

EFFECTIVENESS OF THERASUIT METHOD™ AND THE THERASUIT™

PILOT STUDY

RESULTS OF THE INTENSIVE EXERCISE PROGRAM IN THE PEDIATRIC CEREBRAL PALSY POPULATION

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Objectives:

This study is part of a multi-site ongoing study and was designed to evaluate the effectiveness of an intensive exercise program (TheraSuit Method™) using a Soft Dynamic Proprioceptive Orthotic (TheraSuit™) on children with cerebral palsy by measuring changes which occurred after participating in a treatment session at the Pediatric Fitness Center, Keego Harbor, Michigan.

The primary goal of the outcome study was the assessment of functional skills which have the most influence on the quality of life.

Design: Ongoing study using a group pre-test/post-test design. A four-level diagnostic algorithm has been designed for the complex evaluation of all participants. It includes the preliminary selection, obtaining the initial data necessary to develop the individual exercise program, collection of changes during and after the program and preparation of the individual home exercise program.

Setting: Intensive exercise program at the Pediatric Fitness Center, Keego Harbor, MI.

Length of the study: The results of this study were obtained during treatment sessions from July 2003 – May 2004.

Patients: 20 children (12 females and 8 males) with a mean age 6.3 (range of 2.5 to 13) and with a primary diagnosis of cerebral palsy.

Materials/Methods: During this study we used the TheraSuit Method™ and the TheraSuit™ (Soft Proprioceptive Orthotic- protected by a patent as a “Neurological Motor Therapy Suit”). All participants underwent evaluation pre and post exercise session. All data was recorded using the Gross Motor Functional Measurement form. Additionally, all participants were video taped before and after treatment.

Interventions: An intensive exercise program (consisting of 3 hours of exercises, 5 times a week for 3 weeks) was provided for the qualified participants. Treatment was administered by therapists/trainers trained in the Therasuit Method™. The intense program protocol included individually designed exercise programs for all participants including exercise with and without TheraSuit™.

Measurements and Main Results: All results were statistically evaluated. The results obtained from the study are presented in Fig.1 and Fig.2. In this publication we included only part of the collected outcomes. The study reveals functional improvements in 92% of the participants. Additional progress was made in coordination by 56%, strength by 100%, range of motion by 100%, balance by 62% and movement control by 64%. We noticed a significant improvement in the level of new functional skills learned by our participants during the exercise sessions. In the study group, 90% learned to roll independently, 75% learned to sit without assistance, 49% learned to crawl, 39% gained the ability to stand independently, 33% learned to walk with assistive devices and 21% gained the ability to walk independently.

Conclusions: The results of our study confirm the high level of effectiveness of the intensive exercise method (TheraSuit Method™) in conjunction with the Soft Dynamic Proprioceptive Orthotic (TheraSuit™). In the future, Therasuit LLC will continue to collect, analyze and compare data obtained from other facilities using the TheraSuit™ and TheraSuit Method™ according to the standards and quality established in the industry. We will update this study as soon as the results from other facilities are analyzed and published.

FUNCTIONAL PROGRESS AFTER THERASUIT METHOD™

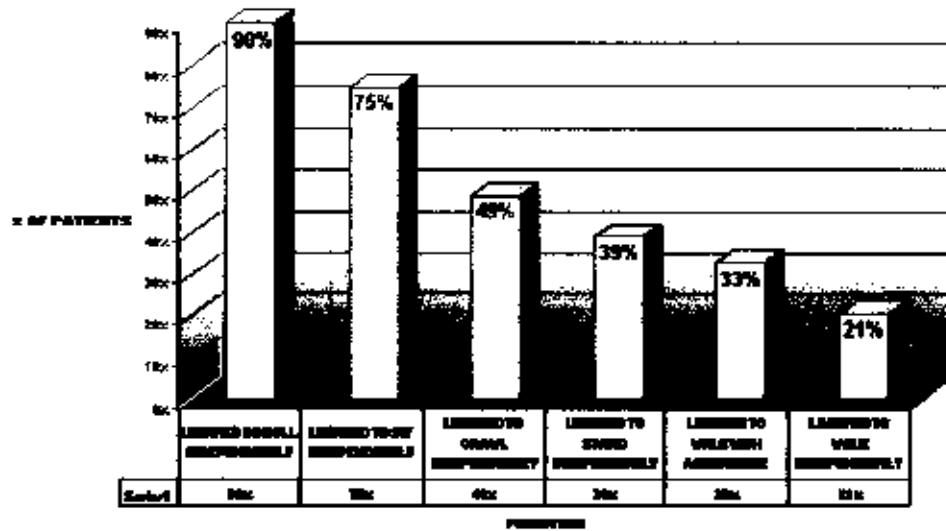


Fig. 1 FUNCTIONAL PROGRESS AFTER THERASUIT METHOD™

IMPROVEMENTS AFTER THERASUIT METHOD™

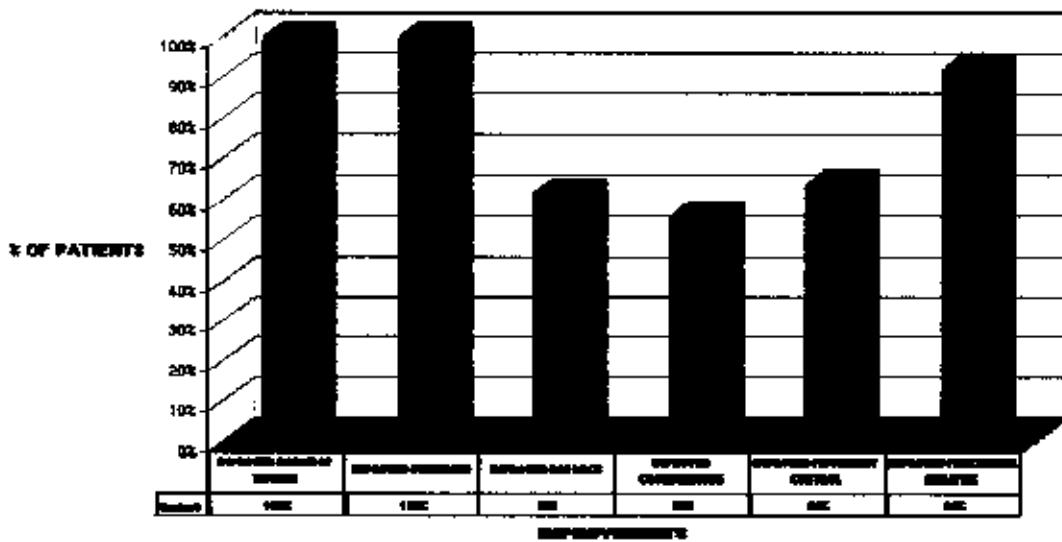


Fig. 2 IMPROVEMENTS AFTER THERASUIT METHOD™