Effectiveness of Occupational Therapy Home Program Intervention for Children with Cerebral Palsy: A Double Blind Randomised Controlled Trial

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Statement of Authentication

The work presented in this thesis is, to the best of my knowledge and belief, original except as acknowledged in the text. I hereby declare that I have not submitted this material, either in full or in part, for a degree at this or any other institution.

Iona Novak
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Abbreviations

Activity-Focused Motor Interventions Model  AFM
Canadian Occupational Performance Measure  COPM
Cerebral Palsy  CP
Children’s Assessment of Participation and Enjoyment  CAPE
Confidence Interval  CI
Eco-cultural Perspective  ECP
Eight Week Home Program Group  8WEEK
Evidence-Based Practice  EBP
Family-Centred Practice  FCP
Four Week Home Program Group  4WEEK
Goal Attainment Scale  GAS
Gross Motor Function Classification System  GMFCS
Human Research Ethics Committee  HREC
International Classification of Functioning, Disability and Health  ICF
Last Observation Carried Forward  LOCF
Manual Ability Classification System  MACS
Determinants of Motor Change Model  DMC
National Health and Medical Research Council  NHMRC
No Home Program Group  NoHP
Not Significant  NS
Quality of Upper Extremity Skills Test  QUEST
Randomised Controlled Trial  RCT
The Spastic Centre  TSC
University of Western Sydney  UWS
Abstract
Home programs are widely used by occupational therapists as a strategy to address health and development needs of children with cerebral palsy. Experts believe they are essential. Despite wide-spread clinical use there is no high quality research evidence proving home program effectiveness. Further there is no information that provides a parent perspective on home programs. The aim of this research was to evaluate the effectiveness of occupational therapy home program intervention for school-aged children with cerebral palsy and identify factors perceived to be important in home program practice from a parent perspective.

A double blind randomised controlled trial design was used to evaluate effectiveness, where parents and evaluators were blinded to intervention. Children were randomised to three groups, home program intervention for eight weeks (“8WEEKS”), home program intervention for four weeks (“4WEEKS”), and a control group, that did not receive home program intervention (“NoHP”). The primary end-point was change in performance of functional activities and satisfaction with function as measured by the Canadian Occupational Performance Measure (COPM), after eight weeks. Secondary end-points were change in COPM scores after four weeks, goal achievement at four and eight weeks as measured by Goal Attainment Scale (GAS), quality of arm movement at four and eight weeks measured on the Quality of Upper Extremity Skills Test (QUEST) and participation levels at four and eight weeks measured on the Children’s Assessment of Participation and Enjoyment (CAPE). Parent experience was explored through semi-structured interviews of parents who participated in the home program trial. Content analysis of interview data was conducted to the level of “open coding” to identify factors.

Results for the primary outcome measure at the primary end point (eight weeks) - Effect of an 8WEEK or 4WEEK home program on COPM scores: comparison between the three groups was conducted using a linear regression model with baseline COPM
performance/satisfaction scores, participant age and severity of cerebral palsy as measured by the GMFCS entered into the model as covariates. Overall, there were statistically significant and clinically important differences in performance of activities and satisfaction with function on COPM when comparing either home program group to the NoHP group at eight weeks. There was no difference between 4WEEKS versus 8WEEKS on COPM performance or satisfaction scores at eight weeks.

Results on secondary outcome measures: compared to NoHP, receiving a home program for either 4WEEKs or 8WEEKs increased COPM performance scores and GAS measures at four weeks, and increased COPM performance and satisfaction scores, GAS measures, and QUEST scores at eight weeks. There were no differences within or between groups on the CAPE at either four week or eight weeks. There were no statistically significant between-group differences between the 4WEEK and 8WEEK home program groups on any secondary outcome measures. This was most likely the result of a protocol implementation flaw that occurred in the study where 4WEEK group participants continued program activity for the final four weeks when they should have suspended it.

Parents perceived their experience of implementing home programs as characterised by five features: “guidance for the journey”, practice makes perfect, they were a necessary “way of life”, they maximised progress and something that made it easier to juggle competing demands. Positive home program experiences were characterised by: support, realistic expectations, flexibility, motivation from goals, activities that translated to real-life, reminders to practice, progress updates and role clarity. Parents advised other parents to: accept the disability, never refuse help, be honest, consider home programs essential, develop routines and view programs as a way of improving the child and parents’ life. No negative experiences were reported. Parents advised professionals that they wanted: support, interdisciplinary co-ordination of programs, advice without pressure and prognostic guidance for future planning.
This dissertation presents new information about occupational therapy home programs. Until this study, there was little research evidence to inform therapist or parent decision-making regarding the therapeutic value of home programs or the parent perspective on home programs. Findings from this dissertation can inform clinical practice and parent decisions regarding the use of home program interventions for children with cerebral palsy.
Chapter One: Introduction

1.1 Introduction
Home programs have been adopted by many professionals, including occupational therapists, as a therapeutic strategy to address health and development needs of children with cerebral palsy (Bazyk, 1989; Gajdosik, 1991; Hinojosa & Anderson, 1991; Law & King, 1993; Molineux, 1993; Schreiber, Effgen & Palisano, 1995). This chapter introduces the research by: identifying a gap in knowledge about home programs, describing the context of home program practice in occupational therapy, identifying key factors of interest for knowledge discovery, presenting study aims and describing the scope and delimitations of the investigation.

1.2 Background
Cerebral palsy is a disorder of movement and posture, and it is the most common physical disability in childhood, with no known cure (Reddihough & Collins, 2003). The incidence of cerebral palsy is 2-2.5 per 1000 live births in Australia (Reddihough & Collins, 2003; Stanley & Watson, 1988; Stanley, Blair & Alberman, 2000; WA Cerebral Palsy Register, 1999) and has not changed in recent decades (MacGillivray & Campbell, 1996; The Australian & New Zealand Perinatal Societies, 1995). In 2007 it was estimated that 33,797 Australians were living with cerebral palsy (Access Economics, 2008). The principal difficulties for people with cerebral palsy are the ability to make controlled movements and maintain upright sitting and standing postures; but it is also common for children with cerebral palsy to have impairments affecting the senses, cognition and communication (Rosenbaum, Dan, Leviton, Paneth, Jacobsson, Goldstein, & Bax 2005). Children with cerebral palsy have for many decades used extensive medical and therapy services to help them achieve their potential (Green, Proch & Gara 1997; Krigger, 2006; Delgado &
Coombes, 1999; Koman, Peterson Smith & Shilt, 2004). Occupational therapy is the second most frequent health service used by these children (Chen, Neufeld, Feely, & Skinner 2004).

Occupational therapists provide assessment, intervention and evaluation services to help children with cerebral palsy maximise their independence (McElderry, 2000). Children with cerebral palsy receive occupational therapy specifically to enhance their independence in movement, self-care, play and leisure skills (Law, Darrah, Pollock, King, Rosenbaum, Russell, Palisano, Harris, Armstrong & Watt 1998). The focus of occupational therapy intervention is on improving the child’s performance of daily activities. Therapy may change child, task or environment constraints limiting the child’s independence (Law et al, 1998). Home programs are a commonly utilised occupational therapy strategy.

A significant part of occupational therapy service for children with cerebral palsy is home program intervention (Piggot et al, 2003). Home programs are: “therapeutic activities that the child performs with parental assistance in the home environment with the goal of achieving desired health outcomes” (Novak, Cusick and Lowe, 2007, p.475).

Professionals have long considered home programs for children with cerebral palsy to be essential for achieving optimal outcomes (Hinojosa, 1990; Howison, 1988). Home programs reflect the belief that parental input into therapy is vital (Bazyk, 1989; Law, Teplicky, King, Kertoy, Rosenbaum, & Burke-Gaffney, 2005; Rosenbaum, King, Law, King & Evans, 1998; Ahmann, 1994; Dormans & Pellegrino, 1998; Roberts & Magrab, 1991); the family context is critical to child health outcomes (Law, Teplicky, King, King, Kertoy, Moning, Rosenbaum & Burke-Gaffney, 2005; Rosenbaum et al, 1998); familiar environments are important for children’s learning (Anderson & Schoelkopf, 1996; Clarke & Allen, 1985); and there is higher likelihood of skill generalisation from practice in natural environments (Dormans & Pellegrino, 1998; Humphrey & Case-Smith, 1996; Moersch, 1985; Rosenbaum et al, 1998). The home program service delivery model also responds to
the need to reduce costs of providing life-long therapy services to people with cerebral palsy (Law & King, 1993; Law et al, 2005). Occupational therapists consider that working with parents via home programs has a greater impact on a child with a disability than any other aspect of intervention (Hinojosa, Sproat, Mankhetwit & Anderson, 2002). As a consequence, increased numbers of parents of children with cerebral palsy are involved in home programs (Law et al, 2005).

Experts claim that children with cerebral palsy cannot make progress without home programs (Hinojosa, 1990; Howison, 1988). Indeed, home programs are considered “routine” clinical practice for children with cerebral palsy (Piggot, Hocking & Paterson, 2003). In spite of this, no high quality research evidence exists evaluating whether this intervention is effective. To date the only study to measure the impact of home programs on desired therapy outcomes for children with cerebral palsy was a pre-post intervention single-group design that piloted a protocol for home programs and explored its impact (Novak, Cusick & Lowe, 2007). A prior literature review identified that much of the literature on occupational therapy home programs was opinion, or description and at that time no experimental studies had been conducted (Novak & Cusick, 2006).

Given the need for effective treatments for children with cerebral palsy and the extraordinary caregiving load on parents, which may extend to implementation of home programs, this research aims to discover whether home programs for children with cerebral palsy have a therapeutic impact. Further to help inform therapists and parents about the home program experience, perspectives of parents involved in home programs were also sought. To set the scene for this research, the following pages present a summary of key issues underpinning the research.

Occupational therapy home programs have common features (Novak & Cusick, 2006; Novak, Cusick & Lowe, 2007) that may in the first instance best be illustrated by a short description of a typical home program encounter experienced by the author. This
may “bring to life” the features of a home program for the therapist, child and parents involved. The child is real, the experiences described are real and taken from the author’s recollection, but the names have been changed.

On the day I met child Hannah and her mum Kate, they had only slept for one hour. This was not unusual for Hannah even though she was seven years old. As I entered their house, I immediately became aware this was no ordinary home environment. Countless details told me that Hannah was the centre of her parents’ world. To begin with, there was no furniture in the living room. I came to understand that the time involved in caring for Hannah, coupled with the financial pressure to work, left no time for relaxation or socialising. In the corner of the family room, I was first struck by mirrors and wooden toys mounted on the wall. It reminded me of a therapy centre but somehow less clinical, because all the fittings had been painted to match the family’s décor. All the furniture in the family room was pushed up against the walls so that a large blanket could be spread across the floor. There lay Hannah, surrounded by toys! I knelt down to say hello, Hannah responded with a smile. I beamed back at her. Hannah had no speech or any other way of saying “hi”.

“I’m not sure what she will do for you today, she hasn’t slept” said Kate. “I am confident there is nothing about her you won’t be able to tell me, because you are the expert in knowing Hannah”, I replied. We moved to discussing Kate’s hopes and goals for Hannah. One of these was for Hannah to keep her hands on the table to play. Kate had brought Hannah’s supportive ‘posture chair’ in from the garage in preparation for the appointment. I learnt that Hannah had never really tolerated sitting up before because her arms constantly got ‘stuck’ behind her body and became bruised by the back of the chair. Kate felt that sitting upright with her arms on the table must surely be an essential step for her helping Hannah to learn to play and eat independently. I helped Kate to understand that Hannah had difficulty keeping her arms on the table and maintaining her grip of toys because her body did not always select the right muscles for the activity. And that the more Hannah tried, the more the wrong muscles volunteered their services. I helped Kate to understand this was because Hannah had “dyskinetic” cerebral palsy, which affected her ability to control her movements and caused involuntary postures.

Despite Hannah’s extreme fatigue and lack of success, Hannah told me through her eye contact with the toys that she was motivated to play. Using spare linen, I mocked-up a modification to Hannah’s seating position, to show Kate how we could begin to reach the goal. The effect of bringing Hannah’s shoulders forward was dramatic; her arms were on the table for the first time. Now we needed to find a way for Hannah to keep her arms in front of her body and practise holding simple objects, like a spoon or a toy. Here began the construction of Hannah’s home program. Kate, Hannah and I had started to build a collaborative connection. Kate had then set the goals for intervention. Now we were ready to find ways to help Hannah achieve these goals.

Hannah’s home program included a “library of ideas” for her parents to choose from, all of which sought to achieve the goal of keeping her arms on the table surface and sustaining her grip on toys. It included practice time in her chair and a grip strength “drag race” game the whole family could play together in the backyard swimming pool. The program also made use of the mirror and toys that her family had already set up in the corner of the family room.

When I visited Hannah and her mum a month later, Kate was in high spirits. Everyone was now sleeping through the night and Hannah had some “new tricks” to show me. Hannah’s chair and table had moved into the once empty living room. Hannah was for the first time engaging in some independent play due to some fine-tuning Kate had made to their daily routine. Kate excitedly told me, that Hannah will now hold onto toys placed on the table-top. She went on to say, “Since we have met you, I have become more aware. We all have. It has given me something different to focus on with her. My husband plays the pool game. We love that game. I have been working on her sitting up in the chair to play. Look at our toy box! [Kate produced a crate of toys that focused on the goal of sustained grip, e.g., spoons and necklaces. Kate had carefully chosen the toys in response to the parent information provided in the home program]. I already had all the toys you suggested but now we use them differently. Her grandparents even noticed the changes the other day, “she didn’t used to do that, did she?” dad said. They were proud; I don’t think they ever thought that Hannah would hold their hand. I hope she will show you, I want to know what you see when you look at her today.”
Hannah and Kate’s story highlights some of the central elements of good home program practice, including: the importance of forming collaborative partnerships with parents, family-led goal-setting, providing home activities that are enjoyable for families to practice, teaching families how best to help their child and giving feedback to parents about their child’s progress (Novak & Cusick, 2006). Although Hannah and Kate’s home program experience is a standard aspect of therapy for children with cerebral palsy, there is no research evidence available to know whether or not this type of intervention has any benefit for children with cerebral palsy, whether the experience of Hannah’s parents is common and what their views or recommendations about home programs might be. The description of Hannah’s home program also identifies how important it is that research evidence is available to inform parent choices and guide therapists. Currently professional and parent decisions regarding home programs are made on the basis of conventions built up over time (Hinojosa, 1990; Howison, 1988; Mayo, 1991; Washington & Schwartz, 1996). Presently it is the belief that home programs are essential rather than research evidence regarding therapeutic impact that underpins their use.

Reasons for home program popularity and the perceptions that they are essential in spite of the lack of evidence, may have something to do with models of health and disability that have influenced policy and practice in recent years. These are: International Classification of Functioning, Disability and Health (ICF) (WHO, 2001), family-centred practice (FCP) (National Centre for Family-Centred Care, 1990) and eco-cultural approaches (ECP) (Wiesner, 2002). These models are briefly summarised here to provide a context for the study problem.

ICF: The need for occupational therapy home program intervention arises from the activity and participation limitations that children with cerebral palsy experience because of their motor and associated impairments. The ICF is a framework of inter-linked concepts that categorise the impact of a condition or disability on a person (WHO, 2001). The first
construct is the “body structures and functions” level [in cerebral palsy muscle weakness and spasticity are examples]. Next are the “activities” level [such as getting dressed and writing] and finally the “participation” level which is about meaningful engagement in daily life activities [such as a community sport]. “Environment” and “personal factors” are also recognised to influence health outcomes and they too form an important part of the framework.

**FCP:** Since children with cerebral palsy live at home in the care of their family, intervention is planned and designed in partnership to reflect family goals. The involvement of parents within occupational therapy services, including home programs, reflects the approach known as FCP (National Centre for Family-Centred Care, 1990). Home programs are routinely used as one FCP service because they inherently recognise the expert caregiving of families (Rosenbaum et al, 1998).

In practical terms, FCP emphasises the:

“right of each family to make autonomous decisions…[and] define the priorities for therapeutic intervention and, with the therapist, help direct the intervention process…[In the family-centred approach] therapy is seen as a dynamic process in which service providers and parents work together as partners to define the therapeutic needs of the child with a disability. Services are designed to fit the needs of families, rather than the families fitting the services or intervention philosophies that are already pre-determined by professionals.” (Law et al, 1998, p.86).

The ICF, together with FCP, provide guidance about what dimensions of health should be addressed within home programs, and how the intervention should be designed. The rationale that explains why a home program is desirable can then be found in the theoretical frameworks of eco-cultural perspectives (ECP), the activity-focused motor interventions (AFM) and the determinants of motor change (DMC) now described.

**ECP:** The home environment is considered an important context for accelerating and consolidating the learning of children with disabilities (Anderson & Schoelkopf, 1996;
Moersch, 1985; Shilton, Jeppson & Johnson, 1987). Thus home programs are designed around the optimal context for learning. This is the third approach underpinning this study and is known as the “eco-cultural” (Wiesner, 2002) perspective. The ECP emphasises the importance of children’s learning occurring in real-life contexts, rather than in clinical settings (Ekstrom, Johansson, Granat & Brogren Carlberg, 2005). Home programs provide a real-life intervention context in which therapy can be embedded in the child’s daily life.

While the ICF, FCP, and ECP provide important foundations for justifying the use of home programs, therapists require specific practice models to inform the selection of intervention techniques. In the case of occupational therapy for children with cerebral palsy, the models recommended for use are the “activity-focused motor interventions” (AFM) (Valvano, 2004) and the “determinants of motor change” (DMC) (Bartlett & Palisano, 2000). These models shape the content of the home program by focusing therapy squarely onto daily “activities” that the child wants to learn.

**AFM**: AFM-based therapy optimises the child’s learning of daily functional tasks, through activity-focused interventions and minimises deterioration through impairment-focused interventions (Valvano, 2004).

**DMC**: DMC-based therapy also focuses on all possible factors that may accelerate the child’s progress, including their unique impairments and skills, and the child’s family who provides the support for learning.

The ICF, FCP, ECP, AFM and DMC models provided the conceptual foundation for home programs developed within this study. From a therapy point of view the programs used motor learning and activity-focused approaches that intervened on child, task and environment factors, including those who support the child. These programs drew on a suite of assessments, processes, interventions and evaluations that were consistent with and informed by these frameworks. Programs were developed collaboratively by the parent and therapist to meet individualised goals compatible with family routines.
al, 1998). In keeping with evidence-based practice conventions, the suite of interventions proposed in home program resources for parents had the highest levels of supporting evidence available (Sackett, Rosenberg, Gray, Hayes & Richardson, 1996) and parent preferences, goals and knowledge of their child was also used to choose the type, quality and focus of home program activities. Specific home program interventions included: (1) child interventions such as goal-focused task training, constraint-induced movement therapy, orthotics, and strength training; (2) parent interventions such as parent education and positive behaviour support; and (3) home environment interventions such as assistive technology. Overall, the home programs provided a focus for developing the child’s functional independence in the activities.

1.3 The Problem under Study

There is surprisingly little investigation of home programs in the area of cerebral palsy treatment, despite overwhelming support and recognition of the importance of home programs for children with a disability in literature (Schreiber et al, 1995). A comprehensive literature review conducted earlier by the author found that:

“there was little [published research] to assist occupational therapists to design, implement or evaluate home programmes from an evidence-based perspective for children with disabilities and children with cerebral palsy in particular. Occupational therapy literature on home programmes is primarily non-randomised or based on opinion, with no articles specifically evaluating the impact or effectiveness of home programme intervention.” (Novak & Cusick, 2006, p. 253).

To date there has been little research to answer the question ‘Do home programs work?’ and until recently there was no guide to home programs for children with cerebral palsy (Novak & Cusick, 2006). The only study investigating occupational therapy home programs was a pilot, and this single group pre-post study showed benefits in children with
cerebral palsy (Novak & Cusick, 2005; Novak, Cusick & Lowe, 2007). The literature is currently therefore only tentative in support for home program benefit.

In addition to questions about whether home programs work, parents also want to know “how much” therapy is enough? Most parents assume more is better (Hinojosa, 1990). There are currently no definitive answers to questions of home program intensity in the research literature. There are suggestions by some authors, based on findings from other fields of clinical practice, that home-based therapy has a greater likelihood of success compared to traditional institution-based therapy programs (Drummond, Weir & Kysela, 2002; Llewellyn, McConnell, Honey, Mayes & Russo, 2003; Rickards, Walstab, Wright-Rossi, Simpson & Reddihough, 2007). These suggestions have, however, not yet been studied for children with cerebral palsy having occupational therapy. In addition, recent emphasis on the importance of practicing activities in natural environments (Damiano, 2006; Eliasson, 2005) with the assistance of family members (Ekstrom et al, 2005) has not been explored in home program outcome research using rigorous designs.

The research problem is further complicated by the lack of information regarding parent perspectives. To date the parent perspective has been absent or reduced to evaluations of parent “compliance” with therapist developed plans (Gajdosik, 1991; Gajdosik & Campbell, 1991; Law & King, 1993; Mayo, 1981; Molineux, 1993; Schreiber et al, 1995; Wortis, Cooper, & Simonson, 1954). There is a need to know if parents are satisfied with their child’s outcomes (Naar-King, Siegal, Smyth & Simpson, 2000) as parent satisfaction is fundamental to whether or not they use a home program at all (Piggot, Paterson & Hocking, 2002). In addition as home programs rely on parent contribution, factors they consider important to the home program experience should be explored.

The problem under study in this dissertation is thus a gap between the widespread use of occupational therapy home programs with children who have cerebral palsy and the absence of rigorous research evidence to inform their design, implementation, evaluation
and consideration of effectiveness. This, together with the need for a parent perspective on home programs, is key to the study rationale.

Figure 1 characterises the study rationale: it presents what is “known” and “unknown” in the field of home programs. The author developed the diagram as an “aide memoire” to the problem under study.

Figure 1: Home Program Knowledge Base Prior to this Research: An Aide Memoire

1.4 Research Aims and Questions
This dissertation study aimed to address a critical gap identified in the literature by conducting two studies. The effectiveness of home program intervention for children with cerebral palsy was evaluated empirically through a randomised controlled trial (RCT). This aimed to provide information about program effectiveness. The RCT included methodological features recommended in literature to produce sound answers to parents’ and therapists’ questions about home program practice. These were: high methodological design quality as per the CONSORT statement, a homogenous study sample, individualised intervention goals and measurement using sensitive outcome measures (Steultjens et al, 2004). Since the study used the gold standard RCT design to produce the highest level of
evidence possible, the findings provide “believable” and “trustworthy” guidance to parents and therapists (Sackett, 1989). Findings will help inform therapists and parents about program impact and outcomes.

The second study explored the parent perspective of implementing the home program, following RCT involvement. It examined and quantified the effectiveness of parent involvement in intervention, in order to provide a new evidence base. These latter findings aim to help inform therapists and other parents about home program practice from the “consumer/collaborator” perspective. Together the studies aim to provide much needed research evidence about home program processes and outcomes for children with cerebral palsy. Figure 2 presents the research design.

Figure 2: Research Design

A double-blind RCT design was used to evaluate the effectiveness of home programs for children aged 4 to 12 in performing functional activities and their parents’ satisfaction with their function. After baseline measures were taken, children were randomised to one of three groups. One group implemented a home program for eight weeks (called 8WEEKs throughout this dissertation), a second group implemented a home program for four weeks (4WEEKs), and a third “wait-list” group did not receive any home program intervention (NoHP). The design of the RCT incorporated recommendations...
arising from previous methodological critiques of cerebral palsy intervention evidence (Boyd, Morris & Graham, 2001; Steultjens, Dekker, Bouter, van de Nes, Lamberegts & van den Ende, 2004), and features of “gold standard” clinical trials (Creswell, 2003; Colditz, Miller & Mosteller, 1989; Herbert, Jamtvedt, Mead & Hagen, 2005; Jadad, Moore, Carroll, Jenkinson, Reynolds, Gavaghan & McQuay, 1996; Pocock, 1983). Research questions to be answered by the RCT are:

1. Does use of a home program (based on FCP, ECP, AFM and DMC approaches) for eight weeks lead to improvements in: parent ratings of performance and satisfaction with functional activities, individualised goal achievement, participation, and upper limb quality of movement for children with cerebral palsy, in comparison to no home program at all?

2. Does use of a home program (based on FCP, ECP, AFM and DMC approaches) for four weeks lead to improvements in: parent ratings of performance and satisfaction with functional activities, individualised goal achievement, participation and upper limb quality of movement for children with cerebral palsy, in comparison to no home program at all?

3. Does use of a home program (based on FCP, ECP, AFM and DMC approaches) for eight weeks lead to improvements in parent ratings of: performance and satisfaction with functional activities, individualised goal achievement, participation and upper limb quality of movement for children with cerebral palsy, more than a home program used for four weeks?

Since the home program intervention is framed, in part, by FCP approaches, the development of goals and activities/strategies used is ultimately directed by parents. Consequently, the type and number of goals, duration of time and frequency of home program implementation were of interest. The RCT provided an opportunity for a fourth question to be answered:
4. What goal areas do parents generate for the home program and how frequently and intensely do they implement home programs?

After completing the home program for either four or eight weeks, children’s parents were invited to participate in a semi-structured interview regarding their perspectives on home program implementation. To date there is no such information in the literature to inform home program choices or decisions by parents or professionals. The specific research questions were:

5. What do parents think influenced them to implement a home program?
6. What were parents’ perceptions regarding the experience of implementing the home program?
7. What would parents like to have been told by other parents about home programs?
8. What would parents like to tell health professionals about home programs?

Because there was no information available on the parent perspective of home program implementation a qualitative approach was used to guide data collection and analysis. As the aim was to gain the parent perspective particularly in relation to implementation issues, it was anticipated that data analysis would be descriptive rather than directed to the development of a conceptual model.

1.5 Scope and Delimitations
The scope of the RCT was restricted to the empirical evaluation of an occupational therapy home program. The home program replicated the model previously piloted by Novak and Cusick (2006). Home program effect was investigated by measuring clinical attainment from baseline on standardised instruments, including the Canadian Occupational Performance Measure (COPM) (Law, Baptiste, McColl, Opzoomer, Polatajko & Pollock, 1990), Goal Attainment Scaling (GAS) (Kiresuk & Sherman, 1968), Quality of Upper Extremity Skills Test (QUEST) (DeMatteo, Law, Russell, Pollock, Rosenbaum & Walter, 1993) and Children’s Assessment of Participation and Enjoyment (CAPE) (King, Law,
King, Hurley, Rosenbaum, Hanna & Young, 2004). The selection of instruments to evaluate the program was made on the basis of their psychometric rigour and relevance to typical clinical therapeutic outcomes of home program practice.

The age range studied and the decision to investigate only one diagnostic group – cerebral palsy – limits the generalisation of these results to broader paediatric diagnostic groups and to pre-school aged children. Narrowing sample attributes was, however, necessary to minimise the number of extraneous variables being measured. A homogenous sample group strengthens the rigour of the RCT and the focus of parental perspectives. Conclusions were drawn from the data about the effectiveness of home program treatment, rather than being confounded by comparing children whose abilities and potential for achieving the desired outcomes were disparate due to different conditions. Cerebral palsy is the most common childhood physical disability, which ensures a potentially wide application of findings to paediatric occupational therapy practice.

1.6 Significance of the Study
This research has the potential to improve clinical practice for children with cerebral palsy by utilising a previously piloted home program on a larger sample, by investigating the effectiveness of the home program intervention and by exploring parents’ perspectives on their home program trial experience. The study is significant in that it is the first study of its kind nationally or internationally to evaluate home program effectiveness.

To date, the focus of home program research has been on whether parents actually practice home program activities (Gajdosik, 1991; Gajdosik & Campbell, 1991; Law & King, 1993; Mayo, 1981; Molineux, 1993; Schreiber et al, 1995; Wortis et al, 1954), how best to measure parental implementation (Gajdosik, 1991; Law & King, 1993; Schreiber et al, 1995) and the effect home programs have on parent-child interactions (Hinojosa, 1989; Hinojosa & Anderson, 1991; Thompson, 1998; Tyler & Kahn, 1976; Tyler & Kogan, 1977). While these studies have made an important contribution to the body of knowledge about
home program intervention, the research question 'Do home programs work?' has not yet been answered or tested in a clinical trial. This research aims to address this evidence gap. The results of the RCT will advance the home program evidence base significantly. They will raise the level of best available evidence from the lowest (level V) to the top of the strength of evidence hierarchy (level I) (Sackett, 1989).

The results of the research will assist professionals and parents to make informed decisions about home programs by adding new evidence to paediatric cerebral palsy research literature by illuminating the parent perspective on implementing home programs.

The results of this study will have implications for health professionals who prescribe home programs and for families who have a child with cerebral palsy. Results will help inform decisions by health professionals and families regarding the amount of time, type and expected outcomes of home programs, thus guiding practice decisions, use of time, resources and funding of therapy services to children with cerebral palsy.

The results of this study will also have applications for the consumers of home programs: families and children with cerebral palsy to inform their planning and decision-making.

1.7 Synopsis
This chapter provided a background for the study, described the problem, presented the aims and objectives, scope and delimitations and potential significance. The next chapter provides an in-depth examination of the background literature.
Chapter Two: Literature Review

2.1 Introduction

Over the past fifty years there has been a revolutionary shift in the approach to paediatric health care, from professionals determining children’s needs in institutional care settings, to parents being recognised as central and expert caregivers (Dunst, Trivette & Deal, 1988; Winton & Bailey, 1997). This transformation recognises that families are better positioned than health professionals to direct, plan and prioritise their child’s health care (Winton & Bailey, 1997). The adoption of this value has necessitated change in the way services are delivered. Whilst hands-on provider-delivered services are still widely used, a greater emphasis is now placed on the home environment as a treatment context (Law & King, 1993). In particular, home programs carried out by family members are used extensively as intervention strategies for achieving desired health outcomes (Hinojosa & Anderson, 1991; Howison, 1988). They are also used as substitutes for provider-delivered intervention due to health resource shortages (Law & King, 1993; Thompson, 1998). In this study, home programs are considered to be one possible strategy for increasing parental caregiving competence, not for the replacement for professional service. Despite the well-documented academic and clinician consensus on the importance of prescribing home programs (Hinojosa & Anderson, 1991; Howison, 1988), there is a paucity of evidence to support their effectiveness and little information from the parent perspective to help inform parents and professionals who are considering home program implementation.

This chapter describes the impact of cerebral palsy on children’s development, the family-centred practice (FCP) framework for intervention that is commonly used with children who have cerebral palsy and a review of current clinical practice for developing
function in children with cerebral palsy. The following chapter (Chapter Three) provides a detailed review of literature specifically relating to home programs.

### 2.2 Definitions and Incidence of Cerebral Palsy

Cerebral palsy is a disorder of movement characterised by muscle weakness and poor voluntary control of movement (Aneja, 2004). Up until recently cerebral palsy has been defined as: “a disorder of movement and posture due to a defect or lesion of the immature brain” (Bax, 1964). In recent years this definition has been revisited and now cerebral palsy is considered a clinical description not a diagnosis because it describes a cluster of diagnostic signs not a disease (Blair & Watson, 2006). This has made cerebral palsy challenging to define and classify (Bax, Goldstein, Rosenbaum, Leviton & Panath, 2005). Nevertheless there is a need for a definition for epidemiological research (Blair & Watson, 2006).

Clinical, diagnostic and research field experts have recently proposed a new international consensus definition:

“Cerebral palsy (CP) describes a group of disorders of the development of movement and posture, causing activity limitations that are attributed to non-progressive disturbances that occurred in the developing fetal or infant brain. The motor disorders of cerebral palsy are often accompanied by disturbances of sensation, cognition, communication, perception, and/or behaviour, and/or by a seizure disorder.” (Rosenbaum et al, 2005).

This new consensus definition reflects changes in the way that health and disability are conceptualised. Most importantly, the World Health Organisation’s International Classification of Functioning, Disability and Health (ICF) (WHO, 2001) has had a profound influence on understandings of health and disability including cerebral palsy. The ICF is a multipurpose classification system designed to provide a scientific basis for understanding and studying health and establishing a common language (WHO, 2001). It is therefore a useful framework for developing an awareness of the multiple implications...
cerebral palsy may have on a person’s life (Rosenbaum & Stewart, 2004). The ICF has two parts: (1) functioning and disability, which includes body functions and structures, activities and participation; and (2) contextual factors, including environmental and personal factors (WHO, 2001). By virtue of their physical disability children with cerebral palsy have changes in their functioning and disability at the body function and body structure level. For example, damage to the motor cortex causes spasticity, which commonly leads to secondary physical limitations such as joint contractures. The body function changes experienced in cerebral palsy can affect the child’s ability to accomplish activities (e.g. fasten buttons, eat with utensils, write their name) and to participate in meaningful life activities (e.g. play community sports, attend mainstream school). The child’s environment and personal factors further influence their abilities and outcome. The child health and disability experience of “Hannah” introduced in Chapter One could, for example, be diagrammatically described in the using the ICF approach (Figure 3) based on the framework developed by Palisano (1997).

**Figure 3: Relationships amongst Components of Health and Contextual Factors for Hannah**

![Diagram of Hannah's Health and Contextual Factors](image)

2.3 Classification of Cerebral Palsy

Cerebral palsy is a complex heterogeneous condition best understood by classifying the motor type, topographical distribution and functional severity (Howard, Soo, Graham, Boyd, Reid, Lanigan, Wolfe & Reddihough, 2005). A sound understanding of cerebral palsy is required for home program intervention planning because the child’s potential and success of intervention is affected by the severity of the movement disorder and the distribution of involvement across the body (Bartlett & Palisano, 2002; Graham, 2005). An overview of motor types, topography and severity is now provided.

Motor Types: The most common description of cerebral palsy is “spasticity”, affecting 83.7% of people with the condition (Stanley, 2000). This description is used when muscles are overactive and display: “a velocity-dependent resistance…to stretch.” (Sanger, Delgado, Gaebler-Spira, Hallett & Mink, 2003, p.91). Spasticity and the accompanying symptoms of loss of selective motor control and balance affect a person’s ability to perform daily functions and can cause secondary impairments such as loss of muscle length, joint dislocation and pain (Gormley, 2001). Co-existing sensory deficits can also significantly impact on function (Gormley, 2001).

“Dyskinesia” has two motor type sub-groups, choreoathetosis and dystonia. Together these two classifications account for 8.6% of cerebral palsy (Stanley, 2000). Choreoathetotic cerebral palsy is: “dominated by both hyperkinesia (increased activity-stormy movement) [and] hypotonia (tone usually decreased)” (Rosenbaum, 2003, p.973). Dystonia is hypertonia (tone increased) with involuntary: “abnormal twisted postures or repetitive movements.” (Sanger et al, 2003, p.92).

“Ataxia” affects approximately 7% of people with cerebral palsy (Stanley, 2000). Ataxia results in tremors and movements with a “shaky” quality. “Ataxic cerebral palsy is characterised by both abnormal pattern of posture and/or movement and loss of orderly...
muscular coordination so that movements are performed with abnormal force, rhythm, and accuracy” (Rosenbaum, 2003, p.973).

Topography: “Hemiplegia” is seen when the leg and arm on only one side of the body are affected (Bleck, 1997; Dormans & Pellegrino 1998) and it accounts for 36.2% of all cerebral palsy (Stanley, 2000). Children with hemiplegia usually can walk and talk independently (Bleck, 1987; Molnar & Gordon, 1976; Stanton, 1992). The majority of children with spastic hemiplegia have normal academic potential and mature to live and work independently as adults (Bleck, 1987).

“Diplegia” is seen when the legs are primarily affected. There may be some involvement of the arms but this is significantly less than the involvement of the lower limbs (Rosenbaum, 2003). Diplegia accounts for 31.6% of all cerebral palsy (Stanley, 2000).

“Quadriplegia” is seen when all four limbs are affected, which functionally compromises the whole body (Rosenbaum, 2003). Diffuse brain damage has occurred for quadriplegia to result and therefore other disabilities also commonly occur, including seizures, intellectual disability, vision and hearing impairments and speech impairment (Rosenbaum, 2005). The severity of associated impairments has a profound impact on the management, functional potential, and life expectancy of a person with cerebral palsy (Blair & Watson, 2006).

Severity: Cerebral palsy is a diverse condition and consequently functional severity varies considerably. Subjective terms like ‘mild’, ‘moderate’ and ‘severe’ have now been replaced with standard classification instruments. The most commonly used instrument for measuring severity is the Gross Motor Function Classification System (GMFCS) (Palisano et al, 1997) that describes a person’s self-mobility and the amount of adaptive equipment used to achieve self-mobility. The GMFCS presents a five-level ordinal classification system (Graham, 2005). The inter-rater reliability (0.93) and test-retest reliability (0.79) of GMFCS are high (Wood & Rosenbaum, 2000). Families, as well as
health professionals, can reliably classify the severity of their children’s cerebral palsy using this instrument (ICC 0.92) (Morris, Galuppi & Rosenbaum, 2004). Levels I and II are more generally thought of as mild impairment with good mobility, Levels III and IV reflect moderate impairment with limited mobility and some ability to maintain an upright posture and Level V is associated with severe impairment without any independent upright posture (Waters, Maher, Salmon, Reddihough & Boyd, 2005). Children with hemiplegia for the most part are classified as level I (87.8%) (Gorter et al, 2004). Children with bilateral involvement (diplegia and quadriplegia), are more severely affected functionally (Gorter et al, 2004). They can have any GMFCS level, but are mostly classified at levels III, IV, and V (Gorter et al, 2004).

More recently, another scale has been developed to complement GMFCS. This scale is the Manual Ability Classification System (MACS) (Eliasson et al, 2006). It is a description of both hands working together within an activity (Eliasson et al, 2006). MACS rates children’s ability to handle objects in everyday activities and everyday environments (Eliasson et al, 2006). MACS evaluates the ability to handle objects and the speed and accuracy of achievement. MACS has good validity and reliability (Eliasson et al, 2006; Morris, Kurinczuk, Fitzpatrick & Rosenbaum, 2006). Families, as well as health professionals, can reliably classify the severity of their child’s upper limb involvement using MACS (ICC 0.96) (Eliasson et al, 2006).

2.4 Parents of Children with Cerebral Palsy
The experience of having a child with a disability is unexpected and is known to be associated with profound feelings of grief, loss and stress (Burke, 1991). As Larson explains: “The acquisition or onset of a disability by a family intrudes on a family’s life blueprint. It drives the family to make sense of this accidental occurrence and to redefine their collective goals, life circumstances, the meaning of life and their identity of the affected family member.” (Larson, 1998, p.865).
Parents of children with cerebral palsy are more likely to have physical and psychological health problems, such as stress, periodic depression (Beckman, 1991; Brehaut, Kohen, Raina, Walter, Russell, Swinton, O'Donnell, & Rosenbaum, 2004; Hansen & Hanline, 1990) and lower incomes in spite of having the same educational levels as other parents (Brehaut et al, 2004). Differences in health and income arise because caring for a child with cerebral palsy is a physical and time-consuming role, which also reduces parents’ availability to work for pay (Brehaut et al, 2004).

Parents who have a child with cerebral palsy begin with the same hopes and dreams that any parent has for their children. Parents feel great loss as they grapple with accepting that these dreams may never be achieved (Burke, 1991). One family described their diagnosis experience as: “Our first reactions were devastation, denial, and disbelief. We wondered if it could be ‘fixed’” (Burke, 1991, p.53). The parenting role is complex, demanding and unexpected (Piggot et al, 2003) and has been referred to as “transformed parenting” (Seideman & Kleine, 1995). Almost all parents of children with cerebral palsy experience a “compelling challenge” to do all that they can for their child (Piggot et al, 2003, p.6). Parents have described this challenge as “coming to grips” with having a child with cerebral palsy and “striving to maximise” the child’s function (Piggot et al, 2003).

This experience frames parent expectations of intervention and their hopes about the potential benefits of intervention (Miller & Bachrach, 1995). Families may seek solutions and cures to remedy their circumstance (Larson, 1998). Therapeutic interventions only improve symptoms and promote development (Larson, 1998) they do not cure the condition (Reddihough & Collins, 2003). There may thus be a mismatch between parental expectations and what intervention can actually deliver. Parent involvement in intervention is therefore a complex interaction of desire to achieve the best for their child combined with personal factors such as hope, guilt, self-assumed parental roles beliefs and expectations (Miller & Bachrach, 1995). The experience has been
described as “the embrace of paradox” (Larson, 1998, p.870) where parents have to manage the opposing forces of loving the child as they are and yet still wanting to erase the disability (Larson, 1998).

Adjustment to having a child with cerebral palsy has been described by parents as a complicated lifelong process, which involves learning new skills at the same time as experiencing an overwhelming care-giving burden (Burke, 1991). In the initial stages, families cope in different ways (Piggot et al, 2003). Some cope by limiting their load in order to make more time available to care for their child with cerebral palsy (Piggot et al, 2003). Others choose to “let things slide”, which for 100% of parents interviewed in two qualitative studies included stopping home program implementation (Hinjosa, 1990; Piggot et al, 2003). The decision to stop participating in a home programs as a coping strategy was related to: (1) implementation time available in competition with other parental responsibilities (Hinojosa, 1990; Piggot et al, 2003); (2) lack of understanding about the rationale for the activities and confidence in implementing them (Piggot et al, 2003); and (3) the child’s lack of enjoyment of the activities (Hinojosa, 1990; Piggot et al, 2003).

Parents are concerned with the quality of their caregiving because they perceive that the quality of the care they provide is directly linked to their child’s outcome. Parents believe that the more time they spend practicing therapeutic tasks at home, the better their child will progress (Thompson, 1998). They also believe that increased competency in parental caregiving responsibilities is an important outcome of intervention (Washington & Schwartz, 1996). “Intervention” should thus be more than a child-centred service; it is also about the quality of parental caregiving competency (Washington & Schwartz, 1996).

2.5 Parents and Home Programs
Parents of children with cerebral palsy feel a “compelling challenge” to do all that they can for their child (Piggot et al, 2003). Many parents of children with disabilities seek out intense hands-on provider-delivered therapy for their children, believing “more therapy is
better” (Hinojosa, 1990, p.157). Australian mothers describe feeling anxious, angry and frustrated when they experienced difficulties accessing therapy services at their desired intensity level. These mothers describe being involved in an ongoing cycle of seeking, waiting for, participating in, and evaluating intervention services (Thompson, 1998). Parents seek sustained intense hands-on therapy even though there is emerging evidence that a higher frequency of hands-on therapy is not necessarily better (Bower, Michell, Burnett, Campbell, & McLellan, 2001). Home programs may be an alternative to hands-on therapy as they provide opportunities for more therapy albeit by parents not professionals.

Research about parents and home programs within the FCP framework is limited. To date, most home program research has focused on parental “compliance” with prescribed home programs (Gajdosik, 1991; Gajdosik & Campbell, 1991; Law & King, 1993; Mayo, 1981; Molineux, 1993; Schreiber et al, 1995; Wortis, Cooper, & Simonson, 1954). Here the assumption was that children would miss out on potential developmental progress because of parental “non-compliance” (Molineux, 1993). Research has also focused on the impact on parent-child relationships when parents were “trained” to become “therapists at home” (Turnbull & Turnbull, 1978; Tyler & Kogan, 1972). One more recent study of parent home program experience moved beyond the compliance model and identified that home programs served to increase motivation because the program enabled parents to see a future for their child (Pigott et al, 2003). Nevertheless parent concerns and anxieties still exist (Pigott et al, 2003). Parents ask questions such as “Is my child missing out?” by having a home program instead of hands-on therapy (Miller & Bachrach, 1995) and “If my child had therapy, would they do better?” (Miller & Bachrach, 1995).

2.6 Health Services used by Children with Cerebral Palsy

The aim of services for children with cerebral palsy is not to cure or achieve normality but to increase the child’s function, health and independence (Krigger, 2006). A range of health
professions provide specialist service selected on the basis of the child’s individual abilities (Koman et al, 2004) and the family’s goals (Law et al, 1998). Professionals may “include a primary physician, physician specialists (neurology, physiatry, orthopedics, neurosurgery, etc.), therapists (physical, occupational, speech, recreational, etc.), orthotist, nurse, psychologist, social worker etc” (Delgado & Coombes, 1999, p. 42). Medical and surgical management is common but is usually accompanied by occupational therapy, physiotherapy and speech pathology (Koman et al, 2004). A recent American cohort study of 814 children receiving rehabilitation that included cerebral palsy as a major diagnostic group found that both occupational therapy and physiotherapy were the primary therapies used: 98% received occupational therapy, 99% received physiotherapy, 97% speech pathology and 60% psychology (Chen et al, 2004).

Occupational and physiotherapy approaches seek to improve the child’s independence and therefore often use specialist equipment such as walking aides and specialist seating orthotics and casting (Chen et al, 2004). Physiotherapy primarily aims to improve the child’s gross motor skills and occupational therapy seeks to improve the child’s independence by addressing upper limb function and self-care skills (Green et al, 1997). Social worker and psychologist services are principally aimed at improving family functioning, via techniques such as mutual aid support groups, developing skills for empowerment and behaviour management (Dabney et al, 1997). The professionals typically work together in teams as follows (Krigger, 2006): the medical specialist develops the comprehensive long-term plan as team leader; the orthopaedic surgeon seeks to prevent contractures, hip dislocation and scoliosis; the physiotherapist focuses on improving movement and strength; the occupational therapist focuses on developing independence in activities of daily living; the speech pathologist optimises the child’s capacity for communication; the social worker identifies community assistance programs; and the psychologist assists with adjustment and coping (Krigger, 2006).
A brief overview of occupational therapy management is now provided as a background to the focus on home programs that follows in Chapter Three.

2.7 Occupational Therapy: An Overview

The aim of occupational therapy with children is to maximise independence in everyday activities and functional potential (McElderry, 2000). Cerebral palsy, of all the physical disabilities, is the largest diagnostic group referred to paediatric occupational therapy (McElderry, 2000) and there is a well-established role for occupational therapists in supporting families to achieve desired health outcomes (Bazyk, 1989; Palisano, Snider & Orlin, 2004). Intervention targets body function and activity limitations, and seeks to enhance quality of life and participation in the community (Case-Smith, 1996, Law et al, 1998). Emphasis is placed on maximising upper extremity function and developing independence in self-care and play (Steultjens et al, 2004). For children with cerebral palsy, occupational therapy intervention involves specialist intervention techniques and adaptive equipment (Ketelaar et al, 2001; Stanton, 1992). Parent counselling and education are also used to optimise the child’s environment and supports (Steultjens et al, 2004). Emphasis on maximising participation in everyday life of children with cerebral palsy through occupational therapy is growing (King et al, 2004) because it is recognised that participation is the context for forming friendships, developing competency and understanding social expectations (Brown & Gordon, 1987). Occupational therapy for children with cerebral palsy uses a variety of techniques to promote independence and function (many of these techniques are also used by physiotherapists). Occupational therapy techniques intervene on different domains, including seeking to improve child factors in the areas of body structure, activity and participation, or altering task and environment constraints to improve the child’s performance (Law et al, 1998). The range of occupational therapy techniques used and the corresponding evidence for effectiveness are discussed in depth in the next chapter (section 3.3.3).
Occupational therapists provide intervention to children with cerebral palsy using a range of service provision models. Therapists have needed to develop new service delivery models to accommodate reduced health care funding, changes in philosophy and new understandings from research. These factors together have influenced the way in which therapy is now provided to children with disabilities (Jirikowic et al, 2001). The models currently used include direct service, consultation and home programs (American Occupational Therapy Association, 1989; Hinojosa et al, 2002; Jirikowic et al, 2001; Law et al, 1993; McEwen & Shelden, 1995).

In the past, direct hands-on therapy was the primary model, with services provided in hospital and outpatient settings several times per week (Jirikowic et al, 2001). Home programs were prescribed for use between treatment sessions (Molineux, 1993). Nowadays therapists may see children less frequently and monitor progress, develop home programs and prescribe adaptive equipment to compensate for loss of function (Jirikowic et al, 2001). In Australia, some children with cerebral palsy receive hands-on therapy services, home programs, and school-based consultative services whilst others have difficulty accessing any services at all. It is not unusual for children with cerebral palsy to have months without occupational therapy, as waiting times for therapy services are common (Thompson, 1998). In “waiting” periods, families experience great anxiety and employ a range of strategies to fill their information and service needs (Thompson, 1998). These can include private occupational therapy services paid for by the family, internet and face-to-face parents support groups and the continued use of previously prescribed home programs.

The continuum of service models offered to children and families aims to be responsive to unique needs by considering the variety of environments in which intervention may occur, the child’s individual needs, and the skills and preferences of the child’s parents and significant others (Dunn, 2000). Chapter Three is dedicated to describing the occupational therapy home program service model in depth.
2.8 Family-Centred Practice

Vast and complex arrays of services are offered to children with cerebral palsy and their families. Selection, implementation and evaluation of these services by parents in partnership with health professionals occur within the framework of FCP.

Since the deinstitutionalisation of care for people with disabilities, children with cerebral palsy have lived at home with their families. Any intervention for these children therefore inevitably now occurs within a family context. As a consequence, connection and partnership with the whole family is critical within any therapy service. In addition, parents also perceive that the quality of their relationships with therapists affects outcomes (Hinojosa, 1990). FCP is a service philosophy based on partnerships between parents and professionals (National Centre for Family-Centred Care, 1990). This section of the literature review considers the FCP approach, and the key features of this model that influence therapy including home programs.

Parents of children with disabilities participating in PROSPECTS (A family support and advocacy group in Peterborough Ontario) have defined FCP as an approach:

“that begins with the child’s and family’s strengths, needs and hopes, and results in a service plan which responds to the needs of the whole family. It involves education, support, direct services and self-help approaches. The role of the service provider is to support, encourage and enhance the competence of parents in their role as caregivers.” (Viscardis, 1998, p.44).

This definition identifies that the focus is the child within the family and the development of parent competence via active support from the therapist. The key elements of FCP include recognition that the family is the constant in a child’s life, facilitation of parent-therapist collaboration, celebration of diversity, recognition of family strengths and coping styles, provision of unbiased information, facilitation of family-to-family support, recognition of children and their families’ needs within the system, implementation of comprehensive family support policies and provision of flexible services responsive to family needs (National Centre for Family-Centred Care, 1990).
FCP assumes that families are capable of making informed decisions concerning the welfare of their child with a disability. Not only that, but parents are also able to work as partners with professionals and they have the right and responsibility to do so (Viscardis, 1998). The focus for decision-making shifts from the expert professional to the expertise of the parents who are the constant and primary caregivers in the child’s life. Parents’ rights to determine what is best for their child and their family are respected regardless of differing professional opinions (Dormans & Pellegrino 1998).

Professionals, including occupational therapists, have needed to reorient and reinvent their service approaches and offerings in the light of this shift of authority from provider to parent. This is because the FCP is a major change from the ‘medical model’ used in the past. Traditionally, the primary focus was the child and the expert professional who made the decisions (Bailey, Buysse, Edmmondson, & Smith, 1992; Dormans & Pellegrino, 1998; Dunst, 1991; King, Law, King & Rosenbaum, 1998; Leviton, Mueller & Kauffman, 1992; Rosenbaum, 1998; Winton & Bailey, 1997). Services were child-centred and health professionals set goals to achieve health improvements for the child, thus making parents passive recipients of therapy services (Hanna & Rodgers, 2002; Rosenbaum et al, 1998). The role of the therapist working in a family-centred approach is different – it becomes one of support to the family to help them meet needs they identify as important (Viscardis, 1998). This is opposite to the way in which professionals were trained in the medical model (Mattingly and Lawlor, 1996). The therapist shifts from being director to being directed (Viscardis, 1998). In the FCP approach, health professionals build collaborative partnerships with parents as the starting point of health care provision (Mattingly & Lawlor, 1998). The term ‘collaborator’ means: “associate, colleague, coworker, teammate, copartner and ally.” (Crais, 1993, p.29). Typically parents and therapists collaborate to share decision-making responsibilities in program planning. Service delivery
and evaluation are also shared to attain therapy outcomes that are meaningful to the family (Hanna & Rodgers, 2002).

FCP aims to empower parents to reclaim the role of decision-maker in their child’s health care (Humphrey & Case-Smith, 1996; Rosenbaum et al, 1998). This includes parents being “given options about the intensity of their involvement as team members” (Viscardis, 1998, p.44). Occupational therapists working in a FCP framework place particular emphasis on building parental caregiving competency (Washington & Schwartz, 1996). Parental caregiving competency is defined as: “the mother’s [and father’s/carer’s] ability to meet her child’s needs, which may include needs related to safety, health, physical, social and emotional status” (Washington & Schwartz, 1996, p.36). Parents receiving occupational therapy with a FCP approach indicated that an outcome of FCP services is a personal perception of increased competency in managing their parenting responsibilities (Washington & Schwartz, 1996). Therapists work to build parenting skills that enhance children’s development (Washington & Schwartz, 1996) and support parents in their caregiving role to promote the children’s functional development (Thompson, 1998).

Recognition of the central role of the family has not only changed thinking and language but has also changed service practice. The FCP approach has been mandated by United States public law such as the Education for all Handicapped Children Act, 1975. In Australia, disability service policies endorse the FCP as “best practice” (Hanna & Rodgers, 2002; NSW Department of Community Services, 1993) and The Spastic Centre of NSW, the principal study site, has also adopted this approach. FCP is recognised as the ‘gold standard’ for service provision for children with cerebral palsy (Dormans & Pellegrino, 1998; Ahmann, 1994; Roberts & Magrab, 1991).

2.9 Synopsis

This chapter outlined the context in which this study is based, by describing the condition, the impact of cerebral palsy on children’s development, the involvement of parents in
home programs, the types of health services provided to children with cerebral palsy, an overview of current occupational therapy practice and ways in which occupational therapists and parents work together to maximise outcomes with the FCP. The next chapter will outline the background and development of the home program used in the study.
Chapter Three: The Home Program

3.1 Introduction
This chapter presents the rationale, design and content of the home program utilised in this study. Section 3.2 outlines the conceptual models that informed program development. Section 3.3 describes the occupational therapy process as applied in the home program. Section 3.4 presents characteristics of home programs, and Section 3.5 follows with the occupational therapy home program design which comprised a series of parent, child and therapist tasks and stages. The therapeutic activities offered to families are in Section 3.6, together with a review of evidence that underpins these activities. Section 3.7 examines evidence relating to home program effectiveness in depth. This concludes the chapter, which is followed by Chapter Four, the randomised controlled trial (RCT).

3.2 Models Informing Home Program Design
This section presents a review of the models that underpin decision-making about children’s learning environments, selection of home program goals, and therapy intervention choices.

3.2.1 Models that Underpin the Home Setting for Therapy
A child with cerebral palsy’s learning can be influenced by child, task, and environmental factors (Law et al, 1998). The ‘ecological approach’ to intervention recognises that there is a complex interaction between the child’s skills, the task they are trying to achieve and the environment in which they are learning (Ekstrom et al, 2005). The ‘ecological approach’ is thus relevant to home programs as it recognises the potential for child/task/environment interactions in real-life contexts, rather than in clinical settings (Ekstrom et al, 2005). The belief is that therapy in everyday settings, such as the home, will facilitate children to develop solutions to problems arising from real tasks they want to master (Gentile & Pick,
As a consequence, skill generalisation is accelerated because natural settings provide a diverse range of learning and problem solving opportunities (Law et al, 1998). In occupational therapy, the focus of learning is functional activity and task mastery. Practice in home environments is motivating for the child because the aim is to achieve functional goals important to the child and family (Ekstrom et al, 2005; Law et al, 1998). These goals are important because family-centred practice (FCP) frameworks emphasize family priorities and preferences. Working within natural environments is considered an extension of FCP (Hanft & Pilkington, 2000). The bringing together of ecological principles and FCP has been is given a specific name: “family-centred functional therapy” (Law et al, 1998). Here the therapist focuses on the practice of functional activities whilst adapting any task and environment constraints that inhibit the child’s performance (Law et al, 1998).

The effectiveness of therapy provided from the FCP approach, with an emphasis on functional therapy, informed by the ecological approach, is an emerging evidence base (Law et al, 1998). An RCT suggested it was effective (Ketelaar et al, 1998). Preliminary evidence (from small single-group pre-post studies) also suggested that this type of intervention leads to improvements in function (such as mobility, self-care and socialisation) and improvements in parent satisfaction with the child’s performance (Ekstrom et al, 2005; Law et al, 1998; Lammi & Law, 2003).

3.2.2 Models that Underpin Home Program Selection and Overarching Goals

Children’s learning experiences are affected by their unique family routines and activities [such as bedtime, homework, watching television, playing computer games, playing sport and visiting grandparents]. The child’s everyday experience is a source of learning (Wiesner, 2002). This understanding of child development is known as the “eco-cultural perspective” (Nihira, Weisner & Bernheimer, 1994; Wiesner, 2002). Task demands, values, goals, relationships, emotions, motivations, and an accepted right way to do things in daily life are learning opportunities and stimuli (Wiesner, 2002). Good occupational therapy practice
therefore seeks to harness these opportunities for learning to make home programs part of a child’s everyday experience.

Interventions based upon the eco-cultural approach seek to help families achieve a “better ecological fit” (Weisner, 2002). This is where families respond to their life circumstances by building and organising sustainable routines that give meaning to their lives (Bernheimer & Weisner, 2007). For the current RCT, there was thus a need to design a home program that could be part of a sustainable family routine or could help to build one. A sustainable home program routine was assumed to better foster the child’s development as it was grounded in daily experiences.

Eco-cultural theorists recognise that what the parent and child do and the way in which they respond to each other is a dynamic “transactional” process that leads to the development of a unique family culture with its own routines (Spagnola & Feise, 2007). This is particularly beneficial for children when the “transactional” process leads to engagement in a “sustainable routine” (Weisner, 2002). Families who implement home programs are creating their own unique family ecology (Gallimore et al 1989). Sustainable routines are proposed to lead to developmental gains and wellbeing in children (Weisner, 2002). Home program routines must therefore be meaningful and sustainable. Sustainable routines are those reinforced and ritualised by parents, and in the case of home programs, reinforcement and ritual is likely when the child improves (Piggot, 2003). Previous research has shown that once a health routine becomes ritualised, it is likely to be sustained over time and the routine itself encourages family members to continue to adhere (Denham, 2002).

3.2.3 Models that Underpin Home Program Motor Intervention Choices
Historically “bottom up” approaches have been used in occupational therapy intervention for motor impairments of children with cerebral palsy. A typical example is Neurodevelopmental Therapy (Law et al, 1998). These approaches aimed to remediate
“delayed, deficient or missing” foundational motor skills on the assumption that this would then lead to functional improvements (Law et al, 1998). The approaches presumed that when the normal movements and sensory responses were developed they would be integrated into daily activities without any specific training in tasks (Eliasson, 2005). These approaches do not, however, appear to produce gains that translate into everyday skills (Brown & Burns, 2001; Law et al, 1998). More recently, goal-directed or “top down” approaches such as “goal-focused task training” (Eliasson, 2005) have been recommended. Here the child is taught strategies for success, given opportunities for multiple practice and enabled to learn through practice (Eliasson, 2005).

The model underpinning these recent approaches is the ‘Activity-Focused Motor Interventions Model’, developed by Valvano (2004). This integrates “motor learning theory” within the International Classification of Function (ICF) framework for paediatric therapy (Valvano, 2004). The model emphasises ways of intervening that optimise the child’s learning and generalisation of functional tasks, whilst accounting for the child’s individual strengths and difficulties (Valvano, 2004). Intervention implemented within the activity-focused model aims to increase participation in meaningful activities based on family priorities. Interventions are either “activity-focused”, involving structured practice and repetition of functional tasks, or “impairment-focused” where the aim is to prevent deterioration (Valvano, 2004).

Two features set this model apart from former “bottom up” approaches. First, the focus is on practicing the action not the pattern of movement. Second, normal movement quality is not the goal of practice, rather the focus is on functional activity performance. The child’s self-selected movement pattern is not changed unless it is unsuccessful or will cause secondary impairments over time (Valvano, 2004). It embraces the thinking of “dynamic systems theory” (Darrah & Bartlett, 1995) where it is proposed that abnormal movements made by a child with cerebral palsy are in fact the functionally and
biomechanically optimal movements available to them given the brain damage that has occurred (Carr & Shepherd, 1987; Darrah & Bartlett, 1995).

In this “top-down” approach impairment-focused interventions are still used to support function and prevent secondary disability, but the difference when compared to “bottom up” approaches is that they are used in the context of functional activity (Valvano, 2004). The activity-focused motor interventions model thus provides the framework for home program functional activity choices in the present study.

3.2.4 Models that Underpin Home Program Design for Motor Intervention
Home programs need to change specific factors to attain agreed goals. The model of determinants of motor change (DMC) (Bartlett & Palisano, 2000) helps identify those factors, which if targeted by intervention may positively influence outcomes. The ICF framework, presented earlier, underpins the motor determinants model. There are five factors or constructs to the model. These are: (1) child primary impairments, which are the body structures such as spasticity; (2) child secondary impairments, which are body structure impairments resulting directly from primary impairments such as contracture secondary to spasticity; (3) child personality characteristics, such as motivation; (4) family ecology, such as family support structures; and (5) access to appropriate health care services. The five constructs are hypothesised to interact to explain the acquisition of motor abilities and resulting activities performance in children with cerebral palsy (Bartlett & Palisano, 2000).

The DMC model helped the therapist identify variables that could be targeted to positively affect motor change. Intervention techniques directed towards the child’s secondary impairment, such as impaired muscle force production (Bartlett & Palisano, 2000) were used in this study. These included structured practice of functional activities (Schmidt & Wrisberg, 2000). The home program was also designed to recognise that the child’s temperament, motivation, and risk taking style may influence their motor outcome.
Consequently, selection of motivating home program activities was achieved through: (a) use of goals that were meaningful to the child and family specifically addressed using the goal-focused task practice technique; and (b) finding out about the child’s enjoyment of activities and ensuring these interests were included in the “library of activity ideas” used in the program. Programs were also individualised, to achieve the best possible fit with the child’s temperament and interests, to enhance motivation during learning (Eliasson, 2005).

The home program also aimed to recognise and work with and within family ecology factors affecting the intervention outcomes. To do this the home program was individualised to accommodate unique family resources, their home environment, their available supports and family expectations (Bartlett & Palisano, 2002).

### 3.2.5 The Home Program Design

Occupational therapy home programs for children with cerebral palsy are informed by theoretical models. The need for intervention arises from activity and participation limitations that children with cerebral palsy experience because of their motor and associated impairments (ICF). Since these children live at home in the expert care of their family, intervention is planned and designed in partnership with the whole family to reflect their goals (FCP). Home programs are routinely used as one aspect of the intervention service delivery continuum because they recognise the expert caregiving of families. As part of the home program design the context for learning is considered (ECP), the program is activity based (AFM) and all of the possible catalysts for influencing change with the child, family and health system are intervened upon (DMC). Figure 4 presents the way in which these various models form the foundation for home program design. The treating occupational therapist in this trial combined the information gathered about family goals, possibilities for influencing change, together with knowledge of the best available evidence to address the focus areas identified.
3.3 The Occupational Therapy Process

The following sections describe the occupational therapy process in home programs for children with cerebral palsy. Assessment and intervention planning, common occupational therapy intervention techniques, research evidence to support these techniques, and evaluation of the occupational therapy home program will be presented.

3.3.1 Occupational Therapy Assessment

The starting point of assessment, when using FCP, is establishing a collaborative partnership between the family and the occupational therapist. Once this foundation is achieved, assessment activities commence. The purpose of assessment is done to gain an in-depth understanding of the child’s unique abilities and limitations (Dunn, 2000). This is done to identify what factors are limiting goal achievement. Consideration of the environment in which the child performs the tasks is also important (Stewart, 1996). Other professions assess abilities, limitations and environment but occupational therapy assessment is uniquely characterised by examination of the child's ability to perform everyday roles and activities (Copley & Kuipers, 1999; Dunst, 1991; Humphrey & Case-Smith, 1996; Powell 1985). Roles evaluated include “productivity” such as play and school
performance, “self-care” such as dressing and eating, and “leisure” such as community sports (Law et al, 1994). The child’s performance of functional tasks and roles is analysed within different environments to reveal individual strengths and limitations, which may benefit from intervention (Case-Smith, 1996).

Sources of information for assessment may include medical records, standardised paediatric assessments that are either norm-referenced or criterion-referenced, skilled observations, interview protocols, ecological measures, and activity analysis to quantify the goal limiting factors identified (Dunn, 2000; Erhardt & Merrill, 1998). Assessment of the child with cerebral palsy routinely includes a measure of motor function (such as range of motion, muscle strength, sensation and analysis of the degree of voluntary movement possible) (Bleck, 1987). Many authors have noted, however, that it is more important to assess functional abilities, such as eating, hygiene, toileting and dressing than motor alone, because changes to body structure impairments do not necessarily translate to activities and participation impairments (Bleck, 1987; Copley & Kuipers, 1999; Harris, 1988; Tardieu, Tardieu, Colbeau-Justin & Lespargo, 1982).

Paediatric occupational therapy assessment is designed to understand why a child is having difficulty achieving a goal important to activities and roles. The process begins with in-depth task analysis because that enables the therapist to analyse the different aspects of the learning process (Eliasson, 2005). It may include assessment of: (a) neuromuscular performance such as reflexes, range of motion, muscle tone, skin integrity, strength and endurance, and postural control; (b) motor performance such as gross motor, fine motor, oral-motor, and praxis; (c) cognitive performance, such as attention, memory, sequencing and problem solving; (d) psychosocial performance such as social engagement; (e) perceptual skills, such as visual discrimination, visual closure, and visual motor skills; and (f) sensory processing, such as tactile and proprioceptive processing (Dunn, 2000).
Not all of these aspects of function are necessarily assessed because the decision about what to assess is informed by family goals, the child’s activities and roles, and whether there is supporting evidence to suggest that the area for assessment is related to the problem or goal (Eliasson, 2005). The child’s problem and the intended outcome of intervention guide assessment decisions (Eliasson, 2005). From the assessment findings, the occupational therapist then determines what is interfering with the child’s function and the attainment of the family’s goals (Case-Smith, 1996, Christiansen, 1991). This is then considered in the light of individual family needs and strengths, the child’s activities and roles and research evidence. This process signifies the end of the assessment phase and the commencement of intervention planning.

3.3.2 Intervention Planning
The intervention plan aims to meet the family’s goals and enhance child function, with solutions and strategies developed in collaboration with the child and their family (Case-Smith, 1996, Christiansen, 1991, Erhardt & Merrill, 1998). After occupational therapy assessment there are often many goals. These are divided into short-term and long-term goals, which together provide a sequenced guide to accomplish the overall objective. Different components of goals are targeted by different interventions. Three discrete stages typify intervention planning (Christiansen, 1991). (1) The first is the establishment of short and long term goals in partnerships with parents, where the therapist responds to information needs of the family. The therapist asks questions such as “What does this mean to you?” to obtain feedback on the family’s perception and understanding (Palisano et al, 2004, p.68). Standardised goal setting approaches can also be used at this stage such as the Canadian Occupational Performance Measure (COPM) (Law et al, 1994) or the Goal Attainment Scale (GAS) (Kiresuk & Sherman, 1968). Both were used in the present study. (2) The second stage is the selection of the intervention technique to reach the goal. (3) Then finally re-evaluation of the child’s progress (Christiansen, 1991).
Therapist intervention planning is done through a process called clinical reasoning. Clinical reasoning is the process used to plan, direct, perform, and reflect on client intervention (Mattingly & Flemming, 1994). Schell (1998) describes four types of clinical reasoning. First, ‘scientific reasoning’ involves developing an understanding of the condition in order to select the best possible intervention. Second, ‘narrative reasoning’ involves understanding the meaning of the disability to the individual and the ability to see the experience from the family’s perspective. Third, ‘pragmatic reasoning’ is an awareness of the context in which therapy occurs, including resources, team members, cost, and practice trends. Finally, ‘ethical reasoning’ is the overarching process in clinical decision-making which it is the ‘what should be done?’ question (Schell, 1998). In the present study clinical reasoning was used to shape the home programs based on the families goals identified, the learning context and supports, the existing child impairment and family ecology factors and the best available evidence for the intervention techniques being selected.

3.3.3 Intervention
Many intervention techniques are available for use with children with cerebral palsy to assist them and their families to reach goals. Techniques serve different purposes. Some seek to assist the child to establish new skills, some modify the task demands to support the child’s performance, some alter the environment to enhance success, while others aim to prevent secondary impairments from occurring (Dunn, 2000). Despite the range of occupational therapy techniques for intervention there is limited high quality evidence available about their effect. At present, some common therapy techniques for people with cerebral palsy lack conclusive experimental evidence to support their effectiveness (Siebes, Wijnroks & Vermeer, 2002). The challenge for occupational therapists in the field of cerebral palsy is the paucity of randomised controlled trials and systematic reviews to guide practice (Boyd et al, 2001). The number of outcome studies being conducted has however
increased three-fold over the last 10 years (Majnemer & Mazer, 2004). Aggregate findings of occupational therapy in systematic reviews and meta-analyses, have resulted in authors concluding that there is insufficient evidence to support or reject occupational therapy and therefore more research of higher methodological quality is needed (Boyd et al, 2001; Steultjens et al, 2004).

The major systematic review which attempted to evaluate the overall effectiveness of occupational therapy intervention for children with cerebral palsy identified forty-seven efficacy research articles (Steultjens et al, 2004). Only seventeen studies were included in the review as the other thirty were of too low a level of evidence or included confounding diagnostic groups in the study sample (Steultjens et al, 2004). Steultjens et al (2004) adopted a narrow definition of intervention techniques used by occupational therapists for children with cerebral palsy: sensorimotor functions, daily activities, parental counselling, assistive devices, splints and comprehensive occupational therapy. The review determined that the overall efficacy of occupational therapy for children with cerebral palsy could not be supported or refuted based on methodological flaws of the research studies (Steultjens et al, 2004). The review identified the critical need for rigorous outcome research to be conducted in occupational therapy. The quality of the systematic review by Steultjens et al 2004 was high because it rigorously reviewed the research literature available about cerebral palsy. Steultjens’ 2004 systematic review was, however, limited in its usefulness because the research question was broad and reviewed the practices of a whole profession, and considered a very heterogeneous diagnostic group, over a long period of time. It is perhaps not surprising that none of the findings were conclusive, because knowledge about cerebral palsy and approaches used in practice has undergone significant change.

In contrast to “whole of occupational therapy” studies, systematic reviews of single occupational therapy intervention techniques have produced favourable findings and recommendations about what to do and what not to do because of the specificity of
research questions asked (Boyd et al, 2001; Teplicky, Law & Russell, 2002; Wasiak, Hoare & Wallen, 2004).

As previously identified, the Steultjens et al (2004) review left out a large number of therapy techniques used by occupational therapists to assist with children who have cerebral palsy to reach their therapeutic goals. These included biofeedback (Dursun, Dursun & Alican, 2004); casting (Lannin, Novak & Cusick 2007); strength training (Dodd et al. 2002); constraint-induced movement therapy (Gordon, Charles & Wolf, 2005); handwriting training (Sudsawad, Trombly, Henderson & Tickle-Degnen, 2002); sports therapy (Van Den Berg-Emons, Van Baak, Speth & Saris, 1998); positive behaviour support (Turner et al, 2006); and training, information and support (Barlow & Parsons, 2003). In addition, within the six categories of intervention used by Steultjens et al (2004), high level supporting evidence for the same approach was excluded when it had been generated by professions other than occupational therapy. Consequently, when specific technique effectiveness is being considered, a wider range of types and sources must be considered. Table 2

Table 2 presents a comprehensive summary of techniques used by occupational therapists working with children who have cerebral palsy, and a summary of the strength of evidence to demonstrate effectiveness using the Sackett (1989) hierarchy (Table 1).

Table 1: Strength of Evidence Recommendation

<table>
<thead>
<tr>
<th></th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Both strong evidence for efficacy and substantial clinical benefit to support recommendation</td>
</tr>
<tr>
<td>B</td>
<td>Moderate evidence for efficacy–or strong evidence for efficacy but only limited clinical benefit–support recommendation for use</td>
</tr>
<tr>
<td>C</td>
<td>Evidence for efficacy is insufficient to support a recommendation for or against use, or evidence for efficacy might not outweigh adverse consequences (e.g. drug toxicity, drug interactions) or cost of the treatment under consideration</td>
</tr>
<tr>
<td>D</td>
<td>Moderate evidence for lack of efficacy or for adverse outcome supports a recommendation against use</td>
</tr>
<tr>
<td>E</td>
<td>Good evidence for lack of efficacy or for adverse outcome supports a recommendation against use</td>
</tr>
</tbody>
</table>

1 Table 2 has been published in the Australian Institute of Health and Welfare’s literature review of the Therapy and Equipment Needs of People with Cerebral Palsy. It has been reproduced with permission (Novak, 2006a).
Table 2: Occupational Therapy Interventions - Evidence and Descriptions

<table>
<thead>
<tr>
<th>Intervention Technique</th>
<th>Strength of Evidence Recommendation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Adaptive Equipment and Assistive Technology</strong></td>
<td>C</td>
</tr>
<tr>
<td>AIM: adapt/ modify task demands to improve independence</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Therapists can play a primary role in</td>
<td></td>
</tr>
<tr>
<td>monitoring &amp; assessing this equipment. Mobility aids</td>
<td></td>
</tr>
<tr>
<td>can include wheelchairs, powered wheelchairs,</td>
<td></td>
</tr>
<tr>
<td>walkers, scooters and vehicle modifications. Environmental control systems include an alternative switching device which can activate and control aspects of the environment. These systems are often used in the home and enable people with disabilities to have greater independence over operating household appliances and/or settings (such as lights). Switches can be activated by actions such as blinking or speaking. The greater the severity of CP the greater the number of products used. Products increase independence in mobility, self-care and social function, they also reduce caregiving burden</td>
<td>Lower level positive supporting evidence</td>
</tr>
<tr>
<td></td>
<td>Berry &amp; Ignash 2003; Craig et al. 2002; Ostensjo 2005; Noronha et al 1989; Pope et al, 1994</td>
</tr>
<tr>
<td><strong>Behaviour Management and Positive Support</strong></td>
<td>A</td>
</tr>
<tr>
<td>AIM: establish/ restore child’s behaviour, adapt/ modify</td>
<td></td>
</tr>
<tr>
<td>parenting behaviour and prevent parent stress.</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Children with CP are 5.3 times more likely</td>
<td></td>
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<tr>
<td>to have behavioural problems, such as: anxiety;</td>
<td></td>
</tr>
<tr>
<td>hyperactivity; dependence and group conflict, than their peers. Positive behaviour support provides training and support to parents about effective parenting. Key aspects of the technique include: safe &amp; engaging environments, positive learning environments, assertive discipline, realistic expectations and taking care of parents</td>
<td>RCT positive supporting evidence</td>
</tr>
<tr>
<td></td>
<td>Turner et al. 2006; Saunders et al 2003; Saunders et al 2002; Crisante 2003</td>
</tr>
<tr>
<td><strong>Biofeedback</strong></td>
<td>C</td>
</tr>
<tr>
<td>AIM: establish/ restore movement through feedback</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Provides feedback (visually or auditory)</td>
<td>Low level supporting evidence</td>
</tr>
<tr>
<td>on muscle activity via a machine</td>
<td>Dursun et al. 2004</td>
</tr>
<tr>
<td><strong>Casting</strong></td>
<td>C</td>
</tr>
<tr>
<td>AIM: establish/ restore muscle length and prevent joint</td>
<td></td>
</tr>
<tr>
<td>contracture</td>
<td>Systematic Review inconclusive</td>
</tr>
<tr>
<td>DESCRIPTION: Casts are made from fibreglass or plaster</td>
<td>Lannin, Novak &amp; Cusick 2007; Auttil-</td>
</tr>
<tr>
<td>of paris and are used to hold a body part in a certain</td>
<td>Ramo et al. 2006; Teplicky et al. 2002</td>
</tr>
<tr>
<td>position to stretch the immobilised muscle</td>
<td></td>
</tr>
<tr>
<td><strong>Constraint-Induced Movement Therapy (CIMT)</strong></td>
<td>B</td>
</tr>
<tr>
<td>AIM: establish/ restore functional non-dominant arm</td>
<td></td>
</tr>
<tr>
<td>movement</td>
<td>RCT positive supporting evidence</td>
</tr>
<tr>
<td>constraining the dominant arm using a mitt, sling or</td>
<td></td>
</tr>
<tr>
<td>cast while providing simultaneous intensive practice of</td>
<td></td>
</tr>
<tr>
<td>movements in the non-dominant arm</td>
<td></td>
</tr>
<tr>
<td><strong>Goal Focused Task Practice</strong></td>
<td>B</td>
</tr>
<tr>
<td>AIM: establish/ restore functional skills of daily</td>
<td>RCT positive supporting evidence</td>
</tr>
<tr>
<td>living</td>
<td>Ketelaar et al. 2001</td>
</tr>
<tr>
<td>DESCRIPTION: Repetitive practice of functional activities for the purpose of gaining mastery</td>
<td>Low level supporting evidence</td>
</tr>
<tr>
<td></td>
<td>Crompton et al, 2007; Eliasson, 2005; Valvano, 2004</td>
</tr>
<tr>
<td><strong>Hand-Arm Bimanual Intensive Therapy (HABIT)</strong></td>
<td>C</td>
</tr>
<tr>
<td>AIM: establish/ restore bilateral hand use</td>
<td>Low level supporting evidence</td>
</tr>
<tr>
<td>bilateral tasks to improve non-dominant hand use in</td>
<td></td>
</tr>
<tr>
<td>children with asymmetric hand use.</td>
<td></td>
</tr>
<tr>
<td><strong>Handwriting Training</strong></td>
<td>B</td>
</tr>
<tr>
<td>AIM: establish/ restore handwriting skills or determine</td>
<td>RCT positive supporting evidence</td>
</tr>
<tr>
<td>alternative output</td>
<td>Sudsawad et al 2002</td>
</tr>
<tr>
<td>DESCRIPTION: Practice at handwriting using movement</td>
<td></td>
</tr>
<tr>
<td>teaching techniques and prescription of adaptive</td>
<td></td>
</tr>
<tr>
<td>equipment, e.g. pencil grips</td>
<td></td>
</tr>
<tr>
<td><strong>Neuro-Developmental Therapy (NDT)</strong></td>
<td>E</td>
</tr>
<tr>
<td>AIM: establish/ restore normal motor development</td>
<td>Systematic Review negative</td>
</tr>
<tr>
<td>DESCRIPTION: Specific handling techniques are used to</td>
<td>Brown &amp; Burns, 2001</td>
</tr>
<tr>
<td>inhibit ‘abnormal’ movement patterns and facilitate</td>
<td></td>
</tr>
<tr>
<td>‘normal’ movement. Movement patterns which are addressed</td>
<td></td>
</tr>
<tr>
<td>often relate to functional, everyday activities</td>
<td></td>
</tr>
<tr>
<td><strong>Oral Sensorimotor Therapy</strong></td>
<td>C</td>
</tr>
<tr>
<td>AIM: establish/ restore oral coordination for eating</td>
<td>Low level supporting evidence</td>
</tr>
<tr>
<td>DESCRIPTION: Exercises &amp; stimulation to address</td>
<td>Hemsley &amp; Balandin 2003; Rogers 2004</td>
</tr>
<tr>
<td>coordination of oral movements &amp; saliva control for</td>
<td></td>
</tr>
<tr>
<td>people with dysphagia (difficulty swallowing)</td>
<td></td>
</tr>
<tr>
<td>Intervention Technique</td>
<td>Strength of Evidence</td>
</tr>
<tr>
<td>------------------------</td>
<td>----------------------</td>
</tr>
<tr>
<td><strong>Orthotics or Splinting</strong></td>
<td>Systematic Review inconclusive</td>
</tr>
<tr>
<td>AIM: adapt/ modify a joint &amp; muscle position for alignment or stretch or to prevent contracture</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Foot and or hand orthoses are external supports/assistive devices fixed externally to the human body for the treatment of neuromuscular and musculoskeletal impairments</td>
<td></td>
</tr>
<tr>
<td><strong>Parent Counselling</strong></td>
<td>Systematic Review positive Barlow et al. 2003; Rousso 1982; Schaller &amp; Garza 1998; Hanzlik, 1989; McConachie et al, 2000</td>
</tr>
<tr>
<td>AIM: establish/ restore parents coping in dealing with issues associated with having a child with a disability</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Therapy may involve counselling for any range of issues including coping with stress &amp; other psychological demands, formal &amp; informal relationships &amp; personal &amp; social issues. These sessions may be held on an individual or group basis &amp; can involve general education, cognitive behavioural counselling, problem solving &amp; work dealing with emotions</td>
<td></td>
</tr>
<tr>
<td><strong>Parent Education</strong></td>
<td>Systematic Review positive Barlow &amp; Parsons 2003; Bennett et al. 1997; Mahon &amp; Cusack 2002; Mahoney et al. 1999; Pennington et al. 2004, Pennington et al. 2005</td>
</tr>
<tr>
<td>AIM: adapt/ modify task demands by empowering person’s significant others with new information and skills</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: The training of persons working or living with a child of school-age is an important component of a therapist’s role. This can involve on numerous topics including, the specific condition/s and needs of a child, supporting inclusion and promoting positive attitudes. Therapists may adapt the learning environment (for example, appropriate seating, accessibility) and integrate therapeutic strategies into curriculum. Components of parental education include: assisting with development, communication partner training and, the encouragement of parents’ skills to engage their children in play and everyday social interaction.</td>
<td></td>
</tr>
<tr>
<td><strong>Play Therapy</strong></td>
<td>RCT positive supporting evidence (low power)</td>
</tr>
<tr>
<td>AIM: establish/ restore play &amp; recreation and an integral part of development</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Play is used as a means to engage a child in tasks &amp; actions that are designed to improve physical functioning. Actions may be repeated to achieve the outcomes set by the game, or a game may be used as a distraction from the intended functional activity. For example, a child may have to maintain a certain posture in order to fulfil the aim of a game, or favourite toys may be incorporated into a therapy session to increase motivation. Play therapy also involves active training to parents</td>
<td></td>
</tr>
<tr>
<td><strong>Physical Activity and Sports Therapy</strong></td>
<td>RCT positive supporting evidence</td>
</tr>
<tr>
<td>AIM: create positive community attitudes towards participation</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Exercise is considered as a form of intervention for children and adolescents and adults with cerebral palsy, and can improve levels of energy, muscle strength, aerobic fitness and gross motor function</td>
<td></td>
</tr>
<tr>
<td><strong>Seating and Positioning</strong></td>
<td>Systematic Review positive but all evidence for functional outcomes of a lower level Farley et al. 2003</td>
</tr>
<tr>
<td>AIM: adapt/ modify the person’s seat to enable the upright posture</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Prescription and manufacture of customised seating cushions with a wheelchair or stroller and/or provision of postural adjustments to enable upright sitting for function and arm use</td>
<td></td>
</tr>
<tr>
<td><strong>Strength Training</strong></td>
<td>Systematic Review positive Dodd et al. 2002; Dodd et al. 2003; Morton et al. 2005</td>
</tr>
<tr>
<td>AIM: establish/ restore muscle strength</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: A series of exercises which provide progressive resistance to muscles designed to improve independent movement and endurance</td>
<td></td>
</tr>
<tr>
<td><strong>Stretching / Range of Motion Exercises</strong></td>
<td>Systematic Review inconclusive</td>
</tr>
<tr>
<td>AIM: prevent joint contracture</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: Stretching can be performed passively (by an external person or with equipment) or actively (by the client) by holding a muscle in a stretched position</td>
<td></td>
</tr>
<tr>
<td><strong>Sensorimotor Therapy</strong></td>
<td>RCT positive supporting evidence (low power)</td>
</tr>
<tr>
<td>AIM: establish/ restore fine motor function</td>
<td></td>
</tr>
<tr>
<td>DESCRIPTION: A series of therapeutic activities practicing of fine motor tasks and games aimed at improving the dexterity and fine motor activities performance such as handwriting and cutting with scissors</td>
<td></td>
</tr>
</tbody>
</table>
Home programs for children with cerebral palsy may use any of these intervention techniques. Since definitive evidence of individual techniques or overall occupational therapy effectiveness is limited, families must therefore consider other important aspects of therapy such as cost, accessibility, time and the effect of the intervention on the family and individual when considering the type of therapy to use (Darrah, Wessel, Nearingburg, & O’Connor, 2004). The choice of home program interventions in the present study was influenced by family goals, whether the aim of intervention was to improve body functions, activity performance, or extend the child’s participation and the strength of evidence available to support effectiveness. The combination of these factors guided clinical reasoning in the intervention phase, recognising that there is little to no evidence about the superiority of one technique over another, making evidence-based decision-making difficult for clinicians and family members (Mayston, 2005).

3.3.4 Outcome Evaluation
Occupational therapy practice is constantly refined by progress evaluation. Evaluation of outcomes is essential for understanding and enhancing the quality of the interventions provided (Unsworth, 2000). For occupational therapists the term ‘outcome’ means the functional consequence of the therapy implemented (Rogers & Holm, 1994). Outcome measurement offers the therapist and family many benefits, including assistance with clinical decision-making, systematic intervention monitoring, effectiveness and efficiency information and accountability (Bowman et al, 2002).

Occupational therapists working with children have traditionally used standardised measures within their practice to evaluate the effect of intervention (Payne, 2002). These tests are usually norm-referenced tools and they may not be the most appropriate because they do not necessarily reflect unique outcomes meaningful to the family and they tend to lack sensitivity to change (Payne, 2002). Individualised outcome measures rather than norm-referenced tools are therefore recommended (Donnelly et al, 2002). Examples of
individualised measures that target unique goal outcomes suitable for children with cerebral palsy are the COPM (Law et al, 1994) and GAS (Kiresuk & Sherman, 1968). In addition to individualised clinical outcomes for children with cerebral palsy, intervention outcomes are also evaluated from the perspective of the family (Wallen & Doyle, 1996). This includes objective evaluation of the child’s achievement of goals set by the family (Wallen & Doyle, 1996). Both the COPM and the GAS measures can be used for family-centred evaluation (Cusick, McIntyre, Novak & Lowe, 2006; Wallen & Doyle, 1996). The COPM and GAS were therefore used in the present study to measure outcomes of occupational therapy home programs from the individual child and their family’s perspective.

3.4 Occupational Therapy Home Programs
3.4.1 Definitions
Most authors who write about home programs assume that readers know the meaning of the term and consequently definitions are implicit (for example, Bazyk, 1989). Molineux (1993) is an exception. Molineux provided a definition for an occupational therapy home program: “activities/exercises and/or paper and pencil worksheets completed at home by the child with parental supervision, between treatment sessions.” (Molineux, 1993, p.23). From this definition it is clear that the role of the parent in the home program is pivotal. The parent assumes responsibility for implementation of the agreed exercises with their child and drives the frequency, intensity and duration of the intervention program. The definition that is proposed by Molineux appears, however, to imply that the occupational therapist is the director of intervention rather than the family. This is seen in the choice of phrases, “between treatment sessions” indicating that the primary director of intervention is the therapist and that the ‘pivotal’ aspect of intervention is the face-to-face contact with the therapist.

This definition is consistent with references to occupational therapy home programs, such as that by Humphrey and Case-Smith (1996): “home programs [are] for the
parents to implement helping the child demonstrate new skills at home” (1996, p.89), or Law and King: “therapeutic regimens to be carried out by the parents and children at home.” (Law & King, 1993, p.983).

In the paediatric physiotherapy literature Schreiber et al (1995) have provided the following definition, the:

“frequent practice of functional skills within a typical daily routine. The frequent practice of functional skills then becomes dependent on the formulation and development of activities that parents and family members can carry out easily in the home. The home program should enhance the functioning of both the child and the family by improving the ability of the caregiver(s) to care for the child and increasing the child’s independence.” (Schreiber et al, 1995, p.60).

To date neither the definition by Molineux, nor that by Schreiber et al captures the family-centred, collaborative, goal focused nature of home programs based on the conceptual frameworks of the ICF, FCP, ECP, AFM, and DMC. Consequently the definition developed by the author in earlier research work has been adopted. Home programs are: “therapeutic activities that the child performs with parental assistance in the home environment with the goal of achieving desired health outcomes.” (Novak, Cusick and Lowe, 2007, p.475).

3.4.2 Historical Perspectives

There has been a polarisation in the cerebral palsy and early intervention literature about the perceived usefulness of home programs. Moersch (1985) observed:

“for the most part, the situation [parents as therapists] is either casually accepted or upheld as being desirable, beneficial, and expedient…There are those who oppose putting parents in the position of teachers or therapists on the grounds that this practice can diminish their roles as mothers or fathers…They caution about the implicit message to the child: ‘You need to get well – you are unacceptable as you are.’” (Moersch, 1985. p135-136).
Yet others have argued that home programs are an essential aspect of healthcare for children with cerebral palsy. Explanation for this polarisation was made by Bazyk (1989):

“Our attitudes and beliefs regarding parent participation have evolved through three stages: (a) the medical model, which involved limited parent participation, (b) the education for all handicapped children act, which viewed parents as teachers and therapists; and (c) public law 99-457, which involves family-centred parent participation.” (Bazyk, 1989, p.723).

Parental training, which was prevalent in the 1980s, first expanded the roles of parents in therapy (Bazyk, 1989). Therapists were no longer the sole providers of intervention; parents became responsible for assuming the role of ‘therapist at home’ (Bazyk, 1989). However, “family-centred participation” is different from the “education for all” model, where the goal of parental training was to assist parents to become one of the child’s “teachers and therapists”. Instead FCP recognises that the parental caregiving role is important in its own right and that this role is unquestionably the most influential on the child’s life. Now the FCP approach is accepted to be best practice (Ahmann, 1998; Roberts & Magrab, 1991). Adherence to this belief fundamentally alters the way in which home programs are delivered. It places a new emphasis on development and enhancement of parenting skills rather than metamorphosing parents into health and education specialists.

Those who have previously opposed home programs advocate that the parent and therapist roles must remain separate because of the potential negative impact on the child’s self esteem (Turnbull & Turnbull, 1978). Many texts cite a 1972 study by Tyler and Kogan, who observed parent-child interactions of children with cerebral palsy. They noted more “negative” behaviour in both the child and mother when the mother was performing therapy activities when compared to performing parenting activities. This study is, now 35 years old and home program practice has changed considerably. Further, the absence of
therapeutic outcomes as a variable of interest when considering the pros and cons of home programs is notable. None of the authors who oppose or advocate for home programs argue their case on the basis of evidence of improved or deteriorating therapy outcomes. While there does appear to be a division regarding the use of home programs, little of this controversy thus appears to be related to outcomes that might be achieved through home programs. There is instead a focus on the process. This lack of discussion may be related to the paucity of evidence regarding outcomes of home programs.

Despite conflicting views, there is a growing trend towards parental involvement in home programs (Hinojosa & Anderson, 1991; Law et al, 2005). This is because home-based intervention, like FCP intervention, can recognise the benefits of expert caregiving of parents in children’s lives (Kwok, 1994; Law et al, 2005).

Intervention provided via home programs is proposed to have many benefits. These benefits are thought to include: empowering parental control of their child’s health care; improving the parents’ ability to care for their child; children and families feeling at ease in their familiar surroundings, thereby creating more favourable conditions for intervention success; allowing for intensive practice and motor learning; better generalisation of new skills because the intervention occurred in a natural setting; increasing the child’s independence; lower cost and disruption to families; better cost-efficiency for the health system; and requiring less face to face contact with the occupational therapist, therefore the child will ultimately be less dependent on others (Hinojosa et al, 1988, Humphrey & Case-Smith, 1996, Molineux, 1993, Schreiber et al, 1995).

3.4.3 Characteristics of Home Programs
When developing a home program, Molineux (1993) outlines three issues for consideration: first, consultation with the family about goals and activities of the home program, second, consideration of parental readiness to be involved in a home program (it
must be recognised that a parent’s ability or capacity to implement a home program will vary and be affected by other aspects of family life) and third, consideration of the potential impact of the home program on the parent-child relationship (Molineux, 1993). These issues will be considered from a FCP perspective, as this is the ‘gold standard’ for paediatric health services (Dormans & Pellegrino, 1998; Roberts & Magrab, 1991). The FCP approach assumes a collaborative decision-making approach to intervention planning, individualisation of services and involvement of the whole family (Rosenbaum et al, 1998).


Six guidelines have been proposed by Bazyk (1989) for developing FCP home programs: the parent becomes the decision maker, the parent’s role does not become one of therapist but rather the occupational therapist builds the parent’s repertoire of skills, parent-therapist collaboration exists, individual differences are recognised, options are provided that fit into each family’s routines and finally and the child is viewed as a family member and the family’s acceptance of their child’s disability must be fostered.

Home programs conducted within a FCP framework, should thus have certain characteristics:

- Recognition and a valuing of the unique and influential role a parent plays in a child’s life (Bazyk, 1988; Dormans & Pellegrino, 1998; Dunst et al, 1988; Kwok, 1994; Turnbull, 1990). Home programs based on FCP principle support families in caregiving roles by building on unique strengths and working to devise strategies that reflect their preferences and aspirations (National Centre for Family-centred Care, 1990).

- Inclusion of significant people in the child’s life, for example, siblings, grandparents etc (Bazyk, 1988; Dunst et al, 1988; Kwok, 1994; Powell, 1996; Shilton et al, 1987;

- Provision of therapy in a natural environment as this leads to development of more realistic goals, strategies and solutions (Anderson & Schoelkopf, 1996; Moersch, 1985; Shilton et al, 1987). Understanding that a child ‘performs’ best in familiar and non-threatening environments (Anderson & Schoelkopf, 1996; Clarke & Allen, 1985). “At the child’s home the therapist has the opportunity to view the child’s characteristic adaptation in its fullest dimension. This is the most significant environment, because it contains those persons who can contribute most to the quality of the child’s life” (Clarke & Allen, 1985, p.146).

- Embedding of therapeutic activities into everyday activities and routines to ease the caregiving strain on families and to ensure that therapy seeks to achieve functional outcomes (Anderson & Schoelkopf, 1996; Moersch, 1985; Stanton, 1992). Stanton, the mother of a child with cerebral palsy, advises other parents: “Your child will need a therapeutic exercise program but it is important to remember that the exercises should be slotted into normal everyday life, which will enable your child to lead a full, happy and active existence.” (Stanton, 1992, p. 26).

- Enabling flexibility in scheduling and reducing additional costs and inconvenience, such as travel time or babysitting, for families whose time and financial resources are already stretched. In addition to being family-centred home programs are a cost effective service delivery model (Bazyk, 1988; Dormans & Pellegrino, 1998; Dunst et al, 1988; Kwok, 1994; Turnbull, 1990).

When home programs are embedded within the FCP framework, the daily caregiving of parents is viewed as an opportunity for therapy (Thompson, 1998). A FCP home program fosters the development of the ‘parental caregiving role’. This is a defining characteristic of FCP home programs and is what sets them apart from former intervention
approaches. It is a move away from expert professionals teaching parents what to do with their children (Bazyk, 1989), to placing a new emphasis on enhancing parenting skills for the purpose of advancing the child’s development, thus easing parental caregiving strain and promoting positive parent-child interactions. While this is positive, the caregiving burden on families may also increase. Australian health policy encourages families to care for their relatives with disabilities at home (Thompson, 1998). When the family member with a disability is a child, the definition of parental caregiving expands to include providing ‘specialist’ services to help the child (Thompson, 1998). This can be a burden. The Australian interpretation of the family-centred approach assumes that: “supporting families in their caregiving role promote[s] the functional development of the child.” (Thompson, 1998). This may mean that home program intervention in an Australian family-centred context may significantly increase the parents’ ‘workload’ within the intervention team. This is because, like North America (Humphrey & Case-Smith, 1996) the direct therapy services that Australian parents seek, may not be readily available at the parents’ desired intensity level (Thompson, 1998). Greater reliance may therefore be placed on outcomes that can be achieved by parents at home.

3.5 Home Program Design

Until recently, no guide for home program design had been developed. As part of this PhD study program an approach was developed to ensure a consistent method was used that reflected the foundational assumptions of ICF, FCP, ECP, AFM, and DMC and the principles of occupational therapy assessment, intervention planning, intervention outcome evaluation, and home programs presented earlier.

The occupational therapy home program design includes five phases: establishing a collaborative relationship with the child's parent, goal setting, constructing the home

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program, supporting the program’s implementation and evaluating the outcomes. Each of these phases will now be described, supported by relevant research evidence. The design is presented in Figure 5. The research evidence is summarised at the end of Section 3.6 in Table 3.

3.5.1 Establishing a Collaborative Relationship with the Child's Parent

The first phase of the home program is establishing an effective relationship with the child’s parent, a partnership that is characterised by collaboration.

The family is the focal point of intervention not the child in isolation (Hanna & Rodgers, 2002) consistent with the FCP approach. Consequently the starting point for the home program is not a conventional assessment of the child’s ‘deficits’ in need of remediation but instead is the establishment of an effective working relationship parents to enable joint goal-setting, planning and program implementation.

Collaboration requires a two-way relationship (Bazyk, 1989). Thus a collaborative relationship between a parent and health professional is characterised by “respect for each other’s opinions and contributions, equality in the status of each partner within the relationship, a developing trust, and a generally positive regard for each other as individuals.” (Crais, 1993, p.29). The collaborative and personal nature of the parent-therapist interaction has been suggested to be critical to the success and likely uptake of a home program. A qualitative study that examined mothers’ perceptions about the influence of therapy on their lives, mothers felt their relationships with therapists were personally important, and that the therapist as a person was often more important than the therapy itself (Hinojosa, 1990). In another qualitative study of mothers’ perceptions of the effects of occupational therapy and physiotherapy the parent-therapist relationship figured predominantly. Mothers viewed therapists as: “(1) a friend; (2) an advocate; (3) a mentor; (4) a trouble shooter; (5) a source of information; and (6) a primary source of support” (Washington & Schwartz, 1996, p.44). In this first phase of the home program, therapists
must therefore understand the significant influence they have in families’ lives, as the very nature of these relationships appears to assist families to develop intervention for their child (Hinojosa, 1990).

In order to establish successful collaborative relationships with families who have children with cerebral palsy, inter-personal skills are critical. A qualitative Australian study demonstrated that therapists’ interpersonal skill, communication skills, and attitudes affected families’ uptake of home programs (Thompson, 1998). When families perceived therapists as ‘friendly’, they were more likely to become involved in their child’s therapy, and conversely when therapists are perceived as ‘unfriendly’, families withdraw their involvement (Thompson, 1998). Another study with families who had at-risk children found self-confidence in working with others, the ability to provide mutual support without defensively guarding their own professional role, flexibility and patience, and the ability to balance the role of learner and expert were important in collaborative relationships (Laadt-Bruno, Lilley & Westby, 1993). These skills are relevant to building collaborative relationships with families who have children with cerebral palsy. Occupational therapists who display flexible, adaptable, and ingenious attitudes along with a breadth of knowledge and skill have also been found to positively influence “compliance” in home health programs (Robinson, 1987).

These interpersonal skills are applied to build relationships that are not only collaborative, but also respectful. Historically, health professionals prescribed home programs to improve the child’s development, without consideration of parental needs and concerns (Bazyk, 1989). When parents have been unable to complete these home program regimens, at the prescribed intensity level, parents have been labeled as ‘non-compliant’ (Bazyk, 1989). The choice and actions taken by parents were fundamentally respected. Health professionals assumed that potential health benefits were lost because of ‘non-compliance’ (Molineux, 1993), without considering whether parent actions were actually in
the child and family’s best interest. The “therapist knows best” attitude (Bazyk, 1989; Hanna & Rodgers, 2002) may erode possibilities for genuine collaboration. In this first stage of the home program, therapists must acknowledge that the parent knows what is best for their child (Viscardis, 1998). Therefore in the family-centred approach, the parents’ insight about how health services should be provided is welcomed (Viscardis, 1998).

Along with the necessary interpersonal skills and attitudinal change, another important aspect of developing collaborative relationships is clear definition of parent and therapist roles. The role of the therapist is one of ‘technical expert’ (Rosenbaum et al, 1998), who supports, encourages, and enhances the care-giving competency of parents (Bazyk, 1989; Viscardis, 1998). The parent has the right to determine and decide what is best for the child (Viscardis, 1998). Parental decision-making gives families the opportunity to choose their preferred level and type of involvement in therapy activities whether great or small, in some areas but not in others, and it is critical that therapists accept and respect these preferences (Bazyk, 1989). Preferences of parents regarding their involvement in a home program must be discussed before developing the program (Molineux, 1993) because families will have different capacities at different times in their lives to carry out home programs (Bazyk, 1989; Kwok, 1993).

In summary, the first step in instituting a ‘best practice’ home program approach is establishment of a collaborative parent-therapist relationship. This relationship is influenced by therapist attitudes, therapist interpersonal skills, parent-therapist role delineation and parental involvement preferences. The first phase of the home program used in the present study followed these principles and practices.

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3 Notwithstanding isolated cases of neglect or abuse where the family or child may be at risk or behaving illegally, this approach should be routine.
3.5.2 Goal Setting

The second phase of the home program is goal setting. The aim of this phase is to establish mutually agreed goals. This is consistent with the FCP foundation. During this phase collaborative activities are likely to include assembling resources, creating a product and working together to achieve a goal (Crais, 1993). Parents and therapists therefore work as a team: “exploring with the parents their needs and priorities regarding interaction with and the care of their child. Do they have any concerns about their child’s feeding, dressing, hygiene, play and interaction with the environment?” (Bazyk, 1989, p. 726). The goals that families typically generate relate to family relationships, child management and daily routines, with the emphasis being on managing the disability and its effect on everyday life (Coles, 2001).

As previously identified in Section 3.3.1 therapists historically generated home program goals from a ‘deficit’ model to pinpoint focus areas for intervention (Case-Smith, 1996). Specific problem identification using this technique still forms an important part of a comprehensive assessment for a child with cerebral palsy (Bleck, 1987; Erhardt & Merrill, 1998) but is not the starting point of collaborative goal setting in the FCP approach. ‘Solution focused’ goal-setting (Berg, 1994) offers an alternative, which includes the whole family and the child (Coles, 2001). The ‘solution focused’ model focuses on the family’s resourcefulness, competence, strengths and their ability to change, which assists families to clearly articulate their goals in a way that is akin to family-centred practice (Coles, 2001).

Goal setting using the solution-focused approach is elicited by ‘the miracle question’ technique (Berg & DeJong, 1998). The miracle question may be posed by the health professional to the family as follows:

“Let’s suppose, tonight when you are asleep a miracle occurs, and a problem or problems that we have been talking about were solved. But when you woke up, you didn’t know this
miracle has happened. What would tell you in the morning that this had occurred? What would you look for that would tell you that this miracle had happened?” (Coles, 2001, p.101).

The miracle question evokes a variety of responses, creating opportunities for the therapist to ask the family about and highlight times when desired changes were happening or had happened (Coles, 2001). This type of goal setting enables families to identify their own solutions leading them towards individualised aspirations (Coles, 2001). This approach builds on the parents’ caregiving capacity.

Once goals have been identified, the ultimate decision about the focus for intervention belongs to the family. Thus it is the therapist’s responsibility to encourage: “parental decision-making based upon appropriately presented information, in the context of clearly defined child and family needs, and built upon child and family strengths.” (Rosenbaum et al, 1998, p. 5). A comprehensive occupational therapy assessment for a child with cerebral palsy provides one part of the “appropriately presented information” (Bleck, 1987; Erhardt & Merrill, 1998). This process has been detailed earlier in Chapter Three, and therefore will not be discussed here in detail. The comprehensive assessment informs goal setting, rather than driving it as it did prior to FCP. The occupational therapy assessment focuses on goal areas identified by the parent and seek to identify ‘why’ attainment of these goals is difficult for the child. Assessment findings used in this way informs the development of the home program by identifying subcomponents or ‘impairments’ pertaining to the goal areas. As the therapist communicates with the family ‘how’ each of the sub-goal areas could potentially be addressed, this process is likely to identify possible home program strategies.

Once the parent has identified goals, the therapist is required to explore with the family their daily routines and the best times for implementing a home program (Bazyk, 1989). This is in keeping with the eco-cultural approach described earlier (Section 3.2.2).
3.5.3 Construction of the Home Program

The third phase of the home program is construction of the program which involves selection of individual therapeutic activities designed to address the family’s goals. The chosen therapeutic activities should be embedded into functional tasks and parents need to be given permission to devise or exchange the selected activities in order to reach their goals. The home program then should be disseminated to the family in a way that reflects their learning style, but is likely to include writing up the program goals and activities supported by pictures and ‘hands-on’ demonstration. This section described these tasks in detail.

Therapeutic activities selected for the home program should be embedded into everyday tasks, to ease the caregiving strain on families and to ensure that intervention seeks to increase the child’s function (Anderson & Schoelkopf, 1996; Moersch, 1985; Stanton, 1992). Section 3.6 describes the range of therapeutic activities that may be considered.

Mothers of children with cerebral palsy are known to integrate their experiences of therapy into their parenting routines and to adapt treatment techniques into a mothering style that meets the unique needs of their child (Hinojosa, 1990). In this phase of the home program construction, valuing parental caregiving competence parent-therapist roles may therefore shift in emphasis. This may mean that it is the parent who devises the ‘therapeutic’ activities for the home program, not the therapist as per conventional therapy. This is because parents are best positioned to know the family’s unique preferences and routines. Parents also have unique creativity and inventiveness for adapting play, furniture, toys and activities to make them therapeutic (Hinojosa, 1990). As Hinojosa and Anderson suggest:

“Therapists must recognise that mothers themselves may offer innovative interventions… mothers' [have] creative skills in their ability to adapt home activities and routines to address
their children’s therapeutic goals. Most of these adaptations suggest that these mothers comprehend basic treatment principles. More importantly, we found that the therapeutic value of the activity can be enhanced by the mother who is adapting it into her daily routine.” (Hinojosa & Anderson, 1991, p.277).

Hinojosa and Anderson’s (1991) qualitative review of mothers’ perceptions of home therapy programs identified three important characteristics of successful home program activities: “(a) they were pleasing for the mother to do; (b) they were not stressful for the child; and (c) they were not stressful for the mother or the rest of the family.” (Hinojosa & Anderson, 1991, p.276). Their study seemed to suggest that if parents select the intervention activities, rather than activities being prescribed by the therapist, it was more likely that activities would suit the family’s routine and the child’s preferences, and that the quality of the selected activities may be enhanced. The therapist must enable, or give permission for, the parent to devise or exchange selected therapeutic activities with new ones that the parent develops in the home context. If the therapist fails to release the role of therapeutic activity selection to the family, families may not carry out a therapist-directed home program. For example, eight mothers of children with cerebral palsy, interviewed and observed in a qualitative study by Hinojosa (1990), all reported choosing not to carry out their therapist-prescribed home program. The mothers explained that this was because of competing responsibilities that demanded their time, not because of perceived lack of importance of the activities (Hinojosa, 1990). Instead, seven of the eight mothers were observed to develop their own intervention program by incorporating therapeutic activities into their mothering style (Hinojosa, 1990).

Once goals have been set and therapeutic activities selected, the therapist should consider how this information will be communicated to the family. In the majority of cases, describing goals and activity suggestions in written and pictorial format is preferred by parents (Case-Smith & Nastro, 1993). Therapists and physicians also report that home
programs are more likely to be completed if therapeutic activities are explained and written down for families (Molineux, 1993; Rappoff & Christophersen, 1982; Simon 1988). Families of children with physical disabilities demonstrated home program participation rates of 77.5%–80.3%, when the home program was given in written format, supported by Polaroid photographs of activities (Schreiber et al, 1995). It is also important to supply families with a recording system to serve as a daily reminder to participate in the home program (Schreiber et al, 1995).

Therapeutic activities ought to be based upon judicious use of the ‘best available’ evidence (Sackett et al, 1996). The appropriate information referred to in the goal-setting phase should also be used in the activity selection and home program construction phase. This way both parents and therapists can make decisions about what activities/techniques/strategies to use on the basis of not only their own preferences, goals and assessment information but also on information about activity effectiveness. Intervention activities that have been proven to be effective (where this evidence is available) are the ones that ought to be recommended by the occupational therapist. Questions about therapeutic activities form parents should be answered with best available evidence. The purpose of blending best available evidence with clinical expertise is to develop home programs that are accurate, effective and safe (Sackett et al, 1996). When the occupational therapist uses this approach, they promote the likelihood of effective intervention (Sackett et al, 1996) and in keeping with the FCP approach act as a resource or ‘technical expert’ to the family so as to extend the family’s skills (Rosenbaum et al, 1998; Viscardis, 1998).

Before recording selected home program activities for the family, it is important to describe how and why the activity will help the child achieve a certain goal (Bazyk, 1989). This process of explanation is likely to require demonstration and training, so that the parents understand how to perform the activities in a therapeutic way (Molineux, 1993; Rappoff & Christophersen, 1982; Simon 1988). Successful training is characterised by the
parent feeling capable of using the therapy technique without feeling overwhelmed. Mothers of children with cerebral palsy suggest that demonstration of one therapy technique at a time is helpful, as it is difficult to remember details about several techniques if they are taught simultaneously (Hinojosa & Anderson, 1991). This point is important to remember when training, as parents of children with disabilities are more likely to implement treatment recommendations when they feel competent and comfortable to do so (Gajdosik & Campbell, 1991). Some families have a higher preference for verbal explanations, others, written explanations, while others prefer modelling or a combination of learning strategies (Bazyk, 1989). So, when the home program activities are developed, they should be prepared into a format to distribute to the family that reflects the family’s preferred learning style (Bazyk, 1989), which is likely to include text, pictures and demonstration.

3.5.4 Supporting the Home Program Implementation
The fourth phase is identifying ways to support implementation of the home program, to ensure families’ needs are being met and can be feasibly carried out. Home programs are not complete once the documentation and demonstration are provided to the family. The literature summarised below indicates that home programs, which are supported in an ongoing way by the therapist, are more likely to be implemented by families.

Families’ report that they learn about caregiving by watching therapists interact with their child (Hinojosa & Anderson, 1991), and by seeking reassurance and feedback from therapists (Thompson, 1998). These facets of support should be built into the implementation phase of home programs. Even though a FCP home program is parent directed, the parent can still seek support as required, if the occupational therapist is available as a consultant or resource to the family (Dunst, 1991): “We serve as consultants to the parents to help them acquire the knowledge and skills they need to care for their
children with special needs... We work together with parents to identify treatment choices, and allow them to decide what fits best for their family.” (Bazyk, 1989, p.725).

Families and mothers in particular, seek active and ongoing support: “Mothers [of children with cerebral palsy] universally acknowledged that they learned to care for and deal with their children by casually observing therapists’ interactions with and treatment of their children.” (Hinojosa & Anderson, 1991, p.277). Mothers of children with disabilities describe constantly seeking reassurance and feedback from therapists about their child (Thompson, 1998). Mothers use therapists’ feedback as a strategy for ensuring they do everything within their power to help their child and to assess whether services are worthwhile (Thompson, 1998).

In addition to building therapist-parent relationships where support-seeking is viewed positively, the following therapist support strategies have been identified in Gajdosik’s (1991) literature review, as leading to a greater likelihood of home program implementation:

- frequent contact with the parent to review the program;
- instruction to the family on how to identify improvements in their child;
- watching the parent perform the therapeutic activities and providing feedback;
- identifying and relaying the child’s improvements to the parent;
- positive reinforcement of the parent, to build their confidence; and
- communication of interest and concern for the family.

The home program implementation phase involves regularly reviewing the home program to support parents to engage in selected therapeutic activities. This assistance includes: (a) building a parent-therapist relationship where support seeking is valued and encouraged; (b) the therapist relaying the child’s improvements to the parent; (c) providing feedback and reinforcement; and (d) providing the family with information about how to
identify improvements in their child’s development. These mechanisms of support were built into the home program utilised in the present study.

3.5.5 Evaluating the Home Program Outcomes

The fifth and final phase of the home program is evaluating outcomes, to ensure that the program has met family goals.

Health program outcome evaluations of any kind typically involve three types: (1) consumer satisfaction evaluation; (2) clinical outcomes evaluation; and (3) cost-effectiveness evaluation (Naar-King et al, 2000). Consumer satisfaction of health programs is a critical aspect of evaluation because consumer satisfaction is linked to health outcomes; there are behavioural consequences of consumer dissatisfaction including lower participation rates; and it provides useful information about the structure, process and outcomes of care (Naar-King et al, 2000). There has to date been no quantitative investigation of parent satisfaction. The only information about parents’ views, are currently in the form of qualitative studies about the home program experience (Case-Smith & Nastro, 1993; Hinojosa, 1990; Hinojosa & Anderson, 1991; Piggot et al, 2002; Piggot et al, 2003; Thompson, 1998; Washington & Schwartz, 1996). The evaluation of clinical outcomes is typically achieved through the use of standardised outcome measures (described in section 3.3.4) and when evaluating the clinical impact of home program intervention, this should be the strategy of choice. In addition to the evaluation of clinical outcomes with standardised measures the achievement of the goals set by families should also be evaluated (Wallen & Doyle, 1996). This type of evaluation provides important information about outcomes meaningful to the family and child (Wallen & Doyle, 1996). Clinical and family measures can be obtained using individualised measures such as the COPM and GAS, (described in Sections 4.10.1 and 4.10.2) (Wallen & Doyle, 1996).
3.6 Therapeutic Activities

Home programs include a suite of therapeutic intervention techniques. Occupational therapy for these children is known to require a combination of approaches to meet individual goals and so for any one child and family a wide range of therapeutic activities

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may initially need to be considered (Copley & Kuipers, 1999, Levitt, 1984, Pedretti, 1996). As the overall effectiveness of occupational therapy for children with cerebral palsy is unproven (Steultjens et al, 2004) individual activity interventions are considered, particularly as there is more detailed effectiveness data for many of these. Only those with highest levels of supporting evidence were included via a process of judicious clinical reasoning. Making decisions based on rigorous research is recommended for optimizing outcomes:

"Therapists who treat people with CP need to optimize their limited therapy time by eliminating those approaches or treatment components that have only marginal positive effects and replace them with evidence-based exercise protocols shown to be more effective in improving current, and potentially future, functioning. In addition, we need to identify more ways to help their patients incorporate ‘activity, activity, activity’ into their lifestyles.” (Damiano, 2006, p.1539).

Selection was also guided by underpinning frameworks and models. These were reviewed earlier and are the International Classification of Functioning, Disability and Health (WHO, 2001), family-centred practice (National Centre for Family-Centred Care, 1990), eco-cultural perspectives (Wiesner, 2002), activity focused motor interventions (Valvano, 2004) and determinants of motor change (Bartlett & Palisano, 2000). Together these focused intervention on developing functional activity performance in the home context to meet family goals. The interventions selected for incorporation into home programs were adaptive equipment, constraint-induced movement therapy, goal-focused task training, orthoses, parent education and positive behaviour support, play therapy, sports therapy, and strength training. Each of these will now briefly be described.

**Adaptive Equipment:** Adaptive equipment is therapeutic devices designed to assist a child to complete a task independently by adapting the task and environment to compensate for their impairments. Equipment included assistive devices to enhance play
and communication such as battery operated scissors and switch toys (Lagone et al, 1999), and positioning systems with wheeled mobility to enable the child to sit upright and self-mobilise to facilitate participation in everyday activities (Farley, Clark, Davidson, Evans, MacLennan, Michael, Morrow & Thorpe, 2003).

**Constraint-Induced Movement Therapy (modified):** Constraint-induced movement therapy (modified) involves constraining the dominant hand to enable “massed practice” of activities using the affected hand. The therapy aims to improve the motor skills of the affected hand and help the child experience success in using the hand so that they will ultimately use the hand more spontaneously and skillfully. It was used with participants who had hemiplegic cerebral palsy and had goals relating to increasing use of the affected hand. Modified constraint-induced movement therapy is positively supported by randomised controlled trial evidence, however it must be noted that it is undergoing more rigorous study (Charles et al, 2006; Eliasson et al, 2004; Hoare, Carey & Wasiak, 2007; Wallen et al, 2007).

**Goal-Focused Task Training:** Goal-focused task training, a type of activities-based therapy, is currently considered by experts to be the most important type of intervention for children with cerebral palsy and for this reason it was used (Damiano, 2006; Eliasson, 2005). The intervention technique is embedded within eco-cultural, family-centred and goal-focused approaches to therapy. Goal-focused task training involves repeated structured practice of functional activities meaningful to the child. The approach is supported by one rigorous randomised trial (Ketelaar, 2001) and emergent lower-level evidence from pilot studies (Crompton. Imms, McCoy, Randall, Eldridge, Scoullar & Galea, 2007; Ekstrom et al, 2005; Law et al, 1998) and multiple baseline studies (Lammi & Law, 2003). The technique was used to help children practice the specific movements they needed to achieve their goals. Handwriting training (Sudsawad et al, 2002) was also
conducted using the goal-focused task training approach, because it is a specific functional
task that children with cerebral palsy need to learn for participation in school.

Orthoses: Orthoses are external devices made from thermoplastic, neoprene and
fiberglass that immobilise the hand for either the purpose of stretching shortened muscles
(casts) or re-positioning the hand to promote better hand function (splints). Casting to
reduce contracture for a child with cerebral palsy is supported positively by one systematic
review (Teplicky et al, 2002) but other systematic reviews have identified the need for more
rigorous efficacy research (Lannin, Novak & Cusick, 2007), especially focusing on the
functional effects of splints (Aurtti-Ramo, Suoranta, Anttila, Malmivaara, & Makela, 2006).

Parent Education and Positive Behaviour Support: Parent education involves the
provision of information to support parents with decision-making and gaining knowledge
about prognosis and therapeutic principles. Positive behaviour support involves supporting
parents to elicit behaviour changes in their child, promoting positive parenting and
preventing parent stress. The home program content included parent education (Ketelaar,
Vermeer & Helders, 1998) and positive behaviour support (Turner et al, 2006) to maximise
the child’s performance by increasing the caregiving competency of the parents. In
addition, the process of goal-setting, program construction and supporting home program
implementation included in-depth discussion about which family members were best
placed to implement the home program, what family routines the home program could be
embedded within, what environmental changes could be made in the family home context
to optimise the child’s independence and feeding-back about the child’s progress and the
parents’ skills. Parent education was adopted within this study because there is high quality
supporting evidence for professional-provided home visit based parent education for
parents with intellectual disabilities (Llewellyn et al, 2003), at risk families (Drummond et
al, 2002) and children with autism and developmental delay (Rickards et al, 2007). It is
therefore reasonable to conceive that the same sort of parent education features of intervention should be integrated into home programs.

*Play Therapy:* Play therapy therapeutically intervenes upon the motor, social and cognitive aspects of normal play and recreation to enhance the child’s general development. Play therapy was used when parents identified the need for their children to learn how to play with toys and interact with play partners. Play therapy that focuses on training parents in alternative ways of engaging with their child is supported by positive evidence for the approach (Hanzlik, 1989). The Hanzlik study was, however, under-powered as an RCT, so caution must be taken in assuming positive effects.

*Sports Therapy:* Sport therapy is the participation of children with disabilities in community-based fitness and endurance activities. The activities and equipment may be adapted to accommodate the child’s disability and enable active participation and independence. Sports and recreation therapy was used with children who had identified a desire to more actively engage in sport, such as soccer or cricket. Children were taught necessary skills using the goal-focused task practice approach. The family was then supported to engage the child in a community-based program that reflected their goals, interests and abilities. Sports therapy is positively supported by systematic review evidence (Van den Berg-Emons et al, 1998; Allen et al, 2004; Damiano & Abel, 1998; Darrah et al, 2004a; Kelly & Darrah, 2005).

*Strength Training:* Progressive resistive muscle strengthening was used to improve a child’s muscle strength when muscle weakness was identified to be the major factor limiting goal performance. Strength training is positively supported by systematic review evidence (Damiano et al, 2002; Dodd et al, 2002).

The therapeutic activities used in the present study and their relationship to underpinning frameworks and models are summarised in Figure 6. This figure was developed by the author: (a) to describe how the interventions fitted together to form a
3.7 Effectiveness of Home Programs: A Gap in Knowledge

Despite the overwhelming support and recognition of the importance of home programs for children who have cerebral palsy, there is a paucity of literature pertaining to their effectiveness in helping families achieve desired health outcomes (Schreiber et al., 1995). This finding was established through a comprehensive review of the home program effectiveness literature (Novak & Cusick, 2006). This literature is summarised in Table 3.

Although evidence is emerging to support home program intervention effectiveness (Novak et al., 2007), until recently, all the literature pertaining to occupational therapy home programs for children with cerebral palsy was focused on two predominant themes. First, parental compliance with prescribed home programs (Gajdosik, 1991; Gajdosik & Campbell, 1991; Law & King, 1993; Mayo, 1981; Molineux, 1993; Schreiber et al., 1995; Wortis et al., 1954), reflecting former “medical model” thinking. Second, qualitative analysis

Since the inception of the family-centred approach, one study that has given new insight into the pivotal role of parents in home programs. Law and King’s (1993) study compared the effect of two different occupational therapy interventions for children with cerebral palsy in a randomised controlled trial. They uncovered a secondary positive relationship between parental participation in a home program and the child's individual outcome. Parents who self-rated their compliance as high had better outcomes in hand function (Law & King, 1993). Parental compliance was the only significant predictor of clinical change, not the type of intervention approach selected (Law & King, 1993). Many factors could have been at work here. This finding highlights the need for more research, designed specifically to evaluate the effectiveness of home programs in reaching desired health outcomes of children with cerebral palsy.

Research about the effectiveness of intense hands-on therapy in institutional contexts for children with cerebral palsy has been shown to have limited effectiveness. Three studies of high rigour, utilising a randomised controlled trial (RCT) design, found that provider-based intense therapy has no added benefits over routine amounts of provider-based therapy (Bower et al 2001; Law et al 1991; Piper et al 1986). What children do at home with their parents is just as important as how much therapy they receive (Bower & McLellan, 1992; Trahan & Malouin, 2002).

It is important for researchers and parents therefore to be able to quantify the parental contribution, at home, to occupational therapy treatment outcomes. At present therapists cannot accurately inform parents about how critical their role is in achieving outcomes but rather just suggest that it is important. The lack of research evidence about the value of parental input may be exacerbating parents’ feeling that the health system is letting them down (Thompson, 1998).
Table 3: Effectiveness of Home Programs Literature Review

<table>
<thead>
<tr>
<th>First Author</th>
<th>Title</th>
<th>Intervention</th>
<th>Method</th>
<th>Level of Evidence</th>
<th>Sample: # &amp; Diagnosis</th>
<th>Key Findings with Results &amp; Analysis</th>
</tr>
</thead>
</table>
| Novak, Cusick & Lowe (2007) | A pilot study on the impact of occupational therapy home programming for young children with cerebral palsy | 6 months occupational therapy home programme with 2 parental support reviews | Pre-Post single group          | C                 | 20 hemiplegic cerebral palsy | a. Goals meaningful to the family were achieved as measured on GAS (p=.000)  
b. Self-care skills improved as measured on the PEDI (p=.001)  
c. Amount of assistance required for carers decreased with self-care as measured on the PEDI (p=.001)  
d. Upper limb quality of movement improved as measured on the QUEST (p=.002) |
| Gajdosik (1991) | Effects of weekly review, socioeconomic status and maternal belief on mother’s compliance with their disabled children’s home exercise program | 3 weeks physiotherapy home programme with weekly review for experimental group | RCT, uncertain power           | B                 | 18 childhood disability | a. Weekly review did not increase compliance (p=.086)  
b. Socioeconomic status, weekly review, and parents’ beliefs in control of their children’s health did not predict compliance (NS)  
c. Socio-economic status predicted therapist’s estimates of compliance with higher status higher compliance prediction (p=.024) |
| Gajdosik (1991) | Issues of parent compliance: what the clinician and researcher should know | Physiotherapy home programmes | Author viewpoint                  | C                 | N/A development delay | a. Disposable treatment items or daily journal are the most accurate way to record compliance  
b. Simplifying the programme and close monitoring positively supports parents |
| Law (1993) | Parent compliance with therapeutic interventions for children with cerebral palsy | Daily OT home programme with 4 hour cast wear | Data collected in a 2x2 factorial design | C but collected during a Grade A trial | 72 cerebral palsy | a. Compliance with home programmes was high 66% for 75% of the time  
b. Of the 5 compliance measures, only parental reporting predicted outcomes |
| Mayo (1981) | The effect of a home visit on parental compliance with a home program | Home programme + home visit for experimental group | RCT, uncertain power           | B                 | 18 delayed development & CP | a. Experimental group improved more than control group (p=.05) in motor development, using independent t-test  
b. Provision of a home visit did not increase compliance (NS)  
c. Mothers of children with severe disability complied more than those with moderate disability (p=.01) |
<p>| Mayo (1978) | Patient compliance: Practical implications for physical therapists: A review of the literature | Physiotherapy home programmes | Literature review                 | C                 | N/A Home programmes are a large part of child’s treatment programme, thus compliance is a key factor. Non-compliance ranges from 15%-94% depending on the population studied and is a factor affecting outcome |</p>
<table>
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<tr>
<th>First Author</th>
<th>Title</th>
<th>Intervention</th>
<th>Method</th>
<th>Level of Evidence</th>
<th>Sample: # &amp; Diagnosis</th>
<th>Key Findings with Results &amp; Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Molineux (1993)</td>
<td>Improving home programme compliance of children with learning disabilities</td>
<td>OT home programme</td>
<td>Author viewpoint</td>
<td>C</td>
<td>N/A learning difficulties</td>
<td>Compliance is a complex concept. Strategies for developing home programmes include: understanding parent readiness; exploring the effect on parent-child relationship and using token economies to reward</td>
</tr>
</tbody>
</table>
| Robinson (1987) | Patient compliance in occupational therapy home health programme: Sociocultural considerations | OT in the home | Author viewpoint | C | N/A | a. Professionals who are flexible, adaptable and have a breadth of knowledge promote compliance  
b. Pressured family life; tedious activities and activities with low perceived importance negatively affect compliance |
| Schreiber (1995) | Effectiveness of parental collaboration on compliance with a home programme | 6 weeks of physiotherapy home programme | RCT, uncertain power | B | 18 | a. Parent-therapist collaboration on programme content did not lead to more compliance than “therapist prescribed” home programmes (p=.70)  
b. Child’s age was not related to compliance (p=.18)  
c. High compliance in both groups may be attributed to family interest and log calendar |
| Tyler (1976) | A home treatment program for the cerebral-palsied child | 28 days of 6.5 hours per day of OT home programme | Single case study | C | 1 cerebral palsy | a. Authors report more normal movement; better tolerance of stimulation; mealtimes were manageable; and improved vocabulary  
b. Parents reported that the programme could be fitted into their schedule |
| Wortis (1954) | The home visit in a cerebral palsy treatment program | OT Home programme and home visit | Interview and home visit | C | 24 cerebral palsy | 3 reasons were identified why programme was not carried out at home: lack of understanding; difficulties in home situation; and emotional disturbances in parent-child relationship |

**Training parents to become “therapists”**

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<tr>
<th>First Author</th>
<th>Title</th>
<th>Intervention</th>
<th>Method</th>
<th>Level of Evidence</th>
<th>Sample: # &amp; Diagnosis</th>
<th>Key Findings with Results &amp; Analysis</th>
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</table>
| Ozonoff (1998) | Effectiveness of a home program intervention for young children with autism | 4 months of psychology ‘TEACCH’ home programme for 30mins per day | Controlled trial non-randomised | C | 22 autism | a. Children whose parents were trained in the TEACCH method improved significantly more than the control in imitation (p=.05), fine motor (p=.01), gross motor (p=.05), and cognitive (p=.01) skills measured on the Psychoeducational Profile-Revised subtests  
b. Mild autism and good language skills predicted outcomes (r=.52, p<.05) |
<p>| Rodgers (1986) | Parents as therapists: A responsible alternative or abrogation of responsibility | N/A | Author viewpoint | C | N/A Parents | With support and guidance parents can become effective change agents for their child, as parents can assume the role of para-professional |</p>
<table>
<thead>
<tr>
<th>First Author (Year)</th>
<th>Title</th>
<th>Intervention</th>
<th>Method</th>
<th>Level of Evidence</th>
<th>Sample: # &amp; Diagnosis</th>
<th>Key Findings with Results &amp; Analysis</th>
</tr>
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<tbody>
<tr>
<td>Turnbull (1978)</td>
<td>Parent involvement in the education of handicapped children: A critique</td>
<td>N/A</td>
<td>Author viewpoint</td>
<td>C</td>
<td>N/A Parents</td>
<td>It is recommended that the parent and therapist role remain separate because of the potential negative impact on the child's self-esteem if the parents become the child's therapist and educator</td>
</tr>
<tr>
<td>Bazyk (1989)</td>
<td>Changes in attitudes and beliefs regarding parent participation and home programs: An update</td>
<td>N/A</td>
<td>Literature synthesis &amp; author viewpoint</td>
<td>C</td>
<td>N/A children with disabilities</td>
<td>Therapist attitudes and practices regarding parent participation and home programmes have evolved. Guidelines for developing family-centred home programmes include: parent as decision maker, parental role development, collaborative programmes, recognising family differences, providing options and considering the child's need</td>
</tr>
<tr>
<td>Viscards (1998)</td>
<td>The family-centred approach to providing services: A parent perspective</td>
<td>Family-centred intervention</td>
<td>Author viewpoint</td>
<td>C</td>
<td>N/A children with disabilities</td>
<td>Key strategies for implementing a FC approach: acknowledge grieving, let parents describe what they want; focus on positive aspects of child, put parents first; tell parents they are doing a good job; provide opportunities to meet other parents and be sensitive to the loss of a dream of a perfect child</td>
</tr>
<tr>
<td>Hinjoosa (2002)</td>
<td>Shifts in parent-therapist partnerships: twelve years of change</td>
<td>Therapist's attitudes towards parents</td>
<td>Survey of OTs</td>
<td>C</td>
<td>199 OTs of clients with DD</td>
<td>Respondents believed that working with parents, more than any other aspect of intervention, had the greatest impact on the child's progress</td>
</tr>
<tr>
<td>Hinjoosa (1988)</td>
<td>Pediatric occupational therapy in the home</td>
<td>OT in the home</td>
<td>Author viewpoint</td>
<td>C</td>
<td>N/A children with disabilities</td>
<td>Occupational therapy offered in the home setting offers more flexibility and solutions suited to the environment. The family and child are also more at ease</td>
</tr>
<tr>
<td>Stephenson (2000)</td>
<td>Advantages and disadvantages of the home setting for therapy: Views of patients and therapists</td>
<td>OT in the home</td>
<td>Qualitative interviews</td>
<td>N/A</td>
<td>Adults with hemiplegia</td>
<td>Five themes were identified: convenience, therapeutic environment, social contact, control and grateful recipient. Therapists identified the home environment was more relevant for intervention and goal setting</td>
</tr>
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<td>First Author</td>
<td>Title</td>
<td>Intervention</td>
<td>Method</td>
<td>Level of Evidence</td>
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| Stewart      | The impact of community pediatric occupational therapy on children with disabilities and their carers | OT in the home | Pre-post design  | C                 | 33 children with disabilities | a. Children's independence improved although many remained dependent for a number of daily living tasks  
b. Carers found the occupational therapy satisfactory but it did not reduce the strain of caring |
| Tyler        | Reduction of stress between mothers and their handicapped children | Parental training for home programme implementation | Pre-post design | C                 | 18 cerebral palsy & DD | Stressful and conflicting interactions were reduced between the parent & child. More change was seen in the parent than the child |
| Wallen       | Performance indicators in paediatrics: The role of standardised assessments and goal setting | Measurement of OT | Author viewpoint and literature review | C | N/A children | Measurement of change in response to occupational therapy must be relevant and meaningful to individual clients and families. Attaining individual goals measured through COPM and GAS may offer more sensitivity than standardised measures |
| Case-Smith   | The effect of occupational therapy intervention on mothers of cerebral palsy | Experience of OT | Qualitative: Interview and ethnography | N/A               | 5 mothers of children with CP | a. 2 themes, "Is anybody listening?" and "Not another one" revealed the importance of listening and continuity of care  
b. Mothers described OT's as skilled agents of change, effective in helping and a valuable sources of information and support |
| Hinojosa     | How mothers of preschool children with cerebral palsy perceive occupational and physical therapists and their influence on family life | Experience of OT and physiotherapy home programmes | Qualitative: Interview & observations | N/A               | 8 mothers of children with CP | a. Mothers reported not having the time, energy or confidence to implement therapist-directed home programmes. Instead they adapted interventions to fit their life-styles and routines. They made play therapeutic  
b. Therapists need to acknowledge such adaptations are important  
c. All mothers seemed to believe more therapy is better |
| Hinojosa     | Mothers’ perceptions of home treatment programs for their preschool children with cerebral palsy | Experience of OT and physiotherapy home programmes | Qualitative: Interview | N/A               | 8 mothers of children with CP | a. All had previously used home programmes but none were currently  
b. Successful activities were: doable, could be integrated into routines, were enjoyable for the child and not stressful for the family |
<table>
<thead>
<tr>
<th>First Author</th>
<th>Title</th>
<th>Intervention</th>
<th>Method</th>
<th>Level of Evidence</th>
<th>Sample: # &amp; Diagnosis</th>
<th>Key Findings with Results &amp; Analysis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Piggot (2002)</td>
<td>Participation in home therapy programs for children with cerebral palsy: a compelling challenge</td>
<td>Experience of OT home programmes</td>
<td>Qualitative: Grounded theory</td>
<td>N/A</td>
<td>4 therapists and 8 parents</td>
<td>2 time-distinct phases described the parental journey of adjustment and participation. Initially, parents were adjusting to the diagnosis, and this precluded their full involvement. Then they entered a phase of high participation, striving to maximize outcomes</td>
</tr>
<tr>
<td>Piggot (2003)</td>
<td>Parental adjustment to having a child with cerebral palsy and participation in home therapy programs</td>
<td>Experience of OT/PT home programmes</td>
<td>Qualitative: Grounded theory - Interviews</td>
<td>N/A</td>
<td>4 therapists and 8 parents</td>
<td>2 time-distinct phases described the parental journey of adjustment and participation. Initially, parents were adjusting to the diagnosis, and this precluded their full involvement. Then they entered a phase of high participation, striving to maximize outcomes</td>
</tr>
</tbody>
</table>
| Thompson (1998) | Early intervention services in daily family life: Mother’s perceptions of ‘ideal’ versus ‘actual’ service provision | Experience of OT intervention | Qualitative: Questionnaires & Interview | N/A | 10 mothers of children with DD | a. Parents used EI to enhance their child’s abilities, what was best for their family was a lesser priority  
b. Relaxed and friendly providers were perceived as having a greater insight into daily family life, and therefore a greater capacity to meet needs  
c. Parents did not experience many ‘ideal’ characteristics of services and providers, suggesting that changes are needed in OT |
| Washington (1996) | Maternal perceptions of the effects of physical and occupational therapy services on care-giving competency | Experience of OT and physiotherapy intervention | Qualitative: Interviews | N/A | 2 Parent-therapist dyads | a. Increased perception of parental competency is an outcome of therapy  
b. Mothers view therapists as a: friend, advocate, mentor, trouble-shooter, source of information and source of support  
c. Effective communication in parent-therapist relationship is essential |

3.8 Synopsis
This chapter has provided the background for the development of the home programs used in the present study. This has been achieved through an in-depth review of the literature pertaining to the models underpinning home program design, the occupational therapy intervention process for children with cerebral palsy, the design of home programs, the therapeutic activities used in the programs and the supporting evidence and a comprehensive review of the effectiveness of home programs. The next chapter will outline the design and results of the RCT.
Chapter Four

Effectiveness of Home Programs for Children with Cerebral Palsy: A Double Blind Randomised Controlled Trial

4.1 Introduction

This chapter presents a double-blind randomised controlled trial (RCT) that evaluated the effectiveness of a home program for improving functional activities performance in children with cerebral palsy. The aim, design, sampling, randomisation, blinding, and validity issues are first presented. The ethical approvals, procedure, instrumentation and materials and data analyses are described. Findings are then presented.

4.2 Aim

The primary aim of the present study was to determine whether using a home program for eight weeks improved parent ratings of performance and satisfaction with function for children with cerebral palsy, compared to using a home program for only four weeks, and how either of these home program outcomes compared with no home program at all. Secondary aims were to determine whether receiving a home program for eight weeks produced greater improvements in individualised goal attainment, upper limb quality of movement, or participation in daily life than receiving a home program for four weeks or not at all. Since the home program intervention included development of goals and activities through a collaborative process that was ultimately directed by the child’s parents, the types of goals and activities selected by parents and the amount of activity involvement could also be investigated. To attain these aims the following four questions were addressed and answered.
1. Does use of an eight week home program lead to improvement in parent ratings of performance and satisfaction with functional activities, individualised goal achievement, upper limb quality of movement and participation for children with cerebral palsy compared to no home program at all?

2. Does use of a home program for four weeks lead to improvement in parent ratings of performance and satisfaction with functional activities, individualised goal achievement, upper limb quality of movement and participation for children with cerebral palsy compared to no home program at all?

3. Does the eight week home program achieve significantly better outcomes compared to the four week home program on parent ratings of performance and satisfaction with functional activities, individualised goal achievement, participation, and upper limb quality of movement outcomes for children with cerebral palsy?

4. What goal areas do parents generate for the home program and how frequently and intensely do they implement home programs?

4.3 Design
The major knowledge gap about home programs is that despite routine use, efficacy has not been established (Novak & Cusick, 2006). Proponents of evidence-based practice maintain that RCTs can best determine the effectiveness of intervention (Herbert, Jamtvedt, Mead & Hagen, 2005). RCTs are considered the gold standard design for judging whether or not an intervention is effective (Herbert et al, 2005; Sackett et al, 1996) because they are unlikely to generate false positive results to therapy effectiveness questions (Sackett et al, 1996). Clinical effectiveness research that is conducted using RCT designs therefore produces the highest level of evidence available (Barton, 2000). Recruitment of adequate sample sizes reaching statistical power for RCTs is, however, difficult to achieve in heterogeneous populations such as cerebral palsy (Butler, Chambers, Goldstein, Harris, Leach, Campbell, Adams & Darrah, 1999).
To date, the highest level of research evidence supporting the effectiveness of home programs is a non-experimental, single group, pre-post intervention, pilot evaluation (Novak et al, 2007). This study had no control or comparison group and consequently provided a lower level of research rigour than an RCT. The previous study is at Level V evidence (Sackett, 1989) and a higher level of evidence such as a RCT (Level I) has not yet been done. A more rigorous research study that uses a control group and RCT design is needed to demonstrate efficacy (Herbert et al, 2005). This is particularly important for research involving children, because any component of improvement observed may be due to developmental maturation.

A double-blind RCT design was therefore was used to investigate home program effectiveness. The study included a treatment comparison group and a no-treatment comparison group. Participants were randomly allocated into one of the three groups in keeping with RCT conventions. After baseline measures, participants were randomly assigned to three groups: a group where the home program was conducted for eight weeks (“8WEEKs”), a group where the home program was conducted for four weeks (“4WEEKs”) and a wait-list group where no home program was conducted until after study completion (“NoHP”). Performance on measures was taken pre and post home program intervention. Participants and evaluators were blinded to group allocation. The study lasted eight weeks in duration. The study is summarised diagrammatically in Figure 7.
The 8WEEK group (n=12) was provided with a home program and asked to implement it for eight weeks. The 4WEEK group (n=12) was also provided with a home program but was asked to implement it for only four weeks. The model of four weeks active therapy followed by a four week break was adopted to emulate a previous study that showed rest periods were as important as active therapy for skill generalisation in children with cerebral palsy (Trahan & Malouin, 2002). The NoHP group (n=12) had no home program for the duration of the study. To maintain participant blinding to group allocation the NoHP were provided with professional documentation such as letters of funding support for equipment and teaching assistant time, whilst they were “waiting” for their home program, which commenced following the study conclusion. It is not unusual for children in this population to have a period of eight weeks with no occupational therapy, as waiting times for therapy services are common in an Australian context (Thompson, 1998).
and can extend to months. After primary end point measures were taken at eight weeks of enrolment group allocation was revealed to participants.

**Dependent Variables:** The dependent variables or expected outcomes from the effectiveness study were the achievement of desired therapy outcomes. More specifically this was measurement by the direction and amount of change in performance of functional activities, satisfaction with function, goal achievement, quality of upper limb movement, and participation in community. The direction and amount of change was measured using Canadian Occupational Performance Measure (COPM) (Law et al, 1990), Goal Attainment Scaling (GAS) (Kiresuk & Sherman, 1968), Quality of Upper Extremity Skills Test (QUEST) (DeMatteo et al, 1993) and the Children’s Assessment of Participation and Enjoyment (CAPE) (King et al, 2004). These outcome measures were selected because of their good scientific rigour and utility when critiqued using the Instrument Evaluation Process Algorithm (Law, 1987). Using this algorithm, all measures had the advantageous psychometric properties of being designed to measure change that was clinically useful, having adequate test construction, and were standardised, reliable, valid and responsive to small changes over time (Law, 1987). More information about these measures is presented in a later section of this chapter (4.10 Instrumentation and Materials).

**Independent Variable:** The independent variable or presumed study cause of functional outcomes was the home program. As previously identified in this thesis, home programs were operationally defined as therapeutic activities designed by the family and therapist to reach mutually agreed goals, to be practiced at home under the direction of the parent. Home program participation was operationalised in terms of frequency, which was defined as how often the family chose to implement the home program and intensity, which was how long the family spent on the selected home program activities per session. Home program duration was also operationally defined as the home program frequency multiplied by the intensity.
The trial was conducted using a pragmatic approach to reflect the practical realities of home intervention for children with cerebral palsy. A pragmatic approach was adopted so that the effectiveness trial would reflect real clinical practice as much as possible (Godwin, Ruhland, Casson, MacDonald, Delva, Birtwhistle, Lam & Seguin, 2003). To control for possible program heterogeneity given the variation that exists in clinical practice, all of the home programs were developed by the same experienced occupational therapist (the principal investigator). It is conceivable that this level of homogeneity of programs may not exactly match real-world clinical practice and could therefore have introduced a “therapist effect” to the study. The methodological benefits of control and precision were deemed to outweigh the risk of a “therapist effect”.

To prevent the chance of the control group receiving the experimental home program intervention during the study, potential contamination effects of other occupational therapy interventions were controlled for via strict inclusion criterion. Potential participants must have been on a waiting list at the time of recruitment (i.e. not receiving other occupational therapy) to reduce the chance of them also receiving a home program during the study period.

In addition, parents recorded on the home program log whether or not they received any other non-study treatment or orthotics from any other therapist (for example, physiotherapy) which enabled an analysis of protocol adherence to be conducted. The log enabled analysis of potential sources of co-intervention bias.

In summary, the study design built on the findings of a previously published home program pilot study (Novak et al, 2007) however it aimed to be more rigorous in that it: (a) used a double-blind RCT design, with an appropriate sample size to provide adequate statistical power to detect any change gained from the home program; (b) included an appropriate control comparison group to account for the effects of children’s maturation; (c) minimised possible reporting and scoring bias by using evaluator blinding and
participant blinding and through taking baseline measures prior to group allocation (The processes for blinding raters and participants are described in Section 4.6); (d) rated the severity of children’s cerebral palsy using the standard Gross Motor Function Classification System and Manual Ability Classification System instruments and then treated severity of cerebral palsy as a covariate in the effectiveness analysis; (e) used individualised goal directed evaluation via the COPM and GAS; and (f) used standardised instruments that captured function and participation including the COPM, GAS, QUEST and CAPE. The first three instruments have sound psychometric properties that demonstrate sensitivity to change in the paediatric cerebral palsy population. The CAPE instrument was the exception, as sensitivity to change was unknown at the time of study design, but it was selected because of the importance of understanding children’s participation and it was the best participation measurement tool available at the time of study design.

4.4 Sampling
The target population for this study was school-aged children diagnosed with cerebral palsy. Because this was a pragmatic trial, a broad “spectrum of the population to which the treatment might be applied” (Godwin et al, 2003), i.e. all cerebral palsy GMFCS severity levels, motor types and topographies, was included within the trial, so that if the intervention did show benefits, it would also apply to a wide range of children with cerebral palsy. A sampling frame of accessible potential research participants was developed from those children on the waiting-list for occupational therapy services from Australia’s largest cerebral palsy service provider, The Spastic Centre of NSW. Potential participants needed to be on the waiting list and meet inclusion and exclusion criteria (described later in this section).

A range of recruitment strategies was used to assemble the convenience sample. Potential participant families needed to volunteer to participate. Recruitment strategies included:
Recruitment advertisements (in Appendix B), study information sheets and consent forms were emailed to all managers and senior occupational therapists within The Spastic Centre of NSW who provided occupational therapy services to children with cerebral palsy, in both rural and metropolitan NSW.

Lists of children with cerebral palsy meeting the eligibility criteria were assembled from the waiting lists held by the senior therapists and managers at The Spastic Centre of NSW. 87 eligible children were identified. They were mailed a recruitment advertisement, a study information sheet and a consent form. A follow-up telephone call was made by a Spastic Centre staff member who was not involved in the study, to check that they had received the correspondence and ask if they had any questions about the study.

Any study enquiries by phone or emails were answered by the Investigator.

Table 4 identifies the final number of participants recruited via each method.

<table>
<thead>
<tr>
<th>Recruitment Strategy</th>
<th>Enquiry Numbers</th>
<th>Number of Excluded Participants</th>
<th>Number of Included Participants</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Spastic Centre of NSW waiting list mail out – self identification as a volunteer participant</td>
<td>11</td>
<td>1</td>
<td>10 (27.8%)</td>
</tr>
<tr>
<td>The Spastic Centre of NSW non-study personnel telephone follow-up to eligible participants</td>
<td>15</td>
<td>0</td>
<td>15 (41.7%)</td>
</tr>
<tr>
<td>Chief Investigator telephone consultations to potential volunteers with more questions</td>
<td>11</td>
<td>0</td>
<td>11 (30.5%)</td>
</tr>
</tbody>
</table>

TOTAL n=36

Participants needed to meet all of the following inclusion criteria: diagnosis of cerebral palsy; child was attending school in any class from kindergarten to year six, i.e. infants and primary school age. As a result of targeting school-aged children, the children were between 4 year 6 months and 12 years old; consent to participate was given by parent or guardian; the child was on an occupational therapy waiting list for a minimum of four weeks; and the child’s parent had some concern about the child’s arm use, determined
through parental interview by The Spastic Centre of NSW intake officer when gathering information about family priorities for occupational therapy services.

Participants were excluded from the study if they met any of the following criteria: child was involved in non-occupational therapy intervention, which focused on developing their upper limb use, e.g. conductive education; child was receiving active occupational therapy services from another service provider whilst they were on The Spastic Centre of NSW waiting list; or the parent stated that they did not want to carry out any form of home program intervention at this time. The exclusion criteria were used to control for potentially confounding occupational therapy co-interventions which may have influenced study outcomes. For ethical reasons, children were not excluded from the study if they were receiving standard medical interventions (such as botulinum toxin) or routine physiotherapy interventions (such as lower limb casting). Parents recorded the use of medical and physiotherapy interventions during the study on the home program log calendar.

To ensure that the sample size was sufficient and was capable of detecting a difference between the groups when one existed, an a priori sample size test of power was performed (Domholdt, 2000). Calculation of statistical power before commencing the trial meant that the known rehabilitation research flaws of inadequate power due to small between-group differences, small sample sizes, and large within-group variability were avoided (Ottenbacher & Barrett, 1990). Further, the use of sample size calculations reduced the chance of home program intervention outcomes being inaccurately rejected from a type II (low power) error (Ottenbacher & Barrett, 1990). The power calculation was based upon data collected by the author in earlier research which piloted the home program (Lowe, Novak & Cusick, 2006). The power calculation was designed to identify the probability of detecting clinical effect in the primary outcome measure (COPM) at an alpha of 5%, power of 80%, using a minimal clinically important difference of 10%. This followed standard
recommendations for achieving adequate power in rehabilitation research (Ottenbacher & Barrett, 1990). In addition, the calculation accounted for a dropout rate of 20% and non-compliance rate of 20% given that level of participation in a home program was a variable the researcher could not control. The power calculation revealed that a sample size of twelve participants per group was necessary to detect clinically worthwhile effect. Therefore, a total of thirty-six participants were recruited and randomised across the three groups.

Sample sizes in other home program and cerebral palsy studies where the COPM was used to measure function were examined (Fragala et al, 2002; Law et al, 1998; Lowe, Novak & Cusick, 2006; Wallen, O’Flaherty & Waugh, 2004). Studies identified through a literature search of Medline databases are summarised in Table 5. These identify sample sizes ranging from 7 (in a single group study) to 72 (in a 4 group design).

<table>
<thead>
<tr>
<th>Study &amp; Citation</th>
<th>Sample Size Used</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Home Program Quantitative Research Studies</strong></td>
<td></td>
</tr>
<tr>
<td>Mayo (1981). The effect of a home visit on parental compliance with a home program.</td>
<td>n = 18 9 experimental, 9 controls</td>
</tr>
<tr>
<td>Schreiber et al (1995). Effectiveness of parental collaboration on compliance with a home program.</td>
<td>n = 18 10 experimental, 8 controls</td>
</tr>
<tr>
<td>Law &amp; King (1993). Parent compliance with therapeutic interventions for children with cerebral palsy.</td>
<td>n = 72 block randomisation divided into 4 different intervention groups of 18</td>
</tr>
<tr>
<td>Gajdosik &amp; Campbell (1991). Effects of weekly review, socio economic status and maternal belief on mother’s compliance with their disabled children’s home exercise program.</td>
<td>n = 18 10 experimental, 8 controls</td>
</tr>
<tr>
<td><strong>Cerebral Palsy Effectiveness Studies using COPM as an Outcome Measure</strong></td>
<td></td>
</tr>
<tr>
<td>Fragala et al (2002). Impairment, disability, and satisfaction outcomes after lower-extremity botulinum toxin A injections for children with cerebral palsy.</td>
<td>n = 7 single group</td>
</tr>
<tr>
<td>Wallen et al (2004). Functional outcomes of intramuscular botulinum toxin type A in the upper limbs of children with cerebral palsy: A phase II trial.</td>
<td>n = 16 standard deviation for COPM not stated</td>
</tr>
</tbody>
</table>

These studies confirmed previous research findings that the standard deviations for the COPM instrument were very narrow, around a mean of 1.2, because of the instrument’s sensitivity to change. These data indicated the study power calculation of a
sample size of thirty-six as being capable of detecting significant clinical change from home program intervention.

4.5 Randomisation
Simple randomisation (Pocock, 1983) was used to allocate the participants into three groups: “8WEEK” (the 8 week home program), “4WEEK” (the 4 week home program) and “NoHP” (no home program). The random allocation numbers were generated using Microsoft Excel. An independent administrator who was off-site to the participants and not in contact with the participants from The Spastic Centre generated the allocation to group sequence. Enrolment numbers and the randomisation envelopes were stored in a location separate from the investigators and off-site to The Spastic Centre of NSW campuses in opaque envelopes in a locked filing cabinet. The opaque envelope corresponding to the participant’s numbered enrolment envelope was opened by non-study personnel after informed consent and baseline assessments were completed, and the group allocation was then revealed to the investigator.

4.6 Blinding
The RCT used a double blind methodology, meaning neither the assessor nor the participant could identify what was being measured (Jadad et al, 1996). Both the evaluators and participants were blinded to group allocation and they were not aware of the study hypotheses. They were not told that other groups would be asked to implement home programs for different periods of time or at different times as part of the controlled experimentation. The participants’ information sheet informed parents that they did not have any choice about which group they were randomly assigned to, but they would receive a home program regardless of group allocation (see Appendix B-4). The risk of accidental un-blinding by participants was assessed to be low because participants were assessed in their own home and therefore had low likelihood of meeting other families in the study who may have been assigned to another group. There was no Spastic Centre service
mechanism in existence that would have allowed for study participants to meet each other. To the author’s knowledge no study participants met each other during the course of the trial.

The proposed benefits of concealing group allocation from both evaluators and participants are a reduction in bias in relation to program participation reporting and in enhancing the quality of outcome measures (Campbell et al, 1995). In this case program participation and outcome measures were goals set for intervention, self-reporting on some outcome measures by parents, self-reporting about home program participation time as measured by the log calendar, and for scoring of the outcome measures by evaluators.

Participants were not disadvantaged by group allocation, as all participants were provided with an individualised home program. The NoHP group waited eight instead of zero weeks for home program commencement. As waiting periods are typically longer than 8 weeks participation in any group was not a disadvantage to the children. Children in the study also maintained their place on the waiting list for Spastic Centre services. Provision of home programs to the control group after the primary end-point maintained blinding to group allocation for the study duration and minimised ethical concern about children waiting for intervention, particularly as eligibility for inclusion in the study specified that children must already be on a waiting list.

The evaluator occupational therapist scoring outcome measures from video recordings did not know the participants’ group allocation nor did they know the order of recordings and they never met participants. Functional activities performance on individualised goal achievement (GAS) and QUEST measures could be made from video recordings, as these measures can be scored this way in clinical practice. Parent ratings of performance and satisfaction on the COPM and the CAPE were administered by an occupational therapist evaluator who was blinded to study design, blinded to group allocation and was not the child’s treating therapist.
Randomisation and double blinding dealt with potential sources of bias and minimised bias in data collection (Jadad et al, 1996), particularly parental self-reporting bias and evaluator scoring bias (Herbert et al, 2005). This maximised the chance that any change detected within the experimental groups was due to the home program intervention, rather than a treatment effect from another source of intervention or bias (Colditz et al, 1989).

4.7 Study Validity
To enhance the study rigour, a range of strategies were used to reduce possible threats to the study’s validity and ensure that the research conclusions were believable and useful (Cook & Campbell, 1979; Domholdt, 2000). These strategies included the use of randomisation, a controlled comparison group and double blinding to improve internal validity. These design features increased the probability that extraneous participant characteristics were distributed evenly across groups (Cook & Campbell, 1979) and increased the likelihood that it was the home programs that caused the change in the outcomes rather than other causes of change, such as maturation (Domholdt, 2000). The sample was recruited using a comprehensive strategy using inclusion and exclusion criteria that reflected the broader cerebral palsy population and thus aimed to enhance external validity of findings (Creswell, 1994; Domholdt, 2000). Finally, construct validity was enhanced through careful development of the research question, study design and selection of robust outcome measures derived from a thorough understanding of the relevant professional literature and clinical practice experience of the investigator (Domholdt, 2000).

4.8 Ethical Approval
Ethics approval to conduct the study was obtained from two committees: (1) the University of Western Sydney Ethics Review Committee (Human Subjects), Protocol Number: 06/031 (letter of approval, 24th March 2006); and (2) The Spastic Centre of NSW National Health and Medical Research Council Human Research Ethics Committee.
EC00402 (letter of approval, 15th March 2006). Appendix 2 presents the application and ethical approval letters of each.

4.9 Procedure

Screening: A sampling frame was developed by the principal investigator from waiting-list data of potential participants meeting the inclusion criteria. After the application of recruitment strategies described earlier in this Chapter, volunteers were screened by the principal investigator over the telephone using an informal interview, which aimed to confirm that the potential participant met all the inclusion criteria and did not have any exclusion criteria.

Baseline Assessment: For each participant, a baseline assessment home visit was conducted prior to randomisation. Baseline assessment included collection of participant demographics: age, gender, classification and severity of cerebral palsy, type of schooling, and family demographics (number of family members and household income status). This was then followed by the administration of the battery of instruments measuring performance of functional activities, satisfaction with function, individualised goal performance behaviour, quality of upper limb movement and participation in the community. These data were used to inform the development of the home program, which was the third phase of the home program. Section 4.10 described the instruments used in the baseline assessment in detail.

Experimental Treatment: To select the intervention techniques used within the home programs the researcher used clinical reasoning, the models that underpin home program design reviewed in Chapter Three, and knowledge of best available supporting evidence. All of the home programs were developed by the principal investigator, to avoid bias being introduced from varying clinical and communication skills and intervention techniques being selected by different therapists.
The home programs were written down for parents and included text and pictures. Every home program was individualised for each child and was designed around the goals set by the family during the initial goal-setting interview using the COPM and GAS. The programs included several hallmark features, which will be illuminated by using “Hannah” as an example (Table 6). Hannah’s actual home program can be seen in Appendix A-1, with the therapist’s clinical reasoning notes added. At the secondary end-point of 4 weeks after home program commencement, Hannah’s goal progress had improved from baseline on 2 of the 5 COPM goals that her family had implemented and on all 3 of the GAS scales. For more information on scores refer to Appendix A-2 and A-3. A discussion was held with Hannah’s family about whether they wanted to replace the goals or continue on with the program with the aim of making more progress. Hannah’s parents chose not to make any changes to the goals and the program as from their perspective it was working and the content and strategies were still relevant and helpful.
### Table 6: Trial Home Program Features Illustrated by an Example of Hannah’s Home Program

<table>
<thead>
<tr>
<th>Program Feature</th>
<th>Hannah’s Home Program*</th>
</tr>
</thead>
<tbody>
<tr>
<td>A title page with the child’s name</td>
<td>“Hannah’s Home Program” (Page 1)</td>
</tr>
<tr>
<td>General home program strategies information</td>
<td>Parent Education information about:</td>
</tr>
<tr>
<td></td>
<td>▪ What the home program is trying to achieve</td>
</tr>
<tr>
<td></td>
<td>▪ General principles for supporting successful learning in children</td>
</tr>
<tr>
<td></td>
<td>▪ The purpose is not to make the parent become a therapist at home</td>
</tr>
<tr>
<td></td>
<td>▪ Current evidence about how long the home program should be carried out (Pages 2-3)</td>
</tr>
<tr>
<td>Tips for carrying out home programs</td>
<td>Parent Education information designed to:</td>
</tr>
<tr>
<td></td>
<td>▪ Empower Hannah’s parents to assume the role of decision-maker about the program</td>
</tr>
<tr>
<td></td>
<td>▪ Empower Hannah’s parents to adapt the therapeutic activities with their own ideas</td>
</tr>
<tr>
<td></td>
<td>▪ Help Hannah’s parents establish a sustainable home program implementation routine (Page 4)</td>
</tr>
<tr>
<td>Goal statements</td>
<td>This program is working if Hannah...</td>
</tr>
<tr>
<td></td>
<td>The zero level of the Goal Attainment Scales (achieved as expected) were stated on this page, to help Hannah’s parents (a) gain realistic expectations for the intervention period and (b) gain knowledge about how to observe Hannah’s progress arising from the home program. (Page 5)</td>
</tr>
<tr>
<td>Goal one: Child activities and parent education</td>
<td>Goal one: “Early construction play”</td>
</tr>
<tr>
<td></td>
<td>▪ Parent education on types of toys that would help Hannah achieve the goal of playing independently without supervision</td>
</tr>
<tr>
<td></td>
<td>▪ Library of early construction activities for Hannah to practice. A range of choices were provided so that Hannah’s parents could choose the ones that Hannah liked to do and were not stressful for the family to implement</td>
</tr>
<tr>
<td></td>
<td>▪ Parent education tips about “cues” to use to help Hannah successful build her repertoire of play skills</td>
</tr>
<tr>
<td></td>
<td>The intervention techniques selected to reach this goal included: parent education, play therapy and goal-focused task practice. (Pages 5-9)</td>
</tr>
<tr>
<td>Goal two: Child activities, parent education and</td>
<td>Goal two: “Keeping arms on the table”</td>
</tr>
<tr>
<td>environmental adaptations</td>
<td>▪ Environmental adaptations (seating intervention) to facilitate Hannah succeeding at the task of sitting with her arms on the tray</td>
</tr>
<tr>
<td></td>
<td>▪ Parent education on how to set up the environment for success</td>
</tr>
<tr>
<td></td>
<td>▪ Library of shoulder flexion activities provided for Hannah to practice. A range of choices were provided so that Hannah’s parents could choose the ones that Hannah liked to do and were not stressful for the family to implement</td>
</tr>
<tr>
<td></td>
<td>The intervention techniques selected to reach this goal included: seating and positioning, parent education and goal-focused task practice. (Page 10)</td>
</tr>
<tr>
<td>Goal three: Child activities, parent education and</td>
<td>Goal three: “Sustaining grip”</td>
</tr>
<tr>
<td>environmental adaptations</td>
<td>▪ Library of grasp activities provided for Hannah to practice. A range of choices were provided so that Hannah’s parents could choose the ones that Hannah liked to do and were not stressful for the family to implement</td>
</tr>
<tr>
<td></td>
<td>▪ Parent education tips about “cues” to use to help Hannah her successfully maintain her grip on toys</td>
</tr>
<tr>
<td></td>
<td>The tasks were adapted to be carried out in the family pool, which was a place Hannah and her dad enjoyed interacting together</td>
</tr>
<tr>
<td></td>
<td>The intervention techniques selected to reach this goal included: parent education and goal-focused task practice. (Page 11)</td>
</tr>
<tr>
<td>Goal four: Child activities, parent education and</td>
<td>Goal four: “Undressing”</td>
</tr>
<tr>
<td>environmental adaptations</td>
<td>▪ Parent education information provided to help Hannah’s parents gain realistic expectations about the likely gains from dressing training within the intervention period</td>
</tr>
<tr>
<td></td>
<td>▪ Parent education tips about “cues” to use to help Hannah complete the steps of dressing using a backward chaining technique were provided</td>
</tr>
<tr>
<td></td>
<td>▪ Environmental adaptations were provided to make the task easier for Hannah to complete (e.g. sitting for stability and size and texture of clothing)</td>
</tr>
<tr>
<td></td>
<td>The intervention techniques selected to reach this goal included: parent education and goal-focused task practice. (Page 12-14)</td>
</tr>
</tbody>
</table>

* Actual home program in Appendix A-1. Page numbers in brackets refer to page numbers in actual home program.

**Participant Involvement:** Study involvement for the child participants meant that they:

- Participated in three assessments, one at baseline before randomisation, and two further follow-up assessments at four weeks (secondary end-point) and at eight weeks (primary end-point). Each assessment was video recorded for blind scoring purposes.
- Participated in the home program as directed by their parent and according to their group allocation (either 8WEEK, 4WEEK or NoHP).
Study involvement for parents meant they:

- Completed an initial demographic survey and participated in an interview about their goals for intervention. This interview was not considered a baseline measure, rather the interview was needed to help develop the home program based on family priorities and preferences.

- Carried out the home program with their child as often and for as long as they liked according to their group allocation. In line with family-centred practice, parents made the decision about how long to implement the home program for. The following text was inserted on all home programs for the purpose of empowering parents to be the decision-makers about implementation of the home program: “What is this home program trying to achieve? This document is a resource for your family, which aims to support your child’s development and health and enhance your parenting expertise. You can exchange the activities suggested here with your own activity ideas that work towards the same goals. Parents’ ideas add value to therapist written programs. General learning principles: (1) movements (skills) are learned best when practiced regularly; (2) new movements (skills) are remembered best when they are learnt in real-life environments and routines; (3) your child’s motivation is key to how much they learn; (4) choose activities they like doing. If the suggested activities aren’t enjoyable, adjust them using your knowledge; and (5) some children require external rewards, if they don’t have the personal motivation for the task you are working on together. This is common with daily routines e.g. dressing, cutlery use etc. Rewards don’t have to be big or expensive, and they don’t have to be food. Rewards can be selected from daily privileges, such as watching a favourite TV show, a bike ride etc. The Good News: This home program is not trying to turn you into a therapist at home, rather enhance the way you parent your child. Home program research indicates that as little as 5-10 minutes per day may help you reach your goals with your child. Decide on your home program routine preference: Different families have different preferences for how they like to carry out home programs. Choose the method that best works...
for your family. Some families like to embed the child activities into routines. Other families like to allocate a certain time for carrying out home program suggestions, like a home work routine.”

- Recorded their home program involvement on a “home program log calendar” (See section 4.10).
- Participated in the baseline, four week and eight week assessments by making appointments, inviting their child to participate in the assessments and completing parent reports on measures (See section 4.10).

**Follow-up Assessments:** The COPM, GAS, QUEST and CAPE instruments were re-administered at four and eight weeks to determine the direction and amount of change in score since baseline.

### 4.10 Instrumentation and Materials

To measure the direction and amount of change in the dependent variable a number of instruments were used (Table 7). Each instrument will be described in detail, exploring the usefulness of the instrument and its psychometric properties.

<table>
<thead>
<tr>
<th>Table 7: Study Instruments and Domain of Measurement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Outcome Measures</strong></td>
</tr>
<tr>
<td>Canadian Occupational Performance Measure (COPM)</td>
</tr>
<tr>
<td>Goal Attainment Scaling (GAS)</td>
</tr>
<tr>
<td>Quality of Upper Extremity Skills Test (QUEST)</td>
</tr>
<tr>
<td>Children’s Assessment of Participation and Enjoyment (CAPE)</td>
</tr>
<tr>
<td><strong>Domain</strong></td>
</tr>
<tr>
<td>Performance and satisfaction with functional activities such as self care, productivity &amp; leisure independence</td>
</tr>
<tr>
<td>Individualised child or family-centred goals</td>
</tr>
<tr>
<td>Quality of upper extremity movement</td>
</tr>
<tr>
<td>Participation in community activities</td>
</tr>
</tbody>
</table>

| **Participant Attribute Measures**                  |
| Gross Motor Function Classification System (GMFCS) |
| Manual Ability Classification System (MACS)         |
| Log Calendar                                        |
| Investigator-designed parent interview schedule     |
| **Domain**                                          |
| Gross motor function                               |
| Manual abilities                                    |
| Home program participation time (self-report)       |
| Participant demographic characteristics and home program goal setting and implementation characteristics (completed in self-report interview format) |

The following detailed descriptions of cerebral palsy outcome measures have been published elsewhere by the principal investigator of this study (Novak, 2006a) for the Australian government report into the therapy and equipment needs of Australians with cerebral palsy and the material has been reproduced with permission.
4.10.1 Canadian Occupational Performance Measure (COPM)

The COPM (Law et al, 1990) is an individualised outcome measure used to detect change in functional performance goals, based on the individual’s perceptions and priorities. The tool was developed conceptually from the Canadian Model of Occupational Performance (Canadian Association of Occupational Therapists, 1991), which has undergone revisions over time. In that model occupational performance is self-care, productivity and leisure, which are influenced by the person’s social roles, their environment, and their personal views both about self ‘performance’ and ‘satisfaction’ with performance (Canadian Association of Occupational Therapy, 2002).

The instrument is administered via a semi-structured interview (Law et al, 1994). Within the interview, the individual is asked to score the relative importance of each problem area on a scale of 1-10, rating both their performance and satisfaction with their performance (Law et al 1990). It is administered as an initial interview and then at subsequent intervals to detect change (Law et al, 1994). Total performance and satisfaction scores are calculated by adding together all of the goal raw scores and dividing the total by the number of goals set, to form a performance score out of 10 and a satisfaction score out of 10 (Law et al, 1990).

While this instrument was designed for use with adults (Law et al 1990), it has also been used to measure the effectiveness of intervention with families and their child with cerebral palsy (Law, Russell, Pollock, Rosenbaum, Walter & King, 1997; Law et al, 1998; Lowe, Novak & Cusick, 2006; Wallen et al, 2004). The instrument is generic and therefore has been successfully adopted in many specialties for measuring individual change, assessing program impact and for quality assurance (Law et al, 1997; McColl, 2000). In this study the instrument was used in a format adapted for children (Cusick et al, 2006). The COPM adapted for children enables parents to identify and rate their child’s performance.
and satisfaction. It omits the sections pertaining solely to adult specific tasks such as ‘unpaid/paid work’ and ‘household management’ (Cusick et al, 2006).

The psychometric properties of the original instrument are accepted to be adequate for its purpose. The test-retest reliability of the instrument ranges from fair to good, 0.56-0.63 for performance and 0.39-0.84 for satisfaction (Law, Polatajko, Pollock, McColl, Carswell & Baptiste, 1994a; Trombly et al, 1998). Criterion validity of the instrument has not been adequately evaluated and is thought to be weak (Chan & Lee, 1997; McColl et al, 2000). Most importantly as an outcome measure, the instrument has been shown to be very sensitive to change in function as perceived by families and therapists (Law et al, 1994). When used to measure parent perceptions of occupational therapy for children with cerebral palsy, the COPM has detected clinically significant change in the domains of self-care, play and mobility (Law et al, 1998). For this reason, the COPM was selected as the RCT’s primary outcome measure.

**4.10.2 Goal Attainment Scaling (GAS) of Home Program Goals**

GAS is an individualised criterion-referenced measure of clinical change, using quantifiable goals (Kiresuk & Sherman, 1968). The process of using GAS involves defining an individual set of goals, assigning a weighting according to the goal’s importance, specifying a range of possible outcomes, and using the scales to evaluate change from intervention (King, McDougall, Palisano, Gritzan & Tucker, 1999). For each goal, a range of possible outcomes is defined, where the expected outcome is given the zero score and outcomes above and below the expected outcome are assigned positive and negative values respectively. At the re-evaluation period, an overall goal attainment T-score is calculated, which reflects any change since baseline across multiple goals (Kiresuk & Sherman, 1968). The GAS T-Score has a mean of 50 and a standard deviation of 10, so any final T-score between 40 and 60 indicates goal achievement as expected (King et al, 1999).
The psychometric properties of GAS are considered acceptable for the purpose of measuring change from rehabilitation in children (Cusick et al., 2006; Palisano, Haley & Brown, 1992; Palisano, 1993). The validity and reliability of GAS have however been criticised, as unintentional bias can occur in the goal setting process (King et al., 1999). In particular, goals can be too easy to attain (Palisano, 1993). Reliability and validity of the instrument can be improved by training evaluators, use of independent blinded evaluators, clear delineation of outcome levels and the use of multiple evaluators (Ottenbacher & Cusick, 1990). In accordance with literature recommendations, all of these strategies were used within the effectiveness study to improve the validity and reliability of the GAS outcome data and to reduce potential sources of evaluator bias (Cytrynbaum, Ginath, Birdwell, & Brandy, 1979; King et al., 1999). GAS is sensitive to clinical change and is capable of detecting small but significant clinical change, which may otherwise be missed when using global assessment procedures (King et al., 1999, Ottenbacher & Cusick, 1993, Palisano et al., 1992, Palisano, 1993, Wallen & Doyle, 1996). Goal attainment also has the added benefit of adopting a collaborative family-centred approach (King et al., 1999). This is a central theme in this study, which supports the adoption of this approach. The GAS instrument is recommended as an occupational therapy evaluation tool for measuring goals that are meaningful and important to families (Wallen & Doyle, 1996).

A semi-structured interview was used as per standard procedures, to elicit goals meaningful to the parent and child using the COPM and GAS instruments for the effectiveness trial. In the interview participants were asked to generate goal focus areas for intervention and to prioritise the relative importance of each of these goals. From the highest priorities developed on the COPM instrument (the primary outcome measure), the researcher also set up the secondary outcome measure of individualised and prioritised (weighted) goal attainment scales for each participant. The GAS goals became measurable.
tasks with predicted levels of achievement, using standard GAS format. The GAS goals developed therefore had the same topic areas as the primary outcome measure.

4.10.3 Quality of Upper Extremity Skills Test (QUEST)
The QUEST is a standardised, criterion-referenced instrument which evaluates the quality of upper extremity function in four domains: dissociated movement, grasp, protective extension and weight bearing (DeMatteo et al, 1993). The QUEST was designed to be used with children aged 18 months to 8 years, who exhibit signs of muscle spasticity (DeMatteo et al, 1993). The QUEST assesses patterns of movement that provide the basis for functional upper extremity activities performance (DeMatteo et al 1993).

Limited research has been conducted into the instrument’s psychometric properties but in general the psychometric properties are considered acceptable (DeMatteo et al, 1993; Hickey & Ziviani, 1998; Sorsdahl, Moe-Nilssen & Strand, 2008). The overall validity of the QUEST is reported to be high as the items are well grounded in theoretical and clinical contexts and demonstrate high to moderate construct validity with comparable measures (Hickey & Ziviani, 1998). Reliability is also high, with (0.91-0.96) inter-observer reliability and (0.95) test-retest reliability for total QUEST scores (Hickey & Ziviani, 1998; Sorsdahl et al, 2008). Sensitivity to change is untested but has been shown to be adequate in previous studies where the QUEST has been used as the primary outcome measure (Lowe, Novak & Cusick, 2006).

A total score out of 100 is developed using standardisation formulas provided in the test administration manual and by averaging the number of sub-domain scores administered (DeMatteo et al, 1993). Of the four possible QUEST test item domains, only “dissociated movement” and “grasp” were measured in the home program effectiveness study. This decision was based on earlier research that found these two sub-domains to have the highest validity, test retest reliability and inter-rater reliability (Hickey & Ziviani, 1998) although this finding has been contradicted in a more recent study published after
the trial was designed (Sorsdahl et al, 2008). The test developers indicate the procedure of producing a total score from only some sub-domains is psychometrically sound (DeMatteo et al, 1993). This procedure has been used in precedent studies (Lowe et al, 2006).

The QUEST is considered the best available tool for assessing upper limb quality of movement in children with cerebral palsy (Hickey & Ziviani, 1998). It is for this reason, along with the aforementioned psychometric properties, that the QUEST was used as a secondary outcome measure for evaluating the impact of the home program on the quality of arm movement.

4.10.4 Children’s Assessment of Participation and Enjoyment (CAPE)
The CAPE measures the participation of children in everyday activities outside the school curriculum (King et al, 2004). The CAPE measures five domains of participation: (1) diversity, which is the number of activities performed; (2) intensity, the frequency of participation as a function of the number of possible activities in each CAPE category; (3) with whom; (4) where the activities were performed; and (5) enjoyment of participating in the activities (King et al, 2004). The CAPE measures participation across ten categories: hobbies, crafts and games, (e.g. computer games); social activities (e.g. going to a party), quiet recreation (e.g. playing with toys), organised sports (e.g. gymnastics), other skill-based activities (e.g. playing an instrument), clubs, groups and organisations (e.g. school clubs), active physical recreation (e.g. dancing), entertainment and education (e.g. going to the movies), jobs, chores and employment, (e.g. taking care of a pet) and other activities (King et al, 2004). There are 55 items in total. An overall score is developed for each domain. For the diversity domain the overall score is out of 55. For the intensity domain the raw score is divided by 55. For the remaining domains, the raw scores are tallied and divided by the diversity domain score (i.e. the number of participation items performed).

The CAPE was designed for use with people aged six to twenty-one years of age, including children with physical disabilities such as cerebral palsy (King et al, 2004). The
instrument can be administered in alternative ways to elicit direct responses from children with physical impairments rather than parent proxy responses (King et al, 2004). The benefits of the CAPE instrument are thought to include being a client-centred measure, user-friendly, engaging for children to use, and flexible to administer (King et al, 2004).

Validity and reliability of the CAPE to date have only been reported by the test developers in the administration manual. The internal consistency reliability (0.76-0.84) and the test-retest reliability are adequate (0.64-0.86) for the diversity, intensity and enjoyment domains (King et al, 2004). The validity of the instrument is considered sufficient (0.64-0.96) (King et al, 2004). Given the increased attention ‘participation’ is receiving in childhood rehabilitation, the investigator chose to use the CAPE as a secondary outcome measure, to provide a preliminary understanding of the participation impact of home programs. A limitation of using the CAPE instrument within the home program effectiveness trial was the lack of sensitivity data available.

4.10.5 Home Program Log Calendar

The families’ participation in the home program was recorded in a self-report home program log calendar designed by the researcher. The precedent for self reporting ‘compliance’, via diaries and calendars is well reported in the mental health and medical literature, with respect to medication usage symptom manifestation, pain levels, and drug-taking behaviour (Jamison, Raymond, Levine, Slawsby, Nedeljkovic & Katz, 2001; Schandry et al, 1996; Rosner et al, 1992; O’Hare et al, 1991). Logbooks have also been employed by therapists to record self-reports of frequency and duration of home exercise program use (Chen et al, 1999; Schreiber et al, 1995; Tooth, McKenna & Colquhoun, 1993). Several authors working with children and families have advocated the use of self-report diaries or calendars (Gajdosik, 1991; Law & King, 1993; Schreiber et al, 1995). Law and King (1993) compared five measures of parent participation in home programs: parent rating of participation level, therapist rating of participation level, therapy attendances,
mean hours of cast wear and daily log books. They demonstrated that self-report measures of parental participation in home programs were more reliable than any other measure of participation level and were the only measure predictive of clinical outcome (Law & King, 1993).

Parental participation in home programs for children with disabilities has been consistently shown to be high, despite the assumptions of health professionals that home program compliance is low (Law & King, 1993; Novak et al, 2005; Schreiber et al, 1995). One study that measured the effect of parent collaboration in developing the home programs via an RCT found ‘compliance’ rates of 77.5-80.3% (Schreiber et al, 1995). They concluded that this high level of compliance might be attributable to families’ interest in doing a home program as well as the method used to report compliance (Schreiber et al, 1995). To collect compliance data, Schreiber et al (1995) provided each family with a daily data collection form to complete. This logbook recorded the number of activities attempted and whether the activity was successfully completed. Compliance was calculated by dividing the number of activities attempted by the number of opportunities to carry out the activities during the study duration. Therefore, the RCT and the earlier pilot study followed a comparable logbook protocol. An earlier pilot study confirmed that families of children with cerebral palsy choose to engage in home programs regularly, with the mean frequency of six months home program participation being 0.90 times per day (SD = 0.11), in other words, less than once a day but approximately 27 times per month (Novak et al, 2007).

A daily logbook was provided to families, but instead of asking families to record whether the daily activities were successfully completed, the study logbook recorded if they did any home program on a day and the amount of time the family spent practicing the activities. Each day families were asked to record how often they chose to engage in the home program (frequency), and how long they spent on the home program activities per
session (intensity). This enabled the home program duration measures to be calculated, which was the home program frequency multiplied by the intensity. The minor modification to Schreiber et al (1995) logbook protocol was made to enable capture of self-selected parental participation intensity levels rather than ‘compliance’ levels with a prescribed regime.

4.10.6 Parent Interview Schedule

Parents were interviewed at baseline about child and parent participant demographic variables for the purpose of describing the sample. Parents were also interviewed at the primary and secondary endpoints. Interviews were about home program goal implementation choices and views to inform practice recommendations about parent preferences and find out the parent perspective including satisfaction levels. The investigator developed an interview schedule to structure the interviews. The same questions were asked of each participant using a semi-structured interview format, as this is considered the best methodology for obtaining factual information at the same time as retaining the opportunity to seek further clarification (Dumholdt, 2000). The interview schedule is outlined in Table 9.

The items in the interview schedule were developed from literature and from the study design features, such as the inclusion criteria and potential covariates identified in previous research. The interview began by confirming that the potential participant met the study inclusion criteria (Part 1 - Table 8) and proceeded to asking questions about child and parent demographic variables (Part 2 - Table 8). The demographic variables were devised from previous cerebral palsy and home program studies and literature recommendations about how to conduct rigorous cerebral palsy research (Steultjens et al, 2004). The demographic items were gender (Stanley, Blair & Alberman, 2000), age (Law, Cadman, Rosenbaum, Russell, DeMatteo & Walter, 1989), type of cerebral palsy (Law et al, 1989), associated impairments (Erhardt & Merrill, 1998; Stanley, Blair & Alberman, 2000),
identification of potential sources of home program implementation support including schooling type, number of people in family, family members at living at home (Gajdosik & Campbell, 1991), languages spoken at home (to ensure that the home program was provided in an appropriate language format) (Gajdosik & Campbell, 1991) and household income (Gajdosik & Campbell, 1991) (which was defined by the Australian Bureau of Statistics’ Mean Equivalised Disposable Household Income of all Households in Australia 2005-2006 percentile ratios). The median of $644.00 per week of disposable income is the midpoint when all people are ranked in ascending order of income.

In the last part of the parent interview (Part 3 - Table 8), which was conducted at the four and eight week follow-up points, parents were asked about their goal implementation choices. These data were collected to determine whether parents were using all or some of the home program supplied to them by the investigator and to help illuminate parental implementation preferences. It was considered important to understand whether or not parents implemented all strategies at once, and if not, why not. It was also important for the treating therapist to ask these questions to ascertain whether or not the home program provided was achievable from the parents’ point of view. This interview question provided parents with an opportunity to discuss challenges they were facing due to program content, to enable program adjustment and fine-tuning if required.

Table 8: Parent Interview Schedule

<table>
<thead>
<tr>
<th>Part 1: Baseline confirmation that your child is eligible to enrol in the study</th>
</tr>
</thead>
<tbody>
<tr>
<td>Please answer the following questions:</td>
</tr>
<tr>
<td>□ yes □ no</td>
</tr>
<tr>
<td>□ yes □ no</td>
</tr>
<tr>
<td>□ yes □ no</td>
</tr>
<tr>
<td>□ yes □ no</td>
</tr>
<tr>
<td>□ yes □ no</td>
</tr>
<tr>
<td>□ yes □ no</td>
</tr>
<tr>
<td>□ yes □ no</td>
</tr>
<tr>
<td>□ yes □ no</td>
</tr>
</tbody>
</table>
Part 2: Baseline understanding of your child’s health and family context

Please answer the following questions. If you do not feel comfortable answering any of the questions you do not need to answer them.

<table>
<thead>
<tr>
<th>Question</th>
<th>Options</th>
</tr>
</thead>
<tbody>
<tr>
<td>Is your child</td>
<td>male? □ female? □</td>
</tr>
<tr>
<td>What is your child’s date of birth?</td>
<td>/ / dd/mm/yyyy</td>
</tr>
<tr>
<td>How old is your child?</td>
<td>years</td>
</tr>
<tr>
<td>What type of cerebral palsy does your child have?</td>
<td>R hemiplegia □ L hemiplegia □ spastic diplegia □ spastic quadriplegia □ dystonia □ athetosis □ ataxia □ unknown</td>
</tr>
<tr>
<td>Does your child have any of the following impairments associated with their cerebral palsy?</td>
<td>speech impairment □ epilepsy □ vision impairment □ intellectual impairment</td>
</tr>
<tr>
<td>What type of school does your child attend?</td>
<td>mainstream, no assistant □ mainstream, with an assistant</td>
</tr>
<tr>
<td>How many people live in your child’s household (include the child)?</td>
<td>people</td>
</tr>
<tr>
<td>Who lives at home with your child?</td>
<td>Birth mother □ Birth father □ Step mother □ Step father □ Siblings □ Grandmother □ Grandfather □ Other</td>
</tr>
<tr>
<td>Does your child’s household speak languages other than English?</td>
<td>yes □ no List:</td>
</tr>
<tr>
<td>Which is the main language used?</td>
<td>Low: Less than $274.00 pw □ Medium: $275-1,072.00 pw</td>
</tr>
<tr>
<td>After tax, which weekly household income best describes the income of the house that your child lives in?</td>
<td>High: Greater than $1,073.00 pw □</td>
</tr>
</tbody>
</table>

Part 3: Follow-up understanding of your goal-setting and implementation choices

On the first time we met to discuss your child’s involvement in the home program study, you set goals reflecting your priority areas for the home program. These were: <Read participant’s COPM goal areas back to them>

Four Week Follow-up
1. Between the first assessment and today, which of these goal areas have you spent time doing home program intervention to try and improve your child’s progress

| Goal 1: <Insert participant’s COPM goal area 1> | Comment: □ yes □ no |
| Goal 2: <Insert participant’s COPM goal area 2> | Comment: □ yes □ no |
| Goal 3: <Insert participant’s COPM goal area 3> | Comment: □ yes □ no |
| Goal 4: <Insert participant’s COPM goal area 4> | □ yes □ no |
Eight Week Follow-up
2. Between the second assessment and today, which of these goal areas have you spent time doing home program intervention to try and improve your child’s progress

<table>
<thead>
<tr>
<th>Goal</th>
<th>Comment</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>Goal 1</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goal 2</td>
<td></td>
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<td></td>
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<tr>
<td>Goal 3</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goal 4</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Goal 5</td>
<td></td>
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</tbody>
</table>

4.11 Data Analyses
All quantitative data collected for this study were stored in individual hard copy files, which were coded by the principal investigator and entered into a Statistical Package for the Social Sciences (SPSS) electronic database (SPSS, Chicago, IL, USA) by a research assistant independent to the study personnel. Descriptive statistics were calculated to summarise the data set across the whole sample and within each group. Inferential statistical methods were used to answer the research questions.

The primary endpoint was the change in total COPM performance and satisfaction scores from baseline to eight weeks. Comparison of the differences between the three groups was possible using a linear regression model, because all data were continuous. The regression model controlled for the covariates of baseline COPM performance and satisfaction scores, participant’s age and severity of cerebral palsy as measured by the Gross Motor Function Classification System (GMFCS) (Palisano et al, 1997). The latter two factors are known confounding variables in cerebral palsy research (Law et al, 1989), so their inclusion as covariates was important as they may provide alternative explanations for any changes in scores observed.
Secondary endpoints were changes in the COPM performance and satisfaction scores from baseline to four-weeks, changes in the GAS t-score, QUEST total score and CAPE from baseline to four weeks and eight weeks.

Statistical significance was set at the conventional level of \( p < .05 \). The size of treatment effect was estimated by comparing differences in group means and their 95% confidence intervals.

Descriptive statistics were also used to analyse the types of goals that families set and implemented and the amount of time they chose to implement a home program. The goal categories for descriptive analysis were based on keywords generated from the COPM headings. The home program implementation time was recorded in minutes on the home program log. This generated a “continuous variable” which could be descriptively analysed using frequency statistics.

Outcome measures were obtained for all participants recruited to the trial. Irrespective of adherence to the study protocol, data were analysed in the group to which participants had been randomised, in accordance with the principle of intention-to-treat (Lachin, 2000). For participants with missing data, the convention of last observation carried forward (LOCF) analysis was used (Pocock, 1983). No missing data was imputed.

4.12 Results

Results are presented in the following order: baseline characteristics of participants (4.12.1, Tables 9-13; Figure 8), participant flow diagram (4.12.2, Figure 9), goal setting characteristics of participants (4.12.3, Tables 14; Figures 10-14), home program implementation practices of participants (4.12.4, Table 15; Figures 15-16), home program intervention techniques selected to reach the participant goals (4.12.5, Table 16) and (f) comparisons of effectiveness across the three groups and within groups (primary outcome followed by secondary outcomes) (4.12.6, Table 17; Figures 17-20).
4.12.1 Baseline Characteristics

Thirty-six parents of children with cerebral palsy meeting the eligibility criteria volunteered to enroll in the RCT. After baseline measurement, 12 participants were randomly assigned to the control group, and to each of the two home program intervention groups. Descriptive statistics were used to describe the baseline characteristics of participants on each of the study variables and report on the nature of the participants’ self-selected level of participation in home programs. Participant baseline characteristics were separated into three topic areas: (a) child attributes (Figure 11 & Table 14); (b) family and environmental attributes to elucidate the child’s home and community context for engaging in a home program (Table 15); and (c) baseline outcome measurement scores (Table 16).

Baseline characteristics of participants in the three treatment groups were almost identical, with no significant differences between groups at baseline on any attribute or measure (p>.05), with the exception of the diversity, enjoyment and intensity domains on the CAPE measure (Table 9).

Analysis of the home program log calendar showed that no children in any group received physiotherapy during the study period that was design to enhance motor outcomes in the upper limb (n=0) or performance of self-care tasks (n=0). The groups were therefore equal at baseline and throughout the study period in terms of amounts of physiotherapy used that may have explained the study result. One child in the 8WEEK group received upper limb botulinum toxin injections two weeks prior to study enrollment and was in therefore in pharmacologically active period for the total study duration, including the baseline assessment (n=1, 3%). No other children in the sample received medical intervention designed to enhance motor outcomes in the upper limb or performance of self-care tasks. No statistical adjustments were made for this one child.
Table 9: Test of Significance on Baseline Measures

<table>
<thead>
<tr>
<th>Measure</th>
<th>8WEEK v 4WEEK (p-value)</th>
<th>4WEEK v NoHP (p-value)</th>
<th>8WEEK v NoHP (p-value)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPM Performance</td>
<td>0.31</td>
<td>0.81</td>
<td>0.46</td>
</tr>
<tr>
<td>COPM Satisfaction</td>
<td>0.85</td>
<td>0.76</td>
<td>0.90</td>
</tr>
<tr>
<td>GAS T-score</td>
<td>0.35</td>
<td>0.07</td>
<td>0.23</td>
</tr>
<tr>
<td>QUEST Total</td>
<td>0.14</td>
<td>0.86</td>
<td>0.08</td>
</tr>
<tr>
<td>CAPE Diversity</td>
<td>0.03*</td>
<td>0.03*</td>
<td>0.93</td>
</tr>
<tr>
<td>CAPE Intensity</td>
<td>0.06</td>
<td>0.04*</td>
<td>0.97</td>
</tr>
<tr>
<td>CAPE With Whom</td>
<td>0.25</td>
<td>0.23</td>
<td>0.09</td>
</tr>
<tr>
<td>CAPE Where</td>
<td>0.51</td>
<td>0.14</td>
<td>0.30</td>
</tr>
<tr>
<td>CAPE Enjoyment</td>
<td>0.01*</td>
<td>0.11</td>
<td>0.10</td>
</tr>
</tbody>
</table>

* p<0.05, a significant difference existed

Child attributes: All children had cerebral palsy (100%), with a range of cerebral palsy sub-classifications (83% spastic, 14% dyskinetic and 3% ataxic) (Figure 8) and a range of severities as measured by the GMFCS (Level I 47%, Level II 14%, Level III 16%, Level IV 7% and Level V 16%). Many participants also had associated impairments with their cerebral palsy (speech impairment 58%, intellectual impairment 42%, vision impairment 39%, epilepsy 22% and hearing impairment 8%). The average age of the children was 7 years and 9 months (SD 2.02 years), with more than half the participants being boys (69%). Child participant characteristics at baseline are presented in Table 10.

Figure 8: Participants’ Cerebral Palsy Classifications
Table 10: Baseline Characteristics of Groups by Child Participant Attributes

<table>
<thead>
<tr>
<th>Variable</th>
<th>Week 4</th>
<th>Week 8</th>
<th>No HP</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Number of boys</td>
<td>n=8</td>
<td>n=8</td>
<td>n=8</td>
</tr>
<tr>
<td><strong>Diagnosis</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cerebral Palsy</td>
<td>n=12</td>
<td>n=12</td>
<td>n=12</td>
</tr>
<tr>
<td><strong>Sub-classification of CP</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Spastic quadriplegia</td>
<td>n=0</td>
<td>n=8</td>
<td>n=3</td>
</tr>
<tr>
<td>Spastic diplegia</td>
<td>n=8</td>
<td>n=0</td>
<td>n=2</td>
</tr>
<tr>
<td>Spastic hemiplegia</td>
<td>n=0</td>
<td>n=1</td>
<td>n=2</td>
</tr>
<tr>
<td>Dystonia</td>
<td>n=1</td>
<td>n=1</td>
<td>n=1</td>
</tr>
<tr>
<td>Athetosis</td>
<td>n=6</td>
<td>n=4</td>
<td>n=4</td>
</tr>
<tr>
<td>Ataxia</td>
<td>n=6</td>
<td>n=4</td>
<td>n=4</td>
</tr>
<tr>
<td><strong>Associated Impairments</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Speech impairment</td>
<td>n=7</td>
<td>n=2</td>
<td>n=6</td>
</tr>
<tr>
<td>Epilepsy</td>
<td>n=2</td>
<td>n=5</td>
<td>n=3</td>
</tr>
<tr>
<td>Intellectual impairment</td>
<td>n=6</td>
<td>n=4</td>
<td>n=4</td>
</tr>
<tr>
<td>Vision impairment</td>
<td>n=1</td>
<td>n=0</td>
<td>n=0</td>
</tr>
<tr>
<td>Hearing impairment</td>
<td>n=0</td>
<td>n=0</td>
<td>n=0</td>
</tr>
<tr>
<td><strong>Severity of CP (Gross Motor Function)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GMFCS Level I</td>
<td>n=6</td>
<td>n=2</td>
<td>n=1</td>
</tr>
<tr>
<td>GMFCS Level II</td>
<td>n=2</td>
<td>n=3</td>
<td>n=2</td>
</tr>
<tr>
<td>GMFCS Level III</td>
<td>n=1</td>
<td>n=1</td>
<td>n=1</td>
</tr>
<tr>
<td>GMFCS Level IV</td>
<td>n=1</td>
<td>n=0</td>
<td>n=0</td>
</tr>
<tr>
<td>GMFCS Level V</td>
<td>n=1</td>
<td>n=0</td>
<td>n=0</td>
</tr>
<tr>
<td><strong>MACS Score: Median (Range)</strong></td>
<td>1.0 (3.0)</td>
<td>2.0 (4.0)</td>
<td>2.0 (4.0)</td>
</tr>
<tr>
<td><strong>Severity of CP (Manual Ability)</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>MACS Level I</td>
<td>n=9</td>
<td>n=1</td>
<td>n=1</td>
</tr>
<tr>
<td>MACS Level II</td>
<td>n=1</td>
<td>n=0</td>
<td>n=0</td>
</tr>
<tr>
<td>MACS Level III</td>
<td>n=1</td>
<td>n=0</td>
<td>n=0</td>
</tr>
<tr>
<td>MACS Level IV</td>
<td>n=0</td>
<td>n=0</td>
<td>n=0</td>
</tr>
<tr>
<td>MACS Level V</td>
<td>n=1</td>
<td>n=2</td>
<td>n=2</td>
</tr>
<tr>
<td><strong>MACS Score: Median (Range)</strong></td>
<td>1.0 (3.0)</td>
<td>2.0 (4.0)</td>
<td>2.0 (4.0)</td>
</tr>
</tbody>
</table>

**Family and Environmental Attributes:** Most children lived at home with both parents (81%) and half of these households were middle income earners (50%). Three-quarters of the families who participated in the study spoke English as their first language (77%). Most children attended a mainstream school (86%) in their local community, with nearly half the group having a Teaching Assistant (41%) to help them access the curriculum. Family and environmental characteristics of the groups at baseline are presented in Table 11.
Table 11: Baseline Characteristics of Groups by Family and Environmental Attributes

<table>
<thead>
<tr>
<th>Variable</th>
<th>8WEEK n=12</th>
<th>4WEEK n=12</th>
<th>NoHP n=12</th>
</tr>
</thead>
<tbody>
<tr>
<td>Schooling: Mainstream</td>
<td>n=11</td>
<td>n=9</td>
<td>n=11</td>
</tr>
<tr>
<td>Household: Two Parents</td>
<td>n=8</td>
<td>n=11</td>
<td>n=10</td>
</tr>
<tr>
<td>Household income status</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Low</td>
<td>n=6</td>
<td>n=3</td>
<td>n=5</td>
</tr>
<tr>
<td>Medium</td>
<td>n=6</td>
<td>n=8</td>
<td>n=7</td>
</tr>
<tr>
<td>High</td>
<td>n=0</td>
<td>n=1</td>
<td>n=0</td>
</tr>
<tr>
<td>Languages spoken</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>English only</td>
<td>n=10</td>
<td>n=9</td>
<td>n=9</td>
</tr>
<tr>
<td>English &amp; other language</td>
<td>n=2</td>
<td>n=2</td>
<td>n=3</td>
</tr>
<tr>
<td>Other language only</td>
<td>n=0</td>
<td>n=1</td>
<td>n=0</td>
</tr>
</tbody>
</table>

Baseline Measure Scores: Baseline measurement scores for participants in the three groups were almost identical with no significant differences on any measures (p>.05), except for the CAPE diversity (p=.03), intensity (p=.04) and enjoyment domains (p=.01) (Table 9). These data are summarised in Table 12. The difference in CAPE scores between groups at baseline may be explained by the low completion rate for all domains with this measure, compared to other instruments (n=14 did not complete this measure; n=22 fully completed this measure). All children completed baseline measures: the COPM (100%), GAS (100%), and QUEST (100%), but over a third (39%) could not complete the CAPE due to respondent burden. When children expressed fatigue and asked to stop the CAPE assessment, their wishes were respected as part of the informed consent process. Before the CAPE interview had commenced, the children actively participated in the QUEST assessment and where possible in the COPM and GAS interviews which took approximately 45 minutes, therefore fatigue was not unexpected. Failure to complete the CAPE instrument affects all the CAPE domain scores. For this study, n=22 participants fully completed the CAPE interviews, creating n=22 CAPE diversity, intensity, with whom, where, and enjoyment domain scores at the three data points. It is therefore unclear whether or not the baseline differences in CAPE domain scores are actually statistically and clinically relevant or simply a function of small groups sizes for this measure.
Table 12: Baseline Measures

<table>
<thead>
<tr>
<th>Variable</th>
<th>8WEEK Mean (sd)</th>
<th>4WEEK Mean (sd)</th>
<th>NoHP Mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>COPM Performance</td>
<td>3.91 (1.51)</td>
<td>3.30 (1.36)</td>
<td>3.44 (1.52)</td>
</tr>
<tr>
<td>COPM Satisfaction</td>
<td>3.71 (1.60)</td>
<td>3.83 (1.37)</td>
<td>3.62 (1.98)</td>
</tr>
<tr>
<td>GAS T-Score</td>
<td>25.12 (1.15)</td>
<td>24.60 (1.43)</td>
<td>28.00 (2.13)</td>
</tr>
<tr>
<td>CAPE Diversity</td>
<td>23.20 (10.21)</td>
<td>11.50 (8.98)*</td>
<td>22.83 (6.08)</td>
</tr>
<tr>
<td>CAPE Intensity</td>
<td>1.99 (0.91)</td>
<td>1.06 (0.85)*</td>
<td>2.01 (0.48)</td>
</tr>
<tr>
<td>CAPE With Whom</td>
<td>2.01 (0.29)</td>
<td>2.14 (0.15)</td>
<td>2.39 (0.44)</td>
</tr>
<tr>
<td>CAPE Where</td>
<td>1.97 (0.52)</td>
<td>1.79 (0.48)</td>
<td>2.28 (0.56)</td>
</tr>
<tr>
<td>CAPE Enjoyment</td>
<td>4.21 (0.44)*</td>
<td>3.57 (0.34)</td>
<td>3.80 (0.30)</td>
</tr>
<tr>
<td>QUEST Total Score</td>
<td>65.34 (22.29)</td>
<td>48.96 (29.49)</td>
<td>50.65 (16.95)</td>
</tr>
</tbody>
</table>

* A significant difference existed at baseline between groups on the CAPE diversity scores (p<.03), intensity scores (p=.04) and enjoyment scores (p=.01) (Table 9). It should be noted that 14 children (n=6 in the 4WEEK group) could complete the CAPE due to respondent burden during the baseline assessment. Failure to complete the CAPE affects all domain scores. It is unclear whether these domain score differences are statistically and clinically relevant or simply a function of small group sizes for this measure.

To test the hypothesis that the amount of CAPE data available for analysis by group size was too small (8WEEK n=10, 4WEEK n=6 and NoHP n=6), the group sizes were increased, by re-calcultating those who were randomised to the home program groups into a single group (8WEEK + 4WEEK, n=16) and comparing them to the NoHP (n=6) using an independent t-test. The result of increasing the group sizes was that variations were evened out and that no difference between groups at baseline on the adjusted CAPE scores existed (where significance was considered p<.05). The adjusted CAPE data scores are summarised in Table 13.

Table 13: Baseline Characteristics of Adjusted CAPE Outcome Measurement Data

<table>
<thead>
<tr>
<th>Variable</th>
<th>8WEEK &amp; 4WEEK Home Programs Mean (sd)</th>
<th>NoHP Mean (sd)</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAPE Adjusted Diversity</td>
<td>18.81 (11.12)</td>
<td>22.83 (6.08)</td>
</tr>
<tr>
<td>CAPE Adjusted Intensity</td>
<td>1.64 (0.97)</td>
<td>2.01 (0.48)</td>
</tr>
<tr>
<td>CAPE Adjusted With Whom</td>
<td>2.05 (0.25)</td>
<td>2.38 (0.44)</td>
</tr>
<tr>
<td>CAPE Adjusted Where</td>
<td>1.90 (0.50)</td>
<td>2.28 (0.56)</td>
</tr>
<tr>
<td>CAPE Adjusted Enjoyment</td>
<td>3.97 (0.51)</td>
<td>3.89 (0.30)</td>
</tr>
</tbody>
</table>
4.12.2 Participant Flow Details

Eighty-seven children were contacted about the study, identified from waiting list data. Eighty-six of the eighty-seven were eligible for participation, producing an eligibility fraction of 98.9%. Thirty-six children from the eighty-six had informed consent to participate given by their parents, establishing an enrolment fraction of 41.9%. They were enrolled in the study and completed baseline measurements formulating the recruitment fraction of 41.3% (eligibility fraction). Baseline data were not collected from non-consenting participants. The participants’ flow details are depicted in Figure 9.

Four weeks after the baseline assessment and again at the eight week follow-up assessment, all but one participant remained in the study, representing a 97.2% retention rate. One participant chose to drop out after baseline measures were taken because of being offered intensive hands-on intervention from another service provider. This participant’s follow-up data were not collected and data were treated as missing. The a priori power analysis had accounted for a 20% dropout, which was not exceeded by the loss of one participant. One participant in the experimental 8WEEK home program group did not implement the home program due to the separation of the parents during the study period. This participant’s data was, however, still included in the analyses in keeping with the intention to treat principle.
Nine participants in the experimental 4WEEK home program group did not cease home program implementation as requested and instead of using the home program for only four weeks, the parents kept using it for eight weeks, because they stated it was beneficial and therefore not in the best interests of their child to stop. In accordance with the principles of family-centred practice, where professionals respect parents’ expertise about knowing what is best for their child, their decisions were respected and these families were asked to record their home program activity on the home program log for weeks 5-8.
4.12.3 Goal Setting Characteristics of Participants

From the COPM interview process, participants varied in the numbers of goals and topic areas identified as priorities for intervention. The goal categories were tallied for descriptive analysis based on categories developed from the keywords on the COPM form headings, productivity, self-care and leisure.

For the whole group, the most common number of goals set using the COPM format was four goals (n=13, 36.1%), followed by two goals (n= 9, 25%), then three goals (n=6, 16.7%), then five goals (n= 5, 13.9%), then a single goal (n=3, 8.3%). The types of goals generated for intervention and categorised by the COPM role areas are described in Table 14.

The participants’ most important goal was overwhelmingly in the productivity role area (75.0%), reflecting the participants’ daily primary occupation as being school students (for example, handwriting and fine motor tasks such as cutting with scissors). For goals two to four, consistently the most important goal role area was self-care for at least half the sample (ranging from 50.0 to 54.5%) (for example, dressing and eating). Leisure was never prioritised as the most important topic area. Only for participants who generated three (or more) goals did leisure ever rise to being the second most important topic area (self care 52.2%, leisure 26.1%, productivity 21.7%) (for example, cricket and swimming active recreation activities).
Table 14: Participants’ Goals Categorised by the COPM Role Area in order of Priority

<table>
<thead>
<tr>
<th>Goal Topic Area</th>
<th>Most Important Goal</th>
<th>2nd Most Important Goal</th>
<th>3rd Most Important Goal</th>
<th>4th Most Important Goal</th>
<th>Least Important Goal</th>
</tr>
</thead>
<tbody>
<tr>
<td>Self Care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal Care</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dressing</td>
<td>n=3</td>
<td>n=8</td>
<td>n=5</td>
<td>n=5</td>
<td>n=3</td>
</tr>
<tr>
<td>Eating</td>
<td>n=1</td>
<td>n=4</td>
<td>n=3</td>
<td>n=3</td>
<td>•</td>
</tr>
<tr>
<td>Toileting</td>
<td>n=1</td>
<td>n=4</td>
<td>n=3</td>
<td>n=1</td>
<td>•</td>
</tr>
<tr>
<td>Bathing</td>
<td>•</td>
<td>n=1</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Functional Mobility</td>
<td>n=2</td>
<td>n=1</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>SELF CARE Sub-TOTAL</td>
<td>n=7</td>
<td>(19.4%)</td>
<td>n=18</td>
<td>(54.5%)</td>
<td>n=12</td>
</tr>
<tr>
<td>Productivity</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Play</td>
<td>n=2</td>
<td>n=2</td>
<td>n=1</td>
<td>n=1</td>
<td>•</td>
</tr>
<tr>
<td>School</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Handwriting</td>
<td>n=13</td>
<td>n=3</td>
<td>n=1</td>
<td>n=1</td>
<td>n=2</td>
</tr>
<tr>
<td>Typing/Computer access</td>
<td>n=2</td>
<td>n=3</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Arm position e.g. at desk</td>
<td>n=2</td>
<td>n=3</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Fine motor e.g. scissors</td>
<td>n=7</td>
<td>n=2</td>
<td>n=3</td>
<td>n=3</td>
<td>•</td>
</tr>
<tr>
<td>Concentration</td>
<td>n=1</td>
<td>•</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>PRODUCTIVITY Sub-TOTAL</td>
<td>n=27</td>
<td>(75.0%)</td>
<td>n=13</td>
<td>(39.4%)</td>
<td>n=5</td>
</tr>
<tr>
<td>Leisure</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Quiet Recreation</td>
<td>•</td>
<td></td>
<td>n=1</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>Active Recreation</td>
<td>n=1</td>
<td>n=1</td>
<td>n=5</td>
<td>n=3</td>
<td>n=1</td>
</tr>
<tr>
<td>Socialisation</td>
<td>n=1</td>
<td>n=1</td>
<td>•</td>
<td>•</td>
<td>•</td>
</tr>
<tr>
<td>LEISURE Sub-TOTAL</td>
<td>n=2</td>
<td>(5.6%)</td>
<td>n=2</td>
<td>(6.1%)</td>
<td>n=6</td>
</tr>
<tr>
<td>COPM TOTAL Number of Goals</td>
<td>n=36</td>
<td>n=33</td>
<td>n=23</td>
<td>n=17</td>
<td>n=6</td>
</tr>
</tbody>
</table>

When all the goals developed for the whole sample were aggregated, there were 115 goals in total. Of the 115 goals, 52 were productivity goals (45.2%), 49 were self care goals (42.6%) and 14 were leisure goals (12.2%). The total number of goals by role area is summarised for the whole sample (n=36) in Figure 10.

Figure 10: Participants’ Goals by COPM Areas
The types of goals set were further broken down into specific topic areas in categories organised in terms of areas of self-care, productivity and leisure applied in the COPM. These data were calculated for the whole study sample (n=36) were summarised in Figures 11-13.

Figure 11: Participants’ COPM Self Care Goals

![Self Care Goals (n=36)]

- Dressing 49%
- Eating 23%
- Toileting 18%
- Bathing 4%
- Mobility 6%

Figure 12: Participants’ COPM Productivity Goals

![Productivity Goals (n=36)]

- Play 11%
- Typing 10%
- Fine Motor 29%
- Handwriting 38%
- Arm Position 10%
- Concentration 2%

Figure 13: Participants’ COPM Leisure Goals

![Leisure Goals (n=36)]

- Quiet Recreation 7%
- Active Recreation 79%
- Socialisation 14%
An analysis of the participants’ planned goal implementation compared to their actual goal implementation was conducted for those randomised to the two home program groups (8WEEKs + 4WEEKs, n= 23). This descriptive analysis was conducted by tallying the total number of goals set for intervention from the original COPM interviews and comparing them to the total number of goals actually implemented, collected from a parent self-report interview at the 4 and 8 week follow-up measurement points.

The results of the RCT revealed that half the participants (n=11 of 23) planned to implement more goals than they actually did, these data were summarised in Figure 14. For participants who set one goal (n=2) all of them (100%) implemented home programs relating to that one goal. For participants who set two goals (n=6), four of the six (66%) implemented programs relating to the two goals. For participants who set three goals (n=2) all of them (100%) implemented home programs relating to those three goals. For participants who set four goals (n=10) only three of the ten (30%) implemented the home program relating to all four goals. For participants who set five goals (n=3), only one of the three (33%) implemented home programs relating to all five goals. Goals that were not targeted through home program practice by families were sometimes lower priority goals but other times were higher priority goals. The mean number of goals planned to be implemented was 3.33 (SD 1.27) and the mean number of goals actually implemented was 2.26 (SD 1.21). This difference was statistically significant (p=.01), when compared using the paired t-test. There was a trend toward those who set more goals being less likely to implement all goals simultaneously. The numbers for this type of analyses were small and therefore must be interpreted with caution. In clinical practice this may mean that families who set one, two or three home program goals may be more likely to implement all the goals as planned. Families who set four or more goals are more likely to implement fewer goals than they planned to. Families commented on reasons why they abandoned goals as including: the interventions being a poorer fit with the family routine compared to other
options in the home program (e.g. behavioural interventions requiring parenting changes from both parents); and gaining greater insight into realistic outcomes from intervention based upon the prognostic discussions held with the therapist. New information about prognosis and the types of gains possible from intervention, led some families to report changing their perceptions about the relative importance of the goals. This parent report data were not collected in a quantifiable or standardised way and is therefore speculative. Further examination of the goal-setting behaviours of families is recommended for another study. These tentative findings may however begin to assist occupational therapists and families to devise sustainable home program routines.

**Figure 14: Numbers of COPM Goals Set Compared to Numbers of COPM Goals Implemented**

```
<table>
<thead>
<tr>
<th>Goals Set</th>
<th>Goals Implemented</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>7</td>
</tr>
<tr>
<td>8</td>
<td>9</td>
</tr>
<tr>
<td>10</td>
<td></td>
</tr>
</tbody>
</table>
```

**Total Number of Home Program Goals**

**Number of Participants (Home Program Groups only)**

### 4.12.4 Home Program Implementation Practices of Participants

The home program was measured through the use of a self-report log calendar. For each day of the study families were asked to record: (1) how often they used the home program i.e., number of times implemented per week (frequency); and (2) how long they spent practicing therapeutic activities each time they practiced, i.e., minutes per practice session (intensity). This enabled home program duration measures to be calculated, that is, the
home program frequency multiplied by the intensity. Home program implementation rates are summarised in Table 15. Because all but two of the families in the 4WEEK group continued using the home program in weeks 5-8, the frequency, intensity and duration data reports are based for all groups on data collected for the 0-8 week period.

Table 15: Home Program Implementation Rates at Primary End-Point

<table>
<thead>
<tr>
<th>Variable</th>
<th>8WEEK n=11</th>
<th>4WEEK n=11</th>
<th>NoHP n=12</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Mean (sd)</td>
<td>Mean (sd)</td>
<td>Mean (sd)</td>
</tr>
<tr>
<td>Home Program Frequency (times used per week) Weeks 0-8</td>
<td>4.18 (0.98)</td>
<td>4.62 (1.93)</td>
<td>0.00 (0.00)</td>
</tr>
<tr>
<td>Home Program Intensity (minutes per session) Weeks 0-8</td>
<td>15.66 (11.00)</td>
<td>17.63 (14.98)</td>
<td>0.00 (0.00)</td>
</tr>
<tr>
<td>Home Program Duration (total minutes implemented at primary end-point)</td>
<td>745.96 (703.61)</td>
<td>572.86 (386.22)</td>
<td>0.00 (0.00)</td>
</tr>
</tbody>
</table>

* One child did not use the home program for family reasons and no participation data was therefore recorded in order to calculate rates. This participant’s data were excluded for the rate calculation only. It was included in all other analyses according to the intention-to-treat principle.

Frequency was the measure of how often families chose to engage in the home program. The mean frequency of home program participation over the 0-8 week duration of the study for the 8WEEK group was 4.18 times per week (sd 0.98) which was essentially the same as the 4WEEK group 4.62 times per week (sd 1.93) (also for weeks 0-8), in other words, less than once a day but approximately 17-18 times per month. There was a statistically significant difference in the mean implementation frequencies between the 8WEEK group and the NoHP group (p=.01) and the 4WEEK group and the NoHP group (p=.01), when compared using an independent t-test because the control group did not have any program they could implement or record in the home program log. Parents were asked to keep the log to maintain consistencies between the groups and to enable analysis of possible sources of contamination. The analysis confirms that the control group did no home program intervention as intended by group allocation and therefore
contamination did not occur during the study period. No difference in home program frequency existed between the 8WEEK group and 4WEEK group (p=.51) (noting that both groups included data from 0-8 weeks).

Intensity was the measure of how long families reported spending doing the selected home program activities per practice session. The mean intensity of home program implementation for the 8WEEK group was 15.66 minutes per session (sd 11.00) (range 4.28 min-40.00 min) and for the 4WEEK group (over the 0-8 week period) was 17.63 minutes per session (sd 14.98) (range 5.00 min-60.00 min). The most common self-selected home program intensity was a modal time of 15.00 minutes for the 8WEEK group, whereas it was 10.00 minutes for the 4WEEK group (both groups across the 0-8 week period). An independent t-test detected a statistically significant difference in the mean implementation intensities between the 8WEEK group and the NoHP group (p=.01) and between the 4WEEK group and the NoHP group (p=.01). This result was expected as the NoHP group had no program to implement but confirmed that contamination did not occur. No difference in home program intensities existed between the 8WEEK group and 4WEEK group (p=.73) for the eight weeks that they were using the home programs. The distribution of self-selected home program intensity rates per session (in minutes) is summarised in Figure 15.
Duration was calculated by multiplying the family’s home program implementation frequency by their self-selected intensity. The mean duration of home program implementation for the eight week study period for the 8WEEK home program group was 745.96 (SD 703.61) minutes and for the 4WEEK home program group over the eight week period was 572.86 (SD 386.22). This result, like the intensity data, demonstrated wide variation about the mean. Only 2 participants (n=2) in the 4WEEK group implemented the home program for four weeks, reflected by the 2 duration scores less than 325 minutes. The rest of the 4WEEK group (n=9) kept implementing the home program for eight weeks (Figure 16).
Since the NoHP did not use a home program at all, there was a statistically significant difference in the mean total home program implementation time (duration) between the 8WEEK group and the NoHP group (p=.01) and the 4WEEK group and the NoHP group (p=.01), when the mean durations were compared using an independent t-test. As mentioned previously this result was expected but confirmed that contamination of the control group did not occur. There was no difference in total implementation time (duration) between the 8WEEK group and 4WEEK group (p=.49), when the mean duration time was tested using an independent t-test. These results are summarised in Figure 16, which shows that the two groups were similar in terms of how much intervention they actually received. The lack of difference in mean implementation duration between the 4WEEK and 8WEEK groups is explained by the nine participants in the 4WEEK group that did not adhere to the study protocol and continued to use the program...
for eight weeks, pushing up the 4WEEK intervention duration nearer the 8WEEK duration.

4.12.5 Intervention Techniques Selected for the Home Programs

The intervention techniques from which the home programs were developed by the parent and therapist are summarised in Table 16. Data are reported for the twenty-three participants that implemented a home program during the trial.

<table>
<thead>
<tr>
<th>Intervention Technique</th>
<th>8WEEK</th>
<th>4WEEK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adaptive Equipment Prescription</td>
<td>n=4</td>
<td>n=4</td>
</tr>
<tr>
<td>Constraint-Induced Movement Therapy</td>
<td>n=0</td>
<td>n=1</td>
</tr>
<tr>
<td>Goal Focused Task Practice</td>
<td>n=12</td>
<td>n=11</td>
</tr>
<tr>
<td>Handwriting Training</td>
<td>n=8</td>
<td>n=6</td>
</tr>
<tr>
<td>Orthotics</td>
<td>n=1</td>
<td>n=2</td>
</tr>
<tr>
<td>Parent Education</td>
<td>n=12</td>
<td>n=11</td>
</tr>
<tr>
<td>Play Therapy</td>
<td>n=1</td>
<td>n=2</td>
</tr>
<tr>
<td>Positive Behaviour Support</td>
<td>n=5</td>
<td>n=4</td>
</tr>
<tr>
<td>Recreation / Sports Therapy</td>
<td>n=3</td>
<td>n=3</td>
</tr>
<tr>
<td>Strength Training</td>
<td>n=2</td>
<td>n=1</td>
</tr>
</tbody>
</table>

The types of intervention techniques used were almost identical across the 8WEEK and 4WEEK groups. The most common technique that was incorporated into the home programs by the therapist to meet family goals was parent education. All participants in both groups (100%) were provided with education from the therapist to support home program implementation, because the technique has strong supporting research evidence (Barlow & Parsons, 2003). The other most common intervention technique, drawn upon by the therapist to develop programs that targeted family goals, was goal focused task practice also referred to as goal-directed training. All participants’ home program content included goal focused task practice (8WEEK group 100% & 4WEEK group 100%). The next most common intervention technique drawn upon by the therapist to develop programs that targeted family goals was handwriting training. Handwriting training is a
specific task from the goal focused task practice technique but is given its own title because of the frequency of use amongst school children (Sudsawad et al, 2002) (8WEEK group 66.7% & 4WEEK group 54.6%).

4.12.6 Home Program Effectiveness

Both home program groups demonstrated significant positive outcomes compared with no home program. These results are now presented in order of the research questions asked under section 4.2 of this chapter.

Primary Outcome: Effect of an 8WEEK or 4WEEK home program on COPM scores:

Comparison between the three groups was conducted using a linear regression model with baseline COPM performance/satisfaction scores, participant age and severity of cerebral palsy as measured by the GMFCS entered into the model as covariates. Overall, there were statistically significant and clinically important differences in performance of activities and parent satisfaction with function when comparing either home program group to the no home program group (noHP), however, there were no differences when comparing the two home program groups to one another. Mean outcome scores and effect sizes are summarised in Table 17.

COPM Performance Scores at 8 weeks - Between group comparisons (Figure 17): After eight weeks, having received a home program for 4WEEKS increased self-reported performance by a mean of 2.4 (95% CI 0.7 to 4.2) when compared to the NoHP group (p=.01). Receiving the home program for 8WEEKS increased self-reported performance by a mean of 1.4 (95% CI 0.6 to 2.2) when compared to the NoHP group (p=.01). Receiving the 4WEEK home program increased self-reported performance by a mean of 0.7 COPM points (95% CI -1.2 to 2.6) when compared to the 8WEEK group, a non-significant and unimportant difference. It is noted the majority of participants in the 4WEEK group continued their home programs during the 5-8 week period.
COPM Satisfaction Scores at 8 weeks: Between group comparisons (Figure 18): After eight weeks, having received a home program for 4WEEKS increased self-reported satisfaction by a mean of 2.5 (95% CI 0.8 to 4.3) when compared to the NoHP group (p=.01). Receiving the home program for 8WEEKS increased self-reported satisfaction by a mean of 1.5 (95% CI 0.3 to 2.6) when compared to the NoHP group (p=.01). Receiving the 4WEEK home program increased self-reported satisfaction by a mean of 0.8 COPM points (95% CI -1.1 to 2.8) when compared to the 8WEEK group, a non-significant and unimportant difference. It is noted the majority of participants in the 4WEEK group continued their home programs during the 5-8 week period.
COPM Performance Scores at 8 weeks: within-group comparisons: Within-group analysis indicated that participants in both the home program groups (4WEEKS and 8WEEKS) improved their performance on the COPM across the 8 week study period. The NoHP group made no change (0.0 COPM Performance points) at 8 weeks (NS p>.05). The 4WEEK group improved by 2.9 COPM Performance points at 8 weeks (p=.01). Finally, the 8WEEK group improved by 1.8 COPM Performance points at 8 weeks (p=.01).

COPM Satisfaction Scores at 8 weeks: within-group comparisons: Within-group analysis indicated that participants in both the home program groups (4WEEKS and 8WEEKS) reported higher satisfaction on the COPM across the 8 week study period. The NoHP group made no change (0.0 COPM Satisfaction points) at 8 weeks (NS p>.05). The 4WEEK group increased by 2.4 COPM Satisfaction points at 8 weeks (p=.02). Finally, the 8WEEK group increased by 1.7 COPM Satisfaction points at 8 weeks (p=.01).
## Table 17: Mean Scores and Estimates of Effect Sizes for all Outcome Measures

### Outcome Score

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Time</th>
<th>No Home Program (n=12)</th>
<th>4WEEKs Home Program (n=11)</th>
<th>8WEEKs Home Program (n=12)</th>
<th>No Home Program vs 4WEEKs Home Program</th>
<th>No Home Program vs 8WEEKs Home Program</th>
<th>4WEEKs Home Program vs 8WEEKs Home Program</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>FUNCTION:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPM Performance Mean Score (sd)</td>
<td>4-weeks</td>
<td>3.4 (±1.5)</td>
<td>4.8 (±2.2)</td>
<td>4.3 (±1.8)</td>
<td>1.6 (0.0 to 3.3)*</td>
<td>0.2 (0.1 to 0.3)*</td>
<td>1.0 (-0.7 to 2.6)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>3.4 (±1.5)</td>
<td>5.9 (±2.2)</td>
<td>5.4 (±1.9)</td>
<td>2.4 (0.7 to 4.2)*</td>
<td>1.4 (0.6 to 2.2)*</td>
<td>0.7 (-1.2 to 2.6)</td>
</tr>
<tr>
<td><strong>SATISFACTION WITH FUNCTION:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>COPM Satisfaction Mean Score (sd)</td>
<td>4-weeks</td>
<td>3.6 (±2.0)</td>
<td>5.1 (±1.8)</td>
<td>4.4 (±2.3)</td>
<td>1.6 (0.0 to 3.2)</td>
<td>0.3 (-0.1 to 0.6)</td>
<td>0.7 (-1.0 to 2.4)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>3.6 (±2.0)</td>
<td>6.1 (±1.9)</td>
<td>5.4 (±2.2)</td>
<td>2.5 (0.8 to 4.3)*</td>
<td>1.5 (0.3 to 2.6)*</td>
<td>0.8 (-1.1 to 2.8)</td>
</tr>
<tr>
<td><strong>FUNCTIONAL GOAL ACHIEVEMENT:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GAS Mean t-score (sd)</td>
<td>4-weeks</td>
<td>26.0 (±2.1)</td>
<td>47.1 (±11.6)</td>
<td>51.5 (±13.9)</td>
<td>22.4 (14.4 to 30.3)*</td>
<td>13.3 (8.6 to 18.0)*</td>
<td>-6.2 (-17.9 to 5.6)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>26.0 (±2.1)</td>
<td>64.3 (±15.4)</td>
<td>60.7 (±15.6)</td>
<td>37.8 (26.9 to 48.8)*</td>
<td>17.9 (12.4 to 23.4)*</td>
<td>0.5 (-13.4 to 14.4)</td>
</tr>
<tr>
<td><strong>QUALITY OF ARM MOVEMENT:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>QUEST Mean Total Score (sd)</td>
<td>4-weeks</td>
<td>46.6 (±19.8)</td>
<td>55.4 (±30.3)</td>
<td>70.2 (±22.4)</td>
<td>6.4 (0.3 to 13.1)</td>
<td>3.9 (-0.5 to 8.3)</td>
<td>-1.1 (-8.7 to 6.4)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>47.3 (±20.0)</td>
<td>59.7 (±26.8)</td>
<td>71.3 (±21.4)</td>
<td>9.8 (2.5 to 17.2)*</td>
<td>4.6 (0.1 to 9.0)*</td>
<td>0.9 (-6.7 to 8.5)</td>
</tr>
<tr>
<td><strong>PARTICIPATION:</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>CAPE Diversity Mean Score (sd)</td>
<td>4-weeks</td>
<td>22.9 (±6.1)</td>
<td>11.5 (±9.0)</td>
<td>24.0 (±9.0)</td>
<td>0.0 (0.0 to 0.0)</td>
<td>0.8 (-0.1 to 1.7)</td>
<td>-2.0 (-4.1 to 0.1)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>22.5 (±6.1)</td>
<td>11.5 (±8.5)</td>
<td>24.0 (±8.8)</td>
<td>0.4 (-1.3 to 2.1)</td>
<td>0.9 (-0.1 to 1.9)</td>
<td>-2.0 (-4.2 to 0.1)</td>
</tr>
<tr>
<td>CAPE Intensity Mean Score (sd)</td>
<td>4-weeks</td>
<td>2.0 (±0.5)</td>
<td>1.1 (±0.9)</td>
<td>2.1 (±0.8)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>-0.1 (-0.3 to 0.1)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>2.0 (±0.5)</td>
<td>1.1 (±0.8)</td>
<td>2.1 (±0.8)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>-0.2 (-0.3 to 0.1)</td>
</tr>
<tr>
<td>CAPE With Whom Mean Score (sd)</td>
<td>4-weeks</td>
<td>2.4 (±0.4)</td>
<td>2.1 (±0.2)</td>
<td>2.1 (±0.3)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.0 (-0.1 to 0.1)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>2.4 (±0.4)</td>
<td>2.2 (±0.2)</td>
<td>2.2 (±0.4)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.1 (0.1 to 0.3)</td>
<td>-0.1 (-0.5 to 0.2)</td>
</tr>
<tr>
<td>CAPE Where Mean Score (sd)</td>
<td>4-weeks</td>
<td>2.3 (±0.6)</td>
<td>1.8 (±0.5)</td>
<td>2.0 (±0.5)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.0 (-0.1 to 0.1)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>2.3 (±0.5)</td>
<td>1.8 (±0.5)</td>
<td>2.2 (±0.6)</td>
<td>0.0 (-0.4 to 0.4)</td>
<td>0.2 (0.1 to 0.4)</td>
<td>-0.2 (-0.6 to 0.2)</td>
</tr>
<tr>
<td>CAPE Enjoyment Mean Score (sd)</td>
<td>4-weeks</td>
<td>3.9 (±0.3)</td>
<td>3.6 (±0.3)</td>
<td>4.2 (±0.4)</td>
<td>0.0 (0.0 to 0.0)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.0 (-0.1 to 0.3)</td>
</tr>
<tr>
<td></td>
<td>8-weeks</td>
<td>3.9 (±0.3)</td>
<td>3.8 (±0.2)</td>
<td>4.2 (±0.4)</td>
<td>0.0 (-0.4 to 0.4)</td>
<td>0.0 (-0.1 to 0.1)</td>
<td>0.0 (-0.5 to 0.4)</td>
</tr>
</tbody>
</table>

Between-group differences adjusted for the baseline value of the outcome, age and GMFCS level

Table Legend: * p<.05 = Primary End Point

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**Secondary Outcomes**

*Performance of functional activities at the mid-point of the study (four weeks) - Between group comparisons:* At 4 weeks, the participants in the 4WEEK group increased their performance of functional activities by 1.6 COPM performance points (95% CI 0.0 to 3.3) in comparison to the NoHP group. And at 4 weeks, the 8WEEK group increased their performance of functional activities by 0.2 COPM performance points (95% CI 0.1 to 0.3) compared to the NoHP group. There were no statistically significant differences between the gains in functional performance between the 8WEEK and 4WEEK groups at four weeks (mean difference 1.0 COPM performance points, 95% CI -0.7 to 2.6 (p=.24)).

*Satisfaction with function at the mid-point of the study (four weeks) - Between group comparisons:* At 4 weeks, the participants in the 4WEEK group increased their satisfaction by 1.6 COPM satisfaction points (95% CI 0.0 to 3.2) in comparison to the NoHP group. However, there were no statistically significant differences between the increased satisfaction experienced in either the 4WEEK or 8WEEK groups at four weeks (mean difference 1.0 COPM satisfaction points, 95% CI -0.7 to 2.6, p=.41) nor between the 8WEEK and NoHP groups (mean difference 0.3 COPM satisfaction points, 95% CI -0.1 to 0.6, p=.15). In other words both the home program groups improved but the 8WEEK did not improve enough to be statistically significant from the control or from the more improved 4WEEK group.

*Individualised Goal Attainment:* Home programs were effective for improving goal achievement in body functions, activities, and participation tasks unique to the child’s everyday life, as measured on the GAS. At the end of the 8-week study period, participants in the 8WEEK group were rated significantly higher on accomplishment of individualised goals than the NoHP group (mean difference 17.9, 95% CI 12.4 to 23.4). Participants in the 4WEEK group were also rated significantly higher on accomplishment of individualised goals than the NoHP group (mean difference 37.8, 95% CI 26.9 to 48.8).
Again, however, there were no statistically significant differences in GAS mean t-score changes between participants who received 4WEEK and 8WEEK home programs (mean difference 0.5, 95% CI -13.4 to 14.4 (p=0.94)). The increase in goal achievement is represented visually in Figure 19. Similar gains were also observed for both home program groups at the mid-point study measurement of four-weeks (Table 17).

**Figure 19: Changes in Goal Achievement**

* A significant difference existed between the home program group and control group

**Secondary Outcomes – Upper Limb Quality of Movement:** At the end of the study (8 weeks), home programs were effective for improving children’s upper limb quality of movement, as measured by the QUEST (Figure 20). This was consistent for both 8WEEK group (where the mean difference was 4.6 QUEST points (95% CI 0.1 to 9.0) in comparison to the NoHP group) and for the 4WEEK group (here the mean difference was 9.8 QUEST points (95% CI 2.5 to 17.2) in comparison to the NoHP group. This clinically important change was not evident at the mid-point of the study (i.e. after 4 weeks), with a mean difference between the 4WEEK and NoHP groups of 6.4 (95% CI -0.3 to 13.1), and between the 8WEEK and NoHP groups of 3.9 (95% CI -0.5 to 8.3). There no statistically significant nor clinically important differences between the 8WEEK and 4WEEK groups at either time point.
Figure 20: Changes in Quality of Arm Movement

* Participation: There were no statistically significant between-group differences in the participation levels of children in any group at either 8 weeks (end of study) or 4 weeks (midpoint) as measured by the CAPE instrument. Nor were there between-group differences on any of the sub-domains of the CAPE instrument when the 4WEEK and 8WEEK groups were compared to the NoHP group (Table 17). The lack of statistical significance, indicating no change/no clinical outcome, was not surprising given the small within-group mean change scores over the study duration (8WEEK group: Diversity 0.8/55; Intensity 0.11/7.0; With Whom 0.09/5.0; Where 0.23/5.0; Enjoyment -0.01/5.0; 4WEEK group: Diversity 0.0/55; Intensity 0.04/7.0; With Whom 0.06/5.0; Where 0.01/5.0; Enjoyment 0.23/5.0; NoHP group: Diversity -0.33/55; Intensity -0.01/7.0; With Whom 0.01/5.0; Where 0.02/5.0; Enjoyment 0.01/5.0). As previously mentioned the quality of data for this analysis was affected by low completion rates and the baseline differences in the diversity, intensity and enjoyment domains. All CAPE results must be interpreted with caution.

* Participation Diversity: There were no between-group differences in the participation diversity of children in any group at either 8 weeks (end of study) or 4 weeks (midpoint) as measured by the CAPE instrument (Table 17).
Participation Intensity: There were no between-group differences in the participation intensity of children in any group at either 8 weeks (end of study) or 4 weeks (midpoint) as measured by the CAPE instrument (Table 17).

Participation With Whom: There were no statistically significant or clinically important differences between groups with respect to ‘with whom’ they interacted with at either the 4 week (mid-point) or 8 week (end of study) assessments.

Participation Where: There were no statistically significant or clinically important differences between groups with respect to ‘where’ they interacted at either the 4 week (mid-point) or 8 week (end of study) assessments.

Participation Enjoyment: Finally, there were no between-group differences in the children’s enjoyment of their participation activities at either 8 weeks (end of study) or 4 weeks (midpoint) as measured by the CAPE instrument (Table 17).

4.13 Synopsis
This chapter outlined the aims, research questions, methodology, results and discussion of the research findings from the RCT. Included was a description of the sample’s attributes, the participants’ score profiles on the study instruments, the types of home program goals developed and the significant improvements participants’ made in response to the home program intervention. The next chapter will present the interview study that explored the perspectives of parents who participated in the RCT home program. The final chapter, Chapter Six, draws together issues and findings from the literature review and the study series in order to make recommendations for education, policy, practice and research.
Chapter Five

Parent Experience of Implementing a Home Program: Semi-Structured Interviews

5.1 Introduction
This chapter presents a study that explored the experience of parents who implemented the home program described in Chapter Four. The study used semi-structured interviews to illuminate the parent perspective with the specific aim of providing information to help inform practice recommendations regarding home program design. The chapter will outline research questions, present the aim, design, data management and analysis methods, and findings.

5.2 Study Rationale
As presented in Chapter Three, parents of children with cerebral palsy believe that home programs make an important contribution to their child’s development and progress (Hinojosa & Anderson, 1991; Piggot et al, 2003; Piggot et al, 20002; Thompson, 1998). Commonly parents tell professionals they believe that the more therapy their children receive, the greater the progress they will make (Hinojosa, 1990; Case-Smith & Nastro, 1993). The assumption is that “more is better” (Hinojosa, 1990; Case-Smith & Nastro, 1993). When home programs are offered parents embrace the programs as a way of providing more therapy, in an attempt to do more for their child.

Parental involvement in home programs has received little research attention. To date studies have explored parental compliance and factors influencing their program follow through such as confidence, competing responsibilities and family routines (Case-Smith & Nasto, 1993; Edwards, Millard, Praskac & Wisneiwski, 2003; Hinojosa, 1990;
Hinojosa & Anderson, 1991; Piggot et al, 2003), parent views about occupational therapist roles (Case-Smith & Nasto, 1993; Hinojosa, 1990; Thompson, 1998; Washington & Schwartz, 1996) and the importance of adequate parental support and their home program input being recognised (Case-Smith & Nasto, 1993; Washington & Schwartz, 1996). Surprisingly, there have been no studies that have explored parent views about home program implementation to help inform practice decisions not only professionals, but of parents as well. This study was specifically targeted to fill this gap. It complemented the study trial presented in Chapter Four by providing detailed information about parent views regarding the trial. The overarching approach of family-centred practice meant that parent choices, decisions and approaches were flexible, the investigator therefore understood that the reasons underpinning parents’ choices were important issues behind home program implementation. This chapter thus helps to inform the interpretation of findings from Chapter Four. This chapter is also important because practice implications of home program effectiveness findings would necessarily be limited unless the parent view about the home programs could also inform these recommendations.

5.3 Aim
This study aimed to describe parent views about the home program described in Chapter Four to help inform practice recommendations for parents and professionals about home program intervention design and implementation. The specific research questions were:

1. What factors are involved in the parent decision to implement a home program?
2. What factors and processes characterise parents’ experiences of implementing the home program and was this any different to the experience of implementing “traditional” home programs?
3. What advice do parents have for other parents about home program intervention?
4. What advice do parents have for health professionals about how to design and prescribe home programs?
5.4 Design
This study used a qualitative methodology for data collection and analysis because little was known about the parent experience, and a description of their experience and views was needed to help fill this gap in literature. The approach adopted was grounded theory to the level of open coding of categories (Strauss & Corbin, 1998). The rationale for selection of grounded theory was that the approach enabled the researcher to develop an understanding of the parents’ experience of home programs and their views about recommendations for other parents who may use home programs and for health professionals who design home programs. The aim was to describe key factors and processes.

Parents’ perceptions of home program implementation were collected via interview. The interview method adopted was semi-structured interviews, which were used to understand the participants’ points of view and circumstances (Dawson, 2002). Interviews were selected as the data collection tool because they enabled parents to describe their experiences, elaborate on their ideas and feelings, and explain concepts that were important to them (Morse & Field, 1995). The interview data provided a rich description of study participants and their experience of the home program.

Interviews were semi-structured (Lofland & Lofland, 1995). Guiding questions were used to help direct the interview. The participants were asked by the interviewer to describe factors, environment, processes and outcomes, with the chief interest of the study being on the parents’ experiences. An interview guide was developed (Robson, 1993) after an extensive review of relevant home program literature presented in Chapter Three. The interview guide contained four key questions. The process was iterative with questions being refined and new topics for exploration emerging (Rubin & Rubin, 1995). The interview format was piloted with one family and their feedback was incorporated into the interview guide, in order to maximise the face and content validity. To commence the interview, parents were asked: “Could you tell me about your experience of deciding to
implement a home program?” Other questions were derived from issues raised in the literature including:

“Can you describe your experience of implementing this home program and was this any different to previous home programs you might have used?”

“What advice would you give other parents who will use a home program?”

“What advice would you give health professionals designing home programs?”

“Some parents tell me they are concerned about ‘missing out’ by being involved in a home program rather than ‘hands-on therapy’. Is this your experience and could you help me to understand what that means?”

5.5 Ethical Approval

Permission to conduct the study was obtained from two separate ethical review committees: (1) the University of Western Sydney Ethics Review Committee (Human Subjects), Protocol Number: 06/031 (letter of approval, 24th March 2006) and (2) The Spastic Centre of NSW National Health and Medical Research Council Human Research Ethics Committee EC00402 (letter of approval, 15th March 2006). Appendix 2 presents the application and ethical approval letters of each.

All eligible participants had been provided with a participant information sheet at the home program study commencement, which was the same as the forms used for the home program trial, described in Chapter Four and presented in Appendix 2. Potential participants were offered an opportunity to ask further questions. They were also informed that they could withdraw their involvement at any time. All participants were assured that their decision to participate or not participate in interviews would not affect the services their child was receiving or their child’s involvement in the effectiveness study. Permission to audiotape the interview session was sought from each parent participant as part of the consent process and at the commencement of the interview. Confidentiality of the interview information and personal identity was guaranteed to each participant. The names
of the participants and their children mentioned in the interviews were removed in order to protect their anonymity.

5.6 Sample and Recruitment

A convenience sample was generated by inviting parents of children involved in the study presented in Chapter Four to participate. The study was described to the eligible parents by the Principal Investigator at two time points in the family’s home. The interview study was explained once at the commencement of the effectiveness study when they were consenting for their child to participate and again after completion of their child’s involvement in the effectiveness study at the 8 week follow-up appointment. All inquiries relating to volunteering to participate were handled by the investigator either in person during the child’s participation in the home program study or over the telephone. Parents were told by the investigator at the commencement of the home program trial that participation in the interviews was voluntary and that they would not be asked to make a decision about their involvement until their child had completed the home program study.

Inclusion criteria were thus:

- parents of a child who participated in either home program groups up to the primary endpoint in the study presented in Chapter Four;
- were able to communicate in English; and
- were volunteers.

Twenty-two of the twenty-four families who participated in the home program trial and were randomised in either the 4WEEK or 8WEEK home program groups met the inclusion criteria. The investigator invited all twenty-two eligible families to participate. Following completion of measurement for the primary endpoint, eligible participants were invited to participate in the interviews.

Parents were asked about child and parent participant demographic variables for the purpose of describing the sample. The investigator developed a demographic survey
based on literature. The demographic survey items were: child’s gender (Stanley, Blair & Alberman, 2000), child’s age (Law et al, 1989), child’s type of cerebral palsy (Law et al, 1989), family place of residence, which was defined by the Australian Bureau of Statistics Australian Standard Geographical Classification (2007), type of dwelling, number of people in family (Gajdosik & Campbell, 1991) and household income which was defined by the Australian Bureau of Statistics’ Mean Equivalised Disposable Household Income of all Households in Australia (2007).

Eight families agreed and gave informed consent to participate in interviews. For six of these families, just the mothers chose to participate. For the other two families, both parents participated. This resulted in the parent sample comprising of eight females and two males. The eight families who agreed to participate lived in different areas of New South Wales, Australia, two in urban settings (population greater than 249,000), and six in rural or “bounded locality” settings (population 200 to 999) and two in remote or “rural balance” settings (population less than 200) (Australian Bureau of Statistics Standard Geographical Classification, 2007). The demographic characteristics of the sample are presented in Table 18.
Table 18: Description of Study Participants

<table>
<thead>
<tr>
<th>Family</th>
<th>Number &amp; Gender of Parent Respondents</th>
<th>Child’s Gender</th>
<th>Child’s Age</th>
<th>Type of Cerebral Palsy</th>
<th>Place of Residence</th>
<th>Type of Dwelling</th>
<th>Number of People in Family</th>
<th>Household Income</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Mother Father</td>
<td>Male</td>
<td>6yrs 3mths</td>
<td>Ataxia</td>
<td>Rural</td>
<td>House</td>
<td>3</td>
<td>Medium</td>
</tr>
<tr>
<td>2</td>
<td>Mother</td>
<td>Male</td>
<td>6yrs 8mths</td>
<td>Spastic Diplegia</td>
<td>Rural</td>
<td>House</td>
<td>2</td>
<td>Low</td>
</tr>
<tr>
<td>3</td>
<td>Mother</td>
<td>Male</td>
<td>7yrs 6mths</td>
<td>Spastic Diplegia</td>
<td>Rural</td>
<td>House</td>
<td>4</td>
<td>Medium</td>
</tr>
<tr>
<td>4</td>
<td>Mother</td>
<td>Male</td>
<td>9yrs 0mths</td>
<td>Spastic Diplegia</td>
<td>Remote</td>
<td>House</td>
<td>5</td>
<td>Medium</td>
</tr>
<tr>
<td>5</td>
<td>Mother Female</td>
<td>Female</td>
<td>6yrs 8mths</td>
<td>Spastic Diplegia</td>
<td>Urban</td>
<td>House</td>
<td>4</td>
<td>Medium</td>
</tr>
<tr>
<td>6</td>
<td>Mother Father</td>
<td>Female</td>
<td>5yrs 5mths</td>
<td>Spastic Diplegia</td>
<td>Remote</td>
<td>House</td>
<td>5</td>
<td>Low</td>
</tr>
<tr>
<td>7</td>
<td>Mother</td>
<td>Male</td>
<td>12yrs 8mths</td>
<td>Spastic Hemiplegia</td>
<td>Rural</td>
<td>House</td>
<td>4</td>
<td>Medium</td>
</tr>
<tr>
<td>8</td>
<td>Mother Female</td>
<td>Female</td>
<td>7yrs 0mths</td>
<td>Athetosis</td>
<td>Urban</td>
<td>House</td>
<td>3</td>
<td>Medium</td>
</tr>
</tbody>
</table>

* Number of people in the family (inclusive of child with a disability) living at home with the child with a disability

5.7 Data Collection Procedures

Interviews were conducted after the primary endpoint data had been collected for the study outlined in Chapter Four. A meeting was scheduled at the participant’s home or a venue of their choosing. All interviews were conducted in English by the investigator. Interviews were audio taped and transcribed verbatim, with participants’ names removed from transcription text to maintain anonymity. Each study participant was interviewed once face-to-face, with four follow-up interviews for four different families carried out by telephone. Telephone interviews were also audio taped and transcribed verbatim using voice recording technology. Couples were interviewed together. Interviews ranged from 20 to 75 minutes (mean 41 minutes, mode 44 minutes).

5.8 Data Analysis

Transcribed data were analysed by reading the text and clustering the sentences, on the basis of keywords, into categories that were exhaustive and mutually exclusive, in line with recommended content analysis procedures (Robson, 1993). For example:
“It’s just kind of like trying to focus it on whatever **guidance you have been given** but because as you said, **we are not therapists so we need someone coming back** at some sort of **regular interval.**”

In this example the keywords “guidance”, “not therapists”, “coming back” and “regular” are identifiable as important parent perspectives, and were identified as categories.

Grounded theory was the approach used to guide the analysis of data to the level of open coding only (Strauss & Corbin, 1998). Open coding using the grounded theory approach was used to identify, categorise, name and describe the parents’ experience and views (Strauss & Corbin, 1998). The process of open coding was commenced by identifying pivotal topics and assigning these topics into categories.

To limit threats to the validity of the analysis, two strategies were undertaken. The first was that the initial open coding and category identification from the transcribed interviews were carried out in parallel by two independent researchers, the principal investigator and an independent research colleague that was not involved in the study design or data collection. They began the open coding process by identifying the pivotal topics and assigning these topics into broad categories relating to the study questions. The independent coding reliability between the two researchers reached greater than 90% inter-rater agreement. The two independent researchers then met to discuss the interpretation of the interview data and to confirm the themes arising.

The second strategy used to limit threats to validity was that, follow-up interviews were conducted by telephone in order to validate that the interpretation of the interview data accurately reflected the parents’ experiences (Anderson, 1991). In the follow-up interviews parents had the opportunity to further clarify their statements.
5.9 Results

The presentation of results is organised into themes around the four key questions asked of participants (Table 19). Four questions were used to organise the parent perspective on home program intervention to help understand why they decide to implement programs, what they experience, and what they would advise parents and professionals.

Table 19: Interview Questions and Categories

<table>
<thead>
<tr>
<th>Questions</th>
<th>Categories</th>
</tr>
</thead>
</table>
| Factors involved in Parent Decision to Implement Home Programs | Guidance for the Journey  
Practice Makes Perfect  
A Part of Life  
Maximising Progress  
Easier to Juggle Competing Demands |
| Factors and Processes Characterising the Home Program Implementation Experience and Comparisons to Traditional Home Programs | Support that Sustains  
Realistic Expectations  
Flexibility  
Goals are Motivating  
Translates to Real-Life  
Reminder to Practice  
Progress Updates  
Role Identity – Parent not a Therapist |
| Advice to Other Parents | Accept the Disability  
Never Refuse Help  
Be Honest  
Home Programs are Essential  
Develop Routines  
Improve Your Life and Your Child’s |
| Advice to Health Professionals | Don’t Leave us Hanging  
Coordinate Please!  
Take the Pressure Down  
Prognostic Guidance Helps Planning |

5.9.1 Factors Involved in Parents’ Decision to Implement Home Programs

There were five categories that described the parent decision to implement home programs. These each incorporate the factors that constitute and influence their decision. These are: (a) they found home programs to be a form of parental guidance; (b) they believed practice makes perfect and home programs were the mechanism for practicing; (c) they viewed home programs as a part of life for children with a life-long disability; (d) they considered home programs a strategy for maximising the child’s progress; and (e) parents...
found it easier to juggle competing demands in the home environment with home programs. These are now described with examples from the data.

**a) Guidance for the Journey**

Three parents described that what influenced them to implement a home program was that home programs provided them with a form of expert “guidance” for fostering their child’s development. One parent simply described a home program as “A kind of guidance from someone who knows what they are doing.” Without the home program parents described becoming “stuck” and unable solve the challenge of how to constantly adapt to meet their child’s ever-changing needs. For example:

“As a parent you don’t really know all the time where your child is at, you get stuck in a rut so you do the same thing over and over again. Your child may not be getting challenged enough. You might not be challenging them enough but for some reason you can’t move outside the box [without a home program]. It’s easy to do what you know works than try something new.”

Parents discussed feelings of doubt about whether they were helping their child reach their potential and whether they where doing things in the best ways possible. This notion was strongly related to their desire to do everything possible for their child and belief that their input was vital to whether or not their child reached their potential. Parents described using home program “guidance” to gain “momentum” to keep moving their child towards the goal of “progress”. They described home programs as providing them with a sense of reassurance about what to do in order to foster their child’s development. One parent explained this concept as: “I suppose guidance is the right word, sort of to know that you are doing something that is actually going to improve.”

They also described home programs as providing them with a form of guidance about how best to do it. The input that a home program provided was a combination of the necessary information about what to do and how to do it. Because the home program
provided information about how to foster the child’s development it informed the perceived quality of the parental input.

The reason why this type of guidance was so important to parents was that it gave them a feeling of confidence in their parenting skills and a belief that they were doing something worthwhile for their child. One parent reflected that the home program kept her feeling “balanced” knowing that her parental input was worthwhile. Collectively these parents strove to confidently and wholly contribute to their child’s development and this quest was guided by the use of a home program. This belief was summarised by a parent who responded to the question ‘What is your experience of implementing a home program?’ by answering:

“Fantastic, because you’ve got guidance and you know, you sometimes might doubt yourself, are you doing it [intervention]? [You] might not be getting anywhere [as a parent] but then having a program at least it is reinforced and makes you feel quite confident [that you are] doing something.”

b) Practice Makes Perfect

Parents believed that the best progress possible was achieved from continual home program practice in the home context. For example: “I reckon she’s going to make the most progress if we practice in the home environment.”

Parents identified that it was their role as parents to help their child practice to make the gains. This belief was linked to their perception of the importance of the parental role in fostering the child’s development. Parents had discovered it was their role to facilitate “therapy practice” at home. One parent observed that no matter what model of therapy service her child received, inevitably it would be her role to practice the therapy strategies at home. “Because really you go and you see your specialist then you come home and you have to practice it.”

A tension existed for parents between the desire to have expert-provided intensive rehabilitation and embracing the reality that they needed to do the “practice” themselves at
home. In the end, parents recognised that their caregiving role was critical to their child’s developmental outcome and that implementing a home program was essential for helping their child to reach their potential. For example:

“We often say that it would be nice if we could just sit back and take [our child] to a therapist who will sit there and do some exercises with her, it would take the pressure off us…Therapy is basically 24/7 and you can’t take your child to a therapist 24 hours a day…So it definitely was important for us to do the therapy.”

Parents unanimously reflected that they were not “missing out” by implementing a home program rather than having “hands-on” therapy, despite this being one of their fears.

“[The home program] worries me because I would prefer to have someone else do it because they would know what they were doing…you kind of think that if you have someone like you here, and you are doing it with [him], and you think she knows what she is doing, and I don’t, I guess. But if someone comes and shows you what to do…I don’t think there is any reason why we can’t practice it which is what we have done.”

When parents did have expert therapy they experienced being given recommendations for practice at home. This led parents to conclude that all therapy became home programs in the end. Parents positively reframed this experience as going to the expert for the ideas and then bringing the suggestions home for practice. For example:

“I didn’t want to go once or twice a week for them [health professionals] to do it with her, I wanted to be involved and do it at home, practice at home, so for me I go to see the expert to get the ideas, but I bring them home and use them anyway.”

Thinking about therapy in this way was important to parents because it helped parents to feel integrally involved in their child’s care and ultimately in their child’s progress.

Some parents had experienced many “hands-on” therapy sessions where their child was distressed or was not motivated to cooperate with the therapist’s instructions. For
example: “We have spent a lot of therapy sessions with her sitting on the ground screaming or refusing to participate anyway.”

These types of experiences led them to conclude that any benefits of those types of therapy sessions would not be realised without their practice at home. For these parents the home program provided a sense of relief because they had more control in the way in which therapy was implemented.

“It did get to the point where he was sick of it [therapy]…And just having it at home and not having appointments all the time made it easier.”

A home program offered parents a process for structuring therapy in a way that their child would cooperate and enjoy the activities.

c) A Part of Life

Parents found that if they built the home program into aspects of the child’s daily life then it became “a part of life”. For some parents rather than home programs being perceived as an additional and competing caregiving responsibility, they structured their child’s life so that the program activities were just one of the everyday tasks that the child did. This phenomenon was described as: “I would definitely just say, putting it into a daily routine where then they are also doing it without probably even realising it, it becomes a part of life.”

In this way, these parents incorporated the home program suggestions into their parenting interactions and family lifestyle, so that their child didn’t even recognise or experience it as ‘therapy’. For example: “She doesn’t realise that it is a therapy type thing, that’s just fun for her… So it is something that the family does too, like if we are all down at the white board or the chalk board, everyone can have a turn and then it is still a fun family activity, but it’s therapy at the same time.”

Others parents described the practice to their child as “homework”, which they did because their child knew and understood homework to be a regular and non-negotiable
routine. This made implementation easier for parents to achieve. For example: “So it is just easy to try and incorporate different types of homework with her every night, it’s just like ‘homework time’ so that it is easy to incorporate.”

Parents who used the strategy of framing the home program as “homework” to their child did so because they found the notion of implementing home programs as “homework” increased their child’s concentration and the child’s likelihood of agreeing to practice the tasks. For example: “I suppose with doing homework, if he has a quiet space and he’s at his desk and he sits down and focuses on it, then he’ll do it.” In addition, framing the home program as “homework” normalised the task for the child with a disability. Homework was a task that the child with a disability understood had to be done by siblings; it wasn’t something extra that they were doing because they had a disability.

d) Maximising Progress

Parents wanted to do whatever they could to maximise their child’s progress. Home programs were one strategy to help them with this goal. Parents described it as their responsibility to try and help their child maximise their progress via a home program. They also described wanting to help their child. For example:

“It’s definitely important for us to do the therapy…Parents have a lot to do at home as well because yeah, parents definitely need to know how to handle their children, someone like [my child] I wouldn’t have it any other way even though I am very hands-on with her because she has the motivation which makes you also want to help her along and do that for her as a parent.”

The desire to do the best for their child brought with it an overwhelming sense of responsibility and intense anxiety. Parents worried about whether they had the necessary skills to meet their child’s needs and wanted to know that they were not just “passing time”. For example:

“If you are a parent not a therapist, it is really daunting to think that suddenly it is my responsibility…. if you are an average parent or a single parent and you are stressed to the
eyeballs and you can’t cope with all that [lack of support with a home program] then you are going to make very little progress.”

Parents wanted reassurance from therapists that their child was making progress because this was the indicator that they used to know whether or not their parental input via a home program was improving their child’s outcome. The outcome of receiving this reassurance was “encouragement” to continue with the home program. For example:

“It is encouraging when you see it from month to month that he has made an improvement, it’s really encouraging it’s like oh ok I am doing something right and I’m not just passing time or trying to help him and not getting anywhere, it’s encouraging…..it’s good for me.”

c) Easier to Juggle Competing Demands

Parents identified that it was “easier” to juggle their competing caregiving responsibilities in the home context and that this was a factor that influenced them to implement home programs. Parents perceived that there were time management benefits to implementing home programs. These advantages included first, the elimination of the need to “rush off” to therapy appointments. For example:

“Well… it has advantages doing it at home because obviously you are not rushing off, because I’ve got two children you don’t have to get them together and off somewhere and also I think [my child] is probably more comfortable doing it here.”

The second advantage was that home programs compared to institution-based appointments enabled parents to simultaneous perform domestic duties such as cooking meals at the same time as supporting the child to do the home program activities. For example: “I can have the dinner on, the three kids can be doing their homework, it’s like [my child] can be involved and the other two can be involved.”

The third advantage was that home programs enabled parents to attend to siblings’ caregiving needs in addition to the child with cerebral palsy. For example, the siblings’ homework could be supervised and supported at the same time as the child with cerebral
palsy’s home program. This meant that the sibling’s routines did not need to be interrupted in order to enable one child to attend therapy. For example:

“So I guess the home program and that side of it, which I do, you know, like [my child] could be tracing over letters while the other two are doing their maths or something, and we just we all do homework together so that side of it is probably quite good."

Finally, flexibility was possible in relation to when to carry out the program to fit around the family’s changing routine, for example when it was raining or when it was dark:

“If it was a nice day we would go outside and do something, but if it is a bit yucky or late at night then do it inside.”

5.9.2 Experience of Implementing the Home Program

Parents identified many factors and processes about the home program that made it useful, supportive and achievable from their experience. Parents described the factors characterising their experience of the home program to include: (a) a much needed source of parenting support; (b) a method for learning realistic expectations of their child; (c) flexibility and individual choices; (d) goals provide a source of motivation to practice; (e) gaining information on therapeutic activities that “translated” to real-life tasks; (f) a reminder to practice the activities; (g) a process for gaining updates about their child’s progress; and (h) gaining clarity about role identity which was a process that enabled them to remain as parents and not try to become therapists. They reflected that the experience of using the home program was different to “traditional” therapy and other home programs which they had previously used and identified factors that highlighted these differences. These findings are now described in detail, with examples from the data.

a) Support that Sustains

Parents described what they needed and wanted was follow-up support from health professionals when they were using a home program. For example: “We are not therapists
so we need someone coming back at some sort of regular interval to sort of say ‘ok well you are doing that fine now so lets move onto whatever’.”

Parents universally described receiving this kind of help and support from the trial home program. They described how the home program experience gave them support and motivation to continue using the program, which they valued as important because they recognised that is was likely that they would be doing home programs for a long time. Home programs also gave them the guidance that they sought about how to provide the best help possible to their child. For example: “Having that support and contact at different intervals keeps you motivated and I guess keeps you focused on what exactly you are doing and trying to achieve.”

More specifically, parents described how they gained “new ideas” to use from listening, watching and talking to the therapists during the support sessions. Parents also described gaining an understanding of “what to do” together with “why” because the therapists explained the theoretical rationale underpinning the activities, which motivated them to practice. They characterised this experience as learning “what to do” by being “shown how” to do the activities in a therapeutic way. For example: “[If a therapist] shows you what to do and explains the hows, and the theory behind it, and the whys and stuff then I don’t think there is any reason why we can’t [use the home program].”

Parents also described using support sessions as a strategy to revise and update the home program to fit with their child’s newly acquired skills. The chance to fine tune the program was important for helping parents to feel that their child was getting what they needed when they needed it most. Parents also described using the support session to “reinforce” whether or not they had practiced the activities correctly. Parents wanted to feel that they had achieved therapeutic accuracy as the therapist intended the activity to be, because this contributed to the feeling that they were doing all that they could for their child. From the home-based support sessions, parents described gaining assurance that the
therapist realistically understood their child’s actual needs by being in the home context. For example: “I think the visiting side of it, you coming to my place, is great rather than you just being on the phone, you can actually see the child and understand it.”

The outcomes of receiving home program implementation support were that parents’ trust in the therapist’s advice grew, which led parents to conclude that the activities that were prescribed were relevant and therefore worthy of practice time. Another outcome described by parents was that they experienced a reduction in the pressure they felt as the child’s main caregiver. The confidence parents had in the therapist’s expert knowledge and guidance helped them believe they would have enhanced ability to foster their child’s development by being involved in the home program. Another related outcome was that parents identified home program support gave them the task analysis assistance they needed to help them problem-solve what to do in order to spark “progress”. This type of home program support led to parents’ perceiving that they were making progress rather than feeling overwhelmed. For example:

“Having someone break down the steps for you makes it easier because you don’t get so fed up and frustrated thinking ‘awh she’s not ready for this… By breaking down the steps you actually move along the stages, and you actually feel you are working on something rather than it being a huge unmanageable task.”

b) Realistic Expectations
The guidance that parents described receiving from the home program is what helped them develop a realistic perception of what type of gains to expect from intervention. Parents observed that the parent education they received form the home program helped them to learn both factual knowledge about their child’s disability and new techniques for helping foster progress. This new knowledge is what provided parents with a realistic understanding of their child’s ability level, which consequently transformed how they interacted with their child. For example,
“For instance, talking to you gave us a different way at looking at her motor behaviour, we knew that she had big disabilities but we didn’t think that ?? and that gave us another tool, in terms of dealing with her.”

Parents believed that practicing the home program activities was their responsibility (“it’s up to us”) and that they learned how to do this from the parent education they received from therapists providing the home program. One parent summarised the parent education aspect of the home program as: “I think a lot of the therapy that you sort of have to do with your child often is about teaching the parent because it is the parents that have to implement the program.”

When parents better understood the trajectory of their child’s disability, they gained the ability to re-think how to move forward realistically with their child. One parent described this enlightenment as: “So not trying to leap Niagara falls but whatever steps [are] in between there.”

The outcomes of developing realistic expectations of the child facilitated the parents’ understanding of the child’s disability. This experience was described by one parent as: “The more we can understand her disability, the better we can work through it.” An additional outcome that parents described was that the process of gaining new knowledge led to them learning new ways of teaching their child.

c) Flexibility

When asked to describe this home program experience compared to previous home programs, parents described the home program as giving them more “flexibility” than they had experienced from other “traditional” home programs. One parent observed that this home program had more choices and this offered parents more flexibility with how to implement the program: “This program was really good because it was just a matter of doing short bursts of different activities…And I found that really good, we didn’t just have to concentrate on one thing at a time, we had a variety of things to do.”
Parents described that the experience of having flexibility and choices was different to traditional home programs because they were used to following a prescribed “lists of activities”. Parents observed that they had to adjust to being provided with choices but they liked the flexibility they gained. For example: “When this didn’t come with suggested activities I thought, hang on, there has got something more here, but I think it actually worked better without a list of activities, because it actually gave more flexibility rather than you must put coins in a money box.”

The outcomes of having more flexibility was that parents could adapt the home program to suit both their child’s preferences and theirs. For example: “I could just do like that 15-20 minutes of whatever I felt like at the time.”

d) Goals are Motivating

When asked to describe this home program experience compared to previous home programs, four parents observed that the process of collaborative goal-setting used to develop the home program activities was different to “traditional” home programs that they had used. They had previously experienced therapist-directed home program goals and home program activities: “I suppose they (the occupational therapists) would choose the goals, whereas this really was about what we preferred and we took it from there.” In addition to the lack of participation in goal-setting, their previous home programs were “lists of activities” prescribed by the therapist that required parents to follow rigid instruction such as “you must…”

The parents identified that the process of working together to set the goals and then using those goals to guide the program content led to parents wanting to practice the program more. One parent likened the experience of partnering with the therapist in goal-setting and program development to the benefits of having a “personal trainer” to motivate you to carry out a fitness program. For example:
“If you have a trainer that will motivate you to keep going. So if I have a program, it motivates you, because it just gives you guidance. There’s always a phone, you know a number on there so you can just ring somebody.”

Parents observed that the outcome of collaborative goal-setting to develop the home program was that the home program became more “motivating” to implement. For example: “I guess that this is more beneficial and more motivating for us. It is something that we choose that is important rather than, ok she really needs to learn the cutting.” Another outcome identified by parents was that the goal-directed home program was more satisfying to implement because it reflected their goals and enabled them to use their own unique creativity to “adapt” the program. One parent’s comment that illustrated this viewpoint was:

“This (home program) was more based on, ok this is what we [want]…it was more based on the result we were trying to get at the end, these are various ways you might be able to achieve it and we just adapted it ourselves anyway. So I think I preferred it this way”

In addition, parents observed that a third outcome of this home program was that the program was better tailored to their child’s needs and their parenting style because of the collaborative goal setting process used to develop the program activities. For example:

“They [the trial home program] were more specifically targeted at her because you did an interview and looked at her interests and exactly what she wanted to achieve…So it was much more specific rather than oh here’s some exercises you can do.”

c) Translates to Real-Life

Parents demonstrated they understood that therapeutic practice ultimately had to “translate” into everyday functional activities in order for the child to generalise the skill being practiced. Parents observed that the actual process of trying to “translate” traditional therapeutic activities into everyday activities was in fact very difficult. For example: “I know every therapist I see says ‘try and incorporate this and try and incorporate this’, into just what you are doing normally, and I do but it’s not as easy as it might sound.”
They observed that many of the therapeutic activities that were regularly recommended for practice at home from professionals were not actually indicative of typical parent-child interactions in the home context and therefore were hard to “translate”. For example:

“Say we used to have say a 45 minute appointment…based on going ‘something is under the table’, ‘something is on the table’, ‘something is in the box’, it’s really hard to try and translate that to three to four weeks of home practice…You just can’t translate that to taking it home and doing it over and over again.”

When parents were asked to describe this home program implementation experience compared to previous home programs, parents said it was more readily translated into everyday functional activities. They identified that a key factor was that they had more choices in terms of the types of activities they could implement. The variety had provided them more creative possibilities for making the practice reflect real-life. The shift in thinking that the home program approach had provided was pleasing to parents. For example: “Some of the things were similar but I think what I liked about this (the home program) was the actual variety.”

Parents also described that the home program was easier to use on a regular basis because the activities were based on their real-life home tasks and equipment. They identified that the home visits conducted by the therapist to set up the home programs were a key aspect of process for matching the activities to their unique family situation. For example: “This was really good because having someone come to your home is really good because they can see what you can use around the home and stuff like that, that’s really good.”

f) Reminder to Practice
Parents reflected that generally speaking it was difficult to maintain momentum for home programs within the context of their busy lives and competing responsibilities. The process of having the home program written down kept the program “active” in the parents’ minds.
and communicated that someone cared about their family. For example: “You know that something is actively happening over a period of time so you keep with it, as opposed to thinking, oh this is just too hard and no-one really cares anyway.”

Parents observed that they were better able to retain and use the home program information regularly when it was written down for them. They also described preferring that the program written down because it helped them to remain goal-focused. For example: “I suppose I prefer things in writing myself so I have a focus of where I am heading…or where I should be heading.”

Parents concluded that the outcome of having the home program written down was that it served as both a “reminder” and a “motivator” to practice the program activities. For example: “I think having a program makes you do it…Having a goal to strive to…If you don’t have to do something then you don’t do it.” An additional outcome was that when the program was written down parents experienced feeling less anxious and confused about what to do because they had a “guideline” to follow. For example:

“I don’t mind a whole bunch of ideas being thrown at me but at the end of the day if you wrote it down in point form for me or put it in say 5 minute bits, it doesn’t mean that I have to do it, it just means that there is a guideline and you know you can run with it…it’s like a safety sort of thing rather than getting confused.”

g) Progress Updates

The majority of parents experienced an intense desire to be regularly updated about their child’s progress. The details of therapists’ observations about progress, both positive and negative, were very important to parents. This was because they found it difficult to observe or remember changes when they spent so much time with the child, whereas they perceived the therapist to be more objective because they were an “outsider”.

“I think it is definitely helpful to have someone document what you say when you say it [referring to COPM and GAS interviews]. Because you tend to forget what your child does or how you feel at that particular moment, and looking back you probably wouldn’t
remember that your child wasn’t doing something so…8 weeks ago or 12 weeks ago I would have forgotten that that wasn’t normal so having that documented makes you realise well, hey she really has improved, you know.”

Parents reflected that when they did not receive support to detect “progress” from the therapist prescribing the programs they experienced feeling demoralised. For example: “We (parents) say ‘well they just come in and give us a whole list of things and then they go away’ and it’s like how are we going to fit this in or that’s not going to work or they don’t even hang around to see if it is going to work.” A distinguishing feature of the home program approach was the use of the COPM and GAS scales to formally record parents’ ratings and observations of their child’s progress at regular intervals. The process of using an outcome measure facilitated a parent-therapist conversation in a structured way about the child’s progress. This process was very important to parents and gave them a method for gaining the therapist feedback they sought. Therapist feedback to parents about the child’s progress served as a key strategy for “consolidating” parental observations of progress. For example:

“Having someone like yourself coming in and saying well she’s static there and she’s improved there sort of just consolidates you know, us thinking she’s done better and then here is another professional saying ‘well from the last time I saw her, and I only saw her for x amount of time she definitely has improved.’”

The meaning that parents attributed to “progress” was integral to their feelings about the usefulness of the home program:

“You knew what you were doing was working, whether it be the same levels or [to a] large degree…so I guess it is reassuring in a way because then you know you are doing the right thing at home.”

The outcome of the therapist providing feedback that the child had made progress via the outcome measurement interview was inextricably linked to parents’ motivation to continue with the program. It was also linked to their feelings of success as a parent.
because it gave them a way of knowing that they had contributed to meeting their child’s needs. For example:

“It is encouraging when you see it from month to month that he has made an improvement, it’s really encouraging it’s like oh ok I am doing something right and I’m not just passing time or trying to help him and not getting anywhere, it’s encouraging…it’s good for me…So it encourages me to work with him more.”

**h) Role Identity – Parent not a Therapist**

Parents reflected that there was an identity tension between wanting to meet all of their child’s needs by becoming a therapist at home and the necessity to remain in the role of parent, both for the sake of the child with a disability and for other family members. They saw both roles as valuable. For example:

“I remember the first thing [initial home program experience] was like reading and trying to define yourself, like are you a therapist at home? And like at the time it was like yes I am, I’m always trying to teach her something, so I backed off and realised that yeah, you can incorporate things into the daily routine but it shouldn’t be the motivating factor for everything that you do anyway…I think I have still maintained a good level on both sides, I am doing therapy but I’m also just a mum.”

Through a process of active reflection, parents had concluded that they could not become therapists even if they wanted to, because they perceived that they did not have the necessary knowledge nor was it their role. They mediated their ongoing need for knowledge by taking their child to see therapists and by seeking support to implement home programs, such as through this home program approach. For example: “I feel better educated helping her, but I don’t feel like a therapist because I still go to them for advice.”

**5.9.3 Advice to Parents about Implementing Home Programs**

The nature and quality of the parental experience of using services and in implementing home programs seemed to affect the type of advice that they wanted to impart to other parents who may be in a similar life circumstance. Advice to other parents was categorised
as follows: (a) accept the child’s disability; (b) never refuse professional help; (c) be honest with the therapist about your capacity to implement a home program; (d) home programs are an essential aspect of a child’s intervention; (e) develop routines for implementing the home program; and (f) home programs offer a strategy for improving your life and your child’s. These themes are now described in more detail.

a) Accept the Disability

Parents collectively observed the initial time period following diagnosis of the child with a disability was characterised by denial. The denial phase began the endless succession of questions about the family’s future. For example:

“First of all you are in denial so you don’t want any help, and that’s natural, you go into that denial and ‘It’ll be right, can’t be as bad as what they are saying’, but then on the other hand you are saying ‘God, what is the future with me, [and] my child.”

The parents had observed that the initial denial phase, whilst understandable, was counter-productive to accepting the professional help, which was needed via home programs, to effectively rear the child. Professionals were not held up as the panacea but rather a vital link to helping the parent achieve the child’s optimal potential. For example:

“You have to realise that they need help and umm professional people don’t have the answers all the time but they do have the guidance for you, but you are their mum and you know best so by all means you have got to have professional help.”

Acceptance of the child’s disability was recommended to parents as the first step towards getting the right kind of help. Acceptance of the disability and acceptance of professional help was perceived as a strategy for facilitating coping with the feelings of unexpected grief. For example:

“You know it’s just getting over that initial shock that something is wrong is the first step you’ve got to take to accept it, and then you can move on…Once you accept that your child has a disability you are better able to cope with the decisions, when people are guiding you, you are better able to cope with that a lot better.”
b) Never Refuse Help

Parents described an ongoing process of tug-a-war between the desire to do everything they possibly could for their child counter-balanced by the realities of life and their disappointment with the lack of available professional support. For example, “The experience we have had with a lot of professionals [is that] they are under resourced and don’t follow you up…because they haven’t got the means to follow you up.” This tension was tempered by striving to “find the balance”, between staying positive and maximising the child’s potential. Parents achieved “balance” by learning to effectively use the little professional help that was available.

For this reason, parents strongly advised other parents never to refuse help, despite the powerful feelings of denial that would be associated with accepting their child’s disability. For example:

“I would say never say no to any type of service or therapy or information you can get your hands on, even if you may not use it or it might not be relevant at the time or for your situation, it is always knowledge that you can have.”

Help from professionals in the form of home programs was considered beneficial for building parental knowledge and coping. Parents used the specialist knowledge they gained about how to address their child’s needs as a tool for improving their confidence.

c) Be Honest

Parents described the process of learning to communicate with their child’s therapist as a very important skill. They identified that communication skills were necessary both because parents know their child best and therefore have the expert knowledge needed but also because the quality of the parent-therapist communication affected the types of services they received. For example:

“There is a lot of communication that parents have to, you know, learn how to communicate to the therapist, which you know, has taken a while because you know your child best and
you have to communicate that to the therapist and umm sort of get that right for them to be able to help you umm.”

Parents advised other parents that it was very important to be “honest” with their child’s therapist about their capacity to implement a home program. They observed that the very nature of the information they shared affected the quality of the therapeutic interaction process and therefore being honest was worthwhile. For example:

“Really ask the parents to be honest about how much time they can spend or if it is too hard or if they think it’s not going to work, or the reality is no, it just doesn’t make sense, or it is not going to happen.”

Parents had observed that by being honest they received a better service outcome. They had observed that the benefits of “honest” communication about their intentions and emotional resources to implement home programs led to therapists constructing more realistic and high-quality program “ideas” and “advice” for them in the first place. For example: “Parents should be really honest about that to actually help the therapists devise a better sort of system or program or ideas or advice.”

d) Home Programs are Essential

Parents wanted other parents to understand that home programs would be essential to them. They described home programs as “necessary” and “essential”: “I think it’s actually quite essential to have a home program.” When parents were asked to describe more about their impressions of home programs being “necessary”, they reflected that this belief was based on observing benefits for both the child in terms of clinical outcomes and for the parent in terms of gaining reassurance. For example: “Yeah, a lot of benefit for me because I know we are on the right track.”

Parents also observed that whilst implementing a home program was extra work, the positive feelings they gained from instigating a home program outweighed not doing one at all. For example: “I’d rather do that [the home program] myself than have nothing.”
The outcome of having a home program available meant for parents that guidance and “tips” were always “handy”. This meant they could naturally incorporate the advice into their child’s daily tasks to maximise progress. For example: “I actually think that it is a lot easier to have a program…You may not sit down and do it everyday but it is always there at the back of your mind so you include it whatever you do.”

e) Develop Routines
Parents observed that the kinds of home programs that they were most likely to practice were the ones that became part of family “routines”. The process of making a home program into a routine was a very active and deliberate plan that parents nurtured, because they recognised that the home program wouldn’t happen without them being very intentional about it. For example: “If you don’t make it part of your routine, then it doesn’t become part of your routine.”

Parents observed that home programs could either be inserted into existing routines or they could create new family routines. Parents observed that because the home program focused the family on practicing the activities that they actually wanted to achieve this focus could lead to new routines being created. One parent described this interplay:

“I actually think it [home program] fits sort of the home routine but also makes it a lot….It [home programs] sort of makes routines or routine tasks, the sort of things you want your child to move along with easier because you actually have the right input.”

Parents used a range or strategies to develop routines that reflected their unique family life. For some they made new routines around the home program that were short focused homework-like routines. For example:

“It was only 5 minutes a day, it was quite easy to fit in and also because [my child] is sometimes reluctant to sit down and write, I found it was easier to get him to focus for five minutes…[we chose to implement the home program] roughly around the same time each time, mostly before bedtime.”
Other families embedded the home program tasks into existing natural family routines to facilitate practice time in natural settings with real-life tasks. For example:

“I mean we play with him all day anyway…so it really just incorporated into what we were doing, and we feed him so the finger feeding stuff was really just us making more of an effort to do additional things to what we had been doing or just modify techniques I suppose. So yeah, I guess this wasn’t like, we didn’t really do it in that we set aside a strict time, and we said like this is therapy time, let’s do therapy, we did more say like an average of say some days it would 10 minutes play on the fish tank incorporate some of the touch stuff and the key words we use in that and then other days it might have been a bit longer because we were doing a few different things with him, so I guess it’s sort of including it in your day.”

For families that chose to embed the tasks within existing family routines, they did so because they found the program easier to implement this way as parents. For example:

“I think it is quite easy to fit into your daily routine as you are doing most of this stuff anyway, it’s just kind of like trying to focus it on whatever guidance you have been given.”

Parents observed that they way they presented the routine to the child affected the child’s enjoyment of activities. Parents described being careful not to make the task appear difficult to the child, rather it was just a natural part of the day: “You don’t make it a chore, you don’t give it as a chore, you make it a time where you and your child can [implement the home program].”

Parents also described that if they embedded the home program within the family routine an outcome was that it was easier to gain their child’s agreement and enjoyment because the child didn’t experience it as “therapy.” For example: “I would definitely just say putting it into a daily routine where then they are also doing it without probably even realising it.”
f) Improving Your Life and Your Child’s

Parents advised other parents that implementing a home program had benefits for the parent as well as the child. They observed that instead of viewing the home program as an extra duty, it was possible and more positive to consider the home program as an opportunity for helping to maximise their child’s success. For example: “You can look at [the home program as] improving your child’s life…That’s your part in that and helping them lead as normal life as possible.”

The parents who were able to adopt this positive stance on home programs described experiencing the following outcomes. First, a reduction in the fears and anxieties that accompanied parenting a child with a disability because implementing the home program engendered feelings of confidence and satisfaction from: “knowing you’d met your responsibilities”. For these parents, the routine of implementing a home program was an important task that they used to reassure themselves that they had met their parenting responsibilities. When parents could confirm that they had been pivotal in enhancing their child’s development through using a home program, they described feelings of increased confidence, which was rewarding to them as a parent. For example: “I’ve learnt a lot and I feel like I need it [home program] because it makes me feel a bit more confident in helping [my child].”

Second, they described that implementing the home program eased the likelihood of “falling into a big guilt trip” and feeling apprehensive about the quality and quantity of their parental input into their child’s development. This was because they knew that they were doing something “worthwhile” for their child. For example:

“I suppose you wanted to try and hopefully make some improvement or at least know what you are trying to do. I mean if you know, it just doesn’t give it a chance to just slip away to nothing.”
For some parents this process seemed to occur regardless of whether or not the child actually made progress, it was the meaning they attributed to making an active contribution to the child’s life that was important. For example:

“It will make you feel good even if you don’t see any progress with your child, actually trying to do something even if you are not seeing a reward straight away it will help the process along…Knowing that you’re actively doing something to, you know, help your child or teach your child is actually very worthwhile.”

Finally, they observed that home programs offered a unique opportunity for strengthening the parent-child relationship because home programs provided an opportunity to encounter success together. For example: “It’s a good thing to work with your child, it’s a good bonding thing and you feel like you have achieved something together.” They conveyed a sense of hope that their child would one day realise that it was the joint parent-child effort that was what led to the gains. They wanted their child in years to come to recollect the experience of using a home program as an affirming interaction between the parent and the child. For example:

“You look back and some of those achievements that you [and your child] have achieved together have been really rewarding….I’d like to think [that my child] can look back and appreciate what we have done together.”

5.9.4 Advice to Health Professionals about Designing and Prescribing Home Programs

Based on parental accounts, the advice to health professionals designing and prescribing home programs is presented in terms of the four themes. The four themes were: (a) support sustains implementation of the home program; (b) coordinate inter-disciplinary home programs; (c) applying pressure to comply with home programs is counterproductive; and (d) prognostic guidance helps future planning. These are now described.
a) Don’t Leave us Hanging

Parents explained that when they felt alone in implementing a home program they experienced feeling “overwhelmed” by the “burden of responsibility”. When parents were overwhelmed they described becoming indecisive about what home program activities to do and questioning whether it was worth “practicing” at all. Parents described wanting professional support to help them implement home programs because they recognised they were more likely to implement a home program if they had ongoing support. For example: “You get caught up with your daily life of you know, bathing and doing all that, and sometimes it doesn’t come into place I suppose, but if you have someone coming back and revisiting, it’s like more of an ongoing thing rather than just go away and do it.”

The type of support that they wanted was advance scheduling of support sessions, telephone support and home visits. For example: “It was nice to know that the help was there and the support…So I could phone you.” “I think the visiting side of it [support], you coming to my place is great rather than you just being on the phone, you can actually see the child and understand it.”

Parents advised health professionals that the process of providing support to accompany home program intervention was very important to both the way parents felt about the home program about to how much they actually implemented the program. When parents experienced advance scheduling of follow-up appointments for the purpose of receiving implementation support, they described an outcome of feeling reassured. They used diary bookings and telephone support as a strategy for managing the anxiety and “burden of responsibility” that they felt when implementing home programs. For most parents it was simply “just knowing that support was available” that led to them feeling comforted and capable of remaining optimistic, instead of being “overwhelmed” by their workload. This was because parents knew they could access help if they needed it: “You are there to contact if you have any [home program implementation] issues along the way.”
Another outcome of professionals’ scheduling ongoing supportive follow-up appointments in advance and offering telephone support was the engendering of hope, because it communicated that “someone cared” about their child’s development needs and the parents’ information needs. It communicated to parents that they weren’t alone in fostering their child’s development. The experience of receiving ongoing support via pre-booked appointments with home program implementation was new to most families who participated in the home program trial, and they welcomed it. For example:

“[In the home program trial] you know that something is actively happening over a period of time so you keep with it, as opposed to thinking, oh this is just too hard and no-one really cares anyway so…[But in the past I’ve experienced being] given a piece of paper in January and someone comes back in August, and says like ‘how did you go with that?’”

One family also identified that an outcome of the support session was that it “reinforced” to the child that what they were doing at home was important because it was the same as what the therapist was doing. Parents used this strategy to increase their child’s cooperation with practicing difficult tasks at home. For example:

“Coming back in and seeing you on the odd occasion is good because it reinforces to them [the child] from another person that this is right what we are doing it, if she’s [the therapist] doing it... Yeah, hearing it from someone else sometimes works.”

b) Co-ordinate Please!
Parents described feelings of despair arising from experiencing a “lack of services” to support them to meet their child’s needs. For example: “At some stages it felt devastating, I mean we need help now, and there was just nothing.” In addition, when they did receive therapy or advice, they described encountering continual frustration with the discontinuity between the varying professional services. They referred to these experiences as the lack of a “co-ordinated approach”. Some parents perceived that a well “co-ordinated approach” would make the single biggest difference to their child’s outcome, yet their experience had taught them they needed to plan to survive and succeed without it. They felt that
professionals had the intentions of collaborating but the resource limitations of the health system prevented collaboration from being achieved. For example: “[In our experience the] people (professionals) working with us…all want to work together but they just don’t have the opportunity to.”

Parents described experiencing feelings of “confusion” and becoming “overwhelmed” when they were receiving multiple home programs from multiple professionals at the same time. In contrast they described that when they received interdisciplinary home programs from “therapists who worked together” it was very helpful. For example:

“Working with therapists, who work together, who can sort of give ideas, you know, how you can incorporate communication, and how you can incorporate physio, sort of occupational therapy even that put together in a home program is great.”

c) Take the Pressure Down

Parents described wanting health professionals to understand the impact that applying pressure to comply with home programs had on families. Parents identified that when professionals applied pressure to comply with home programs it had a negative impact on both the parent and the child. For the parent, they described that when they felt “under pressure” to comply with “a very rigid program” they rapidly concluded that they wanted to discontinue seeing the professional. For example: “When you are given a very rigid program say because if this week we have this, this and this I used to just think ‘oh I don’t want to go back’.”

It was as if the added pressure led to a breaking point for these parents. They also observed that the child inevitably “picked up” on the parents’ feelings and adopted them as their own. Parents believed that this created even more pressure because the parent then had the added workload of trying to “motivate” the child to do the home program activities. Parents observed that professional pressure to comply with home programs set
up intra-personal and inter-personal processes that were counterproductive to achieving progress with their child.

In contrast, parents that participated in the home program trial observed that they did not experience “pressure”. In the absence of pressure, they described an outcome of feeling “more positive” about implementing a home program. For example:

“In the home program trial it was that you weren’t enforcing it, and that makes it better for me…It makes the overall feeling a bit more positive about it…You don't feel like you are under pressure, if you miss a day it’s not an issue.”

\textbf{d) Prognostic Information Helps Plan the Future}

Parents described worrying that they did not have the skills, the knowledge, or the emotional objectivity to determine the direction of intervention across the lifespan without professional “guidance”. Parents described wanting to be provided with prognostic information about their child from health professionals. Their motivation for seeking this information was to receive “guidelines” about priorities for intervention for their child. For example:

“The onus is a lot on the parents to say [to professionals] ‘what do we need?’ ‘What do you require for your children?’ And that’s important! However, as parents we would like to know where our child should be heading. Should our child be heading towards potty training? Or should we be teaching our child to write, you know? Or, independent feeding? Because often as a parent there are many things that are important in your life, but we also would like guidelines from the specialist to say maybe ‘we see your child moving in this direction’.”

Parents identified that therapists were reluctant to give prognostic information. Parents interpreted the therapist’s motivation for avoiding giving prognostic advice as a desire to be respectful and protect them from painful news. Nevertheless, parents found this to be a frustrating and anxiety-provoking experience. To deal with these feelings, they sought comfort in parent support groups, where they sought advice from other parents about possible answers to their questions about the future. For example:
“Therapists don’t like doing that [providing prognostic information] because it is like, you know, ‘who are we to come in and say what is important and what’s not’…But as a parent we are always talking to each other and saying ‘well how do we know what we need for our child.’ I mean sure, I can say well, I can tell you she’s not speaking, can you help me with that, yeah she’s not feeding, but what else? Should she be playing with a rattle or should we, you know, be introducing some more age appropriate toys…We also want guidelines from them [therapists]…that we are moving our child in the right direction!”

Parents believed that it was possible for health professionals to give prognostic guidance without the content of the news devastating parents. One parent suggested a phrase that therapists could use to communicate prognostic advice but still “keeping parents’ spirits up”. For example: “Just to say, ‘this isn’t working let’s try a different angle’.”

Parents identified that an outcome of professionals offering alternative “ideas” and “advice” was the building of resilience for coping with bad news.

Parents advised health professionals that not only could a home program provide “guidance” for what to do now, but that it should educate and provide “guidance” to parents about what to focus on in the future. This type of advice was perceived to provide reassurance and comfort to parents.

5.10 Synopsis
This chapter outlined the aims, research questions, methodology, and findings from parent interviews. Included was a description of the participants’ attributes, the participants’ reasons for choosing to implement home programs, the experience of implementing the home program used in the trial and the participants’ advice to parents and professionals about home program intervention. This chapter illuminated the effectiveness study findings by describing the parents’ perspective. The final chapter, Chapter Six, draws together the findings from the literature review, the randomised controlled trial and the interview study in order to make recommendations for education, policy, practice and research.
Chapter Six: Discussion

6.1 Introduction

Motor and associated impairments of cerebral palsy affect children’s ability to perform daily activities and roles. Home programs are considered to be a strategy to enable sufficient therapeutic activity and practice to maximise a child’s potential to acquire functional skills. Despite the widespread use of home programs within occupational therapy clinical practice, there is limited research evidence to support the effectiveness of this form of intervention. Only a narrative guideline developed from literature (Novak & Cusick, 2006) and one pilot study of a program (Novak et al, 2007) existed prior to this PhD study. The pilot suggested the approach may be effective in helping parents and children reach desired functional goals (Novak et al, 2007). All previous research focused on whether parents actually used home programs and the effect of these programs on parent-child relationships (Novak & Cusick, 2006). This PhD study explored both the effectiveness of home programs for children with cerebral palsy and parent perspectives of the intervention to fill this information gap.

The aims and objectives of the study, presented in Chapter One, were designed to address the significant issues about home programs for clinical practice. Chapter Two established the background and context for the dissertation studies undertaken through a review of the literature. It revealed that cerebral palsy is the most common physical disability in childhood and that home programs were one of the main intervention strategies used to foster these children’s development. Chapter Three provided the background for the design of the home programs used in the present study. The underpinning philosophies and choice of therapy techniques and theories in which home programs are prescribed were described. Furthermore the chapter identified that a gap in
knowledge existed about the effectiveness of home programs and parent perspectives of home programs.

A double-blind randomised controlled trial (RCT) and semi-structured interviews with parents were conducted. The RCT presented in Chapter Four set out to rigorously evaluate whether or not four and or eight weeks of home program intervention, compared to no home program intervention, was effective in assisting children with cerebral palsy to improve their functional activities performance and parent satisfaction with function. After the RCT, the parent experience of implementing the home program was investigated via semi-structured interviews, presented in Chapter Five. The findings of the two studies reported in this dissertation contributed new research evidence for therapists, children with cerebral palsy and their families regarding home program intervention.

This final chapter, presents key findings and discusses study outcomes, research objectives and the existing home program literature base. The contribution of the two studies to the existing body of knowledge is presented. Limitations of the studies are outlined and recommendations for education, policy, practice, and research are made.

6.2 Key Findings
Home program intervention for 4WEEKS and 8WEEKS improved function and parent satisfaction with function for school-aged children with cerebral palsy. Children who used home programs achieved their goals faster and improved their ability to move their arms to a greater extent when compared to children who did not use a home program. Home programs had no impact on how they participated in everyday life when compared with children who had no home program. There were no differences between children who used the home program for 4WEEKS or 8WEEKS, and both did equally well. It should be noted that both groups basically implemented the home program for eight weeks (contrary to instruction).
Parents described home programs as something that was essential for gaining guidance about how to maximise their child’s progress amidst a busy life. Parents described the trial home program as highly beneficial compared to “traditional” home programs in terms of the support, realism, flexibility, motivation, simplicity, reminders, updates and role clarity. They recommended that other parents should accept the disability and accept help. They should also view home program routines as essential in helping parents improve their child’s life. They advised health professionals that the provision of support, coordination, and prognostic information along with a reduction in pressure to do what they were told would improve the home program experience from their perspective.

6.2.1 Major Findings

This PhD set out to answer eight questions (Chapter One). Two studies using different methodologies were designed, conducted and analysed. Twelve major findings answered the eight questions put forward. These findings were:

1. Home program intervention for either 4WEEKS or 8WEEKS led to statistically significant and clinically meaningful improvements in functional activities performance and satisfaction with function at 4 and 8 weeks, for children with cerebral palsy, compared to children who did not use a home program.

2. Home program intervention for children with cerebral palsy also led to statistically significant and clinically meaningful improvements in the rate of goal achievement at both four and eight weeks and improvements in quality of upper limb movement after eight weeks (but not 4 weeks), compared to children who did not use a home program.

3. Home programs had no effect on dimensions of activity participation in everyday life compared to children who did not use a home program.

4. There were no statistically important differences between implementing a home program for 4 weeks or 8 weeks. Children improved equally, but it is important to be aware that both groups essentially implemented the home program for eight weeks.
Parents instructed to use a 4WEEK program continued it after 4 weeks due to its perceived usefulness.

5. Families design home program goals that focus on improving functional activities predominantly in the performance areas of productivity and self-care, for example, handwriting and dressing. There was a trend towards “less is best”. Families who set higher numbers of goals for intervention chose not to actually practice all the goal activities simultaneously. On average, two goals in total was the most likely number of goals that families chose to implement.

6. Families of children with cerebral palsy generally implemented home programs on average four times a week for 15 minutes at a time.

7. Home programs based on the conceptual frameworks of the ICF and FCP, and designed using principles and practices of ECP, AFM and DMC were effective for children with cerebral palsy.

8. Most parents kept using the home program if they thought it was effective, even when they had been asked to stop for the study purpose.

9. Parents believed practice of home program activities was a part of life for children with cerebral palsy and they used home programs to maximise progress, gain parental guidance and for time management reasons.

10. The home program was perceived to provide benefits to parents including support realism, flexibility, motivation, generalisable activities, reminders to practice, progress updates, and role clarification.

11. Parents advised other parents to accept the disability, never refuse help, be honest, develop routines and consider home programs as essential for the child’s development. Home programs also were perceived to provide parents with a positive strategy for improving their child’s life.
12. Parents advised health professionals that effective home programs should include parental support, inter-disciplinary coordination, and prognostic information, without pressure to do what they are told.

In chapter one a figure in the form of an “aide memoire” was presented about what was “known” and “unknown” in the field of home programs before this study was conducted (Figure 1). A second “aide memoire” is now presented to summarise the home program knowledge base now this study has been conducted. It also presents areas for future research (Figure 22), with the implications discussed in more depth in section 6.4.4.

Figure 21: Home Program Knowledge Base after this Research: An Aide Memoire

6.2.2 Randomised Controlled Trial Findings in Detail

Baseline Characteristics: The sample assembled was representative of the general cerebral palsy population in terms of the range of sub-classifications, severities of the condition and number of associated impairments. The sample’s distribution of sub-classifications of cerebral palsy was spastic (83%), dyskinetic (14%) and ataxic (3%), which is in line with...
national cerebral palsy register statistics of the condition’s prevalence in Australia (Stanley et al, 2000). The sample’s distribution of Gross Motor Function Classification Scale (GMFCS) severity was Level I (47%), Level II (14%), Level III (16%), Level IV (7%) and Level V (16%), and was comparable to previously published GMFCS severity data amongst children with cerebral palsy (Nordmark, Hagglund, Lagergren, 2001). The average age of the school children was 7 years and 9 months (SD 2.02 years) and this was normally distributed. More than half the participants were boys (69%) which reflects the naturally occurring distribution of sexes in the cerebral palsy population (Stanley et al, 2000). The sample was thus representative of school-aged children with cerebral palsy, even though the sample was assembled from volunteers. The conclusions from this study are therefore likely to be applicable to the majority of school-aged children with cerebral palsy. It is also likely that the sample represents children who typically access or want to access occupational therapy services and use home programs. These sample attributes, in the context of literature, contribute positively to the external validity of the study’s findings.

Drop-outs and non-compliance: One participant in the 4WEEK home program group dropped out of the trial after baseline measures were taken but before intervention commenced because he was offered intensive intervention from another service provider. None of this participant’s data were therefore available for inclusion in the final analyses and was treated as missing. Otherwise, no participants dropped-out of the trial. Each group had some children who asked not to complete the CAPE secondary outcome measure (n=14, 39%) due to respondent fatigue at baseline. Incomplete CAPE interviews affected all the CAPE domain scores. All of the CAPE findings, for all of the domain scores, must be interpreted with caution due to low response rates. One participant in the 8WEEK home program group deviated from the study protocol by never implementing the home program due to parental separation during the study period and this participant’s data were included in the analysis on the basis of intention to treat. Of interest were the nine
participants in the 4WEEK home program group that deviated from the study protocol by continuing to use the home program for eight weeks instead of stopping after four weeks, because they believed it was helpful for their child (81%). These families were clearly instructed to stop using the home program and “rest” for another 4 weeks to enable measurement of follow-up effects. The deviation from the planned protocol may explain why there were no differences in outcomes between the 4WEEK and 8WEEK groups because effectively their intervention regimens were the same.

**Primary Outcome:** Results from analysis of the primary outcome showed a statistically and clinically important difference between the NoHP group, and those that used a home program both in the 4WEEK group and in the 8WEEK group. At study completion (eight weeks), performance in functional activities (such as dressing, handwriting and catching a ball) had improved by an effect size of 1.4 (95% CI 0.6 to 2.2) ($p=.01$) in favour of the 8WEEK group and by 2.4 (95% CI 0.7 to 4.2) ($p=.01$) in favour of the 4WEEK group, compared to the NoHP group. This was considered clinically important because it equated to functional gains of 14% for the 8WEEK home program group and 24% for the 4WEEK home program group, respectively. The finding that home programs lead to gains greater than 10% in function over an eight week period in children with cerebral palsy is noteworthy within the context of the literature and is important for the field. Previous high-quality clinical trials that have measured the impact of therapy on function in children with cerebral palsy reported functional gains of 4-10% but from longer periods of intervention (Ketelaar et al, 2001; Gorter et al, 2002; Trahan & Malouin, 1999). These data were however collected using different measures. The key difference between this trial and Ketelaar’s landmark RCT was that all the intervention activities were provided by therapists in the Dutch trial (Ketelaar et al, 2001; Gorter et al, 2002), whereas in this trial intervention activities were selected and carried out by parents at home, with the exception of the prescription and manufacture of orthoses and adaptive equipment that was done by the
therapist at the request of the parent after collaborative goal-setting and therapeutic activity selection. The improvements in functional performance produced from home programs provide important new evidence about another effective intervention option for children with cerebral palsy at the ICF level of activity (Damiano, 2006; Eliasson, 2005). The findings now require therapists to critically analyse available intervention options for children with cerebral palsy before commencing an intervention plan.

In addition to important gains in activities performance by children, the results of the primary outcome showed a statistically and clinically important difference between the NoHP group, and those that used a home program in terms of increased parent satisfaction with function. At study completion (eight weeks), satisfaction with performance of functional activities (such as dressing, handwriting and catching a ball) had improved by an effect size of 1.5 (95% CI 0.3 to 2.6) \((p=.01)\) for the 8WEEK group and by 2.5 (95% CI 0.8 to 4.3) \((p=.01)\) for the 4WEEK group, compared to the NoHP group. These findings support the usefulness of home programs producing outcomes that address family priorities and goals (Cusick et al, 2006). This suggests that the home program design and process used in this study “delivered” on the promise of FCP by meeting family generated goals. The results were also clinically important because satisfaction is recognised not only to affect behaviour such as adherence to intervention (Naar-King et al, 2000). Parental satisfaction with their child’s improvement from home programs is known to be fundamental motivator in whether or not they actually implement the program (Piggott et al, 2002). The nine participants in the 4WEEK group perhaps illustrated this point best: they chose not to stop using the home program, even though they had been asked to, because it was producing the kind of results they wanted.

**Secondary Outcomes:** The primary outcome analysis was considered to provide the most important and statistically rigorous results of this RCT. Secondary analyses were also conducted to provide further information to illuminate the primary outcome analysis.
Secondary outcome analyses were conducted using data from the mid-point (four weeks) COPM scores, and then from all the other outcome measures at both time-points (four and eight weeks). The results of the secondary outcome analyses must be interpreted with caution because of the increased probability of Type 1 errors from using multiple tests (Bauer, 1991). Even so, the secondary analyses supported the analysis of the primary outcome, with the exception of the CAPE instrument (which had missing data limitations).

The home program groups significantly differed from the control group (NoHP) (Section 4.12.6, Table 17) in: (a) the rate of performance of functional activities gains (COPM Performance score) after four weeks; (b) the rate of goal achievement (GAS t-score) after four and eight weeks; and (c) the quality of arm movement (QUEST total score) after eight weeks. Findings demonstrated that home programs had a clinically meaningful effect on these three different secondary outcomes.

There was no apparent difference between the home program groups and the control group on the QUEST after four weeks. There was, however, a significant QUEST difference between the home program groups and the control group after eight weeks. This finding suggested that longer periods of intervention were required to facilitate motor change in the upper limb. Longer periods of intervention to effect motor change is to be expected in cerebral palsy (Trahan & Malouin, 1999). Previous upper limb research indicates that the amount of practice required to effect a change in upper limb movement is considerable and this is consistent with the motor learning paradigm where repetitive practice is vital (Bonnier, Eliasson, & Krumlinde-Sundholm, 2006; Eliasson, 2005; Gordon et al, 2005). Eight weeks of home program practice using therapeutic activities founded in the part on the AMF and DMC models, may be the minimum threshold time to promote motor changes in children with cerebral palsy.

There were no differences between home program groups and the control group in participation on any CAPE domain at any time point. The lack of change in participation is
not unexpected given data limitations. It could be due to CAPE limitations in sensitivity which are, as yet, undiscovered. A new and very large population research study (n=818) conclusively demonstrated that children with cerebral palsy who were at school had participation and quality of life identical to their peers from similar neighbourhoods as measured by KIDSCREEN (Dickinson, Parkinson, Ravens-Sieberer, Schirripa, Thyen, Arnaud, Beckung, Fauconnier, McManus, Michelsen, Parkes & Colver, 2007). So the lack of significant CAPE findings within this study may also appear to be in line with the emergent participation and quality of life literature base.

There were never any differences in outcomes between the two different home program groups. This finding may be explained by the two home program groups’ regimens essentially becoming the same, because nine of eleven participants in the 4WEEK group did not adhere to the protocol and instead used the home program for eight weeks. Comparison of the 4WEEK and 8WEEK outcomes is thus practically meaningless. Consequently, the present study demonstrates home programs of 8 weeks are better than no home programs, but a finding relating to home program duration cannot be made. More research is needed using a study that better controls home program implementation duration. More research is needed to explore whether or not there is a critical threshold beyond which more intervention does not lead to greater outcomes. The question of duration and intensity has been previously asked, in a pilot study, which hypothesised that intermittent intensive therapy was better than constant therapy for children with cerebral palsy, because it provided opportunities to consolidate newly acquired skills (Trahan & Malouin, 2002). As yet, this question remains unanswered. In addition, rigorous studies have proven that intensive therapy does not lead to greater outcomes over regular amounts of therapy (Bower & McLellan, 1992; Bower & McLellan, 1994; Bower, McLellan, Arney, & Campbell, 1996; Bower et al, 2001). Trahan & Malouin’s (2002) intermittent intervention model was the impetus for testing a four week home program followed by a four week
break, because if similar results could be achieved with less effort, this would have been of benefit to families’ workload and could have demonstrated “carry over” effects. This study was not able to answer this question with any certainty because the results are confounded by the many participants who deviated from the protocol.

6.2.3 Interview Findings in Detail
Qualitative home program research findings have previously suggested that parents of children with cerebral palsy take on the vocation of fostering their child’s development by striving to be the best parent that they can be (Piggot et al, 2003; Thompson, 1998). Parents in the present study confirmed that they chose to implement home programs as a way of helping them maximise their child’s developmental progress. In agreement with other studies, they described their experience of interacting with their child’s therapist via home programs as one of their main sources of support to enable them to cope and to nurture their parental caregiving competency (Case-Smith & Nastro, 1993; Washington & Schwartz, 1996). This study added to this body of knowledge by revealing more detail about the ways in which parents conceptualise the types of home programs that are effective. These parents described home programs as a form of “guidance for the journey”, which had only been alluded to before this study (Washington & Schwartz, 1996). These parents also interestingly described home programs as ultimately “a part of life” for their children with life-long disabilities. For the first time parents confirmed the propositions of experts, suggesting that home programs are more time efficient to implement than attending institutionally-based services (Bazyk, 1988; Dormans & Pellegrino, 1998; Dunst et al, 1988; Kwok, 1994; Turnbull, 1990).

Parents in this study suggested that home programs were more than therapeutic recommendations for implementation. Their collective narrative presents another definition that complements the therapist definition proposed earlier by Novak et al (2007).
Home programs are a form of guidance and advice, which become a way of life for parents and children. Through regular practice of activities at home, parents maximise their child’s potential. Parents use the guidance and support that they gain from home programs to build confidence about how to help their child.

The findings of parent interviews suggest that implementation of the home program provided both parents and the child with many advantages over traditional “rigidly prescribed” home programs. Thematic analysis of data about the parental experience of implementing the home program revealed eight sub-categories of perceived benefits. Parents described these benefits as including: (a) much needed parental support; (b) parent education for developing realistic expectations of their child’s potential; (c) flexibility; (d) a source of motivation derived from the goals; (e) therapeutic activities were more readily translated into the child real-life activities; (f) reminders to practice; (g) the sought after progress updates; and (h) role clarity about being a parent not becoming a therapist. All of these benefits were highly linked to the parents’ desire to continue using the home program despite competing caregiving demands. This finding was different from former studies where the theme “what home programs?” emerged, to describe parents non-involvement in home programs (Hinojosa, 1990). It appeared the home program approach used in this study led to parents to choose to implement a home program regularly, unlike previous studies where parents had decided to stop using home programs (Hinojosa, 1990). Home programs used in this study appeared to meet parental recommendations of program activities that were “pleasing for the mother …not stressful for the child…[and] not stressful for the mother” (Hinojosa & Anderson, 1991, p.276). Moreover, the collaborative goal-setting and parental decision-making features of the study home programs may have enhanced the program’s quality and the child’s outcome, as anticipated by former research (Hinojosa & Anderson, 1991).
The features of home programs that were pleasing to parents were consistent with previous qualitative research about the parent experience of implementing home programs (Case-Smith & Nastro, 1993; Hinojosa, 1990; Hinojosa & Anderson, 1991; Piggot et al 2002; Piggot et al 2003; Thompson, 1998; Washington & Schwartz, 1996). This was not an altogether surprising finding because the home programs used in the trial were developed from a comprehensive literature review which sought to understand and incorporate parent preferences (Novak & Cusick, 2006). In the interviews, parents verified former research findings when they identified the following home program features as advantageous: (a) implementation support from the prescribing therapist (Case-Smith & Nastro, 1993; Hinojosa, 1990; Thompson, 1998; Washington & Schwartz, 1996), described by parents in this study as “support that sustains”; (b) parent education (Hinojosa & Anderson, 1991; Thompson, 1998; Washington & Schwartz, 1996), described by parents in this study as “guidance for the journey” and “realistic expectations”; (c) regular progress updates (Gajdosik, 1991; Piggot et al 2003), categorised as “progress updates”; (d) instructions in writing so as to act as a reminder to practice (Schreiber et al, 1995), categorised as “reminder to practice”; and (e) a process that enabled them to remain in the role of parent (Case-Smith & Nastro, 1993), which was categorised as “role identity – parent not therapist”. These factors interacted to confirm to parents that the home program was a worthwhile strategy to implement as part of their overarching aspiration to significantly enhance their child’s development.

The findings about the perceived benefits of the home programs used in the trial make a new contribution to the literature. The new findings concluded that the home program design and process presented in this study were more flexible for families to implement. Previous Australian research had found that parents often felt it was difficult to implement advice given via home programs due to the incompatibility of the family and therapist scheduling routines (Thompson, 1998). The home program used in this study was
also more motivating to implement. This finding is in stark contrast to former American and New Zealand studies which found that parents did not implement prescribed home programs but instead adapted the ideas into their parenting style to better meet their child’s needs (Hinojosa, 1990; Hinojosa & Anderson, 1991; Piggot et al 2002; Piggot et al 2003). In the present study, parents did implement home programs (even when they were asked not to). This was because the home program was founded on family-developed goals, with activities that they selected to meet their child’s needs and interests and did not necessarily require a great deal of adaptation to fit into family routines and resources. Furthermore, home programs using the design and activities in this study were more readily generalised and translated to real-life. Previously parents identified that they did not implement home programs when the meaning of the prescribed therapeutic activities were not clear, the child didn’t like them and when the activities couldn’t be transformed by parents into realistic caregiving routines (Hinojosa & Anderson, 1991; Piggot et al 2002; Piggot et al 2003). Parents who were interviewed in the present study reflected that the home programs provided refreshingly clear ways of thinking about therapeutic practice for their child, and that the program was less demanding on parents in terms of needing to think “like a therapist”.

Parents who were interviewed provided data about home programs that they thought should be communicated to other parents. They offered five recommendations. First, was the need to accept the child’s disability. This parental recommendation confirmed the findings of earlier qualitative home program research where parents have disclosed that the feeling of denial at diagnosis significantly affects their ability to implement a home program (Piggot et al, 2002; Piggot et al 2003). This concept had been described by researchers as “coming to grips” with the shock and grief of having a child with cerebral palsy whose caregiving needs may feel overwhelming (Piggot et al 2003). It is known that parents who are unable, or have not yet made the adjustment to, accept the
child’s disability don’t actually implement home programs (Piggot et al 2003). Parents in this study believed that this decision was to their detriment, despite it being an understandable reaction.

Second, parents recommended that parents never refuse home program help from professionals. This recommendation was strongly linked to their understanding of how the feelings of denial surrounding diagnosis may cause a parent to consider rejecting help.

Third, parents recommended to other parents that they be honest with the child’s therapist about their capacity to implement a home program. It was as if they knew that honesty may be difficult for parents to achieve because of the importance parents placed on the parent-therapist relationship (Hinojosa, 1990). Fourth, parents recommended that home programs were essential and necessary for maximising the child’s progress. Parents interestingly chose the same words as experts who have also described home programs as “essential” (Hinojosa, 1990; Howison, 1988). Previous studies have questioned whether these ideas are actually formulated by the parents themselves or whether they are passed on by professionals (Hinojosa, 1990). The results of this study suggest that it is a parent view. Regardless of the source of these ideas, the findings of the RCT, about effectiveness of home programs, suggests that these parents were right to think of home programs as essential – they did indeed make statistically and clinically meaningful improvements.

Finally, parents recommended that parents reframe the experience of needing a home program from one that is stressful because of the extra workload to one where it as strategy for helping to improve their child’s life. The intention behind this recommendation was to reassure parents that their caregiving contribution was vital to the child’s development. The importance of parent contribution is a belief held by most parents (Piggot et al, 2003; Thompson, 1998). Parents also identified that investment in the child’s life via a home program not only had benefits for the child but also for the parent. One parent described this as “I feel like I need it [the home program]”. Parent benefits included:
(a) engendering feelings of confidence from meeting parental responsibilities, a viewpoint that confirmed earlier research about parents needing to feel that they had made an important difference to their child’s life (Piggot et al, 2003); (b) easing the likelihood of feeling guilt, also confirmed by earlier research (Piggot et al, 2003); and (c) positively developing the parent-child relationship. The finding in this study about the home programs building parent-child relationships was vastly different to previous home program literature of the 1970s and 1980s. That research, conducted in the context where parents were trained to be “therapists” and “educators”, found that the parent-child relationship deteriorated as a result (Turnbull & Turnbull, 1978; Tyler & Kogan, 1972). Negative interactions arose from parents “teaching” a child to practice something they did not enjoy or want to do, in an artificial way. The home program approach used within this study appeared to offer the reverse effect. In the result category, Improving Your Life and Your Child’s, parents described the process of helping their child via home programs as potentially fostering positive parent-child “bonding”. For example: “[the home program is] a good bonding thing and you feel like you have achieved something together.” They observed that shared successes, i.e. making gains from the home program together, may positively contribute to the relationship. For example: “I’d like to think [that my child] can look back and appreciate what we have done together [in the home program].”

Parents offered four recommendations to professionals about effective home program intervention. First, they recommended that parents needed to be supported when implementing home programs. Parents stressed the need for scheduling support appointments advance. They used these as a strategy for managing the anxiety and burden of responsibility that they felt when implementing home programs. The availability of support predicting whether or not parents use home programs has been identified in earlier research (Case-Smith & Nastro, 1993; Hinojosa, 1990; Thompson, 1998; Washington & Schwartz, 1996) and was an integral aspect of the home program used in this study. Parents
confirmed that therapist support was vital to their coping and feeling confident with implementing a home program. Second, parents identified that home programs developed using coordinated inter-disciplinary approaches were easier to use and therefore were preferable. Parents who were interviewed suggested that more is possibly to be gained by a coordinated approach than the current commonplace practice of single discipline home programs that parents need to coordinate.

Third, parents recommended to health professionals that pressure to comply with prescribed home programs was counter-productive. They identified that both the parent, and then the child, lost interest in the home program activities as a consequence of added pressure. This parental advice is perhaps a galvanizing call to professionals to move away from prescribing therapist-directed home programs (Molineux, 1993). Much of the home program literature base has been dominated by persistent examination of parent compliance (Gajdosik, 1991; Gajdosik & Campbell, 1991; Law & King, 1993; Mayo, 1981; Molineux, 1993; Schreiber et al, 1995; Wortis et al, 1954). Until this study was conducted, professionals and researchers had neglected to ask whether or not home programs that required compliance were actually effective and whether it was compliance or parent involvement that was critical. These new results suggest that no longer should parents be expected to do what they are told by professionals. Rather their preferences and expert knowledge of their child and family should be encouraged to direct home program decision-making as this program approach was effective (Bazyk, 1989). The parents who were interviewed have made a compelling case for professionals to discard compliance thinking and practices. The implication of this finding for therapists is to stop fearing that parents won’t use a home program (Molineux, 1993). Instead an approach should be to start connecting with parents in a way that taps into their parental aspirations to do everything possible for their child, because it motivates them to implement home programs. Finally, parents recommended to health professionals that they wanted to be
provided with prognostic information about their children to assist them with the daunting responsibility of planning their child’s future intervention. This parental perspective confirmed earlier research that found the absence of prognostic information made it more difficult, not easier, for parents to cope (Piggot et al, 2003).

Consistent with experts, parents believed that home programs were “essential” and a way of helping children “maximise progress” (Hinojosa, 1990; Howison, 1988). Parents also perceived that home programs were helpful for parents in addition to the therapist-intended benefits and outcomes for children. This was a new finding that had not previously been described in the home program literature. Home programs were traditionally prescribed for the benefit of “helping the child” (Humphrey & Case-Smith, 1996). The notion of home programs also being beneficial to parents is consistent with the FCP approach, where intervention is designed to meet the needs of the whole family not just the child.

6.2.4 Significance of the Major Findings

Prior to this dissertation only expert opinion evidence existed to suggest that home programs were essential for children with cerebral palsy to make progress (Hinojosa, 1990; Howison, 1988). All research studies examined in Chapter Three had failed to evaluate home program effectiveness in any way; rather they had focused on whether parents complied, and the impact on parent-child relationships. Home programs were found to be prescribed regularly as part of routine clinical practice for children with cerebral palsy in line with clinicians’ belief systems rather than a critical appreciation of the available research evidence.

This dissertation adds new knowledge to the home program evidence base. First, the parent interviews revealed that parents also believe home programs are essential. Parents and professionals alike based their conviction on the idea that children with cerebral palsy would need multiple opportunities to practice performing functional
activities, given their life-long motor impairments, and that home programs were the way to achieve this practice. Second, the findings of the RCT provide new evidence that suggests clinical experts and parents may have been right all along. The home programs were effective in helping children with cerebral palsy to improve functional performance. In addition, parents were satisfied with gains their children made. Furthermore, children with cerebral palsy who used a home program also achieved their goals more quickly and improved the quality of their arm use more compared to children who used no home program at all. These RCT findings are the highest level of research evidence ever conducted about the effectiveness of home programs.

One of the most counter-intuitive findings of the RCT was that there was no difference in outcomes between the children who used the program for 4 weeks and the children who used it for 8 weeks. Parents in the 4WEEK home program group did not adhere to the RCT protocol and instead used the program for eight weeks. Parents in the RCT chose to continue using the home program because they believed it to be beneficial and they could observe progress. In their view it was in the best interests of their child to carry on and ignore protocol instructions. The primary outcome analysis findings of the RCT indicate that these parents were right. Progress in functional activities performance was statistically significant compared to no home program at all and clinically meaningful after just four weeks. It is logical for them to have chosen to continue using the program, despite joining a research study that advised them to discontinue the practice after four weeks. One interpretation of these findings is that, consistent with the philosophy of FCP, these families did know best all along, and they were wise not to stop using the program. This key finding highlights the need for further research on home program intensity. Future RCTs should consider assigning participants to groups of varying home program intensities, but delay the provision of the home program to eliminate the likelihood of non-adherence to the protocol that occurred in this design.
Professionals have been concerned for some time that parents may not implement home programs (Law & King, 1993; Mayo 1981; Molineux, 1993). This dissertation provided new information about the home program implementation behaviours of parents. The RCT established that families of children with cerebral palsy do use home programs, consistent with their belief systems about home programs being essential. On average families regularly implemented home programs four times per week for around fifteen minutes, equating to an hour of practice per week. This is an important finding for clinical practice. The RCT data show that this one hour of practice per week was sufficient to make the sort of significant progress gains that professionals and parents seek. Parents who seek guidance from therapists about how long they should spend practicing the program can be reassured that the amount of time required to make meaningful progress is one hour per week, distributed across different days. This finding makes an important new discovery to guide parents who describe themselves as having too many competing caregiving responsibilities to achieve ideal home program practice time (Hinojosa 1990; Piggot et al, 2003). In addition, guidance can also now be given about the number of goals to work on simultaneously. The results of the RCT revealed that it was realistic to work on two home program goals simultaneously. While most families will set and prioritise more than two goals, they actually only implement the intervention related to two goals at the same time. This finding has important implications for therapists who work in teams. It seems that inter-disciplinary coordination and prioritisation is essential because implementation of only two goals at once places a limit on how many home program interventions can be provided by the team at the same time.

Therapy researchers have been urging therapists to discontinue using body structure-based therapy approaches that have been proven to be ineffective and replace them with activities-based therapy, as activities-based approaches may offer more likelihood of success (Damiano, 2006; Eliasson, 2005). The evidence base for activity-based
therapy approaches however is still emerging. The findings of the RCT provide new high-quality evidence about the effectiveness of intervention at the activity level of the ICF for children with cerebral palsy that supports these expert claims. The RCT provides the highest level of research evidence ever conducted about home programs, in particular, the goal-focused task practice approach for children with cerebral palsy. In doing so, the RCT suggests that therapists should carefully weigh up evidence for the selection of intervention approaches that they use with these children.

Up until this dissertation little was known about parental perspectives on implementing home programs. This study provides new knowledge about parents’ views and recommendations for designing home programs. Parents perceived that the home program trial approach compared to other “traditional prescribed” home programs were preferable because they offered them many benefits. Provision of ongoing support to parents was vital, confirming earlier research (Case-Smith & Nastro, 1993; Hinojosa, 1990; Thompson, 1998; Washington & Schwartz, 1996). This finding is important because it is known that the way parents feel about the home program directly influences how much they use it (Piggot et al, 2003). One of the key features of the trial home program was that it empowered parents to solve the challenges of day to day life. The provision of this type of therapeutic “guidance for the journey” in all likelihood positively facilitated program sustainability from the parents’ perspective. The home program used in this study offers service providers with a framework for carefully considering the delivery style of home programs that they provide to parents of children with cerebral palsy. The type of home program used in this trial was implemented by parents, was perceived as beneficial by parents, and led to clinically meaningful gains. A summary of the key difference between “traditional” home programs and the “trial” home program used in this study is now made to highlight the significance of these findings (Table 20). The information in the table is
Table 20: Comparison of Traditional and Trial Home Programs

<table>
<thead>
<tr>
<th>Traditional Home Program</th>
<th>Home Program Developed for the Present Study</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Who</strong></td>
<td><strong>Who</strong></td>
</tr>
<tr>
<td>“The child [to practice] with parental supervision, between treatment sessions” (Molineux, 1993, p.23)</td>
<td>Parents to gain “guidance for the journey” (Parents, this study, section 5.9.1)</td>
</tr>
<tr>
<td>Children to carry out independently if their parent cannot or is unwilling to be involved in the home program (Wilson, 1998, p.145).</td>
<td>Parents to help them “maximise [their child’s] potential” (Parents, this study, section 5.9.1)</td>
</tr>
<tr>
<td></td>
<td>Parents to help them “juggle competing priorities” (Parents, this study, section 5.9.1).</td>
</tr>
<tr>
<td><strong>What</strong></td>
<td><strong>What</strong></td>
</tr>
<tr>
<td>The traditional home program is:</td>
<td>The trial home program is:</td>
</tr>
<tr>
<td>a standard list of activities, the appropriate ones being ticked off after you have assessed the child…[with] tick the boxes beside the activities you want the parents to employ” (Wilson, 1998, p.144).</td>
<td>A “library of ideas” from which parents choose enjoyable activities to practice that are designed to meet family goals (Novak &amp; Cusick, 2006)</td>
</tr>
<tr>
<td>“Lists of activities” (Parents, this study, section 5.9.2).</td>
<td>“[Individualised activities that were] more specifically targeted at her because you did an interview and looked at her interests and exactly what she wanted to achieve…So it was much more specific rather than oh here’s some exercises you can do” (Parents, this study, section 5.9.2).</td>
</tr>
<tr>
<td>“Activities [that] are taken from the list of the typical treatment session [activities]” (Wilson, 1998, p.144).</td>
<td>A written program based around parent goals. Each goal has individualised supporting text and pictures targeting 3 aspects of the home program intervention: (a) child activities designed for the child to practice to meet goals; (b) parent education tips to facilitate successful task cueing and realistic expectations; and (c) environment modifications to facilitate successful task performance (Novak &amp; Cusick, 2006). A recording home program log is also provided</td>
</tr>
<tr>
<td>Therapeutic equipment that the parent needs to purchase/make to enable the child to practice the list of activities in the home environment (Wilson, 1998, 145).</td>
<td></td>
</tr>
<tr>
<td><strong>How</strong></td>
<td><strong>How</strong></td>
</tr>
<tr>
<td>The traditional home program is constructed by the therapist to meet the therapist’s goals and the parents’ role is to comply (Gajdosik, 1991).</td>
<td>The therapist’s role is to empower the parent to gain the “guidance for the journey” that they need to make decisions about what intervention choices fit best for their child and family.</td>
</tr>
<tr>
<td>“I suppose they (the occupational therapists) would choose the goals” (Parents, this study, section 5.9.2).</td>
<td>“This [home program] was more based on, ok this is what we want… it was more based on the result we were trying to get at the end, these are various ways you might be able to achieve it and we just adapted it ourselves anyway” (Parents, this study, section 5.9.2).</td>
</tr>
<tr>
<td></td>
<td>“This [home program] really was about what we preferred and we took it from there” (Parents, this study, section 5.9.2).</td>
</tr>
<tr>
<td><strong>When</strong></td>
<td><strong>When</strong></td>
</tr>
<tr>
<td>The decision of how long to implement the traditional home program is made/recommended/prescribed by the therapist. The traditional home program is:</td>
<td>The decision of how long to implement the trial home program is made by the parent, in accordance with family-centred philosophy. The trial home program is:</td>
</tr>
<tr>
<td>“Carried out for 30 to 40 minutes…this can be done daily” (Wilson, 1998, p.144).</td>
<td>Carried out when and for how long parents believe it works best. Parents in this study chose to implement the program 4 times per week for 15 minutes per session (This study, section 4.12.4)</td>
</tr>
<tr>
<td>Ongoing. “Parents are expected to carry out (comply with) the therapist’s suggestions at home on a daily basis for extended periods of time” (Mayo, 1981, p.27).</td>
<td>Goal-focused and works towards achievement of specific goals. When the goal is achieved, depending on family preferences, the program is either (a) finished or (b) a new goal is established (by the parent &amp; child) and added into the program.</td>
</tr>
<tr>
<td><strong>Why</strong></td>
<td><strong>Why</strong></td>
</tr>
<tr>
<td>The traditional home program is based upon the belief that:</td>
<td>The trial home program is based upon the belief that:</td>
</tr>
<tr>
<td>The therapist is the expert who teaches parents what to do with their child (Bazyk, 1989) to supplement direct treatment given by the therapist (Gajdosik, 1991).</td>
<td>The therapist is a consultant to the parent to help them acquire the knowledge and skills they need to care for their child (Bazyk, 1989)</td>
</tr>
<tr>
<td>The therapist’s role is to empower the parent to gain the “guidance for the journey” that they need to make decisions about what intervention choices fit best for their child and family.</td>
<td>The therapist’s role is to comply (Gajdosik, 1991).</td>
</tr>
<tr>
<td><strong>Where</strong></td>
<td><strong>Where</strong></td>
</tr>
<tr>
<td>The traditional home program is:</td>
<td>The trial home program is:</td>
</tr>
<tr>
<td>Devised by the therapist before/during/or after a therapy session, in a clinical context, for use in the home environment.</td>
<td>Devised by the therapist and parent during a home visit (and finalised afterwards at the office) for use in the home environment.</td>
</tr>
</tbody>
</table>
6.3 Strengths and Limitations

6.3.1 Appropriate Methodological Design

The research program undertaken used mixed methods. Use of quantitative and qualitative techniques in problem investigation is thought to reduce inherent weaknesses and biases of both methods (Creswell, 2003; Polit & Hungler, 1997) and therefore was a strength of this thesis.

The double blind RCT is considered the gold standard study design for measuring intervention effectiveness (Herbert et al, 2005; Jadad, 1989). That is because the double blind randomised controlled trial design effectively (a) minimises self-reporting bias and evaluator scoring bias (Herbert et al, 2005); (b) maximises the chance that any change detected between groups is likely due to the home program intervention and not some other reason (Colditz et al, 1989); and (c) accounts for individual differences that may have been present at baseline that could have provided alternative explanations for the trial outcome, such as severity and age. Random assignment of individuals to groups reduces the odds of this occurring (Pocock, 1983). The selection of the double blind RCT was therefore considered a strength of the quantitative aspect of this thesis.

The major limitation of the RCT was the large number of participants randomised to the 4WEEK home program group that did not adhere to the study protocol. Nine of the eleven participants (81%) who were allocated to the 4WEEK group used the home program continuously for eight weeks, instead of using the home program for four weeks only and then stopping. The participant-driven protocol variation meant that effectively the intervention received by the 4WEEK home program group was the same as the 8WEEK home program group. This significantly limited the ability of the study to answer questions about the effect of program duration. The lack of difference between the two home program groups may mean that more therapy is not better but this cannot be concluded, given the protocol variation that occurred. This design flaw occurred because the
researcher had the “no therapy” period after the 4WEEK intervention rather than commencing the intervention 4 weeks after the 8WEEK group commenced. This was an error in design, as the desire to explore “carry over” effects by including a “suspend” period, clouded the precision of the design to ask a fundamental question of interest which was whether or not 4 or 8 weeks had different effects. Because the home program practice was directed by the parents in accordance with the philosophy of family-centred practice, a direct instruction to suspend intervention could legitimately be ignored. Future RCTs must control such design flaws and this could be better achieved by delaying the provision of home programs to groups of shorter implementation periods. In other words, ‘wait then implement’, instead of ‘implement then stop’. This was the major design shortcoming of this study. Methodologically this is necessary to enable genuine comparison of outcomes from different implementation regimens.

The aforementioned design flaw also has significant implications in terms of the interpretation of the RCT findings for clinical practice. The types of real-world clinical questions that existed about home program intervention before this study were: “does it work?”, “how should we provide it?” and “how long should we recommend?” After this study, we now know first, that the RCT findings indicate some home program intervention is better than no intervention. Therefore the answer to the question is: “does it work?” is yes, home programs appear to be effective but further research is needed due to the methodological limitations of this RCT. Research needs to tease out: (a) the effectiveness of the program long-term; (b) the effectiveness compared to other treatment alternative; and (c) the optimal ‘dosage”. Second, the RCT findings combined with the qualitative parent interviews answer the question: “How should we provide it?” We now know that the trial home programs appear effective and are preferred by parents over “traditional” home programs. Third, the clinical question of “how long should we recommend home programs are implemented for?” remains unanswered. More research about optimal
intensity is still needed. We now know that parents chose to implement the program for one hour per week (4 times for 15 minutes) and this ‘dose’ appears effective. We still need to understand for how many weeks the home program ought to be implemented for and at what intensity it should be sustained.

Another potential limitation of the RCT was that all of the home programs were developed by the same experienced occupational therapist. It is known that practitioner expertise is central to good evidence-based decision-making (King, Bartlett, Currie, Gilpin, Baxter, Willoughby, Tucker & Strachan, 2008) and that the more family-centred the therapist is, the better the client’s outcome will be (Rosenbaum et al, 1998). The methodological decision to use the same experienced occupational therapist, may have introduced a “therapist effect” into the study. In that the treating therapist had over 15 years experience, was well schooled in family-centred thinking and had critically appraised the best-available evidence for working with this population before developing the trial home programs. It is conceivable that this combination of therapist knowledge and skills is not indicative of standard clinical practice and therefore a “therapist effect” may have contributed to the study’s positive results. On the other hand, the use of one experienced therapist was also a strength of the study. It limited the possibility of the study outcome being negatively affected by variations in: practice, communication styles and evidence uptake, which could have occurred if the programs had been developed by multiple practitioners.

The use of semi-structured interviews about the parental experience of home program intervention illuminated the effectiveness findings of the RCT, by providing recommendations for home program practice. Together the two studies made a substantial new contribution to addressing the knowledge gaps in the evidence base about home programs, which was another strength of the dissertation.
The use of the principal investigator as the treating therapist in the effectiveness trial and as the interviewer in the qualitative study, is a limitation of this study. In ethical terms this meant that a “special relationship” existed between the investigator and parents during the interview phase of the project. This special relationship may have confounded the results of the semi-structured interviews. Parents may have felt obliged to describe the trial home program positively because of the interviewer being their “treating therapist”. No negative viewpoints, challenges or costs to families, about home programs were raised during the interviews. Parents may have omitted details which they felt conflicted with the investigator’s views or avoided casting criticism at their “treating therapist”. To minimise the chance of these types of confounding variables being introduced, at the beginning of all the qualitative interviews a standard introductory phrase was used: “I’d now like to ask you about your experience of implementing the home program. I need you to know that I am not “fishing” for any particular answer during this interview. I came to this study with an open mind, wanting to understand what parents wanted and needed from therapists when using home programs. Anything you can tell me to help me understand your experience (both good or bad) would be appreciated. I especially want to know, if the programs aren’t helpful because I wouldn’t want to be wasting your’s or other parents’ time if that were the case. Do you understand what I am saying? [Wait for the parents’ response] Ok, let’s begin.” Nevertheless the possibility exists that the data collected from interviews was biased because of the special relationship that existed between the interviewer and parent. The qualitative study findings therefore must be interpreted cautiously given this design limitation.

Another limitation of the qualitative interviews was that the data was interpreted by the principal investigator, which may have biased the findings. To minimise the possibility of bias occurring, a second independent coder was used during interview transcript analysis. The independent coder and principal investigator achieved higher than 90% agreement about the arising interview themes. Even so, bias may have unintentionally been
introduced and therefore the qualitative study findings must be interpreted in light of this design limitation.

6.3.2 Adequate Statistical Power
Many previous trials conducted in the field of cerebral palsy research have low methodological quality coupled with inadequate sample sizes (Boyd et al, 2001; Steultjens, 2004). This has limited the usefulness and interpretation of findings. To address known flaws of previous cerebral palsy research, two methodological strategies were employed that can be considered strengths of the RCT. First, the a-priori sample size calculation conducted for the primary analysis of the double blind RCT was intentionally exaggerated to account for participants who may drop-out or not adhere to the protocol (Kirby et al, 2002). The low participant drop-out rate of 3% for the RCT suggested that it was unlikely that the RCT was biased by loss to follow-up. Second, missing data were managed during data analysis via the intention-to-treat principle (Lachin, 2000), where participants’ data were analysed as part of the treatment group to which they were assigned regardless of whether they implemented the intended home program treatment.

In addition to the aforementioned CAPE data quality problems, secondary analysis of the CAPE data was probably also limited by low statistical power, owing to the low completion rate from respondent burden. Low statistical power from missing data further compounded the CAPE inferential analysis interpretation.

6.3.3 Sensitive Robust Outcome Measures
Earlier trials conducted in the field of cerebral palsy research have also been flawed by the selection of outcome measures not sensitive enough to detect meaningful clinical change, which has affected the methodological quality and interpretation of those studies’ findings (Boyd et al, 2001; Steultjens, 2004). The RCT used a suite of robust outcome measures with good validity, reliability and sensitivity to change. These included the COPM (Law et al, 1998) that was adapted for children (Cusick et al, 2006), GAS (King et al, 1999) and the
QUEST (DeMatteo, 1993). The selection of robust and psychometrically sound instruments, sensitive to change in children with cerebral palsy, was a strength of the RCT, because it limited the threats to the validity of results. The one exception to this statement was the adoption of the CAPE measure to capture children’s participation levels. The decision to use the CAPE instrument was a limitation of the study, because the sensitivity of CAPE instrument to detect change was unknown at the time of study design. The CAPE instrument was still chosen because of face validity strengths. In this study, no changes in scores were detected on the CAPE instrument. There are several possible explanations for this finding, in addition to the possibility that home programs do not change participation, these will now be described. (1) As previously mentioned, the sensitivity of CAPE instrument to detect change is unknown. (2) Insufficient numbers of study participants completed the CAPE due to respondent fatigue and therefore the numbers were possibly too small to detect change. (3) The CAPE was developed in North America and little is known about the applicability of the instrument in an Australian context and indeed whether the items measure the sorts of participation activities which Australian children engage in. It is therefore possible that the CAPE instrument was not suitable for the population studied. (4) Very few study participants’ prioritised leisure and recreation goals as the focus of their home program. Most participants implemented two home program goals. For the most important goal, only 5.6% of these goals were leisure related and for the second most important goal only 6.1% were leisure goals. Given that the programs were designed around family goals, this means that very little of the home program content actually targeted changes in leisure and participation. With this in mind, it is reasonable to expect that there would not be any change detected by the CAPE instrument. This proposition provides an alternative way of interpreting the study findings about participation. Instead of concluding that home programs do not change participation, it is probably more accurate to conclude that, the home programs used in this
study targeted changes at the activity level and activity gains were observed in response to the program. The relationship between the family’s goals, the instruments used and the outcomes observed is summarised in Table 21. The table demonstrates that on only one occasion would the CAPE instrument have been suitable for measuring the goal area prioritised by the family and intervened upon during the home program.

Table 21: Relationship between Family Goals, Instruments used and Study Outcomes

<table>
<thead>
<tr>
<th>Family Goal Area</th>
<th>Instrument</th>
<th>ICF Level of Study Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>MOST IMPORTANT GOAL – TOP THREE TOPIC AREAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Productivity: Handwriting (n=13)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>2. Productivity: Fine Motor (n=7)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>QUEST</td>
<td>Body Structures and Activity Level</td>
</tr>
<tr>
<td>3. Self-Care: Dressing (n=3)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>SECOND MOST IMPORTANT GOAL – TOP THREE TOPIC AREAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Self-Care: Dressing (n=8)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>2. Self-Care: Eating (n=4)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>3. Self-Care: Toileting (n=4)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>THIRD MOST IMPORTANT GOAL – TOP THREE TOPIC AREAS</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1. Leisure: Active Recreation (n=5)</td>
<td>CAPE</td>
<td>Participation Level</td>
</tr>
<tr>
<td></td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>2. Self-Care: Dressing (n=5)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>3. Self-Care: Eating (n=3)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>3. Self-Care: Toileting (n=4)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td>3. Productivity: Fine Motor (n=7)</td>
<td>COPM</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>GAS</td>
<td>Activity Level</td>
</tr>
<tr>
<td></td>
<td>QUEST</td>
<td>Body Structures and Activity Level</td>
</tr>
</tbody>
</table>

6.3.4 Control of Co-Intervention and Contamination

Potential sources of trial contamination and co-intervention that could have affected the study findings were controlled. Several strategies were employed. First, strict inclusion criteria were developed that specified participants must be on a waiting list for therapy at the time of study enrolment. This ensured participants were not engaged in varying intensities and types of therapy during the study (i.e. co-intervention) and also ensured participants randomised to the control group did not receive a home program (the experimental treatment) during the study period (i.e. contamination). All participants
enrolled in the study met the inclusion criteria. Second, all of the home programs were developed by the author, to avoid bias arising from varying skills and intervention techniques being selected by different therapists (i.e. co-intervention). Third, the variations in frequency and intensity of home program intervention and use of other therapies were monitored using investigator-developed log calendars, completed by families, in line with recommendations about how to accurately record home program implementation rates (Gajdosik, 1991; Law & King, 1993; Schreiber et al, 1995) (i.e. to monitor levels of possible co-intervention bias). Finally, co-intervention and contamination to the intended intervention was managed during the analysis phase of the study using the intention-to-treat approach (Lachin, 2000). A strength of the randomised controlled trial was therefore that co-interventions and contaminations were avoided and controlled for.

6.3.5 Representative Study Population

It was considered important within this research program to study a representative sample of children with cerebral palsy because it is the most common childhood physical disability. Given that child and parent participants in the RCT were recruited via voluntary participation, it was recognised that the sample could not automatically be assumed to be representative of the population of all families who have children with cerebral palsy. Analysis of the sample attributes revealed that the children were representative of those with cerebral palsy that typically utilise therapy services, by virtue of their inclusion criteria and therefore appear to be representative of the population of children who have cerebral palsy.

In view of the fact that that the research program only studied voluntary participants that were school-aged children with cerebral palsy, the generalisation of the results to broader paediatric diagnostic groups and different aged children especially pre-schoolers is limited. It is standard practice for occupational therapists and other professionals to provide intervention to children with cerebral palsy during their pre-school
years. Indeed, early intervention during these years is considered very important, owing to the window of opportunity arising from early brain development. Children develop rapidly during this period of time and intervention services seek to maximise these children’s outcomes in the years before school entry. Early intervention services typically prioritise providing more intensive hands-on therapy services to younger children and families. In addition, parents’ information and support needs during the years surrounding diagnosis are often greater. The role of home programs in early intervention services is also crucial but not necessarily the same as it is for school-aged children. Given that no pre-school-aged children were included in the study and that service models may be different, the findings of this study cannot be generalised to the pre-school population. More research is needed with a younger sample in order to determine whether these results can be generalised. The decision, however, to limit the sample inclusion criteria to school-aged children with cerebral palsy was intentional in order to represent real-world clinical practice, where it is common for these children to be provided with home programs. This methodological decision was therefore also a strength of the RCT. It ensured that conclusions could be drawn from the data about the effectiveness of home program intervention, rather than being confounded by comparing children whose abilities and potential were dissimilar in the first place.

A limitation of the dissertation was that the study was conducted only within Australia and therefore the generalisability of the results to participants in other countries is not assured as the context for therapy services and home programs may differ. The characteristics of the participants in the RCT were similar to accepted international cerebral palsy population attributes, so it possible that the results may be reproducible in other countries.
6.4 Recommendations

Recommendations for the future development and implementation of home programs stemming from the findings of this study are outlined below. Specific strategies are offered for education, policy, clinical practice and research.

6.4.1 Implications for Education

To enhance the quality of occupational therapy services to children with cerebral palsy it is recommended that education of undergraduate and graduate therapists should consider findings of this research program to be the current best available evidence to guide home program practice. University curricula and continuing professional development course materials should be updated to reflect the finding that home programs using interventions at the activities level of the ICF informed by the AFM and DMC models are an effective way to enhance function in children with cerebral palsy. The cerebral palsy literature base is dominated by research into more established and traditional treatment techniques at the body structures level of the ICF, such as Neurodevelopmental Therapy, where effectiveness is questionable (Brown & Burns, 2001; Law et al, 1998). At the present time interventions at the activities level of the ICF are advised (Damiano, 2006; Eliasson, 2005), where the child is trained to actively integrate and organise task-orientated motor behaviour (Law et al, 1998). Undergraduate students and practicing therapists therefore need to be taught about newer approaches and related evidence. Change of curricula at universities where NDT is advocated is recommended. This may require effort as some of these curricula reflect preferences of therapists who place more weight on learning from clinical leaders than they do on reading (Booth, Booth, & Falzon, 2003; Rappolt et al, 2002; Stevenson et al, 2004). Education is one of the most effective dissemination strategies available for integrating new knowledge into practice. Specialist undergraduate and postgraduate paediatric education programs could therefore bridge this knowledge gap by training therapists to (1) critically appraise the emergent evidence base about therapy at the
activities level of the ICF (Damiano, 2006; Eliasson, 2005); (2) accurately identify indicators and realistic goals for home program intervention (Eliasson, 2005); (3) judiciously clinically reason the choice of intervention techniques that they train parents to implement as part of being an evidence-based practitioner (Higgs et al, 2001; Stevenson et al, 2006); and (4) develop familiarity with the skilled use of newer approaches, for example, goal-focused task practice and parent education (Law et al, 1998; Ketelaar et al, 1998; Saunders, Tully, Turner, Maher & McAuliffe, 2003).

The qualitative findings about parents’ experiences of home programs and the comprehensive literature review also provided insights to educators about how to design educational activities to encourage undergraduates to think about their “therapeutic use of self” for home program intervention. New therapists must learn not only to clinically reason about “what” to do but also “how” they do it, because the very nature of parent-therapist interactions also determines whether or not intervention is successful (Hinojosa, 1990).

6.4.2 Implications for Policy
In Australia, disability service policies have endorsed the right to individualised services that meet families’ unique needs using the family-centred approach as “best practice” (Hanna & Rodgers, 2002; NSW Department of Community Services, 1993). Best practice is the: “continuous, collaborative, and systematic process for measuring and examining internal program’s strengths and weaknesses.” (Lewis & Latney, 2002, p.25). It is natural to think of the best foundation for clinical practice for children with cerebral palsy as being a body of well-designed research evidence (Mason, 2002). Along with evidence, professional judgment, proficiency and clinical reasoning are needed to generate best-practice decisions that meet the family’s unique needs (Higgs et al, 2001). The findings of interviews signal the need for policy makers and service managers to give further consideration to the impact of home programs on parental caregiving burden, and shed light upon the factors
of the implementation processes that facilitate or hinder parents to foster their child’s development.

In order for paediatric service providers to achieve best practice, employers may benefit from systematically appraising their therapists’ clinical competency in providing home programs, in particular using the home program design presented in this study. If it is identified that therapists who provide intervention to children with cerebral palsy require additional training and mentoring in order to deliver these specialised treatments (Eliasson, 2005; Ketelaar et al, 1998; Saunders et al, 2003), employer support may be required to achieve this goal. This support may include the, development and implementation of policies designed to promote mandatory training, financial support for continuing professional education and paid work time to engage in such ongoing learning. Provision of specialist training, delivered by clinical leaders, results in greater uptake of evidence-based interventions than does reliance on therapists to make the same decisions from self-directed learning approaches (Booth et al, 2003; Rappolt et al, 2002; Stevenson et al, 2004). Employer supports for this additional staff training is therefore likely to result in longer-term increased quality of care, increased customer satisfaction and thus better outcomes for children with cerebral palsy and their families.

In addition, the twelve major findings of this study provide insights to managers and policy makers about the types of therapy services that are effective and pleasing for families to do. Service improvement and program evaluation initiatives should consider these findings a guideline for revising service delivery policies. This is especially important given that home programs are an integral part of routine clinical practice for children with cerebral palsy and are upheld by service providers as cost-saving measures. Policy should direct funding and resources towards interventions which are proven effective (Klein, 2000). Policy makers therefore may wish to refer to the evidence generated by the RCT
findings when making decisions about the funding of interventions for children with cerebral palsy.

Parents wanted service providers to know that (a) ongoing parental support is essential; (b) the quality of care coordination affects parents stress levels and child outcomes; (c) more prognostic guidance is needed from therapists; and (d) pressure to comply with inflexible services increases family stress and decreases interest in the services being offered. The parental recommendations about support and team coordination have significant impacts for the way service providers and policy makers may choose to spend their limited therapy dollars. Instead of blocks of intensive therapy provided by therapists, the same dollars could be redistributed over longer periods of time where teams offer in-home support and education to families using the home program. Families who were interviewed were intimating that this type of approach was likely to reduce the significant stress and burden of responsibility that they experienced. If indeed this is true, service providers may actually reduce their family support crisis costs because they are investing in early preventative measures. To enable occupational therapists working with children with cerebral palsy to provide these types of flexible services, service providers may need to review budget resource allocations and service delivery policies in light of these findings. Without these changes, the types of interventions occupational therapists can provide to children with cerebral palsy may be limited and therefore potentially ineffectual and inappropriate.

6.4.3 Implications for Clinical Practice

Employers, professional associations and consumers expect and demand that occupational therapists are evidence-based practitioners and offer relevant and effective interventions. The conventions of evidence-based practice compel health professionals to ask important clinical questions, to obtain and interpret research findings, and most importantly to integrate the answers into healthcare services to optimise clinical outcomes (Stevenson et
al, 2006). Yet despite evidence-based practice being widely endorsed and embraced by health professionals, uptake of new research knowledge is known to be slow and inconsistent amongst therapists (Tse et al, 2004; Upton & Upton, 2006). Therapists tend to provide the interventions that they believe are best for the client, not necessarily those the evidence indicates are effective (Stevenson et al, 2006). The challenge for clinical practice is how best to integrate new knowledge developed from this current study into an established and widespread practice of prescribing home programs to children with cerebral palsy. Recommendations for clinical practice are therefore closely linked to employer support strategies recommended in the implications for policy section.

Occupational therapists who work with families and children with cerebral palsy should update their current practice to include implementation of the home program approach presented in this study. Until this study was conducted, little was known about the effectiveness of home programs, or the way in which home programs could be consistently designed and implemented, despite home programs being used extensively with children with cerebral palsy and being considered an essential aspect of care (Hinojosa & Anderson, 1991; Howison, 1988). This study has shown that home programs conducted using the approach outlined in Chapter Three and evaluated in Chapter Four are effective in improving function, improving family satisfaction with their child’s function, improving the rate of goal achievement and improving quality of upper limb movement in children with cerebral palsy. This new information about the effectiveness of home programs is significant because these progress gains reflect what parents and therapists identify as most clinically important for children with cerebral palsy to achieve. The results also suggest that home programs that intervene at the activities level of the ICF should be considered an essential aspect of children with cerebral palsy’s intervention plan. This new information could be gained by therapists via self-directed reading and professional development.
The home programs involved the occupational therapist providing active support to the parent to implement the home program intervention. This is perhaps a paradoxical concept to therapists and managers who tend to view home programs as an indirect therapy approach. The home program approach recommends that occupational therapists remain involved with a family while they are implementing a home program rather than becoming progressively less involved and handing over care entirely to the family. The findings of the parent interviews in particular suggest that the implementation support aspect of the approach is of vital importance to the family achieving and perceiving a successful outcome. The potential clinical gains in terms of improved function from this increased support, appear highly worthwhile.

In order to further advance the home program evidence base which has lagged behind clinical practice, therapists may benefit from exploring mindsets that exist about the usefulness of home programs. Two issues worthy of consideration and re-interpretation in light of the new evidence presented in this dissertation are the value therapists place on home programs in a continuum of service delivery options, and non-compliance thinking. Home programs have been traditionally viewed as a secondary intervention strategy, prescribed to support the expert direct services provided by an occupational therapist. In the RCT function improved (COPM p=.01), the rate of goal achievement improved (GAS p=.01) and quality of upper limb movement improved (QUEST p=.01) all by means of the home program intervention not hands-on therapy. These results indicate that the expert caregiving of parents provided through a home program is highly effective, when supported by the therapist using goal-focused task practice and parent education. These findings could be used as a learning tool to encourage therapists to examine the added value of parental input via home programs and understand the potential implications for families who use therapy services. Instruction in the home program approach and examining the new underpinning evidence base may help therapists better prepare for
interactions with parents of children with disabilities. Parents generally seek intense hands-on therapy, instead of home program intervention, believing that more is better (Hinojosa, 1990). Therapists who understand and use the home program approach are more likely to communicate to parents that this approach is effective and worthwhile. The approach described in this study, could be presented to parents as an effective strategy for enhancing parental caregiving skills, and as a proven strategy to achieve meaningful therapeutic outcomes for the child. Not only are both these outcomes essential for effective intervention but importantly they are now underpinned by good quality evidence.

Another prevalent therapist belief is that parents do not use home programs (Molineux, 1993). The present study identifies that nearly all participants in the RCT did use home programs diligently. The non-compliance mindset about home programs appears to have arisen from occupational therapists’ appraisal of pharmacology compliance literature (Law & King, 1993; Mayo 1981; Molineux, 1993). Views may also have come from anecdote and clinical observation. The findings of the RCT suggest that parents of children with cerebral palsy in fact practice home programs regularly (15 minutes, 4 times per week). It may be that the focus of the study, their role as trial participants and volunteers, and the level of therapist support may have led to home program practice that was greater than “usual”. Even with these caveats it is apparent that participation was regular, consistent and was recommended by participants as worthwhile in the interviews. Non-compliance thinking belongs to a former medical approach to care, where the therapist knew what was best for the child (Bazyk, 1989; Hanna & Rodgers, 2002). It is not relevant when working from the FCP approach. Furthermore, parents in this study advised clinicians that applying pressure to comply with home programs was counterproductive. Pressure to comply tended to make parents want to withdraw from the service. Participants indicated that the absence of compliance pressure coupled with the other key program features, such as parent support, education and progress updates, actually motivated them
to use the home program more. Therapists must weigh up compliance versus family-centred thinking in relation to an intervention approach that truly will facilitate the parents’ central role rather than the therapist in the role of director and decision-maker.

The finding that two goals are the actual number of goals simultaneously implemented by parents (the RCT finding), coupled with their desire for inter-disciplinary home programs (the parent interviews finding), has important implications for clinical practice. Therapists working in multidisciplinary teams need to work very closely with families to identify and prioritise goal areas ensuring that at any one time two goals are the focus. This appears to be the desirable number families for them to successfully adapt recommendations into their family routine. Two goals may reduce the volume of information supplied to a family at any one time and therefore may necessitate change in the way teams work with families in order to provide comprehensive care.

It is also recommended that therapists routinely use outcome measures to detect change following home program intervention. Outcome measurement is already considered by experts to be desirable for good practice, because it offers the following benefits to therapists: assistance with clinical decision-making, provision of a systematic way to monitor intervention, effectiveness and efficiency data generation and accountability (Bowman et al, 2002). The findings of parent interviews highlighted that not only is outcome measurement desirable but that it is in fact essential to the success of home programs. One of the key strategies that the interviewed families used to motivate themselves was getting progress updates from the therapist on outcome measures. Use of standardised outcome measures provides therapists with a way of giving unbiased clinical feedback to families. The COPM and GAS were both suitable for this function. Both tools are psychometrically sound, sensitive to change in this population and have good clinical utility (Cusick, McIntyre, Novak & Lowe, 2006). They also enabled the family to set goals that were meaningful to them for intervention and thus fitting into FCP (Cusick et al,
2006). The fact that the COPM measures also satisfaction is important as satisfaction with care is known to affect how much people use an intervention (Naar-King et al, 2000).

6.4.4 Implications for Research

This study provided answers to important clinical questions about home program intervention for children with cerebral palsy. The study filled the gap in the literature for an RCT to test home program effectiveness (Novak et al, 2007). The study design addressed the need to account for children’s maturation effects which may have partially explained the encouraging results of the earlier pilot (Novak et al, 2007). The study was designed based upon the factors identified in the pilot research (Novak et al, 2007) and had adequate statistical power to detect change. However, many important home program research issues still need to be explored.

Perhaps the most important of these is examining the issue of intensity and duration. More rigorous research, using the RCT design, is now needed about optimal home program intervention intensity and duration. Intense hands-on therapy has been investigated, and no additional benefit over routine amounts of therapy for children with cerebral palsy was observed (Bower et al, 2001). Rather, intermittently increasing the intensity, separated by short rests, may lead to better outcomes for children with cerebral palsy (Bower & McLellan, 1992; Bower et al, 1996; Trahan & Malouin, 2002). Home program intensity needs to be researched, to determine whether or not using an intensive phase of home program intervention, dispersed with short breaks, may also lead to the same or even better outcomes. The findings of such a study will help provide evidence to support or refute the “more is better” thinking that parents and therapists maintain (Hinojosa, 1990).

Researchers conducting paediatric rehabilitation trials in the future must account for parental input given at home as a potential confounding variable in any clinical outcome that is achieved and recorded in the clinic. The specificity of future paediatric
intervention effectiveness studies may be improved through quantification of the parental contribution to the child’s outcome. The extraneous variable of parental input can be measured by researchers using a log calendar.

This RCT was not designed to measure the long-term effect of home programs. Best available evidence in the cerebral palsy field suggests that repeated practice leads to bigger gains and therefore future trials that investigate the effect of home programs over a longer period of time are likely to provide useful information for planning intervention for children with life-long conditions. A study designed to measure the long-term gains from home program intervention may be worthwhile.

More research is needed about the parental experience of implementing home programs, especially in light of resource constraints that underpin the increasing use of home programs. The findings of parent interviews appear to indicate that research exploring the longitudinal impact of home program intervention on both children and families may be warranted. More research is indicated exploring whether the early and sustained provision of support to parents, via home programs, actually builds stronger more resilient families. Based on parent interview data, it is conceivable that the receipt of this type of support may mitigate known consequences of parenting a child with a disability, such as stress and depression (Beckman, 1991; Brehaut et al, 2004; Hansen & Hanline, 1990). This hypothesis may be worth testing in another research study.

Parenting a child with cerebral palsy is stressful and involves complex challenges (Beckman, 1991; Brehaut et al, 2004; Hansen & Hanline, 1990). One of the many challenges involved in “transformed parenting” is implementing home programs. This study has demonstrated that it is possible to provide home programs in a way that does not turn parents into therapists but instead provides role clarity and support that sustains them. These findings are important because Australian parents describe experience great stress using services (Thompson, 1998) and it appears that this model of service helps to alleviate
stress by provision of vital support. Further exploration of this issue in a qualitative study would help illuminate the parent experience of using home programs.

6.5 Synopsis

This chapter discussed study findings in the context of literature, highlighted original discoveries and implications for education, policy, practice and research. The results of this study provide evidence that home programs should be part of routine clinical practice for children with cerebral palsy. Hannah’s mother perhaps summarises this finding best: “I think it’s actually quite essential to have a home program!”
References


Orphius, P. (2003). What is the evidence for increased intensity of physiotherapy leading to better outcomes for children with cerebral palsy. www.thеспasticcentre.org.au


Appendices

Appendix A: Sample Home Program and Outcome Measurement Data for Hannah
Appendix A-1 Hannah’s Example Home Program

Clinical Reasoning Notes

1. Each home program was developed on a “blackboard” background to reinforce the concept that the
   concept that the home program was an “educational” resource to the parent.

2. The program was written down and presented in colour with pictures to reflect parents known home
   parents known home program preferences (Novak & Casick, 2006)

3. Each page included a statement “For support implementing the program call XXXXXXX”, to reinforce
   XXXXXXX”, to reinforce the availability of the therapist to support the home program implementation
   implementation
Clinical Reasoning Notes

The second page of the program included "parent education" information about how to choose what to implement in the home program. This information was based on an understanding of the ecological perspective that sustainable routines are important for family functioning. It also sought to ensure that the parent was the decision-maker, consistent with the philosophy of family-centred practice.

For some families, this page included extra information about how to develop routines, or how to develop a reward system for their child. This information was included or omitted based on the child’s learning needs and the level of motivation identified during the assessment.
This program is working if Hannah...

1. Expands her 'early construction' play
2. Keeps her arms on the table
3. Maintains her grip longer than 1 second for finger-feeding
4. Learns one step of undressing e.g. removing socks

Clinical Reasoning Notes

The third page in the program included “parent education” information about how to detect an improvement in their child, in response to the program. This information was provided to respond to parent’s request to be taught by the therapist about how to detect progress (Novak & Cusick, 2008). The topics were developed by the parents in the goal setting interview. The progress statements were developed from the Goal Attainment Scales, reflecting the expected level of goal attainment from the program (“zero level”).

Clinical Reasoning Notes

1. The program then moved to describing a "library of ideas" about activities designed to assist the family reach their goal. The information was provided as: (a) “parent tips” or “parent teaching instructions” – which were “parent education” and “positive behavior support” interventions designed to enhance parenting skills; (b) “home environment” – which were environmental set up adaptations or specialist equipment designed to facilitate the child’s independence and success; and (c) “child activities” – which were activities for the child to practice to expand their development in the goal area.

2. Information (parent education) was provided to the parent about what would constitute the next developmental stage of play for Hannah, and what toys (environment adaptation) would facilitate Hannah to achieve play in this way.
Clinical Reasoning Notes

The "child activities" were provided after the "parent education" and "environmental adaptations" listed on the previous page.

The child activities linked to the list of toys present in the environmental adaptations section.
Clinical Reasoning Notes

The child activities were linked to parent education strategies about how to perform the activity in a therapeutic way, responding to parent’s request to be taught how to implement the program as the therapist intended it to be (Novak & Cusick, 2006).
Clinical Reasoning Notes

1. A picture was provided to demonstrate how to make the environmental modifications to Hannah’s chair.

   This was provided as a follow-up reminder to the face-to-face demonstration that Hannah’s mother

   (Kate) was provided with, to reflect parent preferences about home program documentation (Novak &

   Czink, 2006).

2. The “child activities” were designed around the family’s unique home routine and environment, where

   swimming in the backyard pool was a regular family activity.
Clinical Reasoning Notes

The program continued onto the next goal focus area, by providing information as: (a) “parent tips” or “parent teaching instructions” – which were parent education and positive behaviour support; (b) “home environment” – which were environmental set up adaptations or specialist equipment designed to facilitate the child's independence and success; and (c) “child activities” – which were activities for the child to practice to expand their development in the goal area.
removing socks

**Parent Teaching Strategy**

✓ You may do this by *backward chaining* where you initially grasp the sock and have Hannah perform step 2. Backward chaining allows Hannah to experience the success of completing the task, which can increase learning and motivation.

**Child Activities**

✓ Step 1. Hannah grasps toe of sock using hand of choice
✓ Step 2. Hannah removes sock by pulling the toe of the sock one way and pulling the foot the other way.

**Clinical Reasoning Notes**

The program concluded with the Child activities for dressing, coupled with the parent education and environmental adaptations to facilitate Hannah’s success. Gain the program included a picture to reflect parent’s home program documentation preferences. (Novak & Cusick, 2006)
## Appendix A-2 Hannah’s Example Canadian Occupational Performance Measure (COPM) Score Sheet

NOTE: The COPM is a copyright instrument. This form has been reproduced here only for the purpose of illustrating appendix data with identifiers removed. All study participants’ data was recorded on original copyright forms, purchased for the purpose of the study.

<table>
<thead>
<tr>
<th>STEP 1: IDENTIFICATION OF OCCUPATIONAL PERFORMANCE ISSUES</th>
<th>STEP 2: RATING PERFORMANCE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>STEP 1A: Self-Care</strong></td>
<td></td>
</tr>
<tr>
<td>Personal Care (e.g. dressing, bathing, feeding, hygiene)</td>
<td></td>
</tr>
<tr>
<td>Hand use for finger feeding</td>
<td>8</td>
</tr>
<tr>
<td>Hand use for spoon feeding</td>
<td>6</td>
</tr>
<tr>
<td>Hand use for undressing</td>
<td>1</td>
</tr>
<tr>
<td>Functional Mobility (e.g. transfers, indoor, outdoor)</td>
<td></td>
</tr>
<tr>
<td>Community Management (e.g. transportation, shopping, finances)</td>
<td></td>
</tr>
<tr>
<td><strong>STEP 1B: Productivity</strong></td>
<td></td>
</tr>
<tr>
<td>Paid/Unpaid Work (e.g. finding keeping a job, volunteering)</td>
<td></td>
</tr>
<tr>
<td>Household Management (e.g. cleaning, laundry, cooking)</td>
<td></td>
</tr>
<tr>
<td>Play/School (e.g. play skills, homework)</td>
<td>Maintains arms onto table top</td>
</tr>
<tr>
<td><strong>STEP 1C: Leisure</strong></td>
<td></td>
</tr>
<tr>
<td>Quiet Recreation (e.g. hobbies, crafts, reading)</td>
<td>Independent play without supervision</td>
</tr>
<tr>
<td>Active Recreation (e.g. sports, outings, travel)</td>
<td>Use of hands to sustain grip of toys</td>
</tr>
<tr>
<td>Socialization (e.g. visiting, phone calls, parties, correspondence)</td>
<td></td>
</tr>
</tbody>
</table>
## Initial Assessment:

<table>
<thead>
<tr>
<th>OCCUPATIONAL PERFORMANCE PROBLEMS</th>
<th>PERFORMANCE 1</th>
<th>SATISFACTION 1</th>
<th>PERFORMANCE 2</th>
<th>SATISFACTION 2</th>
<th>PERFORMANCE 3</th>
<th>SATISFACTION 3</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Independent play</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1.5</td>
<td>1.5</td>
</tr>
<tr>
<td>2. Arms on table top</td>
<td>3</td>
<td>2</td>
<td>5</td>
<td>4</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>3. Finger feeding</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>4. Spoon feeding</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>3</td>
<td>5</td>
<td>3</td>
</tr>
<tr>
<td>5. Undressing</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
<td>1</td>
<td>5</td>
</tr>
</tbody>
</table>

**Performance Score:**
- Initial Assessment: 3.0
- Reassessment: 3.4

**NOTE:** Shading denotes goals worked on by family.
Appendix A-3 Hannah’s Example Goal Attainment Scale Score Sheet

**Goal 1: Arms on table top**  
Time frame: 8 weeks  
Weight: 3

<table>
<thead>
<tr>
<th>Score</th>
<th>Attainment Levels</th>
<th>Baseline</th>
<th>4-weeks</th>
<th>8-weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>+2</td>
<td>Hannah’s arms are “stuck” behind her back 0-25% of the time</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>+1</td>
<td>Hannah’s arms are “stuck” behind her back 25-50% of the time</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>0</td>
<td>Hannah’s arms are “stuck” behind her back 50-75% of the time</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>-1</td>
<td>Hannah’s arms are “stuck” behind her back 75-100% of the time</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>-2</td>
<td>Hannah’s arms are “stuck” behind her back 100% of the time</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

**Goal 2: Holds toy for independently play**  
Time frame: 8 weeks  
Weight: 2

<table>
<thead>
<tr>
<th>Score</th>
<th>Attainment Levels</th>
<th>Baseline</th>
<th>4-weeks</th>
<th>8-weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>+2</td>
<td>Holds cylindrical shaped toy 4-10 seconds</td>
<td></td>
<td>✓</td>
<td></td>
</tr>
<tr>
<td>+1</td>
<td>Holds cylindrical shaped toy 2-4 seconds</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>0</td>
<td>Holds cylindrical shaped toy 1-2 seconds</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>-1</td>
<td>Holds cylindrical shaped toy 0-1 second</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-2</td>
<td>Drops cylindrical shaped toy immediately</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>

**Goal 3: Holds a spoon**  
Time frame: 8 weeks  
Weight: 1

<table>
<thead>
<tr>
<th>Score</th>
<th>Attainment Levels</th>
<th>Baseline</th>
<th>4-weeks</th>
<th>8-weeks</th>
</tr>
</thead>
<tbody>
<tr>
<td>+2</td>
<td>Holds a spoon voluntarily for 0-4 seconds during mealtimes on 2 occasions</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>+1</td>
<td>Holds a spoon voluntarily for 2-4 seconds during mealtimes</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>Holds a spoon voluntarily for 1-2 seconds during mealtimes</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
<tr>
<td>-1</td>
<td>Holds spoon voluntarily for 0-1 second</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>-2</td>
<td>Unable to hold a spoon, does not close hand around spoon and drops immediately</td>
<td></td>
<td></td>
<td>✓</td>
</tr>
</tbody>
</table>
Appendix B: Ethics Approvals
Appendix B-1 Ethics Committees’ Approval Letters

University of Western Sydney

24 May 2006

Iona Novak
Manager Research & Education
Spastic Centre
PO Box 184
Brookvale NSW 2100

Dear Iona,

HREC 06/031 Effectiveness of occupational therapy home program intervention for children with Cerebral Palsy: A double blinded randomised controlled trial

The Committee has agreed to fully endorse the above mentioned research project.

You are advised that the Committee should be notified of any further change/s to the research methodology should there be any in the future. You will be required to provide a report on the ethical aspects of your project at the completion of this project. The form is located on the Research Services Ethics Web Page.

The Protocol Number HREC 06/031 should be quoted in all future correspondence about this project. Your approval will expire 28 February 2009. Please contact the Human Ethics Officer, Kay Buckley on tel: 02 47 360 883 if you require any further information.

The Committee wishes you well with your research.

Yours sincerely,

[Signature]

Associate Professor Louise O’Brien
Acting Chairperson & Deputy Chairperson
UWS Human Research Ethics Committee
Cc Professor Anne Cusick

15/03/2006

Iona Novak  
Cerebral Palsy Institute  
PO Box 184  
Brookvale NSW 2100

Dear Iona,

RE: Effectiveness of Occupational Therapy Home Program Intervention for Children with Cerebral Palsy: A Double Blinded Randomised Controlled Trial

Your application for research and ethics approval from The Spastic Centre has been approved.

This project is now approved for a period of three years. If you need further time to complete the project you will be required to request an extension.

Please supply a one-page summary of your progress on a yearly basis to the Ethics Committee commencing March 2007. A final report on completion and notification of any publications from this project is also requested.

The Ethics Committee wishes you well with this important project,

Yours sincerely,

Sarah McIntyre  
Research Fellow  
On behalf of Research and Ethics Committee

The Spastic Centre is a NHMRC HREC: EC04/C2
Appendix B-2 Ethics Committee Application

National Ethics Application Form

Version 1.1

PROPOSAL TITLE: Effectiveness of Occupational Therapy Home Program Intervention for Children with Cerebral Palsy: A Double Blinded Randomised Controlled Trial.

FOR SUBMISSION TO: Royal Children’s Hospital and Health Services District Ethics Committee (EC00176)
The Spastic Centre Ethics Committee (EC00402)
University of Western Sydney Human Research Ethics Panel (EC00313)

PROPOSAL STATUS: Complete

COMPLETION DATE: 21/04/2007

APPLICANT: Ione Novak

INSTITUTION: The Spastic Centre

ADDRESS: Cerebral Palsy Institute
          PO Box 184
          Brookvale NSW 2100

CONTACT NUMBERS: Business Hours 0409078917
                 After Hours 0409078917
                 Mobile 0409078917
                 Fax 02 94514877

PROPOSAL DESCRIPTION:
Children with cerebral palsy benefit from therapy that is goal-directed in their daily activities and environment. It is hypothesised that their parent’s contribution via home exercise programming is also important for goal achievement. This hypothesis has not been tested in a randomised controlled trial, the appropriate research design for studying intervention effectiveness. Benefits of home programs have been shown in my earlier Masters pilot study, which lacked a controlled comparison group. When measuring children, any improvements observed may be due to maturation and therefore a control group is the preferable design. This study will address this gap.
Study Aims:
1. Determine whether or not home program intervention (Novak & Ousick, 2008) is more effective than no occupational therapy intervention at all for children with cerebral palsy.
2. Determine the family experience of participating in home programs, the factors that affect their participation, and the processes that comprise the home program experience, to identify issues relevant to service design and delivery.

POINTS TO REMEMBER:
This document has been created using the online National Ethics Application Form (NEAF) - available at www.neaf.gov.au. The set of questions that appear in this document have been generated as a result of answers you have provided to specific questions in NEAF. For this reason, the contents of this document are unique to this research ethics proposal and should not be used as the basis for future proposals. New proposals for submission to Human Research Ethics Committees must be generated using NEAF online.

Should you wish to use the contents of this document for other purposes:
- You can copy and paste text out of a PDF document in Adobe Acrobat by using the ‘Tools’ > ‘basic’ > ‘text select’ button.
1. TITLE AND SUMMARY OF PROJECT

1.1. Title

1.1.1 What is the formal title of this research proposal?
Effectiveness of Occupational Therapy Home Program Intervention for Children with Cerebral Palsy: A Double Blinded Randomised Controlled Trial.

1.1.2 What is the short title / acronym of this research proposal (if applicable)?
Home Program Effectiveness

1.2. Description of the project in plain language

1.2.1 Give a concise and simple description (not more than 400 words), in plain language, of the aims of this project, the proposal research design and the methods to be used to achieve these aims.

Children with cerebral palsy benefit from therapy that is goal-directed in their daily activities and environment. It is hypothesised that their parent's contribution via home exercise programming is also important for goal achievement. This hypothesis has not been tested in a randomized controlled trial, the appropriate research design for studying intervention effectiveness. Benefits of home programs have been shown in my earlier Masters pilot study, which lacked a controlled comparison group. When measuring children, any improvements observed may be due to maturation and therefore a control group is the preferable design. This study will address this gap.

Study Aims:
1. Determine whether or not home program intervention (Novak & Cusich, 2005) is more effective than no occupational therapy intervention at all for children with cerebral palsy.
2. Determine the family experience of participating in home programs, the factors that affect their participation, and the processes that comprise the home program experience, to identify issues relevant to service design and delivery.

1.3. Type of Research

1.3.1 Tick as many of the following ‘types of research’ as apply to this project. Your answers will assist HREC in considering your proposal. A tick in some of these boxes will generate additional questions relevant to your proposal (mainly because the National Statement requires additional ethical matters to be considered), which will appear in Section 4 of NEAP.

This project involves:
- [ ] Qualitative research
- [ ] Research on workplace practices or possibly impacting on workplace relationships
- [ ] Research conducted overseas involving participants
- [X] Research involving deception of participants, concealment or covert observation
- [ ] Epidemiological research
- [X] Administration of a drug for research but not clinical research
- [X] Clinical research (excluding those under the CTN/CTX schemes)
- [ ] Clinical trial under CTN/CTX scheme
- [ ] Research involving ionizing radiation
- [ ] Research involving the use of embryos and/or gametes
- [ ] Genetic testing/research
- [ ] Research involving the collection and / or use of human samples
- [ ] Research involving assisted reproductive technologies (ART)
- [ ] None of the above

1.4. Research participants

1.4.1 The National Statement requires additional information to be provided to an HREC where research participants are certain or likely to include any of the categories of people listed in this question. HREC need to know whether you intend to include or to exclude any of these categories. Answer this question by:
(a) selecting any of these categories that are certain or likely to be included as participants in this research project,
(b) selecting any other of these categories that will be excluded from participation, and
(c) selecting any other of these categories who may be adversely affected by this research.

Where you select a category for inclusion, you will be required to answer additional questions later in the form.

1.4.2 Where any of the following participant populations may be involved, the National Statement requires additional information to be provided to the HREC. Tick as many of the following ‘types of
The participants who may be involved in this research are:

<table>
<thead>
<tr>
<th>Research participants' as apply to this project. If none apply please indicate this below. A tick in some of these boxes will require you to answer additional questions later in the form.</th>
</tr>
</thead>
<tbody>
<tr>
<td>a) Intended or targeted</td>
</tr>
<tr>
<td>People whose primary language is other than English (LOTE)</td>
</tr>
<tr>
<td>Children and/or young people (ie. &lt; 18 years)</td>
</tr>
<tr>
<td>People with an intellectual or mental impairment</td>
</tr>
<tr>
<td>People highly dependent on medical care</td>
</tr>
<tr>
<td>People in existing dependent or unequal relationships with any member of the research team, the researcher(s), and/or the person undertaking the recruitment/consent process (eg. student/teacher; employee/employer; warden/prisoner; officer, enlisted soldier; patient/doctor)</td>
</tr>
<tr>
<td>People who belong to a collectivity</td>
</tr>
<tr>
<td>Aboriginal and/or Torres Strait Islander peoples</td>
</tr>
</tbody>
</table>

1.5. Research techniques

1.5.1 The research techniques to be used in this project include (you must tick at least one). Tick as many as apply:

- [ ] Observation of non-identified people in public places
- [ ] Observation of identifiable people in non-public places
- [ ] Interviews - telephone
- [ ] Interviews - face to face
- [ ] Documentary/records analysis
- [ ] Focus groups
- [ ] Data linkage
- [ ] Physical activities / exercises / tests
- [ ] Taping - audio / video
- [ ] Biomedical / clinical interventions, tests, samples
- [ ] Use of complementary or alternative medicine, or a natural therapy
- [ ] Photos
- [ ] Use of gene therapy
- [ ] Survey instrument / questionnaire / diary
- [ ] Use of a medical device
- [ ] Internet / web based research
- [ ] Computer based tests
- [ ] Other techniques
2. RESEARCHERS

2.0. Applicant

Provide the following information for the person making this application to the HREC.

2.0.1. Name and contact details

2.0.1.1 Title
Ms

2.0.1.2 First Name
Iona

2.0.1.3 Surname
Novak

2.0.1.4 Mailing Address 1
PO Box 184

2.0.1.5 Suburb/Town
Brookvale

2.0.1.6 State
NSW

2.0.1.7 Postcode
2100

2.0.1.8 Organisation Name
Cerebral Palsy Institute

2.0.1.9 Position in organisation
Head of Research

2.0.1.10 Business Hours Phone Number
0409078917

2.0.1.11 After Hours Phone Number (optional)
0409078917

2.0.1.12 Mobile Phone Number (optional)
0409078917

2.0.1.13 Fax Number
02 9451 4877

2.0.1.14 Email Address
inovak@tsnsw.org.au

2.1. Principal researcher(s)

2.1.0. How many principal researchers are there?

2.1.1. Principal researcher 1

2.1.1.1. Name and contact details

2.1.1.1 Title
Ms

2.1.1.2 First Name
Iona

2.1.1.3 Surname
Novak

2.1.1.4 Mailing Address 1
PO Box 184

2.1.1.5 Suburb/Town
Brookvale

2.1.1.6 State
NSW

2.1.1.7 Postcode
2100

2.1.1.8 Organisation name
Cerebral Palsy Institute

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Head of Research

2.1.1.10 Business Hours Phone Number
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0409078917

2.1.1.12 Mobile Phone Number (optional)
0409078917

2.1.1.13 Fax Number
02 9451 4877

2.1.1.14 Email Address
inovak@tsnsw.org.au

2.1.2. Describe the qualifications, expertise and experience of the principal researcher relevant to this project.

2.1.2.1 Qualifications
Doctor of Philosophy (In progress)
Masters of Science (Honours) 2005
Bachelor of Applied Science, Occupational Therapy 1993

2.1.2.2 Expertise
Iona Novak has 13 years clinical experience in providing occupational therapy to people with cerebral palsy. She is

Commercial-in-Confidence

Page 5 of 30
2.1.2.3 Experience

Iona Novak has over seven years research experience in designing, implementing and analysing randomised controlled clinical trials for people with cerebral palsy. Research experience includes: designing and researching hand splints for children with cerebral palsy, evaluating the effect of anti-spasticity medications (botulinum toxin A) on upper limb muscles in cerebral palsy, evaluating the effect of functional electrical stimulation on upper limb muscles in cerebral palsy.

2.1.2.4 Name the site(s) for which this principal researcher is responsible.
The Spastic Centre of NSW and The Royal Children’s Hospital Brisbane

2.1.3 Describe the role of the principal researcher in this project.
Iona Novak has been involved in the conceptual development of this project and taking overall responsibility for this study and its development. She will take responsibility for the conduct of the study and the timely progression of the study. This will include data acquisition and management. She will take a lead role in the analysis and interpretation of the data. Jointly with her supervisory team, Professor Anne Cusick and Dr Natasha Lammin, she will also take a lead role in drafting the publication manuscripts and disseminating the work through conference presentations at local, national and international conferences.

2.1.4 Is the principal researcher a student? Yes

2.1.4.1.1 What is the educational organisation, faculty and degree course of the student?

2.1.4.1.1.1 Organisation University of Western Sydney
2.1.4.1.1.2 Faculty Faculty of Biomedical Sciences
2.1.4.1.1.3 Degree course PhD

2.1.4.1.3 Is this research project part of the assessment of the student? Yes

2.1.4.1.4 What training or experience does the student have in the relevant research methodology?
Iona Novak has already completed a research degree with the University of Western Sydney in 2005 - a Masters of Science (Honours).

Iona Novak has over seven years research experience in designing, implementing and analysing randomised controlled clinical trials for people with cerebral palsy, in her role as Head of Research at the Cerebral Palsy Institute.

2.1.4.1.5 What training has the student received in the ethics of research?
Iona Novak has already completed a Masters of Science (Honours) by research degree with the University of Western Sydney. This degree included development of a human ethics application.

In addition to her role as Head of Research at the Cerebral Palsy Institute, Iona is a member of The Spastic Centre of NSW NHMRC HREC Research & Ethics Committees where the committees review numerous human ethics applications each month. Iona has successfully obtained ethical clearance on excess of 20 applications prior to this project application.

2.1.4.1.6 Describe the supervision to be provided to the student.
Iona Novak receives supervision from Professor Cusick (Primary Supervisor) and Dr Lammin (Co-Supervisor). The supervisors are responsible for advising Ms Novak of applicable government and institutional guidelines for the conduct of research, including those covenanting ethical requirements for studies on human or animal subjects, and the University of Western Sydney Code of Conduct for Responsible Research Practice. As per University of Western Sydney procedures, Professor Cusick is in contact with Ms Novak on a regular basis throughout her candidature in the case of a full-time candidature, contact includes formal meetings of around one hour every three to four weeks and in the case of part-time students, meetings are less frequent and at intervals of around five to six weeks during the calendar year. Informal telephone and email is maintained at least fortnightly alongside the formal meetings.

2.1.4.1.7 How many supervisors does the student have? 2

student have?

2.1.4.1.7.1. Supervisor 1

2.1.4.1.7.1. Provide the name, qualifications, and expertise, relevant to this research, of the students’ supervisor

2.1.4.1.7.1.1 Title Prof
2.1.4.1.7.1.2 First Name Anne
2.1.4.1.7.1.3 Surname Cusick
2.1.4.1.7.1.4 Qualifications Bachelor Applied Science (OT) Cumberland College Health Sciences, 1980
Grad Dip Applied Behavioural Science, Cumberland College Health Sciences, 1982
Master of Arts (Psychology), University of Sydney, 1995
Master of Arts (Interdisciplinary Studies), UNSW, 1988
PhD, Faculty of Medicine, UNSW, 1998
Grad Certificate Business Administration, Charles Sturt University, 2004

2.1.4.1.7.1.5 Expertise Professor Cusick graduated from Cumberland College as an occupational therapist in 1980, working in brain injury and psychiatry prior to her academic career. She has maintained her clinical involvement throughout her academic career through advocacy and career roles, and collaborative research in areas including occupational therapy program outcomes in cerebral palsy, aged care and stroke. Professor Cusick has postgraduate qualifications in arts, social sciences, and business administration and she completed her PhD in Medical Education at the Faculty of Medicine, UNSW in 1998. She has a strong clinical research track record in the successful completion and publication of randomised controlled trials in children with cerebral palsy, as well as in the management of contracture in adults.

2.1.4.1.7.1. Supervisor 2

2.1.4.1.7.1. Provide the name, qualifications, and expertise, relevant to this research, of the students’ supervisor

2.1.4.1.7.1.1 Title Prof
2.1.4.1.7.1.2 First Name Natasha
2.1.4.1.7.1.3 Surname Lannin
2.1.4.1.7.1.4 Qualifications PhD, University of Western Sydney, 2006. Thesis title: “The Effectiveness of Hand Splinting to Prevent Muscle Contracture Following Acquired Brain Impairment”. Graduate Diploma (Case Management), University of Melbourne, 1999. Bachelor of Science (Occupational Therapy), Curtin University, 1994.

2.1.4.1.7.1.5 Expertise Dr Lannin is an occupational therapist whose research, clinical and teaching has focused on rehabilitation of both adults and children as a means to improve quality of life. Her program of research focuses on the use of randomised controlled trials to test common rehabilitation interventions. This focus has resulted in scholarly presentation of research projects undertaken in a variety of clinical settings, and examining the relevance and utility of occupational therapy assessments, interventions and outcomes. In addition to clinical project applications, Dr Lannin has had a steady program of research investigating management of muscle
2.2. Associate researcher(s)

2.2.1 How many known associate researchers are there? (You will be asked to give contact details for these associate researchers at question 2.2.1.1)

2.2.2 Do you intend to employ other associate researchers?

No

2.2.1.0. Associate Researchers 1

2.2.1.1. Name and contact details

2.2.1.1.1 Title

Prol

2.2.1.1.2 First Name

Anne

2.2.1.1.3 Surname

Cusick

2.2.1.1.4 Mailing Address 1

Building 3 Campbelltown Campus

2.2.1.1.5 Mailing Address 2

University of Western Sydney

2.2.1.1.6 Mailing Address 3

Locked Bag 1977

2.2.1.1.8 Suburb/Town

Penrith South

2.2.1.1.9 State

NSW

2.2.1.1.10 Postcode

1977

2.2.1.1.12 Organisation name

University of Western Sydney

2.2.1.1.13 Faculty/department/school or centre name as appropriate (optional)

School of Biomedical and Health Sciences

2.2.1.1.14 Position in organisation

Chair, Academic Senate

2.2.1.1.15 Business Hours Phone Number

(02) 46203346

2.2.1.1.19 Fax Number

(02) 46203792

2.2.1.20 Email Address

acusick@uws.edu.au

2.2.1.2. Describe the qualifications, expertise and experience of the associate researcher relevant to this project.

2.2.1.2.1 Qualifications

Bachelor Applied Science (OT) Cumberland College Health Sciences, 1980
Grad Dip Applied Behavioural Science, Cumberland College Health Sciences, 1982
Master of Arts (Psychology), University of Sydney, 1985
Master of Arts (Interdisciplinary Studies), UNSW, 1988
PhD, Faculty of Medicine, UNSW, 1998
Grad Certificate Business Administration, Charles Sturt University, 2004

2.2.1.2.2 Expertise

Professor Cusick graduated from Cumberland College as an occupational therapist in 1980, working in brain injury and psychiatry prior to her academic career. She has maintained her critical involvement throughout her academic career through advocacy and career roles, and collaborative research in areas including professional accreditation, evaluation of therapy program outcomes in cerebral palsy, aged care and strokes. Professor Cusick has a strong clinical research track record in the successful completion and publication of randomised controlled trials in children with cerebral palsy, as well as in the management of contracture in adults.

2.2.1.2.3 Experience

Anne Cusick is Professor and Chair of Academic Senate at
2.2.1.3 Description of the role of the associate researcher in this project.

Professor Cusick is the principle supervisor and has been involved in the conceptual development of this project. She will jointly take responsibility for the conduct of the study and the timely progression of the study. She will take a lead role in the drafting of manuscripts, and will contribute to other papers led by the other CIs and they utilise data from this study.

2.2.1.3.1 Name the site at which the associate researcher has responsibility.

Spastic Centre NSW and The Royal Children’s Hospital (Brisbane).

2.2.1.4 Is the researcher a student? No

2.2.1.0. Associate Researchers 2

2.2.1.1. Name and contact details

2.2.1.1.1 Title
2.2.1.1.2 First Name
Dr Natasha
2.2.1.1.3 Surname
Lannin
2.2.1.1.4 Mailing Address 1
Rehabilitation Studies Unit
2.2.1.1.5 Mailing Address 2
University of Sydney
2.2.1.1.6 Mailing Address 3
PO Box 6
2.2.1.1.7 Suburb/Town
Ryde
2.2.1.1.8 State
NSW
2.2.1.1.9 Postcode
1690
2.2.1.1.12 Organisation name
Rehabilitation Studies Unit, University of Sydney
2.2.1.1.14 Position in organisation
Lecturer
2.2.1.1.15 Business Hours Phone Number
(02) 9909 9234
2.2.1.1.19 Fax Number
(02) 9909 9037
2.2.1.1.20 Email Address
n.lannin@usyd.edu.au

2.2.1.2. Describe the qualifications, expertise and experience of the associate researcher relevant to this project.

2.2.1.2.1 Qualifications

2.2.1.2.2 Expertise
Dr Lannin is an occupational therapist whose research, clinical and teaching has focused on rehabilitation of both adults and children as a means to improve quality of life. Her program of research focuses on the use of
2.2.1.3 Experience

Dr Lannin is an experienced researcher who demonstrates a publication record, successful grant funding for research, and has over 5 years of experience in conducting multi-centre randomised controlled trials. She is a recipient of the prestigious OT-Australia Research Award for her contribution towards the advancement of the research base of occupational therapy. Dr Lannin has extensive clinical experience in using the proposed procedures and currently teaches these procedures to university students and clinicians.

2.2.1.3 Description of the role of the associate researcher in this project.

Dr Lannin is the co-supervisor and has been involved in the conceptual development of this project. She will jointly take responsibility for the conduct of the study and the timely progression of the study. She will take a lead role in the drafting of manuscripts, and will contribute to other papers led by the other CIs and they utilise data from this study.

2.2.1.3.1 Name the site at which the associate researcher has responsibility.

The Spastic Centre NSW and The Royal Children’s Hospital (Brisbane).

2.2.1.6 Is the researcher a student? No

2.3. Other personnel relevant to the research project

2.3.1 How many known other people will play a specified role in the conduct of this research project?

2.3.1.1 Describe the role, and expertise where relevant (e.g. counsellor), of these other personnel. Blind Occupational Therapy Rater - Nicole Sharp

An independent rater needs to be employed to score the children’s home program outcomes data. This task cannot be undertaken by me as the principle investigator as I am not blinded to the children’s group allocation and order of assessments. Nicole is an occupational therapist, who is currently undertaking doctoral studies in the area of cerebral palsy. She has been trained to rate clinical data from video footage by the Principle Investigator. Nicole has been employed by the team on previous occasions to blind rate video footage for randomised controlled trials. Nicole is an employee of the Cerebral Palsy Institute and is covered by the human Ethics Application at The Spastic Centre of NSW, where she also receives indemnity insurance.

2.3.2 Is it intended that other people, not yet known, will play a specified role in the conduct of this research project? No

2.4. Certification of researchers

2.4.1 Are there any relevant certification, accreditation or credentialing requirements relevant to the conduct of this research? No

2.5. Training of researchers

2.5.1 Do the researchers or others involved in any aspect of this research project require any additional training in order to undertake this research? No
3. PROJECT

3.1. Duration and location

3.1.1 In how many Australian sites, or site types, will the research be conducted?

Provide the following information for each site or site type (Australian and overseas, if applicable) at which the research is to be conducted.

3.1.3. Site / Site Type 1

3.1.3.1 Site / Site Type Name

The Spastic Centre

3.1.3.2 Site / Site Type Location

Spastic Centre locations including:
- Sydney North and East Region at the McLeod Centre, 187 Allambie Road, Allambie Heights, NSW; Ryde Centre, 11 Smells Road, Ryde NSW;
- Sydney South West Region at Fairfield City Moncrief Centre, 22B Rainwell Road, Prairiewood NSW;
- Penrith Centre, 222 High Street, Penrith NSW;
- Hunter and Central Coast Region at Stuart Centre, Parklea Avenue, Croudcare Bay, NSW; Kids in the Valley, 417-417 John Street, Singleton, NSW; and 132 Adalade Street, Raymond Tce, NSW 2224; Kids on the Coast, at the Berkeley Centre, 2 Berkeley Road, Pennington NSW.

3.1.3. Site / Site Type 2

3.1.3.1 Site / Site Type Name

Royal Children's Hospital

3.1.3.2 Site / Site Type Location

Herston Road, Herston, Queensland 4029

3.1.4. Provide the start and finish dates for the whole of the study including data analysis

3.1.4.1 Anticipated start date 01/02/2006

3.1.4.2 Anticipated finish date 01/02/2009

3.1.5 Are there any time-critical aspects of the research project of which an HREC should be aware?

No

3.2. Research plan

3.2.1 Describe the theoretical, empirical and/or conceptual basis, and background evidence, for the research proposal, eg. previous studies, anecdotal evidence, review of literature, prior observation, laboratory or animal studies. N5.1.13

Home programs have been seen as important by occupational therapists and physiotherapists for children with cerebral palsy since the 1970s (Finnis, 1975; Hinoyosa & Anderson, 1991; Mayo, 1981; Moorsch, 1985; Schreiber et al., 1995). The Home program intervention has evolved beyond earlier approaches where parents used to assume the role of therapist at home to support expert care between treatment sessions (Elazik, 1989; Saglois, 1991). Now, within the family-centred practice model, the daily caregiving of parents is viewed as an opportunity for therapy (Thompson, 1998). This subtle, yet important change, assumes that supporting families in their caregiving role promotes the child’s development (Thompson, 1998). Occupational therapists now believe that, working with parents in reviewing home instructions and teaching therapy techniques has a greater impact on a child with a disability than any other aspect of intervention (Hinoyosa et al., 2002). As a consequence, increased numbers of parents of children with cerebral palsy are involved in home programs.

What is missing in the field of home program research is that in spite of their persistent popularity, occupational therapists have failed to ask the fundamental question: whether or not home programs actually work? Up until very recently there wasn’t even an evidence-based guideline in existence about what home programs for children with cerebral palsy should look like (Novak & Cusick, 2006). In addition to concerns about what should be done in a home program, parents want to know, how much therapy is enough? operating from the belief that more must be better (Hinoyosa, 1999). There are currently no definitive answers to questions of home program intensity in the research literature. Indeed, there is surprisingly little investigation of home programs in the area of cerebral palsy treatment.
This study fits into a broader cerebral palsy research agenda that is seeking to understand the outcomes of goal-directed intervention, provided in natural environments, within the context of the family-centred approach (Eckstrom et al., 2005; Law et al., 1998).

Much of the home program research prior to adopting Family Centred Practice focussed on (1) whether parents do what they are told, that is whether they comply with prescribed home programs (Molinueux, 1993); the assumption being that potential health benefits were being lost through parental non-compliance (Molinueux, 1993) because therapists knew best (Bazuk, 1989; Hanna & Redgers, 2002); and (2) the impact on parent-child relationships of training parents to become therapists (Turnbull & Turnbull, 1978; Tyler & Kogan, 1972). Less research attention has been given to whether or not these home programs actually help parents achieve their hopes and goals for their child. The efficacy of home programs is a vast gap in our therapy knowledge base. One explanation for this knowledge gap may be that evidence-based practice was adopted well after home programs became standard practice. No one thought to ask the obvious question, do home programs work? Now occupational therapists must take steps to justify the effectiveness of their recommended interventions (Lloyd-Smith, 1997).

3.2.2 State the aims of the research and the research question and/or hypotheses, where appropriate.

The research problem which remains unknown is: What is the impact of home program intervention for children with cerebral palsy? To understand and analyse this question a prospective double-blind randomised controlled trial was undertaken, together with semi-structured parental interviews.

The overall purpose of this study was to evaluate the efficacy of home program intervention for assisting children with cerebral palsy to attain goals meaningful to them, improve their independence in self-care, and improve their participation in everyday life activities. The specific aims of the study were to:

a. Describe and measure the outcomes of implementing protocol home program intervention to children with cerebral palsy
b. Compare the differences in outcomes of implementing a protocol home program for short versus longer periods of time, specifically 4 weeks versus 8 weeks
c. Compare the outcomes of not implementing any home program intervention versus implementing a protocol home program
d. Describe the outcomes of home program intervention from the perspective of the International Classification of Disability and Functioning (ICF) framework
e. Describe the self-selected implementation practices of parents who choose to use a home program
f. Illustrate practice recommendations for parents, therapists, and service managers about protocol home program intervention by understanding the parental experience

3.2.3 Describe how the research design and the methods to be used will enable the research aims to be achieved.

Home programs have been adopted by many professionals, including occupational therapists, as a major strategy for addressing the health and development needs of children with cerebral palsy (Bazuk, 1989; Gajdosik, 1991; Hinjosa & Anderson, 1991; Law & King, 1993; Molinueux, 1993; Schreiber et al., 1995). Widespread uptake has been driven by (1) the need to reduce the significant costs of providing life-long therapy services to people with cerebral palsy (Law et al., 1993); (2) a belief that parental input is important, which grown out of the gold standard philosophy of Family-Centred Practice, where parental care-giving expertise is recognised and fostered (Bazuk, 1989; Rosenbaum et al., 1990; Ahlmann, 1994; Dorman & Pellegrino, 1998; Roberts & Magnier, 1991); and (3) the claims of experts that home programs are essential to achieving optimal outcomes (Hinjosa, 1990; Howson, 1988). Home programs are therapeutic activities, designed by the family and therapist to reach mutually agreed goals, to be practiced at home under the direction of the parent, for the purpose of enhancing the child’s development and fostering parental caregiving competence (Novak & Cusick, 2006).

Given the great need for effective treatments in this population and the overburdened workload of parents, I am setting out to learn whether or not home programs for children with cerebral palsy live up to the claims of experts. I am also seeking to understand the experience of carrying out a home program from a parent’s perspective, for the purpose of informing practice recommendations.

This study utilises mixed methods research. A double-blind randomised controlled trial design will be used to evaluate the efficacy of home programs for achieving goals meaningful to the family. After baseline measures were taken, children were randomised to one of three groups. One group is required to use a home program for eight-weeks, a second group is required to use a home program for only four-weeks, and the third group do not receive any home program intervention. The control group will be given a home program after completing the study. After completing the eight-week quantitative study, the children s
parents will be invited to participate in an optional semi-structured qualitative interview. The purpose of the interview was to illuminate aspects of home program implementation from the parent's point of view to help inform practice recommendations regarding home program intervention.

Occupational therapists need to recognise that, a parent's desire to do everything possible to help their child reach their potential, is what motivates them undertake home programs. Parents of children with disabilities believe that, the development of their child was unquestionably linked to their efforts as the primary caregivers. And the more time they were able to spend repeating and reinforcing therapy sessions at home, the more likely it was that their child would progress and develop (Thompson, 1998). With this acknowledgement comes great responsibility for the occupational therapy profession. To date there is limited empirical evidence to support the claims of experts that home programs make this significant contribution to outcomes (Novak & Cuscic, 2006). The only study to measure the impact of home programs on desired therapy outcomes for children with cerebral palsy was a pilot protocol with methodological limitations (Novak & Cuscic & Lowe, 2005). There has been little research, for example, on whether participation with home programs, affects the rate and magnitude of improvement in desired treatment outcomes. This study aims to contribute to the answer. The double blind randomised controlled design is the accepted methodology for measuring the effectiveness of an intervention and was therefore adopted as the predominant form of research inquiry for this doctoral study (Colditz et al, 1989; Herbert et al, 2005; Jadad et al, 1999).

3.3. Research significance

3.3.1 What is the value of answering the research question and conducting the project? NS 1.13 NS 1.14 NS 1.15

It is hypothesised that the contribution of parents at home, via home programming, makes a significant impact on the outcomes of intervention. For children with cerebral palsy, regular involvement in home program intervention is thought to lead to greater attainment of individual goals, function and movement skills. This hypothesis has not however been tested in a randomised controlled trial, the appropriate research design for studying intervention effectiveness. Benefits of home programs have been shown in an earlier study with this population (Novak & Cuscic, 2005; Novak, Cuscic & Lowe, 2005) but that study lacked a controlled comparison group. When measuring children, a component of any improvements observed may be due to developmental maturation and therefore having a control group is a preferable research design.

Arguably, the most fundamental question 'do home programs work?' has not yet been test in a clinical trial. This study has been designed to begin addressing this knowledge gap identified in the literature. The study objectives will be achieved through scholarly clinical research, using robust instrumentation to measure change in attainment of meaningful goals, function and upper limb movement.

The results of this study, will add to the paediatric research literature by:

a. measuring a protocol-based home program for children with cerebral palsy;
b. furthering what is known about home programs and parental participation by generating a higher level of research evidence about the intervention;
c. providing information about what constitutes home programs for children with cerebral palsy;
d. describing potential program outcomes; and
e. determining the family experience of participating in home programs, the factors that affect their participation, and the processes that comprise the home program experience, to identify issues relevant to service design and delivery.

The results of this study have implications for health professionals who prescribe home programs to families who have a child with cerebral palsy. The results will provide valuable data for quantifying the co-contribution of parents to intervention outcomes, and the conditions and processes that affect the treatment process. This will help inform decisions by health professionals and families regarding the amount, type and expected outcomes of home program based services. Thus guiding best practice, use of time, resources and funding of therapy services to children with cerebral palsy. This research may also have important practical applications for families on waiting lists for services, as home programs might offer an effective intervention strategy for those awaiting entry to services from allied health professions. It will also provide clarification about the variable parent input for future intervention effectiveness research, as traditionally this is not isolated from the contribution of therapists.

The results of this study will also have applications for the consumers of home programs, parents and children. It will provide an understanding of what a home program for a child with cerebral palsy may be like; what home program outcomes can be expected; and what is required to achieve these outcomes. It will also provide a basis for examining whether home programs are an effective and realistic method of service.

delivery for families. There is thus a clear gap in research literature regarding the effectiveness of home programs that needs to be filled.

3.4. Peer review

3.4.1 Has the research proposal, including design, methodology and evaluation undergone, or will it undergo, a peer review process?

3.4.1.1 Provide details of the review and the outcome. A copy of the letter/notification, where available, should be attached to this application.

The study will undergo peer-review by the Spastic Centre Research Committee prior to HREC approval at the Spastic Centre.

Approval for this study to be conducted was granted, see attached letter of approval.

The following questions set (Q3.5 - 3.11) relate to the collection, use and disclosure of information for research purposes. In answering these questions please ensure that you address all issues relevant to the type of project and type of participants that will be involved in your research project. Refer to guidance in relevant chapters of the National Statement, NEGP Guidance and other NHMRC guidelines as appropriate.

3.5. Source and description of information about participants

3.5.1 Indicate the source of the information about participants which will be used in this research project.

[X] Information will be collected directly from the participant.
[ ] Information will be collected from another person about the participant

Information will be collected by accessing a record or an information database held by an organisation other than your organisation.

[ ] Information will be used which you or your organisation collected previously for a purpose other than this research project.

3.5.1.1.0. Information which will be collected for this research project directly from the participant

3.5.1.1.1 Describe the information that will be collected directly from participants. Be specific where appropriate.

The home program participation data was collected via self-report on a log calendar, designed and provided by the researcher, at the commencement of the study. Self-report log calendars or journals have been shown to be the most accurate data collection method for evaluating parent participation in home programs [Law & King, 1993]. Law and King (1993) cautioned that whilst this is the most accurate measure, there is still the possibility that parents may over-estimate their engagement [Law & King, 1993].

Clinical change in response to the home program was captured via a collection of standardised paediatric outcome measures, recommended in literature for recording response to therapy in children with cerebral palsy. These outcome measures included:

(1) Canadian Occupational Performance Measure (COPM) to capture the child’s performance and parental satisfaction with self care, productivity & leisure independence; (2) Goal Attainment Scaling (GAS) to capture change on individualised child or family-centred goals; (3) Children’s Assessment of Participation and Enjoyment (CAPE) to assess the child’s participation in community activities; (4) Quality of Upper Extremity Skills Test (QUEST) to assess the child’s quality of upper extremity movement; (5) Assisting Hand Assessment (AHA) to assess the use of the affected hand during play; and the (6) Melbourne Assessment of Unilateral Upper Limb Function to assess the child’s quality of upper extremity movement.

3.5.1.1.2 The information collected by the research team about participants will be in the following form(s). Tick more than one box if applicable.

[ ] Identified
[ ] Potentially identifiable (coded)
[X] De-identified

3.5.1.1.3 Will consent be sought from participants (or for participants from persons with legal authority) for the collection and use of information about them?

Yes

3.5.1.2.0. Information which will be collected for this research project from another person about the participant

3.5.1.2.1 Describe the information which will be collected from another person about participants.

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Be specific where appropriate

Demographic data; Parent-report of the participant’s goal performance on the Canadian Occupational Performance Measure (COPM) and Goal Attainment Scales (GAS); and Parent report of severity of disability on the Gross Motor Function Classification System and the Manual Ability Classification System.

3.5.1.2.2 The information collected by the research team about participants will be in the following form(s).

- [ ] Identified
- [ ] Potentially identifiable (coded)
- [X] De-identified

3.5.1.2.3 Will consent be sought from participants (or for participants from persons with legal authority) for the collection and use of information about them?

Yes

3.6. Use of information about participants

3.6.1 Describe how information collected about participants will be used in this project.

All information collected about participants will be kept strictly confidential (subject to legal limitations) and the confidentiality, privacy and anonymity of participants will be ensured in the collection, storage and publication of research material through the use of de-identified data. Data will be aggregated across all participants, ensuring that it will not be possible to single out a participant from the rest.

Data will be analysed to answer the stated research questions, pertaining to the effectiveness of home program intervention as evaluated by the different outcome measures used in the trial.

3.6.2 Will any of the information used by the research team be in identifiable or potentially identifiable (coded) form?

No

3.6.6 List ALL research personnel and others who, for the purposes of this research, will have authority to use or have access to the information and describe the nature of the use or access.

Examples of others are: student supervisors, research monitors, pharmaceutical company monitors.

Iona Novak, Prof. Dusick, and Dr. Lannin (all investigators listed on this trial) will have access to de-identified data for the purpose of analysing and reporting the outcome of the trial. It is anticipated that suitably qualified study personnel, Nicole Sharp, will also have access to de-identified study information specifically as a research assistant to score the change on the standardised tools blinded to group allocation.

3.7. Storage of information about participants during and after completion of the project

3.7.1 In what formats will the information be stored during the research project? (eg. paper copy, computer file on floppy disk or CD, audio tape, videotape, film)

Research data will be stored in both paper and electronic form.

Data (both working and archived data) recorded on paper will be stored within an archive box located in the locked offices of principle investigators (Ms Novak). Access to the supervisory team and the research assistant. Paper data and associated documents will be stored according to the “General retention and disposal authority” (University records) set out by the State Records Authority of NSW which includes the joint recommendation of the NIMR and AVCC; section 23.4.2. They will be stored for a minimum of 20 years following project completion including publication; then destroyed using University Archive procedures.

Data stored in electronic form will also be stored at the Cerebral Palsy Institute system in a password protected file held by Ms Novak.

3.7.2 Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored during the research project (eg. will identifiers be removed and at what stage?)

All information will be coded, and stored in a locked filing cabinet, with the principle investigators the only people able to access this cabinet. All measurable steps will be taken to ensure that health information collected will be protected at all times.

No identifiable information will be recorded on any research forms; participant data will be de-identified at the point of collection.

Any identification codes will be stored in a different place from the data records to which they are linked.
Additionally, all consent forms and identifiable information will be stored in a separate, locked filing cabinet to the research data.
Data management will comply with relevant privacy protocols, such as the Australian Standard on personal privacy protection.

3.7.3 In what format will the information be stored after project completion? (eg. paper copy, computer file on floppy disk or CD, audio tape, videotape, film)
After project completion, all digital videos will be archived to DVD and the electronic copy deleted from the pass-word protected file. A copy of the original paper data will be retained by Cerebral Palsy Institute in addition to the archived papers and will be subject to the same storage and destruction conditions as 3.7.1.

3.7.4 Specify the measures to be taken to ensure the security of information from misuse, loss, or unauthorised access while stored after project completion (eg. will identifiers be removed and at what stage? Will the information be physically stored in a locked cabinet?)
All data will be de-identified. All identification codes will be stored in a different place from the data to which they are linked. Information will be archived in accordance with University of Sydney policy; all data will be stored in a locked long term archival facility and destroyed in accord with facility guidelines.
Data management will comply with relevant privacy protocols, such as the Australian Standard on personal privacy protection.

3.7.5 The information which will be stored at the completion of this project is of the following type[s]. Tick more than one box if applicable.
- [ ] Identified
- [ ] Potentially identifiable (coded)
- [X] De-identified

3.7.6 For how long will the information be stored after the completion of the project and why has this period been chosen?
Original data will be safely held for 20 years in accordance with the Joint NHMRC/AJCC Statement and Guidelines on Research Practice as reported in the General retention and disposal authority - university records section 23.6.2.

3.7.7 What arrangements are in place with regard to the storage of the information collected for, used in, or generated by this project in the event that the principal researcher ceases to be engaged at the current organisation?
In the event that the principal researcher Ms Novak ceases to be employed by the Cerebral Palsy Institute, data will continue to belong to The University of Western Sydney, and as such, remain in archived for 20 years.

3.8. Ownership of the information collected during the research project and resulting from the research project

3.8.1 Who owns the information collected for the research project?
Information collected for the research project is jointly owned by the University of Western Sydney, and the Cerebral Palsy Institute.

3.8.2 Who is understood to own the information resulting from the research, eg. the final report or published form of the results?
Information collected for the research project is jointly owned by the University of Western Sydney, and the Cerebral Palsy Institute.

3.8.3 Does the owner of the information or any other party have any right to impose limitations or conditions on the publication of the results of this project?
No

3.9. Disposal of the information

3.9.1 Will the information collected for, used in, or generated by this project be disposed of at some stage?
Yes

3.9.1.1 At what stage will the information be disposed?
Electronic data will be deleted, data stored in an electronic format will be destroyed immediately after

3.10. Reporting individual results to participants and others

3.10.1 Is it intended that results of the research that relate to a specific participant be reported to that participant? NS 1.19

3.10.1.1 Specify in what form the results will be reported to participants.
The family of each individual participant will be verbally informed of (1) their child’s performance and satisfaction on goal achievement as measured by the Canadian Occupational Performance Measure (the primary outcome measure); (2) goal achievement as measured on the Goal Attainment Scale (GAS); (3) child’s participation in community activities profile as measured by the Children’s Assessment of Participation and Enjoyment (CAPE); (4 & 5) child’s quality of upper extremity movement as measured by the Quality of Upper Extremity Skills Test (QUEST) the Melbourne Assessment of Unilateral Upper Limb Function; (6) and the child’s use of their affected affected hand during play as measured by the Assisting Hand Assessment (AHA); at the completion of each measurement timepoint. This is consistent with routine clinical practice.

Participants who designate that they wish to be provided with results of the study will be provided with aggregated results presented in a written, lay summary at the end of the data collection period. Each individual person’s data will not be able to be determined from the aggregated results.

3.10.1.2 How will the results be communicated to participants? eg telephone call, individual letter, copy of publication, consultation with a medical practitioner or other

3.10.1.3 Who will be responsible for communicating the project results to participants? Principal investigator Ms Nowak

3.10.2 Is the research likely to produce information of personal significance to individual participants? Yes

3.10.3 Will individual participant’s results be recorded with their personal records? NS 1.20

3.10.4 Is it intended that results that relate to a specific participant be reported to anyone other than that participant? No

3.10.5 Is the research likely to reveal a significant risk to the health or well being of persons other than the participant, eg family members, colleagues? No

3.11. Dissemination of Final Results

3.11.1 How is it intended to disseminate the results of the research? eg report, publication, thesis

It is anticipated that the results of the research project and methods used will be presented within a university dissertation, one or more journal articles and at least two conference papers. These plans will be openly discussed with all participants during the consent process.

Results will be made available to interested participants. A report will be posted out to participants at the end of the study. All results will refer to aggregated data: code numbers will be used during the entire study process refer to participants. No participant names will be used. It will not be possible to identify individuals through other means as no identifying data is collected.

It is anticipated that these dissemination plans will contribute to public knowledge, allowing improvement in future rehabilitation services for children with cerebral palsy, while protecting the confidentiality and anonymity of participants in accordance with the National Privacy Principles: “If a health service provider has the consent of an individual to collect, use or disclose their health information, then the provider may work with the information within the limits of that consent.” The written consent form seeks approval to collect health information, and informs the subject why this information will be collected, and who else will be aware of the information (ie presentation of a Doctoral thesis and likely publication of study in medical journals).

3.11.2 Will the confidentiality of participants and their data be protected in the dissemination of...
3.11.2.1.1 Explain how confidentiality of participants and their data will be protected in the dissemination of research results

All results will refer to aggregated data; code numbers will be used during the entire study process to refer to participants. No names will be used. It will not be possible to identify individuals through other means as no identifying data is collected.

3.11.3 Is there a risk that the dissemination of results could cause harm of any kind to individual participants - whether their physical, psychological, spiritual, emotional, social or financial well-being, or to their employability or professional relationships - or to their communities? No.

3.12. Benefits/Risks

In answering the following questions (3.12.0 - 3.12.3) please ensure that you address all issues relevant to the type of participants that will be involved in your research project. Refer for guidance to relevant chapters of the National Statement and other NHMRC guidelines as appropriate.

3.12.0 Does the research involve a practice or intervention which is an alternative to a standard practice or intervention? No.

3.12.1 What expected benefits (if any) will this research have for other members of the population to which the participants belong?

The study will provide rigorous, reliable information specific to the population of children with cerebral palsy who use a home program, to help therapists and the families of these children make informed decisions about whether or not to use a home program as a treatment plan. The research will demonstrate whether home programming is effective, whether the addition of long period of involvement in a program (4 weeks versus 8 weeks) results in different outcomes, and whether home programming differs in any way from doing no home program at all. The population of children with cerebral palsy and their families will benefit as home programming will have a proven outcome upon which decisions can be based. As the study uses a home program protocol, the approach to home program practice will have more opportunity to be consistent. The combined effect of consistent practice and informed home program decisions will enhance the service and develop the goal achievement of children with cerebral palsy.

3.12.2 What expected benefits (if any) will this research have for the wider community?

Considerable staff and material resources are expended on the provision of home programs to promote goal achievement in children with cerebral palsy. This intervention is unproven. The findings of this study will permit an evidence-based approach to home program decisions. The use of a consistent protocol will mean more efficient use of therapy resources. The evidence regarding effectiveness of the home program protocols will mean more informed decisions by therapists about their use of time. While efficiency is not an end in itself, there are always opportunities for proven interventions to be more widely used if unproven interventions are reduced. If home programming is demonstrated to be effective, then the protocol will form a gold standard for goal achievement not only in the approach adopted by therapists but also in the expectation that parents of children with cerebral palsy can reasonably have of effective intervention outcomes at home. If home programming is found to be unproven, then the traditional enthusiasm for using this approach in the home may be questioned. Either outcome will assist in facilitating greater equity and access to scarce health and disability resources. The results of the project will provide clear information to therapists which will be invaluable in planning treatment guidelines for treatment of goal achievement, developing independence and quality of arm movement in children with cerebral palsy.

3.12.3 What expected benefits (if any) will this research have for participants? No.

This study will utilize a consistent home program protocol that may mean the quality of home program intervention provided to participating children is less variable than that provided by therapists who do not use a consistent protocol. The home program experience will be highly monitored and supported, and the parent and child may benefit from greater engagement in the home program experience.

At trial commencement it is not possible to estimate whether shorter or longer home program intervention will be better than the other. The consent process will ensure that the participant is fully appraised of the possible risks and benefits associated with the therapeutic interventions to all groups, to allow them to make a personal judgement with respect to trial participation.

Indirect benefits that may occur are:

Providing Extra Information about Independence and Hand Function: The comprehensive assessment
provided to all participants may provide both the participant and the treating therapist with important information not usually gained during routine therapy. It is anticipated that this information will be useful for rehabilitation goal-setting and may lead to more targeted upper limb therapy, without placing an additional assessment burden on the treating therapists.

Extra Monitoring of Independence and Hand Function: participants will have a higher than normal level of monitoring regarding the effects of the home program through the use of study measurements. This may provide participants and their families with more opportunities to discuss their home based rehabilitation program with the researcher and treating therapists.

Access to Treatment: participants may have a faster than normal access to therapy treatment through participation in the research study. There is usually a long waiting list due to limited access to therapy service through The Spastic Centre, and as such, participants in the study are likely to receive a home program before they would normally have received it if not for the study. This will even apply for those participants in the wait-list control group.

3.12.4 Are there any risks to participants as a result of participation in this research project? Yes
3.12.4.1.1 What are those risks? e.g. potential for harm, distress, loss of employability, loss of reputation/standing, exposure to civil/legal/other proceedings NS 1.4 NS 1.1.4

There are minimal risks from being involved in this study, as the intervention is standard occupational therapy practice.

The process of being assessed by a stranger to complete tasks that are difficult can be challenging for a child. Assessment change can be stressful for some children and parents, as it highlights often what the child can’t do. There is a possibility that some children and parents may experience anxiety or stress when undergoing assessment as a result of involvement in this project.

3.12.4.1.2 Explain how these risks will be negated/minimised/managed. NS 1.3

The researchers have attempted to minimise the stress of being assessed by a stranger by: (1) conducting the assessments in an environment familiar and safe to the child, i.e. their home; and (2) selecting outcome measures that are fun for the child to perform, e.g. the AHA uses a child-directed free play session that utilises novel toys, which have no success/fail component. In addition, if either the researcher or parent observes the child, to be undergoing undue stress they will be offered the opportunity to stop or take a rest-break. Or if the child refuses to engage in assessment tasks, their wishes will be respected.

The PhD candidate and the Supervisors have experience supporting families of children with disabilities, and received counselling training as an undergraduate. Parent participants can contact the Principal Supervisor if they prefer not to approach the PhD Candidate.

Alternatively, the family will be asked to seek advice and support from their counsellor at The Spastic Centre. Finally, if these strategies are not helpful, the participant will be referred to the CP Helpline, which is a 24-hour phone service offering counselling. The contact number for the CP Helpline is 1300 30 2938. There will be no cost to the participant for using the CP Helpline and all discussions remain confidential between the CP Helpline and participants, the researchers will not be involved. None of the research team work for the Helpline.

3.12.4.1.3 Explain how these risks will be monitored. NS 1.7

The family will be asked to monitor the distress if any. Throughout the project, all participants maintain their right to stop at any time and their wishes will be respected.

3.12.4.1.4 Explain these risks, if they result in harm to participants, will be reported.

Each participant and their family will be asked to comment on all adverse events (i.e. distress) at every time-point. All adverse events will then be aggregated across the study prior to dissemination. Only aggregate data will be reported during the dissemination process.

3.12.5 Explain how the risks/burden of participation are balanced by the any benefits of the research.

This project aims to measure the effectiveness of occupational therapy intervention as delivered by parents in the form of a home program. It is expected that participating children will improve and benefit their independence, arm movement and participation in everyday life in response to the intervention provided in this study (Novak, Lowe & Cusick, 2005).

No coercion will be involved in any of these research study activities. There are no disadvantages, penalties or adverse consequences to those not participating or withdrawing from the project. Participants are free to
withdraw their consent at any time during the project. Withdrawal will not affect their access to The Spastic Centre services now or in the future.

The principle investigator has carefully assessed both burdens and benefits. The proposed research protocol is consistent with current practice at all research sites involved in the study. Participation in the study asks participants and their families to receive what is considered usual therapy care for a child with cerebral palsy; the difference is in the more structured monitoring and measurement that will occur within the study. The principle researchers are aware that the burdens of research include not only its risks but also the inconveniences or disruptions to participants' lives that may be caused by their participation. The informed consent process will ensure that participants and their families are adequately advised of the risks and benefits involved in the project, including the need for measurement and monitoring.

PARTICIPANT INVOLVEMENT:

Time involvement:
DURATION: 12-weeks, with the option of participating in an additional voluntary interview at the end of the 12-week period.
ASSESSMENT TIME: Children and parents will be required to undergo 3 assessments: The baseline appointment will take 1.5 hours & the follow-up appointments, at 4-weeks and 8-weeks will be 1 hour each.
QUALITATIVE INTERVIEW TIME: Parents will also be asked to participate in a voluntary interview about their experience of home programs. The interview will take approximately 1 hour.
HOME PROGRAM PARTICIPATION TIME:
- Families will be asked to complete the home program intervention for either 6-weeks (experimental group A) or 4-weeks (experimental group B and control group C). Families can self-select their preferred level of involvement with the program. Previous home program research has shown that families of children with cerebral palsy on average self-select to engage in a home program 14.2 minutes per day, 27 times per month (Novak, Cusick & Lawa, 2005).
- Parents will be asked to complete a calendar log; each time the home program is performed. Daily data entry time will take approximately 0.5-1.0 min.

3.12.6 Is it possible that the research will involve No the disclosure of unlawful conduct, or concealment of a crime, by individuals or definable groups?

3.12.7 Explain how the dignity and wellbeing of participants takes precedence over the expected benefits to knowledge.

The research protocol has been designed to ensure that respect for the dignity and well-being of the participants and their families takes precedence over the generation of knowledge. The principle researchers have clearly identified potential risks, however unlikely, and have evaluated the potential benefits of the research. Through informed consent, participants and their families will be adequately advised of the risks and benefits involved in the project in accordance with National guidelines. And finally, the research proposal has in place mechanisms for review and monitoring of data regarding efficacy and safety, and should one treatment be found to be more effective for participants prior to the completion of the study, then the study will be ceased and all participants will be offered the more effective treatment.

3.12.8 Are there any other risks involved in this No research? eg. to the research team, the organisation, others

3.12.9 Is it anticipated that the research will lead No to commercial benefit for the investigator(s) and or the research sponsor(s)?

3.13. Monitoring

3.13.1 What mechanisms do the researchers intend to implement to monitor the conduct and progress of the research project?

Data for each individual will be monitored at each time point by the principle researchers responsible for the site to ensure that there are no adverse events. This information will allow clinical decisions to be made at each time-point regarding whether or not the participant should continue with participation in the study.

4. PROJECT SPECIFIC

Your responses to questions at Sections 1.3 - Type of Research or 1.4 - Research participants indicate that the HREC will require additional information which is specific to your research project. The following table indicates the question sets relating to the project that you will need to complete. If this is not correct please return to sections 1.3 or 1.4 to amend your answer.

4.2 Clinical research not under the CTN/CTX scheme

4.8 Research involving deception of participants, concealment or covert behaviour

4.2. Clinical research excluding under CTN/CTX scheme

4.2.1. The study examines:

4.2.1.1 The administration of a drug / medicine (includes a complementary / alternative medicine) No

4.2.1.2 The use of a medical device No

4.2.1.3 Other No

4.2.2. Provide the following details for the study protocol:

4.2.2.1 Protocol number N/A

4.2.2.2 Protocol version number N/A

4.2.2.3 Protocol version date 01/03/2006

4.2.3 Are there any protocol amendments appended to, or submitted with, the study protocol? No

4.2.4 Provide a statement addressing the following as may be applicable to the project:

a) Method of randomisation

b) Whether the hypothesis offers a realistic possibility that the intervention is at least as effective as standard treatment

c) Placebo use or non-treatment control group - justification, including alternative effective treatments and any risk of harm in the absence of treatment

d) Statistical justification, sample size calculations and method of analysis

e) Response variables and how treated

f) Endpoints

g) Details of contingencies and management of these,

   a) Clustered allocation. Random allocation schedule will be developed by a person not involved in the study. The study will employ off-site, telephone randomisation.

   b) The hypothesis offers a realistic possibility that home program is at least as effective as not being provided with home program intervention.

   c) The study will be using a wait-list control group. There is currently a > 3-18 month waiting list to receive therapy through the chosen sites.

   d) Thirty-six participants, meeting inclusion criteria and giving informed consent, will be recruited. This sample size was determined using an a priori power calculation, based upon data collected by the one of the co-chief investigators in earlier research. The power calculation was designed to identify the statistically significant probability of detecting clinical effect at an alpha of 5%, power of 80%, using a minimal clinically important difference of 10%, drop-out rate of 20% and non-compliance rate of 20%. It is anticipated that a sample size of 12 participants per group is necessary to detect clinically worthwhile effect. Therefore, a total of 36 participants are required across the three groups, when using the Canadian Occupational Performance Measure as the primary outcome measure. Significance levels will be pre-determined at the p .05 level. The size of treatment effect will then be estimated by differences in group means and their 95% confidence intervals. Where possible, outcome measures will be obtained for all 36 subjects, and each subject's data analysed in the group to which allocated in accordance with the principle of intention-to-treat. Analysis of covariance will be used to determine mean treatment effect and 95% confidence intervals for normally
distribution data wherever possible, for non-normally distributed data, bootstrapping will be used to
determine median treatment effect and 95% confidence intervals. In all analyses, baseline scores will be
used as covariates.
(d) Response variables will be: goal attainment 

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CTPM) (primary dependent variable); goal achievement Goal Attainment Scale (GAS); quality of arm
movement – Quality of Upper Extremity Skills Test (QUEST); Assisting Hand Assessment (AHA); Melbourne
Assessment of Unilateral Upper Limb Function; and severity of impairment, Grosse Motor Function
Classification System (GMFCS) and Manual Ability Classification System (MACS) (secondary dependent
variables). All variable data will be checked for its distribution prior to analysis and treated as normal or
non-normal in subsequent analyses.
(f) endpoints: 4 weeks and 6 weeks
(g) Missing data will be handled using the last-known observation method wherever possible; all data will be
treated using intention-to-treat principles even if the child does not complete the study.

4.8. Research involving deception of participants, concealment and/or covert observation.

You have indicated that the project involves deception of participants, concealment and/or covert observation.

4.8.1 Describe the nature of the deception of participants, concealment and/or covert observation.

Once participants have given informed consent to participate in the study, they will be randomly
allocated to either the experimental group A or experimental group B, or the control group C, where they
will receive an individualised home exercise program to complete for either 8-weeks (experimental group A)
or 4-weeks (experimental group B) OR the control group (group C).

Participants will not be informed of their group allocation as part of this study. This study uses a randomised
double blind trial design. Research design experts suggest that double blinding is necessary for knowing
almost anything about whether a treatment really works (Neeseworth et al., 2001).

4.8.2 What are the exceptional circumstances which make this necessary?

Given the large gap in literature identified about home program effectiveness, the randomised double blind
design has been selected to measure its effectiveness. It is well established that Hawthorne Effect, the
phenomenon of altered behaviour or performance resulting from awareness of being a part of an
experimental study, can affect self-reporting during clinical trials (Campbell et al., 1996). In this study it is
foreseeable that participant knowledge of group allocation could significantly bias data collected in relation
to the goals set for intervention; the self-reporting on outcome measures and the amount of time they
choose to engage in and report about carrying out a home program (Campbell et al., 1996). Participants will
be not disadvantaged by the double-blind design, in that all participants, regardless of group allocation, will
be provided with an individualised home program, with the control group C having to wait 6-weeks longer
than the other two groups. The study has been carefully designed by the research team so as not to create an
ethical unease about waiting by ensuring that eligibility for enrolment in the study is that children are on a
waiting list for a service already. Thus by giving consent to participate the family will be receiving an
occupational therapy service sooner than if they had remained on the waiting list alone. Children who enrol
in the study can also remain on the waiting list for The Spastic Centre services so as not to lose their place in
line. The children who enrol from OLC would not normally have been eligible for services from a NSW
therapy provider so this is an “extra” service.

4.8.3 Why would appropriate disclosure compromise the validity of the research?

The National Statement on Ethical Conduct in Research Involving Humans will be adhered to at all times in
this protocol, in line with the NHMRC principles the researchers have established that: (1) participant
knowledge of group allocation would compromise the scientific validity of the outcome of the research and
therefore blinding is necessary; (2) deception, concealment or covert observation is defined to group
allocation and design only, all treatments given to participants will be real and no other facts will be withheld;
(3) there are no suitable alternative design methods, not involving deception for assessing effectiveness in
clinical research. Particularly of an intervention such as home programs where the parental involvement
element is so key (Neeseworth et al., 2001); (4) participants will not be exposed to an increased risk of harm
as a result of the deception, rather all participants will receive an intervention service, for which they are
waiting for on a Spastic Centre waiting list, sooner than if they had remained on the waiting list alone; (5)
adequate and prompt disclosure will be made and debriefing provided to each participant as soon as
practicable after the participant’s participation is completed in the study. This is planned to be given at
completion of the parental interview; (6) participants will be able to withdraw data obtained from them during
the research without their knowledge or consent, this will be reiterated to families during the disclosure
debriefing, (7) concealment is not believed to be a risk to the relationship between researchers and research
in general or the community at large because the participants will benefit from being part of the study,
as they will receive an extra occupational therapy service whilst on the Spastic Centre waiting list.
4.8.4 What alternative methods were considered and rejected?
From a methodological perspective, there are no alternative suitable design methods, not involving deception for assessing effectiveness in clinical research. Particularly of an intervention such as home programs where the parental involvement element is so key (Noseworthy et al., 2001). I have already conducted a pre-post study with this population asking the same research question (Novak, Cusick & Lowe, 2005), and the limitation of this earlier research is that the maturation effect of children could not be controlled for because of the lack of a controlled comparison group, blinded to group allocation.

4.8.5 Are there additional risk factors associated with this activity?

5. PARTICIPANTS

5.1. Participant description

5.1.1 How many participant groups are involved in this research project?

5.1.2 Expected total number of participants in this project at all sites 36

5.1.3. Group 1

5.1.3.1 Group name for participants in this group
Home Program Intervention 8 weeks

5.1.3.2 Expected number of participants in this group
12

5.1.3.3 Age range
4.5-12 years

5.1.3.4 Other relevant characteristics of this participant group
a. diagnosis of cerebral palsy
b. attending school
c. on a waiting list for therapy services that is longer than a 4 week wait
d. not currently seeing another occupational therapist for active therapy
e. informed consent is given by the parent and child

5.1.3.5 Why are these characteristics relevant to the aims of the project?
(a) to determine the effect of home programs, the researchers have chosen a homogeneous diagnosis group in an attempt to reduce variability in analyses. Furthermore, cerebral palsy is one of the most commonly occurring childhood disabilities with a significant lifelong impact on the person, their family and the community. The estimated incidence is around 1,400 live births, with over 600 new cases diagnosed in Australia each year. With so many of these children seeking therapy, it is relevant to determine the effectiveness of one of the main interventions provided to this population.
(b) The chosen services, Spastic Centre and Queensland Cerebral Palsy Health Service, have waiting lists for therapy. Characteristics of all groups in the study are the same due to the chosen design (randomized controlled trial) and so waiting list eligibility for the service is necessary for all groups, not just the control group.

5.1.3. Group 2

5.1.3.1 Group name for participants in this group
Home Program Intervention 4 weeks

5.1.3.2 Expected number of participants in this group
12

5.1.3.3 Age range
4.5-12 years

5.1.3.6 Other relevant characteristics of this participant group
a. diagnosis of cerebral palsy
b. attending school
c. on a waiting list for therapy services that is longer than a 4 week wait
d. not currently seeing another occupational therapist for active therapy
e. informed consent is given by the parent and child

5.1.3.5 Why are these characteristics relevant to the aims of the project?
Group characteristics are consistent across all groups because of the chosen design (randomized controlled trial)

5.1.3. Group 3

5.1.3.1 Group name for participants in this group
Control group

5.1.3.2 Expected number of participants in this group
12
5.1.3.3 Age range
4-5-12 years

5.1.3.6 Other relevant characteristics of this participant group
a. diagnosis of cerebral palsy
b. attending school
c. on a waiting list for therapy services that is longer than a 4 week wait
d. not currently seeing another occupational therapist for active therapy
e. informed consent is given by the parent and child

5.1.3.5 Why are these characteristics relevant to the aims of the project?
Group characteristics are consistent across all groups because of the chosen design (randomised controlled trial)

5.2. Participant experience
5.2.1 Provide a concise detailed description, in not more than 200 words, in terms which are easily understood by the lay reader, of what the participants will experience.
Each participant will have equal chance of being assigned to one of three groups: Experimental A, Experimental B, or Control C. Experimental group A will be provided with a occupational therapy home program to implement at home for 8-weeks. This home program will include activity ideas designed to address the mutually agreed upon family goals for the intervention period. Experimental group B will also be provided with a occupational therapy home program to implement at home but instead for 4-weeks. Control group C will be provided with no occupational therapy treatment or home program for the first 8-weeks of the study. It is not unusual for children in this population to have a period of 8-weeks with no occupational therapy, as waiting times for therapy services are common. Families randomised to the control group C will be given a home program after 8-weeks of enrolment in the study, and asked to use the home program for the next 4-weeks.

ASSESSMENTS
PARENT INVOLVEMENT:
- Parents will be asked to complete a baseline demographic survey to describe child and family participant attributes, such as: age, sex, classification of cerebral palsy, severity of cerebral palsy, parent’s highest education level attained, language spoken at home, occupation etc.
- Parents will be asked to complete a collaborator goal-setting interview about goals for the duration of the study and desired outcomes that would constitute meaningful improvement for the child and family

At all 3 assessments parents will be interviewed about their child’s performance and their satisfaction using the Goal Attainment Scale (GAS) and Canadian Occupational Performance Measure (COPM)

ASSESSMENTS
CHILD INVOLVEMENT: Children will be videoed performing daily activities at all 3 assessments. These have been previously described.

INTERVENTION
CHILD INVOLVEMENT: Children will be asked by their parents to engage in the home program activities at home during their daily routine.

5.3. Relationship of researchers to participants
5.3.1 Specify the nature of any relationship, existing or possible, between the research team or an organisation involved in the research and the potential participants.
Participants are clients of one of the two organisations involved in the research (The Spastic Centre (NSW) or Queensland Cerebral Palsy Health Service).

5.3.2 Describe what steps, if any, will be taken to ensure that the relationship does not impair participants’ free and voluntary consent and participation in the project.
All researchers involved with this project are aware of and practice ethical consent in line with the National Statement on Ethical Conduct in Research Involving Humans, as such, we are aware of the importance of non-coercion for obtaining informed and voluntary consent. Both the consent form and the information sheet clearly state that refusal to participate in, or a decision to withdraw from, the research will not result in any discrimination, reduction in the level of care or any other penalty. As an additional safeguard, the families will be given the opportunity to take the information forms away with them to discuss with family and advocates prior to choosing to participate in the research.

5.3.3 Describe what steps, if any, will be taken to ensure that decisions about participation in the research do not impair any existing or foreseeable future relationship between participants and researcher or organisations.
The researcher will give an explicit assurance that refusal to participate in, or a decision to withdraw from, the research will not result in any discrimination, reduction in the level of care or any other penalty. This is clearly stated in the information sheet and on the consent form.

5.4. Recruitment
5.4.1 What processes will be used to identify potential participants?

The investigation team will assemble a convenience sample of homogeneous participants, with homogeneity determined by participant attributes. This sampling method is necessitated by the fact that the state-wide sampling frame of the NSW & Qld cerebral palsy register, listing potentially suitable participants, is still being established. The CF registers will be contacted as a recruitment source to contact families who have consented to be contacted about research projects. In addition, posters will be placed in the waiting rooms of The Spastic Centre service sites and Queensland Cerebral Palsy Health Service. All potential volunteer participants will receive written and verbal information about the project. The information sheets and consent forms about the study will be provided to occupational therapists and managers working at both sites who may wish to pass these on to potentially eligible families. Where consent is given by the family to release their telephone number to the principle investigator, Iona Novak, a follow-up phone call will be made to explain the study.

5.4.3 Describe how initial contact will be made with potential participants.

The principle investigators, Iona Novak will telephone and/or write and individual letter to potential participants to describe the project and explain that their written consent will be required before enrolment in the study. All participants will be informed that they can withdraw their consent at any time without consequence. Explanation will be given to potential volunteers prior to the request for written consent to participate in the study. All participants, who meet the study inclusion criteria and give informed consent to participate, will be enrolled in the study, until the study is filled.

5.4.2 Is it proposed to 'screen' or assess the suitability of the potential participants for the study?

5.4.2.1 How will this be done?

Use of the CF registers will ensure that all participants have a diagnosis of cerebral palsy. Families will be asked to confirm the child’s date of birth, age, and whether the child attends school and is on a waiting list for occupational therapy services that is longer than 4 weeks.

5.4.4.1 Provide details and a copy of text/script.

Re: A Research Study You May Be Interested In

Dear [Client]:

Researchers at the Cerebral Palsy Institute and the University of Western Sydney, Ms Iona Novak, Professor Anne Cusick, and Dr Natasha Lamin, are studying whether or not home program intervention in children with cerebral palsy helps you achieve your goals and improves your child’s independence. A review of your child’s records suggests you might be eligible to participate in this study. Study participation will last for 8 weeks and will involve at least 3 visits to your home in NSW or in south-east Queensland. At these appointments, your child will have an opportunity to discuss your intervention goals and your child will be assessed. After the assessments are complete, you will be provided with a home program designed to help you reach your goals via the mail. You will be provided with support to implement the program over the telephone.

If you are interested in participating in this study or have questions, please call Iona Novak at [phone number].

5.4.5 If it became known that a person was recruited to, participated in, or was excluded from the research, would that knowledge expose the person to any disadvantage or risk?

5.4.6 Will the research involve the intentional recruitment of any groups whose welfare, rights, beliefs, perceptions, customs or cultural heritage requires specific regard? No 12

5.5 Consent process

5.5.1 Will consent for participation in this research be sought from all participants?

5.5.1.2 Will there be participants who have capacity to give consent for themselves?

5.5.1.2.1 Will there be participants who do not have capacity to give consent for themselves?
not have capacity to give consent for themselves?

5.1.2.1.1 Specify why these participants do not have capacity to give consent for themselves.

Participants will be aged between 4.5 to 12 years. Their parent or guardian will be asked to provide legal consent on their behalf. All children will be asked to provide verbal consent in addition to their legal guardian’s consent to ensure that the child wishes to take part in the study.

5.1.2.1.2 By whom will consent for these participants be given?

Parent or legal guardian.

5.1.2.1.3 On what basis is it believed that these people have legal authority to give consent for these participants?

The birth parents or guardians appointed by the Office of the Public Guardian or Guardian Tribunal (NSW) or Guardianship and Administration Tribunal (Qld).

The following questions relate to participants who are able to provide consent and also to participants for whom consent may be provided by a person with legal authority to do so.

When answering these questions you must describe any differences in the processes followed, or the documentation used, for different groups of participants in your proposal, e.g. processes and documentation for users of facilities/services will differ from those for providers of those facilities/services. Where your proposal involves participants with an intellectual or mental impairment, or people in dependent relationships, additional questions about their consent appear at 6.5 and 6.5 respectively.

5.1.1.3 Describe the consent process, ie how participants or those deciding for them will be informed about, and choose whether or not to participate in, the project.

The principle investigator will explain the project to participants and their family at a convenient location, anticipated to be the clinic where the child is attending therapy. An information sheet will be read to the potential participant and their next of kin/advocate, the potential participant and family will then be provided with the opportunity to ask further questions. The information will be provided to participant at their level of comprehension, ensuring that each potential participant and/or family clearly understands the purpose, methods, demands, risks, inconveniences, discomforts and possible outcomes of the research, and the consequences of participation.

Voluntary choice to participate will be ensured through the consent process. The information sheet and consent form will be left with the participant’s family to allow opportunity for them to discuss participation in a non-coercive environment.

Informed consent will be obtained in writing. A copy of the signed consent form will be left with the participant’s family. Each participant will be informed that they are free at any time to withdraw consent to further involvement in the research project without any repercussions.

5.1.1.4 If a participant or person on behalf of a participant chooses not to participate, are there specific consequences of which they should be made aware, prior to making this decision?

There are no consequences for choosing not to take part in the study. All participants and their families will be informed of this during the consent process.

5.1.1.5 If a participant or person on behalf of a participant chooses to withdraw from the research, are there specific consequences of which they should be made aware, prior to giving consent?

Each participant will be informed that they are free at any time to withdraw consent to further involvement in the research project without any repercussions.

5.1.1.6 Specify the nature and value of any proposed incentive/payment [eg. movie tickets, food vouchers] or reimbursement [eg travel expenses] to participants.

There are no incentives or payment for taking part in this study. At this time, due to funding, the study is unable to offer reimbursement for expenses incurred in attending therapy for the study. There are no anticipated costs to participants incurred specifically from the project.

5.1.1.7 Explain why this offer will not impair the voluntary nature of the consent, whether by participants’ or persons deciding for their behalf.

Not applicable, there are no incentives.

5.1.1.8 Provide the name and/or position of the contact person for any concerns in relation to the ethical conduct of the research / complaints process?

Institutional ethics approval has been granted from University of Western Sydney (nominated contact person to whom complaints from research participants, researchers, or other interested persons may be made is the Human Research Ethics Committee telephone (02) 42203346, Spastic Centre (nominated contact person (02) 9451 9822) and The Royal Children’s Hospital (nominated contact person is Amanda Smith, telephone 07 3629 1067.

5.1.1.9 Will a participant or person on their behalf who withdraws from the research be able to withdraw data about the participant?
6. PARTICIPANTS SPECIFIC

6.1. Research conducted in Australia involving persons whose primary language is other than English (LOTE)

You have indicated that the project involves persons whose primary language is other than English (LOTE).

6.1.1 Describe what steps will be taken to ensure each participant’s free and voluntary consent and participation in the project given that the person’s language is other than English? NS 4.2.1

For potential participants whose primary language is other than English, an interpreter service will be arranged to ensure that each participant is making informed voluntary consent. The principle investigator will meet with the family with the interpreter present so that the project can be explained to them in their primary language and provide them with an opportunity to ask questions. Interpreter services will be arranged for all subsequent follow-up appointments.

6.1.2 In what language(s) will the research be conducted?

[ ] English
[ ] Other

6.1.3 Will participants be provided with written information in the language in which the research will be conducted?

Yes

6.2. Research involving children and/or young people

You have indicated that the project involves children and/or young people.

6.2.1 Why is participation of children or young people indispensable to this research? NS 4.1 (b)

The research question posed is important to the health and well-being of children or young people: home programs are one of the most common interventions used to treat children with cerebral palsy. Currently, this treatment is provided without evidence to support whether or not this is an effective treatment.

The participation of children or young people is indispensable because information available from research on other individuals cannot answer the question posed in relation to children or young people: adults with newly acquired acute conditions engaging in home programs may have different motivation factors to children with lifelong disabilities. Therefore, the participation of children is essential to know whether or not home programs are effective for the treatment of children with cerebral palsy.

The study method is appropriate for children or young people; and the circumstances in which the research is conducted provide for the physical, emotional and psychological safety of the child or young person.

6.2.2 Explain why the research is not contrary to the best interests of the children / young people. NS 4.3

The research protocol has been carefully designed to minimize risks of harm or discomfort to participants, and to ensure that all participants (including those assigned to the wait-list control group) have equal access to home program intervention.

6.2.3 How has this study been designed to be appropriate for children or young people?

The protocol has been carefully designed based on a thorough review of current literature as well as prior observation and approved previous studies. The principle investigator, Ms Novak, and Principle Supervisor, Professor Cusick, have completed a review of previous studies (Novak & Cusick, 2006), and have trialed the protocol in clinical practice with children with cerebral palsy to ensure that it is acceptable to children and their families (Novak, Cusick & Lowe, 2006).

The study method is appropriate for children or young people. The randomised controlled trial has been designed so that the selection, recruitment, exclusion and inclusion of research participants is fair and that all three groups have the opportunity to receive the home program intervention.

6.2.4. Indicate from whom consent for the participation of these children/young people will be sought. (You may select more than one option.)

6.2.4.1 Child or young person participant

Yes

6.2.4.2 Parent/ guardian

Yes

6.2.4.3 A person or organisation required by law

No

6.3. Research involving persons with an intellectual or mental impairment

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You have indicated that the project involves people with an intellectual or mental impairment.

6.3.1 Describe the nature of the intellectual or mental impairment eg. permanent, temporary or fluctuating?

Intellectual impairment is the second most common impairment associated with cerebral palsy, after a speech impairment. The intellectual impairment, if present at all, is permanent and life-long.

6.3.2 Describe how the consent process will take into account the nature of the impairment.

In this trial, participants will be aged between 4.5 to 12 years. Their parent or guardian will be asked to provide legal consent on their behalf. All children will be asked to provide consent in addition to their legal guardian’s consent to ensure that the child wishes to take part in the study. In the case where the child has an intellectual impairment, if their consent can be obtained verbally because the child is non-verbal, appropriate alternative communication devices or accepted non-verbal communication methods used by the child will be accepted by the investigators. These may include, non-verbal gestures or use of a communication board or device.

6.4. Research involving deception of participants, concealment or covert behaviour

You have indicated that the project involves deception of participants, concealment or covert behaviour.

6.4.1 Will participants who have participated in research involving deception be debriefed?

6.4.1.1 How will participants who have participated in research involving deception be debriefed?

Adequate and prompt disclosure with de-briefing will be provided to each participant as soon as practicable after the participant’s participation is completed in the study. This is planned to be given at completion of the parental interview.

6.4.1.2 What mechanism will provide for participants to withdraw their data following this debriefing?

Participants will be able to withdraw data obtained from them during the research without their knowledge or consent, this will be reiterated to families during the disclosure debriefing session. Concealment is not believed to be a risk to the relationship between researchers and research in general or with the community at large because the participants will benefit from being part of the study, as they will receive an extra occupational therapy service, whilst on The Spastics Centre of NSW waiting list OR for QLD residents a service that they would not normally have been entitled to from a NSW service provider.
7. RESOURCES

7.1. Project Funding / Support

7.1.1. Indicate how the project will be funded? Indicate whether funding is confirmed or sought and whether there will be a budget shortfall.

7.1.1.1. External competitive grant

7.1.1.1.1 Confirmed or Sought? Not Sought

7.1.1.2. Internal competitive grant

7.1.1.2.1 Confirmed or Sought? Not Sought

7.1.1.3. Sponsor

7.1.1.3.1 Confirmed or Sought? Not Sought

7.1.1.4. By researcher’s department / organisation

7.1.1.4.1 Confirmed or Sought? Confirmed

7.1.1.4.2 % of Project 100

7.1.1.5. Other

7.1.1.5.1 Confirmed or Sought? Not Sought

7.1.1.6. Shortfall

7.1.1.6.1 Confirmed or Sought? Not Sought

7.1.1.4.0. By researcher’s department / organisation

7.1.1.4.1 Name of department(s)/organisation

Cerebral Palsy Institute, an initiative of The Spastic Centre

7.1.2 Will the project be supported in other ways? Yes

eg. in-kind support/equipment by an external party eg. sponsor

7.1.2.1.1 Describe the support and indicate the provider.

Cerebral Palsy Institute are supporting the project with the in-kind donation of staff member release time and the use of infrastructure support time such as, administration assistant time & research assistant time.

University of Western Sydney and University of Sydney are supporting the project with the in-kind donation of student supervision.

7.2. Duality of Interest

7.2.1 Describe any commercialisation or intellectual property implications of the funding/support arrangement.

Nil. There are no expected commercialisation from intellectual property anticipated from this project. Therefore no arrangements have been made.

7.2.2 Does the funding/support provider(s) have a financial interest in the outcome of the research? No

NS 2.21

7.2.3 Does any member of the research team have any affiliation with the provider(s) of funding/support, or a financial interest in the outcome of the research? No

NS 2.21

7.2.4 Does any other individual or organisation have an interest in the outcome of this research? No

NS 2.21

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8. APPROVALS

8.1. Ethical review

Some HRECs may require researchers to provide information additional to that contained in a NEAF proposal. For this reason, it is prudent to check whether the HREC(s) to whom you propose to submit this proposal require additional information.

8.1.1 To how many Australian HRECs (representing site organisations or the researcher's organisation) is it intended that this research proposal be submitted?

A list of NHMRC registered Human Research Ethics Committees (HRECs), along with their institutional affiliations and contact details is available on the NHMRC website at the following web address: http://www.nhmrc.gov.au/ethics/humanreces/information.htm#.

8.1.1.1. HREC 1

8.1.1.1.1 Name of HREC

Royal Children's Hospital and Health Services District Ethics Committee (EC00179)

8.1.1.1.1.1 Provide the start and finish dates for the research for which this HREC is providing ethical review.

8.1.1.1.1.1.1 Anticipated start date or date range

1/05/2007

8.1.1.1.1.1.2 Anticipated finish date or date range

01/02/2009

8.1.1.1.1.2 For how many sites at which the research is to be conducted will this HREC provide ethical review?

1

8.1.1.1.2.1. Site 1

8.1.1.1.2.1.1 Name of site

Royal Children's Hospital

8.1.1.1.2.1.2 Which of the researchers involved in this project will conduct the research at this site?

Principal Researcher(s)

Ms Isla Novak

Associate Researcher(s)

Yes

8.1.1.1.2.1.3 Have you previously submitted an application, whether in NEAF or otherwise, for ethical review of this research project to any other HRECs?

2

8.1.1.2. HREC 1

8.1.1.2.1. Name of HREC

University of Western Sydney Human Research Ethics Panel (EC00513)

8.1.1.2.2 Status of this review

Approved

8.1.1.2.3 Explain why an application for ethical review was submitted to the HREC(s) identified in answer to question 8.1.2.1, e.g. it may be for another phase of the research project which has very different characteristics. Describe the wider project context, where appropriate.

The project was submitted to the University of Western Sydney Human Research Ethics Panel (EC00513) because this is the institution where the Principle Investigator is enrolled as a Doctoral student.

8.1.2.2. HREC 2

8.1.2.2.1. Name of HREC

The Spastic Centre Ethics Committee (EC00402)

8.1.2.2.2 Status of this review

Approved

8.1.2.3 Explain why an application for ethical review was submitted to the HREC(s) identified in

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answer to question 8.1.2.1, e.g. it may be for another phase of the research project which has very different characteristics. Describe the wider project context, where appropriate.

The project was submitted to The Spastic Centre Ethics Committee (EC00402) because this is the site 1 for the project and where the Principle Investigator is employed. Recruitment of participants to the trial has been underway at this site for 12 months. The trial already has > 60% of the needed participants recruited from this site. The sampling frame of eligible participants at this site has almost been exhausted and therefore it is necessary to seek approval to recruit from another site to fill the trial.
9. DECLARATIONS AND SIGNATURES

9.1 Project Title
Effectiveness of Occupational Therapy Home Program Intervention for Children with Cerebral Palsy: A Double Blinded Randomised Controlled Trial.

9.2 Human Research Ethics Committee to which this application is made
Royal Children’s Hospital and Health Services District Ethics Committee (EC00175)
The Spastic Centre Ethics Committee (EC00602)
University of Western Sydney Human Research Ethics Panel (EC00319)

9.3 Signatures and undertakings

Applicant / Principal Researchers (including students where permitted)
I/we certify that:
- All information is truthful and as complete as possible.
- I/we have had access to and read the National Statement on Ethical Conduct in Research Involving Humans.
- The research will be conducted in accordance with the National Statement.
- The research will be conducted in accordance with the ethical and research arrangements of the organisations involved.
- I/we have consulted any relevant legislation and regulations, and the research will be conducted in accordance with these.
- I/we will immediately report to the HREC anything which might warrant review of the ethical approval of the proposal (NS 2.37), including:
  - serious or unexpected adverse effects on participants;
  - proposed changes in the protocol; and
  - unforeseen events that might affect continued ethical acceptability of the project.
- I/we will inform the HREC, giving reasons, if the research project is discontinued before the expected date of completion (NS 2.38).
- I/we will not continue the research if ethical approval is withdrawn and will comply with any special conditions required by the HREC (NS 2.45).
- I/we will adhere to the conditions of approval stipulated by the HREC and will cooperate with HREC monitoring requirements. At a minimum annual progress reports and a final report will be provided to the HREC.

Ms Iona Novak
Cerebral Palsy Institute
Signature
Date

Associate Researchers

Prof Anne Dusick
University of Western Sydney
Signature
Date

Dr Natasha Lammin
Rehabilitation Studies Unit, University of Sydney
Signature
Date

Supervisor(s) of student(s)
I/we certify that:
- I/we will provide appropriate supervision to the student to ensure that the project is undertaken in accordance with the undertakings above;
- I/we will ensure that training is provided necessary to enable the project to be undertaken skilfully and ethically.

Commercial-in-Confidence
Prof Anne Cusick  
Signature  
___/___/____

Dr Natasha Lannin  
Signature  
___/___/____

Heads of departments/schools/research organisation

I/we certify that:
- I/we are familiar with this project and endorse its undertaking;
- the resources required to undertake this project are available;
- the researchers have the skill and expertise to undertake this project appropriately or will undergo appropriate training as specified in this application.

Title  First name  Surname

Position  Organisation name

___/___/___  Signature
## 10. ATTACHMENTS

### 10.1 List of Attachments

<table>
<thead>
<tr>
<th>Core Attachments</th>
<th>Attachments which may be required/appropriate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment/Invitation</td>
<td>Copy of advertisement, letter of invitation etc</td>
</tr>
<tr>
<td>Participant Information</td>
<td>Copy or script for participant</td>
</tr>
<tr>
<td></td>
<td>Copy or script for parent, legal guardian or person responsible as appropriate</td>
</tr>
<tr>
<td>Consent Form</td>
<td>Copy for participant</td>
</tr>
<tr>
<td></td>
<td>For parent, legal guardian or person responsible as appropriate</td>
</tr>
<tr>
<td></td>
<td>For, optional components of the project eg. genetic sub study</td>
</tr>
<tr>
<td>Peer review</td>
<td>Copy of peer review report or grant submission outcome</td>
</tr>
<tr>
<td>HREC approvals</td>
<td>Copy of outcome of other HREC reviews</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Attachments specific to project or participant group</th>
<th>Attachments which may be required/appropriate.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research involving deception of participants, concealment or covert behaviour.</td>
<td>Participant information/consent form to be provided retrospectively to participants</td>
</tr>
<tr>
<td>People whose primary language is other than English (LGET)</td>
<td>English translation of participant information/consent forms</td>
</tr>
<tr>
<td>Children and/or young people (i.e. &lt; 18 years)</td>
<td>Information/consent form for parent, legal guardian or person responsible</td>
</tr>
<tr>
<td>People with an intellectual or mental impairment</td>
<td>Information/consent form for legal guardian or person responsible</td>
</tr>
<tr>
<td>Survey instrument / questionnaire / diary</td>
<td>Copy of instrument/questionnaire/diary pro forma</td>
</tr>
<tr>
<td>Interviews - telephone</td>
<td>Copy of script/outline</td>
</tr>
<tr>
<td>Interviews - face to face</td>
<td>Copy of script/outline</td>
</tr>
</tbody>
</table>
### 10.2 Participant information elements

**Core Elements**

Provision of information to participants about the following topics should be considered for all research projects.

<table>
<thead>
<tr>
<th>Core Elements</th>
<th>Issues to consider in participant information</th>
</tr>
</thead>
<tbody>
<tr>
<td>About the project</td>
<td>Full title and / or short title of the project</td>
</tr>
<tr>
<td></td>
<td>Plain language description of the project</td>
</tr>
<tr>
<td></td>
<td>Purpose / aim of the project and research methods as appropriate</td>
</tr>
<tr>
<td></td>
<td>Demands, risks, inconveniences, discomforts of participation in the project</td>
</tr>
<tr>
<td></td>
<td>Outcomes and benefits of the project</td>
</tr>
<tr>
<td></td>
<td>Project start, finish, duration</td>
</tr>
<tr>
<td>About the investigators / organisation</td>
<td>Researchers conducting the project (including whether student researchers are involved)</td>
</tr>
<tr>
<td></td>
<td>Organisations which are involved / responsible</td>
</tr>
<tr>
<td></td>
<td>Organisations which have given approvals</td>
</tr>
<tr>
<td></td>
<td>Relationship between researchers and participants and organisations</td>
</tr>
<tr>
<td>Participant description</td>
<td>How and why participants are chosen</td>
</tr>
<tr>
<td></td>
<td>How participants are recruited</td>
</tr>
<tr>
<td></td>
<td>How many participants are to be recruited</td>
</tr>
<tr>
<td>Participant experience</td>
<td>What will happen to the participant, what will they have to do, what will they experience?</td>
</tr>
<tr>
<td></td>
<td>Benefits to individual, community, and contribution to knowledge</td>
</tr>
<tr>
<td></td>
<td>Risks to individual, community</td>
</tr>
<tr>
<td></td>
<td>Consequences of participation</td>
</tr>
<tr>
<td>Participant options</td>
<td>Alternatives to participation</td>
</tr>
<tr>
<td></td>
<td>Whether participation may be for part of project or for whole of project</td>
</tr>
<tr>
<td></td>
<td>Whether any of the following will be provided: counselling, post research follow up, or post research access to services, equipment or goods</td>
</tr>
<tr>
<td>Participants rights and responsibilities</td>
<td>That participation is voluntary</td>
</tr>
<tr>
<td></td>
<td>That participants can withdraw, how to withdraw and what consequences may follow</td>
</tr>
<tr>
<td></td>
<td>Expectations on participants, consequences of non-compliance with the protocol</td>
</tr>
<tr>
<td></td>
<td>How to seek more information</td>
</tr>
<tr>
<td></td>
<td>How to raise a concern or make a complaint</td>
</tr>
<tr>
<td>Handling of information</td>
<td>How information will be accessed, collected, used, stored, and to whom data will be disclosed</td>
</tr>
<tr>
<td></td>
<td>Can participants withdraw their information, how, when</td>
</tr>
<tr>
<td></td>
<td>Confidentiality of information</td>
</tr>
<tr>
<td></td>
<td>Ownership of information</td>
</tr>
<tr>
<td></td>
<td>Subsequent use of information</td>
</tr>
<tr>
<td></td>
<td>Storage and disposal of information</td>
</tr>
<tr>
<td>Unlawful conduct</td>
<td>Whether researcher has any obligations to report unlawful conduct of participant</td>
</tr>
<tr>
<td>Financial issues</td>
<td>How the project is funded</td>
</tr>
<tr>
<td></td>
<td>Declaration of any duality of interests</td>
</tr>
<tr>
<td></td>
<td>Compensation entitlements</td>
</tr>
<tr>
<td></td>
<td>Costs to participants</td>
</tr>
<tr>
<td></td>
<td>Payments, reimbursements to participants</td>
</tr>
<tr>
<td></td>
<td>Commercial application of results</td>
</tr>
<tr>
<td>Results</td>
<td>What will participants be told, when and by whom</td>
</tr>
<tr>
<td>Core Elements</td>
<td>Issues to consider in participant information</td>
</tr>
<tr>
<td>---------------</td>
<td>------------------------------------------------</td>
</tr>
<tr>
<td></td>
<td>Will individual results be provided</td>
</tr>
<tr>
<td></td>
<td>What are the consequences of being told or not</td>
</tr>
<tr>
<td></td>
<td>being told the results of research?</td>
</tr>
<tr>
<td></td>
<td>How will results be reported/published?</td>
</tr>
<tr>
<td></td>
<td>Ownership of intellectual property and</td>
</tr>
<tr>
<td></td>
<td>commercial benefits</td>
</tr>
<tr>
<td>Cassation</td>
<td>Circumstances under which the participation of</td>
</tr>
<tr>
<td></td>
<td>an individual might cease</td>
</tr>
<tr>
<td></td>
<td>Circumstances under which the project might</td>
</tr>
<tr>
<td></td>
<td>be terminated</td>
</tr>
</tbody>
</table>

**Research Specific Elements**
Provision of information to participants about the following topics should be considered as may be relevant to the research project.

<table>
<thead>
<tr>
<th>Specific to project or participant group</th>
<th>Additional issues to consider in participant information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Research involving deception of</td>
<td>Explanation (retrospectively) of why deception,</td>
</tr>
<tr>
<td>participants, concealment or covert</td>
<td>concealment or covert observation was necessary</td>
</tr>
<tr>
<td>behaviour.</td>
<td></td>
</tr>
</tbody>
</table>
Appendix B-3 Consent Form

Home Program Effectiveness

Consent to Participate in Home Program Effectiveness Project

My child ________________________________ (name of) has been invited to participate in the above named research study. I have discussed the study with one of the researchers. I acknowledge that I have received and read the Information Sheet, which includes the aims of this study, the procedures involved in this study, including any inconvenience, risk, discomfort or side effects, and their implications. I understand that my child’s assessments will be videotaped for the purpose of scoring by an occupational therapist that does not know the order of the videotapes.

I understand that I ________________________________ (name of) have been invited to participate in an interview and what my participation in the project will involve. I understand that when I am interviewed the interview will be audio-taped. I understand that I do not have to answer any questions that I do not want to answer.

I understand that mine and my child’s participation in this study is entirely voluntary and that I can withdraw at any stage. If I withdraw, this decision will not affect in any way, my future treatment or my relationship with The Spastic Centre. I also understand that the information relating to my participation in the study is strictly confidential. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

I understand that the research project will be carried out according to the principles in the National Health & Medical Research Council Statement on Human Experimentation. I understand that if I have any questions about my rights as a research participant I may contact The Spastic Centre Ethics Committee on (02) 8451 9022.

I understand that if I have any questions relating to my participation in this research study, I may contact Iona Novak on 02 9972 8146 or Anne Cusick on 02 4920 3346, who will be happy to discuss them with me.

I hereby freely agree to participate in this research study.

Your Name: ________________________________

Your Signature: ___________________________ Date: ______________

Your Relationship to Child: ________________________________

Witness Name: ________________________________

Witness Signature: ___________________________ Date: ______________
Appendix B-4 Participant Information Sheet

Home Program Effectiveness

Information Sheet for Participants & Families/Carers

What are home programs?
Home programs are therapy activities carried out by you and your child at home frequently within your usual everyday routine. The activities are designed to help you reach your goals. The aim of a home program is to (1) improve your child’s independence and (2) enhance your parenting skills by providing you with more information about how to progress your child’s development.

What is the purpose of the study?
You and your child are invited to participate in a research project about the effectiveness of home programs. The project is called “Home Program Effectiveness”.

For children with cerebral palsy, regular involvement in a home program is thought to lead to better achievement of goals, abilities and movement skills. In the past, therapy focused on trying to fix underlying problems through expert ‘hands-on’ therapy in therapy centres. But it has been recognised that the most effective therapy for children with cerebral palsy is the kind where children practice real activities in everyday environments. This newer type of therapy naturally involves parents and recognises your expertise in knowing your child best. But, how much of a difference it makes involving parents in the therapy has not yet been researched. This is important to know because it helps determine how much therapy, organisations like The Spastic Centre need to provide.

There are two aims to this research project:
1. To work out how much of a difference it makes by parents being involved in therapy through a home program
2. To understand the experience of participating in a home program from a parent’s perspective

This project is being conducted as part of a Doctorate of Philosophy at the University of Western Sydney. The research team includes: Iona Novak, Manager of Research and Education at The Spastic Centre, who is studying as a PhD student; Professor Anne Cusick from University of Western Sydney & Natasha Lannin from who supervising the project.

What will you need to do?
1. The study will last for 12 weeks. If you agree to your child’s participation in the study, he or she will be provided with a home program designed to meet your goals. Your child might also be provided with a hand splint to wear for a set number of hours per week, if the occupational therapist assesses that this will benefit them.

Children will be randomly allocated to one of three groups. This means that you will not be able to choose which group your child is allocated to. Regardless of which group you are in, you will be provided with an individual home exercise program designed to help your child achieve the goals we agree on together at the start of the study.

Three times during the study, we will assess your child’s play and independence; you will be given the appointment times in advance. These assessments will be videotaped for scoring by
an occupational therapist that does not know the order of the videotapes. The researchers will be looking to see how big a contribution parent involvement through home programs makes to the outcomes of therapy.

2. You as a parent, will also be invited to participate in an optional interview as part of the research project. This interview is about understanding your experience as a parent involved in a home program with your child. We could talk in private or you can ask a friend to be there with you. Everything will be kept strictly confidential. The interview will take around 1 hour and may involve a follow up telephone call. The interviewer will also ask you for your permission to tape-record the interview conversation so that we can analyse them. Your participation is voluntary. If you decide to take part, you do not have to answer any questions that you do not want to answer. You can also stop being part of the interview at any time you want to. Whether you take part in the interview or not, any services or support you are now receiving will not be affected.

Are there benefits in participating?
Occupational therapy is beneficial for children with cerebral palsy and helps them improve their independence and use their arms more effectively. All children participating in the study are expected to make improvements from the occupational therapy home program. In addition, by participating you will be receiving an extra occupational therapy service from The Spastic Centre whilst you are on the waiting list for ongoing services.

Are there any discomforts, side effects and risks involved with the study?
The occupational therapy home program provided in this study will be delivered in the way that is normal clinical practice. There are no added risks with this intervention.

As part of your child’s occupational therapy, he/she may be asked to wear a splint or cast. Wearing a splint or cast can raise the risk of skin breakdown if a pressure area develops. In addition, a small percentage of people can develop a temporary skin allergy from wearing a splint or cast. This will be managed in the standard way by ensuring the splints are prescribed and moulded by an experienced occupational therapist and by providing you with information about:

- How to introduce splints slowly to minimise the risk of pressure areas developing;
- What to do if an allergic reaction occurs or a pressure area develops that does not go away within 10 minutes of removing the splint.

The occupational therapist who fits the splint or cast to your child’s hand will monitor your child for signs of discomfort, and make any necessary adjustments or cease the splint wearing if the child is experiencing discomfort. This is standard clinical practice.

None of the assessments that will be taken of your child’s progress involve discomfort or any known risks. The assessments will take around one and a half hours to complete on three occasions.

Privacy and Disclosure of Data
The University of Western Sydney and The Spastic Centre respect all aspects of your privacy and you can be assured that your personal details will remain confidential at all times. Only the researchers will have access to information about your child, you and the other participants. When the project is finished, a report about the study will be written. This report will be available for other people to read. The report will only present statistical and research findings. It will not reveal identifying information about any individual and no one will be named. All study information will be stored in locked cupboards or password protected electronic files. All long-term storage is the University Archives Facility.
Consent and Withdrawal

Participation in the study examining the effectiveness of home programs is entirely voluntary. We will only assess your child and prescribe a therapy program if you sign a consent form. Your child will also be asked if they wish to participate in each assessment activity. If they choose not to, their wishes will be respected. If, in the future, you change your mind about being involved, you can withdraw your consent to participate. You do not need to provide any reason. This will not disadvantage you in any way or effect services you are currently receiving from The Spastic Centre.

You may access the information collected about your child at any stage, by contacting The Spastic Centre. You will be informed about your child’s progress throughout the study and will also be provided with a copy of the study results.

This Information Sheet is for you to keep. If you have any questions or would like to know more about this project, please contact:

Iona Novak
Occupational Therapist, PhD candidate
The Spastic Centre of NSW
Ph: 02 9972 8146
Email: inovak@tsconsw.org.au

Anne Cusick
Professor, Principle Supervisor
University of Western Sydney
Ph: 02 4620 3346
Email: a.cusick@uws.edu.au

Should you wish to make a complaint about the conduct of the research project, please contact:

Sarah McIntyre
Human Research Ethics Committee
The Spastic Centre
Telephone: 02 9451 9022
Fax: 02 9452 4677
Email: smcintyre@tsconsw.org.au

NOTE: This study has been approved by the University of Western Sydney Human Research Ethics Committee or Panel (indicate Committee or Panel). The Approval Number is .................

If you have any complaints or reservations about the ethical conduct of this research, you may contact the Ethics Committee/Panel through the Research Ethics Officers (tel.: 02 4736 0883 or 4736 0884). Any issues you raise will be treated in confidence and investigated fully, and you will be informed of the outcome.
Appendix B-5 Study Recruitment Advertisement

Tired of waiting?
Is your child on our waiting list?
Do you want occupational therapy at home?
Join our research study and we can help you now!

Home Program Study

- The aim of the study is to work out what are the benefits of providing occupational therapy at home
- A very experienced occupational therapist will visit you at home, 3 times over 8 weeks
- The 1st appointment will involve setting goals you want to achieve and an assessment of your child
- You will be given ideas on how to (1) stimulate your child's development and (2) how to enhance your parenting skills to help achieve your goals
- You will be provided with support and training

To find out more call: Iona Novak, Occupational Therapist, 0409078917
Appendix C: Glossary

Co intervention “Co intervention occurs when one group or the other receives different medical care based partly or totally on their group assignment” (Mayer, 2004, p.81)

Contamination “Contamination occurs when both groups receive the same therapy as the experimental group” (Mayer, 2004, p.81)

Effectiveness “Usefulness of a particular treatment to the individuals receiving it under typical clinical condition, usually determined by non-experimental methods in outcomes research” (Domholdt, 2000, p.503).

Efficacy “Biological effect of treatment delivered under carefully controlled conditions, usually determined by randomised controlled trial” (Domholdt, 2000, p.504).