Statistical Analysis Plan

Effect of delorme resistance exercises versus treadmill training on locomotor abilities in cerebral palsy after Achilles tendon release

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1. INTRODUCTION

Cerebral palsy is defined as a cluster of non-progressive motion and posture disorder resulting from irreversible damage to immature brain. The neurological deficit related to Cerebral Palsy is irreversible, muscular fatigue, musculoskeletal limitations and pain are found to be contributory factors in cerebral palsy children that may incorporate a decline in locomotion(1).Cerebral palsy is one of the most important source of disability among children and its incidence is almost 3.6 in thousand live births(2). Children with Cerebral Palsy presents with ambulatory difficulties. The attainment of independent and efficient locomotion is important for musculoskeletal growth and cardiopulmonary progress as well as for functional activities. Therefore, it is an essential aim of rehabilitation in these children(3).

Cerebral palsy children have frequent gait abnormalities secondary to development for which there is intense need for surgical corrections. Excessive Achilles tendon lengthening results in paresis of gastrosoleus and Achilles tendon that contribute to compromised locomotor abilities(4). The cerebral palsy children substitute the functional activities by utilizing alternate movement strategies. The development and persistence of compensatory patterns direct the goal of physical therapist towards minimizing these patterns. Thus ensuring improved muscle coordination and enhanced locomotor activities(5). Strength building resulting from DeLorme resistance exercises is significant for recurrence prevention and for enhancing the muscular performance(6).

Treadmill training is a fairly new approach that is utilized to efficiently train ambulation in Cerebral Palsy children. It stimulates repetitive stepping in an upright position with support,

bearing weight on lower limb. It also enhances strength of lower extremity and improve balance reactions which aid in the locomotion process.(7)

The combined effect of treadmill and endurance training results in significant improvement in strength of muscles and prevents the recurrence of injuries as well as facilitates the rehabilitation. Therefore they play an important role in maintaining the functional capacity thus leading to improved fundamental activities of daily living. In addition, these resistive exercises along with strength also improve balance of the cerebral palsy children ensuing increased social participation. Strength development resulting from these interventions enhances locomotor abilities of the child enabling them to play, work and perform daily life activities efficiently.

Insufficient evidences are available on treadmill training in pediatric population. The current study highlights the effect of treadmill training as compared to DeLorme resistance exercises on locomotor activities in cerebral palsy child. The present study would add to the clinical knowledge of physical therapists by promoting the implementation of treadmill training and DeLorme resistance exercises for this prevalent pediatric neurodevelopmental disorder. The study would decrease the burden of disease among community and enhance the social participation of cerebral palsy children. This in turn would improve the quality of living of these disabling diseased children.

1.1 Study Objectives

To assess the effect of treadmill training as compared to DeLorme resistance exercises on locomotor activities in cerebral palsy children with Achilles tendon lengthening.

1.2 Study design

This is a single blinded Randomized Clinical trial to compare the effects of delorme resistance exercise versus treadmill training on locomotor abilities in spastic cerebral palsy children after Achilles Tendon Release. The study will be conducted at Dimensions Institute for Special Education and Psychological Services. There will be eligibility criteria and random assignment of participants to groups through simple random sampling.

Treatment

Baseline

- Review of inclusion and exclusion criteria
- Informed consent obtained and subject number assigned
- Demography
- Past medical history
- Past physical therapy rehabilitation history
- Medical history
- Prior and concomitant medications
- Vital signs

Week 1 – Clinical Visit

Randomization into group A and group B

Week 2

Treatment administered

Group A: 5 minutes warm up, 15 minutes hot pack, 20 minutes stretching, 15 minutes treadmill training, 5 minutes cool down

Group B: 5 minutes warm up, 15 minutes hot pack, 20 minutes stretching, 15 minutes delorme resistance exercise, 5 minutes cool down

Week 3- 12

Same treatment as week 2

Week 13

Assessment of Outcome measure (Locomotor abilities)

Treatment will be provided for total of 1 hour six times a week for three months.

STATISTICAL METHODOLOGY

Tables of continuous variables, the minimum and maximum statistics, the arithmetic mean and median, the 95% confidence interval, standard deviation, and standard error will be presented for pretreatment and post treatment Group A and B ABILOCO scores.

Hypothesis testing will be carried out at 5% significance level. P values less than 0.05 will be considered as significant.

Drop Outs and Missing data

Drop outs and missing data will be recorded.