

The Scotson technique (Advance, 2005c)

**An exploratory study to establish a theoretical base for the technique
and investigate any potential effects.**

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2005

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Abstract

This exploratory study of the Scotson technique aims to establish an evidence supported theoretical base and to explore any potential effects that could possibly be attributed to the technique.

It was done using the Medical Research Council's "Framework for Development and Evaluation of RCTs for Complex Interventions to Improve Health (MRC, 2000). The pre-clinical phase and phases I and II formed the method. Children attending Advance between November 2002 and September 2004 were recruited into the study.

A potential theoretical base was put forward with links to already established therapeutic treatments. Results show that physical changes occurred in the study population in the areas investigated and that the children continued to develop along expected lines.

In conclusion changes occurred within a population of neurologically damaged children which could not solely be explained by maturation. In order to make a more conclusive statement further research of a comparative nature is suggested.

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1 Background

1.1 Introduction

In 1978, Linda Scotson gave birth to her son, Doran, whose diagnosis of cerebral palsy led her into an investigation into the recovery of children with neurological damage. She developed the charity Advance and subsequently the Scotson technique (Advance, 2005b). Linda felt that evidence that the brain had potential for recovery was not borne out by the long-term results of existing therapies and an idea grew that there was another reason for this lack of progress. Through observation Linda noticed that the majority of children with neurological damage had breathing difficulties and this led to an exploration of an alternative treatment approach. Linda was encouraged in this exploration by Professor Patrick Wall, head of cerebral studies, at University College London. Encouraged to sit the qualifying exams Linda began her PhD. Professor Wall introduced her to the ideas of plasticity and encouraged the use of the term 'restorative' in the approach that was developed. Linda Scotson saw the restoration of a more normal pattern of breathing in neurologically damaged children as a basis for improvement. The hypothesis is that the Scotson technique brings about physical change in children with neurological damage.

The University of Bradford was approached in 2000 to explore some of the Advance's claims and in 2002 a project was commenced. This was an exploratory study following the methods laid down by the Medical Research Council's framework for complex interventions (MRC, 2000). The aims of the study were to contextualise the charity, Advance, develop a theoretical basis for the technique using some of the work from Linda's ongoing research and investigate some of the claimed effects. The results are discussed with a view to making recommendations for further research.

1.1.1 Context of project

Advance is a charity providing a specific therapy; the Scotson technique for children with neurological damage. The therapy is not funded or provided by the National Health Service (NHS). Children and families receiving the therapy pay through private means. The reasons for this situation are that Advance is not a part of the NHS and is seen by many as a complementary or alternative therapy/medicine (CAM).

The question as to what constitutes a complementary or alternative therapy is a difficult one to answer. Professor Edzard Ernst et al (1995, p. 506) state "*complementary medicine is diagnosis, treatment and/or prevention which complements mainstream medicine by contributing to a common whole, by satisfying a demand not met by orthodoxy or by diversifying the conceptual framework of medicine*". It is a treatment considered to be outside conventional medicine or as the Cochrane Collaboration stated in the House

of Lords (2000) select committee report on science and technology a treatment outside “*the politically dominant health systems of a particular society or culture in a given historical period*” (House of Lords, 2000, point 1.12) The problem for Advance is that although alternative and complementary therapies are increasing in popularity (20% of people in the UK have tried CAM) (Ernst et al 2003, House of Lords, 2000); it still tends to be viewed with caution by the funding bodies and not generally seen as a credible treatment. However it must be noted that some CAM’s are available on the NHS and 39% of general practices provide access to CAM for NHS patients (Zollman and Vickers, 1999). In 2004 the Welsh secretary, Peter Hain, floated the idea of CAM being more widely available through the NHS with Tony Blair’s support (Murcott, 2005). Advance felt that if potential clients and healthcare professionals could see that they were taking steps to evaluate the effects of the Scotson technique then it could potentially be seen as a treatment worthy of funding. The House of Lords select committee on science and technology (2000) pointed out that users of CAM are often unconcerned about the limited scientific base or evidence of efficacy to support a therapy. The report states as long as “*the patients are aware of the lack and are not led to believe that the treatment will definitely work*” (House of Lords, 2000, point 4.8) this is acceptable. However the lack of evidence within CAM is not satisfactory. There is recognition by all involved in healthcare that many illnesses, diseases and injuries are self-limiting and in some cases there are unexplained spontaneous remissions (Ernst, 2003).

Spontaneous recovery after injury has been a part of life for centuries. A basic tenet of Hippocratic medicine is that any unexpected recovery is due to the healing power of nature. *“The rise of alternative medicine, which is striving in some cases for a more or less equal footing with conventional medicine, is another testimonial to the power of this position”* (Benton and Tranel, 2000, p.3). Moreover improvement among children may occur naturally during development, even when there is considerable impairment (Rosenbaum, 2003b, Rosenbaum and Stewart, 2003b, Rosenbaum and Stewart, 2003a). Improvements do occur but these can not be universally hailed as evidence of efficacy as anecdotal evidence of this nature is circumstantial and unsafe. There is a need for evaluation and then trials to establish cause and effect (Ernst, et al, 1995, Vickers, 1995, House of Lords,2000b). Advance support this last statement and the study at the Division of Rehabilitation at the University of Bradford was a start, with an understanding that more trials will be required in the future. Advance does not accept the argument put forward by some practitioners of CAM that their approach is so different from conventional medicine that the established methods of research are inappropriate (personal communication 6, February) (Scotson, 2004a)

Modern medicine is becoming more complex and expensive with many healthcare professionals experiencing time constraints due to government initiatives and this could go some way to explaining the reason for the rise in people using CAM (House of Lords, 2000). Time in the past was an added

therapeutic weapon that is becoming less available in the NHS. The government has started the process of exploring the rise in CAM use. The House of Lords select committee on science and technology (sixth report) was set up in 1999 to look at CAM and its increasing popularity and use. (House of Lords, 2000).

The first task of this committee was to tackle the definition of CAM, which was felt to be both confusing and misleading. The committee suggested that *“the complementary disciplines are those that usually, if not invariably, compliment conventional medical treatment, while the alternative disciplines are those that purport to offer diagnostic and therapeutic alternatives to conventional medicine”* (House of Lords, 2000, 1.13). This definition is pertinent to Advance and the Scotson technique. It was suggested that at the beginning of the exploratory study they were an alternative therapy as they offered a therapeutic alternative and an alternative to the conventional stated outcomes for children with neurological damage. By commissioning the evaluation, Advance is showing its commitment to wanting to move away from this label towards the more politically accepted label of a complementary therapy. It is important for Advance to be seen in this way as it could lead to the Scotson technique being part of the prescribed management package for children with neurological damage.

The House of Lords select committee (2000) categorised complementary and alternative medicine into three groups: -

1. The principle disciplines, the big five: -

- a. Osteopathy
- b. Chiropractic
- c. Acupuncture
- d. Herbal medicine
- e. Homeopathy

Osteopathy and chiropractic are already regulated professionally and educationally by Acts of Parliament. This group has a limited but established evidence base.

2. The disciplines which are most often used to complement conventional medicine and do not claim to have diagnostic skills. This group includes yoga and aromatherapy, for example, and has a limited evidence base often citing a placebo effect as the main research finding.
3. The disciplines which offer alternative diagnostic information as well as treatment. They tend to have a philosophical approach and are indifferent to the scientific principles of conventional medicine. The evidence base is largely anecdotal and perpetuated by an oral tradition. Split into a) long-established and traditional systems of healthcare such as ayurvedic medicine, traditional Chinese medicine and b) other alternatives such as crystal therapy and dowsing.

It was acknowledged by Advance that the Scotson technique was based on a particular belief system but knew this must change, in response to any positive or negative evidence. Also change was needed in its clinical and

educational approach in response to any new information. Advance needed to be seen to be moving away from a group three to the more acceptable label of a complementary therapy that is found in the group two disciplines. This would hopefully improve their chances of being accepted as a credible element of the 'conventional' therapeutic treatment for children with neurological damage. Advance could then possibly be seen as an appropriate body for government funding. Advance understand that evidence of safety of the Scotson technique is paramount but that evidence of efficacy will be important in the future as governments will be more likely to use public funding for an effective treatment than for one that is just considered safe.

Advance has acknowledged its status as a therapy outside conventional medicine. Its lack of evidence base put it at a disadvantage in its goal to be accepted as a credible therapy within the package provided for children with neurological damage through public funding. This study began the process of evaluation that was essential groundwork for carrying out a robust trial into the efficacy of the Scotson technique. An evidence based theory is proposed that has links with already accepted therapies within conventional medicine.

2 Theory.

2.1 Development of a theoretical base for the Scotson technique.

2.1.1 Existing theory.

The existing philosophy behind the Scotson technique is complex. Its main premise is that children with neurological damage have a compromised respiratory system. Advance proposes that this compromised system means that the children cannot respond efficiently to the dual demands of metabolic need and postural stability. Metabolic needs including oxygen demand for reorganisation within the central nervous system, through the mechanisms of plasticity. The respiratory system has a secondary role in supporting posture by providing trunk stability to allow functional movement of the limbs.

Advance states that the Scotson technique begins with three basic assumptions:-

1. *“The crippling motor problems that increase as the children develop are not only because of the brain injury but also because of other changes occurring in the muscular skeletal system especially the respiratory system including the diaphragm”* (Scotson, 2005a).
2. *“The pressure changes in the thorax and abdomen created by the movement of the diaphragm have a profound effect on muscular skeletal and neurological development and maintenance”* (Scotson, 2005a)
3. *“The brain’s outgoing signals are in fact entirely limited by the degree of electrical activity present in the body”* (Scotson, 2005a).

Advance see a new picture emerging with “ *the diaphragm as a key organ on which the development and maintenance of the body’s physical structure and both general and cerebral metabolic function depends*” (Scotson, 2005a).

2.1.2 Revised theory.

This was the situation regarding the theory behind the Scotson technique when the project started in 2002. These were abstract ideas with little documented evidence base that needed a more scientific foundation. The assumptions were then altered to form three new statements that could be investigated through systematic searches of existing literature and thereby formulate a possible theory as to how the Scotson technique could potentially work. The three statements are:

1. The diaphragm in a child with neurological damage is potentially compromised and may not have developed in the expected way. This could be due to neuromuscular insufficiency and the biomechanical constraints of a poorly developed musculoskeletal system that has often not worked against gravity. This could mean that the diaphragm potentially can not fulfil its dual roles of respiration and postural stabilisation.
2. The diaphragm is the central generator of the respiratory system. If it is not functioning properly then it cannot fulfil its respiratory role adequately.

Therefore its dual role is compromised; as respiration must always take

priority then the functional stability of the neurological child is disadvantaged. The premise of the Scotson technique is that increased diaphragmatic function potentially could improve a number of aspects for these children.

3. That by providing a respiratory type pressure through the Scotson technique that these pressures could possibly contribute to improving blood supply to the trunkal area which could potentially improve the function and activity of the diaphragm and other respiratory muscles. It is proposed that these rhythmical pressures could have local and central influence.

2.2 Diaphragm.

The central theme of the theory is the role of the diaphragm within the respiratory system of infants. The biomechanics of the infants rib cage leads to a reliance on the diaphragm (Prasad, 1995, Devlieger, et al, 1991, Dimitriou, et al, 2003, Muller and Bryan, 1979, Heldt and McIlroy, 1987(a), Heldt and McIlroy, 1987(b)). In addition to its function as the main respiratory muscle for infants the diaphragm has the ability to stabilise the trunk and spinal column during limb movements and sitting (Daggfeldt and Thorstensson, 1997, Dickinson, et al, 2004, Hodges and Gandevia, 2000a, Hodges and Gandevia, 2000b, Hodges, et al, 2001, McGill, et al, 2003, Mori,

et al, 2001, Sinderby, et al, 1992, Hussain, 1996). Although the majority of this work has been done with a healthy adult population it should be appropriate to extrapolate the information to apply to children. Gaining trunk stability before functional limb movement is a core aim of management of children with neurological damage usually achieved via orthotics or seating systems but also through targeted training of the trunk (Butler, 1998, Butler and Major, 1992, Butler, et al, 1991, De Groot, et al, 1995, Hadders-Algra, et al, 1998). Strengthening of the trunk muscles also has a history within the musculoskeletal discipline of physiotherapy where a strong core of abdominal and spinal muscle is seen as contributing to improved function (Hodges and Richardson, 1996, Hodges, et al, 2001, Mottram and Comerford, 1998, O'Sullivan, et al, 1997, Panjabi, 1992)

It is widely accepted that the chest geometry and as a consequence the diaphragm of a child & an adult are different. As a child matures its chest geometry changes making respiration more efficient (Openshaw, et al, 1984, De Groote, et al, 2000, Dimitriou, et al, 2003, Scammon, 1927). It is proposed by Advance that the neurologically damaged child retains some immaturity in its developing respiratory system leading to biomechanical and metabolic disadvantages for that child (personal communication, 11 January) (Scotson, 2005d)

2.2.1 Development of the respiratory system

The differences between the child and the adult's respiratory system and chest geometry are many. Infant ribs are horizontally positioned which leads

to an absence of the biomechanical 'bucket handle' movement that increases the antero-posterior diameter of the ribs. It also means that the diaphragm's angle of insertion into the ribs is almost horizontal rather than the more efficient domed shape (Alexander, et al, 1993, Marcus, 2001, Openshaw, et al, 1984, Prasad, 1995, Muller and Bryan, 1979). The rib cage is very compliant due to the high cartilaginous content of the ribs; this allows compression during birth but then places it at a mechanical disadvantage (Marcus, 2001, Heldt and McIlroy, 1987(b), Heldt and McIlroy, 1987(a)). This mechanical disadvantage leads to a phenomena known as paradoxical breathing, where part or all of the chest wall moves inwards on inspiration and outwards on expiration (Middleton and Middleton, 2002). Although the chest wall may be initially compliant, persistent weakness leads to the lungs becoming stiff. This is possibly due to microatelectasis and the respiratory muscles becoming increasingly 'stiff' due to cross bridge formation and increased collagen (Booth, et al, 2001, De Deyne, 2001, Friden and Lieber, 2003). A 'stiff' chest will lead to decreased oxygen supply, decreased maximal muscle tension development and an inefficiency of the respiratory muscles which can lead to fatigue and poor development (Guslits, et al, 1987, Laghi and Tobin, 2003, Mier, 1991). In addition many children with neurological damage have spinal deformities which place them at further mechanical disadvantages. The children can become more dependent on intercostal and accessory muscles that become hypotonic during rapid eye

movement (REM) sleep leading to increased diaphragmatic activity and consequent fatigue (Marcus, 2001, Laghi and Tobin, 2003).

Weakness of the intercostals means that the stability of the rib cage during inspiration is decreased and therefore a large proportion of diaphragmatic activity is expended distorting the rib cage inwards; paradoxical breathing. When this occurs, to maintain an adequate tidal volume the diaphragm has to shorten more leading to a decrease in the maximal force it can exert. (Heldt and McIlroy, 1987(a), Heldt and McIlroy, 1987(b)). This distortion of the rib cage increases the work of an already inefficient diaphragm and increased energy expenditure which can lead to hyperinflation problems. Hyperinflation can lead to an increase in pH which can have a detrimental effect on muscle activity as an imbalance of electrolytes alters impulse transmission. All children have a higher resting metabolic rate than adults and with chest distortion diaphragmatic work may reach 10% of their metabolic rate which can contribute to fatigue and a failure to thrive (Guslits, et al, 1987, McCool, et al, 1989, Dimitriou, et al, 2003). The high metabolic cost of breathing in this way is borne by the diaphragm which fatigues easily, often in these circumstances apnoea or breath holding is used to rest the diaphragm (Dimitriou, et al, 2003, Guslits, et al, 1987, Heldt and McIlroy, 1987(a), Muller and Bryan, 1979).

The adult shape develops as the infant becomes more upright against gravity; the effect of gravity is to pull the anterior ribs down. This changes the chest cavity from the infantile circle, with its limited capacity for further

expansion, to a mature ovoid (Dimitriou, et al, 2003, Howatt and DeMuth, 1962, Openshaw, et al, 1984, Scammon, 1927, Marcus, 2001).

2.2.2 Development of the diaphragm

The diaphragm of an adult consists of approximately 50% fatigue resistant type I fibres whereas the neonate has only 25% and the preterm infant as little as between 10-20% making it histochemically more prone to fatigue and overloading (Mier, 1991, Muller and Bryan, 1979, Dimitriou, et al, 2003). Coupled with this many preterm and low birth weight infants need ventilatory support immediately after birth and prolonged mechanical ventilation can cause an impaired respiratory function through disuse atrophy (Dimitriou, et al, 2003).

The diaphragm goes through many changes in the post natal period; changing its shape from flat to domed, increasing its thickness and improving the apposition between it and the chest wall (Dimitriou, et al, 2003, Al-Bilbeisi and McCool, 2000, McCool, et al, 1997, Rehan, et al, 2001). It could be assumed, and is by Advance, that the normal developmental changes are enhanced by respiratory demand, the effects of gravity and functional biomechanical stresses. If these do not occur the diaphragm may not develop correctly. Advance proposes that the diaphragm of a neurologically damaged child would retain some of the features of an immature diaphragm or may return to an immature state due to disuse atrophy. The diaphragm is a skeletal muscle and needs to work in its correct capacity to develop the appropriate ratio of muscle fibre types (Dimitriou, et

al, 2003). The mass of the diaphragm will also determine strength and endurance. The mass of the diaphragm, it is suggested, is related to weight and height of children and adults but as with most muscles within the human body there is much variation from person to person (Rehan, et al, 2001, Rehan, et al, 2000, McCool, et al, 1997). It is generally agreed that the size of the diaphragm affects inspiratory strength and that its cross-sectional size can be increased by general and specific exercises (McCool, et al, 1997, Pryor, et al, 2001, Darnley, et al, 1999, Rehan, et al, 2001, Rehan, et al, 2000). If a child has had prolonged ventilatory support, intrauterine growth problems or neurological damage this will affect the growth of the diaphragm. The thickness of the diaphragm enables it to function properly across its diameter and throughout its range of motion (Rehan, et al, 2001, Rehan, et al, 2000, Wait and Johnson, 1997, McCool, et al, 1997, Dimitriou, et al, 2003, Aliverti, et al, 1997). Increasing the thickness will increase the cross-sectional diameter of the diaphragm and this will in turn decrease diaphragmatic wall tension which improves vascularisation of the area. Advance supposes that if the respiratory system is not functioning properly due to a poorly developed diaphragm. Then such a diaphragm will have decreased thickness and vascularisation will be poor. Also if transdiaphragmatic pressure is increased due to lung stiffness or altered chest wall biomechanics this could lead to increased intramuscular pressure, capillary collapse, impeded blood flow and eventually impaired muscle function. Various authors support this view (Aliverti, et al, 1997, Coirault, et

al, 1999, Rehan, et al, 2001, Rehan, et al, 2000, Wait and Johnson, 1997, Massery, 2005). Advance then reason that, a technique that improves blood flow to the abdominal and thoracic area could potentially improve the situation (personal communication, 6, February) (Scotson, 2004a)

The various problems associated with an altered diaphragmatic shape, (length and thickness) and the altered 'tone' within the skeletal muscles of children with neurological damage means that often the diaphragm is unable to relax properly. This inability to relax means that between contractions the diaphragm is unable to return to its optimal resting length so it can generate the functional capacity it needs for efficient respiration. Also the relaxation phase allows blood to perfuse the diaphragm as intramuscular pressures reduce. Skeletal muscle is dependent on an adequate blood flow to maintain an energy supply and remove toxins (Coirault, et al, 1999, Massery, 2005).

The ventilatory muscles and especially the diaphragm require high energy phosphate compounds to drive the biochemical and physical processes of contraction and relaxation. An adequate blood flow ensures this process (Coirault, 1999, Chaitow, 2002). Blood flow also influences muscle function through the removal of waste products which, if present would have a negative effect on the contractile processes. Skeletal muscle extracts its nutrients from arterial blood by increasing the number of perfused capillaries. It is essential to match perfusion to metabolic demands so that normal diaphragmatic contractile function is maintained. The diaphragm is well supplied with capillary anastomoses and is relatively resistant to ischemia.

Metabolic demands are the most important determinant of ventilatory blood flow and therefore increased activity will increase blood flow in the diaphragm (Coirault, et al, 1999, Hussain, 1996, Rochester, 2001). The diaphragm is a skeletal muscle so blood flow can be decreased by mechanical compression of the blood vessels through muscle contraction, this is particularly important in children with neurological damage; their muscles are often in a state of 'stiffness'; not fully contracted and not fully relaxed. It could be supposed in these cases that blood flow could be impeded. Many of the children also have hyperinflation problems and this causes strong positive pleural and abdominal pressure swings that increase diaphragmatic vascular tone leading to decreased perfusion.

The diaphragm is working at a biochemical and mechanical disadvantage which could theoretically lead to fatigue and respiratory insufficiency which is often masked by the child's reduced ability to exceed their ventilatory capacity (Laghi and Tobin, 2003). This sets up a vicious cycle that the neurologically damaged child often cannot break.

2.2.3 Diaphragm as a postural muscle

In addition to its respiratory function the diaphragm acts as a trunk stabiliser contributing to trunk stability during limb movement through its influence on the thoracic and abdominal cavities. The research in this area has been undertaken by a small group of authors, using normal subjects but the results have been consistent over a number of years and seems to have been accepted by others (Hodges and Gandevia, 2000b, Hodges, et al,

2001, Al-Bilbeisi and McCool, 2000, Hodges, et al, 1997, Hodges and Gandevia, 2000a, Hodges, et al, 2001, McGill, et al, 2003, Mori, et al, 2001, Sinderby, et al, 1992, Zedka and Prochazka, 1997, Massery, 2005).

The diaphragm's contribution to postural stability is not fully understood. The contraction of the diaphragm, increases intra-abdominal pressure and may contribute to a lessening of axially directed compressive forces acting on the spine (Al-Bilbeisi and McCool, 2000, Daggfeldt and Thorstensson, 1997). Or the increase in intra-abdominal pressure could maintain the hoop-like geometry of the abdominal muscles (Hodges, et al, 1997). Contraction of the diaphragm decreases intra-thoracic pressure which decrease the stiffness of the thorax this could potentially increase its ability to respond to postural perturbations and respond accordingly (Al-Bilbeisi and McCool, 2000). Massery (2005) uses the illustration of a carbonated drink can to explain the relationship between respiration and posture. The tin (skeleton) is thin and inherently weak but when there are no openings it is functionally strong. The strength is not from the tin (skeleton) but from the internal pressures generated by muscles. The trunk comprises of two chambers that are separated by the diaphragm and each chamber is capable of creating individual pressures. These chamber pressures are maintained by the surrounding trunkal musculature especially the diaphragm. *'The trunk muscles act as one continuous functional unit, providing the core support for pressure regulation that allows the individual to multi-task'* (Massery, 2005). If the tin's shell is weakened and the internal pressure is not maintained then

the tin can collapse due to the external pressure. A weak diaphragm and respiratory muscles unable to generate enough internal pressure to counteract the external pressure of gravity could result in a 'collapse' of some of the musculoskeletal structures in the trunk and spinal area (Shirley, et al, 2003). Advance feels that this 'collapsing' is a major problem for many of the children attending the centre. The weakness may not just be due to neurological dysfunction but also to the fact that these muscles are being used uniquely to support multiple body systems. The dual demands of postural stability and ventilation could potentially put enormous strain on an already struggling musculoskeletal system leading to fatigue and weakness. The dual roles of the diaphragm are proposed to be co-ordinated by the central nervous system through rapidly conducting oligosynaptic pathways from the motor cortex, where it has its own representation (Gandevia and Rothwell, 1987, Corfield, et al, 1998). It is also thought to be mediated separately by areas in the brain stem (Corfield, et al, 1998, McKay, et al, 2002, Mori, et al, 2001, Rekling and Feldman, 1998a). Also due to the many attachments of the diaphragm, that there may be a number of further influences at spinal and interneuron level (De Troyer, 1997a, Zedka and Prochazka, 1997, Rimmer, et al, 1995, De Troyer, et al, 1997).

The rhythmical action of the diaphragm is thought to be initiated from the brain stem where it is integrated with other, non-respiratory, activities (Hodges, et al, 2001, McKay, et al, 2002, Mori, et al, 2001). Respiration is interrupted briefly during expulsive actions such as coughing and during

other activities such as lifting (Al-Bilbeisi and McCool, 2000, De Troyer, et al, 1997, Hodges, et al, 2001) but other sustained postural tasks must integrate with respiratory function. Initially it was thought that during such activities the final output to the diaphragm was a summation at the phrenic motor neurone of the two opposing demands but it is more likely that whatever the circumstances, respiratory needs are the overriding drive (Hodges, et al, 2001). Other muscles may then take over the activity of spinal stabilisation. Zedka and Prochazka (1997) showed that the activity of erector spinae increased during hand movement and Hodges et al (2001b) showed an increase in the activity of the scalene and parasternal muscles. De Troyer et al (1987) found that triangularis sterni, a muscle with neuronal connections to the abdominals could be recruited into non-respiratory muscular activity as could rectus abdominus and the external obliques (Hodges, et al, 1997, Hodges, et al, 1997, De Troyer, 1997a). Advance supposes from this that if the respiratory drive always takes precedence then in neurologically damaged children the compromised diaphragm has a decreased ability to fulfil its postural role. This may mean that other trunk muscles, such as erector spinae, take on that role. Shirley et al (2003) showed that spinal stiffness, which contributes to postural stability, changes throughout the respiratory cycle and could be affected by poor internal pressure. Over activity of the trunk extensors is often seen in such children and this can interfere with trunk rotation and limb activity in sitting and standing (De Groot, et al, 1995, Dickinson, et al, 2004, Hadders-Algra, et al, 1998). When

pain is present in the trunk area then trunk muscle recruitment for stability and limb movement is altered (McGill, et al, 2003, Hodges and Richardson, 1999, Comerford and Mottram, 2001). Advance would argue that many of the children attending the centre have pain. A reduction in postural activity by the diaphragm decreases the quality of trunk stability resulting in 'stiffness' often in a collapsed state rather than stability with movement (Comerford and Mottram, 2001, De Groot, et al, 1995, Hodges and Richardson, 1999). This can lead to decreased postural control, pain and maybe further damage to the musculoskeletal system.

Advance suggests that in the majority of children attending the centre the diaphragm is compromised and can not fulfil the dual functions of respiration and postural stability. The diaphragm works both tonically and phasically to accommodate its split function (Hodges, et al, 1997, Hodges and Gandevia, 2000a, Hodges, et al, 2001, Hodges and Gandevia, 2000b, Hodges, et al, 1997, Hodges, et al, 2001, Al-Bilbeisi and McCool, 2000, Gandevia, et al, 2002). This takes a high level of neuromuscular control which could be assumed to be compromised in a large number of children with neurological damage. The diaphragm's muscular make-up develops in response to functional demands. If it is not used correctly perhaps due to the biomechanical constraints of the musculoskeletal system, neuromuscular insufficiency, and the inability to synchronise the competing respiratory and postural demands then it is suggested by Advance that the diaphragm of a neurological damaged child remains physiologically disadvantaged for

longer. Children with such damage also have a higher resting metabolic rate thereby needing an increase in oxygen with a respiratory system that cannot fulfil this need. Advance suggests there must be some metabolic trade off and this may mean there is less oxygen for neuroplastic changes which could lead to potential improvement. Advance feels that the present approach of management pushes some children beyond their respiratory capabilities and certainly beyond the capabilities of a restricted respiratory system. The Scotson technique focuses on the muscles around the trunk especially the ones around the attachment of the diaphragm and hopes to influence the diaphragm through the application of gentle pressure.

Advance suggests that the weakness of the diaphragm is exhibited by the children attending the centre by the biomechanical make-up of the thoracic cage. The development of certain breathing patterns such as the predominance of upper chest breathing to supplement the diaphragm, the use of apnoea/breath holding to rest the fatigued diaphragm and the poor sitting balance indicate to Advance an evidence of diaphragmatic immaturity. Advance feels that the children would appear to get 'trapped' into a dysfunctional cycle of breathing, in order to maintain homeostasis. Respiration is always the main drive and therefore the postural fine tuning afforded by a normal functioning diaphragm is not available for the children to access. This primary respiratory need could potentially leave the trunk muscles, which have both a respiratory and postural function, with inadequate power to maintain the internal pressures needed to meet the

demands of any postural activity. The tendency could be then to recruit accessory muscles for ventilation rather than the diaphragm contributing further to the abnormal musculoskeletal picture due to overuse (Massery, 2005).

There is evidence that the diaphragm has a dual role and that role could be compromised by biomechanical abnormalities and cortical dysfunction which many of the children at Advance exhibit. It is proposed by Advance that the mechanisms that the Scotson technique may be accessing are both central and local.

2.3 Central mechanisms.

2.3.1 Reticulo-spinal system.

The reticulospinal tract originates from the medullary and pontine reticular formation. The reticular formation is a complex matrix of neurones found throughout the brain stem. It is a relatively old part of the brain stem and its neurones fulfil a number of functions necessary for survival. The reticulospinal tract predominately has an influence on muscle tone and posture (Crossman and Neary, 2000, Nathan, et al, 1996).

The utilisation of breathing enhancement through the Scotson technique may be seen as an opportunity to influence the motor system through the

reticulospinal network via the duality of some of the respiratory muscles especially the diaphragm. A number of authors have identified a fast conducting cortico-spinal efferent to the abdominals (Mori, et al, 2001, Hadders-Algra, et al, 1998, McKay, et al, 2002), while others are more specific relating this input to the diaphragm (Gandevia and Rothwell, 1987). Besides this very separate neural control of the diaphragm from the motor cortex there has also been some work done that shows excitation of the diaphragm via the brain stem and particularly the reticular formation during quiet breathing (Lanini, et al, 2003, McKay, et al, 2002, Mori, et al, 1987, Gandevia and Rothwell, 1987)). It is thought that cortical influences are activated during the voluntary alteration of breathing. The reticulo-spinal system has been shown to have an adaptive role in rhythmical activities such as locomotion and breathing (Brocard and Dubuc, 2003.). Breathing's reflex motor output requires no conscious input but can be modulated behaviourally during speech, holding the breath and the playing of a wind instrument. This modulation is thought to be carried out by the cortex and the respiratory centres of the brain stem, the modulation by the reticulo-spinal system maybe in response to sensory input. Passive movements can increase ventilation through peripheral proprioceptive activity (De Troyer, 1997a, McKay, et al, 2002). It has also been suggested that position can affect the brain stem through the vestibular system (Mori, et al, 2001). Certainly other proprioceptive mechanisms could come into play in terms of specific positions and manoeuvres in the trunkal area. The suggestion is

that this could be another mechanism whereby the Scotson technique accesses the central nervous system through specific positioning and handling of the children.

2.3.2 Central pattern generators.

A central pattern generator (CPG) is said to be a neural circuit that produces a self-sustaining pattern of behaviour that needs neither sensory nor central input (Bate, 1999, Fenelon, et al, 1998, Hooper, 2000, Marder and Bucher, 2001.). The presence of CPG's within the animal population is accepted and the idea of CPG's within humans is gaining credence especially in terms of locomotion and respiration. CPG's are often seen as a new idea but were in fact suggested by Brown (1911) but forgotten as reflex activation of locomotion gained favour (Brown, 1911, Forssberg, 1985, Forssberg, 1999, Marder and Bucher, 2001.) It is thought that rhythmical CPG's are essential for respiration and locomotion. Respiratory networks have been noted in early foetal development, showing extended periods of spontaneous rhythmical patterned activity (Fenelon, et al, 1998, Gramsbergen, 2001, Hooper, 2000). Rhythmical motor patterns such as breathing and locomotion are complex yet stereotypical and repetitive. They are thought to be initiated at spinal level but modulated by via higher centres and external factors such as behaviour (Bate, 1999, Bizzi, et al, 2000, Fenelon, et al, 1998). Criticism of the idea of central pattern generators usually takes the form, that being stereotypical and repetitive they cannot be sensitive to

external influences (Thelen, et al, 1987, Thelen and Spencer, 1998). This criticism ignores the complex nature of the rhythmical patterns as both human and animal work has shown that CPG's are malleable and have inherent plasticity (Bizzi, et al, 2000, Taylor and Lukowiak, 2000, Bate, 1999, Fenelon, et al, 1998, Forssberg, 1985, Forssberg, 1999, Guadagnoli, et al, 2000). Within the work on CPG's for human locomotion there has long been the concept that the activity is controlled supraspinally and that this control is adaptable (Forssberg, 1985, Forssberg, 1999). That the system is potentially plastic can be best seen in the maturity of gait from infant stepping to adult plantigrade walking (Forssberg, 1985, Forssberg, 1999, Guadagnoli, et al, 2000). The initial circuitry may be simplistic, anencephalic infants can perform infant stepping, but motor behaviour increases in complexity as connectivity is established and increased. This maturity may also be due to the release of neuromodulators both centrally and peripherally helping to shape the CPG (Bate, 1999, Fenelon, et al, 1998, Forssberg, 1985, Forssberg, 1999, Hadders-Algra, et al, 1996, Hadders-Algra, et al, 1997, Pflugger, 1999, Rekling and Feldman, 1998b, Smith, et al, 2000). It has been suggested that the site for the respiratory CPG's is the brain stem, the reticulospinal formation. More particularly the medial medullary reticular formation (MRF) (Mori, 2001b) or rostral ventrolateral medulla, specifically the prebötzing complex (Rekling and Feldman, 1998b, Smith, et al, 2000) The MRF has projections via the reticulospinal system to the diaphragm and abdominal muscles and receives sensory information from various sensory

organs and also input from the cerebral cortex. The vestibular system responds to changes in posture via the labyrinthine receptors and its input into the MRF may contribute to adjusting diaphragmatic activity during movement and postural activities (Mori, et al, 2001). All the work on specific sites for the CPG has been small studies on animals but extrapolation could be made to humans. These studies linked with the earlier work in humans provide a potential explanation as to why the Scotson technique may contribute to improving respiratory function in children with neurological damage. It is also interesting to note that the reticulospinal formation is also suggested as the site for the locomotion CPG's. The site of the CPG for breathing with its sensory and cortical connections and its links via the reticulospinal system to the diaphragm, make it a potential area that the Scotson technique could access. Evidence that central pattern generators are also thought to be plastic means that if the Scotson technique does access the area there is a possibility that it could bring about change in respiratory behaviour.

2.3.3 Neuroplasticity.

Neuroplasticity is the brain's ability to organise itself by forming new neural connections throughout life. It also allows neurones in the brain to compensate for injury or disease and to adjust their activities in response to new situations or changes in their environment (Porter, 1999.) The ideas of neuroplasticity are not new they have a history from the 1800's especially in

the immature brain but the neural maturation theory with its unfolding of pre-existing patterns and higher centre control was dominant up until the 1980's when evidence of adult plasticity began to emerge (Benton and Tranel, 2000, Konishi, 2004). It is true that the cerebrum has specialised functional areas but evidence shows it is capable of considerable plasticity. This is demonstrated by the ability to learn new skills throughout a human lifetime (Hadders-Algra and Gramsbergen, 2001, Hadders-Algra, 2001, Mulder and Hochstenbach, 2001, Turkstra, et al, 2003).

The concept that the compensatory capabilities of the immature brain following a focal brain injury are superior to the adult brain are widely accepted and often termed the Kennard principle (Chugani, et al, 1996, Johnston, 2004, Kennard, 1936, Kennard, 1938, Staudt, et al, 2002). How this neuroplasticity occurs is a matter of continuing debate. Initial work was on animals which brings problems of extrapolation (Kolb, et al, 2001, Baram, 2003, Black, 1998) especially as they are often done in highly controlled environments with a largely homogeneous population and rehabilitation is rarely addressed (Turkstra, et al, 2003). Recent human studies have used new technology which has opened up more possibilities through the use of transcranial magnetic stimulation (TMS) and magnetic resonance imaging.

The improvements in function that potentially result from neuroplasticity are reorganisation and compensation not recovery (Kolb, et al, 2001, Johnston, 2004, Grafman, 2000, Farmer, et al, 1991). There is no single mechanism for neuroplasticity and its success depends on a number of factors. The

majority of studies into the mechanisms in children have been done on children with hemiplegic cerebral palsy but the few studies that have been done on a mixed cerebral palsy population also indicate a similar mechanism of reorganisation. This reorganisation takes many forms. There is usually enhanced participation of the unaffected hemisphere (Johnston, 2004, Kolb, et al, 2001). This involvement could result in ipsilateral cortical projections; these are of a primary motor type and often result in mirror movements of the unaffected side (Carr, et al, 1993, Carr, 2000, Eyre, et al, 2000, Eyre, et al, 2001, Farmer, et al, 1991, Brouwer and Ashby, 1991, Kastrup, et al, 2000, Nezu, et al, 1999, Staudt, et al, 2002, Staudt, et al, 2004). It is thought that the presence of mirror movements could indicate an immaturity of the nervous system (Mayston, et al, 1999). Each motor cortex initially develops bilateral corticospinal projections to both sides of the body but in individuals without neurological damage the ipsilateral corticospinal projections are withdrawn (Eyre, et al, 2000, Eyre, et al, 2001, Kastrup, et al, 2000, Krageloh-Mann, 2004, Nezu, et al, 1999, Staudt, et al, 2004). Mayston et al (1999) showed that mirror movements were present in non-neurologically damaged children and adults but this was not due to ipsilateral projections but to the simultaneous activation of crossed corticospinal pathways originating from both cortices. Thickbroom et al (2001) noted that sensory activity in children with neurological damage often remains in the affected hemisphere. This may explain some of the movement anomalies, as inter hemispheric connectivity is often impaired (Konishi, 2004).

Another mechanism of ipsilateral hemisphere involvement could be of the premotor type which results in increased activity and connectivity within the hemisphere but no projections (Staudt, et al, 2002, Staudt, et al, 2004, Kastrup, et al, 2000, Farmer, et al, 1991, Carr, et al, 1993, Carr, 2000).

Carr et al (1993) suggest other mechanisms of reorganisation such as the 'unmasking' of existing ipsilateral corticospinal projections with increased connectivity or new corticospinal projections from the unaffected hemisphere developing. Later work suggests rather than 'new' connections that non-specific glial cells become specific (Kastrup, et al, 2000, Johnston, 2004, Turkstra, et al, 2003). It is also thought that existing axons could undergo collateral 'sprouting' to by-pass the lesion or that expected 'pruning' of axons does not take place. All these events would lead to increased connectivity (Dong and Greenough, 2004, Eyre, et al, 2000, Eyre, et al, 2001, Kolb, et al, 2001, Rapoport, 1999).

Neuroplasticity of the central nervous system does not guarantee improved or enhanced function (Johnston, 2004). This has to be mediated by other factors both internal and external.

Internally there has to be enough oxygen for the increased activity (Johnston, 2004, Dong and Greenough, 2004). This could potentially be a benefit of the Scotson Technique, as one of the claims for the technique is that it enhances respiration. Also other chemicals need to be present to mediate and guide the reorganisation (Kolb, et al, 2001, Johnston, 2004, Turkstra, et al, 2003)

Externally the children need to concentrate on specific tasks within an enriched environment. An enriched environment alone does not equal improvement and although the task needs repetition this must be done with active attention to enhance representational plasticity in the motor cortex. Practice can only be done within the constraints of the existing musculoskeletal system (Turkstra, et al, 2003, Nudo, 2003, Mulder and Hochstenbach, 2001, Mateer and Kerns, 2000, Dong and Greenough, 2004). There are elements within the Scotson technique that could potentially tap into these activities that enhance neuroplastic mechanisms.

The evidence that neuroplasticity occurs throughout the human lifespan continues to grow and that it is enhanced in children is well established. Even so caution has to be applied. The size and site of the lesion plus the point in time at which it occurred will have some bearing on the eventual outcome, all authors agree on this. Also the children within the exploratory study for Advance are far from homogeneous and care, making extrapolations from the general study to a specific child, must be taken.

2.4 Other mechanisms.

Advance suggests that there are additional ways in which the Scotson technique could be affecting neurologically damaged children.

2.4.1 Positioning.

Advance uses different positions throughout the application of the technique and believes that these can have beneficial effects on the respiratory system particularly the use of prone. There are changes in diaphragmatic activity in different postural positions due to an alteration in inter thoracic and inter abdominal pressures. The abdominal contents or a firm surface pushing against the diaphragm and stimulating it through increased proprioception and perhaps muscle spindle activity (De Deyne, 2001). The particular positions that the children are put into could be accessing the postural function of the reticulo-spinal system through proprioception and repetitive breathing patterns (De Troyer, 1997a, Gandevia and Rothwell, 1987, Lanini, et al, 2003, McKay, et al, 2002, Mori, et al, 2001, Gandevia, et al, 2000). Correction of abnormal alignment is thought to alter the child's perception of the body schema and consequently to feed into the child's body awareness. (De Troyer, 1997a, McKay, et al, 2002, Mori, et al, 2001)

2.4.2 Prone.

The various arguments about the ideal position for a child at rest or sleeping have never been more controversial as placing infants into prone. Placement in the prone position for any length of time, has been said to increase the risk of sudden infant death syndrome (Rehan, et al, 2000, Numa, et al, 1997). In prone the diaphragm can be seen to be significantly thicker, a benefit but it is also shorter which puts it at a mechanical disadvantage. This situation could decrease strength and increase work which could potentially increase cortical representation. However prolonged prone could compromise the infants ability to respond to stress. Despite these misgivings prone is seen as an advantageous position for infants especially low birth weight or pre-term infants. Although some authors state that prone does not increase residual capacity or oxygenation (Numa, et al, 1997). The general consensus is that prone increases gas exchange, decreases energy expenditure more than can be explained purely by the fact they are laying down, increases the time spent in quiet sleep and decreases central apnoea (Masterson, et al, 1987, MacIntrye, 2003, Monterosso, et al, 2002, Heimler, et al, 1992, Balaguer, et al, 2003). There is difficulty in comparing the various studies as the populations are often not similar or carried out on normal low birth weight or pre-term infants, the presence of neurological deficits being an exclusion criterion. A systematic review by Monterosso et al (2002) concluded that, in terms of respiration, the prone position was physiologically more beneficial to pre-term infants. Also that it was critical that there was a

balance between active and passive muscle tone in the trunk and a balance between ventral and dorsal muscle strength which can be achieved by frequent position changes (Hadders-Algra, 2001). This muscular balance in the trunk has been cited in many papers as an essential component of the achievement of sitting balance (Butler, 1998, Butler and Major, 1992, De Groot, et al, 1995, Hadders-Algra, et al, 1998).

2.4.3 Microcirculation.

It is claimed the microcirculation within the muscles is altered in children with neurological damage. To support this Advance cites anecdotal evidence from the parents for this such as, cold limbs, poor skin condition, altered hair growth and altered colour of the skin (Scotson, 2005c). If these are true changes the alteration could be due to the premise that each tissue controls its own local blood flow in proportion to need. The blood flow in the capillaries is governed by pre capillary sphincters plus the contraction of skeletal muscle, as they have no contractile properties (Guyton, 1991, Marieb, 2005, Sherwood, 2001). Muscles in the majority of children with neurological damage have an increase in muscle tone and often have spasticity or even contractures. This means that oxygen levels are decreased but the tissue continues to consume oxygen with the consequence that carbon dioxide, acid and metabolites rise (Chaitow, 2002). Matching perfusion to metabolic demands is critical for maintaining normal muscle contractile function (Friden and Lieber, 2003, Hussain, 1996, Booth,

et al, 2001). A prolonged, relative ischaemic state and disuse can lead to muscle fibre changes such as, abnormal hypertrophy and atrophy, increases in connective non-contractile tissue and increased cross bridges at rest leading to the muscles being described as being 'stiff' (Marbini, et al, 2002, Ito, et al, 1996, Friden and Lieber, 2003). Advance concludes from this information that the microcirculation of the respiratory muscles needs improving.

2.4.4 Rhythmical compression.

The main claim of Advance is that the gentle on/off pressure of the Scotson technique increases hyperaemia through a number of potential routes. The compression of the muscles could further decrease an already compromised blood flow. A release of the pressure would then potentially increase blood flow. Advance surmises that repetition of this action in a particular area could lead to a perceived increase in metabolic demand which would consequently increase blood flow.

A recent paper by Morris and Woodcock (2004) investigates the use of short duration intermittent compression to produce short lived hyperaemia in the arteries of people with arterial disease. They concluded that the external pressure could be below diastolic pressure and of short duration to cause a reactive hyperaemia in supply arteries. The mechanism for this has been suggested to be either the suspension of the veno-arteriolar reflex or a myogenic response.

The veno-arteriolar reflex is a sympathetic axon reflex normally constricting the precapillary vessel (Guyton, 1991, Marieb, 2005, Morris and Woodcock, 2004, Sherwood, 2001). During compression pressure within the vessels decreases, reducing the reflex and allowing dilatation.

The myogenic response occurs particularly in the arterioles and precapillary sphincters. The vessels contract if intravascular pressure rises, stretching the vessel and causing a stretch reflex response (Sherwood, 2001, Marieb, 2005, Morris and Woodcock, 2004, Guyton, 1991). This could occur because the vessels have an increase in sensitivity (Guyton, 1991). The muscles in neurologically damaged children tend to exhibit hyperreflexia, an increased sensitivity to stretch.

Advance also feels that the rhythmical nature of the technique could be accessing the cyclical opening and closing of the pre-capillary sphincters, the natural vasomotion of the circulatory system (Guyton, 1991, Marieb, 2005, Sherwood, 2001)

Another potential route could be that the compression of the tissues could cause a sudden stretch of the small vessels leading to smooth muscle contraction in the arterioles and precapillary sphincters. This would cause vasoconstriction followed by vasodilation (Guyton, 1991, Marieb, 2005, Sherwood, 2001).

In orthopaedics some authors suggest that circulatory deficits contribute to pain, poor healing and poor rehabilitation (Selfe, et al, 2002, Taylor and George, 2001, Taylor, 2001). All these authors see the consideration of the

circulatory system as a vital part of a musculoskeletal assessment. Selfe et al (2003) conducted a small non-randomised study on a group of young patients. Measurement of the circulatory condition around the knee was not objectively measured but the subjective question; *'Do your legs feel cold even in warm surroundings?'* was posed (Selfe et al, 2003, p.140). This is similar to questions about the condition of the skin posed at Advance (Scotson, 2005c). The implication could be that musculo-skeletal patients and children with neurological damage with poor circulation are likely to have poorer rehabilitation outcomes unless circulatory deficiencies are addressed. Advance would argue that the Scotson technique addresses the issues of circulation and could potentially improve it. This is an area that has limited evidence, in the field of neurologically damaged children, but it is worthy of further investigation.

The gentle compression of the technique could stimulate a stretch reflex within the joints of the rib cage, vertebra and respiratory muscles that through proprioceptive efferents could possibly stimulate the respiratory centres in the brain stem (De Troyer, 1997a, Guyton, 1991). It could potentially access the reticulospinal system to increase respiratory activity.

Advance suggests that an improvement in muscle circulation could potentially improve functionality and perhaps reduce spasticity. Also that by improving the breathing patterns of the children the intra thoracic and intra abdominal pressures could potentially be normalised thereby improving

postural stability. This may also contribute to musculoskeletal improvement by counteracting the effects of gravity (Massery, 2005, Shirley, et al, 2003).

3 Method

3.1 Methodology

The evaluation of a completely new therapy, an alternative therapy, for children with neurological damage presents a number of problems. There are two main areas of difficulty:

1. The identification of areas that need exploration to show potential effects of therapy.
2. The heterogeneous nature of the study population.

These factors have a bearing on the methodology used for the exploration of the Scotson technique. The charity preferred a quantitative approach in the form of a comparative study. An initial baseline for exploration had to be established and this required a qualitative approach. Advance needed to explicitly state the expected aims of the Scotson technique and appropriate outcomes were necessary to show whether these aims had been achieved. These were essential steps as the theory for the potential effects of the Scotson technique and the technique itself had not been formally described.

An exploratory study is seen as part of the process of establishing the therapy.

The discussion document 'A framework for development and evaluation of RCTs for complex interventions to improve health' was published by the Medical Research Council in April 2000 (MRC,2000). The document recognises '*the unique challenges which arise in the evaluation of complex interventions*' (MRC, 2000, p. 1) and as such does not set out a rigid step by step guide but a framework to determine '*the state of knowledge*' (MRC, 2000, p.1). This is an ideal framework for the evaluation of the Scotson technique, a therapy outside mainstream healthcare that does not have an established theoretical base. The framework has five phases: pre-clinical and phases I – IV.

3.1.1 Preclinical/ Theoretical phase:

Exploration of a theoretical basis for the expected effects of the intervention. This involves taking ideas developed by the individuals or the organisation, exploring the ideas using available accepted evidence and seeing if that evidence could support the reported effects.

3.1.2 Phase I/ Modelling:

This phase involves identification of the components of the intervention and the underlying mechanisms that could influence the outcome of the therapy.

It is about developing an understanding of the intervention and its possible effects. It could include observational studies to increase that understanding.

3.1.3 Phase II/ Exploratory trial:

This phase is to test the evidence so far. It should lead to the establishment of an appropriate control group, what outcome measures would be appropriate and the 'dosage' of the therapy. At this stage the discussion document is leading up to a randomised controlled trial (RCT). If such a trial is not appropriate it is at the end of this stage where discussions about future trials are made. The exploratory phase is also the stage to determine the reliability of the elements of the intervention.

3.1.4 Phase III/ Main trial:

In the Medical Research Council's framework this would be a RCT but it could be a controlled trial using minimisation.

3.1.5 Phase IV/ Long-term implementation:

To establish the long-term effectiveness of the therapy in a broader context. This would mean following up the original trial population after they had stopped attending Advance.

This evaluative study has mainly concentrated on the pre-clinical phase and phases I and II. The recommendations suggest a method for a future trial (phase III).

In the preclinical phase the researcher explored the theoretical basis for the effects expected by the charity. This involved taking the ideas developed by the director of Advance, exploring the ideas using available accepted evidence and establishing whether the evidence could support the reported effects.

Phase I involved the identification of the components of the Scotson technique, established through observation and interviews. It also involved an identification of potential underlying mechanisms that could potentially have an influence on the outcomes of the technique. The aim was to begin the process of understanding the technique and its possible effects.

Phase II involved a testing of the technique in its present form. It informed the establishing of an appropriate study and control population, what outcome measures would be used and the 'dosage' of the therapy. This phase also determined the reliability of the elements of the technique by using video tapes to give feedback regarding a particular way to collect the data (Campbell, et al, 2000).

Finally a future study was proposed (phase III).

3.2 Background

The following describes the project carried out for the charity Advance.

The project started in July 2002 and finished in July 2005. The collection of data took place between November 2002 and September 2004. The data collected was based on an initial idea from Advance that the technique caused a change in the physical shape of a child's chest. Normative data was available from the Department of Trade and Industry (DTI, 1995) for the majority of measurements taken. This enabled the data from the children at Advance to be compared with normative data for their age, gender and in some cases nationality. The study explored whether the children with measurements some distance from the normal ranges would, through the course of the treatment, move towards more normal values. This enabled change to be tracked. Some measurements could not be compared with the normative data but the charity felt they were worth collecting (Scotson, 2005d). Change could be due to maturation of the child and may have happened without the treatment (Ernst, 2003, Rosenbaum, 2003c, Rosenbaum and Stewart, 2003, Benton and Tranel, 2000). Change alone does not constitute an effect but it would help to identify aspects of change that could be investigated in the future. It is part of the exploratory process to fully describe the population under study and the emerging theories behind the technique.

The children were videoed in lying and sitting. Analysis of the videos using the Peak Motus™ software was planned but unfortunately the equipment broke down and it could not be repaired so this approach had to be abandoned. This was disappointing as the Peak Motus™ was a validated

assessment tool. However the validation was for analysis of limb movement rather than posture and breathing. (Selfe, 1998, Selfe, 2000). Instead a more pragmatic qualitative approach was used to analyse these videos. Observation is used to assess change in a clinical setting both at a consultant and healthcare professional level and that it has an acknowledged place in the assessment of children (Pomeroy, et al, 2003, Mackey, et al, 2003). It is hoped that these videos can be analysed in the future through the Simi system™.

3.2.1 Timetable

Table 3.1 project timetable

Planning July'02 -Nov '02	Recruitment & data collection Nov '02 - Sept '04	Six months checking data Oct '04 –March '05	Analysis & report writing April '05 – July '05
5 months	23 months	6 months	4 months

3.2.2 Project setting

The project took place at Advance, the Institute for Advanced Neuromotor Rehabilitation, in East Grinstead, West Sussex.

Data was then sent to the University of Bradford, Division of Rehabilitation studies.

3.2.3 Charity personnel

Two therapists and two trainee therapists take the measurements and videos.

At the university there is a part-time project officer (RS).

3.2.4 Ethics

The University of Bradford, Division of Physiotherapy Postgraduate Research Committee granted ethical approval for the project on 1st September 2001.

3.3 Methods

3.3.1 Participants.

All children who attended Advance between November 2002 and September 2004 were eligible for inclusion in the project. There were no inclusion or exclusion criterion. No one declined to enter the study.

3.3.2 Consent

Consent was sought from all eligible participants either as an individual or through their parent or carer. There are issues involved in gaining consent in situations where children are participants. Children are considered to have

'capacity' or not (DOH, 2002). People aged 16 to 18 are entitled to consent on their own and following the 'Gillick' competence (House of Lords, 1985), it was ruled that any child who had sufficient intelligence to enable them to fully understand what was involved also had 'capacity' to consent. Where a child lacks 'capacity' consent can be given on their behalf by a parent or carer (DOH, 2002) but it is still deemed good practice for the child to be involved in the decision making process. As a large number of the families were from France the consent form was forward translated into French (Appendix 2). This was done by the administrator, who is French, and to check the consistency of the translation a backwards translation into English was carried out by a member of staff in the modern languages department at the University of Bradford.

The study was explained to the families and children by the therapists at Advance. A research information and consent form was given to them to read (Appendix 1 & 2) and signed if they agreed to participate.

3.3.3 Treatment technique.

Information about the treatment technique was gathered through interviews with the director and the two senior therapists plus from the information given to parents (Advance, 2004a) and a video (Scotson, 2004b). All children receive the Scotson Technique based on the stated assumptions concerning the biomechanics of the respiratory system and especially the diaphragm.

Prior to coming for the initial assessment the parents/carers are asked to complete an extensive questionnaire giving general information and also information about structural abnormality, functional abnormality, cognition and physiological elements such as seizures or chest infections. It also asks at this early stage about commitment in terms of time to the programme; hours per day and years (Advance, 2004b).

All children are evaluated by the director on their first visit and then every other visit. This evaluation is video recorded and a copy is given to the parents/carers. This evaluation is largely observational supplemented through:

1. Photographic and video comparison of the child's structure from one visit to the next
2. Extensive structural measurements which are compared with both normal values and the child's previous evaluation
3. Computerised measurements of abdominal and thoracic breathing patterns which are compared to normal values and the child's previous evaluation
4. Three-dimensional computerised spinal probe measurements in relation to the shoulder and pelvic girdles comparing these both with normal values and the child's previous evaluation

The first two measures have been done since the project began but the latter two have only just been added.

The child is then given the first prescription based on the evaluation (Appendix 3). The therapists carry out the first prescriptions and the senior therapist are trained to ask about seizures and tailor the therapy to the individual (personal communication, 10, January, 2005) (Kilsby, 2005, Paxton, 2005,). The prescription although individual to each child follows a pattern and is seen by Advance to become more complex over time. An example of this would be that the first prescription works round the diaphragm using eight placements divided between the front, back and sides using either one or two hands (personal communication, January, 11th) (Scotson, 2005d). Subsequent prescriptions are more complex, working upwards from the diaphragm and downwards into the pelvis using two hands. If anything adverse occurs '*such as an increase in seizures*' (Personal communications, January, 10 & 11th) (Kilsby, 2005, Scotson, 2005d, Paxton, 2005) the therapists and parents would be advised to return to the diaphragm and become lighter, more gentle and to break the exercises into shorter periods of time. Advance states that from time to time parents would be returned to working on smaller areas of the diaphragm (personal communication, 11 January)(Scotson, 2005d). The prescriptions are seen as '*developmental in line with the development of the respiratory system from birth onwards*' (personal communication, 7 April) (Scotson, 2005d) and adapted to individual needs within the areas of application and timing. The prescriptions are sequential and the director (LS) is developing

their complexity over time. Eventually it is envisaged that there will be a finite number of core prescriptions which can be adapted to the individual.

The technique consists of:

- Placement of the child (fully clothed or shorts and tee shirt) in a position of comfort with their body fully supported, no weight bearing. The child should be in a relaxed position *'within the potential of its existing structure'* (Advance, 2004b). No gaps between the body and the supporting surface. The body is *'never forced into a more 'normal' appearance'* (Advance, 2004b). The positioning should relieve tension as any tension is thought to impede blood flow (Personal communication, 10, January) (Paxton, 2005, Kilsby, 2005). The position is dependent on the area being treated but frequent position change is encouraged.
- Positioning in prone with the chest supported by firm cushions or folded towels to ensure the trunk is relaxed.
- The trunk area being treated. On the anterior aspect, the trunk is divided into 18 areas, extending from the neck to the waist. On the posterior aspect the trunk is divided into 16 areas again from the neck to the coccyx (Appendix 4 & 5). These were the only areas treated during the project.
- Towels being placed between the operator's hands and the child's body.
- Pressure being applied by the operator. This pressure should be light, gentle and when using two hands, alternating. Copying the *'natural' breath of the body, a 'breathing' pressure creating a 'wave' effect'* (Personal communication, 10, January,) (Paxton, 2005, Scotson, 2004b, Kilsby, 2005).

- Small, oscillating movements coming from the shoulder blade whilst keeping the elbow and wrist firm but relaxed all in straight alignment. The hand creates a flat platform and should be in contact with the towel, with no concavity between the palm and the towel. Advance place emphasis on the evenness of the platform, any concavities should be filled by towels. The hand at all times should be relaxed. The operator keeps in contact with the towel throughout the manoeuvre (Personal communication, 10, January) (Paxton, 2005, Kilsby, 2005) (Scotson, 2004b, Advance, 2004b).
- The application of very gentle pressure. Descend to the count of five and then without 'pulling off' ascend again to the count of five. Wait approximately one second then start again. Both the compression and the decompression must be very slow, there is no pause when the depth is reached and a slow decompression starts immediately. (Personal communication, 10, January)(Kilsby, 2005, Paxton, 2005) (Scotson, 2004b, Advance, 2004b).

The technique is initially done on the child by the therapist. Then the parent/carer carries out the technique, using the therapist as a model. They then take over the treatment of the child as their technique improves. The idea behind this is that the parent/carer's will eventually become their child's therapist. Advance is a *'teaching institute for parents/carers'* (Advance, 2005a). The technique can be applied with the child watching television, listening to music or even when they are asleep.

3.3.4 Towels

Towels play an important part in the delivery of the Scotson technique.

Advance state that the towels are used to:

- Increase the 'pneumatic' capacity of the applications. That the movement through their 'airiness' allows a slow gentle compression and decompression (Advance, 2004b).
- Fill the gaps between the bones allowing a more even and consistent pressure. The towels also ensure there are no gaps between the body and the surface.
- To trap air the towels should be '*soft and fluffy*' (personal communication, 10, January) (Paxton, 2005, Kilsby, 2005) (Scotson, 2004b). Instructions about the number of towels is given in the parent information pack (Advance, 2004b).

3.3.5 Dosage

- The families attend Advance initially for five days, two hours on each day. They are encouraged to continue the technique at home for two hours per day for six days a week.
- Five, 5-day visits are usually made in the first year and four the following year, after which the frequency and duration of return visits, becomes more individual.

- Initially the technique is done to each area three times as both parents have to practice but after that it is once to each area.
- Application over an area will take approximately five minutes followed by five minutes rest. The operator then moves to another area on the prescription. The session takes a maximum of 20 minutes treatment with at least 10 or even 20 minutes rest. The technique period can be divided into once, twice or three times per day. The technique is very tiring for the child even if they are asleep (Scotson, 2004b).

The amount of time that parents can spend on the technique varies from week to week. As a consequence Advance has become more flexible in its approach to the dosage but still maintains that two hours per day is preferable.

3.3.6 Video recordings.

The children were video recorded during the evaluation and then in sitting and in lying for the project. The original idea was that the sitting and lying video recordings would be analysed using the Peak Motus™ motion analysis machine but technical difficulties which could not be rectified meant that this was not possible. Another video analysis system has been purchased but will not be functional until after the project is finished. Any analysis which is eventually undertaken will be forwarded to Advance.

Each child was video recorded in a room separate from the main treatment area. The room was painted blue to reduce glare and there were no

windows. The distance and height of camera from bed same each time. The distance from the bed was 192cm and the height of the tripod 88cm. This was maintained by marking the floor and the tripod with white paint. Two metre calibration sticks were put at different heights on the wall behind the bed. Also every 20 centimetre was marked with white paint.

The camera used was a Sony handycam, DCR-TRV 50E with a small light.

Each child was videoed in each position for two minutes. They had reflective markers on the following bony points:

- Ends of the shoulders
- Anterior superior iliac spines
- Umbilicus
- Middle of the sternum

It is accepted that the application of the reflective markers from session to session and from child to child may vary. This was addressed through feedback from the researcher watching the process on video and through the therapists practicing and making appropriate changes.

The video tapes were then sent to the University of Bradford and a time code was written onto the video using a HORITA SR50/TE PAL time code generator to facilitate analysis.

3.4 Outcomes

As this is an evaluative project the outcomes are exploring the areas of interest for the charity which were the potential changes in:

- Physical measurements of the chest.
- Sitting posture.
- Breathing patterns.

All these measures were taken at baseline which was the first attendance, and then each time the child attended Advance.

3.4.1 Baseline information

A baseline data sheet was filled in and each the child was video recorded (Appendix 6).

Child characteristics recorded on the baseline data sheet were:

- Age given as years and months.
- Gender
- Weight and height. If not in kilograms or in centimetres this was converted using a measurement conversion factors table (Barron, 2000). The height was then converted into millimetres by multiplying by 10.
- Presence of a nasogastric tube or percutaneous endoscopic gastrostomy (PEG).
- Nationality. This was recorded as the normative data from the Department of Trade and Industry (DTI, 1995) being used to explore the collected data was

for Europe and North America. If there was no value for a given nationality then it was matched with the United Kingdom in the first place or the United States if there was no UK value. Normative data for children from the Netherlands was presented as the 3rd and 97th percentiles not 5th and 95th as in other countries. This was how the normative data was presented (DTI, 1995).

- Diagnosis. Recorded to establish the mix of children attending. The European Classification of (motor impairment in) Cerebral Palsy (Appendix 7) (SCPE, 2000) was used to record this.
- Hyperbaric oxygen therapy (HBOT).
- Peak expiratory flow measurement in litres per minute and whether this was measured with a peak flow meter or a Wright™ peak flow meter.
- Quantity of treatment.
- Other therapies.
- The postural assessment scale (PAS) (Jonssdottir, et al, 1997) (Appendix 8).
- A narrative of the children's baseline and subsequent breathing patterns (Appendix 9).
- Measurement of the child's trunk in centimetres. These were done at specific points see table 3.2

Table 3.2 trunk measurements

Child lying down on back
Shoulder width from deltoid muscle (callipers)
Chest width (at front) armpit level (callipers)
Chest width at nipple level (callipers)
Chest width at xiphoid level (callipers)
Breadth at level of iliac crests (callipers)
Neck circumference (over larynx/ Adam's apple)
Chest circumference armpit level (tape)
Chest circumference at armpit exp (tape)
Chest circumference at armpit insp (tape)
Chest circumference at nipple level (tape)
Chest circumference at nipple exp (tape)
Chest circumference at nipple insp (tape)
Chest circumference at xiphoid exp (tape)
Chest circumference at xiphoid insp (tape)
Waist circumference (tape over naval)
Child in side lying Using callipers
Chest depth on sternum & spine at nipple level
Chest depth on xiphoid and spine
Hip depth just below iliac crests

All follow up assessments were done following the same format.

3.4.2 Statistical methods

A database was created and checked for errors prior to analysis. Data was analysed using SPSS version 11.5 and with STATA version 8.2 (Stata Corp 2001. Stata statistical software: Release 8.2 College Station, TX). All children were analysed regardless of how many treatments received.

SPSS was used for descriptive analysis. Mean, median and mode were used to illustrate central tendency and interquartile ranges to represent spread across the variables.

Within SPSS the children's measurements were compared with normative values for age to establish whether movement was towards more normal values. A sampling strategy was devised and children were analysed at baseline and third and fifth visit. The reason for this was that the director and the two senior therapists all felt that changes were noticed at the third or fourth treatment (personal communication, 10, January & 11, January) (Kilsby, 2005, Scotson, 2005d, Paxton, 2005). The numbers of children dropped considerably after the fifth treatment. Only the data that could be compared with the normative data from the DTI (1995) was explored, the reason for this was that change in either direction could be highlighted. Also the five children that completed nine visits were analysed at all visits.

All data were standardised to make the measurements a percentage mean for age by dividing the measurement at each visit by the normative mean for their age then multiplying by 100.

It was accepted that this was not comparing like with like and that change could be associated with maturity but it was felt that if change occurred that this could be an area for future investigation.

Pie charts were constructed to illustrate the range of diagnoses, nationalities and additional therapies that the children were receiving.

Box plots were used to illustrate the percentage mean for age of the physical chest measurements plus the waist and neck circumference.

Box plots were also constructed to show comparison between baselines, third and fifth visits for all children and for those who had nine visits.

A histogram was constructed to illustrate the children receiving hyperbaric oxygen therapy.

The change in postural assessment scale (PAS) was explored over time to see if there were any changes. The process was repeated with the breathing narratives.

Sub-group analyses were undertaken into diagnosis, number of hours of treatment, age ranges and gender.

The statistical software package STATA (StataCorp 2005. Stata Statistical Software: Release 8.2 College station, TX: Stata corporation) was used to explore change over time using a repeated measures linear regression model. The predictors used to illustrate this change were; months of treatment since baseline measurements and the age the child was at the

commencement of treatment. A sampling strategy was devised so only variables with comparable normative data were explored.

4 Outcome and baseline measures.

4.1 Introduction

The outcomes and baseline measures were selected to fulfil the exploratory nature of the project. The study aimed to begin the assessment as to the validity of the claims that underpinned the Scotson technique and to identify areas and appropriate methods for further investigation. In depth consultation and discussion was carried out to establish what parameters Advance expected to change and how potentially that could be measured.

4.2 Selection of outcome measures

Advance state three 'radical' assumptions about neurologically damaged children.

1. *"That many motor problems are caused not only because of the brain injury but also because of other changes occurring in the muscular skeletal system including the diaphragm"* (Scotson, 2005a).

2. That pressure changes in the thorax and abdomen occur due to the compromised respiratory system and this has a *“profound effect on muscular skeletal and neurological development and maintenance”* (Scotson, 2005a).
3. *“That the brain’s outgoing signals are entirely limited by the degree of electrical activity present in the body’s tissue”*. (Scotson, 2005a).

Advance claims that the diaphragm is the ‘key organ [of the respiratory system] on which the development and maintenance of the body’s physical structure and both general and cerebral metabolic function depends’ (Scotson, 2005a). It claims that the Scotson technique works on the respiratory system in close connection with other muscle groups and brings about improvement in the three areas stated in the assumptions.

These are large claims and difficult to quantify. The first step in selecting outcome measures was establishing what measurements could identify change resulting from the Scotson technique. Assumptions one and two were deemed suitable for further exploration.

Assumption one and two relate to a compromised respiratory system, especially the diaphragm, and the resulting altered biomechanics. The Scotson technique claimed to facilitate an improvement in these areas. Concurrent claims were that improvement in these areas would improve the action of the diaphragm and the respiratory system and as a consequence enhance plasticity of the brain and general function. Advance claimed that the improvement could be measured by observing a movement of values towards ‘normal’. It was accepted that any improvement in values could be

due to other processes but the Scotson technique could be part of that process. It was decided that as a start this, although flawed, was worthwhile.

4.3 Diaphragm

The diaphragm could not be directly assessed but peak expiratory flow could be measured as a means of evaluating diaphragmatic function. This value was seen as potentially a measure that may show improvement that could be attributed to the Scotson technique.

4.4 Biomechanics

The biomechanical evaluation involved a number of processes. Tracking and comparison of physical measurements in the trunk area (Appendix 10) with available normative data (DTI, 1995). These measurements were identified through negotiation with the director and the senior therapists. Advance thought they best reflected the areas where change appeared to take place. Most selected measurements could be matched with normative data (DTI, 1995) but others were simply of interest to the charity. The measurements were taken using callipers (Matt stainless steel, India imported by GTS UK.) and a tape measure. The methods of measurement were specified in the Department of Trade and Industry book 'Consumer Safety Unit: Childata: The Handbook of Child Measurements and Capabilities – Data for Design Safety' (DTI, 1995). The inter and intra-rater reliability was monitored by RS

who watched a video tape of the first measurements and gave advice and guidance. Secondly the therapists had to take the same measurement three times and then all the therapists had to take the same measurement. The therapists then adjusted their technique if necessary and the process was repeated at a later date. The measurements were taken in centimetres then converted into millimetres by multiplying by ten.

The thoracic index was extrapolated from the measurements by dividing chest depth by chest width. It was felt this measure could add insight to the breathing narratives.

Video analysis with the Peak Motus™ system. Unfortunately technical difficulties which did not come to light until half way through the project made this impossible. Compromises had to be made in a short space of time and two other assessments were used:

1. The postural assessment scale. The decision was taken to record the PAS (Appendix 8) when the children were in sitting. This is not a validated scale but includes qualitative aspects of motor behaviour and evaluation of change is possible (Jonssdottir, et al, 1997). It also reflects the largely qualitative and observational nature of the Advance evaluation.
2. A narrative of the children's baseline and subsequent breathing patterns was recorded with the children in lying. This is not a validated approach but reflective of the areas of interest. It had been noted that the majority of children exhibited some abnormalities during respiration. Advance felt these abnormalities reflected a compromised respiratory system and expected that

these would improve over time. Any change could potentially be an area for future investigation. Eight elements of respiration and posture related to respiration were recorded (Appendix 9)

5 Results

5.1 Participant Flow

211 children attended Advance and consent was obtained for them to be included in the study. The study took place over the period 30th November 2002 to 30th September 2004.

Table 5.1 participant flow

<u>Treatment number</u>	<u>Number of children</u>	<u>Treatment number</u>	<u>Number of children</u>
1	211	5	51
2	144	6	40
3	108	7	29
4	74	8	13
		9	5

Table 5.1 shows the number of children recruited and how many had subsequent treatments. Children were being recruited at different points

throughout the recruitment period and the gaps between the treatments were not uniform.

5.2 Attrition.

Table 5.2 attrition

Reason	Number	%
Continued	152	72.1
Discontinued	52	24.6
Died	2	0.9
Transferred to Advance Glasgow	5	2.4

Table 5.2 shows the attrition numbers. No one declined to enter the study but approximately one quarter dropped out (52/211). This specific data was not collected but reasons cited as family commitments, financial difficulties or unable to commit the time needed (personal communication 11, April) (Scotson, 2005.). In future studies this will need to be tracked more transparently to feed into the on-going evaluation of Advance. It is suggested that a simple form be used to establish the reasons for discontinuing, if the families are willing to disclose this.

The graph 5.1 below shows the ages of the children who discontinued. The gender split was 33 males and 19 females. The majority dropped out after the first treatment (34/52).

Graph 5.1 Children who discontinued

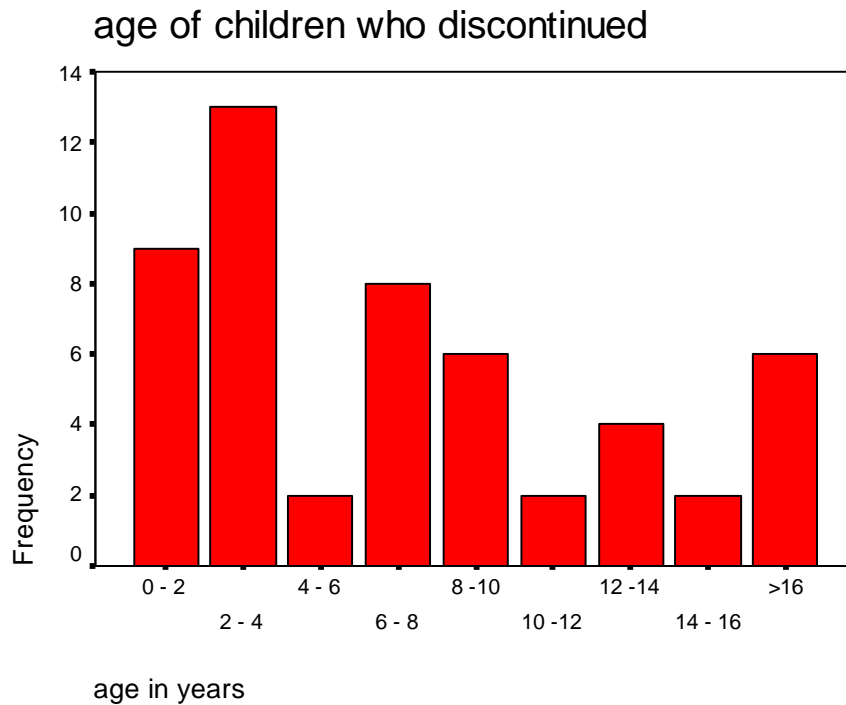


Table 5.3 Number of hours of treatment done daily by parents (Mode)

2 nd	3 rd	4 th	5 th
Rx	Rx	Rx	Rx
2	2	2	2
6 th	7 th	8 th	9 th
Rx	Rx	Rx	Rx
1	1	1	1

From table 5.3 it can be seen that over the study period the number of hours the parents spent doing the technique at home daily decreased.

5.3 Baseline characteristics of the group

5.3.1 Personal characteristics

Table 5.4 shows the age and gender mix of the study population

Table 5.4 age and gender mix

(n=211)		
Age (Years)	Mean	6.08
	Range	0.4- 25
	median	4.33
	mode	4
Gender	Male	145
	Female	66

5.3.2 Baseline diagnosis

The majority of children had the diagnosis of cerebral palsy (172/211). This group was divided into subgroups using the European classification of (motor impairment) cerebral palsy (SCPE, 2000). This recording was patchy due to cerebral palsy often being the only diagnosis and Advance not having the expertise to give a finite diagnosis. Of the remaining children 34 had a diagnosis of 'other' and five had no diagnosis.

Pie chart 5.1 shows the wide range of conditions seen at Advance with cerebral palsy and cerebral palsy in combination with other conditions being the largest group.

Pie Chart 5.1 diagnosis

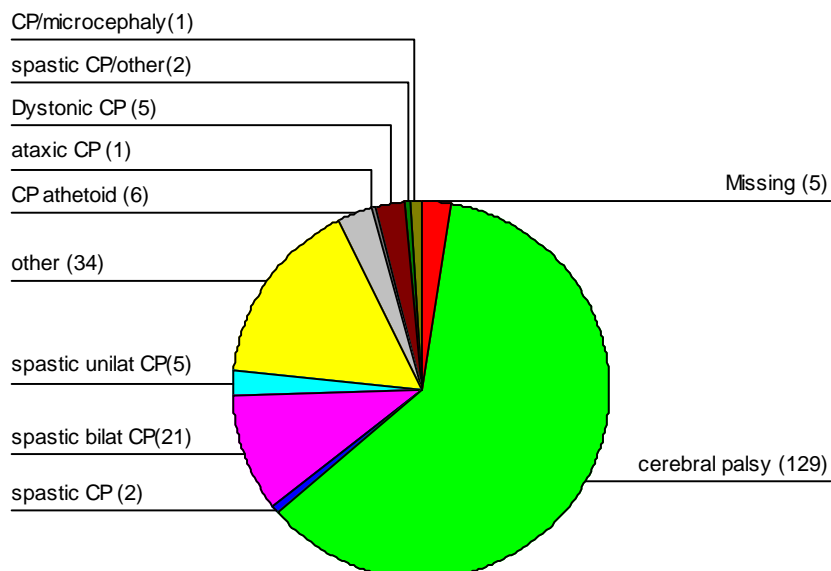
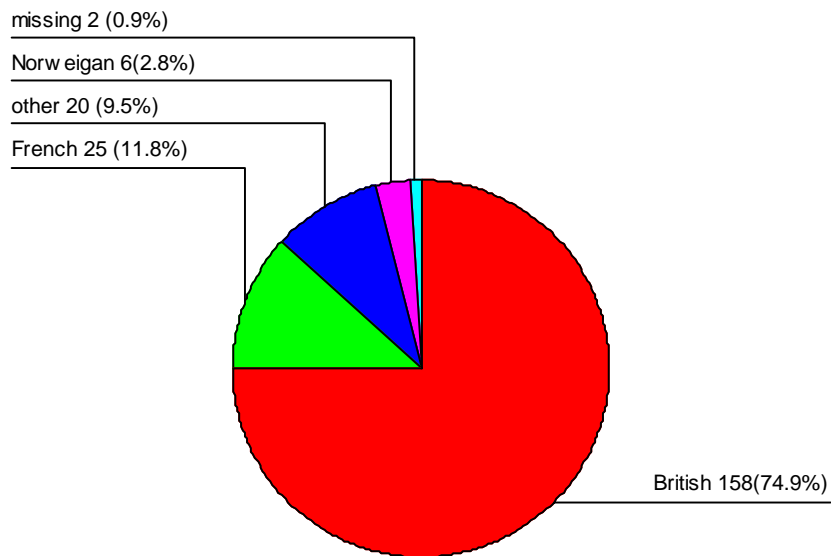


Table 5.5 diagnosis of "other"

Other diagnosis	
Brain injury	Freeman Sheldon Syndrome
West Syndrome	Autism
Reduced oxygen	vaccine damage
Drop foot	ADHD dyspraxia
General motor dyspraxia	Growth hormone deficiency
Microcephaly	Cerebral haemorrhage
Global developmental delay	Cranial stenosis
Epilepsy	Chromosome disorder
William's syndrome	Myoclonic absence seizures
Neck injury	Leigh's disease

5.3.3 Nationality

Pie Chart 5.2 nationality



As pie chart 5.2 shows the majority of the children in the study come from the UK, with France and Norway contributing the next largest groups. There was a mix of nationalities classed as 'other' as can be seen in table 5.8.

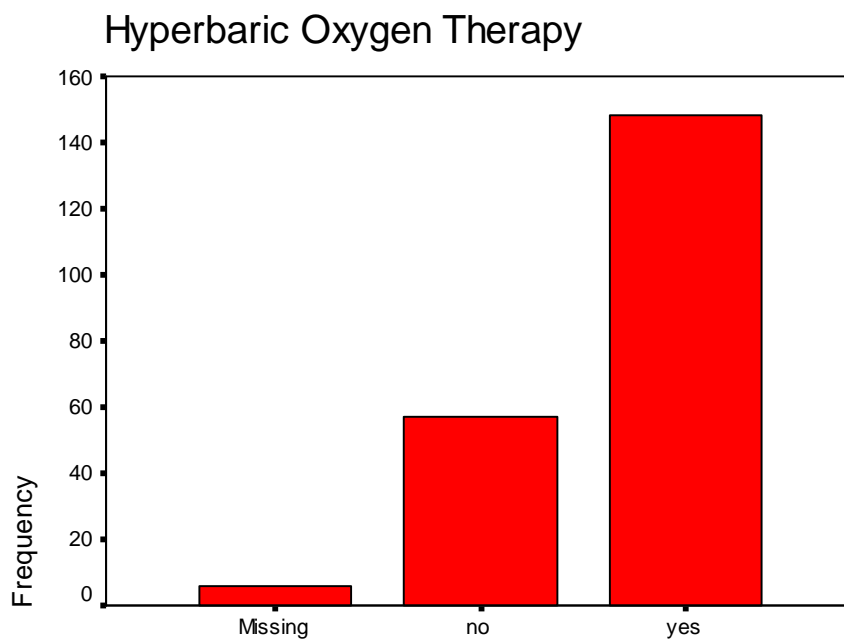
Table 5.6 "other" nationalities

Swedish	Belgian	Dutch	Danish
American	Portuguese	Italian	
German	Yugoslavian	Irish	
Indian	Bermudian	Austrian	

5.3.4 Hyperbaric Oxygen therapy

This is an optional component of the treatment package when a child attends Advance. As can be seen the majority of children have the technique plus a session of hyperbaric oxygen therapy. Six children have missing values for this variable. Graph 5.2 below shows the break down.

Graph 5.2 Hyperbaric Oxygen Therapy

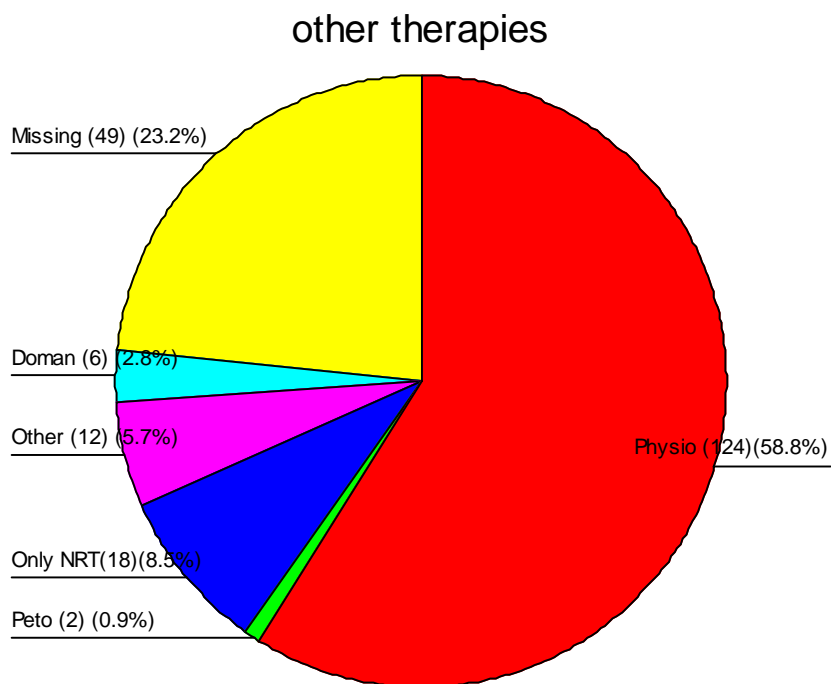


N=211

5.3.5 Other therapies

The majority of children attending Advance were receiving other therapies besides the Scotson technique. Pie chart 5.3 looks at the main breakdown of other therapies the children are receiving. Although physiotherapy is the main 'other' therapy, this was often recorded as 'Bobath' on the form. This may indicate some confusion amongst parents and staff about the nature of the therapy termed 'Bobath'. Bobath is a concept of treatment within physiotherapy.

Pie Chart 5.3 other therapies



There were a number of other concurrent therapies classed as 'other' in the above that the families were involved in. Many of them would be classed as 'alternative' therapies and not provided by the NHS. Table 5.7 shows the make up of the 'other' concurrent therapies.

Table 5.7 concurrent therapies "other"

Concurrent therapies			
Cranial osteopathy	Bowen	Tomatisse	Vojta
Acupuncture	Brainwave therapy	Yoga	Reflexology
Reiki	Homeopathy	NACD	BIBIC
Sacrocranial osteopathy	Hydrotherapy	Hippotherapy	Music therapy

5.3.6 Nasogastric or percutaneous endoscopic gastrostomy

Only 11 out of the 211 had supplementary feeding in place.

5.3.7 Peak Expiratory Flow

Only 20 children out of 211 managed to register a peak flow meter reading.

Sixteen used the vitalograph and four the Wright's peak flow meter™.

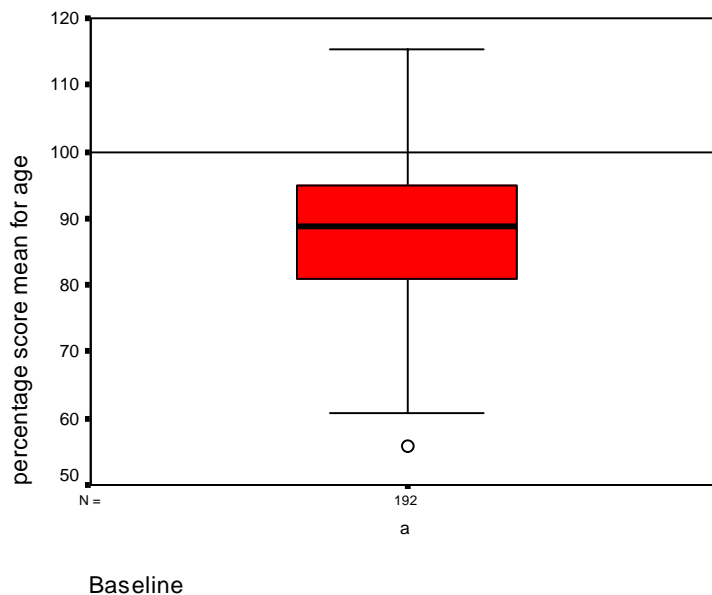
6 Baseline physical measurements

All scores have been calculation as a percentage of the normative mean score for age. The reference line on all the box plots indicates 'normal' (100%). The missing data may not be a missing reading but due to the

particular age not having an applicable reading. Two readings, chest width and circumference at armpit, were not applicable for children under two years of age and so percentage of the normative mean for age could not be calculated. The majority of measurements are clustered around the 100% reference line which indicates the normal percentage mean for age.

6.1 Shoulder width

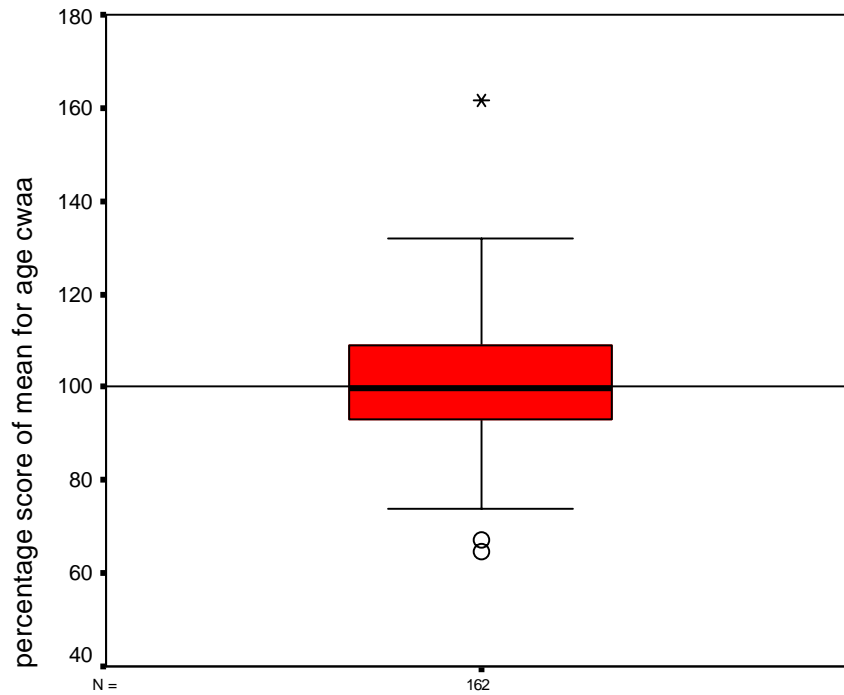
Figure 6.1 baseline shoulder width



The majority of children had shoulder width measurements at baseline below the average for their age.

6.2 Chest width at armpit

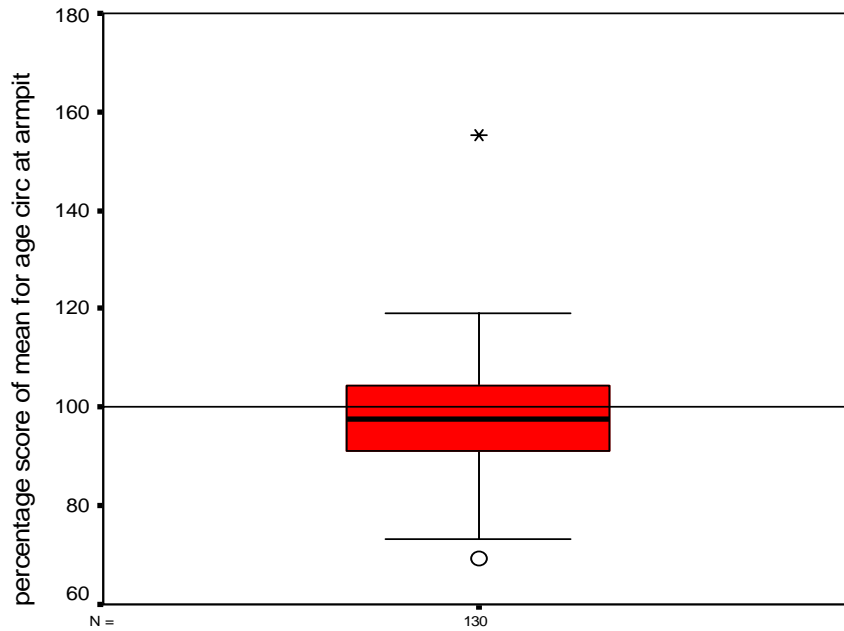
Figure 6.2 baseline chest width



At baseline the children were clustered around the average for their age.

6.3 Chest circumference at armpit

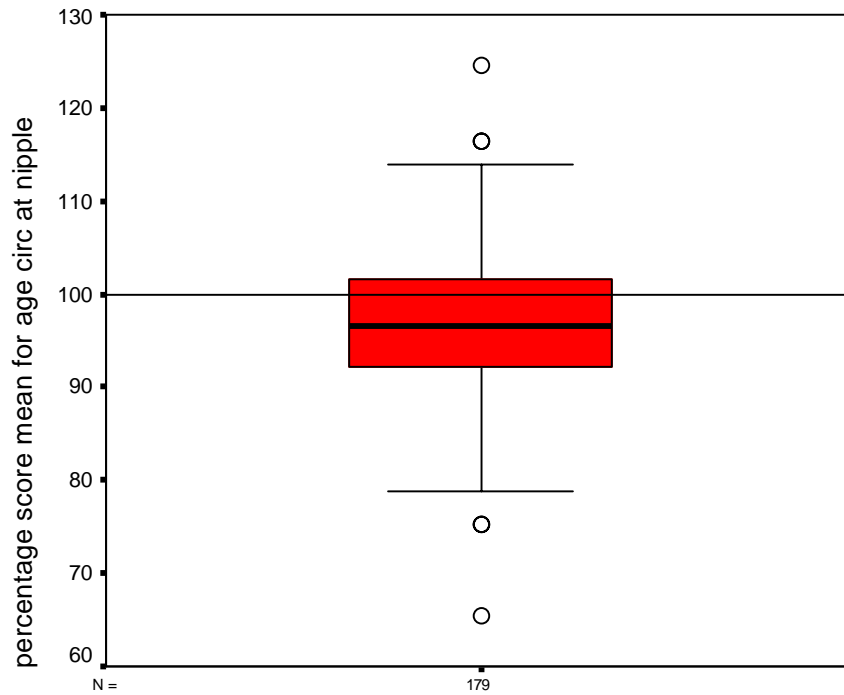
Figure 6.3 baseline chest circumference armpit



At baseline the children were clustered around the average reading for their age.

6.4 Chest circumference at nipple

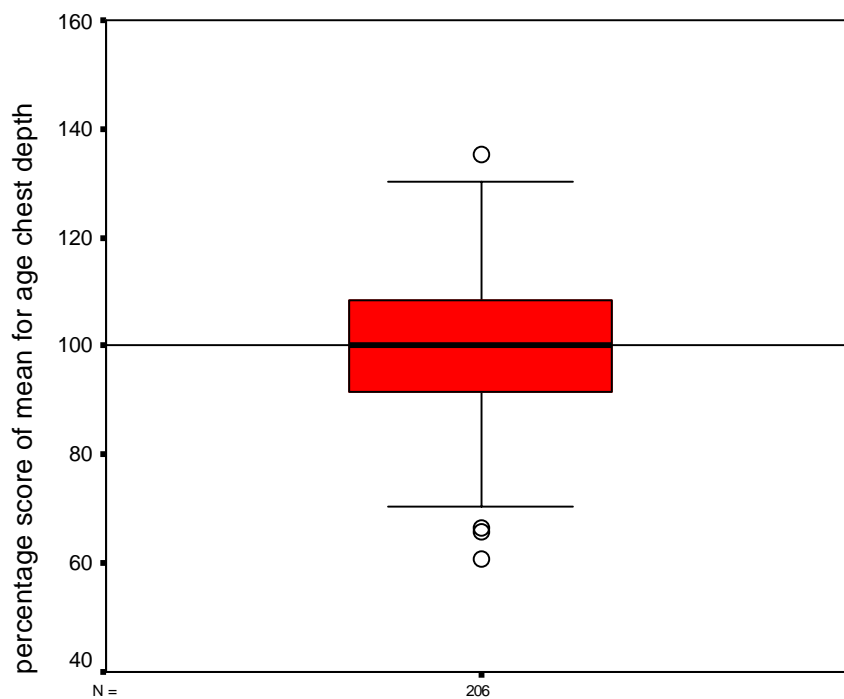
Figure 6.4 baseline chest circumference nipple



The children's measurement for chest circumference at nipple at baseline is slightly below the average reading for children of the same age.

6.5 Chest Depth

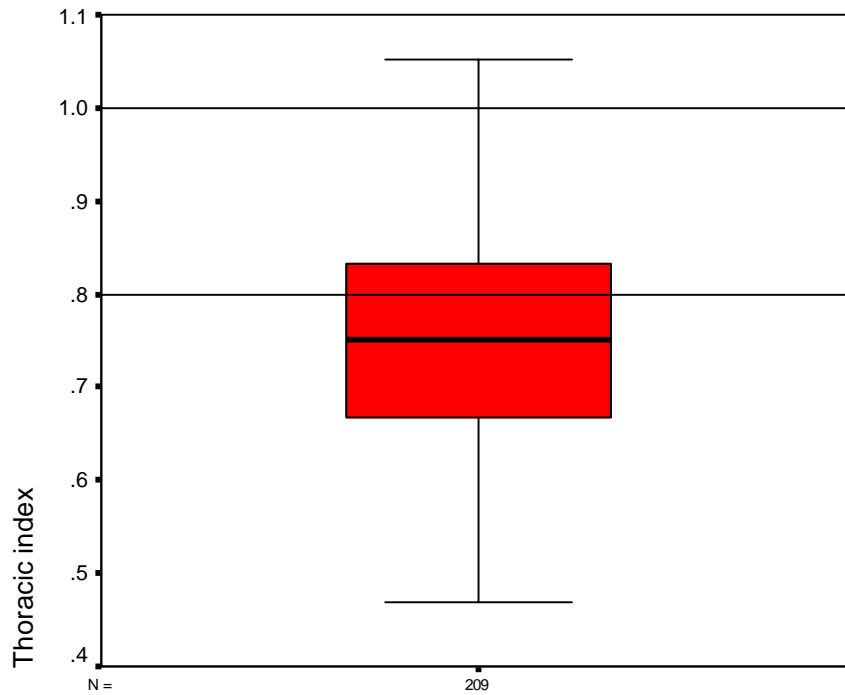
Figure 6.5 baseline chest depth



At baseline the measurements for chest depth are clustered around the average reading for children of the same age.

6.6 Thoracic index

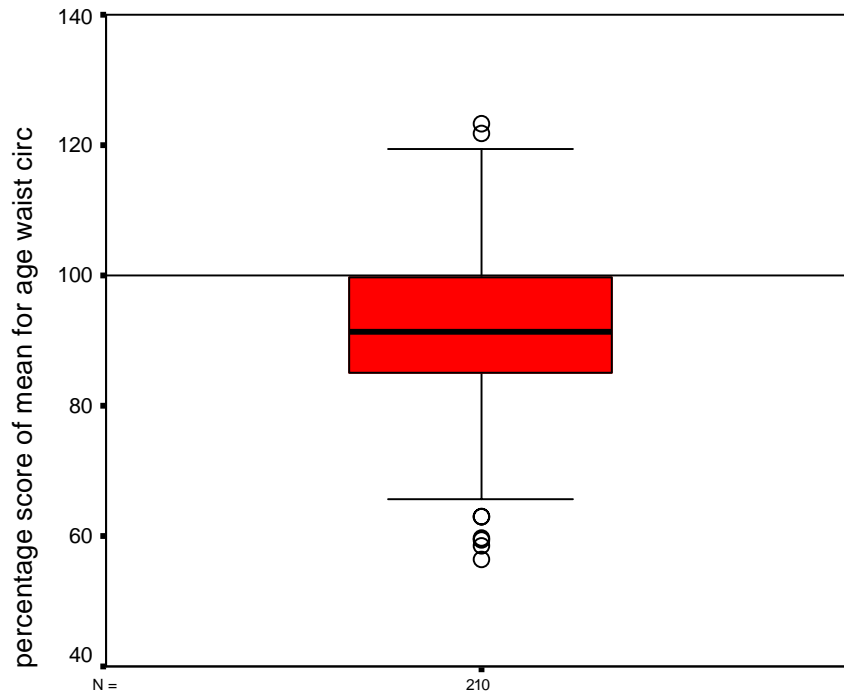
Figure 6.6 baseline thoracic index



The reference lines on this box plot shows 1 as a score that would indicate a more circular chest and 0.6 as a more mature ovoid chest shape. The majority of children are within the reference lines.

6.7 Waist circumference

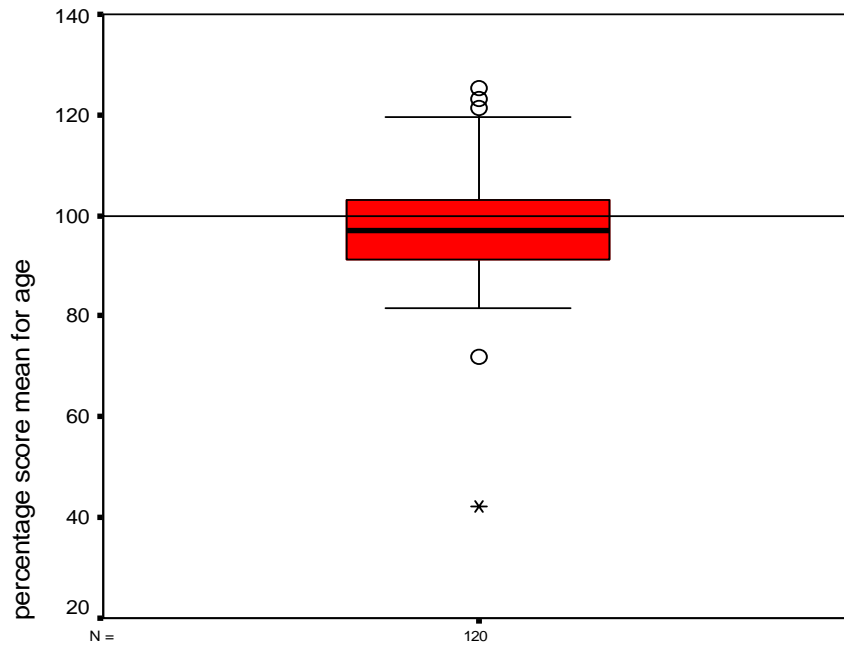
Figure 6.7 baseline waist circumference



The majority of children are below the average measurement for children of the same age.

6.8 Neck circumference

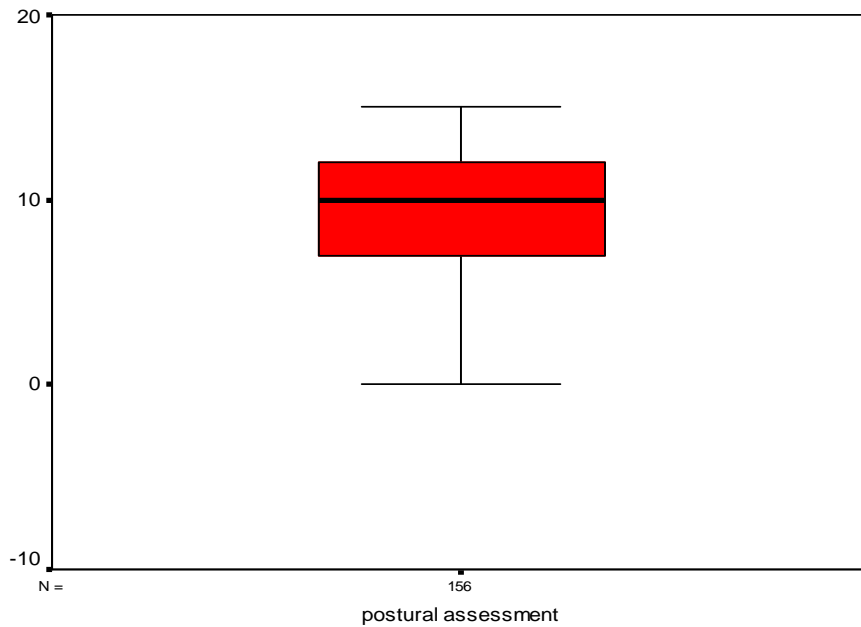
Figure 6.8 baseline neck circumference



At baseline the children are grouped around the average measurement for children of the same age.

6.9 Postural Assessment Scale

Figure 6.9 baseline PAS



The PAS is a score out of 15. The median score for children at baseline was ten.

6.10 Peak Flow

As table 6.1 indicates the peak flow readings of the children showed a wide variation of readings even within the small group able to register a reading.

Table 6.1 baseline peak flow

Peak Flow (ml per sec)

	Mean	Minimum	Maximum
a			
n=20	105	10	245

6.11 Breathing Narratives

Table 6.2 baseline breathing narratives

	Breath holding	Primarily upper chest breathing	Lat rot upper arms	Primarily abdominal breathing
Present	82 38.90%	42 19.90%	91 43.10%	162 76.80%
Absent	102 48.30%	142 67.30%	93 44.10%	22 10.40%
	Mouth breathing	Irregular rhythm	Paradoxical breathing	Hyperinflation
Present	133 63.00%	159 75.40%	41 19.40%	101 47.90%
Absent	51 24.20%	25 11.80%	143 67.80%	83 39.30%
Missing	n = 27 12.80%	-	-	-

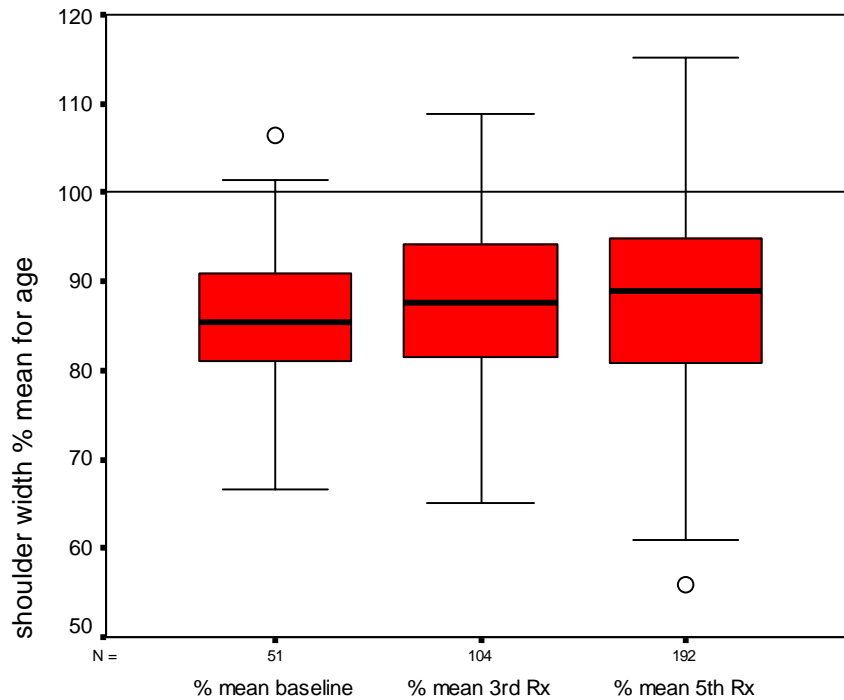
Table 6.2 indicates the breathing patterns that the children exhibited at baseline. There were some abnormalities in the breathing patterns and a majority of children exhibiting the more normal primarily abdominal breathing.

7 Outcomes at third treatment and fifth treatment

It was reported by the director and the two senior therapists (personal communication, 10, January & 11, January) (Kilsby, 2005, Paxton, 2005, Scotson, 2005d) that they begin to see changes at the third or fourth treatment. The decision was made to analyse data from the third and fifth treatment. After the fifth treatment the numbers of children drop so this was decided as a cut off point (treatment e n = 51). The missing data may not be a missing reading but due to the particular age not having a corresponding value within the normative data tables (DTI, 1995). Some data points were not applicable for children under two years of age so that percentage score mean for age could not be calculated. A small percentage of children (<25%) stopped treatment. The 211 children did not have an equitable number of treatments; therefore numbers drop through the treatment cycle.

7.1 Shoulder width

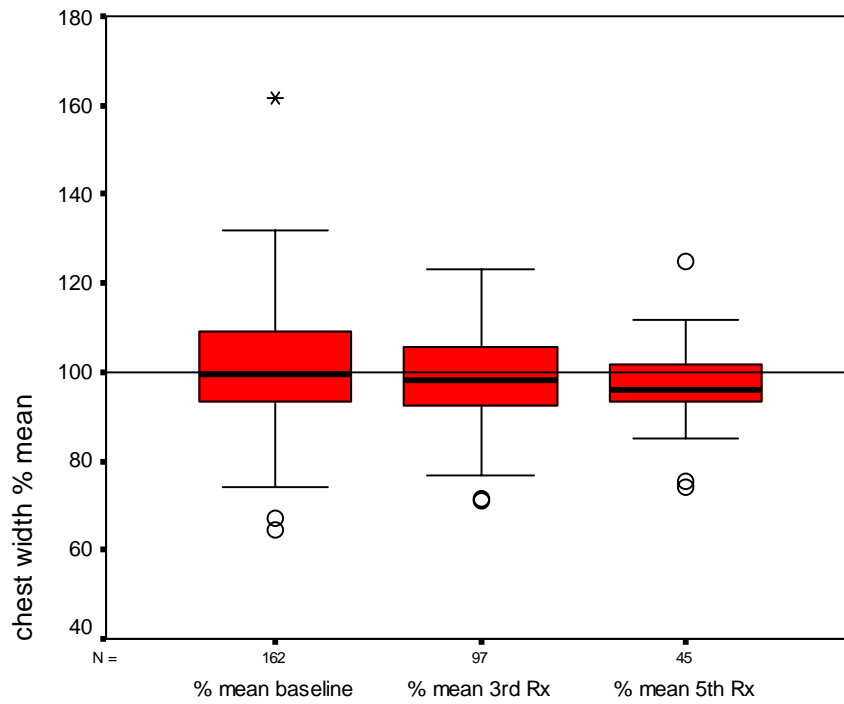
Figure 7.1 shoulder width at baseline 3rd & 5th



There were 192 valid cases and 19 missing at baseline, 104 valid and 107 missing at third treatment and 51 valid and 160 missing at fifth treatment. The children's measurements over the study period moved towards the norms for their age, this change was statistically significant.

7.2 Chest width armpit

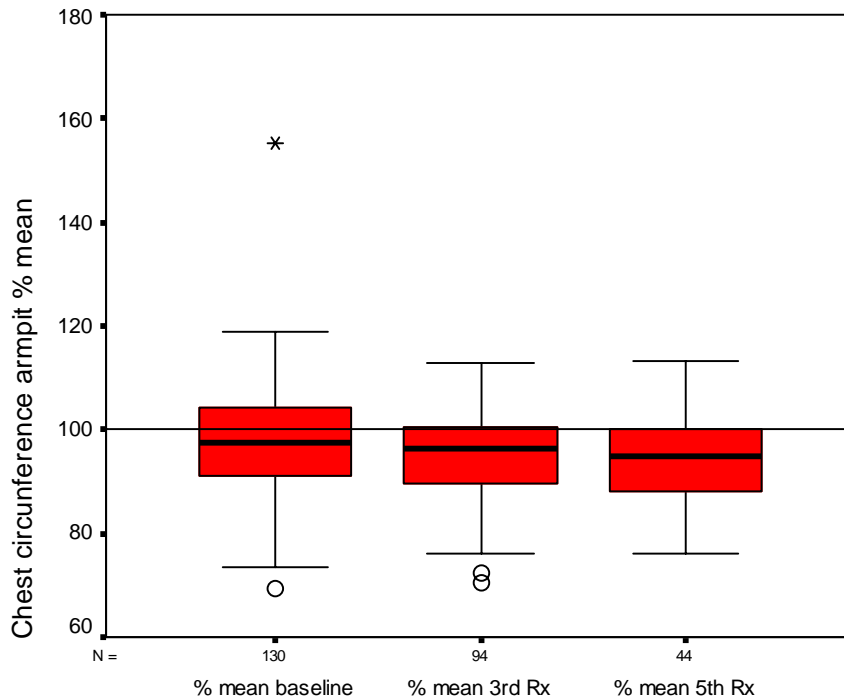
Figure 7.2 chest width at baseline, 3rd & 5th



There were 162 valid cases and 49 missing at baseline, 97 valid cases at third treatment and 45 valid at fifth treatment. The width of the chest at the armpit decreases over time and is statistically significant.

7.3 Chest circumference armpit

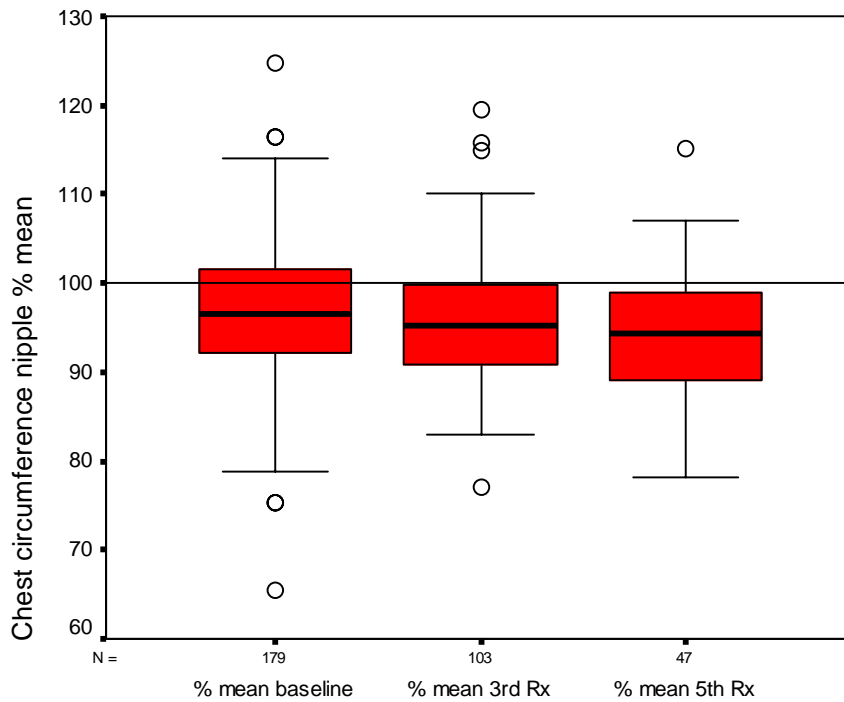
Figure 7.3 chest circumference armpit baseline, 3rd & 5th treatment



There were 130 valid cases and 81 missing at baseline. The numbers of missing is due to there being no normative data for children under two years of age. There were 94 valid cases at the third treatment and 44 at the fifth. There is a fall in the chest circumference at armpit measurement but it is not significant and is suggestive of normal development.

7.4 Chest circumference nipple

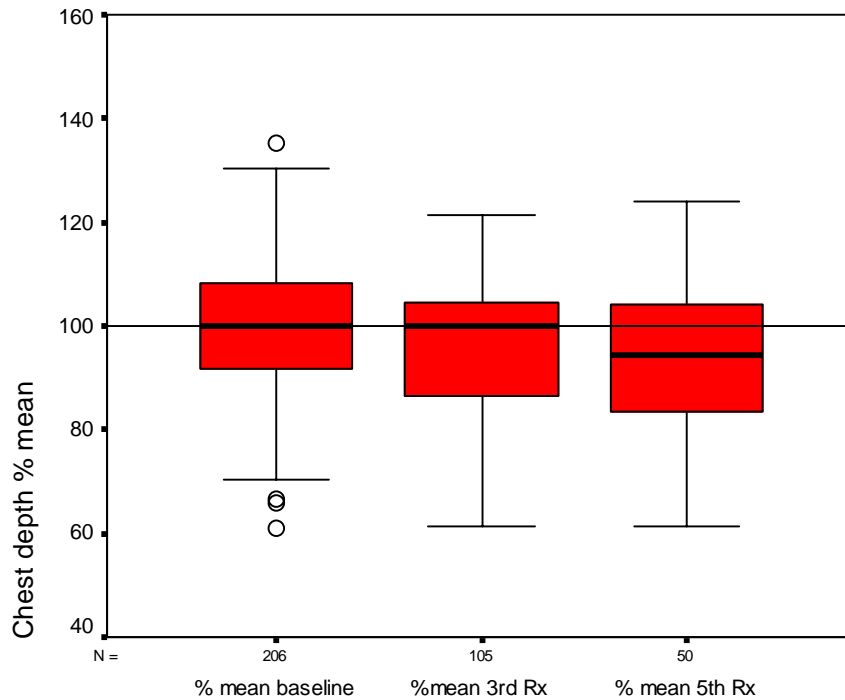
Figure 7.4 chest circumference nipple baseline, 3rd & 5th treatment



There were 179 valid cases and 32 missing at baseline, 103 valid cases at the third treatment and 47 valid at the fifth. There is a downward trend over time but the majority of children remain grouped around the average value which is suggestive of a normal development pattern.

7.5 Chest depth

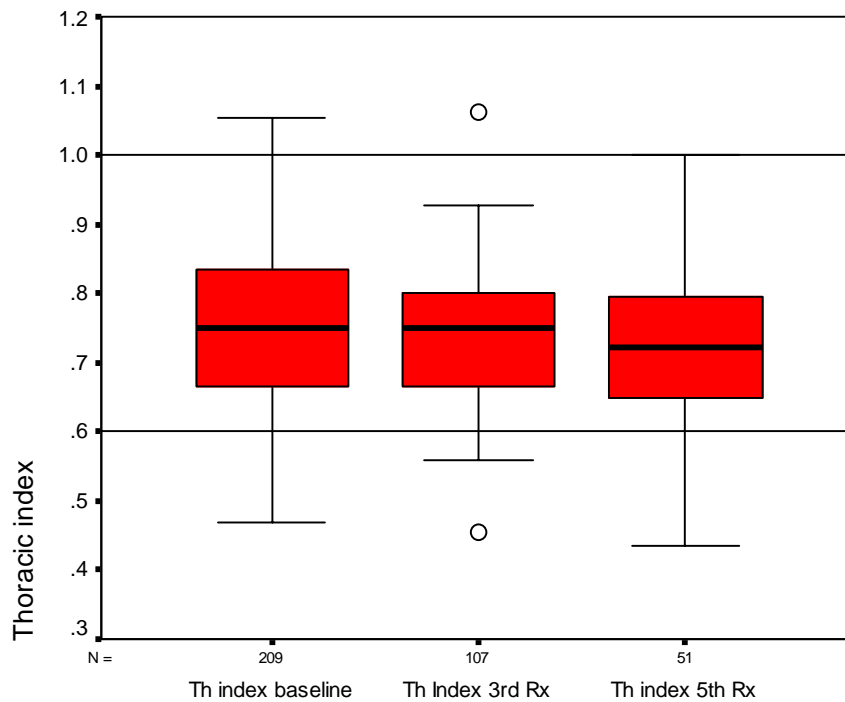
Figure 7.5 chest depth baseline, 3rd & 5th treatment



There were 206 valid cases and 5 missing baseline, 105 valid cases at the third treatment and 50 valid at the fifth. The chest depth over time increases with age and remains clustered around the average measurement.

7.6 Thoracic index

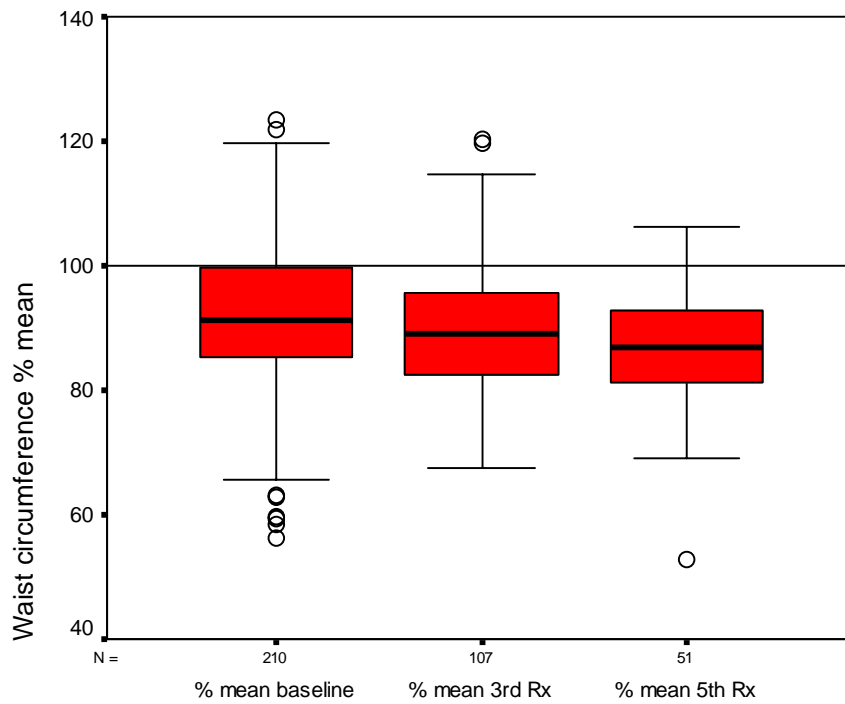
Figure 7.6 thoracic index at baseline, 3rd & 5th treatment.



There were 209 valid cases and 2 missing at baseline, 107 valid cases at the third treatment and 51 valid at the fifth. There is very little change over time with the measurements remaining within normal limits. The reference lines on the box plot shows 1 as a score that would indicate a more circular chest and 0.6 as a more mature ovoid chest shape. The majority of children are within the reference lines.

7.7 Waist circumference

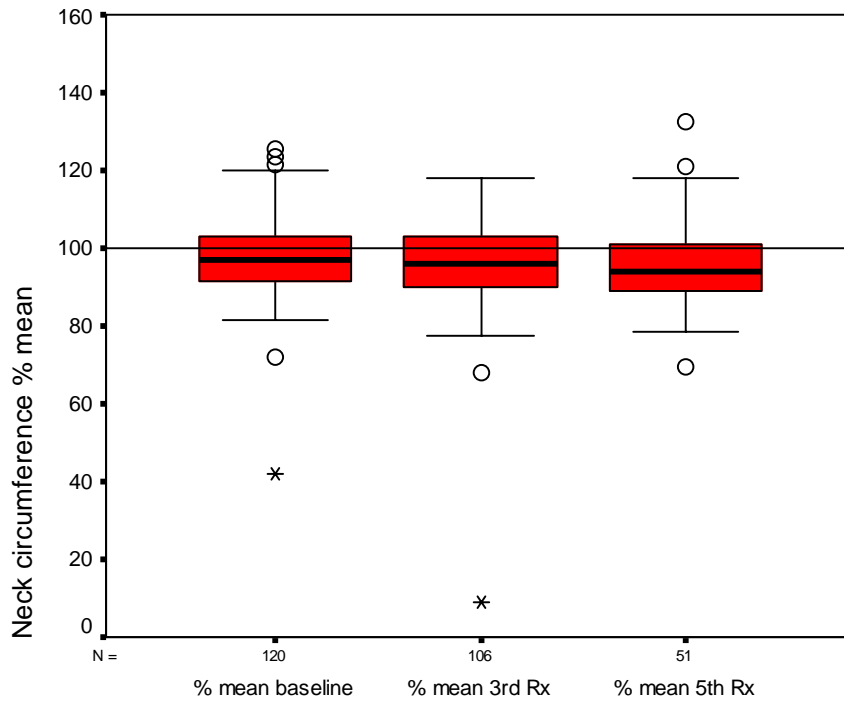
Figure 7.7 waist circumference at baseline, 3rd & 5th treatment.



There were 210 valid cases and 1 missing at baseline, 107 valid cases at the third treatment and 51 valid at the fifth. The children start smaller than average and continue to get smaller.

7.8 Neck circumference

Figure 7.8 neck circumference at baseline, 3rd & 5th treatment.



There were 120 valid cases and 91 missing at baseline, 106 valid cases at the third treatment and 51 valid at the fifth. The children remain clustered around an average measurement although there is a decrease in neck circumference over the time.

7.9 Postural Assessment Scale

Table 7.1 PAS 3rd & 5th

	PAS baseline	PAS 3 rd Rx	PAS 5 th Rx
N Valid	156	89	43
Mean	9.47	9.75	9.95
Mode	10.00	11.00	10.00
Minimum	.00	.00	4.00
Maximum	15.00	14.00	14.00

There is little change to the PAS over time with the mode remaining the same.

7.10 Peak flow

Table 7.2 shows little difference between the scores over time. The minimum and maximum rise over time.

Table 7.2 peak flow 3rd & 5th

Peak Flow (ml per sec)	Mean	Minimum	Maximum
	Baseline		

n=20	105	10	245
3 rd Rx			
n=21	153	30	420
5 th Rx			
n=11	110	30	320

7.11 Breathing Narratives

Table 7.3 breathing narratives at 3rd treatment

	Breath holding	Primarily upper chest breathing
Present	11 5.20%	15 7.10%
Absent	93 44.10%	88 41.70%
	Mouth breathing	Irregular rhythm
Present	62 29.40%	72 34.10%
Absent	42 19.90%	32 15.20%
	Lat rot upper arms	Primarily abdominal breathing
Present	48 22.70%	92 43.60%

Absent	56	26.50%	12	5.70%
	Paradoxical breathing		Hyperinflation	
Present	9	4.30%	35	16.60%
Absent	95	45.00%	69	32.70%

Missing n = 107 50.70%

7.12 Breathing narrative

Table 7.4 breathing narratives at 5th treatment

	Breath holding		Primarily upper chest breathing	
Present	0	0.00%	2	0.90%
Absent	51	75.80%	49	23.20%
	Mouth breathing		Irregular rhythm	
Present	31	14.70%	24	11.40%
Absent	20	9.50%	27	12.80%
	Lat rot upper arms		Primarily abdominal breathing	
Present	20	9.50%	49	23.20%
Absent	31	14.70%	2	0.90%
	Paradoxical breathing		Hyperinflation	
Present	0	0.00%	9	4.30%
Absent	51	24.20%	42	19.90%
Missing	n = 160	75.80%		

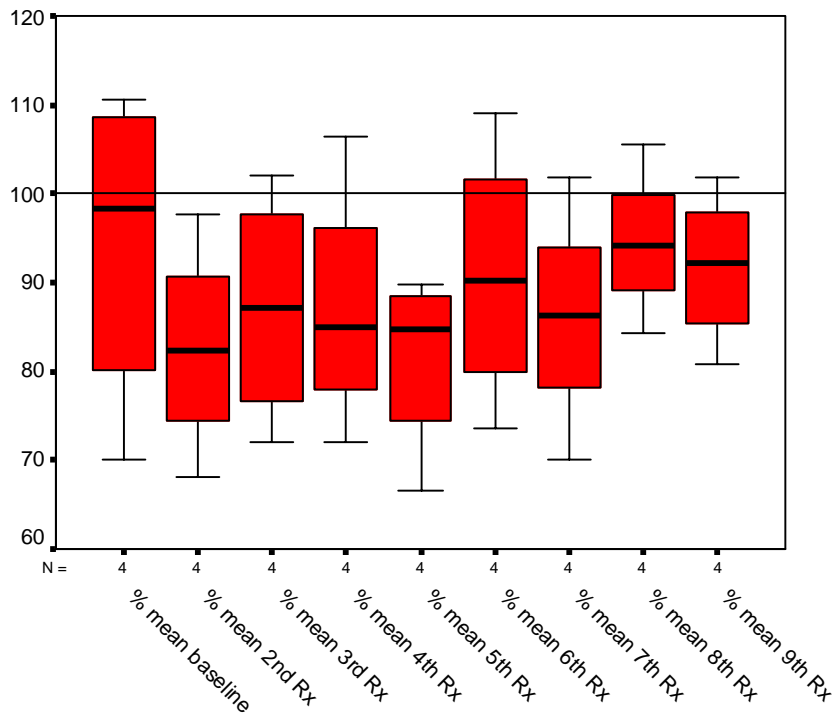
Tables 7.3 and 7.4 show the breathing narrative for the third and fifth treatments. The elements such as breath holding and paradoxical breathing that are seen as undesirable elements of respiration decrease in incidence over time.

8 Outcomes for the five children that had nine treatments.

Only five children completed nine treatments in the study time.

8.1 Shoulder width

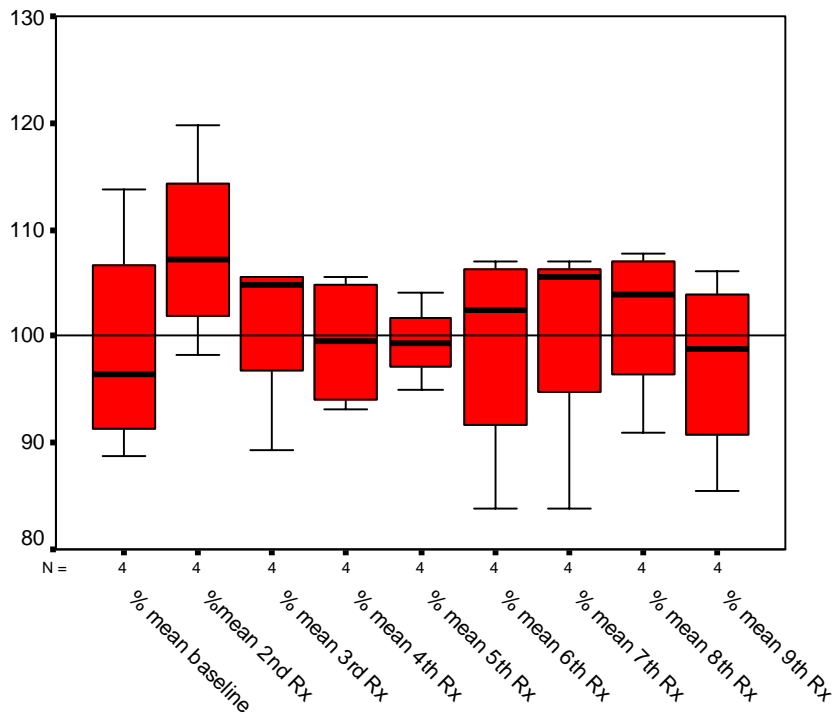
Figure 8.1 shoulder width subgroup 5



The subgroup of nine children follows a similar pattern to the main group with some over time changes but a general clustering around the average values for shoulder width.

8.2 Chest width

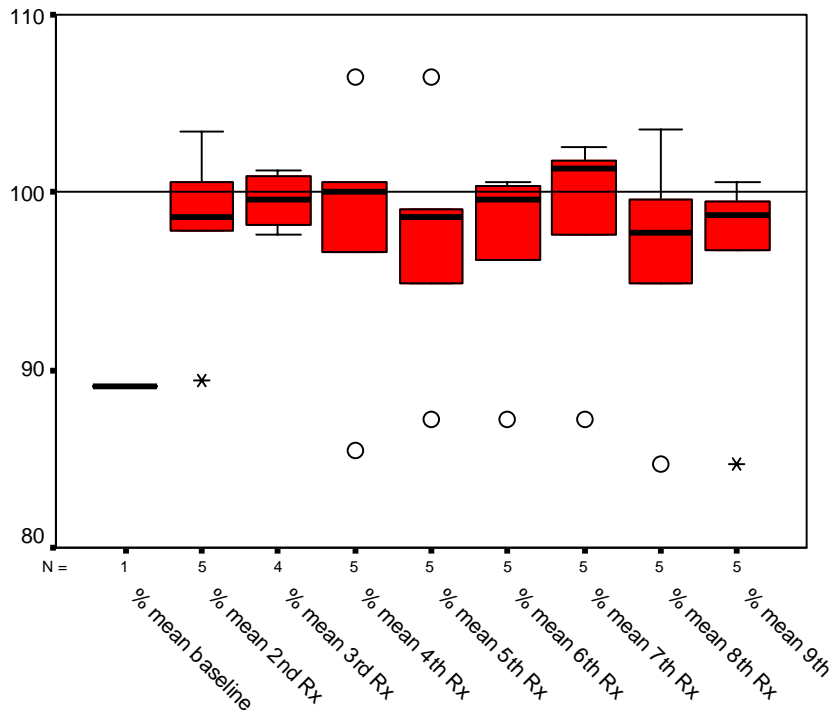
Figure 8.2 chest width subgroup 5



The subgroup of nine children remains grouped around the average chest width measurement for their age.

8.3 Chest circumference armpit

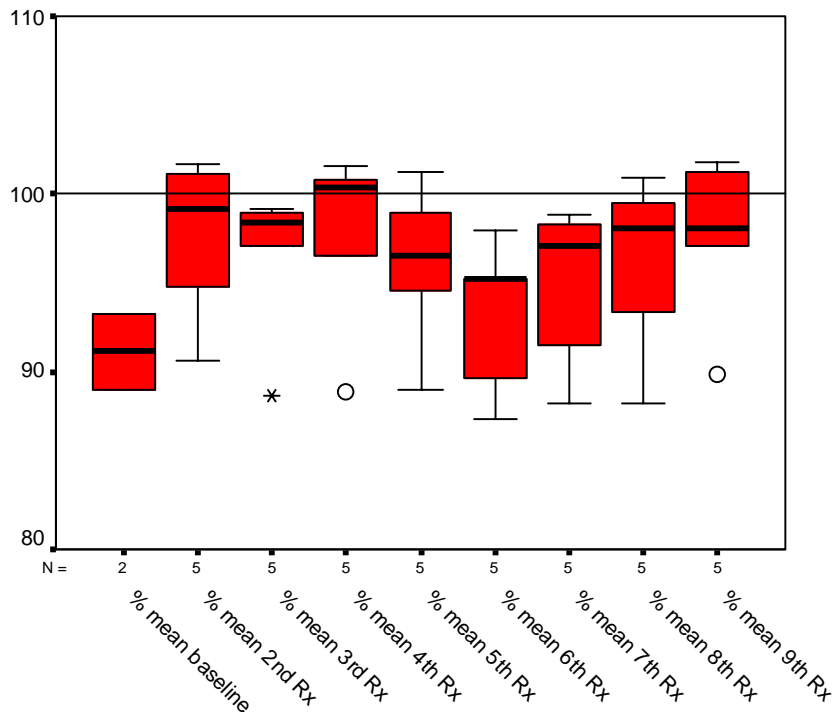
Figure 8.3 chest circumference armpit subgroup 5



The subgroup of five shows little change over the time when looking at chest circumference at armpit with the majority being clustered around the average measurement for their age.

8.4 Chest circumference nipple

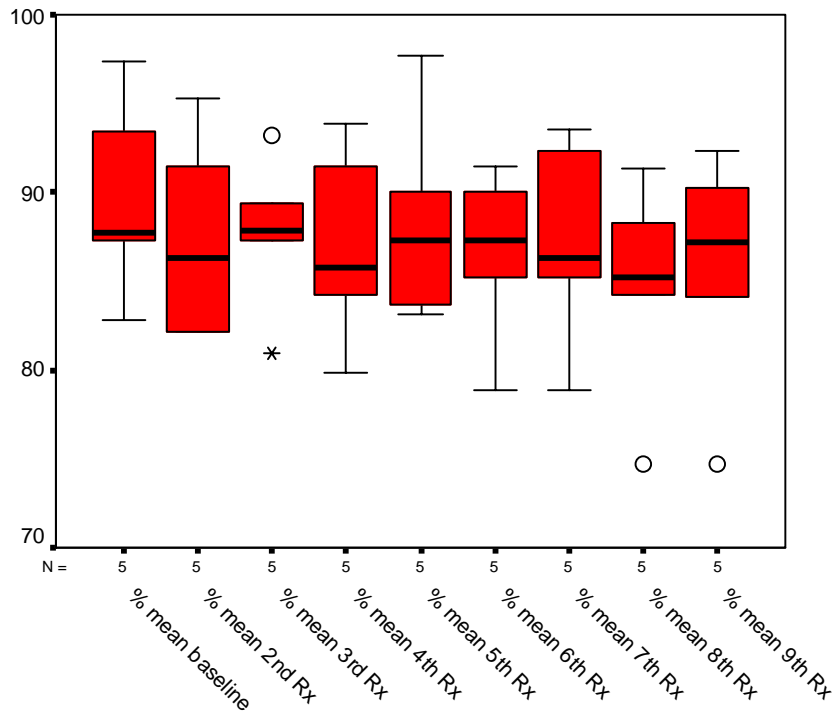
Figure 8.4 chest circumference nipple subgroup 5



The subgroup is slightly below average measurement for their age and displays some variation over time.

8.5 Waist circumference

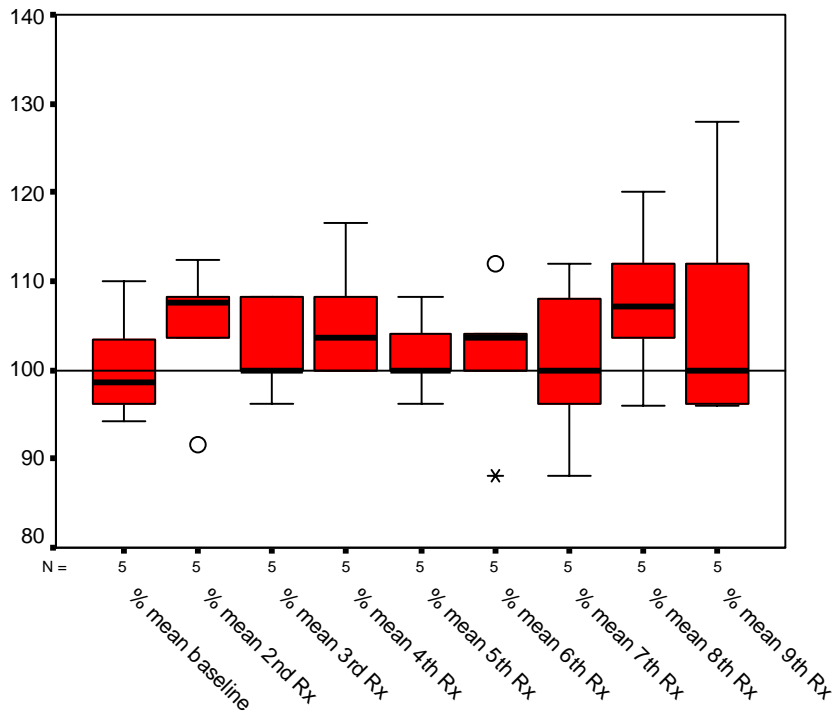
Figure 8.5 waist circumference subgroup 5



As with the main group, the subgroup starts below average and remains so.

8.6 Chest depth

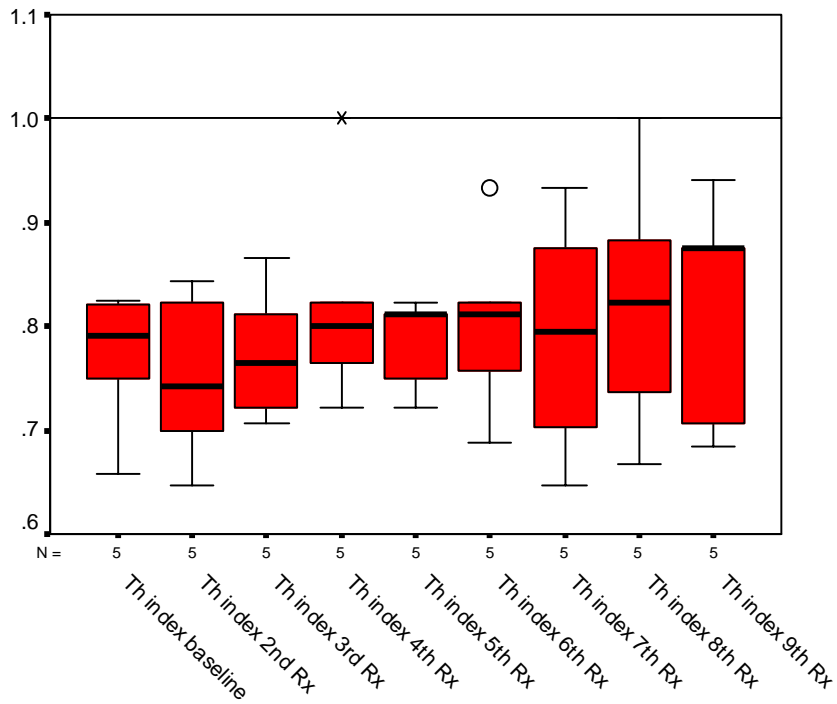
Figure 8.6 chest depth subgroup 5



The subgroup starts off slightly above average for their age and remains so over time.

8.7 Thoracic index

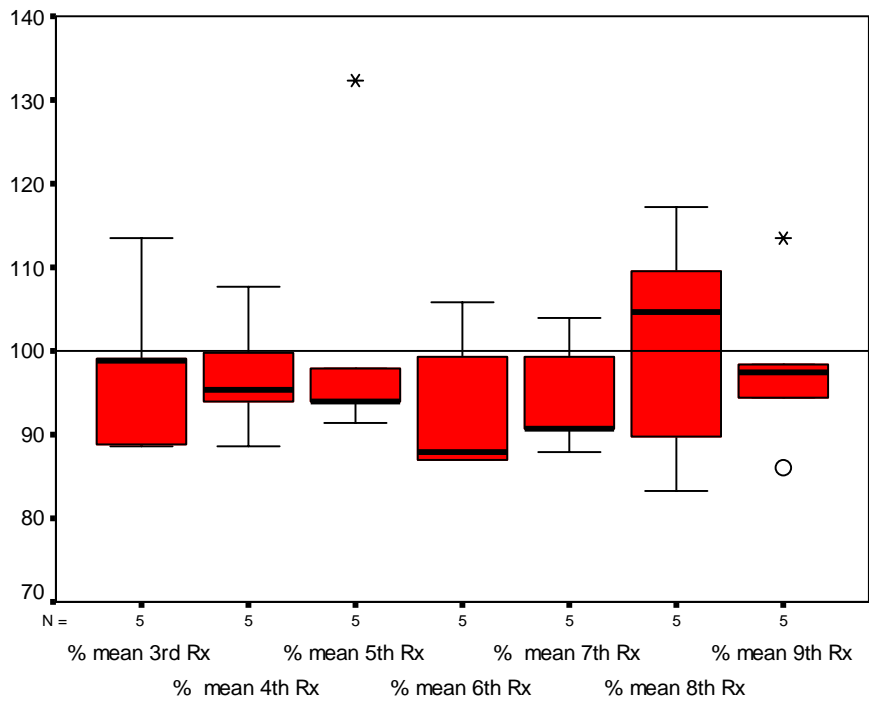
Figure 8.7 thoracic index subgroup 5



The children remain within normal limits over the time they were observed.

8.8 Neck circumference

Figure 8.8 neck circumference subgroup 5

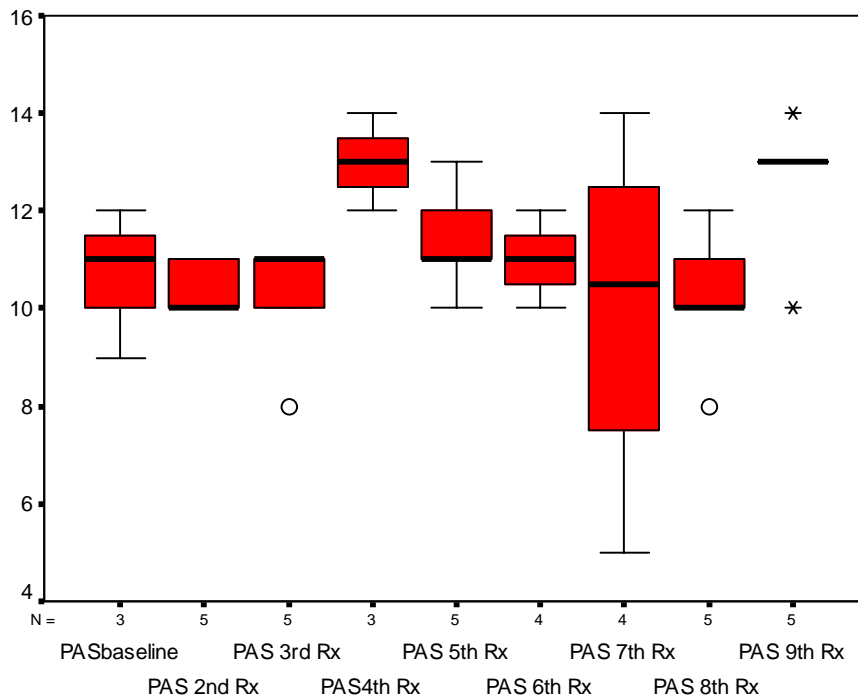


The children are clustered around normal values with little change over time.

There are no values for this group at baseline and second treatment.

8.9 Postural assessment scale

Figure 8.9 PAS subgroup 5



The children show little change over time except for the seventh treatment. This reading would suggest some problem with the collection of this data at this point. Table 8.1 shows the mean scores for the subgroup across all nine treatments. The mean score rises over time as does the minimum and maximum scores.

Table 8.1 PAS subgroup of 5

	PAS baseline	PAS 2ndRx	PAS 3rdRx	PAS 4th Rx	PAS 5th Rx
Mean	10.6	10.4	10.2	13	11.4
Mode	9	10	11	12	11
Minimum	9	10	8	12	10
Maximum	12	11	11	14	13
	PAS 6th Rx	PAS 7th Rx	PAS 8th Rx	PAS 9th Rx	
Mean	11	10	10.2	12.6	
Mode	11	5	10	13	
Minimum	10	5	8	10	
Maximum	12	14	12	14	

8.10 Breathing Narratives

Table 8.2 breathing narrative subgroup of 5

N = 5

Treatment	Breath holding	Mouth breathing	Primarily upper chest br	Irregular rhythm
baseline	3	4	5	4
2nd	3	4	5	4
3rd	5	3	5	2
4th	5	3	5	2
5th	5	4	5	5
6th	5	4	5	1
7th	5	4	5	2
8th	5	4	5	1
9th	5	3	5	1
Treatment	Lat rot upper arms	Primarily abdominal breathing	Paradoxical breathing	Hyper - inflation
baseline	2	5	1	3
2nd	4	5	5	1
3rd	1	5	5	1
4th	1	5	5	1
5th	2	5	5	1

6th	2	5	5	1
7th	3	5	5	2
8th	4	5	5	2
9th	4	5	5	1

Table 8.2 shows that unlike the main group the subgroup changed their breathing patterns very little over the study period.

9 Analysis with the STATA software

All the data was then analysed using STATA version 8.2(Stata Corp 2001. Stata statistical software: Release 8.2 College Station, TX). The data were cleaned removing any codes for missing data, then only specific variables were analysed considerably reducing the data base. The specific variables were chosen because they had percentage normative mean for age calculated or that they were of particular interest to Advance.

Table 9.1 variables chosen for STATA analysis

Variables	Variables
Identity Code	Chest circumference nipple % mean for age
Age	Waist circumference
Gender	% mean for age

Shoulder width % mean for age	Chest depth % mean for age
Chest width % mean for age	Neck circumference % mean for age
Chest circumference armpit % mean for age	Thoracic Index

For all the above outcome variables, a repeated measures linear regression model was used. Rather than treatment episode which, could vary from child to child, the number of months since baseline were chosen as a predictor. In addition the child's age at commencement of treatment was also used as a predictor of the outcome in the model. Where either of these elements was significant, an interaction between the elements was investigated.

9.1 Shoulder width

There was a statistically significant increase in shoulder width for each month of treatment ($P < 0.001$). The rate of increase is less in children who are older at the commencement of treatment. This is be indicative of normal maturation but the continued increase in shoulder width at an older age is statistically significant ($P < 0.001$). This could indicate that the treatment has some effect whatever the age.

9.2 Chest width at armpit

There is a statistically significant decrease in the chest width at the armpit for each month of treatment ($P < 0.001$). The rate of change in the older children is slightly greater than for shoulder width ($P = 0.002$). This again could indicate an effect other than maturation and is worth further exploration

9.3 Chest circumference at armpit (percentage mean for age).

The mean value for the children was slightly greater than the norm. The fall per month of treatment is not significant ($P = 0.289$) and the children who were older at commencement of treatment were closer to the norm for their age. This indicative of normal maturation.

9.4 Chest circumference at nipple (percentage mean for age).

The children start on average with a measurement slightly below the norm and remain so throughout the treatment period. Neither age at commencement of treatment, time since baseline measurements nor their interaction were significant ($P = 0.32$ for the model).

9.5 Chest depth (percentage mean for age).

On average the children commence with a chest depth greater than the norm for their age. There is a move towards normal over the months of treatment but this is borderline significant ($P=0.057$). The initial difference between chest depth and the normative value for their age is smaller as the age at commencement of treatment rises.

9.6 Thoracic index

The mean value for the sample was slightly greater than the norm. The fall per month of treatment although not significant ($P = 0.805$) shows a movement towards the norm. The age of commencement of treatment was significant ($P<0.001$) indicating that the rate of change was greater for older children. This could be an area worth investigating further.

9.7 Waist circumference (percentage mean for age).

The children commence with a waist circumference lower than the norm for their age and this moves progressively further away from the norm for each month of treatment. Also the older the child at the commencement of treatment the further away from the norm they are. All these elements were statistically significant ($P=0.001$). This was unexpected and needs exploration.

9.8 Neck circumference

Neither age at commencement of treatment, months since baseline measurement or their interaction were significant ($P=0.79$ for the model).

9.9 Neck circumference (percentage mean for age).

The mean value for the children was slightly larger than normal neck circumference at baseline. This decreased each month of treatment and was statistically significant ($P=0.036$). It must be noted that although the P value is statistically significant is not necessarily clinically significant as the differences are very small and could potentially be due to measurement error. This rate of reduction was independent of the age at commencement of treatment (test of interaction $P=0.71$). This shows that change occurred over the time when the children were receiving treatment.

10 Discussion

10.1 Introduction

This was an exploratory study of the Scotson technique provided for children with neurological damage at the charity Advance, East Grinstead. This is a therapy offered outside the governmentally provided healthcare system. To be potentially incorporated within this system, Advance felt it was necessary to; establish an evidence base for the therapy provided, to comprehensively explain the package that constituted the technique and to explore the possible effects. This theoretical modelling phase (MRC, 2000) was essential to move the Scotson technique from a collection of abstract ideas and feelings to a potential concrete intervention that could be subjected to a robust trial in the future.

The study followed the early phases of the structure proposed by the Medical Research Council (2000) as being appropriate for the evaluation of complex interventions. Normative data (DTI, 1995) was used to illustrate variations from the norm within the study population and to track change in line with normal development. It is a descriptive study using a clinical population within the centre established to provide this innovative therapy. The staff is experienced in the delivery of the Scotson technique. The researcher is an independent academic situated at a geographical distance from the charity. There were no exclusion criteria, so all children attending Advance during the study period were eligible for inclusion.

10.2 Strengths and weaknesses of the study

Families self-referred to the intervention and paid through private funds as they believed the therapy would be beneficial. Therefore the population was a self-selecting group. The measurements were carried out by centre staff with limited research experience and who were already convinced of the benefits of the technique. This situation could possibly have influenced the results. However the staff did not know what a positive outcome measurement for the individual should be, as in some cases an increase was positive and in others a decrease. Another weakness was the incompleteness of the video data. Some of the video recordings for the children were not taken, this was sometimes due to the child being too young or being unsettled or unwell. Other reasons are the competing pressures of running both a therapeutic training course and a research study at the same time. The majority of video recordings were eventually located at Advance but this took considerable time.

10.3 Shoulder width

At baseline the majority of children had a shoulder width just below the measurement classed as the 'normal' when calculated as a percentage of the normative mean for age. This increased with age as expected. The older the child at commencement of treatment the slower the increase, this is

probably indicative of a steeper rise in the younger children which levels off with maturity. The age on commencement of treatment and the number of treatments is statistically significant ($P < 0.001$), so although the improvement is slower in older children it is still moving towards a more normal value. Future investigation is recommended in this area.

10.4 Chest width at armpit

At baseline this measurement was slightly larger than normal. There is a statistically significant decrease in the chest width for each month of treatment. This result is unusual as it may have been expected that the children's chest width being smaller would increase with maturity. Reduction in chest width could be seen as a positive outcome. It could be linked to the altered shape of the children's chest. Advance and other authors (Alexander et al, 1993, Massery, 1991, Massery, 2005) have cited children with neurological damage as often having a wide flattened chest or hyperinflated 'barrel' chest. This is seen in 47.9% (101/211) of the children at Advance. The rate of change when looking at the age at commencement of treatment is slightly greater than the change in shoulder width. All these points indicate that further exploration could be useful in the future.

10.5 Chest circumference at armpit

The children start on average with a slightly greater than normal measurement. This does reduce over time but this is not significant. In addition the older they are at commencement of treatment the closer the measurement is to the norm. The results would seem to indicate that the children are following a normal pattern of maturation.

10.6 Chest circumference at nipple

The results were not statistically significant indicating that there was little change with the majority of children being clustered around the average value for their age. This suggests a normal pattern of development.

10.7 Chest depth

At baseline the children start with chest depth measurements slightly smaller than the norm, these increase with age. There is some interaction between the age at commencement of treatment and the rate of increase in chest depth. This suggests that there is more change when the children are younger and less as they mature. This is indicative of a normal pattern of maturation and shows that the children attending Advance continue to develop normally in this area.

10.8 Thoracic index

The mean baseline thoracic index for the children was slightly greater than the norm. Advance expected that the children would have immature chest biomechanics and this would be reflected in the thoracic index. An immature chest shape is circular usually seen in children up to two years of age (Warwick and Hansen, 1976, Scammon, 1927, Howatt and DeMuth, 1962). After this age the chest shape should become more ovoid (Openshaw et al, 1984, De Groote et al, 2000). A circular chest would have a thoracic index closer to one and an ovoid nearer to 0.6. There is not a strong indication that the thoracic index moves towards the more adult reading of between 0.8 – 0.6 (Howatt and DeMuth, 1962, Openshaw, et al, 1984, Scammon, 1927) when analysed in relation to the number of months of treatment. It does change linearly with age and is statistically significant. It was expected that the younger children (under two years of age) would change more quickly, (Scammon, 1927, (Openshaw, et al, 1984). In fact the children regardless of age on commencement of treatment changed with a gradual linear fall, this could indicate the process of maturation but equally as the change is gradual even in the younger children it could be suggested that the change is something other than maturation. This area warrants further exploration. The original idea about the retention of an immature chest was not necessarily incorrect but the levels at which the measurements were taken needs to be clarified.

10.9 Waist circumference

At baseline the children are lower than the norm. Advance expected that this would be the case as the abdominals are assumed to be underdeveloped. The distance from the norm is also more evident in the older children. Advance predicted that there would be an initial small rise in the waist circumference followed by a decrease. This they argue is due to the rib cage became more separated from the pelvis with an increase in intra abdominal pressure which is said to be achieved by the purported improved breathing.(Scotson, 2005b). This measurement gets progressively further away from the norm for each month of treatment and is statistically significant. This could be reflecting a biomechanical change that is necessary before improvement can take place but nothing conclusive can be stated at this time. Research into core stability training has reported a decrease in waist size following specific exercises (Hodges and Richardson, 1996, Hodges, et al, 2001, Mottram and Comerford, 1998, O'Sullivan, et al, 1997, Panjabi, 1992). This is a measurement which needs further analysis.

10.10 Neck circumference

At baseline the measurements for the children were slightly larger than the norm. This decreased by a small amount each month after treatment had commenced regardless of age. This is significant statistically and clinically. Advance state that prior to receiving the Scotson technique therapy the children develop larger necks as the accessory muscles that tend to be

recruited in compensation for a weak diaphragm are in the neck area and tend to be overdeveloped (Scotson, 2005b, Massery, 1991, Massery, 2005). Further examination would be appropriate.

10.11 Postural assessment scale (PAS)

This is a subjective score and was carried out by one assessor from the video recordings. The first scoring was carried out in December 2004 and repeated in April 2005. There were some discrepancies but generally the scores remained the same. There are concerns about the validity of the PAS as the quality of the videos occasionally made it difficult to make confident judgements. The range of scores was from zero to 15. At baseline the mean score was 9.47 out of a possible 15 with the mode being 10. Anecdotally the parents reported to Advance that they felt the children's sitting posture improved. At the third and fifth treatments, despite the anecdotal evidence, the results remained very similar. The mean rose slightly over time from 10.6 to 11.4 and the minimum value rose from zero to four. This may mean that the assessment is not sensitive enough or that there is a mismatch between perceived and actual improvement.

10.12 Peak expiratory flow

The inclusion of a peak expiratory flow measurement aimed to evaluate whether the Scotson technique improved the function of the respiratory

system. A vitalograph although easy to use was not particularly reliable and a Wright Peak™ flow meter (Ferraris medical Ltd) considered more reliable (Desmond, et al, 1997, Eigen, et al, 2001). There were problems associated with obtaining this information:

1. Wright Peak™ flow meter was very big for children to use.
2. Normative data was only available from five year to 15 (Godfrey, et al, 1970). The child had to be a minimum of 100cm and a maximum of 190cm in height
3. Some children were unable to blow whatever their age.
4. The measure was one of ability to use the equipment not necessarily a measure of forced expiratory volume. A training period is usually recommended (Eigen, et al, 2001, Lara- Perez, 2001, Quanjer, et al, 1997). It was not possible to do an extensive training period with the children, so the reading was taken as the best of three and adequate rest given in between.

A progression could potentially show that some children could improve their technique and it is possible that this improvement was in part due to the Scotson technique. Only 20 of the 211 children in the sample managed to register a peak flow reading at baseline. Although the minimum reading improved by the fifth treatment the maximum reading did not. It is concluded that there is insufficient data to make an assessment and any comment would be speculative. Other element to be collected in future studies would

be the number of children who had needed respiratory support in their early years and how many chest infections they had had over the last 12 months.

10.13 Breathing narratives

The data for the breathing narratives is not complete as some of the videos were missing, some children were distressed during filming or the video recording is of poor quality.

It was thought by Advance that the majority of the children would present with some breathing pattern irregularities. At baseline it can be seen that just less than 40% (82/211) of children were exhibiting breath holding which could be indicative of a need to rest a fatigued diaphragm. The upper chest and paradoxical breathing was seen in less than 20% (41/211) of the children Advance thought that more children would exhibit these patterns due to immature chest biomechanics. A large proportion of children used mouth breathing (133/211) and exhibited irregular rhythm (159/211). Nearly half the children presented with lateral rotation of the upper arms (91/211) and hyperinflation (101/211). Lateral rotation of the arms can lead to lumbar extension and elevation of the rib cage especially if the spine lacks mobility. This would perhaps make the work of breathing less but also increase the appearance of a hyperinflated chest. This may have altered the thoracic index. A large number of children (76.8% - 162/211) presented with the more normal pattern of abdominal breathing.

All the elements within the breathing narratives improved over the period of time to the fifth treatment. Lateral rotation of the upper arms remained a relatively strong element of the breathing pattern (20/52) and abdominal breathing continued to be the major breathing pattern (49/52).

The baseline breathing narratives could have a high percentage of abnormal features because this was the first time the children had been videoed and there may be elements of anxiety involved which could have contributed to an abnormal breathing pattern. By the fifth treatment the majority, who were video recorded, may have become less anxious about the process.

The breathing narratives were very subjective and did not constitute a reliable or valid measure. However they were useful in starting the process of identifying particular elements of the children's breathing patterns and may help Advance to focus on the areas of importance for future studies.

10.14 Subgroup analysis – children that had received nine treatments

These children were aged between two and five years and four out of the five had a diagnosis of some form of cerebral palsy. The fifth child had a diagnosis of global developmental delay.

Throughout the study these children largely followed the patterns of the larger group, with its patterns of normal maturation except in the area of waist circumference. Another exception was the postural assessment scale. The score for this group at treatment g needs to be questioned as it does not follow the general pattern. However there is insufficient information to make

anything but speculative comments about this. The breathing narratives show little change throughout the nine treatments and many of the proposed abnormal features remain or in fact increase. However, the breathing appears to become more regular.

10.15 Additional issues

10.15.1 Sample size

A formal sample size calculation was not appropriate for this type of exploratory study. The study was carried out between November 2002 and the end of September 2004. A total of 211 children were recruited into the study and had a baseline treatment. A number of points about the sample size are addressed.

- Children were recruited throughout the study period; therefore, potentially some of the 211 could have been recruited in the last week of data collection.
- The gaps between the treatments were not uniform and in some cases the gap between was as much as 12 months.

10.15.2 Heterogeneity

The study group was not homogeneous and this is often a criticism of studies in this field (Adams, et al, 2000, Bower and McLellan, 1994, Bower, et al, 2001, Brown and Burns, 2001). This is accepted as a problem. The

sample has a diverse age range from four months to 25 years. The gender mix is approximately a 3:1 male to female. This is fairly typical gender split in children with neurological conditions (Herder, 1998, Hutton, et al, 2000).

10.15.3 Diagnosis

The majority of children in the sample had a diagnosis of cerebral palsy 80.1% (172/211). This is a reflection of a normal distribution within a population of children with neurological damage, as cerebral palsy is one of the more common conditions (Bax and Brown, 2004, Rosenbaum, 2003a). The diagnosis of cerebral palsy brings its own problems. Cerebral palsy is 'an umbrella term covering a group of non-progressive but often changing, motor impairment syndromes secondary to lesions or anomalies of the brain arising in the early stages of its development' (Bax, 1964, MacKeith, et al, 1959, Mutch, et al, 1992, p.547). Rather than note a blanket term of cerebral palsy it was hoped that a more specific diagnosis could be recorded using the Survey of Cerebral Palsy in Europe document (appendix 7) (SCPE, 2000). Unfortunately this proved difficult as many families had not been given such a specific diagnosis and the recorders were not skilled enough to make that clinical decision. It would be easy to dismiss this due to the reliance on lay people for diagnostic information but this problem is not isolated to the lay population. Many doctors are reluctant to specifically label a child and recording is not uniform from area to area, or country to country (Blair and Stanley, 1997, O'Shea, 2002, Paneth, et al, 2003).

10.15.4 Nationality

The children were from a number of countries. The majority of children were British (158/211 -74.9%) but there was a sizable representation from France (25/211–11.8%) and Norway (6/211-2.8%). This is not a typical representation of a population treated with a National Health Service therapy but reflects how that population differs when the therapy under evaluated is private with a self referral system.

10.15.5 Hyperbaric oxygen

The charity Advance was originally the Hyperbaric Oxygen Trust and so this element remains a part of the Scotson technique. The majority of children receive hyperbaric oxygen as part of their treatment package but a third did not. Hyperbaric oxygen is a technique whereby 100% oxygen is delivered to the body's tissues under increased atmospheric pressure. It is usually used for the treatment of carbon monoxide poisoning and decompression illness in divers. Its inclusion in the treatment package for children with cerebral palsy could be due to the belief that cerebral palsy, and similar neurological conditions, are largely caused by a lack of oxygen to the developing brain. Oxygen lack is a cause in approximately 10% (Blair and Stanley, 1997). The theory is that with low levels of oxygen the brain receives enough oxygen for survival but not for function. Advance subscribe to this theory as they claim

that the children attending the centre potentially have compromised respiratory systems with possibly low levels of oxygen.

The guidelines for the ethical use and application of hyperbaric oxygen therapy (HBOT) are set down by the Undersea and Hyperbaric Medical Society (UHMS, 2003) an international professional organisation. Based on research evidence and experience, 13 specific medical conditions are approved for treatment with HBOT and cerebral palsy is not one of them (Rosenbaum, et al, 2001). In a large randomised, placebo-controlled trial with HBOT for children with cerebral palsy there was no difference between either group, although both improved (Collet, et al, 2001). A similar study with children with cerebral palsy by Hardy et al (2002) showed similar results. In both studies it was accepted that the improvement, which could be the placebo effect, is worth investigating further (Hardy, et al, 2002, Collet, et al, 2001, ahrq, 2003, Koman, et al, 2004, Rosenbaum, et al, 2001). Certainly champions of HBOT advocate the use of single photon emission computerised tomography (SPECT) to show how HBOT appears to increase blood flow in the brain (Neubauer, 2001). There are side effects with HBOT such as, rupture of the eardrum and potential lung problems but they have not been major problems in adult studies (Rosenbaum, et al, 2001, Collet, et al, 2001). The evidence indicates that until further research is done the proof for HBOT is inconclusive.

10.15.6 Concurrent therapies

The majority of children in the study were having other therapies in conjunction with the Scotson technique. The main therapy was physiotherapy (121/211 – 57.4%). Only 8.5% (18) children were having the Scotson technique alone. 23.2% of children (49) did not have anything recorded in the 'other therapies' box, it could be presumed that this was an indication that they were only having the Scotson technique. The range of concurrent therapies was large and many would be classed as alternative or complementary in the House of Lords (2000a) paper on science and technology.

10.15.7 Supplementary feeding support

A perception amongst the staff at Advance was that a large number of children attending the centre would be receiving supplementary feeding support in the form of a nasogastric tube or a percutaneous endoscopic gastrostomy (PEG). Children with neurological damage may have poor nutrition and can fail to thrive. In addition feeding and eating can bring the risk of aspiration if a child has a reduced gag reflex (Henderson, et al, 2002, Kong, et al, 1999, Kumode, et al, 2003, Rogers, 2004). However, only 11 out of 211 children had supplementary feeding support in place.

11 Conclusion

The results show that even at baseline many of the children have only slight deviation from the expected physical measurements with very few falling outside the 5th or 95th percentile. These slight deviations are repeated throughout many of the children's physical measurements and when combined could potentially contribute to the child's overall physical, functional and social difficulties. The results show some areas of statistical significance which warrant further investigation these namely being: shoulder width, chest width, thoracic index and neck circumference and waist circumference. In the areas where there was no statistically significant difference there was still change in a positive direction demonstrating that maturation continued. A cautious interpretation of the data suggests that some beneficial changes occur with the Scotson technique in the areas explored in this study. Further research needs to focus in on these areas and comparisons need to be made with other similar physical therapies.

12 Recommendations

It is recommended that Advance carries out a matched, minimised comparative trial, to compare the Scotson technique with a similar treatment therapy.

12.1 The questions

1. Does the Scotson technique cause physical changes in shoulder width, chest width at armpit, chest circumference at the level of the 10th vertebra, thoracic index, neck circumference and waist circumference in line with expected changes seen in children without neurological damage? Do the same changes occur if the children are treated with a similar physical therapy?
2. Does the Scotson technique improve function in the stated population? Do the same changes occur if the children are treated with a similar therapy?

12.2 The population

- Inclusion criteria would be British children aged between 2 – 12 years of age with a diagnosis of cerebral palsy. Greater homogeneity could be achieved by restricting inclusion to children with a specific diagnosis of hemiplegic cerebral palsy.
- Exclusion criteria would be any children with the above attributes who were receiving any concurrent physical therapy.
- All children must have confirmed informed consent. This must be timely and appropriate for the client group.
- Data collection to take place at Advance, East Grinstead and another specified site. The sites should be as similar as possible in terms of facilities and personnel.

12.3 Recruitment

Specific dates to be set for recruitment and for subsequent follow-up. It is recommended that observations are taken at baseline then every six months for at least two years.

12.4 Design

- Ethical approval. This needs to be obtained from the local research ethics committee (LREC) associated with each study site. There could be a number of these.
- Randomisation would not be ethical as the families have chosen to receive the technique provided at Advance. A viable alternative would be minimisation. A number of potential confounding variables are identified and then each participant is specifically allocated thereby hopefully reducing the between-group differences. This would involve identifying any imbalances which could potentially exist between the groups and minimising them (Pocock and Simon, 1975, Treasure and McRae, 1998).
- An independent assessor who is 'blinded' to which therapy the child was receiving. This is important as the therapists and the families will not be 'blinded'. The assessor ideally should come from a healthcare background and be attached to a (local) university; this would secure the research infrastructure, critical evaluation and supervision. It

could form part of a PhD. Funding for this post could be sought through the Department of Health or the Research Council for Complementary Medicine (RCCM).

- A pilot study would be required to inform the power calculation which will establish the number of subjects needed for a given statistical power. The statistical power is a measure of how likely the study is to produce a statistically significant result for difference between the groups (Bowling, 2002, Sim and Wright, 2000). The pilot study would also enable trial procedures to be checked and altered if necessary. A statistician needs to be involved at an early stage.
- Outcome measures would need consideration. As the exploratory project seems to have demonstrated a change in chest and trunk shape this would make a useful area of study with the trial. Areas to be measured could be; shoulder width, chest width, thoracic index, neck circumference and a new measurement, chest circumference at the level of the 10th thoracic vertebra to hopefully capture any changes in the flaring of the lower ribs. The perception that these alterations lead to an improvement in function would be another area to explore. The Gross Motor Function Measure (GMFM 88) (Ruck-Gibis, et al, 2001, Russell, et al, 2000) is an outcome measure that is recommended by several physiotherapy interest groups (Appendix 11) as an appropriate measure of function. To enhance the quality of the measurements the assessor(s) would need training and the

observations carried out a number of times in one assessment visit.

Any equipment needed for the outcome measures should be purchased.

- Full record of baseline characteristics to assess between group similarities
- A precise definition of the therapy to be provided by both groups. This should include broad principles of the treatment package, a statement about the holistic aims and individually tailored programmes. The treatment package description should be precise so that the study can be repeated in the future. It should include the timing of the therapy, personnel involved, length of treatment sessions, equipment usage and dosage (intensity, frequency and duration). Any advice about home therapy should be explicit.
- Decisions about the information to be collected, checking of the information and secure storage. Recording of adverse events, side-effects, attrition and refusals to enter the study.
- Statistical methods. To compare the primary outcomes two methods might be needed. The GMFM 88 is ordinal data and would be analysed using Mann-Whitney *U*- test. The newer version GMFM 66 has been improved through Rasch analysis and the standard GMFM is transformed into an interval measure and the independent *t*-test could be used. The physical measurements are ratio data so the independent *t*- test would be used. Analysis to be done on ‘an

intention to treat' basis. Potential subgroup analysis could be gender differences, age category differences and severity.

12.5 Conclusion

Advance initially could be classed within group three of the House of Lords (2000) groupings of complementary and alternative medicine. Advance acknowledged that the basis for many of their claims was little more than enthusiasm for an approach. An approach that gave an alternative view and hope to families of children with neurological damage in the absence of a definitive governmental funded treatment. The starting point for this study was Advance's recognition that this situation was unacceptable in the current climate of evidence based healthcare. It also accepted that such a situation would not enable them to be seen as a therapy which is complementary to conventional therapy and could possibly be funded by government agencies in the future (House of Lords, 2000). The charity commissioned an exploratory study of the Scotson technique through the Division of Rehabilitation Studies, University of Bradford. This study used the methods set out in the Medical Research council's "[A] Framework for the development and evaluation of RCTs for complex interventions in healthcare" (MRC, 2000). This was to establish an evidence supported theoretical base, explore whether any effects were occurring in relation to the technique and suggest what areas would be appropriate for study in a future research project. By choosing to explore the potential effects of the Scotson technique Advance has made considerable steps towards the establishment of the technique as a credible therapy for neurological damage. It has shown itself willing to be judged by scientific principles,

undergo detached evaluation and not just rely on anecdotal information that is neither academically filtered nor peer reviewed. The study was not undertaken to boost patient numbers for the charity, as recruitment was steady through media exposure and word of mouth. There are many factors limiting research in this field. In 1995 only 0.08% of NHS research was spent on CAM (Zollman and Vickers, 1999) and many funding bodies are reluctant to release monies for such research. Bodies with large resources such as pharmaceutical companies have little commercial interest in CAM. Also the organisations offering CAM are often small with no academic infrastructure consequently having limited access to computer programmes, library facilities and statistical support (Zollman and Vickers, 1999, Ernst, 2003, Ernst, et al, 2004). It must be remembered Advance did not have to undertake this evaluation and it was, and will be in the future, costly.

The study has demonstrated both positive and negative changes which are worthy of further investigation. The tracking of the children over two years has shown that, in the areas explored, that it does no harm and the children continued to develop along expected lines.

The theory as to why the Scotson technique could potentially work has been developed, giving the technique a plausible evidence base with links to already accepted therapeutic modalities. Advance appreciates that this initial exploratory study is only the beginning. The next step is to take this theoretical base and test it in a robust process against a comparable population, receiving a different therapeutic technique. This should help to

identify any effects positive and negative. Also the work done in this initial exploratory study needs to be continued, tracking the children over a longer treatment period to ensure the treatment causes 'no harm'.

The study only considered potential physical changes in a specific area. Any beneficial outcomes must be viewed cautiously and the temptation to extrapolate from the specific outcomes to more general whole body outcomes should be avoided. Advance needs to distance itself from other alternatives in group three (House of Lords, 2000) and resist the urge to promote the Scotson technique as being a panacea for a wide range of disparate conditions. It should try to establish for which particular population the technique is most appropriate and concentrate on those children.

Appendix 1

Research Information and Consent Form

Title of Study: A study to investigate the effect of the Scotson technique therapy on neurologically damaged children

Researcher: Rachael Sharples, University Teacher, Member of Chartered Society of Physiotherapy, Division of Rehabilitation Studies, University of Bradford

Supervisor: Dr Debbie Hepworth. Senior Lecturer, Member of Chartered Society of Physiotherapy, School of Life Sciences, University of Bradford. Supported by Dr. Pam Bagley. Health Lecturer, Member of the Chartered Society of Physiotherapy, Division of Rehabilitation Studies, University of Bradford.

FUNDING – Advance

You are invited to participate in a research study which is investigating the effect of ScotsonTechnique therapy on neurologically damaged children. This study is scheduled to run for 3 years.

This study involves your child being measured and video-taped by staff at Advance. This will take 15 – 30 minutes. These measurements and video tapes will be coded and sent to the University of Bradford for analysis. All data at the end of the study will be returned to Advance.

Patient confidentiality will be maintained at all times.

You are under no obligation to agree to participate in this study. If you decide not to participate your treatment at Advance will not be prejudiced in any way.

Do you consent to taking part? Yes/No

Please sign Date

Child's Code No

Appendix 2

Information sur la recherche et Consentement

Titre de l'Etude:

C'est une étude pour examiner les effets de la thérapie Scotson chez les enfants lésés cérébraux.

Chercheuse:

Rachael Sharples, Professeur Universitaire, Membre de la "Chartered Society of Physiotherapy", Agrée de l'Etat, Division Physiothérapie, Université de Bradford.

Patron de Thèse:

Dr Debbie Hepworth, Senior conférencier, Membre de la 'Chartered Society of Physiotherapy', Agrée de l'Etat, School of Life Sciences, Université de Bradford.

Appuie de Pam Bagley: Senior conférencier, Membre de la 'Chartered Society of Physiotherapy', Agrée de l'Etat, Division Physiothérapie, Université de Bradford.

Fonds – Advance:

Vous êtes invités à participer à une étude de recherches qui va examiner les effets de la thérapie Scotson chez les enfants neurologiquement lésés. Cette étude devra durer 3 ans. Pour cette étude il est nécessaire que votre enfant soit mesuré et filmé sur cassette video par un employé d'Advance. Ceci prend de 20 à 30 minutes à chaque visite. Ces mesures et videos seront codés et envoyés à l'Université de Bradford pour analyse. A la fin de cette étude, toutes les informations seront rendues à Advance.

Confidentialité de chaque patient sera maintenue à tous moments.

Vous n'êtes sous aucune obligation de participer à cette étude. Si vous décidez de ne pas faire partie de cette étude, votre programme à Advance n'en sera en aucun cas affecté.

Consentez-vous à prendre part? Oui / Non

Signature:

Date:

Appendix 3

NAME:

1st Visit Exercises

Time

Diaphragm position:

5 minutes FD2 Front middle

5 minutes FD1 FD3 Over floating ribs 2 hands together

5 minutes FD1 FD3 Over floating ribs alternating hands

5 minutes CT Back central tendon over spine

5 minutes BD1 BD2 Lower back ribs on each side spine 2 hands

5 minutes BD1 BD2 Lower back ribs on each side alternating hands

SIDES

5 minutes FD1 On lower ribs

5 minutes FD3 On lower ribs

NOTES:

Exercise photos

Portrait picture

Assessment video/VCD

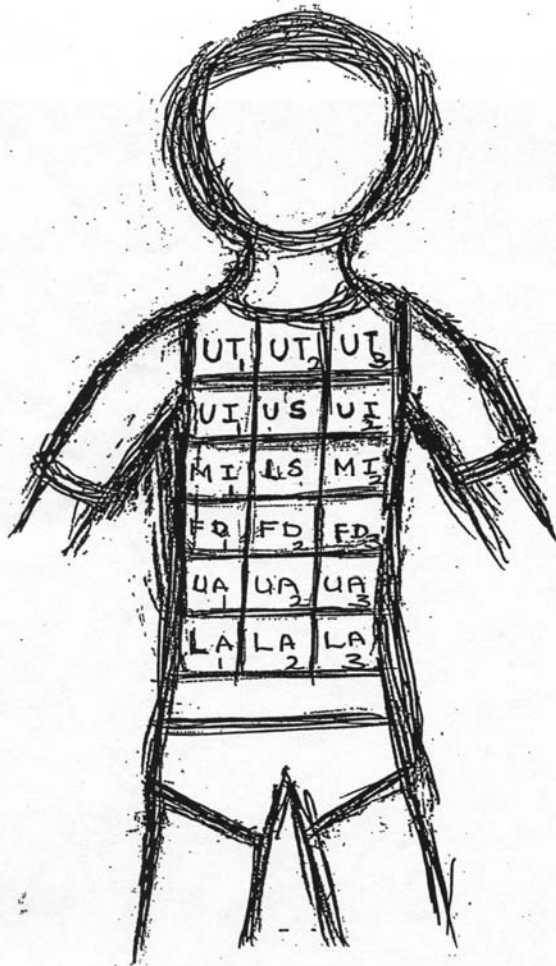
Exercise techniques video/VCD

Folder

Appendix 4

FRONT TRUNK

EXERCISES



NAME:

DATE:

Exercise times & Order

Abbreviations

UT - Upper Thorax
UI - Upper Intercostal
MI - Mid Intercostal
FD - Front Diaphragm
US - Upper Sternum
LS - Lower Sternum
UA - Upper Abdomen
LA - Lower Abdomen

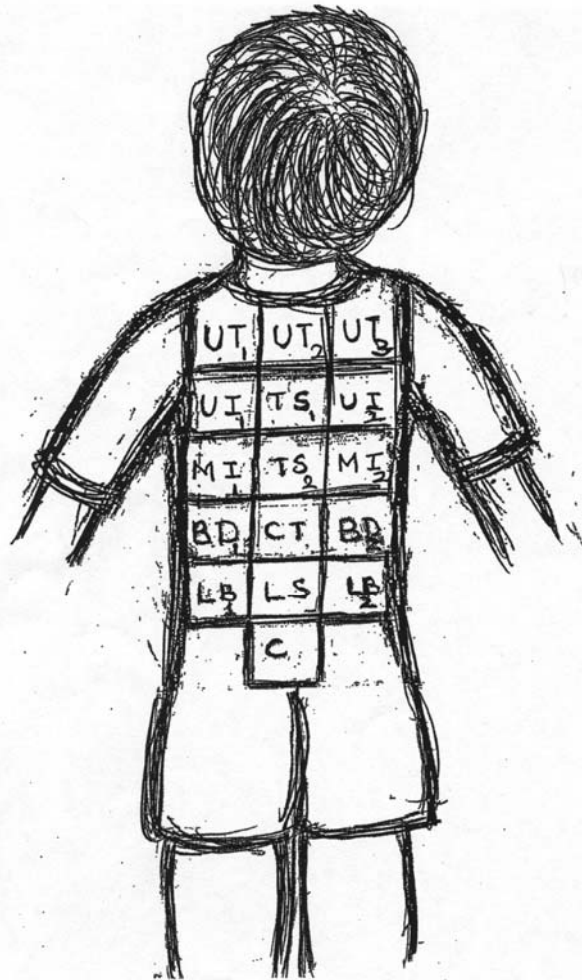
1

Appendix 5

BACK

EXERCISES

Exercise Prescription



Abbreviations

- UT - Upper Thorax
- UI - Upper Intercostal
- MI - Mid Intercostal
- TS - Thoracic Spine
- BD - Back Diaphragm
- CT - Central Tendon
- LB - Lower Back
- LS - Lumbar Spine

Appendix 6

TO BE FILLED IN EACH TIME THE CHILD IS VIDEOED

Date:			
Child's Code N°			
Treatment code		Nationality	Male
			Female
Age:		Years:	Months:
Weight:		Height:	
NG	PEG		
Diagnosis: -			
Hyperbaric Oxygen		Yes:	No:
Peak flow reading (best of three). Note if vitalograph or Wright			
Treatment (including breaks) hours that parents have			

managed <u>daily</u> since last visit.	
How many treatment sessions from the centre this visit?	
Other therapies tried?	

Appendix 7

Spastic cerebral palsy characterised by at least two of the following: -	<ol style="list-style-type: none"> 1. Abnormal movement pattern of posture or movement. 2. Increased tone not necessarily constant 3. Pathological reflexes (increased reflexes, hyperreflexia or pyramidal)
Spastic bilateral cerebral palsy	Limbs on both sides of the body involved
Spastic unilateral cerebral palsy	Limbs on one side of the body are involved

Ataxic cerebral palsy characterised by both: -	<ol style="list-style-type: none"> 1. Abnormal pattern of posture and/or movement. 2. Loss of orderly muscular coordination so that movements are performed with abnormal force, rhythm and accuracy
Dyskinetic cerebral palsy is dominated by both: -	<ol style="list-style-type: none"> 1. Abnormal pattern of posture or movement. 2. Involuntary, uncontrolled, recurring and occasionally stereotyped movements.
Dystonic cerebral palsy is dominated by both: -	<ol style="list-style-type: none"> 1. Hypokinesia (reduced activity-stiff movements). 2. Hypertonia (tone usually increased).
Choreoathetotic cerebral palsy is dominated by both: -	<ol style="list-style-type: none"> 1. Hyperkinesia (increased activity – stormy movements) 2. Hypotonia (tone usually decreased).

Appendix 8

The Modified Posture Assessment Scale

Head and neck

Score 5 if neck is in good symmetrical alignment, head is in midline.

Score 4 if child demonstrates minimal forward or lateral neck flexion, asymmetry, or capital hyperextension

Score 3 if child demonstrates minimal to moderate forward or lateral neck flexion, asymmetry or capital hyperextension

Score 2 if child demonstrates moderate forward or lateral neck flexion, asymmetry or capital hyperextension

Score 1 if child demonstrates moderate to severe forward flexion or lateral neck flexion, asymmetry or capital hyperextension

Score 0 if child demonstrates severe forward or lateral neck flexion, asymmetry or capital hyperextension

Shoulder

Score 5 if shoulders are symmetrical and not protracted

Score 4 if child demonstrates minimal asymmetry of shoulders or minimal protraction

Score 3 if child demonstrates minimal to moderate asymmetry of shoulders minimal to moderate protraction

Score 2 if child demonstrates moderate asymmetry of shoulders or moderate protraction

Score 1 if child demonstrates moderate to severe asymmetry of shoulders or moderate to severe protraction

Score 0 if child demonstrates severe asymmetry or severe protraction

Trunk

Score 5 if child demonstrates evidence of symmetrical trunk control with erect sitting posture

Score 4 if child demonstrates evidence of minimal trunk asymmetry or weakness such as minimal lateral trunk flexion or minimal forward trunk flexion

Score 3 if child demonstrates evidence of minimal to moderate trunk asymmetry or weakness, such as minimal to moderate lateral trunk flexion or minimal to moderate forward trunk flexion

Score 2 if child demonstrates evidence of moderate trunk asymmetry or weakness, such as moderate lateral trunk flexion or moderate forward trunk flexion

Score 1 if child demonstrates evidence of moderate to severe trunk asymmetry or weakness, such as moderate to severe lateral trunk flexion or moderate to severe forward trunk flexion

Score 0 if child demonstrates evidence of severe trunk asymmetry or weakness, such as severe lateral trunk flexion, or severe trunk flexion

Appendix 9

Breathing narrative elements

- Breath holding
- Mouth breathing
- Primarily upper chest breathing
- Irregular rhythm
- Lateral rotation of the upper arms
- Primarily abdominal breathing
- Paradoxical breathing
- hyperinflation

Appendix 10

Measurements

Child's Code No

Child lying down on back	In cm
Shoulder width from deltoid muscle (callipers)	
Chest width (at front) armpit level (callipers)	
Chest width at nipple level (callipers)	
Chest width at xiphoid level (callipers)	
Breadth at level of iliac crests (callipers)	
Neck circumference (over larynx/ Adam's apple)	
Chest circumference armpit level (tape)	
Chest circumference at armpit exp (tape)	
Chest circumference at armpit insp (tape)	
Chest circumference at nipple level (tape)	
Chest circumference at nipple exp (tape)	
Chest circumference at nipple insp (tape)	
Chest circumference at xiphoid exp (tape)	
Chest circumference at xiphoid insp (tape)	
Waist circumference (tape over naval)	
Child in side lying Using callipers	
Chest depth on sternum & spine at nipple level	

Chest depth on xiphoid and spine	
Hip depth just below iliac crests	

Appendix 11

- Physiotherapists in Management Support (PPIMS)
- Association of Paediatric Chartered Physiotherapists (APCP)
- Association of physiotherapy Managers (ACPM)
- Chartered Society of Physiotherapists (CSP)

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