THE EFFICACY OF THE NEURODEVELOPMENTAL THERAPY TREATMENT APPROACH IN 4 - 7 YEAR OLD CHILDREN WITH CEREBRAL PALSY

BY

LOUISE FITZPATRICK

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MISS S IRWIN-CARRUTHERS

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DECLARATION

I, the undersigned, hereby declare that the work contained in this thesis is my own original work and that I have not previously, in its entirety or in part, submitted it at any university for a degree.

Signed: Date:

Louise FitzPatrick

ABSTRACT

Although the neurodevelopmental therapy (NDT) treatment approach is used extensively in the management of children with cerebral palsy, there is currently very little documented research to support its efficacy. The purpose of this study was to evaluate the efficacy of NDT in terms of its effect on motor function in a group of 10 cerebral palsy children. A multiple simple single-subject design was used in which the children each acted as their own controls. A 5 week baseline period, during which no intervention was received by the children, was followed by a 5 week intervention phase during which the children received twice weekly NDT treatment. The children were assessed at the beginning and end of each phase using the Gross Motor Function Measure (GMFM), and an assessment tool, which allowed the establishment of individualised outcome measures, called TELER. The group of children demonstrated no statistically significant gains in motor function on either of the outcome measures during the baseline phase of the study. However during the intervention phase the overall improvements demonstrated by the group on both the GMFM and TELER were statistically significant. Nine out of the ten children achieved greater improvements in their goal total GMFM scores during the intervention phase than during the baseline phase. Similarly all of the children achieved a greater number of clinically significant improvements on the TELER outcome measures. NDT was beneficial and useful in promoting motor function in this group of cerebral palsy children.

ABSTRAK

Alhoewel die Neuro-ontwikkelingsterapie (NOT) behandelingsbenadering wydeverspreid gebruik word in die behandeling van kinders met serebrale verlamming, is daar huidiglik baie min gedokumenteerde navorsing om die effektiwiteit daarvan te staaf. Die doel van hierdie studie was om die effektitiwiteit van NOT te evalueer met betrekking tot die impak daarvan op die motoriese funksie van 'n groep van 10 kinders met serebrale verlamming. 'n Veelvuldige eenvoudige enkeling –subjek raamwerk is gebruik waarvolgens die kinders elk as hul eie kontrolegoep ageer het. 'n 5-weke basislyn fase, waartydens die kinders aan geen intervensies onderwerp is nie, is gevolg deur 'n 5-weke intervensie fase waartydens die kinders twee keer per week NOT behandeling ontvang het. Die kinders is geevalueer aan die begin en einde van elke fase met die Oorhoofse Motoriese Funksie Maatstaf (OMFM)/Gross Motor Function Measure (GMFM), asook 'n evalueringsmaatstaf genaamd TELER, wat die bepaling van geindivualiseerde resultate moontlik gemaak het. Die groep kinders het geen statisties bewese vordering in motoriese funksies getoon volgens beide die evalueringsmaatstawwe tydens die basislyn fase van die studie nie. Daarteenoor het die groep tydens die intervensie fase oorhoofs gesproke statisties bewese vordering getoon met betrekking tot beide die OMFM en die TELER. Nege uit die 10 kinders het groter vordering getoon met hul totale OMFM resultate tydens die intervensie fase as gedurende die basislyn fase. Al die kinders het tegelykertyd 'n groter hoeveelheid substantiewe kliniese verbeterings getoon met betrekking tot hul TELER uitkomste. NOT was voordelig en nuttig in terme van die verbetering van motoriese funksie in die groep van serebraal verlamde kinders.

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CHAPTER 1
INTRODUCTION

In South Africa today, and indeed in many other parts of the world, the vast majority of young children in whom a diagnosis of cerebral palsy is made are referred by their paediatricians to a physiotherapist. Over the years there have been many different approaches and treatment methods adopted in the management of these children. It would seem that despite a reasonably good understanding of the anatomy of the central nervous and neuromuscular systems, the physiological mechanisms behind their functioning have, in the past, been poorly understood. This has provided a platform for the conception and development of a variety of treatment approaches[1], some orthodox and others considerably less so, for these children. These approaches have, in many cases, been based on purely speculative mechanisms of functioning of the nervous system, with some having made drastic claims of being able to afford complete cures. The neurodevelopmental therapy (NDT) approach to the management of the cerebral palsy child is probably the approach most commonly adopted by physiotherapists today when treating children with cerebral palsy. NDT makes no claims to cure cerebral palsy but rather its ultimate goal is to optimise both the child's functional abilities and his/her participation in daily life.

Although used extensively in the management of children with cerebral palsy, over the last few years NDT has come under much criticism in the literature for this continued use in light of the lack of documented research to support its efficacy[2,3,4,5,6]. Ottenbacher *et al*[6] performed a quantitative review of published studies investigating the effectiveness of NDT on children with developmental delay or disability (including cerebral palsy). Following their analysis they concluded that overall treatment effects were small in subjects receiving NDT.
A review by Parette and Hourcade[7] concluded that as research paradigms became more rigorous, support for therapeutic intervention decreased.

There is currently very little evidence to support the efficacy of NDT in the management of cerebral palsy, but in spite of this there is still a great demand for this form of therapy[8]. Children continue to be referred for this as well as other rehabilitation and therapeutic services[9]. There is a heightened awareness in both the public and private sector and an increase in legislation, concerning the rights of handicapped children[7,10,11]. Improved health care has meant that children more commonly survive premature or complicated deliveries; birth defects; post-natal illnesses and complications; meningeal infections; and head injuries to name but a few. In addition there is improved early identification of those with developmental delays or deviations. It would seem that not only is the demand for therapeutic intervention greater but it is increasing.

Therapeutic intervention is frequently given on a long-term basis in the cerebral palsy child and involves great expense to the parents, particularly in the private sector. Patients who attend state hospitals for therapy are often from the lower socio-economic groups and the cost of transport, as well as lost earnings when time must be taken off from work, are a significant expense to these families. If we are to continue to offer NDT as a form of intervention for cerebral palsy children we have a responsibility to both the child and his family to demonstrate conclusive evidence of its effectiveness and benefits. Insurance and medical aid schemes, government

departments (health and education) and our fellow medical professionals are also demanding the need for justification of our treatment approaches, both in terms of their practical efficacy and theoretical basis. We can no longer ignore the need for evidence based practice.

Outcome research in the areas of developmental medicine and cerebral palsy has not been as extensive or of the quality of that in other branches of medicine[12,13] and there is a tremendous lack of evidence for much of what is practised in these areas[14]. It is only recently that concerted attempts have been made to evaluate the outcomes of NDT critically. The methodological difficulties encountered in such evaluations are numerous. The majority of studies have been poorly designed and executed in relation to the type of study design used; sampling and the definition of criteria for subject inclusion; matching control and experimental groups; clearly defining the intervention procedure; and the choice of outcome measure[6,7,9,10,12,15,16].

The randomised controlled clinical trial has long been considered the 'gold standard' in medical research for proving a relationship between treatment and clinical outcome[9,17]. This however requires a homogenous group of patients receiving identical treatments in order to restore function to an agreed physiological norm[9]. In cerebral palsy this is exceedingly difficult to achieve - each child is different and the expected outcome of each child is different. The randomised controlled clinical trial also requires treatment to be withheld from the control group, which is considered by many to potentially raise ethical concerns[10,11,16,18].

In addition to difficulties with the study design, much of the problem with the lack of evidence supporting the use of NDT probably stems from the lack of a suitable outcome measure that can accurately detect change following therapeutic intervention. Outcome measures need to be valid and reliable and must be able to be applied to the tremendous variation seen in cerebral palsy. In the NDT approach treatment is centred around specific functional goals or tasks. The degree of attainment of these goals or tasks by a child should surely provide us with a means of assessing how effective therapy has been. If we could combine a standardised means of setting valid and reliable goals with a valid and reliable means of measuring the attainment of these goals we would have an assessment tool that would be applicable to each and every cerebral palsy child irrespective of his/her level of disability.

This study used an alternative study design from the randomised controlled clinical trial traditionally used in the medical and paramedical fields to establish cause-effect relationships, to investigate the efficacy of the NDT treatment approach in children with cerebral palsy. Both a standardised assessment tool (the Gross Motor Function Measure[19]) and a tool which allows for specific goal setting for individual children (TELER[20]) were used to this end. The objectives that were established for the study follow.

OBJECTIVES

The aim of this study is to evaluate the efficacy of NDT in the management of cerebral palsy children, in terms of its effect on motor function, where efficacy is defined as the extent to which a therapy is more useful and beneficial than useless and harmful for the purpose for which it is advocated[10].

The study will also investigate the feasibility of using TELER as an instrument with which to measure outcome in cerebral palsy children treated by NDT.

Null Hypothesis

The null hypothesis is:

$H_0 : \mu = 0$ (i.e. NDT has no treatment or treatment-like effect on motor function in the child with cerebral palsy);

and the alternate hypothesis is:

$H_1 : \mu \neq 0$ (i.e. NDT has a treatment and/or treatment-like effect on motor function in the child with cerebral palsy).

Research Questions

1. Is NDT plus a home programme more effective than a home programme alone in promoting motor function in the child with cerebral palsy?

2. If a change in motor function occurs, is this change attributable to the NDT received by the child?

3. Is the TELER system a feasible outcome measure to use in terms of detecting clinically significant change in gross motor function in cerebral palsy children treated by NDT?

4. Could the GMFM assist in establishing the validity of TELER indicators used to trace change in children with cerebral palsy?

The following chapter provides a background to the NDT treatment approach, the theoretical assumptions underlying it, and how it is currently used in the treatment of cerebral palsy children. This is followed by a comprehensive review of the studies published to date that have investigated the outcomes of NDT in the treatment of cerebral palsy children. The different study designs employed are discussed, as are the issues in measuring outcome in this group of children. Rationale is given for the choice of the two outcome measures to be used in this study, each of which is presented and discussed in turn. A detailed description of the methodology that was used is presented in chapter 4; and is followed by the presentation and discussion of the results that were obtained.

CHAPTER 2

THE NEURODEVELOPMENTAL TREATMENT APPROACH: PAST AND PRESENT

2.1 Introduction

The term neurodevelopmental therapy (NDT) is, in this study, used to denote the use of the Bobath concept in the evaluation and treatment of children with cerebral palsy. Although there has in recent years been some controversy about the use of this term, it was originally proposed by the Bobaths themselves and has been used in this study as it acknowledges the dual nature of the impairment in cerebral palsy[21]. The Bobath concept has most recently been defined as: "a problem solving approach to the assessment and treatment of individuals with disturbances of function, movement and tone due to a lesion of the central nervous system. The goal of treatment is to optimise function. The ongoing process of assessment and treatment is directed towards those impairments interfering with function as well as towards integrating improved control into participation in daily life."[22]

The NDT approach developed gradually and was the result of the observations and work of Dr Karel and Mrs Berta Bobath that began in the 1940's. Specifically it was noted that certain methods of handling spastic patients resulted in changes in the postures and movement exhibited by these patients and, with continuing observation, as well as attempts to explain such observations, the NDT approach was born. The Bobaths[23] emphasised that NDT was not a "method of treatment" as this would imply something rigid and standardised; rather it was a flexible approach to management which would accommodate the tremendous variations seen in cerebral palsy. As newer understandings of movement and movement control have evolved so has the approach grown and developed[24]. The Bobaths[23] themselves have said: "Since we began our treatment in 1943 we have been learning constantly, and experience has taught us to change our approach and our emphasis on certain aspects of our treatment." Nonetheless the basic concept has stayed the same[25] with the emphasis being on the neurological aspect of the movement disorder and the therapist's ability to observe and analyse this disordered movement.

This chapter will give an overview of the approach and the theories that have supported and changed NDT from its early origins through to how it is utilised today in the treatment of the child with cerebral palsy. It is beyond the scope of this chapter to argue in depth the merits and demerits of all the theories and ideas presented. It is intended only to demonstrate how change and progress in theoretical thinking has brought us to where we are today in the application of the NDT approach to the treatment and management of the child with cerebral palsy.

2.2 NDT: The Early Years

At the time when the Bobaths began their work the nervous system was viewed as a hierarchical structure of reflex levels. The hierarchical/reflex model supposed that wilful or volitional movement originates at a cortical level and that as higher centres of the nervous system develop so the reflex activity of the lower centres is inhibited[26]. With maturation of higher levels, the more primitive reflexes disappear and more mature reactions appear. The normal development of an infant was thought to follow this step-like hierarchical process. With a lesion of the brain, loss of the inhibition from higher centres results in a predominance of primitive reflexes and affects the normal postural tone required for normal movement. Abnormal tone or spasticity results. The model also supposed that all movement is reactive and occurs in response to a stimulus[26]. This stimulus/response mechanism and the feedback received by the nervous system from the response allow the learning of a motor skill in normal movement patterns.

Based on this, the Bobaths put forward what they referred to as "a working hypothesis" to explain their clinical observations. They proposed the idea of a normal postural reflex mechanism[27]. This normal postural reflex mechanism provides three essential factors required for skilled functional movement: normal postural tone; reciprocal innervation; and normal automatic movement patterns, that form a background against which all movement takes place. A lesion in the brain such as is seen in cerebral palsy interferes with this normal postural reflex mechanism resulting in abnormal postural tone, disordered reciprocal innervation and abnormal movement patterns[27]. Instead of the higher righting and equilibrium reactions of the normal postural reflex mechanism, abnormal reflexes of the lower levels of the hierarchical structure of the nervous system (the tonic neck, tonic labyrinthine and positive support reflexes) predominate[23,24,27]. In addition the stimulus-response mechanism in a child with cerebral palsy would result in the release of abnormal, primitive reflex patterns. These primitive reflex patterns would result in abnormal sensory feedback which in turn would result in an inability to learn normal movement patterns and the abnormal patterns would be reinforced.

The Bobaths felt that inhibition of these abnormal tonic reflexes was essential in order to gain better postural control and selective, graded movement. Inhibition, in the form of reflex inhibiting postures which stopped these abnormal reflexes and decreased tone, and facilitation of the righting and equilibrium reactions formed a large part of treatment in the early years[23]. The premise was that this would give the child a basis for functional and voluntary movement. Missing components of the developmental sequence were also facilitated. In fact early treatment was rather hierarchical in nature[26], drawing a parallel to an extent with the way the nervous system was viewed at the time.

The initial use of reflex inhibiting postures to inhibit abnormal postures and decrease tone was soon realised to be too passive as these reflex inhibiting postures did not really allow for sufficient movement. The Bobaths began using key points of control from which abnormal patterns of movement could be inhibited and more normal patterns of movement facilitated[23,24,25]. Inhibition of the abnormal patterns was necessary for the facilitation and development of the more normal movement patterns. In addition Mrs Bobath stressed the importance of analysing the child's movement to assess which patterns of movement were being used and which movement

components were missing. This combination of facilitation and inhibition is still used as part of the NDT approach and the observational skills of the therapist remain of paramount importance. She must be able to identify the movement patterns that need to be changed and must have a logical plan of the normal patterns that need to be facilitated.

As the normal development of an infant was thought to follow a predictable sequence based on the hierarchical development of the levels of the nervous system, so too was recovery from brain damage thought to follow a similar sequence. Consequently early NDT treatment of the cerebral palsy child followed the normal sequence of development and therapy was progressed according to this sequence. This aspect of the approach has been criticised extensively in the literature[28], however the Bobaths themselves had already abandoned this aspect of treatment, noting that even normal children do not adhere to such a strict developmental sequence. "Treatment should not attempt to follow the sequence of development. ....Rather it should be decided what each child needs most urgently at any one stage or age and what is absolutely necessary for him in preparation for future functional skills or for improving the skills he has, but performs abnormally. ....There is no time to waste on unspecified developmental treatment, for we cannot expect that such treatment will automatically carry over into functional skills later on."[23].

2.3 NDT: Current Theoretical Thinking

Current theoretical assumptions underlying NDT philosophy have changed considerably over the last ten years, both during the Bobaths lifetime and since[16]. Not only has our view of the nervous system and its role in motor control undergone considerable change, but the underlying theoretical base has been increased to include aspects of motor learning theory, the behavioural sciences, muscle physiology and biomechanics[28].

Many authors have written reflecting their thoughts and ideas surrounding the structure of the nervous system and its role in motor control, but there does not seem to be one consistent "best" theory and there is even less consistency in naming the proposed theories. We have systems theories, control systems frameworks, dynamic systems approaches, dynamical action theories, distributive models, parallel distributive control models, motor programming theories, and task oriented theories. Some are theories that stand alone and others are based on combinations of more than one theory.

Gordon[28] is quoted as saying that it is important that we: "...evaluate a model not in terms of its theoretical purity, or 'rightness' , but in terms of its usefulness, that is, whether the model generates practical ideas for solving our clinical problems." And indeed, our change in thinking regarding the nervous system and how it controls movement came about with the realisation that the hierarchical/reflex model does not and cannot account for the complexity of movement and postural adjustments that are observed and occur in the performance of normal movements. Posture and movement cannot only be due to a feedback system because if we observe normal movement we see that postural adjustments take place in anticipation of movement. These adjustments have been demonstrated in studies looking at human postural responses and are task or context dependent[29]. They appear to

occur automatically and are certainly not initiated at a conscious/cortical level. They are predictive but can be modified by instructions making them adaptive to the circumstances of the movement[30]. So as well as using feedback systems for postural adjustments during movement the nervous system must use feed-forward systems which enable it to initiate, anticipate, and control movement[24,31]. The currently accepted "best" model of the nervous system is a combination of elements taken from several theoretical sources and is referred to as the distributive control or systems model[24,32]. Some of the concepts of this model (in particular systems theory) are fairly abstract and there are problems with relating them to the anatomical structure of the nervous system. In reality it is most likely that our motor control system possesses properties of both the hierarchical and distributive control models[33].

The distributive control model describes movement as being initiated and controlled centrally and peripherally. Neural control is distributed throughout the nervous and musculoskeletal systems in a flexible interaction[34]. Groups of neurons distributed throughout the nervous system are responsible for the execution of motor programmes. These motor programmes result in coupling of groups of muscles and joints together into motor patterns or motor synergies. These motor programmes are not purely reactive but are predictive and centrally generated. Brookes[30] refers to motor programmes as: "a set of muscle commands that are structured before the motor act begins and can be sent to the muscles with the correct timing so that the entire sequence can be carried out in the absence of peripheral feedback", highlighting their predictive nature. Some motor programmes are genetic but most are laid down as movement is learnt and perfected. For this learning and perfection to take place the nervous system must be a functionally flexible structure. Initially motor programmes require feedback from the different sensory systems but once learnt they can be initiated without any feedback. Central to the distributive control model is the idea of a feed-forward mechanism which allows for the anticipatory control of movement. However, the feedback mechanism first introduced in the hierarchical/reflex model remains important for the learning and modification of movement. Any movement that has not yet been learned is feedback dependent and learned movements depend on sensory information that is fed back from peripheral sense organs (muscle spindles, joint receptors and cutaneous receptors) when adjustments to the programmed movement are required[30,31]. Movement can be initiated at any one point in the group of neurons responsible for that particular motor programme. Initiation can occur in response to a sensation (e.g. sight, sound, pain); it can be cognitive; and it can be automatic (e.g. a balance reaction).

A pure systems model views movement as a result of the interaction and co-operation of many different systems (not just the nervous system), each contributing to different aspects of motor control[26]. Much of the systems model is based on the work of Bernstein[34] and the suggestion that motor control is distributed throughout the body; a link with the distributed control model. These systems may extend outside the body as is illustrated by Shumway-Cook and Woollacott[32], who in their description of a systems model see movement as resulting from an interaction between the individual, the environment and the required task. This idea of interaction between these three systems ties in with the ideas that surround motor learning theory.

Motor learning is the study of acquisition and/or modification of movement. It can also refer to the re-acquisition of movement that has been lost due to injury[32]. Brookes[30] has defined it slightly differently saying that: "Motor learning is concerned with the co-ordination of joints and as a matter of detail with the muscles that move and hold them.". The infant is born with only rudimentary motor abilities but spends the early years of infancy and childhood (and beyond) learning and practising movement in order to establish the motor programmes discussed earlier. The infant and child must learn the motor skills that allow them to accomplish specific motor tasks within a particular, not always constant environment. This need to solve specific motor problems in the environment results in the development of motor skills. It is not so much movement that is being learnt as rather strategies for solving problems[28]. Again, as with the systems model of the nervous system and motor control, we see a solution to a problem occurring as the result of an interaction between the individual, the task and the environment[32]. This learning is never directed at the control of single muscles but instead concerns the choice and timing of many[30].

A review of several sources[26,28,30,32,35,36] reveals that a successful learning process is dependent upon several factors:

* The individual must understand the behavioural goal that the motor programme or task to be learnt will enable them to accomplish.
* The task and accompanying goal must be relevant and meaningful to the individual and the task must be carried out in a relevant and meaningful environment, which may not always be constant.
* The individual should play an active role in finding ways to achieve the desired goal, as problem solving and active participation are important for learning. Individuals learn by actively attempting to solve problems.
* Practice of the task is essential, but this does not mean just repetition of the motor act. The situation and context in which a task is practised needs to be changed. It is not so much the motor act that is important but rather the problem solving strategy.
* The individual must get feedback regarding performance of the task. Feedback can be both extrinsic and intrinsic. Intrinsic or proprioceptive feedback is dependent on self-initiated movement, emphasising the importance that any individual involved in the learning of motor control should be allowed to initiate and execute a movement in order to achieve a desired goal. Extrinsic feedback is really feedback from the environment. It includes visual and verbal feedback as well as knowledge about the results of the task. In fact, two way communication between the nervous system and the sensory system is important for feedback and where lacking may need to be "substituted" for. A visually impaired patient may need more verbal feedback than a sighted patient, for example.
* Successful accomplishment of a task and achievement of the desired goal as a result of movement, independently or with assistance, will enhance the learning process.
* The attention of the individual to the required task is important. Motivation, alertness and concentration will all effect the execution and learning of the task, as will cognitive function.

The idea of using the motor learning process has been incorporated by Carr and Shepherd[36] into their Motor Relearning Programme aimed at the rehabilitation of the stroke patient. Rehabilitation has much in common with the process of motor learning which has broadened our theoretical base and contributed further to the way we view both assessment and treatment[16,24]. It is important to realise though, that one does not "do motor learning therapy" but that it has application to how we approach our patients[35].

2.4 NDT: Current Practice

Although much of the basic NDT philosophy remains in the current approach to the assessment and treatment of the cerebral palsy child, there is also much that has altered and developed over the years. Gordon[28] views the reasons for change occurring in a therapeutic approach as being twofold. Firstly change occurs because current approaches are not adequate to solve clinical problems as they are perceived by therapists. For a long time an inadequacy of the NDT approach was the lack of carryover of more normal movement patterns into functional, everyday activities. Secondly, approaches change because the theoretical assumptions underlying current approaches do not fit with the current knowledge. He goes on to say that when current approaches are perceived as inadequate both practically and theoretically that optimal conditions exist for therapeutic innovation.

Gordon[28] and Irwin-Carruthers[37] have both written regarding the processes by which therapeutic approaches or strategies can be developed. The inductive process is the process by which the Bobaths developed the NDT approach. It involves observing the patient in the clinical setting and determining effective treatment strategies depending on the patient's response to handling. Only then does one turn to the theory to find a model which supports the clinical findings. The other way in which a therapeutic approach can develop is by first looking at the theoretical assumptions and based on these formulating treatment methods. This is a deductive process and is part of the process by which the NDT approach has altered, grown and developed. It is important to remember that new theoretical models and advances in theoretical thinking do not in and of themselves provide new treatment techniques. What they do provide is a new perspective to the way in which we view our patients[35], our treatment philosophies[28] and our role as therapists[35]. It is only the therapist with her analytical skills, her clinical experience and her knowledge of the underlying theory, who can devise practical and effective treatment strategies and techniques for the patient.

The early years of the NDT approach saw the movement patterns and patterns of abnormal tone exhibited by the cerebral palsy child described purely in terms of the abnormal tonic reflexes. Both assessment and treatment were very much reflex driven. The Bobaths later felt that they had overestimated the role of these reflexes[23] as they were not always consistent and alone could not account for the variations of posture and tone observed. It is now recognised that increased tone is not only due to neural mechanisms, but has many non-neural components as well. Recent writings[24] and practical experience remind us however that these reflexes are certainly used in motor activities by some cerebral palsy children, and must be taken into account during assessment as they may need to be inhibited while retraining or practising motor tasks.

Today assessment is comprehensive and functional. It includes many more aspects of the child and his disability. The focus is no longer solely the nervous system and its role in the resulting disability, but includes other non-neurological systems and the role they play in the child's ability (or disability) to function. Essential to the assessment is the therapist's ability to observe and analyse the child's movement and functional skills[25]. Patterns and sequencing of movement, postural alignment and adjustment preceding and during movement, and movement problems must all be analysed, from both a neurological and a biomechanical point of view. A thorough assessment of muscle length and flexibility, joint ranges of movement, and the mobility of fascia and neural tissue is also carried out. It is well documented that central nervous system abnormalities can and do produce secondary peripheral abnormalities which contribute to motor control difficulties and compound the disability[38,39]. These peripheral abnormalities occur in the form of shortening of muscles and tendons, deformity of bony structures, subluxation and/or dislocation of joints and adverse neural tension[38]. A concise picture of the child and his functional abilities and disabilities is obtained through, not only assessment in a physiotherapy gymnasium, but also in other "real-life" situations. Observation and assessment of the baby as he is handled by his mother, or the older child as he functions and interacts in the classroom, playground or in his own home, for example, form an important part of assessment. Treatment is given according to this detailed analysis and tailored to the individual[25]. The therapist must identify the primary constraints to motor behaviour and determine whether these constraints can be compensated for or eliminated[26].

Although current practice surrounding assessment and treatment are presented separately, it is important to point out that there is much overlap between the two in actual practice. Key to both is the therapist's continual observation of the child's response to handling. A thorough initial assessment of a child is essential, but with each treatment session the therapist is constantly observing the child's response to handling and his performance during treatment and then adapting treatment techniques and aims accordingly.

Treatment today still involves techniques of inhibition and facilitation, but remembering the words of Bly[24], who writes: "Today we must still remember that inhibition alone is not sufficient to change the patient's movement patterns. The child has to be an active participator in the process. Misinterpretation of the inhibition/facilitation process in NDT has resulted in therapists spending entire treatment sessions trying to inhibit abnormal tone before they try to facilitate movements. The therapist's handling techniques must combine inhibition of abnormal movement patterns while incorporating (and facilitating) active movement and problem solving by the patient.". A child who learns a new movement pattern needs to be able to apply that movement pattern in a variety of contexts and environments, so in addition to learning new movement patterns, the child needs to learn problem solving strategies to enable him to solve motor problems[28]. This has led to treatment being structured around specific functional tasks that are relevant to the child. The child can even be involved in the selection of these tasks.

It is also now accepted that techniques of inhibition alone are no longer sufficient, in many instances, for addressing the problem of increased tone. The Bobaths viewed increased tone, abnormal postural tone and spasticity as being synonymous. In terms of the hierarchical/reflex model of the nervous system spasticity was very simply described as the loss of higher inhibitory influences over lower level reflexes resulting in an

exaggerated stretch reflex[40,41]. In an individual with an intact and normally functioning nervous system normal tone consists of a balance between inhibitory effects on stretch reflexes mediated by the dorsal reticulospinal tract and facilitatory effects on extensor tone, mediated by the medial reticulospinal tract, and to a lesser extent the vestibulospinal tract[40]. In an individual with damage to higher centres of the brain (cortical motor areas, caudal brainstem and the dorsal reticulospinal pathway)[40] the mechanisms which inhibit and/or mediate stretch reflex activity (via the reticular formation)[40] are missing, resulting in abnormally high activity in the stretch reflex which manifests as spasticity.

It is however beginning to become apparent that all increased tone that is seen in our patients is not just due to spasticity but to other external and peripheral factors as well. There are certain non-neural components that reflect the mechanical and elastic characteristics of the muscle and connective tissue that resist lengthening[32]. It has even been suggested that there are aspects of the behavioural sciences that have an influence over tone[28]. The fact that spasticity associated with various neurological disorders responds differently to different medications is evidence that spasticity is not a singular entity[39]. Clinical experience tells us that this is true even within conditions - look at the varied response by cerebral palsy children injected with Botulinum toxin A (Botox). Studies quoted by Carey and Burghardt[42] have demonstrated decreased range of dorsiflexion during gait in both hemiplegic adults and cerebral palsy children, with no activity on EMG recorded in the gastrocnemius muscle. They suggest that this is probably due to pathologic changes in the properties of contractile elements in the muscle and/or to connective tissue stiffness. One author[43] suggests that patients with central nervous system lesions unconsciously shift from normal neuronal control of muscle tension to a more mechanical control tension with resulting changes in the mechanical properties of the muscle, which could include both contractile and non-contractile (connective tissue) elements[41]. Habitual postures with poor postural alignment; stereotypical movement patterns within limited movement ranges; the use of fixation; and the frequent need for prolonged positioning are all factors that occur in the child with cerebral palsy as a result of the underlying defects in postural control and muscle activation. If we look logically at these factors it is clear that adaptive shortening of soft tissue structures must occur. This includes shortening of muscles, myofascia and nervous tissue. (50% of nervous tissue is in fact connective tissue.)

This new understanding of increased tone has led to the incorporation of many other techniques of treatment into the NDT approach. Myofascial release, soft tissue mobilisation, neural mobilisation and joint mobilisation may all be used in the cerebral palsy child to assist in achieving the mobility, range, and alignment that he needs for normal movement. These passive mobilisation techniques form only part of treatment and used in isolation will not enable the child to successfully accomplish a motor task using normal movement patterns. These techniques address only non-neural, secondary changes and it is important to remember that the disability with which we are dealing stems from a primary, underlying lesion in the central nervous system. Ideally these secondary changes should be prevented but in reality they occur in almost all cerebral palsy children and it is important that they are addressed during treatment.

In preparation for the selected task (or tasks) the therapist must ensure that the child has the necessary ranges of movement in his trunk, pelvic and shoulder girdles, and extremities. Inhibitory or facilitatory techniques directed at decreasing or increasing tone, as well as various soft tissue and joint mobilising techniques and stretching may be used to this end. Improved postural and biomechanical alignment, with activation of the correct muscle groups is facilitated. Generally activities that incorporate the postures and components of the selected motor task are facilitated and practised by the child. It is important that postural adjustments that precede and/or accompany a task are facilitated during execution of the task or a related activity and not separately[37]. As the child actively performs these activities, and/or the task, his movements are guided and assisted by the therapist in more normal patterns using key points on his trunk, shoulder and pelvic girdles, and extremities. Compensatory patterns are inhibited. Of paramount importance is that it is the child who plans, initiates and executes the movement, with guidance and assistance from the therapist. The therapist does not move the child. Throughout treatment the therapist is continually evaluating the child's movement and response to handling and adapting treatment accordingly. Although NDT now focuses on a task specific type treatment, we need to be flexible in the means we use to achieve the task.

Quality of movement has long been considered important by therapists, and children are often prevented from executing a task or performing a movement unless it is carried out correctly, which has in the past led to children being too passive in treatment. However, if we look at any normal child, or even adult, carrying out a motor skill for the first time it is seldom perfect, and requires feedback and practice to refine and perfect it. The same is true of the cerebral palsy child. We have also learnt from our knowledge of motor learning theory that successful accomplishment of a task or attainment of a motor goal enhances the learning process. Horak[26] writes: "Since the nervous system is not a passive recipient of sensory stimuli but actively seeks to control its own perceptions and actions, the child must actively and voluntarily practice motor performance, motivated by the reward of successful accomplishment of task goals."

Drawing on motor learning theory we now incorporate many other strategies in NDT to enhance the learning of more normal movement patterns and of motor strategies by the cerebral palsy child. Extrinsic feed back is given to the child by both visual and verbal cueing; he receives intrinsic feedback by being allowed to self-initiate and execute the movement task. The idea of using specific, relevant functional tasks has already been mentioned, but there is now a heightened awareness of incorporating practice of these tasks into therapy, as well as altering the context and environment in which tasks are carried out and practised. Therapists in a school environment may elect to treat children in the classroom or on the playground, instead of always in the physiotherapy gymnasium. By choosing relevant tasks and involving the child in decisions about goals of therapy, and by carrying out treatment in varied and interesting environments, we are able to encourage the child's participation and interest in the rehabilitation/motor learning process.

Improved quality of movement is important for optimal function[44] and the inhibition of abnormal compensatory patterns is one of our aims when facilitating and practising a functional task[37]. It is important, however, to bear in mind that there may come a time when it is appropriate for the therapist to assist in the development of compensatory strategies to allow a child improved function[26]. The goal of completely normal movement in the

cerebral palsy child is often unattainable[44] as there may be constraints or limitations within the defective neural system on which therapy has little or no effect[26]. One needs to balance the re-education of more normal patterns of movement with the need for functional skills and independence required by the child that may necessitate the acceptance of some compensatory patterns[44]. The older child should be allowed to participate in such a decision.

The theory, for which NDT has been much criticised, of treating according to the normal developmental sequence has already been addressed, and does not form part of the treatment approach today. Another reason for rejecting this theory is that, if we look at our patients from an orthopaedic point of view we are reminded of the importance of upright postures[39]. Weight bearing and muscle activity are essential in assisting with the shaping of joints and bones particularly the acetabulum of the hip joint and the femur[39]. To delay standing a child until he has accomplished all the developmental tasks that precede standing would be disastrous from an orthopaedic perspective. And, if we look logically at how a normal child develops, practices and refines movement we see that he has already progressed to the next developmental level before he perfects the movements at the preceding level.

The NDT/Bobath approach is still viewed by many of the proponents of the systems or task oriented approach to motor retraining, as a purely facilitative model. They view the two approaches as two separate entities and have criticised many aspects of the facilitative model[26,28,32]. Some[32] have however acknowledged the changes that have taken place, and continue to take place, in the NDT approach, with its incorporation of a more task-oriented approach to treatment and many of the principles of motor learning. Unfortunately there appears to be a relatively poor understanding, on the part of many therapists using the NDT or Bobath approach in the treatment of both children and adults with central nervous system disorders, of the theoretical basis for their choice of treatment approach[45,46,47]. In a survey of current practice among members of the Neurodevelopmental Treatment Association in the United States[47] there was a call from respondents for a revision of the theoretical tenets underlying NDT. Respondents felt that the theoretical assumptions as described by the Bobaths needed revision to include recent advances in the understanding of the neurosciences, motor control and motor learning. Such theoretical assumptions have indeed been updated[24], but perhaps there is a need for further and more widespread publication of the theoretical tenets of NDT that underlie best practice.

2.5 Why Should Treatment Work?

If one views the nervous system as a hierarchical structure with its rigid organisation of reflex levels and strict cortical control of volitional movement, then it gives little flexibility to explain recovery or development of normal movement or function following a central nervous system lesion[48]. If, however we view things from a systems point of view we have a much more flexible and adaptable structure with a greater potential for recovery[49]. In fact the normal intact human nervous system does appear to be a reasonably flexible and adaptable structure, capable of change. Its development involves many regressive as well as progressive neural events[39] which continue into the post-natal period and beyond. Functional and structural changes can continue to occur throughout life as a result of the learning process[50]. In addition to this, we now know that a certain amount of regeneration is actually possible within a damaged nervous system[48,49], and that injury-induced cortical re-organisation is a relatively widely recognized phenomenon[51]. Both neuroanatomical and neurophysiological studies in animals have indicated that long-term, widespread structural and functional changes do take place within the brain following damage[52].

Plasticity can be defined as the ability to show modification or change. Shumway-Cook and Woollacott[32] have described neural plasticity as the continuum from short-term functional changes to long-term structural changes. Neural plasticity may play a beneficial role in the recovery of function after brain injury (although there is little empirical evidence to support this[53]) and may help to give some rationale for why NDT treatment in the child with cerebral palsy does, or should, have an effect. Therapy involves the child in both the learning and relearning of motor skills in normal movement patterns. If the learning process in the normal infant, child, or even adult, results in modification of the nervous system, so too should modification occur in the damaged nervous system of a child undergoing a similar learning process. The theory of the mechanisms of neural plasticity which afford recovery following brain damage are far from complete[50] and there is little written about treatment-induced plastic changes in the human brain[51]. Most recent and current research in this field appears to be primarily in the field of brain injury due to stroke and not cerebral palsy[51,53,54,55].

As research is required to further our understanding of the anatomical and physiological mechanisms of neural plasticity, so too is research imperative at a clinical level to demonstrate that these proposed mechanisms of neural plasticity are truly translated into meaningful functional gains for the person with brain injury. Such research into the outcomes of therapeutic interventions for children with cerebral palsy and other central nervous system disorders is lacking and is desperately needed.

CHAPTER 3
LITERATURE REVIEW

3.1 Outcome Studies and NDT

Criticism of the NDT approach abounds in the cerebral palsy literature both here in South Africa and abroad. In his review on therapy methods (which included NDT) for children with neurodevelopmental delay Professor M Leary[5] begins with the following words:

> "In South Africa today an array of interventions is on offer for the child with neurodevelopmental delay. The doctor who believes in evidence based treatment and who wants the best for his or her patients may be hard put to select from the therapies available what is appropriate and cost effective.....".

Eugene Bleck[56] an orthopaedic surgeon who has worked extensively with cerebral palsy children writes:

> "After half a century of sincere and intense effort by professionals to 'treat' cerebral palsy, most now acknowledge that these remedial efforts have been unsuccessful in achieving function ..... perhaps it is time to give up trying to cure the neurological deficits by remedial methods, stop looking for positive studies and get on with the task of helping children and their families."

Also in a review of therapy methods for cerebral palsy, Graves[2] writes:

> "Most claim to be able to improve outcome and a few claim to be able to achieve complete cures. Rigorous examination of such claims fails to support them, whereupon the usual response is that more and better studies are needed or that better tools to measure function are required. .....cerebral palsy is the result of permanent brain damage and therapy can do little to improve the resultant motor and associated impairments.....".

He concludes that: "The claims for functional improvements resulting from therapy methods cannot be substantiated."

Very harsh words indeed, however when one looks at the literature there are very few NDT outcome studies which have been published. The dearth of studies is understandable given the fact that physical therapy has become an accepted form of treatment for these children making the withholding of treatment almost impossible[18]. Very few of the published studies attempting to evaluate the outcomes of the approach have shown conclusive evidence to support its efficacy. Does this lack of evidence really mean that the approach is ineffective or does it stem from the fact that many of the studies in this area are fraught with flaws in their methodology? There are many inherent difficulties in designing and conducting these studies, which will be highlighted in this literature review. Most physiotherapists working in this field will confirm that some positive benefit of their intervention, however small, is evident almost daily.

Perhaps the earliest study looking at physiotherapy treatment outcome in cerebral palsy children was that of Paine[57], published in 1962. Although the study does not specifically evaluate NDT treatment - children in the study were treated by a variety of methods that reflected the current thinking of the period from the 1920's to 1950 and did not include the Bobaths' concepts and approach to management of the spastic patient - it does

however warrant inclusion in this review. It was one of the first studies attempting to evaluate physiotherapy treatment in the cerebral palsy child and with it came the important realisation that: "...There remains the urgent need to distinguish benefits of treatment from spontaneous improvement with increasing age and maturity."[57].

The study was retrospective in nature and included 177 cerebral palsy patients over the age of 14 years (91 were in fact over 20 years of age) for whom detailed information regarding management of their cerebral palsy was available. 103 of these patients had received "intensive" physiotherapy and the remaining 74 were totally untreated. The initial and intermediate status of these patients as detailed in their records and confirmed through questioning was compared with their status as assessed at a follow-up examination during the study period. The patients' "gait, hand function, etc." were assessed using a method determined by the author. Intelligence was also determined although there is no mention about how this was done. The conclusions drawn were that patients with a mild spastic hemiparesis developed a "good" gait whether treated or untreated. Treated moderate and severe hemiparetics had a slightly better gait and fewer contractures than those who were not treated. Patients with spastic tetraplegia, triparesis and paraparesis did less well overall than the hemiparetics. The treated group showed only slightly better outcome in gait and there was less need for orthopaedic surgery in this group. Treatment made no difference to quality of gait or incidence of contractures in those patients with dystonic or athetoid type cerebral palsy.

These are not very encouraging results. However, if one looks at the study design and execution this is hardly surprising. A retrospective study design has many flaws, in particular the questionable accuracy of medical records. There is no control over what other extraneous variables influenced the patients' outcome, and given the long follow-up time it is highly likely that there were other variables which influenced outcome. There is no indication of the time elapsed between the cessation of physiotherapy treatment and this study. A variety of treatment techniques were used for time periods that were not consistent across the entire treatment group. The sample consisted not only of patients with different types of cerebral palsy but also with different severity's of cerebral palsy and there was no matching of patients within the treated and untreated groups; the authors themselves state that there were a higher percentage of mentally defective patients in the untreated group. Outcome measures used were designed by the author for the purposes of the study and are very subjective classifying outcome of gait, for example, as "excellent, good, fair, poor and none". Given when this study was conducted there was certainly not much choice of standardised outcome measures available but one certainly gets the impression that there could have been more objective methods of assessing outcome. The nature of the outcome measures also made any formal statistical analysis virtually impossible. Despite all the flaws in this study we must remember that it was one of the first of its kind. It gave future researchers something to build on and it also pointed towards some of the inadequacies that existed in the treatment techniques of the time.

Carlsen[58], an occupational therapist, seems to have been one of the first to attempt to evaluate the outcome of the NDT approach as described by the Bobaths, although in her study she combined the NDT approach with some of the ideas of sensory integration described by Jean Ayres, calling the approach a 'facilitation' approach.

Her sample consisted of 16 cerebral palsy children aged 1-5 years. The children were paired according to their developmental ages, as determined by a combination of the Denver Developmental Screening Test (DDST) and the Bayley Motor Development Scale. Children were then randomly assigned to 2 treatment groups - one receiving the facilitation approach (NDT) and the other a more functional treatment approach which focused on improving specific developmental tasks (e.g. certain self-care skills). The intervention phase of the study was 6 weeks and consisted of twice weekly 1 hour group sessions, at which the treatment was carried out by the parents of the children under the supervision of the author. A daily home programme was also given to the parents in each group but it was not specified for how long such a programme was to be carried out. Re-evaluation of the children on the DDST and Bayley Motor Development Scale was carried out at the end of the 6 weeks. The facilitation group performed better overall than the group receiving the functional approach with results being statistically significant on the Bayley Motor Development Scale and the gross motor sub-section of the DDST. The fact that the same therapist provided/supervised the treatment sessions for all the children and administered the pre- and post-testing constitutes expectation bias[59] and should be taken into consideration when evaluating the results of this study.

There was no untreated control group in this study. Such a group would have provided important and useful information regarding whether each of the two therapy approaches used was independently beneficial as an intervention for cerebral palsy children, when compared with no intervention at all. Data from 2 pairs of children was omitted from the final analysis because their treatment sessions were interrupted for various reasons. Given the sample size inclusion of this data may have influenced the results and subsequent conclusions of the study. Such results should have been reported. Both the Bayley Motor Development Scale and the DDST are what Kirschner and Guyatt[60] refer to as discriminative measures. They were designed and validated to identify and distinguish between individuals with or without a particular characteristic or function - in this case the characteristics and functional activities that enable one to establish the developmental level of an infant or child. The different types of measures will be discussed in more detail later in this chapter, but what is important in the current context is that both of the aforementioned measures were not designed and have not been validated for measuring change in the cerebral palsy child. Finally there is concern over the combination of sensory integration and NDT techniques in the treatment of cerebral palsy children. This combination of two different treatment approaches into a single approach makes it difficult, if not impossible, to isolate which of the two is of greater benefit. In addition there are several sensory integration techniques which should be avoided in cerebral palsy children. For example linear acceleration such as on a scooter board (mentioned in this study as apparatus) is frequently used in sensory integration treatments and physiologically results in increased extensor tone, an undesirable result in a cerebral palsy child with already increased extensor tone. It is likely that the effects of one treatment approach could negate the effects of the other which may influence overall outcome.

Another of the earlier studies is that by Scherzer *et al*, published in 1976[61]. They compared two groups of cerebral palsy children aged less than 18 months, one receiving a neurophysiologic physical therapy approach (which incorporated NDT) and the other a passive movement regimen. They found that there was no significant difference between the 2 groups in motor status, social maturation or home management, although there was a trend towards better outcomes in the NDT group.

A sample of 24 children was selected, of whom only 22 eventually participated in the study. The sample differed considerably in diagnosis of type of cerebral palsy, severity of involvement and eventual expected intellectual levels. Age of entry into the trial varied from 5 to 17 months which in a condition such as cerebral palsy could constitute lead time bias[59]. Duration of treatment until reassessment varied from 7 to 19 months (all children were reassessed at two years of age irrespective of age of entry into the trial), meaning that there was a considerable difference in the amount of input received by each child. In spite of these, and other variables no attempt was made to match the children in the two groups, nor was any form of stratified randomisation used. The two groups were in no way analysed for potential differences and in fact, the experimental (NDT) group was almost twice the size of the control group (14 versus 8).

The dependent variables measured in this study were motor status, social maturation and home management. Motor status was assessed by means of medical and physical therapy evaluations by blinded assessors. Medical evaluations assessed areas such as general paediatric development, neurological status and social development. The authors designed their own outcome measure to measure motor status for the physical therapy evaluations, with no mention of any testing of its validity or reliability. Details of this outcome measure were not included in the published study. The other two variables were measured using parental interviews, and questionnaires completed by the physiotherapists, for which validity and reliability are difficult to establish. Both are also a potential source of obsequiousness bias, which is the tendency of subjects completing questionnaires/interviews to alter responses systematically in the direction they perceive desired by the researcher[59]. The authors give the results for each of the areas assessed as either "definite/positive change" or "no change" but nowhere is "positive change" defined or quantified. In addition deterioration ("negative change") either did not occur in any of the children or else was incorporated under "no change". This is not really a satisfactory way of quantifying outcome. A passive movement regimen is almost certainly aimed at maintaining range of movement of various joints but no outcome measure was used to determine the effects of this passive movement regimen versus NDT. The results may have shown no difference in the outcomes that were analysed but there may have been significant differences between the 2 groups in passive range of movement and subsequent longer-term need for orthopaedic surgery.

The parents in the group receiving NDT were required to carry out a home programme prescribed by the therapist treating the child, but parents of the control group children were specifically asked not to practise any thing at home. This introduces another variable between the two groups of which there is no mention in the analysis of the results. For the sake of reducing variability between the 2 groups a home programme should have been required of both or not at all. If a home programme is used levels of compliance in carrying it out should be measured and included in the analysis. No attempt is made to do this in this study. In fact such home programmes

have been found to have high rates of non-compliance[62]. As with the previous study there was no untreated control group which again gives no indication as to the success of either of the two regimens under investigation when compared with no intervention at all.

Sommerfeld *et al*[63] carried out a study looking at the effects of NDT on a group of mentally impaired subjects with cerebral palsy. A sample of 19 subjects aged 3 to 22 years were matched for age, severity and type of cerebral involvement, and overall developmental level. The subjects were then paired and randomly assigned to two groups, one receiving two 30 minute sessions of direct physical therapy per week and the other a physical therapy programme carried out by a teacher or aide. This physical therapy programme was set up by a physiotherapist, who then provided 6 weekly follow-up supervision. A group of 10 matched subjects acted as an untreated control group. The respective interventions were carried out over 5 month period.

Three outcome measures were used: the Wilson Developmental Reflex Test, a gross motor test then in use in the school district in question and joint range of movement measured using a goniometer. Neither of the former two of these outcome measures was standardised and concerns have been raised about the reliability of goniometry[64,65]. Joint range can also be dependent on tone which can fluctuate markedly in a cerebral palsy child. The authors did however establish test-retest reliability coefficients for each of the outcome measures used. Of the 24 ranges of movement measured only the 6 most reliable on test-retest (coefficients from 0.71 to 0.99) were selected as outcome measures. Items on the developmental reflex test had reliability coefficients ranging from 0.37 to 0.81 which certainly calls into question reliability of this test. Are reflexes indeed an appropriate indicator of treatment outcome? The gross motor test's reliability coefficient was 0.98. A single blinded assessor administered all the outcome testing. The results indicated no statistically significant differences between any of the pre- and post treatment scores for any of the three groups. The lack of positive findings could be related to insensitivity or lack of validity on the part of the two former outcome measures selected, as well as to the other problems with the outcome measures already highlighted.

There were several problems with the selected sample, the first being the enormous age range (3 -22 years) within relatively small treatment groups. There is no doubt that an NDT therapist's goals and expectations would vary considerably within such an age range and different outcome measures would be more appropriate to certain age groups than to others. The subjects in the sample had very low IQ's of 30 or less so one certainly cannot generalise these results to other populations with higher IQ's. Given what we have learnt about the child being a more active participant in his treatment and the ideas surrounding motor learning this was not an ideal group in which to look at therapy outcome. Lastly, it is unclear whether all of the sample attended the same institution. If they did not yet another variable is added to the study and is a possible source of bias.

A study frequently quoted in the literature is that by Palmer *et al*[66]. Their randomised clinical trial compared the effects of 12 months of NDT to 6 months of an infant stimulation programme followed by 6 months of NDT in 48 spastic diplegics. (Note again the lack of an untreated control group.) They found no significant difference in motor, cognitive and social development between the two groups after 6 and 12 months. In fact the stimulation group achieved somewhat better motor outcome than the NDT group.

The selected sample were defined as being "homogeneous", but this was only in terms of type of cerebral palsy. Age, severity of disability, sex, family characteristics, cause of cerebral palsy, gestational ages and IQ all differed. However, in contrast to Scherzer *et al*[61], the children were stratified according to IQ before randomisation into the 2 treatment groups. Subsequent analysis of the 2 groups revealed no significant difference for the other variables mentioned. Although the sample size seems reasonable when compared with some other studies in this field, it is less than half the size (48 versus 100) originally projected by the authors as necessary for full evaluation of treatment differences between the two groups.

The outcome measures used in this study included the Bayley motor and mental scales; a check-list of gross motor skills compiled by the authors; a neurological examination (which included assessment of deep tendon and pathologic reflexes, and muscle tone) an assessment of contractures; an assessment of the need for bracing and /or surgery; and a social development quotient (Vineland Social Maturity Scale). The issue of the Bayley motor scale not being a valid outcome measure with which to evaluate change in cerebral palsy children has already been addressed in the review of an earlier study. The Bayley mental scale is also a discriminative measure and has not, to the author's knowledge, been validated to measure change in the cerebral palsy child. Besides this, a change in cognitive level seems an inappropriate outcome measure, when the authors themselves state in their introduction that the purpose of physical therapy in cerebral palsy "...is to improve motor development and prevent musculoskeletal complications.". Similarly a measure of social development was inappropriate. The infant stimulation programme consisted of cognitive, sensory, language and motor activities and it would seem that the use of both the Bayley mental scale and of a social development measure tended to favour positive results in the stimulation group. The gross motor skills were assessed on a present or absent basis so no credit was given for a child being able to either initiate or partially execute a motor skill. A more graded scoring system might have influenced the results obtained from this outcome measure. One of the goals of NDT is to promote more normal patterns of movement. However, no measure or observation of improved quality of movement was made during the assessment of gross motor skills. The need for bracing and surgery was utilised as an outcome measure. Many therapists view bracing (splinting) as an adjunct to therapy in order to assist with the attainment of improved motor skills and patterns. It is certainly an unusual way to judge treatment outcome. The children in the sample would have been aged between 24 and 31 months at the completion of the study which is still relatively early for surgical intervention in the cerebral palsy child (only 2 children in the entire sample required surgery at the end of the study). Should the need for surgical intervention not have been the subject of a more long-term follow-up study?

A home programme was given to the parents of children in both of the intervention groups, compliance with which was monitored by home visits. There was however no further mention of compliance in either the results or the discussion. A therapist using the NDT approach would invariably include in her home programme advice regarding handling and positioning techniques to be incorporated into daily activities such as feeding and dressing, often making life easier for the parents. No assessment was made of how the parents felt about the treatment their child was receiving or the home programme they had been given. The NDT group may have scored better in this area. Bax[67] believes that if the care and management of a child can be made easier for the parent or primary care-giver, that in and of itself is justification of the treatment. The absence of an untreated

control group makes it impossible to attribute the changes (or lack thereof) seen in either of the groups to either intervention. There is no measure of the influence of normal maturation and development in this group of children.

In a randomised controlled trial Mayo[68] compared 2 groups of young children with cerebral palsy or motor delay (suspected cerebral palsy), receiving 2 different intensities of NDT (weekly versus monthly) over a 6 month period. The children receiving the weekly NDT together with an individually tailored home programme, performed better overall than the group receiving monthly NDT and a home programme, but these results were not statistically significant.

Sample size was small, including only 29 children. The children had a variety of types of cerebral palsy, with some only having a suspected diagnosis of cerebral palsy - the age range in this study was 4 - 18 months and it is often only after a year of age that a definite diagnosis can be made. In fact only 69% of the sample had an eventual definite diagnosis of cerebral palsy. Children were stratified prior to randomisation according to severity of disability, being classified as either moderately or severely disabled. The less intense/basic regimen consisted of visits to the hospital of about one hour in duration once a month. During these visits the parents received instructions for carrying out the home programme. In contrast the intensive regimen consisted of weekly one hour visits where the child received hands on therapy from a physiotherapist, with the setting of specific therapeutic goals. As with the basic group there was specific instruction in the implementation of the home programme. The home programme formed an integral part of treatment in this trial and yet no attempt was made by the author to measure or assess compliance with the home programme. Mayo[69] herself has stated that studies evaluating therapeutic regimens must ensure maximal compliance.

Seven different outcome measures were used in this trial, the scores of which were combined to give one overall score of motor development. However not all seven were actually measures of motor function which may have affected the validity of this score. In fact the test with one of the highest contributions to the aggregate score was a test of cognitive ability. Two of the outcome measures were standardised and known to be valid and reliable but were not without other problems. The Bayley Mental Development Scale has already been discussed in terms of its relevance to measuring outcome of an intervention surmised to affect motor ability and in terms of its ability to accurately measure change in this group of patients. Fine motor skills were assessed using Gesell and Armatruda's developmental screening inventory. Like the Bayley Scales this is also a discriminative type of measure that was not originally designed to measure change in a cerebral palsy child. The other five were assessment tools that had been designed specifically for the trial, of which four were tested prior to the trial to devise and confirm scoring systems and to establish inter-rater reliability. Validity of these four instruments was not mentioned. These measures covered the assessment of: primitive reflexes, postural reactions, gross motor ability, abnormal movement patterns, and activities of daily living. Again the question arises about the appropriateness of using primitive reflexes as an outcome measure. Firstly primitive reflexes do not measure functional ability. Although they may, and are likely, to be elicited on testing given the underlying damage to the central nervous system, they do not necessarily interfere with function. It is also doubtful that they provide give any indication of change at the level of impairment. Even if they did so this is meaningless to the child unless it is

associated with change at a functional level. In short, the ultimate goal of treatment is the improvement of function and not the inhibition of reflexes per se. As with the study by Palmer *et al*[66] the assessment of gross motor ability seemed to be scored on a present or absent basis, not giving any credit for initiation or partial completion of a motor skill. Scores of various items were however weighted and another outcome measure was included to address the aspect of movement quality (abnormal movement patterns).

Not all children were treated by the same therapists and no mention is made of the number of therapists involved in the trial. This adds another variable to the study as treatment delivered by different therapists may differ in some respects. Three variables were included in the analysis as covariates (mother's level of education, child's age at referral and whether the child was term or preterm), from which the author drew some interesting conclusions. 13 mothers in the intensive group had only a high school education compared with 5 in the basic group, putting the intensive group at a disadvantage according to the author "because mothers without higher education are likely to be less able to participate in the child's programme". This statement is not referenced and neither was any attempt made to assess the level of the mothers' participation in this trial. The intensive group was further felt to be at a disadvantage because they were slightly older and "many feel that the longer therapy is delayed the poorer its outcome will be". However in treating the younger infant with only signs of motor delay, but as yet no definite diagnosis of cerebral palsy, are we not treating a potentially normal infant? If they are normal the outcome of therapy will be better!

There were four children who did not comply with their originally prescribed regimen who were still included in the analysis of the results, as it was felt to exclude them would bias the results. Including them does however mean that there is inconsistency within the groups which may affect outcome. Interestingly, of the 58 children eligible for the study only 29 participated. Of the 29 whose parents did not agree to participate, the majority had mild motor delays and their parents were unwilling to be randomised into the group demanding weekly visits.

Mayo sets out to study the effectiveness of NDT but actually compares the effectiveness of two different intensities of NDT. She states that it is not a study of efficacy of NDT. There needs to be a better distinction between the meanings and interpretations of these two words. Tirosh and Rabino[10] define efficacy as the extent to which therapy is more useful and beneficial than useless and harmful for the purpose for which it is advocated. Effectiveness is then the extent to which this efficacious intervention could be applied to all those who could benefit from it in real practice. Should efficacy not first be established before looking at effectiveness?

More recent studies[70,71] have investigated ways of determining more objective measurable change following NDT, particularly in older children where changes are more likely to be of a qualitative nature. Rather than attaining a new skill, an already existing skill will be easier to initiate, faster, smoother and more efficient[70]. These studies have used kinematic analysis on the body part of interest (e.g. the arm in reaching) and then video taped the action for observation and analysis of the rest of the body. The validity and reliability of the instrumentation used for kinematic analysis has been established.

Using a before and after-type study design Kluzik *et al*[70] assessed reaching before and after a 35 minute NDT session in 5 spastic quadriplegics, aged 7-12 years. They used kinematic analysis to assess changes in the reaching upper extremity and video recording to assess associated reactions in the non-reaching upper extremity. They concluded that NDT produced measurable and functional results with faster reach in a more mature pattern. The extent to which associated reactions occurred in the non-reaching upper extremity did not differ significantly but other parts of the body (e.g. head and trunk) were not assessed. The children acted as their own controls in the study but no mention is made of intervention being received prior to the study and no baseline period was established prior to intervention for comparison. It cannot therefore be concluded that the change seen was due only to the NDT intervention as there may have been other extraneous variables affecting outcome. The sample was homogenous in terms of type of cerebral palsy but severity of disability was not assessed except in terms of muscle tone. This seems an unusual method to assess disability. As well as being an extremely subjective measure (although inter-rater reliability was established for the method used), muscle tone does not always correlate with levels of disability (or ability). There are many other factors aside from muscle tone that affect level of disability.

A big concern in this study arose in the analysis of the kinematic and video recordings. Video data for 34 out of the total 139 reaches recorded was excluded from analysis for various reasons and only 87 out of the 139 reaches were used in the kinematic analysis. Lack of inclusion of this amount of data in analysis makes for questionable results. In addition the assessors were not blinded as to whether the videos and kinematic data being viewed were pre- or post-treatment and intra-rater reliability was not established for the video assessments. Another concern is that several trials of the reaching task were allowed at each assessment, in other words the children were allowed to practise the outcome being measured. It is possible that it was the practice that affected the outcome and not the NDT intervention. A trial effect analysis was done to see if practising of the reach during the testing affected the outcome but it was found to have no effect. One should however view these results with caution given that this was a very small sample for such statistical analysis and as so much of the assessment data was not used.

On the positive side kinematic analysis is a reliable and valid method of quantifying changes in the qualitative aspects of movement. Attention now needs to be paid to more stringent and rigorous study design when using kinematic analysis as outcome measure. On the other hand, a big disadvantage is the expense of the equipment involved making it a technique that is not readily available for general use by either clinicians or researchers

Another study using kinematic analysis is that by Jonsdottir *et al*[71]. Using a group of 8 spastic quadriplegics aged from 10 to 15 years old, they looked at the effects of practice versus NDT on postural control during a reaching activity. The children received a week of no intervention at all, followed by a week of either practice or NDT. This was followed by a further week of no intervention and then a week of practice or NDT, which ever had not been received initially. The intervention weeks consisted of 5 daily sessions, each lasting 35 minutes, of the relevant intervention. The chosen outcome, postural control, was assessed from a video tape using the Postural Assessment Scale and by means of kinematic analysis of the displacements of the head and trunk. A modified version of the Postural Assessment Scale was used for which inter-rater reliability, measured as part of the study, was poor with a coefficient of only 0.49. The results demonstrated no significant difference in any of the

variables measured for either NDT or practice. The elimination of one subjects data from the pooled data resulted in a significant improvement on the Postural Assessment Scale following NDT.

Several concerns arose surrounding this study, many of which have already been highlighted in this review as they pertain to other studies. Of particular concern in this study was its weak study design. The 2 weeks of no treatment were supposedly to serve as baseline periods, and yet no measurements were taken during the course of either of these weeks, so there was no indication of the postural control exhibited by the children whilst receiving no treatment. There may have been significant differences in postural control during the intervention weeks when compared with non-intervention weeks. Postural Assessment Scale data for analysis appears to have only been collected at the beginning and end of each intervention phase, whereas kinematic data was collected at the beginning and end of each treatment session. Particularly in the case of the data collected using the Postural Assessment Scale it would have been possible to assess changes in the children's scores on this scale at the beginning and end of the second no treatment week. This would have given some indication of baseline postural control for comparison. The ideal would have been to have collected data throughout the entire 4 week period, as would be done in a single-subject study design. This study, like the previous study, essentially used a before and after type study design. The use of the single-subject study design in rehabilitation research will be discussed in the following section.

Bower *et al*[72] expanded on some of their earlier work (which will be reviewed in the section that follows dealing with single-subject designs) and carried out a randomised controlled trial in which they assessed the effects of two differing intensities of physiotherapy and two different goal setting procedures on 44 spastic quadriplegics. NDT and many of its principles formed part of the therapy given, although the approach adopted was described as being more eclectic. Although termed a randomised controlled trial there was no untreated control group for comparison with any of the different treatment groups. The outcome measure used was the Gross Motor Function Measure (GMFM).

The total sample constituted 44 children which was calculated as sufficient by the authors to show significant change in the outcomes measured. These children came from 14 different health districts in the south of England and each child was treated by his/her own physiotherapist, meaning that the treatment was delivered by 44 different physiotherapists! Given this situation one calls into question the control over extraneous variables in the trial. Age of entry into the trial varied from 3 to 11 years which introduces lead time bias[59], although the children were stratified according to severity of disability prior to randomisation and there were no significant differences for the variables measured.

Over the two week period 82% of the children improved in terms of motor skill acquisition. Intensive physiotherapy gave better results than regular physiotherapy and the setting of specific measurable goals as opposed to general aims was also associated with better outcome. If one looks at the scores of the GMFM the actual improvements in score are relatively low with overall average improvements ranging from 2.2 to 4.8%. Only one of the average improvements (improvement in goal areas of the GMFM for children for whom specific aims of therapy were set) was statistically significant. The inclusion of an untreated control group in this study

would have added clarity as to how much of this change in score was due to the treatment given and how much was simply due to normal fluctuations in performance. It would not have been difficult to include such a group from whom treatment was completely withdrawn given the short period of time over which the trial took place. All of the children had either a specific goal of treatment or a general aim of treatment established for them, depending on the group to which they were assigned. Some of the children had more than one aim or goal of treatment. At the end of the study less than 50% of these goals/aims had been achieved. This could be due to two things - either therapy was not effective or else therapy may have been effective but the goal/aim set was not achievable over the relatively short 2 week treatment period.

In 1994 DeGangi[73] published a study examining the efficacy of NDT, using a case-study design. Six cerebral palsy children were enrolled in an eight week programme of twice weekly NDT. An eight week period was chosen so that maturational effects were less likely to confound results, but given that 5 out of the 6 subjects were between 1 and 2 years old eight weeks (2 months) is a considerable length of time and normal maturation with increased acquisition of motor skills in this age group is highly likely.

Multiple outcome measures were used to assess the children, only one of which was a standardised and reliable measure, the Peabody Developmental Motor Scales. As has been highlighted previously this is a discriminative measure and its reliability and validity in measuring change in cerebral palsy children has not been established. Observations of qualitative movement and postures derived from the Test of Motor and Neurological Function were made. There is no mention as to how this was done or what the observations included and whether there was any attempt to establish the reliability of such observations. Observations on a check-list compiled specifically for each child were made by the treating therapist and the child's parents twice weekly. No indication of either reliability or validity of this check-list was given. Lastly, there was also a parental interview pre- and post-treatment. All assessments were carried out by the author. All parties concerned knew that the child was undergoing therapy which introduces a very likely expectation bias to the results obtained. An additional source of bias, referred to as obsequiousness bias by Sackett[59], was that the check-lists completed and the parental interview may have yielded more positive results than was actually the case in the desire on the part of both the therapist and the parents to "please" the researcher.

The design of this study was a before and after type design which is well recognised as a weak study design. No baseline or control period was established prior to commencing treatment so there is no indication of how each of these children would have changed over an 8 week period of no NDT intervention. It is virtually impossible to state conclusively that the change seen in the children following the study is due solely to NDT. On the positive side this type of methodology allows for detailed description and discussion of therapy goals and treatment techniques used for each child. It can also be very feasibly argued that given the range of problems and disability seen in cerebral palsy more individualised outcome measures are required to measure change accurately in an individual child. Nevertheless this must still be done in a scientific manner and every attempt should be made to ensure their validity and reliability. Setting specific treatment goals for a child is a common way of tailor-making an outcome measure but some sort of standardised testing designed to measure change in children with cerebral palsy should be incorporated. The idea used in this study warrants follow-up but some sort of control or baseline

is required in order to better demonstrate that change measured or seen is attributable to the intervention strategy under investigation - not to chance, maturation, or any other extraneous variable or concurrent intervention. The single-subject design provides a means of doing just this, whilst still avoiding the complexities and problems associated with measuring outcome in cerebral palsy children using group study designs.

3.2 Evaluating Outcome Using a Single-Subject Design

The single-subject design, first used by researchers in the psychology, psychiatry and education fields[74,75], is defined by Sim[74] as: "A quasi-experimental, prospective design utilising a sample of one, involving the sequential introduction and withdrawal (or modification) of an intervention (the predictor variable), to determine its effect on one or more outcome variables, through repeated measurement."
There are several different names for the single-subject study design which occur in the literature: single-subject designs, single-system designs, single-case experiments, 'n' of one or small 'n' designs, and idiographic research[75].

The most basic form of single-subject design is the simple baseline single-subject, or AB, design. A baseline is established during a period of no intervention (A) and this is then followed by a treatment or intervention phase (B). Repeated measurements of a chosen outcome variable are taken during both phases and the changes in these variables between each of the phases are attributed to the treatment or intervention given. This is considered the least powerful of the single-subject designs as one cannot be entirely certain whether the difference in response is attributable to a confounding variable. It is however more powerful than a straight forward "before and after"-type study design as it gives some chance for the control of confounding variables and it takes into consideration temporal effects. The withdrawal or ABA (see figure 3.1) design is the same as the AB design except that following the intervention phase the treatment is withdrawn and a withdrawal, or "second baseline" phase is instituted. Treatment can again be instituted following this withdrawal phase giving an ABAB or withdrawal-reinstatement design. Changes in the outcome variables from one phase to the next can be attributed to the treatment or intervention given.

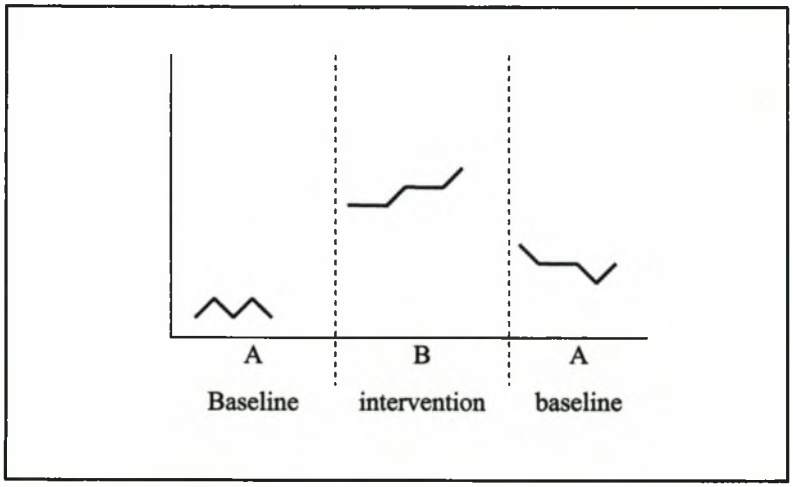

FIGURE 3.1: Graphical representation of the ABA single-subject design

The ABA and ABAB forms of the single-subject design are more powerful and more reliable than the simple AB design but they have their own associated problems. If, for example, a skill is acquired during the intervention phase of a study involving the ABA design, this skill may then be maintained due to other factors during the withdrawal phase. Consequently withdrawal of treatment may not have the desired "negative" effect and will yield similar results to those seen during the treatment phase. Martin and Epstein[76] also question the desirability and ethical implication of ending on a non-treatment phase in the case of the ABA design. The ABAB design addresses this latter problem however the problem of carryover of a skill/behaviour from the treatment to the withdrawal phase remains. The order of intervention and baseline phases can be varied depending on the requirements of the study being undertaken (BAB, AABA etc.). More than one intervention (e.g. a second intervention C) can be assessed in an ABAC-type design. In each of these study designs the patient is essentially acting as his own control so many of the characteristics that may vary between patients in group studies will be constant (e.g. age, sex, educational level, socio-economic status) and differences in outcomes cannot be blamed on lack of homogeneity[17]. Analysis of the results is generally by visual inspection (Figure 3.1) and not by statistical methods. The advantage of this is that it may help in defining clinical significance, as statistical significance does not always mean clinical and useful change for the patient. With each of these single case-study designs the ethical question of total withdrawal of a treatment or intervention remains an issue which needs to be addressed in the planning of such a study.

Many authors have written in favour of this study design for use in the rehabilitation research[74-78], but there are also those who have raised concerns over it[79]. The randomised controlled clinical trial provides the ideal method of demonstrating a cause-effect relationship and is considered to be the most powerful research design[17]. Nonetheless it is a tricky and expensive undertaking particularly in the rehabilitation field. There are often not sufficient patient numbers to make up the homogenous group required by the rigorous inclusion and exclusion criteria of such a study[17,75]. Institutions often object to the withholding of treatment from patients[75] and time and resources are often insufficient for the execution and follow-up of such studies.

The randomised controlled clinical trial is generally considered to have good external validity (the extent to which the findings of a study can be applied to a wider population, beyond the specific conditions of the study[74]). In group studies like the randomised controlled clinical trial, results are based on aggregate data and therefore the findings for the group may not be representative of any one individual within the group[17,74] (i.e. the mean findings for the group may be the result of scores from two extremes meaning that the individuals within the group either performed very well or very poorly but no individual demonstrated average performance). Specific characteristics of the individuals who benefited well from the intervention may be difficult to identify and generalising the results to a wider population may be less successful than was initially anticipated. A single-subject design has only one or a small group of patients who are not representative of a larger target population as would be with a group study. The single-subject design gives a poor indication of response at the aggregate level, but does give a good indication of the likely response of a specific individual with specific characteristics relevant to improved outcome[17,74]. Wood Dauphiné[75] addresses this issue of lack of ability to generalise the results of a single-subject study to a patient group. This is a common criticism of this type of research and emphasises the need for replication of studies and aggregation of outcomes[17,74,75,76].

Martin and Epstein[76] published an article specifically addressing the issue of assessing treatment outcome in cerebral palsy using single-subject designs. Therapy with cerebral palsy patients is a highly individualised process because of the tremendous variability seen within the patient population. Because of this variability in pathogenesis, pathology, and in resulting disability, group studies investigating treatment outcome are extremely difficult to carry out. The randomised controlled clinical trial may not necessarily be an appropriate way of looking at treatment outcome in this patient group[76], although it has long been considered the gold standard of research in the medical world. In fact opinion seems to be that single-subject study designs are well suited to many of the chronic conditions (including cerebral palsy) seen by physiotherapists[74-76]. Wood Dauphiné[75] states that: "...for patients with very rare conditions, those with diverse manifestations from such problems as head injury or those with multi-system disorders and functional impairments, single-subject approaches may offer the only way of determining the efficacy of treatment.".

A potential disadvantage of the single-subject design in the cerebral palsy context is, however, the need for repeated measurements during the baseline and treatment phases. If regular daily or even weekly measurements are taken variables measured must be selected very carefully to ensure that they have the potential for change over these short periods as was done in the study by Laskas *et al*[80] reviewed below. Alternatively, baseline and treatment phases must be of sufficient duration to allow change in variables to take place, but not too long that there is a temporal effect and other variables such as normal development come into play. Another consideration would be to modify the single-subject design as was done by Bower and McLellan[81] (reviewed below) and measure outcome variables only at the beginning and end of each of the phases of the study. This way one can measure potentially larger changes but without having to prolong each phase of the study.

Perhaps one of the biggest concerns raised pertaining to use of the single-subject design in rehabilitation research is that it will be seen as an alternative to the randomised clinical trial. Bithell[79] feels that use of the single-subject design, as opposed to the more highly regarded randomised clinical trial, in the field of rehabilitation research will result in the loss of credibility of this research in the wider scientific community. Single-subject studies should really be viewed as adjuncts to the more traditional group study designs[75]. They often give rise to questions and hypotheses which can eventually be investigated using group study designs and they also provide useful 'pilot' type studies for later design of group studies. Table 3.1 lists the differences between group and single-subject study designs.

TABLE 3.1 Comparison between group and single system studies

	GROUP STUDIES	SINGLE SYSTEM STUDIES
Focus of study	Extensive On two or more groups of subjects	Intensive On a single subject/system
Basic design	Prospective Concurrent Experimental design	Prospective Time-series Experimental design
Control	Independent control group	Subject acts as own control
Allocation to groups	Randomisation (?matching)	Not applicable
Manipulation of the predictor variables	Usually one off Pre-determined	Usually intermittent Adjustable
Measurement	Usually pre- and post-test	Repeated across phases thro'out study
Analysis	Between subject Statistical	Within subject Visual and/or statistical

From: Sim J. The external validity of group comparative and single system studies. Physiotherapy (1995) **81**: 263-270.

The idea of using the single-subject design to investigate the effects of NDT was first addressed by DeGangi and colleagues in 1983[82]. Their aim, using a single-subject design, was to develop a reliable method of measuring short-term objective changes in cerebral palsy children and to measure the immediate effects of NDT and play interventions. Four children all with a diagnosis of cerebral palsy and ranging in age from 10 to 22 months participated in the study. Each child received 8 treatment sessions over a period of 5 weeks, with each treatment session consisting of a 25 minute NDT session followed by a 25 minute play session (or vice versa). Testing was carried out at the beginning of the first session, following the first session and following the second session. This simple AB/BA single-subject design was replicated over the 8 sessions.

The aim of a non-intervention phase is to establish a baseline of the child's performance without intervention which is not achieved with the design that was used. The outcome items, which were used for testing as described above, were specifically selected by each child's regular physiotherapist (not the same therapist as was carrying out the study intervention). They were based on goals that would have normally been set for therapy, expected to be achieved within a 4 to 5 week period (i.e. the duration of the study). Each outcome item was rated as being "better after NDT"; "better after play"; or "equal" for each of the 8 sessions. These outcome measures are not appropriate for the way in which this study has been designed and the outcome items have been scored/measured. Outcome items should have reflected goals or changes that were achievable over a single treatment period. A better single-subject design for the outcome items that were established and the manner in which scoring was done would have been an AB design where A was a baseline period of, for example, 8 sessions of non-specific play followed by B, 8 sessions of NDT intervention. Testing using the outcomes measures established could have been administered at the beginning and end of each session during each phase or at selected intervals during each

phase. With the study as it was performed one also needs to question the issue of carry over of the effects from a 25 minute NDT session into a play session and how this would affect the outcome testing following the play session. These fundamental flaws in the basic study design are good reason for viewing any results from this study with caution.

The outcome measures that were used were not standardised measures although individualised outcome measures are feasible and even encouraged in this type of study design[17]. However test items used in this study have been criticised for being simplistic and incomplete[83]. Tests were videoed for later scoring by blinded assessors. Results showed no difference in the items tested/scored following the NDT and play sessions. Tape raters were psychology students who, although trained in a methodology for rating the videos, are understandably not skilled in child development and the observation of subtleties of quality of posture and movement exhibited by these children. The inter-rater reliability correlation coefficients for various test items ranged from 0.56 to 1, but only test items with "adequate" correlation coefficients were used in the data analysis, but these still ranged from 0.67 to 1. The greatest concern in this study, however remains the inappropriate way in which the single-subject study design was used. This methodology cannot be concluded to be reliable for measuring short term outcome in the cerebral palsy child following NDT and one certainly cannot draw any conclusions as to the effectiveness of NDT.

Again looking at short-term effects of NDT, Lilly and Powell[84] used similar methods to those of DeGangi *et al*[82] but modified them somewhat in an attempt to address some of the concerns raised by the DeGangi study. Nonetheless this study raises concerns of its own. The same single-subject type design was used to measure the immediate carryover effects of NDT and play intervention on dressing skills in two spastic diplegics. No significant difference between the effects of the two interventions was found.

Intervention took place over a 12 week period but it was unclear in the study the exact manner in which intervention took place. NDT and play sessions were alternated during one treatment session as in the DeGangi study but this only occurred once a week for 6 of the 12 weeks. In addition one subject appears to have received a weekly session of NDT and the second subject twice weekly NDT for the other six weeks. NDT and NDT/play sessions occurred randomly during the 12 weeks. Clearly there was very little structure to the way in which intervention was administered. Similar concerns to those in the DeGangi *et al*[82] study about the way the simple baseline single-subject design was applied arose here. Again there was no real establishment of any sort of baseline with which to compare the results of treatment. There is thus a question of whether the two interventions provided were sufficiently different to have produced a difference in outcome.

Test items, which in this study were certain appropriate dressing skills, were administered with the NDT/play sessions only - at the beginning of the session, following NDT and again following play. In the cases where play followed NDT no mention was made of the possibility of carryover from the NDT session affecting the child's performance when testing following the play session. No testing was done associated with the NDT only sessions which makes one question the role of these sessions in this study. Test items were video taped for later rating by blinded assessors. In contrast with the DeGangi[82] study the assessors in this study were OT's experienced in

assessing and observing children with cerebral palsy. There were however eleven such raters who each scored "a few" criteria, but it then appears as if only scores from two raters were used in the results, for whom reliability scores ranged from 0.5-1.00. Assessing outcomes using video recordings is something that requires some sort of standardised measure with which to allocate scoring and needs sufficient instruction and training to be useful and reliable. The authors themselves question whether training was sufficient in this study given the diminished inter-rater reliability. The assessors were required to score on subtleties such as changes in tone which are unlikely to be reliably detected on video tape. The play sessions were administered by an occupational therapy student (the first author) who, given her undertaking of such a study, obviously has knowledge of NDT principles. These may well have been incorporated into the play sessions which introduces bias to the intervention provided. In addition how often does play not constitute part of a NDT treatment session? It is therefore again questionable as to how different the two interventions being provided were and as to whether they were different enough to have produced a difference in outcome.

This study provides no more of a reliable methodology for measuring short term outcome following NDT than the DeGangi study[82]. Both, with their inappropriate use of the single-subject design and the subsequent inability to establish any proper baseline, really amount to straight forward before and after-type studies.

Better use of the single-subject design was made by Laskas *et al*[80], who used a single-subject withdrawal design (ABA) to look at the immediate effects of NDT. The subject was a 2.5 year old child with a diagnosis of spastic quadriplegia. The baseline phase of the study consisted of a twenty minute session of free-play for 7 consecutive days, immediately followed by the intervention period consisting of a twenty minute NDT session for 9 consecutive days. The withdrawal or second baseline phase followed immediately after this and was exactly the same as the initial baseline phase. At the beginning and end of every session dorsiflexor muscle activity during a posterior equilibrium reaction was measured using an EMG biofeedback instrument. In addition a behavioural measure was taken involving the direct observation and recording of the number of times the child's heel contacted the floor during seven trials of coming from sitting on a stool to standing. It appears that the position of the foot/heel was noted only once the child was in standing but this was not entirely clear. Both measurements were taken by two observers with good inter-rater reliability (98% and 99% respectively). Visual inspection of the results showed improved dorsiflexor muscle activity as well as improved heel contact during the treatment period as compared with the two baseline periods.

The same therapist who provided the therapy sessions was one of the observers taking the EMG and heel contact measurements which was a possible source of bias although reliability with a second independent observer was good. However, neither of the observers was blinded as to whether the measurements being taken were before or after treatment nor to whether the session was freeplay or NDT. In reporting the measurements there was no mention as to whether it was the left or right lower extremity that was being referred to, or both. This is essential as one side of the body is almost always more severely affected in a spastic quadriplegic. Exactly the same prescribed NDT regimen was used in all of the 9 treatment sessions which may mean that treatment given was not optimal for the entire treatment phase. In the normal clinical setting treatments are frequently modified and progressed from one session to another, according to the child's response. A concern when viewing the results

was the tremendous fluctuation in day to day EMG readings. This could have been due to errors in the actual equipment. It could also have resulted from the fact that there are many factors (physiological, psychological and external) that affect muscle tone and hence will affect the reading of muscle activity generated by an EMG. These readings were hence subject to error and may not have been reliable measurements.

As with all single-subject designs the results cannot be generalised to a wider population and, although useful for generating information about treatment outcomes for individual patients, similar individual studies must be replicated and the results reviewed concurrently before any conclusions can be drawn about various sub-groups of children with cerebral palsy.

Earlier work of Bower and McLellan in 1992[81] used a slightly modified single-subject design to look at the effect of periods of increased exposure to physiotherapy on the rate at which motor goals were achieved. Although they describe the type of physiotherapy received in the study as being of the 'eclectic school', it incorporated and was based on many of the ideas and principles of the NDT approach and was characteristic of the approach to therapy adopted by NDT therapists today.

The sample consisted of seven children with spastic quadriplegia and severe learning disabilities, aged from two to twelve years. Each child acted as his own control in a withdrawal ABA single-subject design, where A was a period of 'normal' physiotherapy (± 30 minutes per week) and B a period of intensive physiotherapy (± 5 hours per week). These two different intensities of therapy were given by different therapists meaning that at each phase of the study two variables were altered, intensity of therapy and therapist. This could have influenced the results of the outcome measures as well as the conclusions drawn from these results. Children were assessed at the beginning of the study, before and after the intensive treatment period, and again at the end of the study. Normally in a single-subject design assessments would be done at various intervals throughout each of the phases of the study. Outcome measures included the child's performance of two specific measurable goals set individually for each child prior to the study, the Gross Motor Function Measure (GMFM) and a questionnaire completed by the child's parent/primary caregiver. All the assessments were carried out by the same therapist who provided the intensive therapy which introduced a likely expectation bias[59] to the outcomes measured.

Statistically significant improvement was seen in the average GMFM score for the group and visual inspection of the data revealed increased rate of acquisition of goals set during the intensive therapy phase. Of interest were the results of the parental questionnaire which revealed that parents perceived that the children regressed during the third phase of the study where they again received 'normal' therapy. This was not the case when assessed with the more objective measures. This supports the view that a parental assessment is subject to bias and may lack reliability. The results of this study were positive and promising but care must be taken in generalising them to the paediatric cerebral palsy population as a whole. The single-subject design looks specifically at how individual patients with specific characteristics respond to an intervention - results or outcomes are obtained for individuals rather than for a group. However, the design resembles that of a "matched" control and treatment group in that it is possible to compare outcomes for each of the phases of the study as if one were comparing treatment and

control groups. This however means that conclusions are being drawn from an extremely small sample size which again demands that caution be taken in generalising results.

Although the authors clearly stated that their goal was to study differing intensities of therapy it would have been useful to have a phase of no intervention in order to observe how much of a carry over effect there was, whether significant deterioration took place, or whether the children in fact continued to improve. Depending on results obtained his could have strengthened the argument in favour of physiotherapy intervention for this patient group. Of note is the comment by the authors that the process of defining measurable and meaningful goals appeared to have assisted the therapists in planning and executing treatment.

The results of these studies using a single-subject design, particularly those of Bower and McLellan[81] and Laskas *et al* [80], certainly seem more promising than the results of the studies using group designs that were reviewed. The single-subject design may well be a more appropriate way of evaluating treatment outcome in cerebral palsy. More importantly, the data and information collected from a number of single-subject studies may enable the design and execution of more methodologically sound group studies.

3.3 Issues in Measuring Outcome

Virtually all the authors who have written on the subject of measuring treatment outcome in the child with cerebral palsy are in agreement over one important issue, that being the lack of an appropriate assessment tool. Campbell[85] feels that this lack of a suitable tool to measure the change and progress (or lack thereof) seen in cerebral palsy children receiving NDT is one of the major reasons for the lack of positive outcome studies providing evidence in favour of NDT. Indeed this also applies to many of the other medical and surgical interventions used for the cerebral palsy child. Therapists working in this field are generally poor about keeping accurate and clear documentation in which specific goals are set; appropriate treatment plans established; and treatment outcomes evaluated. Such a tool is essential to enable us to measure outcome in cerebral palsy children following NDT intervention, both for the purposes of research and for use in the clinical setting.

Why is measuring outcome in this group of patients so difficult?

Cerebral palsy has been defined as: ".....a dynamic (changing) disorder of posture and mobility being the motor manifestation of non-progressive brain damage (static encephalopathy) sustained during the period of brain growth in fetal life, infancy or childhood."[86]. Although the actual lesion in the brain that has occurred in the cerebral palsy child is non-progressive or static, the clinical picture changes over time. Rosenbaum *et al*[87] propose that these changes are probably due to a number of things, including the development and maturation of the central nervous system, the evolution of motor patterns at both reflex and volitional levels, motor learning, and therapy. One could add to these the influence of secondary, non-neurological factors such as change in muscle length and properties of muscle fibres and other connective tissues; joint and bony deformities; poor postural and/or biomechanical alignment; as well as a host of other extraneous factors. Clearly there are many things that influence change in the child with cerebral palsy making measurement of change specifically due to

therapeutic intervention (NDT) extremely difficult. A measuring instrument, therefore, not only needs to be able to detect change but also to indicate, together with careful and rigorous study design, to what exactly this change is attributable. Furthermore, as is pointed out by Boyce *et al*[88] change seen in the clinical picture of a cerebral palsy child is often small and may occur over a relative long period of time. Many of the outcome measures that have been used in the studies already reviewed were not capable of detecting these small changes.

There is a lack of clarity on what constitutes positive outcome or clinically significant change in the cerebral palsy child and one of the big dilemmas seems to be what to actually measure as outcome. Campbell[85] suggests that what we measure is determined by three things. Firstly by how we view the nature of the problems seen in cerebral palsy, secondly by which of those problems we think we can compensate for or improve with treatment, and lastly by which potential outcomes are most important. On the issue of outcome measurement Fetters[89] feels that we need to decide upon and define what actually constitutes functional movement and useful change. In addition we must decide whether normal patterns of movement, as advocated by the NDT approach, are an important goal of treatment or rather whether the goal of treatment should be functional outcome as defined by the child and family? Clearly the answers to these questions are going to vary from child to child, family to family, clinician to clinician and researcher to researcher.

There appears to be some consensus in the literature as to the fact that change in gross motor ability in the cerebral palsy child can be twofold. There may be an improvement (or deterioration) in the child's repertoire of gross motor skills, for example the child who could only sit with arm support progresses to being able to sit with both arms free. On the other hand there may be improvement in the quality with which a child executes a gross motor skill, for example a child who consistently walks with marked back-kneeing and who then learns to control this, thus improving his gait pattern. Boyce *et al*[88] refer to these as changes in gross motor function and gross motor performance respectively. And so which do we measure, the "quantity" of movement that is achieved by the child or does one look of the "quality" of the movements? Boyce *et al*[88] advocate the use of more than one outcome measure to accurately detect and evaluate all the changes that are seen in cerebral palsy children.

Other authors[85,90,91] have taken a slightly different view and have proposed theoretical frameworks for the assessment of outcome in the cerebral palsy child. Their models have been based on the World Health Organisation's classification of impairment, disability and handicap[92] as well as work by Nagi[93] which introduced the concept of functional limitations. Campbell[90] proposed dividing the disabling process into five dimensions: pathophysiology, impairment, functional limitations, disability, and social limitations. If one views cerebral palsy as it fits into the proposed framework there are three dimensions at which treatment and outcome measures are primarily directed. Those being the dimensions of impairment, functional limitation and disability[90]. Most outcome measures published to date, however, measure change in functional limitation and few exist for measuring change in impairment and disability[85]. In 1999 the World Health Organisation updated its classification of impairment, disability and handicap in the ICIDH-2[94]. The Enablement Model of the ICIDH-2 has been accepted by the American NDT Association. This model looks at impairment, activity and participation. Activity is synonymous with functional ability and replaces the 'disability' of the old model. Participation

replaces the old 'handicap'. Consequently most measurement of outcome occurs at the activity level, and currently very little occurs at the impairment and participation levels.

Whatever the theoretical arguments there remains little consensus as to what exactly we should be measuring to document outcome following NDT intervention in the child with cerebral palsy. If we look at the definition of NDT treatment[22] from the previous chapter we see that these children have: "....disturbances of function, movement and tone....." and that: "The goal of treatment is to optimise function. The ongoing process of assessment and treatment is directed towards those impairments interfering with function as well as towards integrating improved control into participation in daily life.". This definition seems to encompass all the aspects of the ICIDH-2[94] (impairments, functional ability/activity and participation) as well as the aspect of movement quality. Perhaps we should carefully and systematically be directing treatment and measurement of outcome at each of these aspects in order to see which, if any, give optimal outcome. For this however we need valid and reliable outcome measures that can accurately detect change in each of these aspects.

Research studies published thus far have, as yet, not proved NDT to be an efficacious intervention for the child with cerebral palsy and many have blamed this on the lack of a suitable reliable and valid outcome measure. The validation of an outcome measure is however seemingly best achieved by seeing if it detects change following a known efficacious intervention. This situation has left researchers and clinicians in this field in something of a dilemma and alternative means of validating these outcome measures need to be devised and put to the test. The group who designed and validated the Gross Motor Function Measure[95] have done exactly this as will be discussed in the following section.

What are the requirements of an outcome measure for measuring treatment outcome in the cerebral palsy child?
An outcome measure must accurately detect change (or lack thereof) in a subject, in a valid and reliable manner, where such change truly exists.

Rosenbaum *et al*[87] and Boyce *et al*[88] both site the work of Kirshner and Guyatt[60] who have formulated a logical and meaningful way of categorising health measures. Health measures may be described or classified as being discriminative, predictive, or evaluative. A discriminative measure is one which distinguishes between individuals with or without a particular characteristic or function. Many of the gross and fine motor developmental scales are discriminative measures. A predictive measure is one which, based on the presence or absence of certain defined characteristics, categorises an individual according to his or her expected outcome or eventual status. The example given by Rosenbaum *et al*[87] and Boyce *et al*[88] is that of the Bleck Scale of Locomotion. An evaluative measure is one which measures a change in function or characteristics over time. This change may be due to some sort of intervention or merely due to normal maturation or development. Measures may be designed and used for one or more of these purposes, but it is extremely important when embarking on the design and development of a measure that its purpose is clearly defined. All measures must be validated for the purpose(s) for which they are intended[88]. To measure outcomes following NDT treatment of the cerebral palsy child we need an evaluative outcome measure. In the outcome studies reviewed earlier many used what

were really designed as discriminative measures for the purpose of evaluation without first investigating their validity as evaluative measures.

All outcome measures whatever their purpose must be reliable and valid. Reliability refers to the extent to which the outcome measure gives consistent results when repeated measures are taken by one (intra-rater reliability) or more (inter-rater reliability) observers for the same subject, in the absence of any change in the subject[96]. The degree of reliability of an outcome measure is improved by standardisation of the outcome measure, selection and recommendation of who should be using the outcome measure, and training observers in the use of the outcome measure[96]. There are several different types of validity that are referred to in the literature[96]. Validity is essentially the extent to which a measure actually does measure what it is intended to measure. So, for example an outcome measure designed to measure the change in motor skills of a cerebral palsy child following a period of NDT intervention should show a change in score when there has been true change in motor skills[88].

In addition to reliability and validity the most important feature of an evaluative measure is its responsiveness[87,88]. Responsiveness is the outcome measure's ability to detect any change, whether positive or negative and irrespective of magnitude, that has occurred in any one subject on whom the measure is being used. In order to ensure responsiveness items selected for inclusion in the outcome measure must be relevant and, in the course of designing the outcome measure, the number of responsive items should be increased and similarly non-responsive items should be eliminated. Furthermore several options for scoring individual items should be given so that instead of an item being considered either present or absent, credit is given for ability to either initiate and/or partially complete the item[87,88]. More specifically, an evaluative measure designed to measure the effect of NDT intervention in the cerebral palsy child, must be responsive to small changes in quantity or quality (depending which it is designed to measure) of movement occurring over relatively short periods of time. If it is only responsive to larger changes over longer periods of time it is difficult to rule out the effects of normal development and maturation. Remembering that this outcome measure must not only be suitable for use in a research situation where study design can control for such a variable, but must be able to be used in the clinical situation in day to day treatment of these children. It must be able to assess motor capabilities across a wide range of children with cerebral palsy, both young and old with mild through to moderate through to severe disability, and it must address the characteristics of disordered movement that make the motor behaviour of cerebral palsy children unique.

The disadvantages of many of the outcome measures commonly used in studies investigating the efficacy of NDT as a treatment for children with cerebral palsy have already been addressed during the course of the literature review. For the purposes of the current study two outcome measures were selected, the first being the Gross Motor Function Measure[19,95], which has already been mentioned in the literature review. The second, an outcome measure known as TELER[20,97] has yet to be used in a published study in this field. The Gross Motor Function Measure was selected because it is the only outcome measure which has been developed and validated for the expressed purpose of measuring change in gross motor skills in children with cerebral palsy. Although as yet unused in the published literature in this field TELER was selected for this study because it provides a flexible means of assessing outcome in individuals undergoing treatment. Outcome measures can be tailor made to suit

the patient. In the cerebral palsy/NDT field where each child is unique in terms of his disability and where treatment is task specific and goal directed, TELER may provide a means of determining the degree of goal attainment in each unique individual and so indicating the effects of treatment. Referring back to the ICIDH-2[94], the Gross Motor Function Measure is probably most effective in measuring change at the level of activity/functional ability. By virtue of its flexibility, TELER, on the other hand, could probably be structured to assess change at all three levels, as well as incorporating some of the qualitative aspects of movement.

3.4 The Gross Motor Function Measure

The Gross Motor Function Measure (GMFM)[19,95] (Addendum 1) is described by Campbell[85] as "...the only modern standardised test developed specifically for use with children with cerebral palsy." It is an evaluative measure.

Construction

Normal gross motor developmental milestones form the basis for the five dimensions of the GMFM[19]. The five dimensions are (i) lying and rolling; (ii) sitting; (iii) crawling and kneeling; (iv) standing; and (v) walking, running and jumping. Within each dimension are a number of activities or items, totalling 88 in all for the 5 dimensions. These 88 items were selected based on a literature review and the clinical judgement of experienced clinicians. Items were selected on the basis that they were considered to be particularly sensitive to the problems exhibited by the cerebral palsy child[19]. In other words they were activities that were judged to be clinically important. For obvious reasons the items had to be measurable and they had to have the potential to show change in function. Items were grouped according to test starting position and arranged within each dimension in a developmental sequence. The motor ability range of the selected items was considered to be about 5 years, meaning that any normal 5 year old should be able to complete all the items included in the measure.

The arrangement of items into 5 dimensions was done primarily for scoring purposes[19]. Each item is scored on a 4 point scale from 0 to 3. A score of 0 means the child is unable to even initiate the activity; 1 is scored if the child can initiate the activity or completes less than 10% of the activity; 2 is scored if the child partially completes the activity (10% to less than 100% of the activity); and for full completion of the task a score of 3 is awarded. Specific definitions for initiation, partial completion and full completion are described for each item in a test manual. Designing the scoring in such a way that credit is given for initiation or partial completion of an item will increase the responsiveness of the measure to change even, in the cases where relatively small changes occur[87,88].

It was decided in the initial construction that no one dimension of the GMFM should be weighted and all dimensions should contribute equally to the total score. Weighting would have occurred if the scores were simply added to get a total, as each dimension contains a different number of items. Hence a total score is calculated by calculating a percentage score for each of the 5 dimensions and then finding the mean of the 5 percentage scores.

One or more dimensions of the GMFM may be identified as a goal area for a particular child. Generally these would be dimensions in which a child is expected to change. Using only the identified dimensions, a goal total score can be calculated by obtaining the mean for only the goal dimensions. A worked example of calculating a goal total score is given in Addendum 2.

Validity and Responsiveness

A study[95] was undertaken in 1989 to validate the GMFM for its responsiveness to change in the motor function of children with cerebral palsy. The validation study sample included 111 cerebral palsy children aged less than 20 years (minimum age is not specified); 25 children with head injuries; and 34 normal children aged less than 5 years. The younger age groups (less than 3 years and 3 to 6 years) of the cerebral palsy group were over-sampled as it was considered that they were more likely to exhibit change than the older children. All the children underwent 2 assessments approximately 6 months apart. As there was no other accepted criterion or "gold standard" evaluative measure of motor function for the target group, other measures of change judged to be assessing the same thing had to be established in order to validate the GMFM's responsiveness. Three measures were chosen: parents' rating of change in motor function, physical therapists' rating of change of motor function; and change as assessed by an independent therapist viewing video tapes. A series of hypotheses were drawn up about how change in scores on the GMFM would relate to change in scores on the other 3 measures. The hypotheses and the subsequent findings are summarised in table 3.2. From these findings it was concluded that the GMFM was a valid measure with which to detect change in cerebral palsy children.

TABLE 3.2: Hypotheses and subsequent findings for validation of the GMFM

HYPOTHESIS	RESULTS
1. Correlation's between change in GMFM scores and video assessment scores greatest (>0.45) Correlation's with parents' scores lowest (0.30-0.45).	• GMFM and video assess correlation = 0.82 • GMFM and PT assess correlation = 0.65 • GMFM and parents' assess correlation = 0.54
2. Controlling for age: change in GMFM scores for mild CP > change in scores for moderate CP > change in scores for severe CP.	• Within age groups, no statistically significant difference in change scores between mild, moderate and severe groups
3. Change in GMFM scores for normal children under 3 yrs > change in scores of normal children 3 yrs and over.	• Statistically significant difference in changes in scores for the two groups supporting hypothesis
4. Change in GMFM score for head injured children > change in score for normal pre-school children > change in score for CP children	• Statistically significant differences in changes in scores supporting hypothesis • Head injury 15%, normal group 11%, CP 6%

To demonstrate the responsiveness of the GMFM a stable and responsive group of children were identified. Children were classified as stable if both their parents and therapist considered them as not having changed or changed only a little at the second assessment. The responsive group were then those children whose parents and therapist agreed that change had occurred. If a measure is responsive to change and stable in the absence of change then there should be little change in scores obtained by a stable group of subjects and a greater change in scores obtained by a responsive group of subjects. When the GMFM scores of the stable and responsive groups in this study were compared there was a significant difference in scores form the first to the second assessment in the responsive group. This difference was not significant in the stable group the with an average over-all difference of 1.26% compared with 9.64% for the responsive group.

Reliability

In the GMFM validation study[95] steps were taken to minimise both inter- and intra-rater variation and maximise reliability. All therapists participating in the study were trained in the use of the GMFM and were required to reach a predetermined level of agreement with a criterion video tape. Both inter- and intra-rater reliability were measured during the course of the study. Results revealed intra-class coefficients of ≥ 0.87 and 0.92 respectively for each of the five dimensions scored. The GMFM has been designed in such a way as to minimise variation in its scoring and thus maximise reliability. A child can only achieve a score for actions that are actually observed by the person administering the measure. In other words what the child 'does do' rather than what he 'can do' is measured. All items scored must be achieved independently eliminating the need for subjective estimates of 'amount' or 'level' of assistance required. All items included in the measure are defined in clear and objective terms and an accurate description of what is required to achieve each particular score is given in the GMFM manual[19]. The design and construction of the measure minimises error arising from the measure itself. It is still recommended that therapists wanting to use the GMFM attend a training workshop. Participants in training workshops have been shown to significantly improve their level of agreement with a criterion video tape[98]. An accepted level of agreement with a criterion video tape, which should be reached by therapists using the measure, has been established.

Clinically significant change

The minimum amount of change in GMFM total score estimated by Russell *et al*[95] as representing minimum clinically important change is 1.825%. In the validation study the therapists and parents were required to judge the magnitude and importance of change in gross motor function and these judgements were then compared to the actual change in GMFM scores. Based on these results Almeida *et al*[99] defined clinically meaningful change on the GMFM as follows:

* a change in score of less than 1.4% constituted no change or negative change,
* a change in score of 1.4% to 6.9% constituted a small positive change,
* a change in score of 7.0% to 24.5% constituted a medium positive change and
* a change in score of 24.6% or greater constituted a large positive change.

Use in research

Since its development the use of the GMFM in various studies looking at outcomes in cerebral palsy children has shown further evidence of its validity and responsiveness.

McLaughlin *et al*[100] used the GMFM to assess a group of spastic quadriplegics and a group of spastic diplegics prior to, and 12 months following, selective dorsal rhizotomy (SDR) and post-operative physiotherapy. Total average improvements in GMFM scores of 9% and 9.8% were seen in the 2 groups respectively. The quadriplegics improved most in the sitting and crawling dimensions and the diplegics in the standing and walking dimensions. These were the expected areas of improvement and corresponded with clinical observation. Two other studies[101,102] used the GMFM to compare outcomes following SDR and several months of post-operative physiotherapy with several months of intensive physiotherapy alone. Improvements in total scores of 11.3% and 12.1% in the SDR groups and 5.2 and 4.4% in the physiotherapy groups were seen after the relevant time periods. In one of these studies 4 out of the 6 children in the SDR group changed to using a less assistive walking device (e.g. from using a walking frame to using a cane). Flett *et al*[103] used the GMFM as one of the outcome measures in a study comparing Botox injection with fixed plaster cast stretching in the calf muscle of cerebral palsy children. Although the groups did not differ in outcome, they both showed improved GMFM scores over a 6 month follow-up period with the greatest change in score occurring in the first 2 months following intervention. Two of the studies[72,81] reviewed in the section on NDT outcome studies used the GMFM as an outcome measure and both of the these demonstrated the ability of the GMFM to detect change in cerebral palsy children receiving NDT over a relatively short period of time. The results of these studies indicate that the GMFM is measuring change when change is truly occurring and they contribute further to the validity of the GMFM.

Other authors have demonstrated correlation's between the GMFM, or certain dimensions thereof, and other measures. In their study to relate physiological fitness to the GMFM, Parker *et al*[104] found a significant relationship between the standing and walk/run/jumping dimensions of the GMFM and peak and mean anaerobic power of the legs. Damiano and Abel[105], and Drouin *et al*[106] correlated GMFM scores with different variables measured using different valid gait analysis tools. Damiano and Abel[105] concluded that both gait analysis and the GMFM are valid indicators of motor function in children with cerebral palsy.

3.5 The TELER System

TELER is an acronym for **T**reatment **E**valuation by **LeR**oux's Method[20,97]. It was developed by AA LeRoux, a statistician, following a request for advice on how to measure outcome/effectiveness of physiotherapy for children with cerebral palsy. LeRoux realised the need for a means to assess often small changes in individual patients undergoing what he describes as a 'dynamic treatment delivery process'[97]. The treatment delivery process in group studies is generally a static delivery process - treatment is standardised and ignores both the individuality of the patient and the independence of the practitioner, and in essence an artificial treatment environment is created[97]. When using the NDT approach in treating the child with cerebral palsy, the therapist is constantly working in partnership with the child, observing the child's responses to handling and treatment, and

then modifying and progressing treatment accordingly. The therapist tailor-makes the treatment to meet the needs of the child. This accurately describes LeRoux's 'dynamic treatment delivery process'[97].

The initial idea behind the TELER system was that the best way to show effectiveness of physiotherapy was to change the way in which therapists keep their patient records. The TELER system provides a simple means of clinical note making, allowing one to plot how a patient has changed whilst under treatment and how his/her treatment plan has developed. Changes in the patient can easily be detected and correlated with either changes in the treatment plan or other factors influencing the patient. The effectiveness of treatment is thus assessed routinely as part of the treatment process. This facilitates effective delivery of care; effective management of services providing the treatment or care and effective clinical audit[20,97]. It provides a means of enabling us to detect whether change seen in a patient is attributable to a specific cause[20,97] and so becomes a useful research tool/outcome measure when looking at the efficacy of a particular method of treatment. The system is simple and effective and can be adapted for virtually any clinical situation as it is not prescriptive. It is designed to accommodate a dynamic treatment delivery process and is sensitive enough to detect small changes in a patient's abilities which provide the patient in question with large benefits. The basic tools of TELER are outcome measures (called TELER indicators) and treatment plans.

TELER Indicators

When using the TELER system the therapist decides on the outcome measures depending on the particular patient and the particular setting. Obviously this requires specialist clinical knowledge of the patient and the type of treatment or care being administered. In the TELER system these outcome measures are called TELER indicators[20,97]. The TELER indicator is essentially an ordinal measuring scale for tracing change in a patient receiving therapy or care.

Each indicator has 6 reference points coded 0-5. The title of the indicator is generally a long term treatment objective and each code a short term treatment objective required for achievement of the long term goal. Code "0" indicates a deficit to be addressed (alleviated or avoided) and code "5" indicates that the deficit has been alleviated or avoided. In an acute condition the patient's admission code would generally be "0", with code "5" indicating the ultimate goal of treatment. On the other hand an admission code of "5" in a patient with a chronic condition would indicate the patient's status on admission and a code of "0" would describe a deficit to be avoided. For example, code "5" on an indicator for patient with a spinal cord injury, on admission to a rehabilitation unit may be "full range of movement at hip, knee and ankle joints". Code "0" on this same indicator, which would be the deficit to be avoided, could then be "restricted movement at all three joints". The cerebral palsy child has a chronic condition, but also has the potential to change (improve or deteriorate). In this case code "0" would be the ultimate deficit to be delayed or the child's current status and code "5" would be the ultimate goal for the child.

The deficits described by the indicators can be:

* Physical and functional[20] e.g. unable to get from sitting to standing; unable to perform certain activities of daily living
* Non-physical and functional[20] e.g. depression; intolerance of strangers/therapist
* Non-functional[20] e.g. lack of knowledge about a condition/child's condition; negative attitude

Each code on a TELER indicator must be a clinically significant outcome for the patient which must be able to be observed[97]. As a group the 6 code definitions must provide an indicator with face validity, construct validity and predictive validity[20]. The issues of validity and reliability of the TELER system and indicators are addressed later in this section. There are 3 types of TELER indicators depending on the way in which the codes for that indicator are defined:

1. Function indicators, are defined hierarchically with each code being a prerequisite for the next. The title of the indicator describes an activity or purpose of an activity. Code 0 describes the reason for the activity - usually that the patient is unable to achieve the activity in question. Code 5 describes the desired outcome and codes 2 - 4 describe intermediate outcomes. Correct order of acquisition of each of the codes is essential. An example of a function indicator follows.

Proficiency With Walking Aid

0	Unable to stand with appliance
1	Stands with appliance, holds on, unable to step
2	Steps with manual facilitation/ support from therapist
3	Steps independently, requires assistance to move appliance
4	Steps independently, requires assistance with steering
5	Steps and steers independently with appliance

2. Component indicators are not hierarchical but merely list important components required for a functional activity. The codes 0 - 5 indicate the number of listed components that a patient is able to achieve. Order of acquisition of the listed components is unimportant, it is simply a case of the more the better. An example of a component indicator follows:

Independent Dressing

Puts on tracksuit top (not zip)

Puts on tracksuit pants

Puts on socks

Puts on shoes (not laces)

Zips up tracksuit top

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

3. Quiz-type indicators are different from both component and hierarchical indicators. Usually the indicator consists of a series of questions or true or false statements (the quiz), the responses of which translate onto a 6 point TELER reference scale. Quiz-type indicators can be used to assess things such as a patient's' knowledge or perceptions regarding a condition; and a patient's expectation of or satisfaction with treatment, for example.

LeRoux[20] defines an outcome as being clinically significant when it can be justified with clinical or other knowledge; the change denoted by the difference between two successive outcomes can be explained with clinical or other knowledge; and if time is needed for such change to occur, this can also be explained with clinical or other knowledge. An outcome could also be defined as being clinically significant if it can be justified by the patient in some circumstances. He goes on to explain that the codes or outcomes on a TELER indicator must satisfy the following conditions:

* Each outcome is a clinically significant outcome.
* The progression from one outcome to the next is clinically significant.
* The outcomes reflect what is actually happening to the patient, as seen by the clinician, the patient and the carer.

By virtue, then, of the way in which a TELER indicator is established, the difference between two successive indicator codes is defined as a clinically significant change[20]. These changes can be positive (improvements), negative (deteriorations) or "0" (no change).

For each patient presenting with a deficit or deficits a TELER indicator must be established and codes defined. This may just require verifying that an existing indicator is appropriate, or it may require defining a new indicator. This is often perceived as one of the disadvantages of using TELER[20].

There is no rule regarding the interval between measurements. It is suggested that, when the interval between clinically significant changes is long, as is often the case with cerebral palsy (and other chronic conditions), that measurements be made at regular intervals rather than at each treatment session. (LeRoux[20] suggests monthly or 3 monthly intervals). If required measurements can be made at the beginning and end of a treatment session. This will show whether treatment has an immediate effect and whether the effect is sustained or transient.
Two or more groups of indicators may be used to measure outcome over a period of time. The indicators may be any of the three types.

TELER Evaluation

The main purpose of TELER is to evaluate the effectiveness of treatment or care received by a patient. The design of the TELER form which allows for the documentation of both a treatment plan and change occurring in the patient as traced by the TELER indicators, facilitates such an evaluation. Using the TELER form one is able through visual inspection correlate changes in the patients performance with aspects of treatment. This is best explained by means of a worked example which can be found in Addendum 3.
A patients performance on one or a group of TELER indicators can also be plotted graphically to illustrate his performance over time.

Validity and Reliability of TELER

LeRoux[20] provides comprehensive support for the validity and reliability of the TELER system and its indicators based on the theory of measuring scales. This argument probably holds for the system, but the system is entirely dependent upon the indicators established when using it. These indicators are established at will by the clinicians using the TELER system and the theoretical argument for the validity and reliability of the indicators does not necessarily translate into practice. LeRoux[20] echoes this sentiment saying: "A TELER indicator has the potential to provide ordinal measurements that are perfectly valid and reliable. That potential may or may not be realised depending on how effectively the indicator is used."

As has been illustrated by the GMFM reliability of a TELER indicator is going to be primarily contingent upon the manner in which the indicator and each of its codes are defined. The instructions for what constitutes a particular code must be clear and explicit. LeRoux[20] suggests that the fact that codes must, by definition, describe outcomes that are clinically significant maximises their reliability. By definition an indicator which does not have content validity is not a TELER indicator[20,97]. LeRoux[20] argues that because the definitions of an indicator's codes are based on clinical knowledge and are relevant to the deficit presented by the patient, an indicator must have content validity. He goes on to argue that in practice content, concurrent and construct validity "are all established simultaneously, to the extent that the group of clinicians who are to use the indicator define it's codes by consensus.". The users of TELER are therefore free to develop the validity of the indicators they have established to the extent that these users find appropriate.
At the time of preparing this study there were no studies published in peer-reviewed form that had investigated either the reliability or validity of the TELER system or its indicators. A proposed study[107] aiming to validate indicators for use particularly in the rehabilitation of adult stroke patients has resulted in the publication of a catalogue of valid indicators[108] for use in the aforementioned field. It is essential, if TELER is going to be used

both clinically and for research purposes, that the validity and reliability of the indicators being used are established and that results of such validation studies are published. One of the advantages of TELER is that it is not designed or intended to be prescriptive and indicators can be tailor-made to suit the needs of the each individual patient. With the development of lists of valid and reliable indicators one may move away from this flexible system towards a more prescriptive and rigid system. This is clearly an area that needs to be addressed and researched in detail.

The primary aim of the current study with respect to TELER, was simply to look at the feasibility of using TELER as an outcome measure in children with cerebral palsy receiving NDT. The perceived potential usefulness of the GMFM in assisting with the establishment of validity of indicators addressing gross motor skills was commented upon. This study was not intended to investigate and establish valid TELER indicators for use in the field of cerebral palsy.

CHAPTER 4
METHODOLOGY

4.1 Study Population and Sampling

The study population consisted of educable cerebral palsy children attending Vista Nova School for Cerebral Palsy Children in CapeTown.

For inclusion in the study the children had to:

- Be aged more than four years and less than seven years at time of entry into the study.
- Have a definite diagnosis of cerebral palsy.

Children were excluded from the study if they:

- Were due to undergo/underwent any surgical intervention during the study period. Surgery prior to the study period was acceptable. The fitting or use of any orthopaedic appliances or devices (eg. ankle-foot orthosis (AFO), supramalleolar orthosis (SMO), rollator, Kay-walker) was also acceptable as such devices are routinely included in and as an adjunct to the practice of NDT.
- Were due to receive/received Botox injection during the course of the study.
- Began taking medication which had an effect on the central nervous system, or changed a pre-existing regimen of such medication, during the study period. The child had to be considered to be stable on any pre-existing regimen of such medication for inclusion in the study.
- Had uncontrolled epilepsy or any progressive central nervous system disorder.
- Were already involved in any pharmaceutical trials.
- Underwent hyperbaric oxygen treatment during the course of the study.
- Received physiotherapy treatment during the school holidays (see Study Design)

4.2 Study Design

A multiple single-subject (AB) study design was used in which the children acted as their own controls. The study design is illustrated in figure 4.1. "A", the baseline phase was a period, specifically the June/July school holiday, during which no physiotherapy treatment was received by the child, apart from any home programme normally carried out by his/her parents or care-giver. Such a home programme generally consisted of basic positioning and handling techniques as well as stretching of key muscle groups. "B", the intervention phase followed on immediately from the baseline phase. This was a period during which active physiotherapy treatment, using the NDT approach, was received by the child. Treatment sessions were carried out twice a week and each session lasted 30-45 minutes. In addition the home programme as described in "A" was continued.

Assessments of the children in the sample were done three times during the study period - at the beginning of the baseline phase (A), at the end of the baseline phase (beginning of the intervention phase) and at the end of the intervention phase (B).

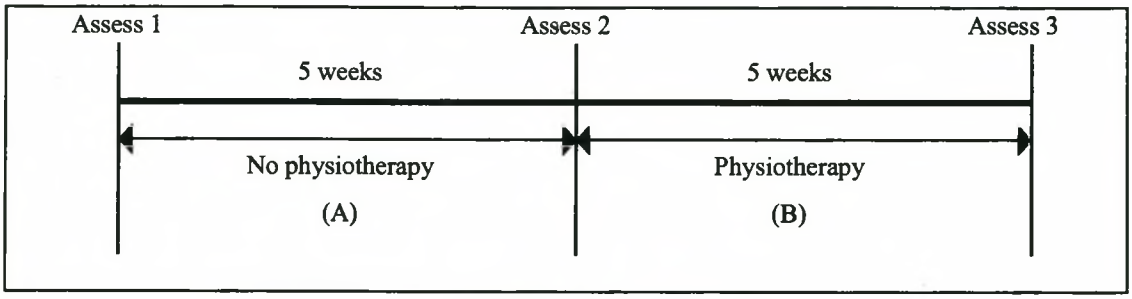

FIGURE 4.1: The study design

4.3 Outcome Measurements

Change in motor function was measured using two different assessment tools, namely the Gross Motor Function Measure (GMFM)[19,95] and TELER[20,97].

Although formal training in the administration of the GMFM is recommended it is not an essential. Due to distance and cost constraints the researcher was unable to undergo such training. However detailed study of the GMFM test manual was made and both the administration and scoring of the test were practised. Following this the researcher's agreement with a criterion video tape was evaluated. This criterion tape is normally used to evaluate the level of agreement of participants following a formal GMFM training workshop. The chosen accepted level of agreement with the criterion video tape is kappa $\geq$ 0.80. This kappa statistic weights disagreements between the rater's scoring and the criterion scoring so that the further a person is away from the correct score the more they are penalised[19]. The researcher's level of agreement with the criterion video tape was 0.96.

It is estimated that the GMFM should take approximately 45-60 minutes to administer[19]. Based on this sufficient time was allowed for each child, with time built in to accommodate the carryover of testing to the following day if necessary. This is allowed for example in the case of a child who tires easily such that his performance is affected. All items feasible for a child to attempt were tested. A verbal explanation and/or demonstration of the item to be tested was given and the child was allowed to perform the item, with assistance if necessary, to ensure he understood what was required. The child was then allowed 3 attempts at executing the item without any assistance and the best of these 3 attempts was scored[19]. A difficult or uncooperative child was scored based on observation of spontaneous movement during play. Only observed items performed without any 'hands-on' assistance were scored. No credit was given for reported or perceived performance.

If the child used any walking aids and/or orthoses the entire test was first completed without the respective aids and/or orthoses and then the walking aids and/or orthoses were applied in the testing of the standing and walk/run/jumping dimensions only. It was anticipated that these were the dimensions that would be affected most by the use of such aids. The aids were applied for the same items at all three assessments. This ensured that any

changes in score were a result of change in function and not due to the fact the aid was applied at a different item number.

A total score for each of the 5 GMFM dimensions was obtained and the total score for each dimension was expressed as a percentage. The average of the percentage scores for each dimension gave the child a total GMFM score. Based on the gross motor deficits represented by the TELER indicators established, one or more dimensions of the GMFM were identified as goal areas for each child and calculating the average score for these dimensions gave the child a goal total score.

Prior to commencing the baseline phase (A) the therapists of the children in the sample together established and agreed upon three TELER indicators for each of the children. The indicators centred around the short to medium term treatment goals envisaged for the children. The researcher assisted in this process only with her knowledge of the TELER system and the process for establishing of indicators. The researcher had had no contact with the children at this stage so was not involved in any way with the selection of treatment goals. The indicators established represented primarily various gross motor skills, activities of daily living and some other factors affecting treatment, for example the child's tolerance of therapy. Details of these indicators can be found in Addendum 4. Only function and component indicators were established.

When assessing the childs performance on the indicators an explanation and/or demonstration of the activity required was given to the child. The child was then allowed 3 attempts at the activity and the best attempt was used to award a code as per the established indicator. In the case of dressing activities the child's dressing/undressing was observed at the time of the GMFM assessments and again at a physiotherapy treatment session (for both of which the children changed into shorts and T-shirts) occurring during the same week as the assessments. The best of the 2 performances was used to code the relevant TELER indicator. In the case of the two indicators involving tolerance of therapy and concentration during therapy, the child's behaviour during the GMFM assessments was observed and 2 physiotherapy treatment sessions were observed during the assessment weeks. Again the best performance was used to award the TELER code.

The TELER indicator codes applicable to each child for each of his or her three indicators were noted at the initial assessment and then again at the second and third assessments. The number of clinically significant improvements or deteriorations shown by a child on each of his/her indicators between assessments 1 and 2 were counted, these numbers were totalled to give a single number indicating the clinically significant change shown by the child during the baseline phase This was repeated for the treatment phase of the study using the difference in indicator codes between assessments 2 and 3. A TELER score was also calculated for each child at each assessment by summing the codes obtained on each of the three indicators.

4.4 Intervention/Therapy

Children in the sample were treated by their respective physiotherapists at the school during the intervention phase of the study, meaning that 3 therapists were involved in providing NDT treatment in this study. The same therapist saw the child throughout the intervention phase of the study. All the physiotherapists involved in the study had successfully completed a basic two month paediatric NDT course. Two of the therapists had been treating cerebral palsy children in a school situation for more than 10 years. The third therapist had been treating cerebral palsy children in a school setting for just more than 5 years and had previously worked in the area of orthopaedic rehabilitation for several years.

In addition to physiotherapy some of the children in the sample were receiving occupational therapy and speech therapy. It was presupposed that speech therapy was unlikely to affect change in gross motor function although occupational therapy may well have an effect especially where functioning of the upper extremities is concerned. The approach to treatment of motor dysfunction used by the occupational therapists who treated the children in the sample was that of NDT and so this was considered an adjunct to the physiotherapy, with similar treatment principles and goals. Occupational therapy sessions were received once a week by 9 children in the sample. The approach adopted by the physiotherapists treating the children in this study was that of NDT. Therapy was given on a one to one basis and followed the treatment principles and methods that were described in detail in chapter 2. The TELER indicators that were established for each child provided the specific activities or functional goals around which therapy was structured.

Equipment used by the therapists included therapy balls and bolsters, balance boards and beams, as well as a variety of smaller toys. All equipment used would be routinely found in any physiotherapy department involved in the treatment of neurologically handicapped children.

Therapy was carried out primarily in the school's physiotherapy gymnasium, but also on occasion in the playground and other school areas of the school. For example towards the end of a treatment session children learning to become independent with their walking aids would practice walking with their aids and negotiating the way back to their classrooms under the guidance of the therapist. Little actual treatment was carried out in the classroom itself, but aspects of therapy were carried over into the classroom situation by the teachers and classroom assistants at the request of the physiotherapist.

4.5 Implementation

Prior to commencing the study the physiotherapists involved in the treatment of the children were informed of the overall study design and instructed in the use of TELER. This was done in the form of a workshop together with the researcher and the study supervisor. Before the commencement of the baseline phase (A) the children included in the sample were evaluated by their therapists and TELER indicators established as already described. At the commencement of the 5 week "no intervention" period all children in the sample were assessed by the researcher using the GMFM and the recently established TELER indicators. The same assessments were repeated, under the same conditions, at the end of this 5 week period. The children then began the five week treatment/intervention period (B) consisting of two treatment sessions per week. At the end of this treatment period the children underwent a third and final assessment using the GMFM and the TELER indicators. Children were treated by their respective physiotherapists, as described above, at the school during the treatment phase of the study.

All assessments were carried out by the researcher. All assessments (except for one) were carried out at the school in the physiotherapy gymnasium during regular physiotherapy time. One initial assessment was carried out by the researcher at the child's home as this particular child was unable to get to school during the week of the initial assessments, but would be at school during the treatment phase of the study.

No attempt was made to assess the nature of home programmes specific to each child or to measure compliance with such programmes as it is presumed that these remained constant for the duration of the study. Compliance with home programmes for chronic conditions (like cerebral palsy) is generally considered to be poor[62]. Therapy was administered in a school setting so parents were not present during the treatment sessions providing little opportunity for the therapists to explain and emphasise the home programmes. Parents who were not carrying out any sort of home programme during the term-time, were considered unlikely to start with such a home-programme over a relatively short school holiday period. On the other hand the parent who regularly carried out a home programme was considered likely to be fairly consistent in the administration thereof.

The study commenced during the last week of the second school term of 1999 when the initial assessments were completed. The second assessments were completed during the fifth week of the study, at the beginning of the third school term and the treatment/intervention was commenced immediately thereafter and was allowed to run for a full 5 week period, with final assessments being done at the end of this second 5 weeks (i.e. in the eleventh week of the study).

4.6 Statistical Analysis

GMFM

The total and goal total scores obtained by each child were plotted graphically and trends were analysed visually. The multiple single-subject design utilised resembles that of a "matched" control and treatment group design and it is possible to compare outcomes for each of the phases (baseline and intervention) of the study in the same way that the treatment and control groups would be compared in a group design.

The Wilcoxon signed rank test is a non-parametric test designed to measure differences in median between two related samples. A non-parametric test is used as there is no basis for assuming a distributional form for a measured outcome in the population studied. Accordingly the Wilcoxon signed rank test was applied on the GMFM data to determine whether statistically significant changes in GMFM scores were achieved for either the baseline or treatment periods.

TELER

The codes of the three indicators at each assessment were plotted graphically and trends in the children's performance were analysed visually. From the TELER indicator codes the total number of improvements and/or deteriorations between assessments 1 and 2, and then assessments 2 and 3 were counted for each child. In addition a TELER score was calculated for each child at each assessment by summing the codes obtained on each of the three indicators.

The TELER data was analysed to determine two things, firstly whether deficits (represented by the indicators) responded to treatment and secondly whether patients responded to treatment. Although a deficit cannot respond to treatment without the patient also responding to treatment the two responses may not be the same. This is because more than one indicator was used used to trace change in the children in this study. If only one indicator had been used the response of the deficit and the patient would have been the same[109]. The former was done by calculating the chi-squared statistic for the expected versus the observed number of indicators having final code of 0, the observed number having a final code of 1 (2, 3...etc.) at assessment 2 (baseline phase) and at assessment 3 (intervention phase). The chi-squared statistic is calculated by way of the following formula:

$$D^2 = \Sigma (O_i - E_i)^2 / E_i$$

where D^2 is the chi-squared statistic, O is the observed value and E the expected value.

The effect of treatment on the patients was determined by calculating the chi-squared statistic to ascertain whether the change seen was attributable to the treatment given. The t-test was used to test the null hypothesis, that is to test whether treatment had an effect. The formula for the t-test is as follows:

$$t_{n-1} = \frac{X - \mu}{s / n^{0.5}}$$

where X is the average number of improvements, $\mu = 0$ as per the null hypothesis, s is the standard deviation and n is the number of patients in the sample.

A feature of the TELER indicator is that it produces before and after results linked by covariance which needs to be taken into account in the analysis of the results. In order to do this an alternative probability distribution to the one normally used for calculating the expected values of a chi-squared test was used. The correct, calculated alternative probability distributions that were used to calculate the expected values used in the analysis of the TELER data can be found in Addendum 5.

4.7 Ethical and Legal Considerations

The proposal for this research was approved by Research Committee C, University of Stellenbosch.
Permission for the study was obtained from the following:

* The Western Cape Education Department (Director of Special Needs Education).
* The principal of Vista Nova School.
* The head of the physiotherapy department at Vista Nova School.

Informed consent was obtained telephonically, as well as by means of a letter and informed consent document (Addendum 6) that was sent to each parent, from the parents of the children participating in the study prior to entry into the study. A signed informed consent document was received from all parents whose children participated in the study. If any parent was concerned about their child's well-being during the study period they were invited to discuss this with the researcher and/or relevant school physiotherapist.

A concern, from an ethical standpoint, with the study design used is the withdrawal of treatment during the baseline phase. For this reason the school holiday time was chosen for the baseline phase. Most children would normally have a break from physiotherapy during this time meaning that at no stage would the child be prevented from receiving physiotherapy. The parents of any child who usually received private physiotherapy during the school holiday were given the option to participate in the study if they so wished, on the understanding that the physiotherapy be stopped for the school holiday period. None of the parents in this situation elected to participate in the study.

CHAPTER 5
RESULTS

5.1 The Sample

A sample of 14 children fulfilled the inclusion criteria for the study. Four of these children were then excluded from the study. Two of the four received physiotherapy during the school holidays which their parents did not want to discontinue for the purposes of the study. One child was due to undergo orthopaedic surgery (adductor releases) midway through the study period which his parents were unhappy to delay. The fourth child was absent from school during the week of initial assessments and had been so for some time. His mother was contacted by the researcher and she promised to bring him in to school for his initial assessment, but did not do so. He was considered by the school staff too unreliable to include in the study due to his erratic school attendance.
This left a sample of ten children for inclusion in the study.

Age

The average age of the children in the sample was 6 years, 0 months. The children's ages ranged from 4 years 10 months to 6 years 10 months. (Median 6 years 5 months). Details of the children included in the study are summarised in table 5.1.

TABLE 5.1: Details of the sample

CHILD	SEX	AGE ON ENTRY INTO STUDY	DIAGNOSIS	SEVERITY OF DISABILITY
1	female	4yrs 10mths	ataxic	severe
2	female	5yrs 8mths	left hemiplegic	mild
3	male	6yrs 10mths	right hemiplegic	moderate
4	male	6yrs 5mths	athetoid	moderate
5	male	6yrs 8mths	right hemiplegic	mild
6	male	6yrs 7mths	left hemiplegic	mild
7	female	6yrs 7mths	left hemiplegic	mild
8	female	6yrs 8mths	spastic diplegic	severe
9	female	4yrs 10mths	spastic quadriplegic	severe
10	male	5yrs 3mths	spastic diplegic	moderate

Details of the diagnosis and severity of disability of the children in the sample are summarised in figures 5.1.1 and 5.1.2 which follow.

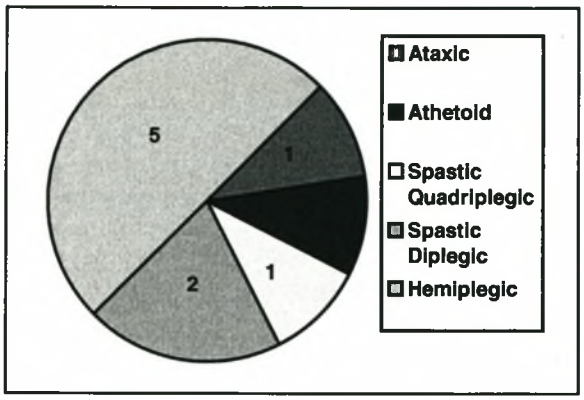

FIGURE 5.1.1: Diagnoses

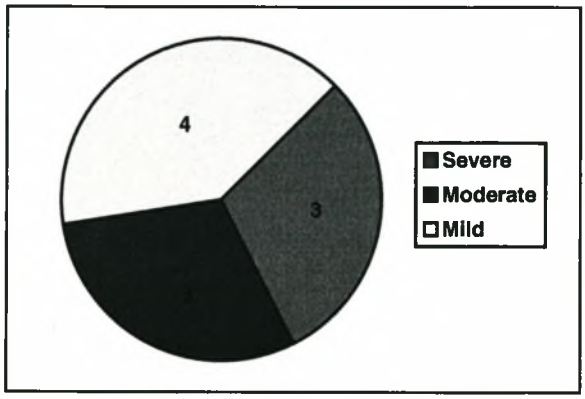

FIGURE 5.1.2: Severity of disability

As the study design was that of a multiple single case study, the results for each individual child in the study are presented first, followed by the results of the group as a whole as measured by the GMFM and TELER.

5.2 Single Subject Outcome

In this section only the title/description of the TELER indicators established for each child are given. Details of the codes for each indicator can be found in Addendum 4. A dimension on the GMFM was considered a "goal area" if one of the TELER indicators set fell into that dimension or reflected components of the dimension. In the tables which follow showing GMFM scores for each of the children in the sample, dimensions considered to be goal areas for the child in question are marked with a subscript "g". All GMFM scores reported are percentages.

Child 1

Child 1 was female and was aged 4 years and 10 months at the time of entry into the study. Her diagnosis was that of a non-progressive ataxia. In addition she showed characteristics of pervasive personality disorder. She was considered by her physiotherapist to be severely disabled. In addition to physiotherapy she received speech therapy and occupational therapy. She used a reverse-walker but, on entry into the study, needed to be placed in it and assisted when using it to walk. Child 1 disliked therapy and showed tremendous resistance to it.

The following TELER indicators were established for her:

1. Proficiency with a walking-aid
2. Dynamic floor-sitting
3. Tolerance of therapy

She was very uncooperative during the first and second assessments, particularly with the items on the GMFM, and more co-operative during the third. Assessment was done primarily by observation of her movement during play. She was seen for a total of 9 treatment sessions during the intervention phase of the study.

The graph below shows the codes of the TELER indicators at each of the 3 assessments. Between assessment 1 and 2 (the no-treatment period) there was 1 clinically significant deterioration on indicator 1, and between assessments 2 and 3 (the treatment period) there were a total of 9 clinically significant improvements.

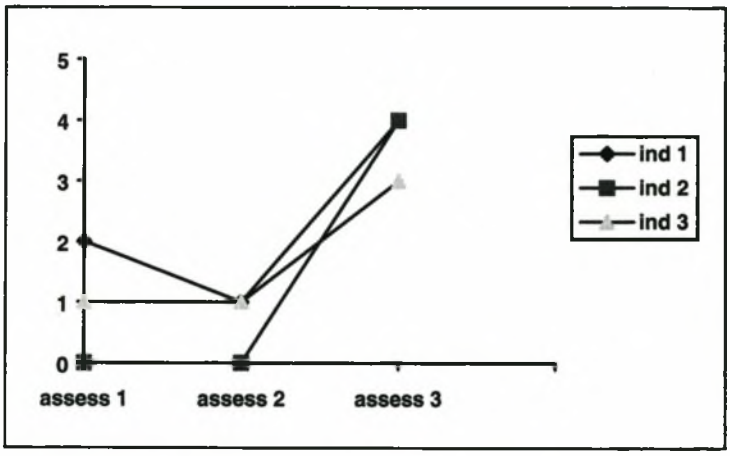

FIGURE 5.2.1: Performance on TELER indicators

Based specifically on the TELER indicators the sitting and walking/running/jumping dimensions of the GMFM were considered to be goal areas for the treatment period. Results for each dimension at each of the three assessments, followed by total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.2.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	31.4	31.4	35.3
Sitting$_g$	63.3	68.3	90.0
Crawl/kneeling	31.0	33.3	38.1
Standing	2.6	2.6	23.1
Standing +aids	12.8	refused	33.3
Walk/run/jump$_g$	4.2	4.2	8.3
Walk/run/jump$_g$ +aids	6.9	refused	12.5

TABLE 5.2.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	26.5	28.0	39.0
Goal total score	33.7	36.2	49.2
Total score +aids	29.1	refused	41.8
Goal total score +aids	35.1	refused	51.3

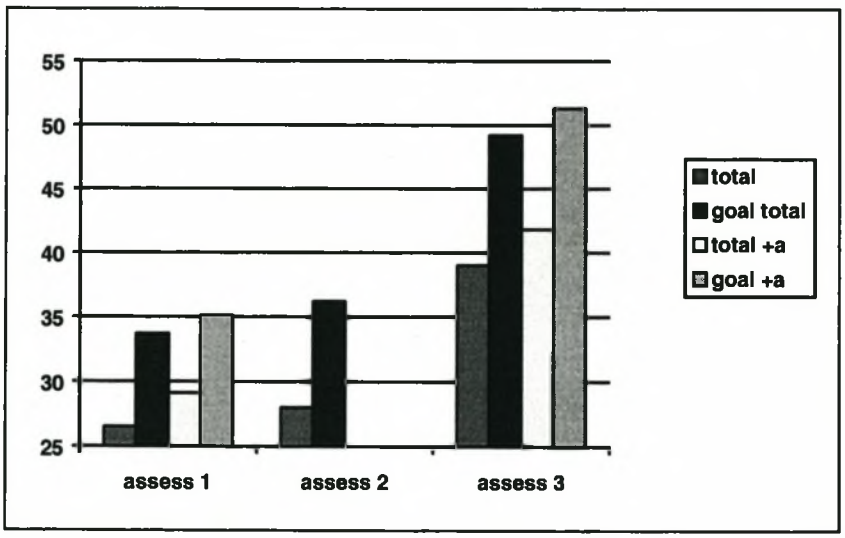

FIGURE 5.2.2: Total and goal total GMFM scores

During the baseline phase child 1's total and goal total scores improved by 1.5% and 2.5% respectively. Improvements in these scores during the treatment phase were greater, being 11.0% and 13.0% respectively. Changes in total and goal total scores with walking aids could not be assessed as child 1 refused to use her walking aid at assessment 2.

Child 2

Child 2 was a female aged 5 years and 8 months at time of entry into the study. She was a left hemiplegic considered by her therapist to be mildly affected - she was independently ambulant and had limited use of her left upper extremity. In addition to physiotherapy she received both speech and occupational therapy. She was fitted with both a left ankle-foot orthosis (AFO) and a right supramalleolar orthosis (SMO). Although these are considered "aids" when scoring with the GMFM, they made no difference to her functional ability and she achieved the same GMFM scores both with and without "aids". No scores "with aids" are reported.

The following TELER indicators were established for child 2:

1. Attain Standing Through 1/2 Kneeling Using Support
2. Improve Ball Skills
3. Standing Balance for Dressing

Co-operation during all three assessments was excellent and all test items on the GMFM were scored. A total number of 9 treatment sessions were received by child 2 during the intervention phase of the study.

The graph below shows the codes of the TELER indicators at each of the 3 assessments. Between assessment 1 and 2 there were a total of 2 clinically significant improvements, accounted for by indicator 3. Between assessments 2 and 3 a total of 4 clinically significant improvements were seen with 3 clinically significant improvements on indicator 2 and 1 on indicator 1.

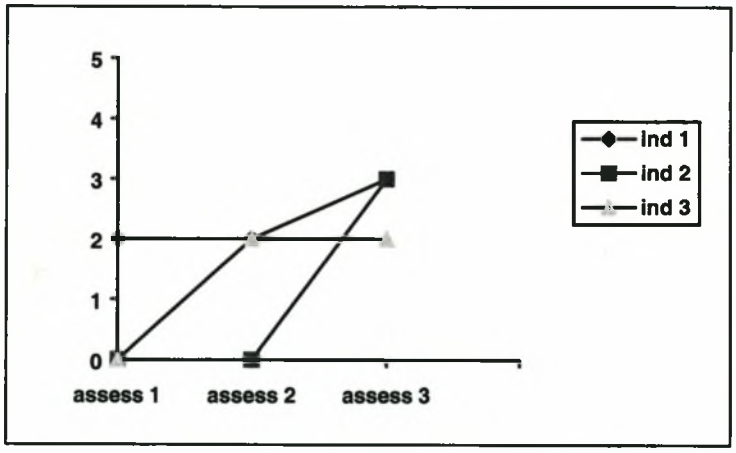

FIGURE 5.3.1 Performance on TELER indicators

Based on the TELER indicators established the crawling/kneeling and standing dimensions were considered to be goal areas for the treatment period of the study. The crawling/kneeling dimension was identified as a goal area following the establishment of the TELER indicators, however when GMFM testing was done a score of 100% was achieved by child 2. It was decided to retain the dimension as goal area as movement quality was poor in this dimension (the TELER indicator addressed movement quality) and it was felt that the score achieved had the potential to deteriorate. Results for each dimension at each of the three assessments and total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.3.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	100	100	100
Sitting	98.3	100	100
Crawl/kneeling$_g$	100	100	100
Standing$_g$	79.5	92.3	92.3
Walk/run/jump	84.7	87.5	90.3

TABLE 5.3.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	92.5	96.0	96.5
Goal total score	89.7	96.2	96.2

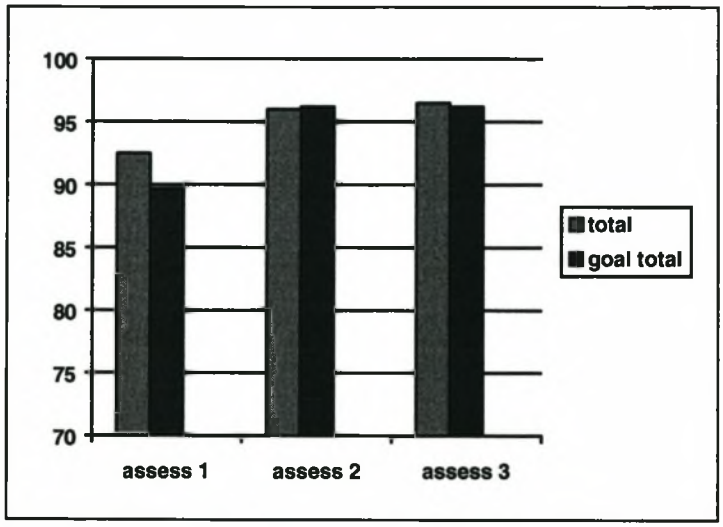

FIGURE 5.3.2: Total and goal total GMFM scores

Child 2 showed a greater improvement in both total and goal total scores between assessments 1 and 2 than between assessments 2 and 3. Improvements in total and goal total scores were 3.5% and 6.5% respectively for the no-treatment phase, but 0.5% and 0% respectively for the treatment phase.

Child 3

Child 3 was a male with a right hemiplegia. He was aged 6 years and 10 months at the beginning of the study. He was described by his therapist as moderately affected. He was independently ambulant but his right upper extremity was severely affected. He also received occupational therapy and had been fitted with a right hand splint which he did not use and hence was not worn during any of the assessments. He was also fitted with an AFO but as with the previous child it did not make any difference to his GMFM scores when assessed with and without, so again no scores "with aids" are reported.

The following TELER indicators were established for child 3:

1. Dynamic Weight-Bearing on an Extended Arm in Side-Sitting
2. Improved Gait Pattern (Heel-Strike)
3. Standing Balance for dressing

Co-operation when assessing on all three occasions was good and all GMFM test items were scored. Child 3 received a total of 10 treatment sessions over the 5 week treatment period.

Performance on each of the three TELER indicators is illustrated below. Child 3 achieved 1 clinically significant improvement between assessments 1 and 2. All 3 indicators showed 1 clinically significant improvement at assessment 3, giving a total of 3 clinically significant improvements for the treatment phase.

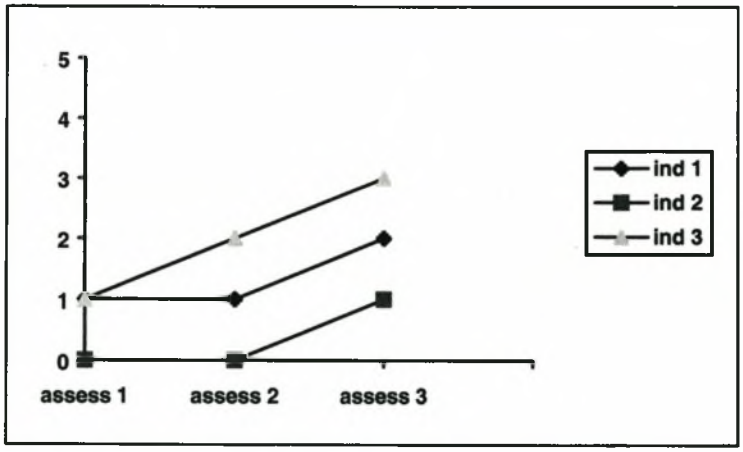

FIGURE 5.4.1: Performance on TELER indicators

Based on the TELER indicators the sitting, standing and walk/run/jumping dimensions were identified as goal areas in the GMFM for the treatment period. Results for each dimension at each of the three assessments as well as total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.4.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	90.2	92.2	92.2
Sitting$_g$	95.0	96.7	98.3
Crawl/kneeling	73.8	78.6	78.6
Standing$_g$	87.2	92.3	94.9
Walk/run/jump$_g$	76.4	79.2	87.5

TABLE 5.4.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	84.5	87.8	90.3
Goal total score	81.8	85.7	91.2

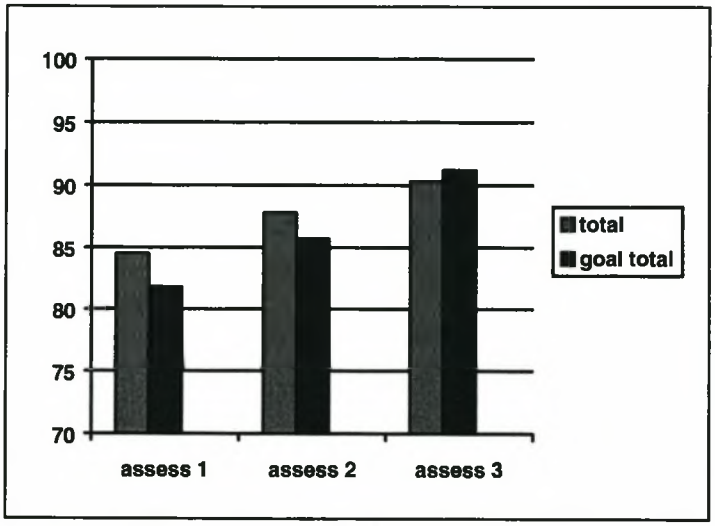

FIGURE 5.4.2: Total and goal total GMFM scores

Child 3's total GMFM scores improved by 3.3% during the no-treatment phase and by 2.5% during the treatment phase of the study. His goal total scores, however, showed greater improvement during the treatment phase (5.5%) than during the no-treatment phase (3.9%).

Child 4

Child 4 was diagnosed as athetoid. He was aged 6 years and 5 months at the start of the study. He was classified, by his therapist, as moderately affected in terms of his level of disability although he was independently ambulant. In addition to physiotherapy he received speech therapy. He had not been fitted with any orthotics and did not use any other aids.

The following TELER indicators were established for him:

1. Dynamic Standing Balance
2. Independent Undressing
3. Lateral Weight Transfer in Stepping onto a Raised Surface

Child 4's co-operation during all assessments was excellent and all test items on the GMFM were scored. He received only 6 treatment sessions during the 5 week treatment period as he was absent from school with an upper respiratory tract infection for almost 2 weeks of this period. This infection was not severe and is unlikely to have affected performance in any way.

Performance on these indicators is illustrated in the graph below. Child 4 achieved only 1 clinically significant improvement between assessments 1 and 2, being on indicator 1. However he achieved 3 clinically significant improvements on each of the three indicators giving a total of 9 clinically significant improvements between assessments 2 and 3.

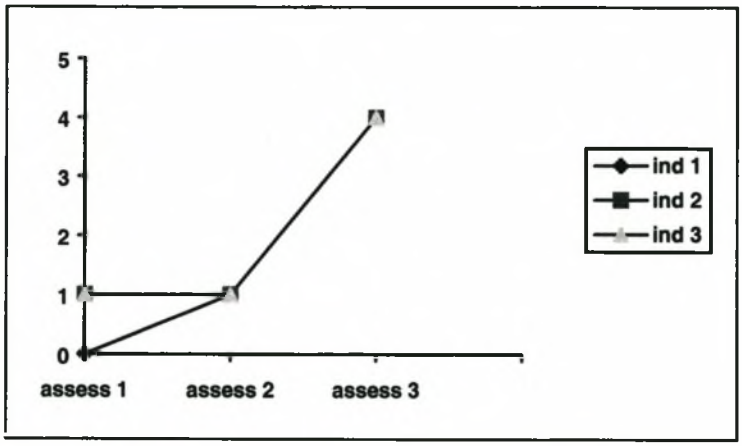

FIGURE 5.5.1: Performance on TELER indicators

Based on the TELER indicators the following dimensions of the GMFM were identified as goal areas for the treatment period of the study: standing and walk/run/jumping. Results for each dimension at each of the three assessments and total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.5.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	98.0	96.1	96.1
Sitting	93.3	95.0	100
Crawl/kneeling	88.1	88.1	92.9
Standing$_g$	74.4	76.9	87.2
Walk/run/jump$_g$	56.9	58.3	72.2

TABLE 5.5.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	82.2	82.9	89.7
Goal total score	65.7	67.6	79.7

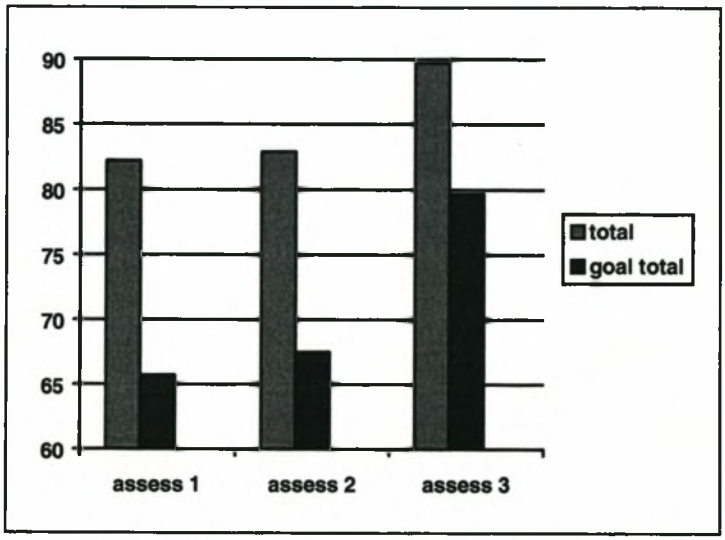

FIGURE 5.5.2: Total and goal total GMFM scores

Child 4 showed improvements in his total and goal total scores of 0.7% and 1.9% respectively during the no-treatment phase. The improvements in these two scores were greater for the treatment phase with a total score improvement of 6.8% and a goal total improvement of 12.1%.

Child 5

Child 5 was male, aged 6 years and 8 months on entry into the study. He was a right hemiplegic who was mildly affected in terms of motor disability but severely disabled in the area of speech. He also had very poor concentration and was very easily distracted. He received both speech and occupational therapy in addition to physiotherapy. He did not use any aids or orthoses.

The following TELER indicators were established for child 5:

1. Independent Dressing
2. Concentration/Attention During an Activity
3. Reciprocal Gait When Walking Downstairs

Although child 5 co-operated reasonably well during the assessments, his first and second GMFM assessments took 10 to 15 minutes longer to complete when compared with the other mildly affected children in the sample. This was due to his poor concentration. His final assessment took approximately the same length of time as the other mildly affected children. All GMFM test items were completed at each assessment. Child 5 received a total of 9 treatment sessions during the treatment period of the study.

Performance on the TELER indicators is shown on the graph below. No clinically significant improvements were achieved at the second assessment but a total of 5 clinically significant improvements were achieved for the three indicators at the third assessment.

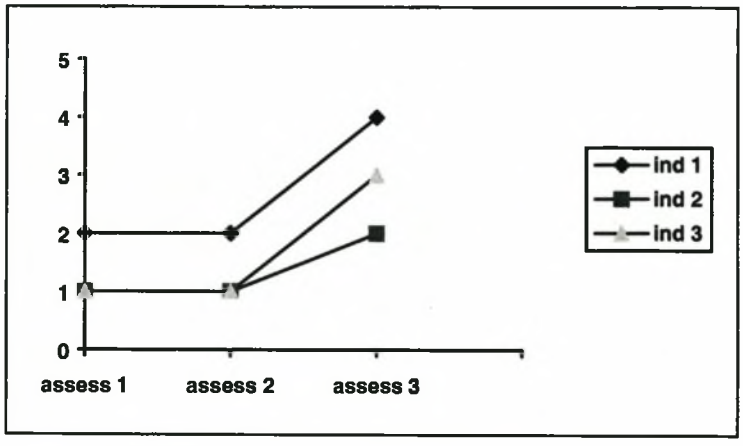

FIGURE 5.6.1: Performance on TELER indicators

Based on the TELER indicators just the walk/run/jumping dimension of the GMFM was identified as a goal area for the treatment period of the study. Results for each dimension at each of the three assessments and total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.6.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	98.0	100	100
Sitting	100	100	100
Crawl/kneeling	100	95.2	100
Standing	92.3	92.3	97.4
Walk/run/jump$_g$	88.9	86.1	94.4

TABLE 5.6.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	95.8	94.7	98.4
Goal total score	88.9	86.1	94.4

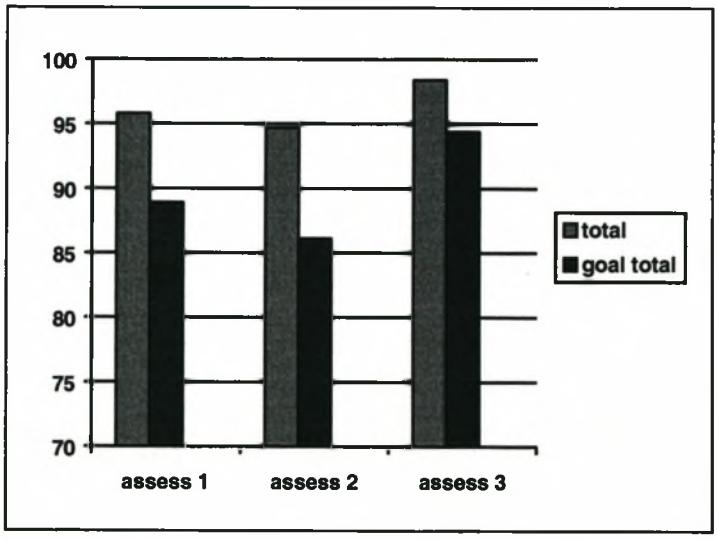

FIGURE 5.6.2: Total and goal total GMFM scores

During the no-treatment phase child 5's total and goal total scores both deteriorated. The total score deteriorated by 1.1% and the goal total score by 2.8%. The total score then showed an improvement of 3.9% during the treatment phase and the goal total an improvement of 8.3% for the same phase.

Child 6

Child 6, a male, aged 6 years and 7 months on entry into the study, was a left hemiplegic. He was considered by his therapist to be mildly disabled. He was independently ambulant with a more affected left upper extremity. He had an AFO for his left foot but as with some of the previous children this did not affect his GMFM scores when tested with his AFO versus without it. He received occupational therapy in addition to physiotherapy.

The following TELER indicators were established for child 6:

1. Ball Skills
2. Standing Balance for Dressing
3. Reciprocal Gait when Walking Downstairs

Co-operation during the administration of the assessments was good and all GMFM test items were completed. Child 6 had 8 treatment sessions during the treatment phase of the study.

Performance on the TELER indicators established is shown in the graph below. Child 6 showed no clinically significant improvements between the first two assessments, but at the third assessment showed a total of 7 clinically significant improvements with improvements on all of the indicators set.

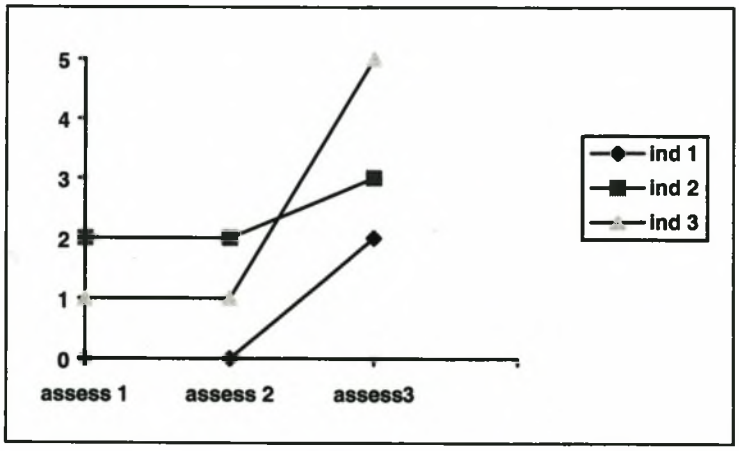

FIGURE 5.7.1: Performance on TELER indicators

Based on the TELER indicators the dimensions of the GMFM considered to be goal areas for the treatment phase of the study were standing and walk/run/jumping. Results for each dimension at each of the three assessments as well as total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.7.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	98.0	98.0	98.0
Sitting	98.3	100	100
Crawl/kneeling	95.2	97.5	100
Standing$_g$	89.7	92.3	94.9
Walk/run/jump$_g$	87.5	90.3	94.4

TABLE 5.7.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	93.8	95.6	97.5
Goal total score	88.6	91.3	94.7

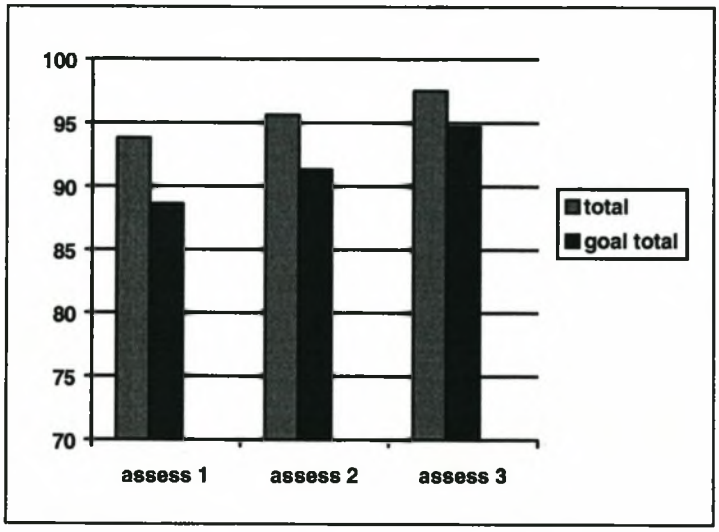

FIGURE 5.7.2: Total and goal total GMFM scores

Child 6 showed improvements in his total and goal total GMFM scores of 1.8% and 2.7% respectively between assessments 1 and 2. Between assessments 2 and 3, the treatment phase, there were also improvements in these scores with a total score improvement of 1.9% and a goal total score improvement of 3.4%.

Child 7

Child 7 was also a left hemiplegic. She was aged 6 years and 7 months at the beginning of the study period. She was considered by her therapist to be mildly disabled. She was independently ambulant but had poor use of her left upper extremity. She did not use any aids nor did she have any orthoses. She received occupational therapy and in addition was receiving weekly horse riding and hydrotherapy. These activities were discontinued during the school holidays. However, as her school attendance for the treatment period was rather erratic only one session of each horse-riding and hydrotherapy were received during the treatment period. Their potential effects were therefore considered to be negligible.

The following TELER indicators were established for child 7:

1. Improved Gait Pattern (Heel-Strike)
2. Ball Skills
3. Standing Balance for Dressing

Child 7 co-operated well with all of the assessments and all GMFM test items were completed at each of the three assessments. Her school attendance was very erratic during the treatment phase of the study and she received only 5 treatment sessions.

The graph below shows the performance on each of these indicators at each assessment. No change was seen between the first and second assessments but a total of 5 clinically significant were made between the second and third assessments with improvement being seen on all three of the TELER indicators.

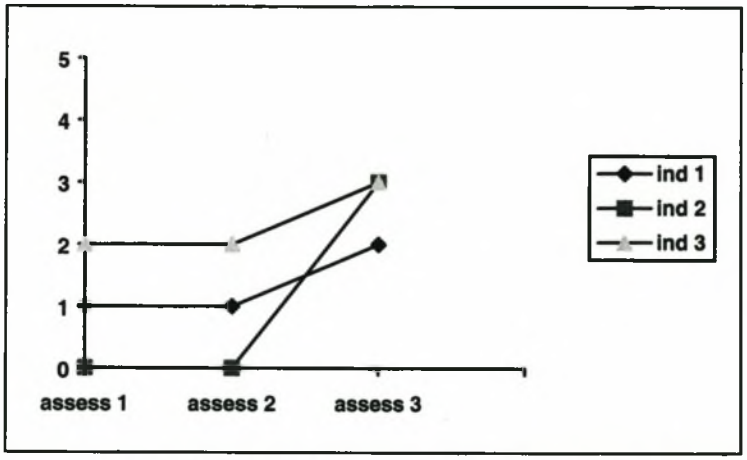

FIGURE 5.8.1: Performance on TELER indicators

Based on the TELER indicators the standing and walk/run/jumping dimensions of the GMFM were considered to be goal areas for the treatment phase of the study. Results for each dimension at each of the three assessments and total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.8.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	96.1	96.1	96.1
Sitting	98.3	100	100
Crawl/kneeling	100	100	100
Standing$_g$	87.2	84.6	97.4
Walk/run/jump$_g$	86.1	87.5	94.4

TABLE 5.8.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	93.5	93.6	97.6
Goal total score	86.6	86.1	95.9

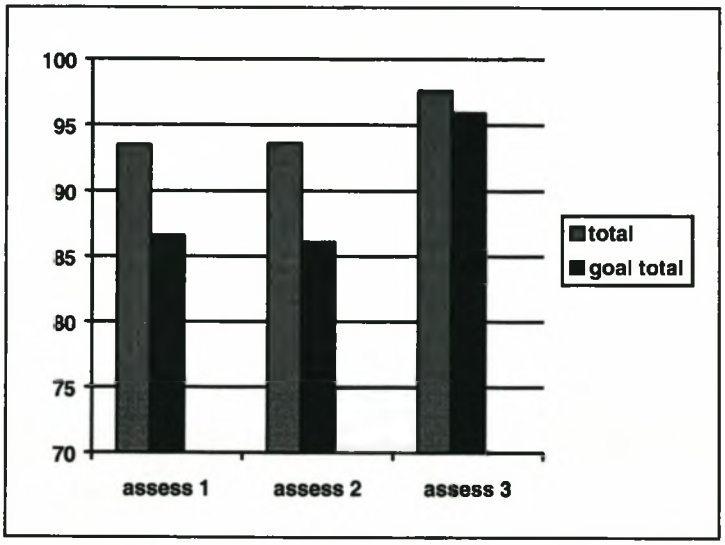

FIGURE 5.8.2: Total and goal total GMFM scores

During the no-treatment phase of the study child 7 showed an improvement in total score of 0.1% and her goal total score deteriorated by 0.5%. During the treatment phase her total score improved by 4% and her goal total score improved by 9.8%.

Child 8

Child 8 was a female spastic diplegic. She was 6 years and 8 months at time of entry into the study. She was ambulant with elbow-crutches and wore bilateral AFO's. These AFO's had been fitted just prior to the study and replaced knee-ankle-foot orthoses that she had been wearing previously. She was considered by her therapist to be severely disabled. Child 8 received occupational therapy in addition to her physiotherapy.

The following TELER indicators were established for child 8:

1. Balance in 1/2 Kneeling
2. Walking Without Back-Kneeing
3. Dynamic Standing Balance

Her co-operation during the assessments was good and all test items on the GMFM were completed. Child 8 received a total of 11 treatment sessions during the treatment phase of the study.

Her performance on the TELER indicators established is shown in the graph which follows. Child 8 showed no clinically significant improvements between assessments 1 and 2, however there were 4 clinically significant improvements between assessments 2 and 3. These improvements were accounted for by indicators 2 and 3. Indicator 1 showed no change throughout the study.

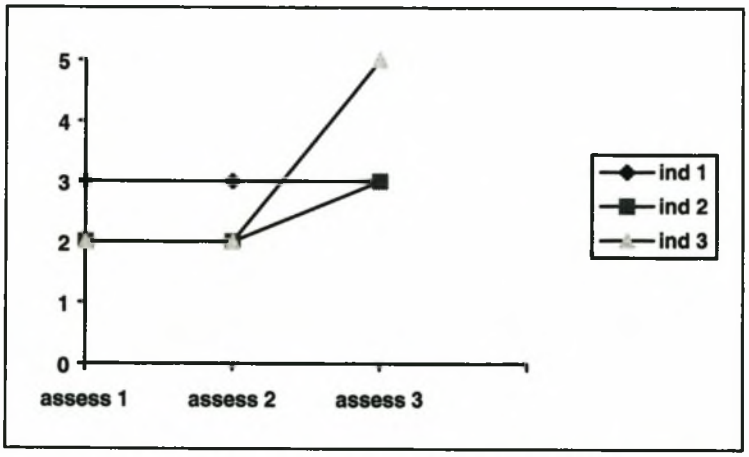

FIGURE 5.9.1: Performance on TELER indicators

Based on the TELER indicators the areas of the GMFM identified as goal areas were crawl/kneeling, standing and walk/run/jumping. Results for each dimension at each of the three assessments as well as total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.9.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	96.1	94.1	96.1
Sitting	95.0	96.7	100
Crawl/kneeling$_g$	81.0	78.6	90.5
Standing$_g$	43.6	43.6	61.5
Standing$_g$ +aids	61.5	61.5	76.9
Walk/run/jump$_g$	11.1	15.3	15.3
Walk/run/jump$_g$ +aids	19.4	25.0	27.8

TABLE 5.9.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	65.4	65.7	72.7
Goal total score	45.2	45.8	55.8
Total score +aids	70.6	71.2	78.3
Goal total score +aids	54.0	55.0	65.1

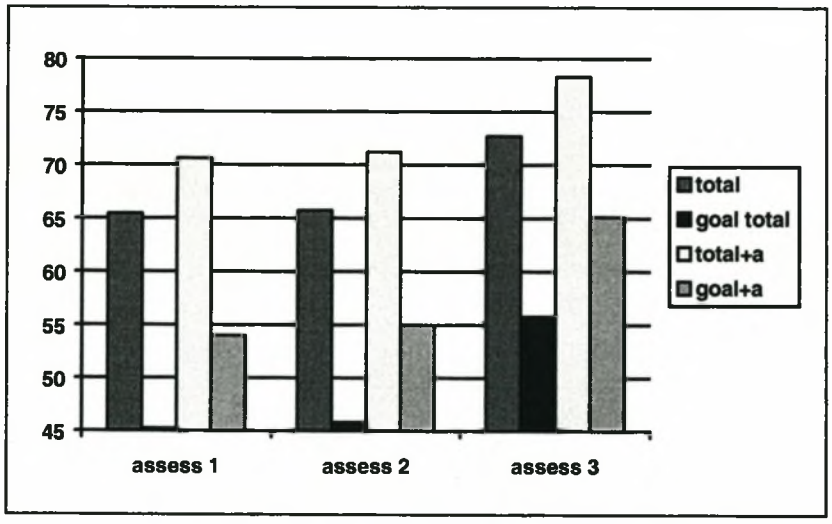

FIGURE 5.9.2: Total and goal total GMFM scores

Child 8 had equal improvement (0.3%) in her total and goal total scores for the baseline phase. During this phase her total and goal total scores with walking aids improved by 0.6% and 1.0% respectively. Improvements for the treatment phase were greater. Total and goal total scores improved by 7.0% and 10.0% respectively and total and goal total scores with walking aids by 7.3% and 10.1% respectively.

Child 9

Child 9, a female, was aged 4 years and 10 months at time of entry into the study. She was a spastic quadriplegic who was severely disabled. At the beginning of the study she could step independently with the aid of a reverse walker if placed in the walker and required assistance with steering. She was fitted with bilateral AFO's. Child 9 received occupational therapy as well as physiotherapy.

The following TELER indicators were established for child 9:

1. Performance of Activities Without using Pronation/Ulnar Deviation of Forearms/Wrists
2. Attainment of Upright Kneeling
3. Proficiency With Walking Aid

Her co-operation during the assessments was reasonably good, but she tended to tire quickly due to the effort involved in moving. Each assessment was done over two sessions and all test items on the GMFM were completed over the two sessions. Child 9 was received 13 treatment sessions during the treatment period of the study.

Performance on the TELER indicators established is illustrated in the graph below. She showed a total of 3 clinically significant deteriorations between first and second assessments. At the third assessment she showed 5 clinically significant improvements on the indicators set. All deteriorations and improvements were accounted for by indicators 2 and 3. There was no change on indicator 1 throughout the study period.

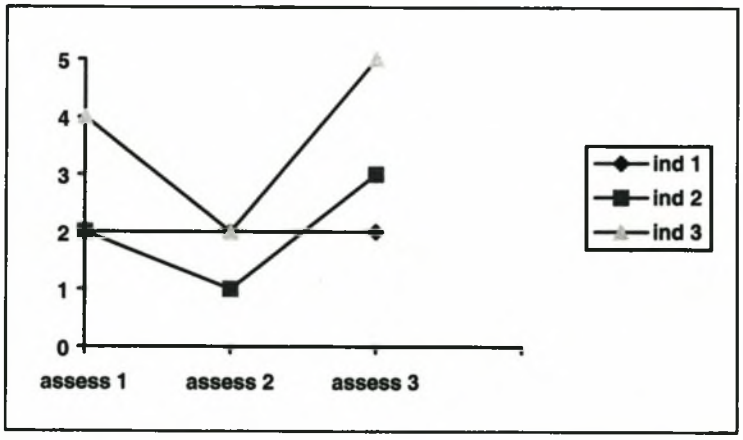

FIGURE 5.10.1: Performance on TELER indicators

Based on the TELER indicators the crawl/kneeling and walk/run/jumping dimensions of the GMFM were considered goal areas for the treatment phase of the study. Results for each dimension at each of the three assessments and total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.10.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	84.3	84.3	82.4
Sitting	46.7	53.3	56.7
Crawl/kneeling$_g$	35.7	26.2	33.3
Standing	12.8	5.1	12.8
Standing +aids	23.1	15.4	23.1
Walk/run/jump$_g$	6.9	6.9	9.7
Walk/run/jump$_g$ +aids	11.1	9.7	13.9

TABLE 5.10.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	37.3	35.1	39.0
Goal total score	21.3	16.6	21.5
Total score +aids	40.2	37.8	41.9
Goal total score +aids	23.4	18.0	23.6

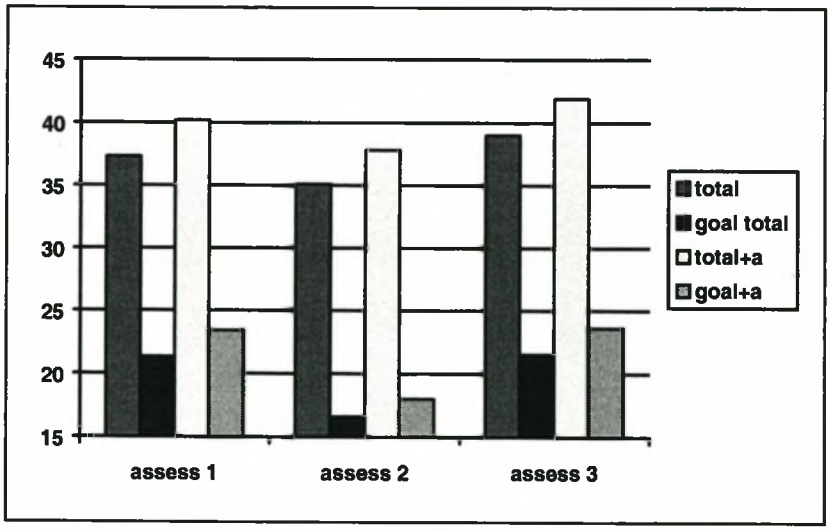

FIGURE 5.10.2: Total and goal total GMFM scores

Total and goal total scores deteriorated by 2.2% and 4.7% respectively during the "no treatment" phase of the study, as did total and goal total scores with walking aids, by 2.4% and 5.4% respectively. All of these scores improved during the treatment phase, however. The total score improved by 3.9%, the goal total by 4.9%, the total with walking aids by 4.1% and the goal total with walking aids by 5.6%.

Child 10

Child 10 was a male aged 5 years and 3 months on entry into the trial. He was a spastic diplegic who was considered by his therapist to be moderately disabled. He was independently ambulant and was fitted with bilateral AFO's although these made no difference to his functional ability and did not affect his GMFM scores when tested with versus without. Child 10 also received occupational therapy.

The following TELER indicators were established for him:

1. Balance in 1/2 Kneeling
2. Improved Gait Pattern (Heel-Strike)
3. Lateral Weight Transfer When Walking on Stairs

Co-operation during all assessments was good and all test items on the GMFM were completed. Child 10's first assessment was carried out at home as he was unable to attend school during the week of the initial assessments due to transport difficulties. The subsequent two assessments were carried out at school under the same conditions as for all the other children. He received a total of 14 treatment sessions during the intervention phase of the study.

Performance on the TELER indicators established is illustrated in the graph below. Child 10 showed 1 clinically significant improvement on both indicators 1 and 2 at the second assessment, giving a total of two clinically significant improvements. At the third assessment indicators 1 and 2 again each showed one clinically significant improvement and indicator 3 showed a total of 3 clinically significant improvements. This gave a total of 5 clinically significant improvements for the treatment period.

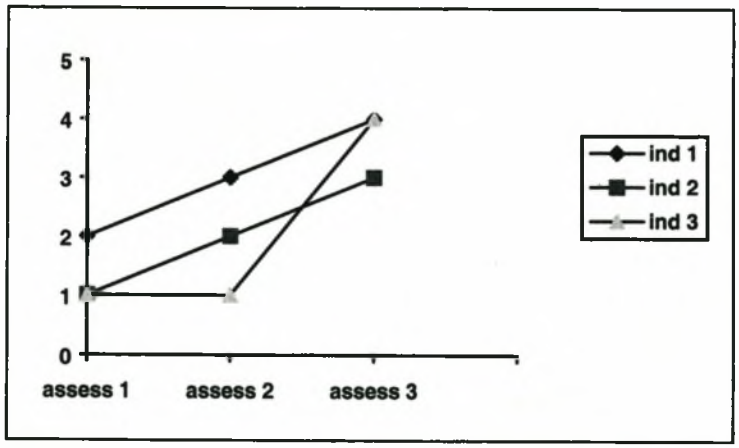

FIGURE 5.11.1: Performance on TELER indicators

Based on the TELER indicators the dimensions of the GMFM considered to be goal areas for the treatment period of the study were crawl/kneeling, standing and walk/run/jumping. Results for each dimension at each of the three assessments as well as total and goal total scores are presented and illustrated in the tables and graph that follow.

TABLE 5.11.1: Scores for GMFM dimensions

DIMENSION	ASSESS 1	ASSESS 2	ASSESS 3
Lying	94.1	94.1	98.0
Sitting	85.0	86.7	95.0
Crawl/kneeling$_g$	78.6	81.0	90.5
Standing$_g$	61.5	61.5	76.9
Walk/run/jump$_g$	43.1	47.2	58.3

TABLE 5.11.2: Total and goal total GMFM scores

	ASSESS 1	ASSESS 2	ASSESS 3
Total score	72.5	74.1	83.8
Goal total score	61.1	63.2	75.2

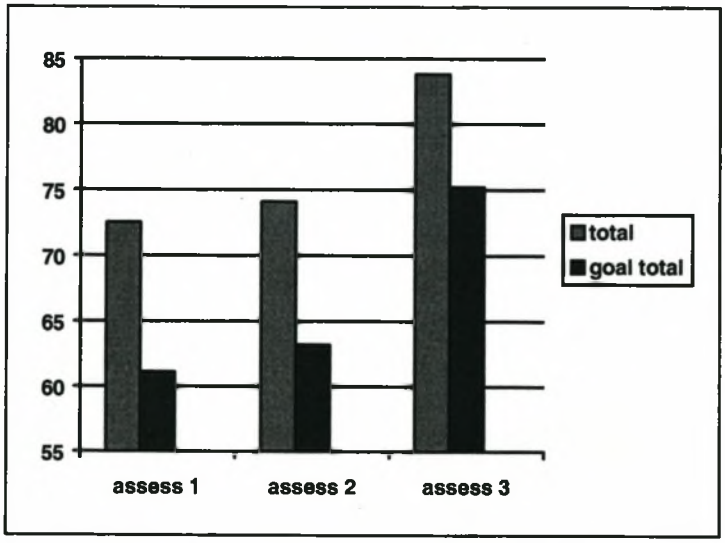

FIGURE 5.11.2: Total and goal total GMFM scores

Child 10's total and goal total GMFM scores improved by 1.6% and 2.1% during the no-treatment phase of the study. Following the treatment phase of the study his total score improved by 9.7% and his goal total score by 12.0%.

5.3 The GMFM

Goal Areas

The sitting, crawl/kneeling, standing and walk/run/jumping dimensions were all identified as goal areas for various children in the sample. Only the lying dimension was not identified as a goal area for any one of the children. The number of children for whom each of the dimensions was identified as a goal area is presented in table 5.12. Each child had a minimum of one dimension as a goal area and the maximum number of dimensions identified as goal areas for any one child was three.

TABLE 5.12: Number of children for whom GMFM dimensions were goal areas

DIMENSION	NUMBER OF CHILDREN
Lying	0
Sitting	2
Crawl/kneeling	4
Standing	7
Walk/run/jumping	9

Change Following Baseline Phase (A)

The lying, standing and walk/run/jumping dimensions of the GMFM had mean improvements of 0.01% (SD=1.32); 1.27% (SD=5.30) and 1.67% (SD=2.16) respectively, following the no-treatment phase of the study. None of these changes was statistically significant at the 5% level as indicated by the Wilcoxon signed rank test. The crawling dimension showed a deterioration of -0.48% (SD=4.17) but this deterioration was not statistically significant at the 5% level. The mean improvement of 2.35% (SD=1.93) in the sitting dimension was statistically significant at the 1% level as indicated by the Wilcoxon signed rank test (p=0.004).

Total scores showed a mean improvement of 0.94% (SD=1.79) which was not statistically significant (p=0.13) and total scores of only goal areas a mean improvement of 1.22% (SD=3.24), also not statistically significant as indicated by the Wilcoxon signed rank test (p=0.32).

Change Following Treatment/Intervention Phase (B)

The mean improvements following the treatment phase seen in 4 of the 5 GMFM dimensions were statistically significant at the 5% level as indicated by the Wilcoxon signed rank test. The mean improvements for each dimension are shown together with their standard deviations and p values in table 5.13. Only the mean improvement of 0.79% (SD=1.88) in the lying dimension was not statistically significant as indicated by the Wilcoxon signed rank test. This dimension was not a goal area for any of the children in the study

Total scores showed a mean improvement of 5.11% (SD=3.43) which was statistically significant at the 1% level. The mean improvement in total scores of goal areas was greater at 7.9% (SD=4.30) and was also statistically significant at the 1% level.

TABLE 5.13: Mean change in GMFM scores for the treatment phase

DIMENSION	MEAN	STD. DEVIATION	P-VALUE
Lying	0.79	1.88	0.25
Sitting	4.33	6.69	0.03
Crawl/kneeling	4.53	4.11	0.02
Standing	9.49	7.04	0.004
Walk/run/jump	6.23	4.26	0.004
Total score	5.11	3.43	0.002
Goal total score	7.9	4.30	0.004

The standing and walk/run/jumping dimensions had the largest mean changes following the treatment period. These were the two dimensions most commonly identified as goal areas for the children in the sample.

The mean total scores and mean goal total scores at each of the 3 assessments have been plotted in figure 5.12, illustrating the mean improvement seen for each of the phases of the study.

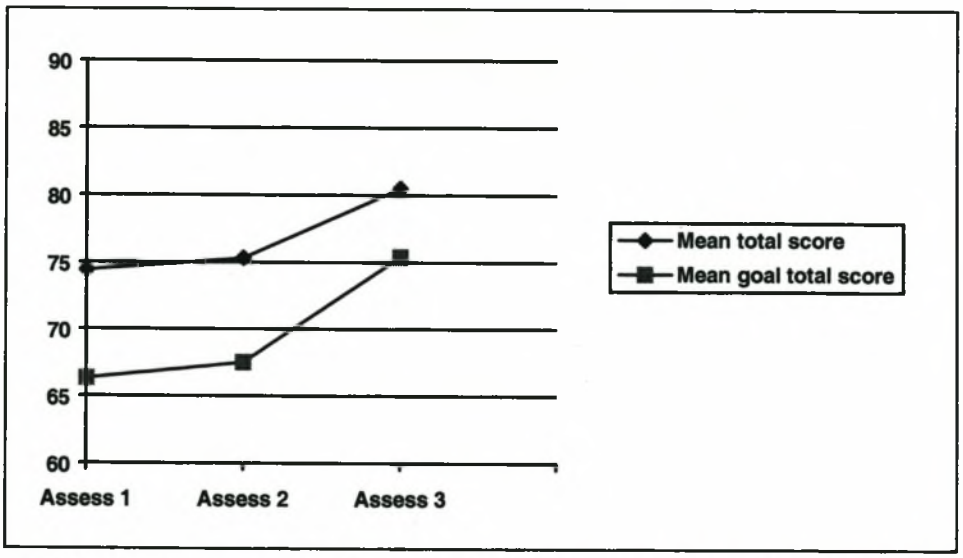

FIGURE 5.12: Mean total and goal total GMFM scores at each of the 3 assessments

Testing With Orthoses and/or Walking Aids

Of the children in the sample, four were fitted with orthoses and used no walking aids (children 2, 3, 6, 10); two were fitted with orthoses and used walking aids (child 8 used elbow crutches and child 9 used a reverse-walker and both wore bilateral AFO's); and one child (child 1) used a walking aid (reverse-walker) only. Children 4, 5 and 7 used neither orthoses nor walking aids.

TABLE 5.14: Use of orthoses and/or walking aids

	No. of children
Orthoses only	4
Orthoses and walking aid	2
Walking aid only	1
No orthoses/walking aid	3
Total	10

Testing with walking aids and/or orthoses was done in the standing and walking dimensions only as it was anticipated that these were the dimensions that would be affected most by the use of such aids. In addition the reason for fitting such aids is to improve function in these areas. In accordance with the recommendation in the GMFM manual[19] the aids were applied for the same items at all three assessments. This ensured that any changes in score were a result of change in function and not due to the fact the aid was applied at a different item number.

Three out of the four children who used orthoses only, showed absolutely no difference in the scores for these two dimensions when tested with and without their respective orthoses. The fourth child (child 2) in this sub-group did however show a difference in scores for the standing dimension, scoring 86.1% when tested with, and 84.7% when tested without her orthoses. This occurred at the first assessment only and the difference in score was accounted for by a single item (item 87: walks down 4 steps, alternating feet) within the dimension. Child 2 scored a 1 (walks down 2 steps, same foot leads consistently) for this item without orthoses and a 2 (walks down 4 steps, alternating feet inconsistently) with orthoses. At the two subsequent assessments she scored 3 (walks down 4 steps, alternating feet consistently) and 2 respectively for this item and there were no difference between scores when testing with and without her orthoses.

All the children who used walking aids showed a difference in scores in the standing and walking dimensions when tested with and without their aids. These scores were presented earlier in tables 5.2.1; 5.2.2; 5.9.1; 5.9.2; 5.10.1 and 5.10.2. No formal statistical tests were carried out on this sub-set of results because of the small sample size (n = 3). In addition child 1 refused to use her walking aid at the second assessment, so a full set of results is only available for 2 children. An average score was calculated for the standing and walk/run/jumping dimensions tested without walking aids at each assessment for each of the children. The same was done for these two dimensions when scored with walking aids. These averages are presented in tables 5.15.1; 5.15.2 and 5.15.3.

TABLE 5.15.1: Average scores of standing and walking dimensions with and without walking aids for child 1

CHILD 1			
	ASSESS 1	**ASSESS 2**	**ASSESS 3**
Average with walk aids	9.9	refused	22.9
Average without walk aids	3.4	3.4	15.7

TABLE 5.15.2: Average scores of standing and walking dimensions with and without walking aids for child 8

CHILD 8			
	ASSESS 1	**ASSESS 2**	**ASSESS 3**
Average with walk aids	40.5	43.3	52.4
Average without walk aids	27.4	29.5	38.4

TABLE 5.15.3: Average scores of standing and walking dimensions with and without walking aids for child 9

CHILD 9			
	ASSESS 1	**ASSESS 2**	**ASSESS 3**
Average with walk aids	17.1	12.6	18.5
Average without walk aids	9.9	6.0	11.3

All three children had higher average scores when tested with their walking aids in the relevant dimensions with an average difference between these two sets of scores of 9.5%.

Changes in score for the baseline and treatment phases of the study were similar for the two averages. Between assessments 1 and 2 child 8's average score for the two dimensions improved by 2.1% without and 2.8% with walking aids. Between assessments 2 and 3 the improvement in her average score was 8.9% without and 9.1% with walking aids. Child 9's average score deteriorated between assessments 1 and 2, by 3.9% without and 4.5% with walking aids. Between assessments 2 and 3, however, there was improvement in average scores of 5.3% without and 5.9% with walking aids. Similar comparisons for child 1 are not possible as she refused to use her walking aid at assessment 2.

5.4 TELER

Three TELER indicators were established for each child, giving a total of 30 indicators for the group. These TELER indicators described deficits exhibited by the children. The TELER data was used to establish the effect of treatment on both the children in the sample and on the deficits represented by the indicators.

Effect of Treatment on Deficits

The 30 indicators were tabulated in table 5.16.1 according to their codes at assessment 1 (code before) and assessment 2 (code after). Table 5.16.1 illustrates that the majority of indicators (22) had the same codes at assessment 1 and 2. In other words there was no change in the indicators for the baseline (no treatment) phase of the study. There were 3 indicators that deteriorated and 5 that improved for this phase. (E.g. one indicators code at assessment 1 was 2 and improved to a 3 at assessment 2.) The total number of observed indicators with codes of 0, 1, 2, 3, 4 and 5 at assessment 2 were obtained from this table. Using these observed values and expected values calculated using the alternative probability distribution (Addendum 5), the chi-squared statistic for the no treatment period was calculated to be 5.75 which was not statistically significant at the 5% level. This calculation is shown in table 5.16.2.

The same process was repeated in table 5.16.3 for the indicator codes at assessment 2 (code before) and assessment 3 (code after), giving a set of observed "codes after" for the treatment phase of the study. Table 5.16.3 shows that only three indicators codes remained the same from assessment 2 to assessment 3, otherwise all indicator codes improved over the treatment phase. The chi-squared statistic for the treatment phase was calculated to be 21.80, which is statistically significant at the 1% level. (see table 5.16.4), indicating that the treatment given had the effect of reducing the deficits presented by the children.

TABLE 5.16.1: Number of TELER indicators by code before and code after for the baseline phase

Indicator code after	**Indicator code before**						**Total**
	0	1	2	3	4	5	
0	5						5
1	1	9	2				12
2	1	2	7		1		11
3			1	1			2
4							
5							
Total	7	11	10	1	1		30

TABLE 5.16.2: Chi-squared analysis of outcome codes on 30 indicators for the baseline phase

Code after	Observed (O)	Expected (E)	$(O - E)^2 / E$
0	5	6.26	0.25
1	12	8.72	1.24
2	11	6.91	2.43
3	2	5.04	1.83
4 and 5	0	3.419	
Total	30	30	5.75

TABLE 5.16.3: Number of TELER indicators by code before and code after for the treatment phase

Indicator code after	Indicator code before						Total
	0	1	2	3	4	5	
0							
1	1						1
2	1	3	2				6
3	2	3	6	1			12
4	1	5	1	1			8
5		1	2				3
Total	5	12	11	2			30

TABLE 5.16.4: Chi-squared analysis of outcome codes on 30 indicators for the treatment phase

Code after	Observed (O)	Expected (E)	$(O - E)^2 / E$
0	0	5.78	5.78
1	1	8.71	6.82
2	6	7.17	0.19
3	12	5.17	9.01
4 and 5	11	3.57	
Total	30	30	21.80

Effect of treatment on patients

A TELER score for each child at assessment 2 was calculated by adding the codes scored by the child on each of his 3 indicators. This was repeated at assessment 3. The number of children expected to have a particular TELER score (0-15) at each of the assessments was then calculated using the alternative probability distribution (Addendum 5). All the expected values were much smaller than is required to obtain a valid result for a chi-squared test, and it was necessary to truncate the TELER score scale. Consequently, the number of children having a TELER score of 5 or less and 6 or more on their three indicators at assessment 2 (following the baseline phase) were counted. Using these observed values and similar expected values the chi-squared statistic for the 10 children's TELER scores on three indicators was calculated to be 2.07 (see table 5.17.1). This value was not statistically significant, indicating that there was no discernible developmental effect, or other treatment-like effect, during the baseline phase.

TABLE 5.17.1 Chi-squared analysis for TELER scores on three indicators at assessment 2

TELER score	Number of patients		$(O - E)^2 / E$
	Observed (O)	Expected (E)	
5 or less	8	5.76	0.868
6 or more	2	4.26	1.197
Total	10	10.02	2.065*
* not significant at the 5% level (one tailed)			

Similarly a chi-squared statistic was calculated for the 10 children's TELER scores on three indicators at assessment 3, following the treatment phase of the study (see table 5.17.2). The calculated statistic was 13.21 which was statistically significant at the 1% level, indicating the improvement seen was attributable to treatment given.

TABLE 5.17.2: Chi-squared analysis for TELER scores on three indicators at assessment 3

TELER score	Number of patients		$(O - E)^2 / E$
	Observed (O)	Expected (E)	
5 or less	0	5.70	5.701
6 or more	10	4.31	7.507
Total	10	10.01	13.208*
* significant at the 1% level (one tailed)			

The average amount of improvement per child for the treatment phase was 5.6 clinically significant improvements (SD=2.07).

A t-test on this average to determine if it is greater than 0 (no clinically significant improvement) gave a t-value of 8.57 which is statistically significant at the 1% level, confirming the results of the chi-squared analysis, and showing that a real improvement, attributable to the NDT given, was demonstrated by the sample of 10 children for the treatment period.

CHAPTER 6
DISCUSSION

6.1 Outcome Demonstrated by the Group

This study used two outcome measures, the gross motor function (GMFM) and TELER, to look at the effect of neurodevelopmental therapy (NDT) on a sample of 10 children with cerebral palsy using a single subject study design. Both the GMFM and TELER showed that there were statistically significant improvements in the respective outcomes measured for the intervention phase of the study. Changes measured following the baseline phase were not statistically significant. As its name indicates, the GMFM is a measure of gross motor function and the TELER indicators established for this study addressed essentially gross motor skills. It can therefore be concluded that the NDT received by the children during the intervention phase of the study had a significant effect on the children in the area of gross motor function.

Controlling for normal development and other treatment-like effects

One of the difficulties in conducting research aimed at looking at treatment outcome in the young child with cerebral palsy is controlling for the effects of normal development and maturation. In the young child who is still developing, learning and perfecting motor skills it is difficult to differentiate between change that is due to the intervention under consideration and change that would have occurred even in the absence of intervention. It can be said that normal development, a non-treatment stimulus, can have a treatment-like effect. The single subject design with its baseline period allows this treatment-like effect of normal development to be separated from any treatment effect. In this study the analysis of the TELER data for effect of treatment on patients indicated that there was no treatment-like effect, resulting from normal development or from any other unidentified non-treatment stimulus, during the baseline phase of the study. The absence of any statistically significant changes in GMFM scores and the absence of any effect of treatment on the deficits represented by the TELER indicators further supported these findings. If any treatment-like effect had occurred during the baseline phase, it would have been taken into consideration when analysing the data obtained for the intervention phase to determine whether a treatment effect had occurred during the intervention phase.

The TELER data analysed for effect of treatment on patients indicated that a treatment effect did indeed occur during the intervention phase, again supported by the statistically significant results in the other data analysed. It is important to note however, that this treatment effect may still have included stimuli with a treatment-like effect. Nonetheless it can be argued that, a treatment which has no intrinsic effect but which triggers a stimulus with a treatment-like effect is worth giving if the stimulus cannot be triggered in any other way[109]. If such a treatment-like effect occurred during the intervention phase, and not during the baseline phase, it can be argued that it was probable that the stimulus that caused the treatment-like effect was triggered by the intervention given. A way of confirming this would have been to have included a withdrawal phase in the study design (ABA) in an attempt to show that following a further period of no intervention there was again no treatment or treatment-like effect.

It was not possible to include a withdrawal phase in this study as the school authorities would not permit the withholding of physiotherapy treatment from any child. The study was thus designed around a school holiday which served as the initial baseline phase. To have included the following school holiday as a withdrawal phase would have resulted in a treatment phase of approximately 10 weeks and then a withdrawal phase of only just more than one week. This was considered to be too short a time relative to the treatment phase to see any significantly measurable change in outcome.

GMFM scores

Total GMFM scores improved by a mean of 5.11% for the treatment phase as opposed to 0.94% for the baseline phase. The mean improvement in goal total scores was 7.9% for the treatment phase and 1.2% for the baseline phase. These results compare favourably with the figures for mean change scores reported by Russell *et al*[19] from their validation study. Mean improvements in total scores for spastic hemiplegics, which constituted half of the group in the current study, in Russell *et al's* study[95] were 4.8% in the 3 to < 6 year old group and 1.9% in the ≥ 6 year old group. Changes for spastic diplegics were less at 2.8% in the 3 to < 6 year old group and 2.3% in the ≥ 6 year old group. These changes occurred over 5.1 and 5.4 months respectively and the type and amount of therapy intervention received by the children was not specified. The GMFM results for the current study are also comparable with other studies in which children have received periods of NDT oriented physiotherapy intervention[67,76,96,97]. Of particular interest are the groups in the studies by Steinbok *et al*[101] and Wright *et al*[102]. Both groups were control groups for studies investigating outcome following selective dorsal rhizotomy (SDR). The two groups consisted of spastic diplegics aged 3 to 6 years old who received twice weekly physiotherapy over periods of 9 and 12 months respectively. The respective groups had total score improvements of 5.2% and 4.4%. These are similar findings to those of the current study although the time periods over which the changes occurred were vastly different. This may be because, in the 2 SDR studies, the children in the control groups were all candidates for SDR, so overall level of disability of the groups was likely to have been more severe and the general rate at which change occurred may have been slower. Alternatively it is possible that CP children undergoing treatment go through some sort of cycle of skill acquisition with periods of improvement in function being followed by periods of "consolidation" during which little or no change occurs, hence the seemingly much slower rate of change in function seen over a longer time period. Studies have been carried out looking at differing intensities of therapy[68,81] but ideal time periods of treatment and patterns of treatment over time are still areas for investigation.

Statistical versus clinical significance

Each code on a TELER indicator is considered to represent a clinically significant outcome and the difference between two successive codes, a clinically significant change[20,97]. Each child in the sample demonstrated a total of at least 3 (maximum 9) clinically significant changes on the 3 indicators established for them during the intervention phase. NDT intervention had the effect of reducing the deficits (as represented by the indicators) presented by the children and the change experienced by the group of children was attributable to the NDT. It is feasible to conclude that real, clinically significant change was experienced by the group. The mean change in GMFM total scores during the intervention phase fell within the range constituting small positive clinically meaningful change, as defined by Almeida *et al*[99]. Similarly the mean improvement in goal total scores could be

classified as denoting medium positive clinically significant change. Both scores are markedly greater than the 1.825% estimated by Russell *et al*[19] as representing the minimum clinically important change. The fact that the changes in score in the current study occurred over a far shorter time-frame than those in the Russell *et al* study further adds to the likelihood that they represented clinically meaningful change.

Evidence from both the assessment tools used strongly suggests that the improvements seen for the group of children as a whole were clinically significant. It is important to distinguish between results which are statistically significant and those which are clinically significant. In many instances improvements measured, that sophisticated statistical methods show to be "statistically significant improvements", may not represent improvements that are clinically meaningful for the patient. Equally so, a set of results may not reach statistical significance but the actual change experienced by the patient may be clinically meaningful and consequently clinically significant. Many of the NDT outcome studies reviewed have dismissed NDT as not being effective based solely on the lack of statistical significance of the results but none have attempted to look at clinical significance.

6.2 Single Subject Outcome

Child 1

Child 1 was classified by her therapist as severely disabled and scored correspondingly low GMFM scores. A significant contributing factor to these low scores was, however, her very uncooperative behaviour. A child can only achieve a score for an item on the GMFM based on what is observed. In the case of a child not co-operating with testing one can observe the child's general movement and play, trying to encourage test items, and then score those items observed. A score cannot be awarded on the basis of what the examiner thinks the child can achieve. Child 1's actual motor abilities were almost certainly better than reflected by her GMFM scores, particularly for assessments 1 and 2. Uncooperative behaviour in itself can be disabling for the child and makes the application of any therapeutic regimen extremely difficult. Part of therapy becomes trying to overcome this resistance to being handled and to co-operating together with the therapist. One of the TELER indicators established for child 1 addressed the issue of tolerance of therapy. At assessment 3 two clinically significant improvements had been achieved on this indicator. Improvement in this area was also reflected in her GMFM scores - a portion of the increase in score seen was due to the completion of more items on the test than at the previous two assessments. This was demonstrated particularly in the sitting and standing dimensions where scores increased by 21.7% and 20.5% respectively. Her uncooperative behaviour also resulted in her complete refusal to use her walking aid independently for the GMFM testing with walking aids at assessment 2, although she would use it with assistance. Her TELER indicator ('proficiency with walking aid') reflected this deterioration in function with her walking aid, whether due to an actual reduction in functional ability or just plain stubbornness.

Indicator 2 addressed her ability to move between long sitting and side sitting in the execution of a play activity and 4 clinically significant improvements were made on this indicator during the treatment period. Interestingly,

there was a corresponding increase in the scores achieved for other transitional movements on the GMFM (e.g. getting from sitting to 4 point kneeling and from floor sitting to sitting on a bench), which were not solely achieved through better co-operation, as some of them had been attempted at previous assessments.

It is likely that much of the reason for the improvements achieved through NDT treatment in this child stemmed from her improved co-operation. Therapy involves a co-operative process between the child and the therapist. The child plans, executes and practises movement while the therapist facilitates, guides and provides feedback regarding the movement. If one of the parties involved in this process is uncooperative it is unlikely that therapy can be effective. In addition, we have seen from the theories of motor learning that the attention of the individual to the required task is important. Motivation, alertness and concentration all affect the ability of the child to execute and learn functional activities and tasks[30].

Child 2

Child 2 was the only child whose GMFM total and goal total scores improved more during the baseline phase than during the intervention phase. This was accounted for by a large improvement in the standing dimension score during the baseline phase which then did not change during the intervention phase. One of the TELER indicators established for child 2 addressed standing balance required for dressing. Two clinically significant improvements were achieved on this indicator during the baseline phase and none during the treatment phase. It would appear that the improvement seen in standing balance was a genuine improvement. It could be argued that this improvement occurred because the scores achieved in the initial assessment were not indicative of the child's normal level of performance, but this is unlikely as one would expect a lower than normal level of performance to be reflected in the other dimensions as well. The supposition is that this was genuine improvement due to some stimulus having a treatment-like effect. Perhaps the increased freedom of activity and mobility during the school holiday as opposed to being restricted to a classroom environment, where a large portion of time is spent sitting, may have had some treatment-like effect. The lack of improvement in gross motor function during the intervention phase may have resulted from the fact that other motor related skills were in the process of being practised and learnt. TELER indicator 2 was a component indicator addressing the child's ability in the area of ball skills and 3 clinically significant improvements were achieved on this indicator during the intervention phase. As well as requiring standing balance, ball skills require strength, co-ordination and control in the upper extremities, and good hand-eye co-ordination. If we look at the normal development of an infant or young child a period of rapid acquisition or improvement of skills in one particular area is often accompanied by a short period of stasis in other areas.

Child 3

Child 3's GMFM total scores also improved by a greater margin during the baseline phase than during the intervention phase but the difference was relatively small. His goal total scores however, improved more during the intervention phase than the baseline phase. The baseline phase showed small improvements in each of the dimensions, whereas during the intervention phase there was little or no change in all of the dimensions except for the relatively large change in the walk/run/jumping dimension. This was a goal area and hence accounted for the changes seen in the goal total scores. As with the previous child the general mobility afforded by the school

holiday time may have accounted for the small improvements seen. The second TELER indicator focused on an improved gait pattern and this formed one of the goals around which treatment was centred. Although the therapist focused on improving a specific aspect of the gait pattern (heel strike) in the treatment sessions, little actual improvement was seen in this aspect of the gait pattern, with there being only one clinically significant improvement on the TELER indicator. There was however an improvement in other aspects of gait reflected by the GMFM. In particular there was improvement in the child's ability to walk up and down stairs in a reciprocal fashion. From being consistently non-reciprocal, his gait when walking up and down stairs became consistently reciprocal. This is essentially an improvement in gait pattern, although it is a different aspect of gait from that which was addressed by the TELER indicator and the treatment. The TELER indicator established may have been an invalid means of measuring change in gait pattern or may have focused on an aspect of the gait pattern that was too advanced for the child to achieve at his then current level of function.

Children 4 and 7

Children 4 and 7 received the least number of treatments of all the children in the sample during the intervention phase and yet they achieved among the highest changes in total and goal total scores on the GMFM. The biggest changes in scores seen for both children were in the dimensions considered to be goal areas based on the TELER indicators that were established for them. If one then looks at the individual items within these goal dimensions which improved during the intervention phase there appears to be a strong link between these items and the ultimate goals/component parts of the TELER indicators. For example one of child 4's three TELER indicators was a component indicator consisting of items which challenged his ability to balance in standing. Another was a function indicator which addressed his ability to laterally transfer his weight in standing in order to step up onto a raised surface. Each of these indicators demonstrated 3 clinically significant improvements during the intervention phase. The items on the GMFM which improved over the same phase addressed the functions of single-leg balance in standing; coming to stand from high kneeling through half kneeling; stepping over a stick held at knee height; and walking up and down stairs without support. These items link closely with the TELER indicators which formed the basis of the goals around which treatment was structured. Similar links can be shown for child 7, although her improvements on her TELER indicators were not as good as she demonstrated a similar problem with the indicator addressing gait pattern to that of child 3.

From this we can conclude one of two things. Either less treatment is better, or the positive effect of NDT intervention is strongly associated with the accurate establishment of goals or tasks around which treatment is centred. The latter is the more likely if we go back to our knowledge of the theoretical assumptions on which NDT is based.

Child 10

In fact child 10's case would lend support to the latter line of thought as he received the most number of treatment sessions and also had among the highest improvements in GMFM score. Child 10's TELER indicators addressed the areas of balance in half kneeling, improvement of his gait pattern and lateral weight transfer in order to step up onto a raised surface. Items responsible for the improvement seen in the GMFM scores strongly reflected the components of movement and functions included in these indicators. Items that improved during the treatment phase included single leg balance; coming to stand from kneeling through half-kneeling; cruising; kicking a ball and walking up and down stairs. In addition there were considerable improvements in the sitting dimension (not a goal area) and in items of the crawl/kneeling dimension not directly related to kneeling and half-kneeling, for example reciprocal crawling and crawling downstairs backwards. There are two possible explanations for child 10's relatively large improvements in 4 out of the 5 dimensions on the GMFM during the intervention phase. The first is that child 10 actually had a longer baseline phase than other children in the sample as he had been absent from school for almost two weeks prior to commencing the baseline phase. Although, his pre- and post baseline phase assessments were done at the same time as the other children's assessments. This may have meant that at his second GMFM assessment his level of function may have been slightly lower than it would ordinarily have been after a school holiday. The reinstitution of therapy may have then resulted in a period of rapid 'catch-up'. This is unlikely, though, given the minimal change in scores between assessments 1 and 2. The second possibility is that there was a genuine improvement in both goal and non-goal areas, indicating that, although NDT is goal oriented and task specific, the effects of therapy are not limited to these goal areas. This idea is expanded in the discussion around child 8.

Child 8

Child 8 child demonstrated above average increases in her total and goal total GMFM scores but, in contrast to this, her total number of clinically significant improvements on the TELER indicators was below the average for the sample. Some of the individual items on the GMFM that were responsible for the increase in score did however relate to the TELER indicators. A large increase was seen in the standing dimension, particularly in the items where dynamic balance (indicator 3) played a key role. In addition, as with child 10 other items not as closely and directly related to the indicators improved. Examples of these were crawling backwards down stairs, lowering from standing to sitting on the floor and attempting to squat, all of which require among other things, an element of eccentric control. This aspect of eccentric control was not directly addressed by any of the goals around which therapy was structured. This would seem to indicate that making therapy goal directed and task specific does not limit the child to improvement in that one single activity or task. The continual facilitation and practice of different components of movement must have an effect on the execution of other functional activities, or aspects thereof, as well. Improvement in areas apart from goal areas may also be due to enhanced problem solving abilities on the part of the child. By involving the child actively in problem solving and the practice of functional tasks, whilst guiding and facilitating more normal movement, the therapist is able to assist the child in developing and learning both normal motor programmes and problem solving strategies.

The lack of progress seen on TELER indicators 1 and 2 may have been due to lack of validity on the part of the indicators although they appeared to make clinical sense (i.e. have content validity). Alternatively the time frame

over which the intervention phase took place may have been too short for change to be seen on either of these indicators. There is a definite need for some means of establishing validity of TELER indicators if the TELER system is to be used as an outcome measure in this field. This issue will be addressed later in this discussion.

The walk/run/jumping dimension tested with walking aids demonstrated larger improvement during the baseline phase than during the treatment phase. This may be because the increased freedom afforded child 8 during the school holiday period gave her opportunity to practice walking with her crutches in a greater variety of situations. Motor learning theory holds that altering the environment and situation in which a task is practised enhances the learning of that task. This highlights the importance of the child being able to practice functional activities and tasks both in and outside of the therapeutic situation.

Child 9

Child 9 was the most severely disabled child in the sample. She deteriorated on 2 of her TELER indicators during the baseline phase. Her GMFM total and goal total scores, when tested both with and without her walking aid, also deteriorated during this phase. These scores then improved again to approximately the same as the initial scores (i.e. pre-baseline phase) following 13 treatment sessions during the intervention phase. This would seem to indicate that a large role of therapy in the more severe child, in addition to improving function, is to prevent deterioration in function. It is in this situation, where the child is too disabled to practice specific motor tasks alone, that the importance of involvement of the parents or caregivers becomes particularly apparent. Although one cannot, and should not, expect parents to become therapists an important aspect of NDT, based on the theories of both motor control and motor learning as well as some of the proposed mechanisms of neural plasticity, is repetition and practice of motor skills. In the case of a more severely disabled child assistance with such 'practice' will almost certainly be required and the therapist will do her best to incorporate activities requiring assisted practice into functional activities that are part of the parent and child's daily routine. In the school situation there is little parent-therapist contact and the involvement of the parent in the rehabilitation process is not as easily facilitated as it is in the situation where a parent is regularly accompanying his/her child to therapy. It becomes difficult to convey the importance of allowing the child opportunity to practice certain activities. In the case of child 9 a simple task requiring regular practice, but nonetheless requiring assistance, was the use of her reverse walker. Given the deterioration that occurred specifically in the use of her reverse walker during the baseline phase, as was reflected by both TELER and the GMFM, it was unlikely that she was using the walker at home. This deterioration was reflected in other areas as well, including her ability to maintain upright kneeling and other items especially in the standing dimension. A withdrawal-reinstatement (ABAB) single subject design would have been useful in a child like this to determine if this alternating pattern of deterioration and improvement would continue.

Because of her severe disability child 9 was frequently treated by her physiotherapist and occupational therapist together. This was the reason for TELER indicator 1 addressing the area of hand function. In light of the extent of her disability and the extent of involvement of all four extremities some of the components of this indicator were unrealistic expectations for this child to achieve over a 5 week treatment period. There was no change on this indicator for the entire study period.

Children 5 and 6

Both the total and goal total scores achieved by child 5 deteriorated during the baseline but these small deterioration's were accounted for by only four test items and could be considered negligible. Balance in half kneeling on both the left and right (2 items) deteriorated; he was unable to walk forward 10 steps on a straight narrow line as he had been able at the initial assessment; and his single leg balance on his unaffected leg deteriorated. There was no improvement or deterioration on any of the TELER indicators which supports the thought that these deterioration's in GMFM scores probably didn't reflect any clinically significant change. Those items which had deteriorated following the baseline period then improved again to pre-baseline level following the intervention phase. It is highly possible that child 5's poor concentration affected his performance in these items as they all required concentration, even when being performed by an able-bodied child. Child 5 was a very mild hemiplegic and scored very high overall on the GMFM. From a clinical point of view it was extremely difficult to judge whether the changes seen on the GMFM were indeed real change or just normal fluctuations in performance and it is questionable how responsive the GMFM is to change in such high functioning children. His changes in level of ability would appear to be better judged by more complex functional tasks such as dressing (TELER indicator 1). His improvement on TELER indicator 3 (reciprocal gait when walking downstairs) was however reflected by change in a related item on the GMFM.

A similar argument applies to child 6, who was also a very mild hemiplegic. He demonstrated only a small difference between his improvements in GMFM scores for the baseline and the intervention phases. His TELER indicators gave a better indication that improvement had occurred for the intervention phase and these indicators addressed more complex functional activities.

6.3 Why Did the Treatment Work?

Why did the NDT treatment received by this group of children have an effect on improving their motor function and are these changes of a permanent nature? Without a longer term follow-up study of these children, looking specifically at the sustainability of the motor skills learnt as a result of the therapeutic process, the second question is rather more difficult to answer. However if we turn to the concept of neural plasticity, introduced earlier in this dissertation, we can find a possible explanation for the effects of NDT intervention and we can make some hypothetical projections about the sustainability of these effects.

Kidd *et al*[50] state that learning is only a redevelopment of an already existing nervous system. The NDT treatment approach involves the child in the process of both the learning and relearning of motor skills in normal movement patterns. If the learning process in the normal individual results in modifications to the nervous system then it is logical to expect modifications in a damaged system under-going a similar learning process. In fact Plautz *et al*[110] have proposed, following animal experimentation that, motor skill acquisition or motor learning is a pre-requisite factor in driving modification of the primary motor cortex. Modification of the nervous system under these conditions is referred to as function induced neural plasticity. Neural plasticity is also evident in the process of

post-natal maturation and in the degree of spontaneous recovery that occurs following an injury to the central nervous system (CNS). The mechanisms of neural plasticity playing a role in the effects of treatment are probably those which are function induced.

Neural plasticity results from both the formation of new connections within the CNS and the enhanced effect of already existing synapses[50]. Held[48] discusses the concepts of both synaptogenesis or regenerative sprouting and reactive synaptogenesis or collateral sprouting which result in the formation of new connections within the CNS following damage. These mechanisms, however occur in the more acute stages following brain injury and are highly unlikely to have been involved with the improvements seen in the children in this study. The more likely mechanisms involved here are those of the enhanced effects of existing synapses. Shumway-Cook and Woollacott[32] have described neural plasticity as the continuum from short-term functional changes to long-term structural changes. Kidd *et al*[50] support this view in their description of mechanisms resulting in increased synaptic effectiveness. They describe short- or medium-term changes which are primarily biochemical or physiological in nature, and which then play a role in effecting longer-term structural or anatomical changes. These changes take place at three different locations: the presynaptic terminal, the post-synaptic membrane, and the post-synaptic nucleus[50].

Repetitive use of a synapse causes a series of biochemical changes in the pre-synaptic terminal[50]. These changes cause an increase in the fusion of transmitter vesicles to the presynaptic membrane, the resultant effect of which is an increase in the amount of chemical neurotransmitter released. Increased release of glutamate (the neurotransmitter) enhances the effectiveness of the potentiated synapse for periods not exceeding 1 hour[50], a relatively short-term physiological change. One of the effects of this increase in efficiency of the synapse in an increase in size of the presynaptic bouton. This may contribute further to the effectiveness of the synapse by increasing the surface area from which chemical transmitter vesicles can be released[50]. The increased presence of glutamate at the synapse in turn results in local postsynaptic changes which essentially involve the increased effectiveness of the potentiated synapse. The exact mechanisms involved here are uncertain[50] but the increased amounts of glutamate appear to be sufficient to cause a greater degree of opening of a particular subtype of sodium channel in the post-synaptic membrane. This allows more sodium than normal through the post-synaptic membrane, resulting in greater post-synaptic potentials[50] and accordingly a stronger motor response. It is also logical that an increased amount of neurotransmitter will take longer to disperse thus prolonging the motor reaction. These effects again are short to medium term, lasting for a matter of hours[50]. Genuine long-term changes involve more permanent anatomical changes which are brought about in part by the biochemical changes involved in synaptic potentiation described above. The anatomical changes which can occur include the increased growth of dendritic spines, which is essentially a proliferation of the post-synaptic membrane; an increase in size and number of presynaptic boutons; and migration of presynaptic terminals[50].

These are the most likely mechanisms in affording improvement in motor function/skill in a brain damaged child receiving NDT treatment. All are dependent on one single thing: the repetitive use of the synapse in question. The more the neural pathway is stimulated and used, the better will be the response.

The NDT intervention received by the children in this study was goal oriented and task specific. The therapy process involved the inhibition of abnormal movement patterns and compensatory behavioural strategies. The specific goals of therapy were facilitated and practised in normal movement patterns. This partnership of inhibition and facilitation ensured that the 'correct' or desired neural pathways were stimulated and the practice ensured that these correct pathways were stimulated repetitively. Over the 5 week treatment period at very least short-term functional, physiological changes must have occurred. The more able-bodied child who was able to continue practising the relevant functional tasks outside of the therapy situation is more likely to have begun to show something in the way of structural changes within his/her CNS. The changes in motor function in such a child are more likely to be sustainable. In the case of the more severely disabled child where assistance is required in order to practice motor tasks, practice may not occur often enough to afford structural changes in the nervous system. An example of such a case is child 9 who deteriorated in both her TELER and GMFM scores following the baseline phase. Such a deterioration would be unlikely in the presence of actual structural changes to the nervous system. The sustainability of changes in motor function in such a child is questionable. The aim of NDT is to assist the child in developing motor control and in learning both the motor programmes and problem solving strategies required for optimal functioning in everyday activities. Shumway-Cook and Wollacott[32] view learning as 'a continuum of short-term to long term changes in the capability to produce skilled actions'. This view of learning reflects the corresponding changes in the nervous system from short-term functional changes in the form of increased efficiency/effectiveness of the synapses to longer term structural changes as the capability to produce skilled actions improves.

In addition to recovery seen as a result of treatment there is also a certain amount of spontaneous recovery that occurs following brain damage. The children in this study were at a stage where the effects of spontaneous recovery were highly unlikely to be having any positive influence on their progress. There are however some aspects to spontaneous recovery that warrant mention. Following damage to the CNS two things happen. There is actual cell death in the damaged area and there is a secondary physiological shut down of neural activity in neurons close to or associated with the damaged area[48,49]. Inhibition of these neurons, or diaschisis, may be caused by neural shock, oedema, disruption of local blood flow and/or partial denervation of postsynaptic neurons[48.49]. Although this usually resolves spontaneously it has been suggested that one way early therapy may work is to stimulate inhibited neurons to resume functioning. However, there is also the suggestion that this inhibition may be more than just transient[49] and so stimulation of inhibited neurons through therapy may be a mechanism of recovery in the older child too.

Some mechanisms of spontaneous recovery following brain damage do not always result in changes that are beneficial to the individual. The collateral and regenerative sprouting mentioned earlier may result in abnormal connections which contribute to abnormal compensatory patterns and spasticity[49]. On the other hand such axonal sprouting may be useful in that it maintains a functional level of excitability within the damaged area[48]. There are many structural synapses present in the brain which are not normally functional because of over-riding competition from other synapses. In the case of damage to the primary functional neural pathway and/or experiential factors the so-called 'silent' structural synapse may become functional[32]. Probably related to this is the phenomenon of denervation supersensitivity in which the sensitivity of the postsynaptic neuron to reduced

levels of neurotransmitter is increased. Both these mechanisms may again contribute to spasticity. All the children in this study had sustained their brain damage in the peri-natal period and all were aged over 4 years and 9 months, so all could be considered to have established CP and to be well out of the acute stage of the condition. An element of spontaneous recovery may have occurred in the early stages of development of the children in this study. The resultant synapses from such recovery would thus be firmly established and functioning and could be the cause of the compensatory patterns and spasticity exhibited by these children, in some cases compounding their disability.

More recently published studies in the field of neural plasticity have demonstrated evidence of long-term changes in the cerebral function of both animal[52,110,111] and human[51,53,54,55] brain-injured subjects following rehabilitation. Studies looking at the effects of physical therapeutic intervention in stroke (hemiplegic) patients have noted the following changes in the cerebral cortex of these patients post such intervention. There is an increase in the size of the motor output area in the affected hemisphere[52,54,55] as well as shifting of the centre of motor output maps indicating the recruitment of adjacent areas of the brain[51,55]. Neuronal excitability in the damaged hemisphere for the muscles targeted by the therapeutic intervention is enhanced[55]. Activity has also been found in the undamaged hemisphere without associated mirror movements occurring in the unaffected limb[53]. In each of the studies these changes have corresponded with clinical improvement in the patient's motor performance. This evidence certainly seems to indicate that structural and functional changes do indeed occur in brain injured individuals following physical therapeutic intervention. It is important to remember however for the purposes of this study that the findings of the aforementioned studies were for stroke patients undergoing an intervention that was not NDT. Although the theoretical arguments may apply to the children in this study further research is required to investigate the effects (if any) of NDT on the mechanisms of neural plasticity in the child with cerebral palsy.

6.4 Issues Arising from the Use of the GMFM

A 'Function' Measure?

Although termed a 'function' measure the GMFM does not assess items in functional contexts and many of the items do not give any idea of the child's level of ability in many everyday functional activities. For example the item assessing single leg balance requires the child to balance for 10 seconds without holding on. Single leg balance is something that may be required when putting on a pair of trousers for instance. The execution of this activity probably requires the child to balance for longer than 10 seconds and in addition the child has the whole dynamic component of the non-weight bearing leg to contend with. One of the TELER indicators addressed this very issue and demonstrated clearly the lack of correlation between simply standing and balancing, and using single leg balance in a functional task. Bower and McLellan[81] have highlighted the same issue in the discussion of their study.

Another example involves the child's level of ability with a walking aid. The GMFM item "walks forward ten steps", when tested with a walking aid, doesn't necessarily give any idea about the child's level of independence with the walking aid. Such a child may not be able to get in and out of the walking aid alone, use it on uneven

surfaces, or even to walk from the physiotherapy gymnasium back to the classroom. Some aspects of such independence are reflected or hinted at in other dimensions of the test. An example being the item in the standing dimension looking at the child's ability to come from sitting to standing, which can and should be tested with a walking aid if the child uses one. It is important to be cautious when using the dimensions of the GMFM in isolation as has been done in previous studies[112]. Damiano and Abel[105] suggest that the walk/run/jumping dimension can be used in isolation to assess ambulatory status but this is not entirely true in the more severely disabled child who may be ambulant in a more limited sense.

Campbell[85] has criticised the GMFM for not assessing skills in their natural context, meaning that it is in essence not a disability scale. It also does not assess aspects of movement such a speed and endurance. One of the aims of NDT is to improve the quality of movement in the child with cerebral palsy, an aspect which is not assessed by the GMFM and which has earned it criticism as an outcome measure. The GMFM was however designed specifically to look at 'quantity' rather than 'quality' of movement, and the authors are clear about the distinction between these two aspects of movement[87]. A measure, the Gross Motor Performance Measure (GMPM)[113,114], has been developed by the same group to look at the qualitative aspects of movement and can be used in conjunction with the GMFM.

Testing With Orthoses and/or Walking Aids

Children who were fitted with orthoses demonstrated no difference in scores when tested on the GMFM with and without their orthoses. All the orthoses in question were fitted on the lower extremity. Such orthoses are generally fitted to support or give stability to a joint. They correct its position, providing improved alignment and preventing unwanted movement at the joint in question during weight-bearing activities. For example an AFO both corrects the alignment of the ankle joint and foot and maintains a neutral position at the ankle joint during heel strike, preventing toe walking or dragging of the toes during walking. The primary aim of orthoses fitted in this group of children was to improve movement quality and such orthoses are unlikely to have had an effect on the children's functional abilities. These findings are in keeping with Russell *et al*[19] who found minimal difference between mean total and goal total scores (where goal areas were the standing and walk/run/jumping dimensions) when testing with and without orthoses in the small group of children from their validation study who used orthoses only.

All three children in the current study who used walking aids demonstrated a difference in scores in the two dimensions in which the walking aids were applied when tested with versus without walking aids. The average difference in total scores was 3.8% and in goal total scores (where goal areas were considered to be the standing and walk/run/jumping dimensions) was 9.5%. Russell *et al's*[19] mean difference in scores for a similar group were 4.2% and 10.9% respectively. Both these differences were statistically significant.

The GMFM was initially designed to be administered independently without the child using any walking aids or orthoses and the authors now advocate retesting the child who normally uses a walking aid or orthoses following an initial testing without the aids or orthoses[19]. Most of the studies that have used the GMFM as an outcome measure have not reported results for testing with walking aids and orthoses. In the vast majority of studies no

reasons were given for so doing. Wright *et al* [102] used the GMFM as an outcome measure in their 1 year follow-up study of CP children post selective dorsal rhizotomy (SDR) and reported no scores for testing with walking aids/orthoses. They did however report that over the follow-up period some of the children in the sample changed to a less supportive walking aid indicating that there was improvement in the area of assisted ambulation. The lack of GMFM testing with walking aids is unfortunate as it may have highlighted important evidence regarding the responsiveness of the GMFM in this area. McLaughlin *et al*[100] report "varying degrees of improvement" in assisted ambulation in their sample of CP children following SDR but again no GMFM sores for testing with walking aids and orthoses were given, although the GMFM was used as an outcome measure. There is evidence to suggest that the GMFM is responsive to changes resulting from the application of walking aids and orthoses[19]. The results of this study would seem to lend support to this, particularly in the application of walking aids.

The use of walking aids consistently improved the children's level of functioning as indicated by the GMFM scores in the two dimensions in which the walking aids were applied. Nonetheless, care must be taken in the interpretation of these results and what they meant in terms of the child's level of functional independence. In the standing dimension for example, item 53 requires the child to maintain the standing position without any support ("arms free") for 3 seconds to obtain a score of '3'. Child 9 who was ambulant with a reverse walker scored '1' for this item (1 = maintains standing, 2 hands holding on, 3 seconds) when tested without her walker. She was then tested on this item with her walking aid and, with the support of her walker she stood for 3 seconds and scored a '3'. In both instances she required both her hands to be holding onto a supporting object and in neither situation were either of her hands free. In this situation the improved score achieved through the use of a walking aid made little difference to her functional ability. On the other hand, in the walk/run/jumping dimension for item 69 (standing: walks forward 10 steps) the same child scored a '0' (unable to achieve) without her walker and a '3' with her walker. In this situation her walking aid meant the difference between being able to walk and not being able to walk, an obviously important difference in functional ability. There is a definite need for further research into the use of walking aids and orthoses when using the GMFM as an outcome measure. The dimensions and items which reliably measure change in function with walking aids need to be identified, as do those items which actually reflect a meaningful difference in functional ability when tested without and then with the walking aid in question. The role of orthoses needs to be closely investigated. It needs to be ascertained exactly the extent to which they are contributing to the child's functional ability and whether assessing an essentially independently ambulant child both with and without orthoses is a meaningful exercise.

The 'Ceiling'

The four mild hemiplegics (children 2, 5, 6, 7) in the sample achieved the four highest total and goal total scores on the GMFM. In fact all of these children achieved scores of 100% or just less for the first three dimensions of the GMFM. Two of these children showed very little change in their total and goal total scores over the study period. In addition to this it was difficult to judge from a clinical point of view if there had been any change in these children over the study period. The question arises as to how sensitive the GMFM is to change in such high functioning children. Such children may reach a ceiling on the GMFM and some other means may be needed to assess changes occurring in them as a result of treatment. A more appropriate way of assessing change in these children might be by means of more complex, functional tasks that are relevant to the child. The use of the

TELER system and indicators allowed for this in this study. Examples of such functional tasks included various dressing activities, stair walking and ball skills. Actual items from the GMFM could be expanded upon in formulating such activities. Another means of assessing change in these children might be by way of the GMPM. Higher functioning children may reach a stage where their functional level has reached its limit for improvement and changes beyond this may be of a more qualitative nature. The GMPM[113,114] addresses movement quality.

Clinical Judgement

Therapists were required to judge the levels of disability of each of the children they were treating as severe, moderate or mild prior to the commencement of the study. The three children classified by their therapists as severe achieved the three lowest total scores on the GMFM at all three assessments. The three children classified as moderate achieved the next three lowest GMFM total scores and the four children classified as mild achieved the four highest GMFM total scores at all three assessments. The same was true for the goal total scores. When using the GMFM in clinical practice a therapist is required to make such an assessment of the child's level of disability. This is a subjective assessment based on clinical judgement and experience. It would appear, from the aforementioned results, that a therapist who is familiar with a child is able to assess reasonably accurately that child's level of disability. These results also add to the evidence in support of the validity of the GMFM.

6.5 Issues Arising from the Use of TELER

The feasibility of using TELER

The current theoretical thinking surrounding motor control and motor learning which underlies NDT has had a tremendous influence on the way in which we view our patients and on our approach to treatment. Treatment has become increasingly more task specific and goal directed. Treatment is no longer a simple case of inhibiting the abnormal and facilitating normal movement patterns. The child is actively involved in the process of learning movement patterns and strategies. In this study the use of the TELER system involved the setting of TELER indicators. The indicators addressed deficits presented by the children that were to be addressed by treatment, so were in essence goals of treatment for a particular child. The structure of the TELER indicator, with code 5 representing the desired outcome and codes 1 - 4 representing intermediate outcomes enabled the ultimate treatment goal to be broken down into smaller goals or tasks. The indicator provided both a means of clarifying the goals or tasks around which treatment was to be oriented and a means of measuring the degree of goal attainment. The therapists involved in the study all commented that they found the process of goal setting; breaking the goal down into component parts; and then writing this all down in a structured format, worthwhile and useful. They all agreed that it provided structure and clarity to their treatment sessions.

In this study the child's progress on the relevant established TELER indicators was traced over the study period with particular note being taken of the influence of the addition of a treatment intervention, namely NDT. In the normal clinical setting the TELER system and indicators would enable a therapist to monitor the influences of many factors on the performance of a child with cerebral palsy. Such factors could include changes in specifics of the treatment plan devised for the child; surgical intervention; Botox injection; the fitting of an orthotic; and

illness. There are undoubtedly many others. Given the positive response from the therapists involved in this study to the use of TELER indicators, as well as the response of the indicators and the system to the application of NDT intervention following a school holiday period, it would appear that it is indeed feasible to use the TELER system in a such an environment. TELER would facilitate the process of goal setting which would in turn help to direct and focus treatment sessions. It would allow the effects of NDT and other medical or surgical interventions on the child to be monitored. It would also help to identify those children whose conditions deteriorate significantly during school holidays and steps could be taken to address this. The process of report writing at the end of a school term would be facilitated as it could be easily identified from TELER the nature of and reasons for the child's performance.

The importance of functional goals

Some of the indicators established addressed correct movement patterns but lacked a functional goal, whereas others addressed correct movement patterns in the context of a specific functional goal or task and others merely addressed a functional goal or task without concern for the movement patterns involved. Those indicators which were more functionally oriented, demonstrated better outcomes than those that did not. These results were not tested for statistical significance and are merely based on visual inspection. In their study Bower *et al*[72] found the setting of specific goals was associated with better outcome following NDT intervention than the setting of broad generalised aims. This is an area worth investigating in future studies as it relates well to current theoretical thinking underlying the NDT approach. The importance of treatments being goal directed and task specific is constantly being emphasised and in order for learning to take place and result in a permanent positive change in motor ability the task must be meaningful for the child.

The validity of TELER indicators

Although the TELER system is reasoned to be a valid and reliable system for assessing the outcome of patients under treatment or care, the indicators established for individual patients may be neither valid nor reliable. The indicators in this study were established purely based on the clinical judgement and consensus of the treating therapists. They were valid and reliable in as much as the therapists felt that the indicators established were relevant to the deficits exhibited by each of the children and that the codes of each of the indicators reflected clinically significant outcomes for the children concerned.

If TELER is to be used in the area of cerebral palsy it is important, for both the clinical setting and for research purposes that the indicators being used are valid and reliable. Normal movement indicators have been established and validated for use in stroke patients[108] and so should some way be found for validating indicators for use in cerebral palsy children. Crude visual inspection of the results of this study seems to indicate that improvement on TELER indicators addressing aspects of gross motor function is associated with improvement in similar items on the GMFM. The GMFM is the only outcome measure that has been validated specifically for measuring change in children with cerebral palsy. It may be a useful tool in assisting with establishing the validity of TELER indicators that address gross motor activities. This would certainly be a worthwhile area of research to pursue. A word of caution, however: the TELER system was specifically designed as flexible system by which outcome measures can be tailor-made for the individual patient. Is establishing a set of valid and reliable indicators not

moving towards a more prescriptive and rigid system? The challenge is going to be to establish valid and reliable indicators that retain this element of flexibility.

6.6 Limitations of the Study

Although the results of this study demonstrated both statistically and clinically significant improvements in motor function in the group of children studied, indicating that the NDT approach is effective when used to treat 4 - 7 year old children with cerebral palsy, they must be viewed with caution for several reasons.

The statistically significant results occurred in the analysis of the results achieved by the children as a group. This was a group of only 10 children which is a very small sample size from which to start making vast generalisations about the effects of treatment on the wider population of cerebral palsy. Nonetheless, by virtue of the study design, these results were achieved using two perfectly matched 'treatment' and 'control' groups.

Not all the children in the sample received the same number of treatment sessions which adds another variable to the whole treatment situation. Children not receiving the required 10 treatment sessions could not practically have been excluded from the analysis as this would have left a ridiculously small sample. The possible effects of the variations in number of treatment sessions as they apply to specific children have already been highlighted in the discussion around the single subject outcomes. This was a difficult variable to control as most of the missed treatments occurred due to absenteeism of the part of the child. On the other hand, over-treating also occurred in this study with some children receiving more than the required number of treatments.

Sackett[59] describes a form of bias occurring in analytic research called 'therapeutic personality bias', where a therapist's convictions about the efficacy of an intervention may influence both the outcomes (positive personality) and their measurement (desire for positive results). The desire on the part of the therapist for positive results was demonstrated in this study in that two of the therapists treated some children for more than the required 10 treatment sessions. This is a perfectly avoidable situation and should not have been allowed to occur. It was probably not made clear enough at the outset of the study the importance of adhering to the required number of treatment sessions. In hindsight closer monitoring of the intervention phase with a chart on which each therapist could mark off each of the 10 treatment sessions as they were completed may have helped avoid this situation.

The NDT given was the only variable that changed between the baseline and intervention phases that was specifically designed to have an effect on the gross motor skills of cerebral palsy children. Nonetheless there were other changes that occurred between the two phases and their possible effects on the children's outcome cannot be ignored. Notably the children went from a school holiday situation back into a structured school system and a variety of academic and non-academic activities. It is unlikely that these other activities were entirely responsible for affording the changes in gross motor function that were seen, but their effects cannot be ruled out either. It was not possible in this study to have both the baseline and intervention phases during a school term as

the school authorities would not allow the complete withdrawal of any therapeutic interventions from any child normally receiving such an intervention. This problem of withholding treatment for the purposes of establishing control groups or baseline phases has been highlighted by other authors[10,11,16,18]. This refusal on the part of parents, institutional authorities and even therapists to withhold NDT treatment from a child, even for relatively short defined periods of time, is interesting in light of the lack of documented evidence in support of the efficacy of NDT. One wonders at the motivation, on the part of parents for seeking therapeutic intervention, and on the part of institutions and therapists, for providing intervention. Are we trying to appease our own consciences or are we genuinely providing these children with an effective therapy that is making meaningful changes to their lives? Refusal to withhold treatment also prevented the use of a single subject withdrawal design (ABA). This design is preferable to the AB design in that it provides opportunity to demonstrate increased support for the effects of the intervention under consideration.

The TELER indicators established for this study were valid and reliable in that they were agreed upon for each child by the 3 therapists who were involved in treating the children for the study. At the time that the TELER indicators were established the researcher had had no contact with the children and merely facilitated the setting of the indicators based on her knowledge of the TELER system and the process for establishing indicators. All 3 therapists knew each of the children and used their clinical knowledge, expertise and judgement to establish indicators tracing clinically meaningful change for each of the children. Beyond this the validity of the indicators was not established. Not all of the indicators used may have been sufficiently valid for tracing the changes in the children and/or deficits that were intended.

Expectation bias is a marked short coming of this study. The researcher, who assessed the children before and after the baseline and intervention phases, was clearly not blind as to whether the children had received treatment or not. This was a difficult situation to avoid as even an independent party assessing the children would almost certainly have guessed when the children had been treated and when not, given the way in which the study had to be structured around a school holiday. The ideal way to alleviate this would have been to have the independent party carry out blind assessments of video recordings of each of the children. This however brings about its own associated problems. A trial GMFM assessment of a child not included in the study (but of similar age to the children in the sample) was video taped for purposes not associated with the study. This recording eventually had to be abandoned as the child was so distracted by the camera, trying to 'perform' for it and as a consequence, affecting his performance on the test. This may not occur as a rule but Bower and McLellan[9] have noted previously that performance measured under stressed or artificial circumstances may give rise to misleading results. In the situation of the current study there was no way to video-tape the children without them being fully aware of the presence of a camera which only encouraged the budding acting talents of 5 and 6 year old hemiplegics!! If video recording is to be used as part of the assessment process it is important that a standardised method of assessing these recordings is established. This could have been done by way of TELER in this study, but as has been pointed out already there are limitations involved with the validity of the TELER indicators. The alternative would have been to use recordings of the GMFM assessment, but then the question arises as to whether the whole or only part of the assessment is used for this purpose. Problems have been highlighted by Russell *et al*[98] with using only parts of the assessment, in terms of item selection and levels of inter and intra-rater

reliability. Quality of video taping is also an issue in terms of trying to achieve the best view of the item to be tested. Subtleties of weight shift and initiation of movement may also be more difficult to judge from a video recording. An additional constraint in this study was simply financial as there are significant costs involved in the criterion testing for the GMFM. An ideal situation would be an initial pilot study to test a valid and reliable means of assessing video recordings, followed by a study such as the current one using video-recordings to assist in blind assessment of outcome.

6.7 Recommendations

The results of this study suggest evidence in favour of the efficacy of the NDT approach in the treatment of cerebral palsy children. The study has also highlighted several issues from which recommendations can be made pertaining both to areas of future research as well as to current clinical practice, particularly in the school situation.

Research

1. There is a tremendous need for well designed, methodologically sound outcome studies in this field. The literature review highlighted the lack of such studies and the growing need for evidence based practice. A small number of studies have demonstrated positive outcomes in cerebral palsy children receiving NDT and more are needed to further support the beneficial effects of NDT.

2. This study, as well as others that were reviewed during the course of this study, demonstrated that the single-subject design can be very effectively used to evaluate outcome in cerebral palsy children receiving NDT. The use of the single-subject design in future research in this field is recommended, both in an attempt to provide evidence to support the use of NDT as well as to assist in the planning and execution of larger group studies.

3. TELER provided a useful means of measuring outcome in the children in this study. It allowed for the establishment of individualised outcome measures, so accommodating the vast range of unique problems demonstrated by the various children. It provided a means of measuring the degree of attainment of the treatment goals set for each of the children. The use of TELER in this field is an area of worthwhile future research. The reliability and validity of the TELER system and its indicators needs to be demonstrated and further guidelines for its use in research in the area of cerebral palsy need to be established.

4. The elimination of expectation bias is important in studies such as this one, and was one of the short-comings of this study. In a case where it is difficult to blind assessors to the intervention received by the child, blinded assessment of video recordings is probably the most feasible means of assessment. It is recommended however that, prior to commencing such a study, a standardised, valid and reliable method of performing such assessments is established. It is also recommended that, if at all possible, the set-up is such that the children being video taped are unaware of such taping as it may affect their performance.

Clinical Practice

1. TELER appeared to be a feasible system for monitoring change in cerebral palsy children undergoing therapy in a school setting. The implementation of such a system in schools, hospital out-patient departments and private practices treating children with cerebral palsy is highly recommended. It would provide a useful means of monitoring a child's performance whilst under treatment and of measuring the effects of such treatment. It would facilitate the writing of reports for other medical practitioners, for parents, and for medical insurance purposes. The effects of other interventions provided for the child could easily be assessed using TELER. Most importantly though it would enable a therapist to assess the effects of treatment on a child as part of the treatment process and it would help to direct the delivery of effective and beneficial treatment for the child.

2. The importance of goal setting and goal directed, task oriented treatment was once again highlighted in this study and is something which should be done as a matter of course when using the NDT approach in the treatment of cerebral palsy children. Setting of specific, measurable, functional goals around which treatment is structured appears to be a necessary part of effective treatment. The establishment of the TELER indicators in this study required that these selected goals were written down and in some cases the goals had to be broken down into component parts. This facilitated both the process of setting specific goals, as opposed to just having general aims of treatment. It also seemed to play an important role in helping to structure and direct treatment.

3. The results of this study indicated that a home programme, particularly in the case of the more severely disabled child, may play an important role in the overall management of the child with cerebral palsy. In the school situation, where regular contact with the child's parents is not always easy, it is recommended that some way be found of over coming this so that such a home programme can be established. This may require home visits or specially arranged meetings with parents at the school. It is also recommended that the effects of such a home programme are monitored to ensure that the extra time and effort involved on the part of the therapist and the parents is actually beneficial to the child.

CHAPTER 7
CONCLUSION

This study set out to investigate the efficacy of the NDT approach in the treatment of a group of young school-going children with cerebral palsy, where efficacy was defined as the extent to which a therapy is more useful and beneficial than useless and harmful for the purpose for which it is advocated. Specifically the effect of NDT on the children's gross motor skills was investigated by way of the gross motor function measure (GMFM) and a tool, which allowed the establishment of individualised outcome measures, called TELER. A multiple single subject design with a baseline phase of no NDT treatment, apart from any home programme normally carried out by the child's parents, followed by an intervention phase of twice weekly NDT treatment was used to this end.

The results of the study found NDT to have a positive effect on gross motor function in this group of children. The group of children made greater overall statistically and clinically significant improvement in gross motor skills whilst receiving NDT intervention than they did during the baseline phase. NDT was more effective in promoting gross motor skills in these children than any home programme which they may have been receiving. NDT was the only variable which changed between the two phases of the study which was specifically designed to have an effect on gross motor skills, so it is feasible to conclude that the improvements demonstrated by these children were attributable to NDT. It is not possible to extrapolate the results of this study to the wider cerebral palsy population owing to limitations of the study that have already been highlighted. These results do however add to a small group of studies also using the single subject design which have demonstrated positive outcomes in cerebral palsy children receiving NDT treatment.

TELER appeared to be a feasible means of assessing the results of NDT intervention in this group of children. It provided a way of measuring the degree of attainment of the goals of therapy that were established for each child and the goal setting process facilitated the planning and execution of treatment. Given the flexibility of the TELER system it would be an appropriate system for measuring outcome in this field in the future, both on an ongoing basis in the clinical setting, as well as in the context of research and outcome studies. However the validity of TELER indicators for use in cerebral palsy children needs to be investigated further and the GMFM may be able to assist with this process.

The single subject design enabled closer investigation of individual children within the small study group and relationships between certain factors unique to each child and a successful response to treatment were noted. Successful treatment outcome seemed to depend on the accurate establishment of functionally oriented goals. Practice of these goals in different contexts and environments, both in- and outside of the therapy situation appeared important along with periods without treatment to consolidate newly learnt motor skills. An effective home programme for the severely disabled child appeared necessary to avoid deterioration of function during periods of no treatment. NDT may have more of a maintenance-type role to play in the severely disabled child rather than affording large improvements in motor function.

The need for evidence based practice in the field of cerebral palsy and NDT is growing. As well as being able to justify our treatment approach to insurance and medical aid schemes, government departments (health and education) and our fellow medical professionals, we have a responsibility to the children we are treating and their families to provide evidence of the efficacy of the treatment we are offering them. This study indicated that NDT was both useful and beneficial in improving motor function in a group of children with cerebral palsy. Together with a small, but hopefully increasing, number of other studies it has contributed towards fulfilling this need for evidence based practice.

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ADDENDUM 1

THE GROSS MOTOR FUNCTION MEASURE

Check (✓) the appropriate score:

Item	A: LYING AND ROLLING	SCORE	
1.	SUP, HEAD IN MIDLINE: TURNS HEAD WITH EXTREMITIES SYMMETRICAL	0 ☐ 1 ☐ 2 ☐ 3 ☐	1.
2.	SUP: BRINGS HANDS TO MIDLINE, FINGERS ONE WITH THE OTHER	0 ☐ 1 ☐ 2 ☐ 3 ☐	2.
3.	SUP: LIFTS HEAD 45°	0 ☐ 1 ☐ 2 ☐ 3 ☐	3.
4.	SUP: FLEXES R HIP & KNEE THROUGH FULL RANGE	0 ☐ 1 ☐ 2 ☐ 3 ☐	4.
5.	SUP: FLEXES L HIP AND KNEE THROUGH FULL RANGE	0 ☐ 1 ☐ 2 ☐ 3 ☐	5.
6.	SUP: REACHES OUT WITH R ARM, HAND CROSSES MIDLINE TOWARD TOY	0 ☐ 1 ☐ 2 ☐ 3 ☐	6.
7.	SUP: REACHES OUT WITH L ARM, HAND CROSSES MIDLINE TOWARD TOY	0 ☐ 1 ☐ 2 ☐ 3 ☐	7.
8.	SUP: ROLLS TO PR OVER R SIDE	0 ☐ 1 ☐ 2 ☐ 3 ☐	8.
9.	SUP: ROLLS TO PR OVER L SIDE	0 ☐ 1 ☐ 2 ☐ 3 ☐	9.
10.	PR: LIFTS HEAD UPRIGHT	0 ☐ 1 ☐ 2 ☐ 3 ☐	10.
11.	PR ON FOREARMS: LIFTS HEAD UPRIGHT, ELBOWS EXT., CHEST RAISED	0 ☐ 1 ☐ 2 ☐ 3 ☐	11.
12.	PR ON FOREARMS: WEIGHT ON R FOREARM, FULLY EXTENDS OPPOSITE ARM FORWARD	0 ☐ 1 ☐ 2 ☐ 3 ☐	12.
13.	PR ON FOREARMS: WEIGHT ON L FOREARM, FULLY EXTENDS OPPOSITE ARM FORWARD	0 ☐ 1 ☐ 2 ☐ 3 ☐	13.
14.	PR: ROLLS TO SUP OVER R SIDE	0 ☐ 1 ☐ 2 ☐ 3 ☐	14.
15.	PR: ROLLS TO SUP OVER L SIDE	0 ☐ 1 ☐ 2 ☐ 3 ☐	15.
16.	PR: PIVOTS TO R 90° USING EXTREMITIES	0 ☐ 1 ☐ 2 ☐ 3 ☐	16.
17.	PR: PIVOTS TO L 90° USING EXTREMITIES	0 ☐ 1 ☐ 2 ☐ 3 ☐	17.
	TOTAL DIMENSION A	☐	

Item	B: SITTING	SCORE	
18.	SUP, HANDS GRASPED BY EXAMINER: PULLS SELF TO SITTING WITH HEAD CONTROL	0 ☐ 1 ☐ 2 ☐ 3 ☐	18.
19.	SUP: ROLLS TO R SIDE, ATTAINS SITTING	0 ☐ 1 ☐ 2 ☐ 3 ☐	19.
20.	SUP: ROLLS TO L SIDE, ATTAINS SITTING	0 ☐ 1 ☐ 2 ☐ 3 ☐	20.
21.	SIT ON MAT, SUPPORTED AT THORAX BY THERAPIST: LIFTS HEAD UPRIGHT, MAINTAINS 3 SECONDS	0 ☐ 1 ☐ 2 ☐ 3 ☐	21.
22.	SIT ON MAT, SUPPORTED AT THORAX BY THERAPIST: LIFTS HEAD TO MIDLINE, MAINTAINS 10 SECONDS	0 ☐ 1 ☐ 2 ☐ 3 ☐	22.
23.	SIT ON MAT, ARM(S) PROPPING: MAINTAINS, 5 SECONDS	0 ☐ 1 ☐ 2 ☐ 3 ☐	23.
24.	SIT ON MAT: MAINTAINS, ARMS FREE, 3 SECONDS	0 ☐ 1 ☐ 2 ☐ 3 ☐	24.
25.	SIT ON MAT WITH SMALL TOY IN FRONT: LEANS FORWARD, TOUCHES TOY, RE-ERECTS WITHOUT ARM PROPPING	0 ☐ 1 ☐ 2 ☐ 3 ☐	25.
26.	SIT ON MAT: TOUCHES TOY PLACED 45° BEHIND CHILD'S R SIDE, RETURNS TO START	0 ☐ 1 ☐ 2 ☐ 3 ☐	26.
27.	SIT ON MAT: TOUCHES TOY PLACED 45° BEHIND CHILD'S L SIDE, RETURNS TO START	0 ☐ 1 ☐ 2 ☐ 3 ☐	27.
28.	R SIDE SIT: MAINTAINS, ARMS FREE, 5 SECONDS	0 ☐ 1 ☐ 2 ☐ 3 ☐	28.
29.	L SIDE SIT: MAINTAINS, ARMS FREE, 5 SECONDS	0 ☐ 1 ☐ 2 ☐ 3 ☐	29.
30.	SIT ON MAT: LOWERS TO PR WITH CONTROL	0 ☐ 1 ☐ 2 ☐ 3 ☐	30.
31.	SIT ON MAT WITH FEET IN FRONT: ATTAINS 4 POINT OVER R SIDE	0 ☐ 1 ☐ 2 ☐ 3 ☐	31.
32.	SIT ON MAT WITH FEET IN FRONT: ATTAINS 4 POINT OVER L SIDE	0 ☐ 1 ☐ 2 ☐ 3 ☐	32.
33.	SIT ON MAT: PIVOTS 90°, WITHOUT ARMS ASSISTING	0 ☐ 1 ☐ 2 ☐ 3 ☐	33.
34.	SIT ON BENCH: MAINTAINS, ARMS AND FEET FREE, 10 SECONDS	0 ☐ 1 ☐ 2 ☐ 3 ☐	34.
35.	STD: ATTAINS SIT ON SMALL BENCH	0 ☐ 1 ☐ 2 ☐ 3 ☐	35.
36.	ON THE FLOOR: ATTAINS SIT ON SMALL BENCH	0 ☐ 1 ☐ 2 ☐ 3 ☐	36.
37.	ON THE FLOOR: ATTAINS SIT ON LARGE BENCH	0 ☐ 1 ☐ 2 ☐ 3 ☐	37.
	TOTAL DIMENSION B	☐	

Item	C: CRAWLING AND KNEELING	SCORE	
38.	PR: CREEPS FORWARD 6'	0 1 2 3	38.
39.	4 POINT: MAINTAINS, WEIGHT ON HANDS AND KNEES, 10 SECONDS	0 1 2 3	39.
40.	4 POINT: ATTAINS SIT ARMS FREE	0 1 2 3	40.
41.	PR: ATTAINS 4 POINT, WEIGHT ON HANDS AND KNEES	0 1 2 3	41.
42.	4 POINT: REACHES FORWARD WITH R ARM, HAND ABOVE SHOULDER LEVEL	0 1 2 3	42.
43.	4 POINT: REACHES FORWARD WITH L ARM, HAND ABOVE SHOULDER LEVEL	0 1 2 3	43.
44.	4 POINT: CRAWLS OR HITCHES FORWARD 6'	0 1 2 3	44.
45.	4 POINT: CRAWLS RECIPROCALLY FORWARD 6'	0 1 2 3	45.
46.	4 POINT: CRAWLS UP 4 STEPS ON HANDS AND KNEES/FEET	0 1 2 3	46.
47.	4 POINT: CRAWLS BACKWARDS DOWN 4 STEPS ON HANDS AND KNEES/FEET	0 1 2 3	47.
48.	SIT ON MAT: ATTAINS HIGH KN USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0 1 2 3	48.
49.	HIGH KN: ATTAINS HALF KN ON R KNEE USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0 1 2 3	49.
50.	HIGH KN: ATTAINS HALF KN ON L KNEE USING ARMS, MAINTAINS, ARMS FREE, 10 SECONDS	0 1 2 3	50.
51.	HIGH KN: KN WALKS FORWARD 10 STEPS, ARMS FREE	0 1 2 3	51.
	TOTAL DIMENSION C		

Item	D: STANDING	SCORE	
52.	ON THE FLOOR: PULLS TO STD AT LARGE BENCH	0 1 2 3	52.
53.	STD: MAINTAINS, ARMS FREE, 3 SECONDS	0 1 2 3	53.
54.	STD: HOLDING ON TO LARGE BENCH WITH ONE HAND, LIFTS R FOOT, 3 SECONDS	0 1 2 3	54.
55.	STD: HOLDING ON TO LARGE BENCH WITH ONE HAND, LIFTS L FOOT, 3 SECONDS	0 1 2 3	55.
56.	STD: MAINTAINS, ARMS FREE, 20 SECONDS	0 1 2 3	56.
57.	STD: LIFTS L FOOT, ARMS FREE, 10 SECONDS	0 1 2 3	57.
58.	STD: LIFTS R FOOT, ARMS FREE, 10 SECONDS	0 1 2 3	58.
59.	SIT ON SMALL BENCH: ATTAINS STD WITHOUT USING ARMS	0 1 2 3	59.
60.	HIGH KN: ATTAINS STD THROUGH HALF KN ON R KNEE, WITHOUT USING ARMS	0 1 2 3	60.
61.	HIGH KN: ATTAINS STD THROUGH HALF KN ON L KNEE, WITHOUT USING ARMS	0 1 2 3	61.
62.	STD: LOWERS TO SIT ON FLOOR WITH CONTROL, ARMS FREE	0 1 2 3	62.
63.	STD: ATTAINS SQUAT, ARMS FREE	0 1 2 3	63.
64.	STD: PICKS UP OBJECT FROM FLOOR, ARMS FREE, RETURNS TO STAND	0 1 2 3	64.
	TOTAL DIMENSION D		

Item	E. WALKING, RUNNING AND JUMPING	SCORE	
65.	STD, 2 HANDS ON LARGE BENCH: CRUISES 5 STEPS TO R	0 ☐ 1 ☐ 2 ☐ 3 ☐	65.
66.	STD, 2 HANDS ON LARGE BENCH: CRUISES 5 STEPS TO L	0 ☐ 1 ☐ 2 ☐ 3 ☐	66.
67.	STD, 2 HANDS HELD: WALKS FORWARD 10 STEPS	0 ☐ 1 ☐ 2 ☐ 3 ☐	67.
68.	STD, 1 HAND HELD: WALKS FORWARD 10 STEPS	0 ☐ 1 ☐ 2 ☐ 3 ☐	68.
69.	STD: WALKS FORWARD 10 STEPS	0 ☐ 1 ☐ 2 ☐ 3 ☐	69.
70.	STD: WALKS FORWARD 10 STEPS, STOPS, TURNS 180°, RETURNS	0 ☐ 1 ☐ 2 ☐ 3 ☐	70.
71.	STD: WALKS BACKWARD 10 STEPS	0 ☐ 1 ☐ 2 ☐ 3 ☐	71.
72.	STD: WALKS FORWARD 10 STEPS, CARRYING A LARGE OBJECT WITH 2 HANDS	0 ☐ 1 ☐ 2 ☐ 3 ☐	72.
73.	STD: WALKS FORWARD 10 CONSECUTIVE STEPS BETWEEN PARALLEL LINES 8" APART	0 ☐ 1 ☐ 2 ☐ 3 ☐	73.
74.	STD: WALKS FORWARD 10 CONSECUTIVE STEPS ON A STRAIGHT LINE ¾" WIDE	0 ☐ 1 ☐ 2 ☐ 3 ☐	74.
75.	STD: STEPS OVER STICK AT KNEE LEVEL, R FOOT LEADING	0 ☐ 1 ☐ 2 ☐ 3 ☐	75.
76.	STD: STEPS OVER STICK AT KNEE LEVEL, L FOOT LEADING	0 ☐ 1 ☐ 2 ☐ 3 ☐	76.
77.	STD: RUNS 15 FEET, STOPS & RETURNS	0 ☐ 1 ☐ 2 ☐ 3 ☐	77.
78.	STD: KICKS BALL WITH R FOOT	0 ☐ 1 ☐ 2 ☐ 3 ☐	78.
79.	STD: KICKS BALL WITH L FOOT	0 ☐ 1 ☐ 2 ☐ 3 ☐	79.
80.	STD: JUMPS 12" HIGH, BOTH FEET SIMULTANEOUSLY	0 ☐ 1 ☐ 2 ☐ 3 ☐	80.
81.	STD: JUMPS FORWARD 12", BOTH FEET SIMULTANEOUSLY	0 ☐ 1 ☐ 2 ☐ 3 ☐	81.
82.	STD ON R FOOT: HOPS ON R FOOT 10 TIMES WITHIN A 24" CIRCLE	0 ☐ 1 ☐ 2 ☐ 3 ☐	82.
83.	STD ON L FOOT: HOPS ON L FOOT 10 TIMES WITHIN A 24" CIRCLE	0 ☐ 1 ☐ 2 ☐ 3 ☐	83.
84.	STD, HOLDING 1 RAIL: WALKS UP 4 STEPS, HOLDING 1 RAIL, ALTERNATING FEET	0 ☐ 1 ☐ 2 ☐ 3 ☐	84.
85.	STD, HOLDING 1 RAIL: WALKS DOWN 4 STEPS, HOLDING 1 RAIL, ALTERNATING FEET	0 ☐ 1 ☐ 2 ☐ 3 ☐	85.
86.	STD: WALKS UP 4 STEPS, ALTERNATING FEET	0 ☐ 1 ☐ 2 ☐ 3 ☐	86.
87.	STD: WALKS DOWN 4 STEPS, ALTERNATING FEET	0 ☐ 1 ☐ 2 ☐ 3 ☐	87.
88.	STD ON 6" STEP: JUMPS OFF, BOTH FEET SIMULTANEOUSLY	0 ☐ 1 ☐ 2 ☐ 3 ☐	88.

TOTAL DIMENSION E ☐

Was this assessment indicative of this child's "regular" performance? YES ☐ NO ☐

COMMENTS:

ADDENDUM 2

WORKED EXAMPLE ILLUSTRATING GMFM TOTAL AND GOAL TOTAL SCORES

GMFM

SUMMARY SCORE

DIMENSION	CALCULATION OF DIMENSION % SCORES	GOAL AREA (indicated with x)
A. Lying and Rolling	Total Dimension A / 51 = 43 / 51 x 100 = 84 %	A. ☐
B. Sitting	Total Dimension B / 60 = 28 / 60 x 100 = 47 %	B. ☐
C. Crawling and Kneeling	Total Dimension C / 42 = 15 / 42 x 100 = 36 %	C. ☒
D. Standing	Total Dimension D / 39 = 5 / 39 x 100 = 13 %	D. ☒
E. Walking, Running & Jumping	Total Dimension E / 72 = 5 / 72 x 100 = 7 %	E. ☒

TOTAL SCORE = $\frac{\%A + \%B + \%C + \%D + \%E}{\text{Total \# of Dimensions}}$

= $\frac{84 + 47 + 36 + 13 + 7}{5} = \frac{187}{5} = 37\ \%$

GOAL TOTAL SCORE = $\frac{\text{Sum of \% scores for each dimension identified as a goal area}}{\text{\# of Goal Areas}}$

= $\frac{36 + 13 + 7}{3} = 19\ \%$

ADDENDUM 3

WORKED EXAMPLE ILLUSTRATING THE TELER EVALUATION

TELER™

BASIC FORM

Patient: X

Treatment Plan

	4/6	7/6	10/6	14/6	17/6	21/6
Exercise 1	✓	✓	✓	✓	✓	✓
Exercise 2	✓	✓	✓	✓	✓	✓
Exercise 3		✓	✓	✓	✓	✓
Exercise 4				✓	✓	✓

Outcome Record

Indicators:												
Indicator 1		0		0		1		2		3		4
Indicator 2		0		1		2		2		3		4
Indicator 3		1		1		1		3		4		4
										1		3
								1		2		
						1		2				
		1		2		2						
		2		1								

Number of 5 codes

4 codes

3 codes

2 codes

1 codes

0 codes

PT/OT/SLT:

ADDENDUM 4

TELER INDICATORS

CHILD 1

Indicator 1: Proficiency With Walking Aid

0 Requires complete supervision to use appliance

1 Placed in standing with wlk aid, is able to step independently, requires assistance to move wlk aid

2 Placed in standing with wlk aid, is able to step independently, requires assistance with steering

3 Placed in standing with wlk aid, is able to walk independently with wlk aid in physio gym

4 Placed in standing with wlk aid, is able to walk independently with wlk aid from class to physio/in playground

5 Able to come from sit at classroom table to stand and walk independently with aid

Indicator 2: Dynamic Floor-Sitting

0 No dynamic floor sitting - consistently sits with wide base and no weight transfer through pelvis

1 Long sits with facilitation to do an activity

2 Side sits to left and right with facilitation to do an activity

3 Moves between long sit and left/right side sit with facilitation

4 Moves between long sit and left/right side sit with facilitation whilst completing form-board puzzle

5 Moves between long sit and left/right side sit independently whilst completing a puzzle

Indicator 3: Tolerance of Therapy

Leaves class and comes to therapy without crying/resistance

Tolerates being handled by therapist for 1 activity with some crying/resistance

Tolerates being handled by therapist for 1 activity without crying/resistance

Tolerates >1 activity (not involving use of large equipment) during therapy

Tolerates use of 1 piece of large equipment (ball, roller etc.) during therapy

Scoring for indicator 3:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 2

Indicator 1: Attain Standing Through 1/2 Kneeling Using Support

0 Unable to achieve

1 Balances in upright kneeling on right independently

2 Stands through 1/2 kneeling on right, transferring weight forward onto left with support and facilitation

3 Stands through 1/2 kneeling on right, transferring weight forward onto left with support only

4 Stands through 1/2 kneeling on right, transferring weight forward onto left without support, minimal facilitation

5 Stands through 1/2 kneeling on right, transferring weight forward onto left independently

Indicator 2: Ball Skills

Catch a bean bag, thrown by therapist 3 consecutive times in both hands and throw with one hand

Throw a bean bag up in the air with 1 or two hands and catch with two hands 3 consecutive times

Catch a medium size ball thrown by therapist 3 consecutive times using both hands

Throw a medium size ball up in the air with two hands and catch with two hands 3 consecutive times

Throw a medium sized ball to therapist by bouncing it accurately into a hoop lying on the floor 3 consecutive times.

Indicator 3: Standing Balance for Dressing

Balances on right leg and then left leg with support for >10 sec

Balances on left leg without holding on for 10 sec

Balances on right leg without holding on for 10 sec

Balances on left leg in order to put right leg into trousers without losing balance

Balances on right leg in order to put left leg into trousers without losing balance

Scoring for indicators 2 and 3:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 3

Indicator 1: Dynamic Weight-Bearing on an Extended Arm in Side-Sitting (right side)

0 Unable to achieve

1 In side-sitting, wt on fore-arm, able to move over wt-bearing arm

2 In side-sitting, elbow ext maintained with a gaiter, able to move over wt-bearing arm with assistance

3 In side-sitting, elbow ext maintained with a gaiter, able to move over wt-bearing arm without assistance

4 In side-sitting, able to wt-bear on ext elbow (no gaiter) and move over wt-bearing arm with assistance

5 In side-sitting, able to maintain wt-bear on ext elbow and move over wt-bearing arm without assistance

Indicator 2: Improve Gait Pattern (Heel-Strike) (right side)

0 Unable to achieve

1 Non-weight bearing, active dorsiflexion with knee flexed

2 Non-weight bearing, active dorsiflexion with knee extended

3 Achieves active dorsiflexion/knee extension and plantar flexion/knee flexion as moves small roll with foot

4 Heel-strike during gait with facilitation/prompt

5 Heel-strike during gait independently

Indicator 3: Standing Balance for Dressing

Balances on right leg and then left leg with support for >10 sec

Balances on left leg without holding on for 10 sec

Balances on right leg without holding on for 10 sec

Balances on left leg in order to put right leg into trousers without losing balance

Balances on right leg in order to put left leg into trousers without losing balance

Scoring for indicator 3:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 4

Indicator 1: Dynamic Standing Balance

Balance in standing on red block for 20 sec

Maintain balance on red block when pushed slowly

Step onto wobble board and balance for 10 sec

Balance on balance-beam for 10 sec holding on

Balance on balance-beam for 10 sec without holding on

Indicator 2: Independent Undressing (Seated on a block)

Takes off tracksuit top (zip undone)

Takes off trousers (tracksuit pants)

Takes off shoes and socks (laces undone)

Undoes laces and takes of shoes and socks

Unzips tracksuit top and takes off

Indicator 3: Lateral Weight Transfer

0 Unable to transfer weight laterally in standing in order to free NWB leg to step up

1 Lifts and places left/right* foot onto therapists leg with facilitation and support

2 Lifts and places left/right* foot onto therapists leg with support only

3 Steps up onto block with left/right* foot leading with facilitation and support

4 Steps up onto block with left/right* foot leading with support only

5 Steps up onto block with left/right* foot leading independently

*must be able to achieve with both left and right

Scoring for indicators 1 and 2:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 5

Indicator 1: Independent Dressing

Puts on tracksuit top (not zip)

Puts on tracksuit pants

Puts on socks

Puts on shoes (not laces)

Zips up tracksuit top

Indicator 2: Concentration/Attention During an Activity

0 Will not attend to any task/sit at table

1 2-5 minutes attention before distracted

2 5-10 minutes attention before distracted

3 10-15 minutes attention before distracted

4 15-20 minutes attention before distracted on occasions

5 20 minutes consistently

Indicator 3: Reciprocal Gait when Walking Down Stairs

0 Unable to achieve

1 Walks down 5 steps holding rail same foot leads

2 Walks down 5 steps holding rail alternating feet

3 Walks down 10 steps holding rail alternating feet

4 Walks down 5 steps with no support alternating feet

5 Walks down 10 steps with no support alternating feet

Scoring for indicator 1:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 6

Indicator 1: Ball Skills

Catch a bean bag, thrown by therapist 3 consecutive times in both hands and throw with one hand

Throw a bean bag up in the air with 1 or two hands and catch with two hands 3 consecutive times

Catch a medium size ball thrown by therapist 3 consecutive times using both hands

Throw a medium size ball up in the air with two hands and catch with two hands 3 consecutive times

Throw a medium sized ball to therapist by bouncing it accurately into a hoop lying on the floor 3 consecutive times.

Indicator 2: Standing Balance for Dressing

Balances on right and then left leg with support for >10 sec

Balances on left leg without holding on for 10 sec

Balances on right leg without holding on for 10 sec

Balances on left leg in order to put right leg into trousers without losing balance

Balances on right leg in order to put left leg into trousers without losing balance

Indicator 3: Reciprocal Gait when Walking Down Stairs

0 Unable to achieve

1 Walks down 5 steps holding rail same foot leads

2 Walks down 5 steps holding rail alternating feet

3 Walks down 10 steps holding rail alternating feet

4 Walks down 5 steps with no support alternating feet

5 Walks down 10 steps with no support alternating feet

Scoring for indicators 1 and 2:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 7

Indicator 1: Improve Gait Pattern (Heel-Strike) (left side)

0 Unable to achieve

1 Non-weight bearing, active dorsiflexion with knee flexed

2 Non-weight bearing, active dorsiflexion with knee extended

3 Achieves active dorsiflexion/knee extension and plantar flexion/knee flexion as moves small roll with foot

4 Heel-strike during gait with facilitation/prompt

5 Heel-strike during gait independently

Indicator 2: Ball Skills

Catch a bean bag, thrown by therapist 3 consecutive times in both hands and throw with one hand

Throw a bean bag up in the air with 1 or two hands and catch with two hands 3 consecutive times

Catch a medium size ball thrown by therapist 3 consecutive times using both hands

Throw a medium size ball up in the air with two hands and catch with two hands 3 consecutive times

Throw a medium sized ball to therapist by bouncing it accurately into a hoop lying on the floor 3 consecutive times.

Indicator 3: Standing Balance for Dressing

Balances on right and then left leg with support for >10 sec

Balances on left leg without holding on for 10 sec

Balances on right leg without holding on for 10 sec

Balances on left leg in order to put right leg into trousers without losing balance

Balances on right leg in order to put left leg into trousers without losing balance

Scoring for indicators 2 and 3:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 8

Indicator 1: Balance in Kneeling/1/2 Kneeling

Balance in upright kneeling independently

Balance in 1/2 kneeling L or R with support

Get from upright kneeling to 1/2 kneeling on R/L with support

Balance in 1/2 kneeling without support on either leg for 10 sec

Balance in 1/2 kneeling without support on either leg and throw and catch a ball

Indicator 2: Walk Without Back-Kneeing

Able to transfer wt laterally in standing onto L leg without back-kneeing

Able to transfer wt laterally in standing onto R leg without back-kneeing

Able to walk 1/2 length of gym without back-kneeing, with crutches and facilitation

Able to walk 1/2 length of gym without back-kneeing, with crutches and prompting (no facilitation)

Able to walk 1/2 length of gym without back-kneeing, with crutches (no prompting or facilitation)

Indicator 3: Dynamic Standing Balance

Able to maintain weight on legs

Able to balance in standing without holding on

Able to reach for an object without losing balance to left and right

Able to maintain balance when pushed

Stands and throws and catches a bean-bag

Scoring for indicators 1, 2 and 3:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 9

Indicator 1: Performance of Activities Without using Pronation/Ulnar Deviation of Forearms/Wrists

Weight bears on "flat" hands with assistance from therapist

Weight bears on "flat" hands without assistance

Able to actively shuffle cards on flat surface maintaining "flat" hands with assistance

Able to actively shuffle cards on flat surface maintaining "flat" hands without assistance

Able to grasp cone with forearm and wrist in neutral with assistance

Indicator 2: Attainment of Upright Kneeling

0 Unable to achieve

1 Maintains upright kneeling for a short time with support

2 Maintains upright kneeling with support on buttocks long enough to complete a simple form-board

3 Maintains upright kneeling independently long enough to complete a simple form-board

4 Gets into upright kneeling from 4-pt kneeling with assistance of therapist and using support

5 Gets into upright kneeling from 4-pt kneeling using support

Indicator 3: Proficiency With Walking Aid

0 Unable to stand with appliance

1 Stands with appliance, holds on, unable to step

2 Steps with manual facilitation/support from therapist

3 Steps independently, requires assistance to move appliance

4 Steps independently, requires assistance with steering

5 Steps and steers independently with appliance

Scoring for indicator 1:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

CHILD 10

Indicator 1: Balance in Kneeling/1/2 Kneeling

Balances in upright kneeling independently

Balances in 1/2 kneeling L or R with support

Gets from upright to 1/2 kneeling with facilitation and support

Gets from upright kneeling to 1/2 kneeling on right/left with support, no facilitation

Balance in 1/2 kneeling without support on either leg for 10 sec

Indicator 2: Improve Gait Pattern (Heel-Strike)

0 Consistently drags R foot when walking

1 Obtains heel-strike with manual facilitation and AFO only

2 Obtains heel-strike with verbal prompt and AFO in and around physio room

3 Obtains heel-strike with verbal prompt and AFO for entire walk back to classroom

4 Consistently walks with heel-strike when in AFO

5 Obtains heel-strike with verbal prompt without AFO for entire walk back to classroom

Indicator 3: Lateral Weight Transfer

0 Unable to transfer weight laterally in standing in order to free NWB leg to step up

1 Lifts and places left/right* foot onto therapists leg with facilitation and support

2 Lifts and places left/right* foot onto therapists leg with support only

3 Steps up onto block with left/right* foot leading with facilitation and support

4 Steps up onto block with left/right* foot leading with support only

5 Steps up onto block with left/right* foot leading independently

*must be able to achieve with both left and right

Scoring for indicator 1:

0 Unable to achieve any

1 Able to achieve 1

2 Able to achieve 2

3 Able to achieve 3

4 Able to achieve 4

5 Able to achieve all

ADDENDUM 5

ALTERNATIVE PROBABILITY DISTRIBUTIONS FOR CALCULATION OF EXPECTED VALUES FOR CHI-SQUARED ANALYSIS

5.1 Effect of Treatment on Deficits

Probability distributions for numbers of indicators						
Code after	Code before					
	0	1	2	3	4	5
0	0.278	0.274	0.130			
1	0.351	0.340	0.241	0.111		
2	0.225	0.229	0.259	0.222		
3	0.106	0.128	0.222	0.333	0.333	
4	0.034	0.048	0.111	0.222	0.333	0.500
5	0.006	0.012	0.037	0.111	0.333	0.500
Total	1.000	1.004	1.000	0.999	0.999	1.000

Probability that a patient with a TELER score on three indicators at Assessment 1 has a TELER score on the same three indicators at Assessment 2 obtained by chance									
Assessment 1 TELER score	**Score per indicator**	**Assessment 2 TELER score**							**Total carried forward**
		0	1	2	3	4	5	6	7	
2	0, 0, 2	0.010	0.026	0.115	0.154	0.194	0.180	0.147	0.093	0.919
	0, 1, 1	0.008	0.068	0.136	0.185	0.192	0.180	0.112	0.069	0.950
3	0, 1, 2	0.008	0.040	0.092	0.148	0.182	0.180	0.147	0.105	0.902
4	1, 1, 2	0.016	0.036	0.086	0.140	0.177	0.173	0.151	0.107	0.886
7	2, 2, 3		0.002	0.011	0.033	0.073	0.121	0.158	0.175	0.573
8	2, 2, 4				0.006	0.026	0.068	0.123	0.170	0.393

Probability that a patient with a TELER score on three indicators at assessment 1 has a TELER score on the same three indicators at Assessment 2 obtained by chance									
Assessment 1 TELER score	**Score per indicator**	**Assessment 2 TELER score**								**Total**
		8	9	10	11	12	13	14	15	
2	0, 0, 2	0.051	0.023	0.007	0.002	0.000	0.000	0.000	0.000	1.002
	0, 1, 1	0.035	0.011	0.005	0.001	0.000	0.000	0.000	0.000	1.002
3	0, 1, 2	0.058	0.028	0.011	0.003	0.001	0.000	0.000	0.000	1.003
4	1, 1, 2	0.065	0.033	0.014	0.005	0.001	0.000	0.000	0.000	1.004
7	2, 2, 3	0.160	0.122	0.078	0.041	0.017	0.005	0.001	0.000	0.997
8	2, 2, 4	0.191	0.168	0.124	0.074	0.035	0.012	0.003	0.000	1.000

Probability that a patient with a TELER score on three indicators at Assessment 2 has a TELER score on the same three indicators at Assessment 3 obtained by chance										
Assessment 2 TELER score	**Score per indicator**	**Assessment 3 TELER score**								**Total carried forward**
		0	1	2	3	4	5	6	7	
2	0, 0, 1**	0.008	0.068	0.136	0.185	0.192	0.180	0.112	0.069	0.950
3	0, 1, 2	0.008	0.040	0.092	0.148	0.182	0.180	0.147	0.105	0.902
	1, 1, 1	0.015	0.062	0.127	0.178	0.191	0.159	0.123	0.076	0.931
4	0, 2, 2	0.005	0.027	0.061	0.111	0.156	0.175	0.166	0.131	0.832
	1, 1, 2	0.016	0.036	0.086	0.140	0.177	0.173	0.151	0.107	0.886
5	1, 2, 2	0.004	0.021	0.056	0.104	0.150	0.173	0.168	0.136	0.812
6	1, 2, 3		0.003	0.018	0.053	0.111	0.154	0.182	0.74	0.695
7	2, 2, 3		0.002	0.011	0.033	0.073	0.121	0.158	0.175	0.573

Probability that a patient with a TELER score on three indicators at assessment 2 has a TELER score on the same three indicators at Assessment 3 obtained by chance										
Assessment 2 TELER score	**Score per indicator**	**Assessment 3 TELER score**								**Total**
		8	9	10	11	12	13	14	15	
2	0, 0, 1**	0.035	0.011	0.005	0.001	0.000	0.000	0.000	0.000	1.002
3	0, 1, 2	0.058	0.028	0.011	0.003	0.001	0.000	0.000	0.000	1.003
	1, 1, 1	0.041	0.019	0.007	0.002	0.000	0.000	0.000	0.000	1.000
4	0, 2, 2	0.087	0.048	0.022	0.008	0.002	0.001	0.000	0.000	1.000
	1, 1, 2	0.065	0.033	0.014	0.005	0.001	0.000	0.000	0.000	1.004
5	1, 2, 2	0.094	0.054	0.027	****	0.002	0.001	0.000	0.000	1.001
6	1, 2, 3	0.14	0.086	0.049	0.022	0.004	0.002	0.000	0.000	0.999
7	2, 2, 3	0.160	0.122	0.078	0.041	0.017	0.005	0.001	0.000	0.997

ADDENDUM 6

INFORMED CONSENT DOCUMENT

THE EFFICACY OF THE NEURODEVELOPMENTAL THERAPY TREATMENT APPROACH IN 4-7 YEAR OLD CHILDREN WITH CEREBRAL PALSY

STATEMENT ON BEHALF OF CHILD

I, the undersigned, ... (ID no. .....) in my capacity as parent/guardian of ..... (ID no. .....) of (address).....

.....

A **Declare that:**

1. My child has been asked to take part in the above-mentioned research project being undertaken by a masters student in the Department of Physiotherapy at the University of Stellenbosch.

2. It has been explained to me that:

2.1 This study will evaluate the type of physiotherapy treatment that my child is receiving at school and how the therapy is benefiting him/her.

2.2 My child will be assessed by the researcher during one of his normal school physiotherapy sessions in the last week of the school term. He/she will then have a 5 week period (the duration of the June/July school holiday) receiving no physiotherapy. I will continue as usual with any home programme that I normally provide during this time. A second assessment will be carried out following this period and then my child will receive physiotherapy twice a week from his usual physiotherapist for a period of 5 weeks. At the end of the study a final assessment will be carried out. Any treatment goals set for my child following the assessments will be discussed with me by the researcher and/or my child's physiotherapist.

2.3 All treatments and assessments will be carried out during my child's normal school day.

3. I understand that the period of "no treatment" should have no negative effects on my child as this period will be during a normal school holiday and as I am to continue with any home programme that I would normally perform during this period. I also undertake not to seek physiotherapy treatment for my child from any other sources (eg a private physiotherapist) during this "no treatment" period.

4. I understand that any orthopaedic surgery and/or Botox injection required by my child will be delayed until the completion of the trial unless it is felt that such a delay will adversely affect my child.

5. I have been assured that all information obtained pertaining to my child during this study will be treated as confidential. The results of the study will be used in a masters thesis and may be published at a later stage in a physiotherapy/paediatric journal.

6. The results of the study and their implication will be discussed with me and I will be given the freedom to choose regarding the preferred methods of treatment for my child in the future.

7. I have been informed that I may refuse to allow my child to participate in this project (and also that my child may withdraw from the project at any stage) and that such refusal or withdrawal will not in any way affect my child's current or future physiotherapy treatment. I also understand that the researcher may withdraw my child from the project if this is in the interests of my child.

8. The information given above has been explained to me in English, of which I have good command and understanding, by .... and that I was given adequate opportunity to ask questions and that all my questions were answered satisfactorily.

9. There was no pressure placed on me to agree to my child's participation in this project and I understand that my child may be withdrawn at any time without any sort of penalty.

10. Participation in this project holds no extra costs/expenses for me or my child.

B I willingly agree to my child's participation in the aforementioned project.

Signed at ..... on .....19.....

....

Signature of parent/guardian Witness

STATEMENT BY/ON BEHALF OF RESEARCHER

I, ... declare that:

1. I have explained the information contained in this document to .....
   parent/guardian of .....

2. I have asked him/her to question any aspects of the document which are unclear.

3. This discussion took place in English and that no translator was required.

Signed at ..... on .....19.....

....

Researcher/Researchers representative Witness

FURTHER IMPORTANT INFORMATION

Thank you for agreeing to allow your child to participate in this study. If at anytime during the course of the study you are at all concerned about the well-being of your child or if there is anything that you wish to discuss relating to your child's participation in this study and/or your child's physiotherapy management, please do not hesitate to contact Mrs Louise FitzPatrick at 021-614106 after 7pm.

ADDENDUM 6

INLIGTINGS- EN TOESTEMMING DOKUMENT

DIE DOELTREFFENDHEID VAN DIE NEURO-ONTWIKKELINGSTERAPIE BEHANDELINGS BENADERING IN KINDERS VAN 4-7 JAAR MET SEREBRALE GESTREMDHEID

VERKLARING NAMENS DIE KIND

Ek, die ondergetekende, ... (ID nr. .....)

in my hoedanigheid as ouer/voog van..... (ID nr. .....)

van (adres) .....

.....

A **Bevestig dat:**

1. My kind gevra is om deel te neem aan bogemelde navorsingsprojek wat deur 'n meestersgraad-student van die Departement Fisioterapie van die Universiteit van Stellenbosch onderneem word.

2. Daar aan my verduidelik is dat:

2.1 Hierdie studie sal die tipe fisioterapie wat my kind by die skool ontvang, evalueer asook tot watter mate hy/sy daardeur bevoordeel word.

2.2 My kind sal deur die narvorser gedurende een van sy normale skool fisioterapie-sessies in die tweede laaste week van die skool kwartaal evalueer word. Hy sal dan vir 5 weke (die duur van die Junie/Julie-vakansie) geen fisioterapie ontvang nie. Ek sal gedurende die tyd voortgaan met enige tuisprogram wat ek normaalweg uitvoer. 'n Tweede evaluering sal dan gedoen word en my kind sal vervolgens vir twee maal 'n week fisioterapie van sy gewone fisioterapeut vir 5 weke ontvang. Aan die einde van die studie sal 'n finale evaluering gedoen word. Enige behandelings-doelwitte wat vir my kind gestel is, sal met my deur die navorser en/of my kind se fisioterapeut bespreek word.

2.3 Alle behandelings en evaluerings sal gedurende my kind se normale skooldag gedoen word.

3. Ek verstaan dat die tydperk van "geen behandeling" hoef geen negatiewe effek op my kind te hê nie, omdat die tydperk gedurende 'n skoolvakansie is en omdat ek met die normale tuisprogram sal voortgaan. Ek onderneem verder om geen ander fisioterapie-behandeling vir my kind van ander bronne (bv 'n privaat fisioterapeut) gedurende hierdie "geen behandelings" tydperk te bekom nie.

4. Ek verstaan dat enige ortopediese chirugie en/of Botox inspuiting wat my kind nodig het sal uitgestel word totdat die studie verby is, tensy dit blyk dat so 'n uitstel my kind negatief sal beïnvloed.

5. Ek meegedeel is dat die inligting wat ingewin word as vertroulik behandel sal word. Ek is wel bewus daarvan dat die resultate van die studie gebruik sal word vir 'n meestersgraad-tesis en gevolglik gepubliseer mag word in 'n fisioterapie of pediatriese joernaal.

6. Die resultate van die studie en die implikasies daarvan met my bespreek sal word. Ek sal verder die reg behaal om die geskikte metode van behandeling vir my kind se toekoms te kies.

7. Ek meegedeel is dat ek mag weier om my kind te laat deelneem aan hierdie projek (asook dat my kind te enige tyd deelneme daaraan mag staak), en dat sodanige weiering of staking nie op enige manier my kind se huidige of toekomstige behandeling by hierdie inrigting sal benadeel nie. Ek verstaan ook dat die navorser my kind van die projek mag onttrek indien dit in my kind se belang geag word.

8. Die inligting wat hierbo weergegee is, deur ..... aan my in Afrikaans verduidelik is, dat ek die taal goed matig is, dat ek geleentheid gegee is om vrae te vra, en dat al my vrae bevredigend beantwoord is.

9. Daar geen verpligting op my geplaas is om toestemming te verleen om my kind te laat deelneem aan hierdie projek nie, en dat ek besef dat my kind se deelname ten enige tyd gestaak mag word sonder enige benadeling.

10. Deelname aan die projek geen addisionele koste vir my of my kind inhou nie.

B Ek stem hiermee vrywillig in dat my kind mag deelneem aan die bogemelde projek.

Geteken te ..... op ..... 19.....

....

Handtekening van ouer/voog Getuie

VERKLARING DEUR OF NAMENS NAVORSER

Ek, ... verklaar dat:

1. Ek die inligting van hierdie dokument aan..... ouer/voog van .....verduidelik het.

2. Ek hom/haar versoek het om vrae aan my te stel indien daar enigiets onduidelik was.

3 Hierdie gesprek in Afrikaans plaasgevind het en dat geen tolk gebruik is nie.

Geteken te.....op .....19.....

....

Navorser/Navorser se teenwoordiger Getuie

VERDERE BELANGRIKE INLIGTING

Baie dankie vir u kind se deelname aan hierdie studie. Indien daar ten enige tyd, tydens die duur van die projek kommer by u ontstaan oor die welstand van u kind, of indien daar enigiets is wat u wil bespreek aangaande u kind se deelname in hierdie studie en/of u kind se fisioterapie behandeling, moet u nie huiwer om Mev. Louise FitzPatrick te kontak by 021-614106 na 7pm nie.