasyopakrama is employed in this study -Abyanga, basti, upanaha,sirodhara and physiotherapy along with controlled cases of physiotherapy. **Material and Methods :** The current research is a prospective , open label, randomized controlled clinical trial consisting of total sample size of 40 participants diagnosed with spastic cerebral palsy. 20 each in study and controlled. **Study group** will be treated with *Sarvanga abyanga* with rasa taila for 15minutes,*Parisheka* with *dasamoola Kashaya* for 15minutes, *Masha godhumadhi upanaha* for 3hour, *Matrabasti* with rasa taila (dose as per the age) after food and Physiotherapy For 30 minutes . All the procedures will be done daily for a period of 15days. Similar course of treatment will be repeated for 2 times with a gap of 15days in between. During the period of 15 days gap parents is advised to continue the exercises at home for 30 minutes every day. **Control group:** will be subjected to physiotherapy with Paediatrics physiotherapy directed gross motor activities and exercises for 15days. Similar course of treatment will be repeated for 2 times with a gap of 15days in between. During the period of 15 days gap parents is advised to continue the exercises at home for 30 minutes every day. **Conclusion**: The findings of the study could potentially demonstrate that the Ayurveda Therapeutic intervention along with Physiotherapy is more effective as Physiotherapy alone in the management of spastic cerebral palsy.

Keywords - Spastic cerebral palsy, *sarvanga vaata roga*, Physiotherapy , Ayurveda therapeutics.

Trial registration : Clinical Trial Registry Of India (CTRI/2023/10/059262)

BACKGROUND AND RATIONALE

Cerebral palsy is diagnostic term used to describe a group of permanent disorders of movement and posture causing activity limitation that are attributed to non-progressive disturbances in the developing fatal or infant brain.[1] Motor disorder accompanied by disturbance of sensation, perception, cognition, communication and behaviour as well as by epilepsy and secondary musculoskeletal problem. [1] Estimated incidence is 2.95 per 1000 children with male to female ratio of 1.4 : 1.2 Prevalence has increased as a result of the enhanced survival of very premature infants weighing less than 1000gm at a rate of 15 per 100.[2] This disease requires multi modal therapy for the management. Physiotherapy is considered as current gold standard treatment for the management of CP. Other modalities like surgical interventions are used in conditions like orthopedic deformities and severe contractures.[3] Medications like baclofen pump inhibitors, oral muscle relaxants and Botox injections are also in vogue for selected case managements in CP.[4] yet, none are considered as complete treatment.

In Ayurveda, Previous researches have tried to correlate cerebral palsy for *vata vyadhi* of early onset or *samvardhana vikara*.[5,6] So far, research on cerebral palsy with Ayurveda selected procedure have evaluated therapeutic effects on cerebral palsy. No documented / evidence-based publications are available on effect of Ayurveda therapy along with physiotherapy. However, there are evidences of combining physiotherapy with home based traditional interventions from complementary and alternative medicine.[7] Thus, this study would be of first of its kind to compare Ayurveda therapeutics combined with Physiotherapy over Physiotherapy alone in children with spastic cerebral palsy. If proven useful, this can lead to more effective treatment modality for managing spasticity.

In Ayurveda, there is no direct and explicit reference for Cerebral palsy. On analysis of symptom complex and scattered references available in the context of *samvardhana ghrita*, *akala pravahanajanya vyadhi*, *phakka chikitsa* and *vata vyadhi* context, this particular disease can be viewed as *sarvangavata roga* of varied etiopathogenesis. Spasticity is the cardinal manifestation of spastic cerebral palsy involving predominantly single limb (monoplegia), both lower limbs (diplegia), one upper and lower limb with the other lower limb (triplegia) and all the four limbs (quadriplegia).Such references are dealt in the context of *Pakshaghata* and *sarvanga roga* with *karma kshaya*, *chestahani*, *gatrastabdhata* and *vikunchana* being most predominant features. Other features include *ruja* and *vakstambha*.[8] Thus, this particular disease can be understood on the basis of *sarvanga roga* due to predominant *vata dushti.* Hence, general line of treatment adopted will be as per *samanya vatasyopakrama*.[9] *Abhyanga, parishekasveda, Upanaha* and *basti* are amongst the *vatahara upakrama* that are taken for evaluation in this trial. *Rasa Taila* [10] is *vatahara taila* mentioned in the context of *vatavyadhi chikitsa* of Arogya Raksha kalpadhruma. It consists of *bala, taila, ksheera*, *cchagamamsa* as major ingredients and is postulated to be *vatahara, balya*

and *brimhana*. *Parisheka sveda* with *Vatahara dravya* is useful in relieving the *ruja, gatrastambha* and *vikunchana. Dashamula* [11] are considered to be the group of ten drugs consisting of *bilva*, *agnimantha, shyonaka, patala, gambhari, brihati, kantakari, gokshura, shalaparni* and *prishnapani* which are *vatakapha hara* and *shothahara* in nature. Whenever, *gatrasankocha* is associated with *vikunchana,* local *Upanaha sweda* is mentioned to relieve the symptoms. Thus,*Upanaha sveda* is considered as choice of therepy to relieve *gatrastambha* and *vikunchana* (spasticity). Considering the varied symptom complex and *gambheerata* (deep engraved pathology) of the disease multiple external therapies with physiotherapy is selected for evaluation in this trial.

OBJECTIVES

Primary objective:

To assess and grade the spasticity in children with Ashworth spasticity grading [12] and goniometry

To evaluate the effect of Ayurveda therapeutic procedures and physiotherapy on spasticity in children with cerebral palsy

Secondary objective:

To evaluate the effect of Ayurveda therapeutic procedures and physiotherapy on gross motor functions and milestones in children with cerebral palsy

To compare the combined effect of Ayurveda therapeutic procedures and physiotherapy on quality of life in children with cerebral palsy

Trial design

It is designed as a prospective, randomized, controlled, open-labelled multicentric equivalence trial with two parallel groups and primary end point of change in the ICF and Quality of life at the end of 3 months. Randomization will be performed as block randomization with 1.1 allocation.

Study setting

Both groups will receive treatment for the spastic cerebral palsy

TRIAL GROUP- Ayurveda intervention and Physiotherapy from SDMIAH Kaumarabhritya OPD/IPD Bengaluru

CONTROL GROUP - only physiotherapy treatment from SDM Dharwad paediatric Physiotherapy unit.

Eligibility criteria

Patients must provide written, informed consent before any study procedures occur

ICD-10-CM G80

Inclusion criteria:

1. Children of either gender aged between 2-10years with developmental delay and spastic or diagnosed cases of spastic cerebral palsy
2. Children whose parents are willing to sign the informed assent
3. Diagnosed case of spastic cerebral palsy with well controlled epilepsy

Exclusion criteria:

1. Children with uncontrolled seizure disorders
2. Children with severe contracture requiring surgical intervention
3. Children with other form of severe disability

Interventions

All the medication for the intervention are procured from GMP – Certified pharmacies that align with the

manufacturing standards laid down in Ayurveda Pharmacopoeia of India, as applicable

For study group

20 subjects in the study group will be treated with

1. *Sarvangaabyanga* with *rasa taila* for 15minutes
2. *Parisheka* with *dasamoolaKashaya* for 15minutes
3. *Masha godhumadhiupanaha* for 3hours
4. *Matrabasti* with *rasa taila* (dose as per the age) after food
5. Physiotherapy For 30 minutes

All the procedures will be done daily for a period of 15days. Similar course of treatment will be repeated for 2 times with a gap of 15days in between. During the period of 15 days gap parent is advised to continue the exercises at home for 30 minutes every day

For Control group:

20 subjects in control group will be subjected to physiotherapy with Paediatric physiotherapist directed gross motor activities and exercises for 15days.Similar course of treatment will be repeated for 2 times with a gap of 15days in between. During the period of 15 days gap parent is advised to continue the exercises at home for 30 minutes every day.

Outcomes

Primary outcome measure :

1.Reduction in spasticity

2.Improved range of movement

3.Improved gross motor function

4.Improved quality of life

Secondary outcome measures:

Decreasing in drooling , improvement in chewing and speech

Sample size :

Sample size was determined based on the standard deviation and the percentage of improvement in a previous trail. Using the prevalence formula N= z2 pq/ d2

Estimated sample size is 256. considering the cost, the availability of patients and duration of the study it is planned to take up 40 children 20 in each group Using Co-crane formula for Previous work SD/√n = 0.5/√40 = 12.15

Considering drop outs, taking 20 samples in each group.

Recruitment:

Children of either gender aged between 2-10years with developmental delay and spasticity or diagnosed cases of spastic cerebral palsy visiting SDMIAH Kaumarabhritya opd/ipd shall be enrolled for trial intervention.

Similarly 2-10years with developmental delay and spastic or diagnosed cases of spastic cerebral palsy visiting Pediatric Physiotherapy OPD in SDM Physiotherapy college, Dharwad will be enrolled for control group .

METHODS

Study design – intervention, Prospective, randomized, controlled, parallel group, clinical study

Allocation: Random 1:1 allocation

Blinding – open-labelled

Data collection methods

Data will be collected through the specially designed Case Report Form (CRF) and the

assessment tools consisting of International classification of Function, Goniometry, Modified Ashworth scale of spasticity, Muscle power test and Quality of life Questionnaires

Data management

Data collected will be entered in the CRF specially designed for the study by the researcher and will be later transferred to MS office excel and IBM SPSS version 26.

Statistical methods

For statistical analysis, the data will be obtained using Case Report Form (CRF) designed by incorporating all aspects for the study and will be compiled on to a MS Office Excel Sheet. Data will be presented in tabulations and an Analysis will be done using SPSS version 20. Descriptive Statistics will be done by frequency, mean, standard deviation and standard error, median and percentile. Inferential statistics will be done by fixing level of significance at $P<0.0$. Subjective data will be assessed with non-parametric tests namely Wilcoxon-signed rank test for before and after treatment differences within group. While parametric data with Mann Whitney U test for between the trial and control group. Freidman test may be used for multiple comparison of more than 2 sets within the same group. Numerical data will be analyzed with paired and unpaired t test for between groups and within group before and after the trial. Categorical data would be assessed with Chi-square test. The magnitude of the efficacy will be assessed by Effect size.

Data monitoring

Data will be monitored by the researcher, the guide and the therapist. They will take responsibility for monitoring intervention protocol, adverse effects and enrolment of participants. Periodic data will be submitted to department research and data monitoring committee for trial progress and data monitoring through the periodic review meetings and site visits if required. They will also audit data and carry out any interim analysis on need basis. All kinds of changes in study methods and treatment shall be reported to the Ethical Review Board via the principal investigator. Home based sensory stimulation activities will be regularly monitored through the electronic media.

Safety measures and managing adverse effects

Although it is anticipated that the mentioned protocol won't result in any serious side effects, the monitoring team will take note of any unexpected occurrences that do happen during or after intervention and will principally inform the relevant specialists about them. The concerned therapist will make a note of adverse events with the therapies in their record and later let the lead investigator know. Before beginning, the child's parents will be asked about any food allergies. They will be oriented about the probable adverse events with oral medication and therapies so that they shall inform principle investigator at the earliest. Any significant negative effects will be noted and published in the trial's final publication.

Ethical issues and informed consent

This research protocol has been reviewed and approved on October 8, 2022 by the Institutional Ethics Committee of Sri Dharmasthala

Manjunatheshwara Institute of Ayurveda and Hospital (SDMIAH) granted the trial ethical approval (SDMIAH/IEC/55/2022) & Institutional Ethics Committee of SDM Dharwad University granted the trial ethical approval(SDMIEC/2023/555).CTRI/2023/10/059262 - on 30/10/23 the trial has been registered prospectively with the Clinical Trial Registry India (CTRI). The researcher will adhere to the Helsinki statement, to maintain ethical principles. The trial participants will sign a written informed consent before enrolment. The respondent's participation will be voluntary and they will have the ability to leave at any point during the trial. Withdrawal from the trial will not make any effect on their treatment process. The completed trial data set will be made available to the primary investigator, data auditors, and authors when the procedure has been made anonymous If there are any unfavourable consequences, there will be post-trial treatment. However, the research findings may be disseminated through publication in open-access peer-reviewed journals and conference presentations.

Study status

Study has been completed and 20 participants have been enrolled in each group

Dissemination

After the end of the trial, a research paper will be submitted to an indexed journal for publication of the original research. Besides the trial, a seminar will be conducted to share the results with relevant stakeholders. A structured awareness program will also be organized if the study results are found to be effective. The trial results will be published as open access to ensure maximum visibility of the original research.

DISCUSSION

Estimated incidence is 2.95 per 1000 children with male to female ratio of 1.4 : 1.2, Prevalence has increased as a result of the enhanced survival of very premature infants weighing less than 1000gm at a rate of 15 per 100. In view of multi modal therapy in cerebral palsy like Physiotherapy, occupational therapy, Ortho procedures, medical management are some commonly used procedures, first time Ayurveda therapeutical procedure taken along with physiotherapy in trial group and Physiotherapy alone in controlled group, compare the results between the groups done. Better outcome from Ayurveda and Physiotherapy has been seen in current trial.

Supporting information

Nothing specific

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