

REPORT FOR THE BOARD OF THE CEREBRAL PALSY EDUCATION CENTRE: QUALITATIVE STUDY OF A TRANSCUTANEOUS ELECTRICAL STIMULATION GARMENT (MOLLII SUIT) TO REDUCE PAIN, IMPROVE CAPABILITIES AND QUALITY OF LIFE IN CHILDREN WITH CEREBRAL PALSY MAY 2019



ABSTRACT

A small but rigorous feasibility study was completed from August through December 2018 to evaluate the feasibility, practicalities and experiences of ten children who participated in a Monash University, ethics approved project involving wearing the MOLLII suit for 6 weeks per a specific protocol. This report describes qualitative findings from the study. Qualitative data was collected via a semi-structured interview with participants. The identity of participants is confidential and data is the person's described lived experience. In this project, ten parents and one teenager participated in the interviews. Three overall themes were derived from the data: Practicalities complying with the wearing protocol; Child's experience and the impact of wearing the suit; and Parents' experiences and the impact of being in the trial. Overall the suit was acceptable to most children and families, perceived to be 'relaxing' and easy to include in the weekly schedule by most families. It is important to note the variability and individualised responses to the Mollii suit – each family had a different response, with some common themes and individual differences. The changes perceived by parents included improvements in attention, energy levels, concentration, improved standing posture, joint positioning, motor skills and reduced pain. These findings were not objectively verified in the qualitative study as the purpose of qualitative research is to capture experience rather than 'measuring' change. Overall it appears that the Mollii suit wearing schedule of every second day for 6 weeks was acceptable and practical for families. All parents recommended that other families participate in a trial of the Mollii suit prior to committing to purchase of ongoing use of the suit. The positive experiences described by families makes the Mollii suit a worthwhile and important consideration when looking at the strategies available for early intervention for children with cerebral palsy and like disabilities.

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BACKGROUND TO STUDY

Cerebral Palsy (CP) describes a group of developmental disorders of movement and posture, causing activity restriction or disability attributed to acquired or developmental abnormalities in the brain before 24 months of age. CP is often a complex condition as people frequently have movement or motor impairment alongside other common coexisting conditions including limitations in sensation, cognition, communication and/or behaviour as well as secondary musculoskeletal problems and other issues.² Living with CP is challenging for the child/person as well as the family charged with their care and support needs. CP has a prevalence of approximately 1 in 500 neonates, with 17 million people affected worldwide.³ The overall prevalence of CP in high-income countries is 2.11 per 1000 live births⁴ and 2.0-2.8 per 1000 live births in low and middle income countries.⁵ In Australia, after a long period of stable prevalence at 2-2.5 per 1000 live births, the rate of CP declined to 1.4-2.1/1000 in the 2007-2009 period.⁶

The site for this study is the Cerebral Palsy Education Centre (CPEC—see <https://cpec.org.au/>) based in Glen Waverley Victoria. CPEC is a unique not-for-profit organisation that provides specialist early intervention services for children with cerebral palsy and like disabilities. Eighty per cent of children go on to attend mainstream school with ongoing CPEC therapy support in the local school of their choice. All children receiving service at CPEC are lifetime National Disability Insurance Scheme users due to the extent of their needs and disabilities. CPEC is staffed by professionals: occupational therapists, speech language pathologists and physiotherapists. Research has occurred at the centre, including investigations into the cost of raising a child with CP to age 6 years⁷ and service use and choice from families' perspectives.⁸ Families at CPEC have a full complement of services to support their child and family. However, what we know is that families seek new and innovative interventions. When new therapies, devices or technologies present in the field or on the internet, CPEC investigates suitability, risk and benefits to children/young people with CP and their families in order to advise families.

A convenience sample was recruited through CPEC. The Chief Executive Officer of CPEC is an occupational therapist and a chief investigator. CPEC are funding the study as agreed by the board of directors. The sample included children and young people with spasticity. The most common type of motor disorder experienced by children with CP is spasticity which causes musculoskeletal impairments often with associated pain and results in increased caring needs for their parents/carers and both health and therapy needs. The progression of musculoskeletal difficulties may occur with advancing age.² While traditional therapies form a staple in the lives of children, young people and adults with CP, there are limitations within the evidence base as to what assists people to manage and participate in daily life and prevent future complications^{9,10}. Families have access to many options including comprehensive multi or transdisciplinary programs. Other 'techniques' or interventions such as serial casting, orthoses, Botulinum toxin A injection (BoNT-A) are also available to manage spasticity and reduce pain, however most research occurs with children with less severe CP.¹¹

Rationale for current study

Families of children with CP are known to seek and investigate interventions that may help their child with CP. Several families at CPEC trialled the Mollii suit and had remarkable and noteworthy responses. Hence, CPEC is now committed to investigating the Mollii suit as an intervention for the

first time in Australia. The Mollii is a new technology of electrical stimulation that has had some preliminary testing with people with muscle spasticity, including children with CP. It is a non-invasive device that is worn at home by children and young people with CP. Mollii developers claim that the suit achieves gains in strength and motor function.¹⁶ The Mollii suit is a whole-body garment with multiple electrodes individually programmed to stimulate the selected muscle groups according to clinical judgement of patients' needs. A number of unpublished studies available on the manufacturer's website (<http://inerventions.se/en/research/>) have suggested that the Mollii suit could be an effective option for people with spasticity (adults and children). Improvement in mobility, gait, function, quality of life and reduction in spasticity measured by questionnaires in Sweden and observed by clinicians in Australia all point to the potential of this new technology in children with CP. At this point, however, there are no randomized controlled trials or independent comparative observational studies supporting the evidence of the treatment efficacy/effectiveness for the multiple electrodes whole-body stimulation. The National Institute for Health and Care Excellence (NICE) concluded that the key uncertainty with the Mollii suit is that the evidence base is still under development.¹⁷

Considering the potential of the Mollii suit and the need for evidence, CPEC has provided funding to conduct a feasibility study of the Mollii suit in Australian children with CP. The feasibility study examined the acceptability, treatment outcomes and costs of the Mollii suit. Ethics approval was sought from Monash University.

Background of Transcutaneous Electrical Stimulation

Electrical stimulation, transcutaneous electrical nerve stimulation (TENS) or neuromuscular electrical stimulation (NMES), have shown to be effective in pain relief and muscle tone reduction. A systematic review showed significant evidence, based on 14 randomised controlled trials (RCTs) with 550 study participants evaluating the effect of TENS, for management of limb spasticity.¹² Another review of electrical stimulation for children with CP showed that use of NMES offered benefits such as increased muscle strength, range of motion and function in children with CP.¹³ In combination with dynamic splinting, NMES was more effective than either treatment on its own in improving function and posture.

Electrical stimulation has also been tested specifically in children with cerebral palsy. A systematic review was conducted to examine the quality and results of research specifically addressing the efficacy of electrical stimulation in strengthening or improving the motor function of children with CP using threshold electrical stimulation (TES) or NMES.¹⁴ Two out of six TENS studies in the systematic review reported statistically significant improvements, two studies reported no statistically significant effects but documented a perceived positive treatment effect as reported by parents/carers, and the remaining two case reports described improvements. A randomised placebo-controlled trial was conducted to investigate the efficacy of NMES and TES in 60 children with cerebral palsy.¹⁵ The electrical stimulation was only tested in legs with two electrodes (one proximal and one distal position). After 16 weeks of treatment, no differences were observed for strength or function. However, statistically significant differences were observed between NMES and TES versus placebo for impact of disability and the difference continued at the 6 week follow-up between TES versus placebo.

STUDY PROTOCOL

The full ethics approved study protocol is eighty-three (83) pages long and available from Claire Cotter or Helen Bourke-Taylor. This report presents an overview of the research protocol pertaining to the qualitative component of the overall feasibility study.

This feasibility study will examine the acceptability, treatment outcomes and costs of the Mollii suit as an intervention for children with cerebral palsy. At the time that the study occurred, little was known about the Mollii suit, protocols for wearing the suit, expected outcomes from wearing the suit and cost versus benefit for children and young people with cerebral palsy. The Mollii suit is a non-invasive therapeutic technology that broadly aims and claims to reduce pain and improve capabilities and quality of life for people with neurological impairments.

The primary objectives were to assess the feasibility of the Mollii suit for children with cerebral palsy and the appropriateness of the intervention protocol and outcome measures. The secondary objectives were to evaluate the acceptability and costs of the Mollii suit to the families of children with cerebral palsy. The Mollii suit costs \$15,000 to purchase outright and can be used for approximately 3 years.

The study used a sequential explanatory mixed method design with a stepped wedged design and randomisation of participants into two groups to examine the changes in clinical outcomes, acceptability of the methods used to evaluate the outcomes, and an economic assessment of the intervention.

This study evaluated the feasibility and appropriateness of the Mollii suit and study protocol for children and young people with cerebral palsy. The study found that the majority of children experienced different positive changes and with the parents recommending that all of the other children at the centre trial the suit. However, due to the limited sample size and the differing positive changes experienced, no definitive conclusions could be determined.

In the future, a larger pilot study or a randomised control trial may be run and that larger study will be informed by learnings from this feasibility study.

Overall, this study determined appropriateness of measurement tools used to detect changes in function, quality of life and pain following a six week intervention period using a protocol of wearing the Mollii suit for one hour every second day for 6 weeks. The suit was worn in the child/young person's home environment.

Qualitative interviews with 10 parents and one teenager occurred post follow-up to investigate further information about the intervention and the study protocol including measurement tools, costs, and family impact issues. Qualitative interviews were semi-structured and five (5) occurred face to face and five occurred over the phone for family convenience.

The study proceeded to recruit CPEC families after ethics was approved through Monash University (see Appendix C, D and E for explanatory statements, consent forms and approval letter from the University). The protocol involved a 12 week study. The qualitative data collection points are shown in figure 1.

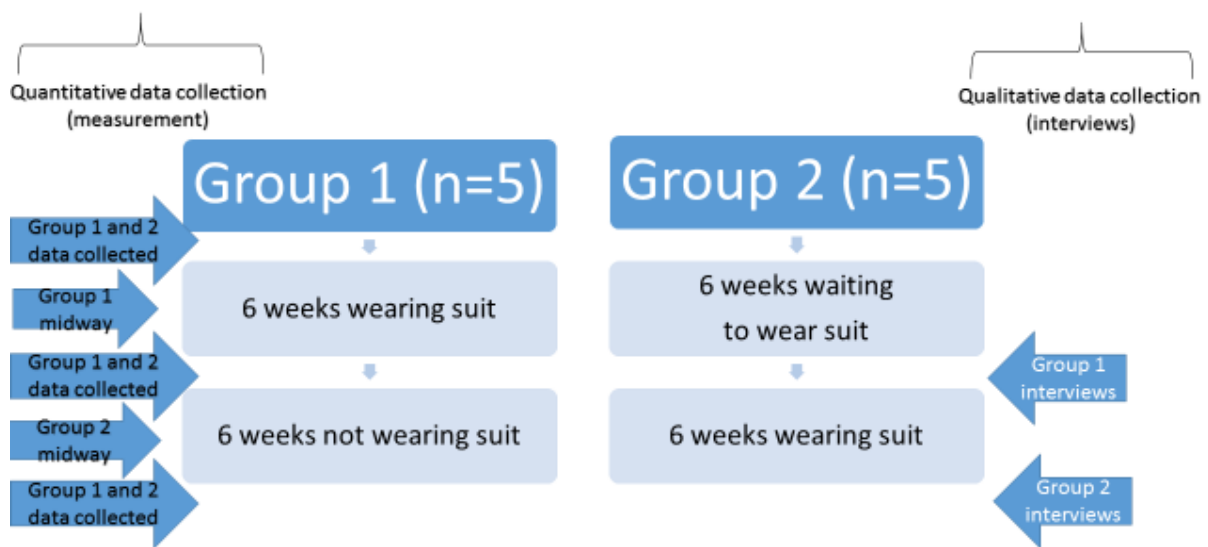


Figure 1: Group 1 and 2 and exposure to Mollii, data collection point's quantitative (left side) and qualitative (right side).

THE QUALITATIVE STUDY RESEARCH QUESTIONS AND INTERVIEW GUIDE

Research questions drive the research methods. In Qualitative research, research questions ground the research so that answerable questions are asked in interviews that will enable views, experiences and opinions to be collected for analysis. The research questions are listed below, followed by the interview guide questions. Participants were provided with the interview guide so they were aware of the questions to be asked. No person participated without providing informed consent. All participants are not identifiable.

Feasibility Research Questions

1. How feasible is the usual treatment wearing protocol to support adherence for children and youth with cerebral palsy across a six-week intervention?
2. How acceptable and practical is the wearing regime and the measurement protocol across the 12-week period of wearing and not wearing the Mollii suit?
3. What were the experiences of families including the wearing of the Mollii suit across six weeks of regular use?
4. How do parents describe the experiences and observations of their children's reactions to the Mollii suit during usual daily life and activities?

Qualitative study Interview guide questions

1. What was a typical day like for you when you were involved in the Mollii suit study and your child wore the suit every second day for one hour?
2. These questions are about the practicalities of the suit in your usual daily life.
 - a. Was it difficult to get on/off?
 - b. Was it difficult for your child to tolerate?
 - c. How did your child respond with it on/afterwards?
 - d. Any other expected or unexpected reactions, difficulties, benefits?
3. Did you notice any changes in your child's pain, mood, capabilities or any other aspect of their daily life across the six weeks? Please describe in detail.
4. What advice would you give to another family about the Mollii suit and ease of use, benefits or drawbacks on use?
5. What advice would you give to service providers/health professionals about the Mollii suit?

METHODS FOR QUALITATIVE DATA COLLECTION AND ANALYSIS

Data collection:

All interviews were audio recorded. Interviews were sent in the form of MP3 files to a professional transcription service. Interviews were returned fully transcribed. All interviews were checked by researcher 3 by listening and checking the transcript. Transcripts were then re-identified with pseudonyms and sent back to each participant for checking and correcting or for adding anything additional that the participant wanted to add.

Methodology for data analysis:

Semi-structured interview guides (see previous section). Data was analysed using an inductive process with research questions guiding identification of important and relevant descriptions, as applied in previous qualitative studies investigating participants' reactions to interventions.

Researchers involved in the data collection and data analysis included the interviewer (Monash University academic) author; and one CPEC staff (project manager) and Monash university associate researcher. Data was analysed systematically using manual means. The data analysis process was structured and records scrupulously kept to ensure corroboration between researchers and to ensure a dependable record of data analysis procedures. The process is presented graphically in table 1 and highlights reading verbatim transcripts through to summary of three themes.

Table 1

Data analysis process from transcribed interviews through to three main themes.

Stages	Major data analysis activity occurring at stage	Number of researchers involved
1	Cleaned interviews sent to participants for verification. Researchers read and reread 10 interviews.	2
2	Two researchers read 10 interviews and identified rich text that was highlighted with key concepts identified to label like concepts and representational quotes. Researchers meet to compare key concepts and quotes across interviews.	2
3	Four researchers view interview transcripts to identify concepts and categories create category maps for whole group. Category maps identified like concepts and drafted potential relationships between concepts for the group (eg. Descriptions of donning suit; child's activities when wearing suit).	4
4	Three researchers cross checked with each interview to ensure category maps have all concepts for each interview.	3
5	Researchers agreed on overall themes and subthemes derived through a method of constant comparison between interview data from all participants. Three overarching representational themes were finally derived. The stage was finalized when key representational quotes were identified from within each participant groups as a common view or a contrasting view within that category, sub theme. Researchers compared views on categories of meaning within interviews and related these to subthemes and themes overall.	4

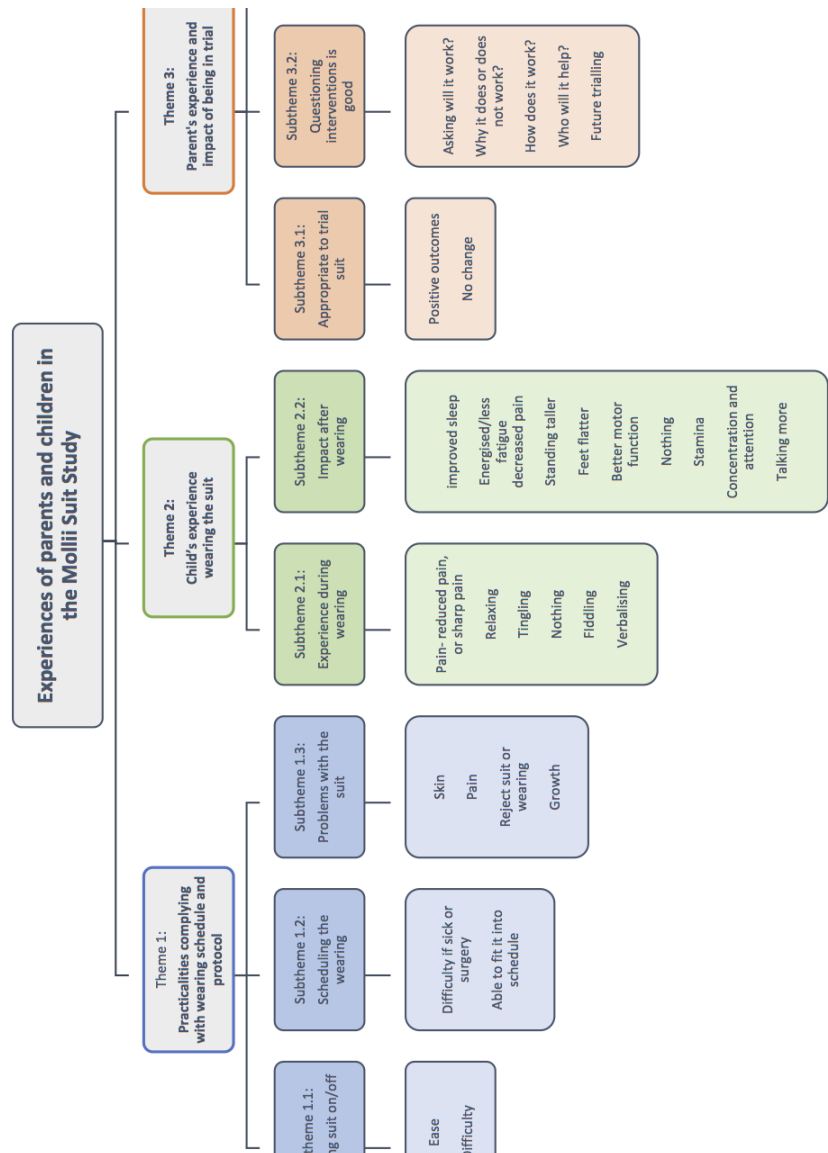
FINDINGS

Ten families participated in the study. Ten mothers participated in the interviews and one teenager with cerebral palsy also participated in the interview with his mother. All participants were de-identified to protect their identity and right to privacy. See table 2 for summary of participants. See Appendix F for detailed descriptions and verbatim results of the participants in this study.

Table 2 Characteristics of participants

Pseudonym	Age range	Communication	Family	Educational setting	Technology required by child/teenager for the following:								
					Drinking/ Eating	Toileting	Comm	Mobility	Hands	Safety	Therapy	Participation	Transport
Reece	4-6 years	Spoken language	Parents, 2 siblings	Kindergarten									
Charlie	4-6 years	Spoken language, PODD communication book (AAC)	Parents, 1 sibling	Child care									
Lorraine	4-6 years	Spoken language	Parents, 2 siblings	Kindergarten									
Layla	10-12 years	Spoken language	Parents, 1 sibling	Primary school									
Jarrod	13-16 years	Spoken language	Mother, 1 sibling	Secondary school									
John	13-16 years	Spoken language	Parents, 1 sibling	Primary school									
Adelaide	4-6 years	Spoken language	Parents, 2 siblings	Kindergarten									
Brie	7-9 years	Spoken language	Parents, 2 siblings	Primary school									
Milo	10-12 years	Spoken language	Parents	Primary school									
Liam	4-6 years	AAC (electronic), and spoken language	Parents, 2 siblings	Kindergarten									

Figure 1 Thematic map from qualitative interviews and themes.



Three themes were derived from the data following the inductive process. The themes represent the overall findings of families collectively. Figure 1 presents the overall themes. The participants offered different experiences and opinions following participation in the feasibility study. Some representational quotes are included in Appendix G under each theme. The themes and subthemes were defined as follows:

Theme 1: Practicalities complying with wearing schedule and protocol—Descriptions of how easy or difficult the suit was to use at home

Subtheme 1.1: Getting suit on and off

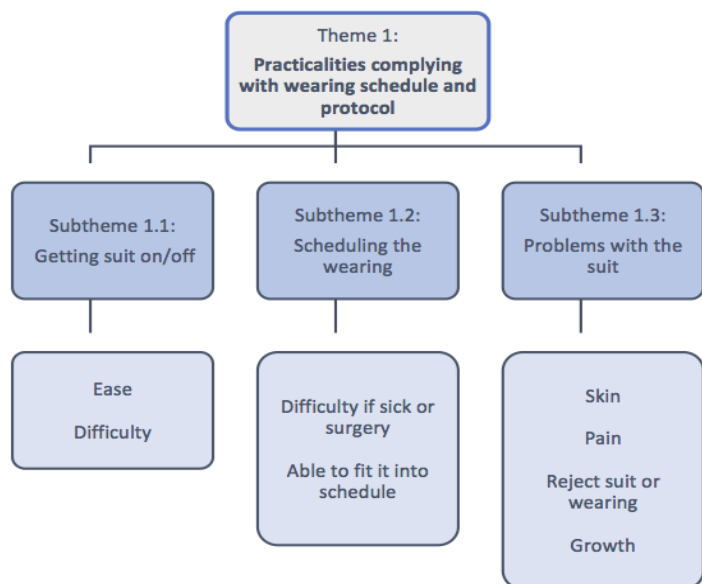
- Ease
- difficulty

Subtheme 1.2: Scheduling the wearing

- Difficulty if sick or surgery
- Able to fit it into schedule

Subtheme 1.3: Problems with the suit

- Skin
- Pain
- Reject suit or wearing
- growth



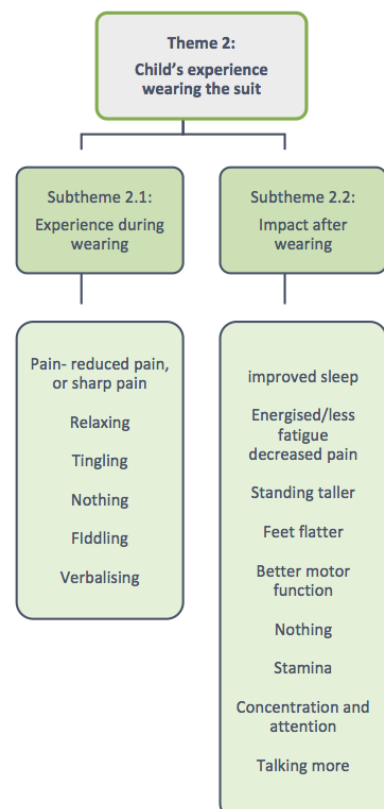
Theme 2: Child's experience wearing the suit—what children described or were observed to experience when they were wearing the suit at home. Descriptions were related to children's experience during or after wearing the suit.

Subtheme 2.1: Experience during wearing

- Pain- reduced pain, or sharp pain
- Relaxing
- Tingling
- Nothing
- Fiddling
- verbalizing

Subtheme 2.2: Impact after wearing

- Energised/less fatigue



- Standing taller and feet flatter
- Decreased Pain
- Improved Sleep
- Better motor function
- Improved Balance
- Improved Stamina
- Concentration and attention
- Talking more
- No change

Theme 3: Parents experience and impact of being in trial—parents described their opinion and experience about the Mollii suit as an intervention for their child. They described their satisfaction with being involved in the research project itself. Parents recognised that having the choice to trial interventions, consider the effect for their child and make an informed decision about whether they wished to pursue an intervention for their child, were all steps forward for their family’s choice and control of interventions for their child.

Subtheme 3.1: Appropriate to trial suit

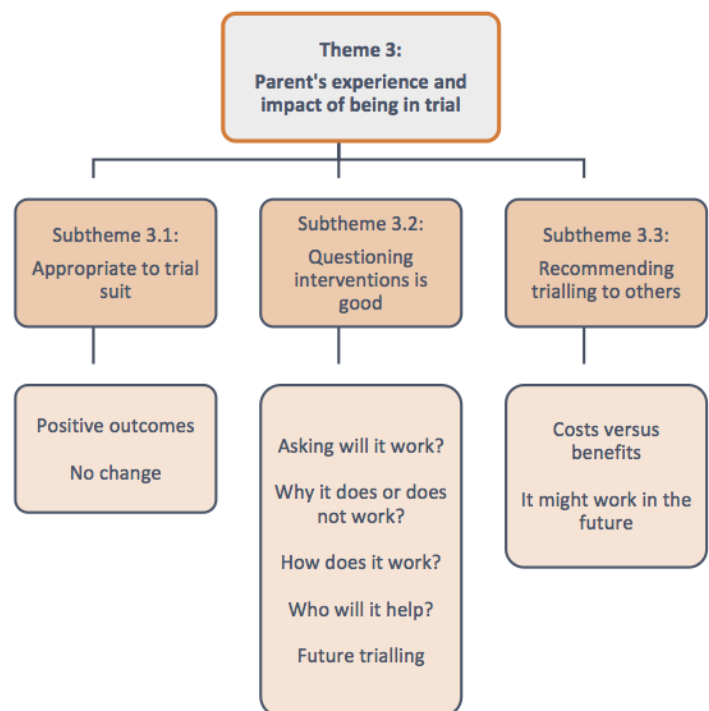
- Positive outcomes
- No change

Subtheme 3.2: Questioning interventions is good

- Asking will it work
- Asking why it does or doesn’t work
- How does it work
- Who will it help?
- Future trialling

Subtheme 3.3: Recommending trialling to others

- Costs versus benefit
- It might work in the future



Appendix G provides verbatim quotes from the participants in the Mollii study. Only representative quotes are presented. Not all quotes repeating the same or similar findings are presented. The voice of all families is made available here. Only the child's name appears next to the quote, although in most circumstances the mothers were interviewed.

DISCUSSION

All participants in the Mollii study expressed agreement that being involved in the study assisted their knowledge about the Mollii suit and appreciated being involved in the feasibility study. In relation to the research questions that drove the qualitative interviews with parents, the following outcomes were identified:

The treatment protocol designed for families was feasible and practical for families. Most families were able to adhere to the protocol. Events that prevented adherence to the protocol included a child needing surgery or a child getting ill with gastro. The intervention was easily adhered to for 6 weeks and attending CPEC for assessment was achievable for families as well. The qualitative study investigated the acceptability of the suit and families found the suit acceptable to wear. Donning the suit was more difficult for some children due to spasticity. Families who had experience with using lycra body splints tended to describe the Mollii suit as easy to don, doff and wear, compared to other families who tended to describe the Mollii suit as more difficult to use. Some children learned to don the suit independently quickly. The experience of families was that the suit was easy to include in daily life. All families finished the protocol regardless of whether they had observed or detected any changes for their child. All families were compliant with the protocol and did not engage in activities such as wearing it more if they perceived a good effect or less if they perceived less effect.

Families described an array of reactions to the Mollii suit from no changes in function to improvements in sleep, standing taller and feet flatter on the ground, balance, fine motor skills, daily life routines, stamina, concentration and attention and being able to talk more. Families noted a reduction in pain for some children and no change in pain for others. Some children were more energised after wearing the suit, demonstrating more active behaviours. It is important to note that these changes were all perceptions and lived experiences and need to be cross referenced with performance changes as measured in the quantitative part of the research.

The next section summarises implication and recommendations based on the findings of the qualitative interviews.

IMPLICATIONS AND RECOMMENDATIONS:

The implications of families' experiences in the Mollii Feasibility study are:

1. Gains for their child.

There was large variation in the perception of changes experienced by children and parents and very individualised responses – that is, each child experienced their own range of changes, some the same as others, but also different ones. The range was from one teenager expressing satisfaction with the suit and explaining how he had reduced pain in his knees and could stand longer, through to another family who believed that their child did not have any gains in function at all. Regardless of whether the child experienced improvements, all families expressed satisfaction and appreciation for being in the trial and having the opportunity to try for themselves.

2. Families expressed unreserved support for others to trial the Mollii suit for themselves.

Parent's perceptions of the impact of the trial was that they thought that it was an appropriate way to work out if the Mollii suit was going to be something they invested in. All families had questions such as why and how does it work, will it work for my child in the future if it didn't work now and is the cost worth the benefit.

3. The Mollii suit is easy to use and acceptable as an intervention or families to trial.

The Mollii is acceptable to families as it is usually easy to don and doff and wearing the suit is mostly comfortable for children. The six week trial period with every second day wearing is acceptable to families. The Mollii suit is easy to fit into an evening wearing schedule every second day.

4. The Mollii suit needs to be carefully checked by the suppliers to ensure that it is correctly programmed and the right fit for the child before the trial period starts.

There was an issue with the suit size for one child that needed to be addressed during the fitting or immediately once a problem arose. The suit seemed to be too small or a poor fit and left the child somewhat uncomfortable. In another instance the programming or battery seemed to be a problem and required re-programming. However, even with these initial concerns the suit was then acceptable to the child and family.

5. Four children experienced sharp pain in a localised area when wearing the suit.

The experience of pain appeared to be related to programming or the positioning of limbs when wearing the suit. There was one incident of reddened skin that was photographed and reported by the mother. The problem was immediately rectified with the supplier and no further pain was experienced.

Recommendations:

- 1. The positive experiences described by families makes the Mollii suit a worthwhile and important consideration when looking at the strategies available for early intervention for children with cerebral palsy and like disabilities.**
- 2. Families support the trialling of the suit as opposed to purchasing a suit outright.**
- 3. Only children with the ability to communicate and alert others about pain or discomfort and indicate the location of the pain should be included in future trials of the suit. Similarly, families considering use should consider their child's ability to alert them to a problem with the suit. However, this is not a limiting factor for CPEC because all children can or learn to communicate.**
- 4. The fitting and programming of the suit should undergo a standardised procedure that enables the child and family to confirm the size and programming before they take the suit home for the trial, and to be able to contact the supplier at any time if there are any difficulties.**
- 5. Any discomfort experienced from the suit should be reported to the supplier immediately and the suit should not be worn until the problem has been addressed and resolved.**
- 6. Outcomes must be measured both qualitatively and quantitatively in future studies so that a more detailed impact of the suit can be further measured and understood.**

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APPENDICES:

DOCUMENTATION RELATED TO APPROVED MONASH UNIVERSITY ETHICS STUDY

A. SYNOPSIS OF PROTOCOL FOR QUALITATIVE DATA COLLECTION RELATED TO WHOLE STUDY

Principal investigators Name and address	Associate Professor Helen Bourke-Taylor Monash University Peninsula Campus Claire Cotter Cerebral Palsy Education Centre PO Box 211, Glen Waverly, Victoria 3150 Associate Professor Annette Joosten Registered Occupational Therapist and Australian Catholic University Dr Sophy TF Shih Deakin University 221 Burwood Hwy, Burwood. Victoria. 3125 Burwood Campus
Study title	Feasibility study and economic assessment of a transcutaneous electrical stimulation garment (Mollii Suit) to reduce pain, improve capabilities and quality of life in children with cerebral palsy
Protocol number	1
Study aims	The feasibility study will examine the acceptability, treatment outcomes and costs of the Mollii suit as an intervention. The Mollii suit is a non-invasive therapeutic technology aiming to reduce pain and improve capabilities and quality of life. The context of the study is the child/young person's home environment. The primary objectives are to assess the feasibility of the Mollii suit in children with cerebral palsy and the appropriateness of the intervention protocol and outcome measures. The secondary objectives are to evaluate the acceptability and costs of the Mollii suit to the families of children with cerebral palsy. The Mollii suit costs \$15,000 to purchase outright. Costs and savings will be

	calculated.
Study design	The Mollii suit feasibility study will use a sequential explanatory mixed methods design with a stepped wedged design and randomisation of participants into two groups to examine the changes in clinical outcomes, acceptability of the methods used to evaluate the outcomes, and an economic assessment of the intervention. This study will evaluate the feasibility and appropriateness of the Mollii suit and study protocol for children and young people with cerebral palsy, prior to conducting a larger pilot study or a randomised control trial in the future. This study will determine appropriateness of measurement tools used to detect changes in function, quality of life and pain following a six week intervention period using a protocol of wearing the Mollii suit for one hour every second day for 6 weeks. Qualitative interviews with parents will occur post follow-up to investigate further information about the intervention and the study protocol including measurement tool, costs, and family impact issues. A health economics assessment will be embedded in the feasibility study to evaluate the economic consequences of the new treatment technology. Data for the economic evaluation will be collected via a specifically designed study diary.
Number of centres	Single centre
Number of study participants	Up to 20 children with cerebral palsy
Eligibility criteria	1) Inclusion criteria: • Aged 5-18 • Receiving services from CPEC • Gross Motor Function Classification level I to III, Manual Classification System levels I to III, Communication Functional Classification System I to IV • Children/young people agree to wear the Mollii suit as per procedures and consent to the study • Parents/carers agree to assist their child to wear the

	Mollii suit as per procedures • Family able and available to fully participate in allocated step wedged group • Ability to communicate and self-report the assessment • Medical practitioner's approval that no contraindications are present precluding wearing the Mollii suit. 2) Exclusion criteria: • Individuals with electrical implanted devices • Individuals with medical devices that are affected by magnets, such as shunts • Individuals with cardiovascular diseases, infectious diseases, malignance (cancer), fever, pregnancy, rashes or skin problems • Individuals who subjectively express discomfort wearing the suit.
Study procedures	The participants will be recruited from children who receive their early intervention or school aged services through Cerebral Palsy Education Centre. The intervention is the Mollii suit which is fitted and programmed by the Mollii suit distributors, Metier Medical Advanced Rehabilitation Technologies (ART) and will be administrated by trained health care professionals: occupational therapists and physiotherapists. The Mollii suit will be fitted and programmed for each participant by a therapist. Participants will be involved in the Intervention phase of the study for 6 weeks with treatment duration of 60 minutes/session for every second day.
Outcome measurements	Outcome measurement and tools • Body Structure and function – BOT-2 UE, ASAS and hand held dynamometer • Performance and activity - PEDI-CAT, GMFM, mTUG, 1 Minute Walk Test • Pain – Pain Scale and Pain Diagram • Quality of life - PEDsQL Cerebral Palsy Module and CHU9D

	for children, and AQL8D for parents/carers • Acceptability – one to one interviews
Data analyses	Descriptive analysis of demographic variables and significance test on the change of outcomes measured pre and post intervention. Sample size for a future RCT will be calculated using G*Power(1) program. Inferential statistics: Both independent t-tests and a Generalized Estimating Equations (GEE) model may be used for analysing the longitudinal data. Based on data from pre, during, post, and follow up time points for all outcome measures to determine any differences in between group outcomes. If data are normally distributed Friedman and Wilcoxon signed rank tests will be used so as to reduce the chance of type 1 error due to the small sample size. Cost and economic assessment will be conducted using the cost diary of activities across 12 weeks (see Appendix III) Interviews will be analysed using a thematic approach. Manual methods of analysing data will be used to manage the qualitative data.

B. CPEC MEDICAL APPROVAL LETTER

All participant's received medical permission prior to enrolling in the study:



Cerebral Palsy Education Centre Inc.
PO Box 211, Glen Waverley, Victoria, 3150,
Australia
Phone 03 9580 0700 | Fax 03 9580 0669
Email: info@cpec.org.au | Internet:
www.cpec.org.au
ABN: 81 553 364 708 | ACN: A0040915L

To: Pediatrician or General Practitioner

Dear Sir/Madam,

Please find attached information about the Mollii Suit – Mollii is a unique assistive device for people with spasticity, motor disability, increased or decreased muscular tension. Mollii provides electrical stimulation via a specially designed garment, thus helping the body to relax and increase movement, function and activity. It is reported as being particularly effective in reducing spasticity, pain and enabling movement.

You are receiving this information because your patient and their family have expressed interest to participate in research about the Mollii suit- *a Feasibility Study and Economic Assessment of the Mollii Suit to reduce pain, improve capabilities and quality of life in children with cerebral palsy*. In the research, the child will wear the suit for one hour every second day for six weeks. This research is occurring through a collaboration between Cerebral Palsy Education Centre and Monash University.

There are some contraindications for wearing the Mollii Suit. It is not to be used with patients who have had electrical implanted devices or medical devices that are affected by magnets, such as shunts, including those patients who have undergone Deep Brain Stimulation (DBS), Intrathecal baclofen pump (ITB), pacemakers and shunts for hydrocephalus. Mollii is also contraindicated if a person has cardiovascular disease, malignancy (cancer), infectious disease, fever, pregnancy, rashes or skin problems.

Please confirm that the patient does not have any contraindications to being a participant in the Mollii study should the child and family chose to do so. Please complete the following:

I, Dr. _____ confirm that
_____ (patients name) does not have any of the
contraindications listed above.

Thank you for your assistance with this information. Please contact me if you have any further questions or queries.

Yours sincerely
Cerebral Palsy Education Centre

Claire Cotter
Chief Executive Officer

Learning for Life

C. EXPLANATORY STATEMENT ABOUT THE STUDY FOR PARENTS



Occupational Therapy Program
Faculty of Medicine, Nursing and Health Sciences

Explanatory Statement

Project title: Feasibility study and economic assessment of a transcutaneous electrical stimulation garment (Mollii Suit) to reduce pain, improve capabilities and quality of life in children with Cerebral Palsy (Project number 13096): parent interviews.

Principal researchers:

- Associate Professor Helen Bourke-Taylor, Department of Occupational Therapy, Monash University
- Ms Claire Cotter, Chief Executive Officer, Cerebral Palsy Education Centre
- Associate Professor Annette Joosten, Department of Occupational Therapy, Australian Catholic University
- Dr Sophy Shih, Senior Research Fellow, Deakin University

Your Consent

You and your child are invited to participate in the research project title at the top of this page. Please read this Explanatory Statement in full before making a decision to participate. This information sheet is yours to keep.

The purpose of this research

This project investigates the feasibility of applying and wearing the Mollii suit every second day for 6 weeks, as well as your perspective and experiences about how acceptable and practical the wearing schedule and the measurement protocol was for your child and family. The project seeks to hear about your experiences when your child was wearing of the Mollii suit, and what happened after regular use. The study will find out about parents experiences and observations of their children's reactions to the Mollii suit during usual daily life and activities. Further, this research project will measure any changes that your child experiences in terms of their pain, quality of life, spasticity, and other functional skills such movement or daily living skills. There is one overall study with two parts: one involving your child and measuring the effects of the Mollii suit, and this study which interviews parents to gather their experiences and perspectives.

Possible benefits

Participation in this study may or may not benefit your child. The research team will be collecting data about your child's pain, spasticity, mobility, use of their hands or speech. Your participation will assist us to collect data that may reveal new knowledge about what may assist people with cerebral palsy. The benefit of interviewing parents like you is that your experiences with the Mollii suit and your child and families perspective provides a record to share with other families who may consider this intervention in the future. Because little is known about the effect of Mollii suits and the wearing protocol on children/young people with cerebral palsy, the overall benefit of this study is that we will know more about effects, if any.

What does the research involve?

The research involves a short interview about your experiences and opinions of the Mollii suit and the research. You have already agreed to the research project that has enabled your child and family to trial the Mollii suit. This study requires a short semi-structured interview that will be recorded for accuracy. The interview can occur over the phone, via Skype or face to face at a location convenient to you (home, CPEC, other). Participation is voluntary. If you agree to participate, you will need to provide informed consent by signing the consent form.

How much time will the research take?

It will take you about 30 minutes to complete the interview.

Inconvenience/discomfort

There are no inconveniences or discomfort associated with this study aside from time.

Payment

There is no payment for participation in this research.

Can I withdraw from the research?

Being in this study is voluntary and you are under no obligation to consent to participation. You may withdraw at any time up until data analysis has commenced.

Confidentiality

Your name and your child and families details will be kept in a password protected electronic storage system at Monash University. Your details will be accessible only to the researchers. You will be allocated a pseudonym and you will not be identifiable to others, once data analysis starts.

Storage of data

Data collected will be stored in accordance with Monash University regulations and Victorian privacy laws and kept in secure electronic storage for 5 years. A report of the study may be submitted for publication, but individual participants will not be identifiable in any publication or on the website.

Use of data for other purposes

In the future, it is possible that this data may be used for other research purposes. For example, future research may investigate the Mollie suit and compare findings with this study. This research would serve as comparative data. By selecting the box on the the Consent Form you agree to your data to be used in this manner.

Results

All reports that result from this research will be shared with you at the end of the research. The results of the study will be presented as group data.

Is the research approved?

The ethical aspects of this research have been approved by the Human Research Ethics Committee of Monash University. This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

If you would like to contact the researchers about any aspect of this study, please contact the Chief Investigator:	If you have a complaint concerning the manner in which this research project is being conducted, please contact:
Associate Professor Helen Bourke-Taylor PhD Department of Occupational Therapy School of Primary Health Care Faculty of Medicine, Nursing and Health Sciences Monash University - Peninsula Campus PO Box 527, Frankston, Victoria, 3199 Phone 039 904 4470	Executive Officer Monash University Human Research Ethics Committee (MUHREC) Building 3e Room 111 Research Office Monash University VIC 3800 Tel: +61 3 9905 2052 Fax: +61 3 9905 3831 Email: muhrec@monash.edu (Please reference project number 13096)

Thank you.

Helen Bourke-Taylor

Associate Professor, Department of Occupational Therapy, Monash University

D. CONSENT FORM FOR PARENTS



Occupational Therapy Program
Faculty of Medicine, Nursing and Health Sciences

CONSENT FORM

Qualitative study: Parents of children/young person with cerebral palsy

Project title: Feasibility study and economic assessment of a transcutaneous electrical stimulation garment (Mollii Suit) to reduce pain, improve capabilities and quality of life in children with Cerebral Palsy (Project number 13096)

I have been invited to take part in the Monash University research project specified above.

I have had the project explained to me. I have read and understood the Explanatory Statement and I hereby consent to participate in this project.

I consent to the following:	Yes	No
I agree to be audio-recorded during the interview so that my exact words may be recorded and later transcribed for analysis by the research team.	☐	☐
All data from my interview as well as data extracted from the questionnaires will remain anonymous without names or identifying details and that I and my child will remain anonymous in any reports or publications.	☐	☐
I may ask at any time, prior to study completion, for my data to be withdrawn from the project.	☐	☐
My data will be kept in secure storage and accessible only to the research team.	☐	☐
I will receive copies of any publications resulting from this research project	☐	☐
My data may be used in future studies that investigate the Mollii suit although I will not be identifiable.	☐	☐

Name of Participant _____

Participant signature _____ Date _____

E. ETHICS APPROVAL NOTICE FROM MONASH UNIVERSITY



Monash University Human Research Ethics Committee

Approval Certificate

This is to certify that the project below was considered by the Monash University Human Research Ethics Committee. The Committee was satisfied that the proposal meets the requirements of the *National Statement on Ethical Conduct in Human Research* and has granted approval.

Project Number: 13069
Project Title: Feasibility study and economic assessment of a transcutaneous electrical stimulation garment (Mollii Suit) to reduce pain, improve capabilities and quality of life in children with Cerebral Palsy
Chief Investigator: Assoc Professor Helen Bourke-Taylor
Approval Date: 13/06/2018
Expiry Date: 13/06/2023

Terms of approval - failure to comply with the terms below is in breach of your approval and the *Australian Code for the Responsible Conduct of Research*.

1. The Chief Investigator is responsible for ensuring that permission letters are obtained, if relevant, before any data collection can occur at the specified organisation.
2. Approval is only valid whilst you hold a position at Monash University.
3. It is responsibility of the Chief Investigator to ensure that all investigators are aware of the terms of approval and to ensure the project is conducted as approved by MUHREC.
4. You should notify MUHREC immediately of any serious or unexpected adverse effects on participants or unforeseen events affecting the ethical acceptability of the project.
5. The Explanatory Statement must be on Monash letterhead and the Monash University complaints clause must include your project number.
6. Amendments to approved projects including changes to personnel must not commence without written approval from MUHREC.
7. Annual Report - continued approval of this project is dependent on the submission of an Annual Report.
8. Final Report - should be provided at the conclusion of the project. MUHREC should be notified if the project is discontinued before the expected completion date.
9. Monitoring - project may be subject to an audit or any other form of monitoring by MUHREC at any time.
10. Retention and storage of data - The Chief Investigator is responsible for the storage and retention of the original data pertaining to the project for a minimum period of five years.

Thank you for your assistance.

Professor Nip Thomson

Chair, MUHREC

CC: Ms Claire Cotter, Dr Sophy Shih, Associate Professor Annette Joosten

List of approved documents:

Document Type	File Name	Date	Version
Explanatory Statement	explanatory statements for groups 1 and 2	22/04/2018	1
Consent Form	consent forms for groups 1 and 2	22/04/2018	1
Questionnaires / Surveys	Interview questions for qualitative measure	23/04/2018	9
Questionnaires / Surveys	Demographic Tools	23/04/2018	9
Supporting Documentation	Attachment 1 - Mollii Suit	24/04/2018	1
Supporting Documentation	Attachment 2 - Letter CPEC re. Mollii Study	24/04/2018	1
Supporting Documentation	Attachment 3- letter medical permission	24/04/2018	1

F. METIER AGREEMENT FOR THE PRODUCT TO BE USED IN THE TRIAL.



Innovative Medical Safety Technologies

Att: Claire Cottler
Chief Executive Officer
Cerebral Palsy Education Centre Inc.
PO Box 211
GLEN WAVERLEY VIC. 3150

Dear Claire

**Re: Feasibility Study and Economic Assessment of Transcutaneous Electrical Stimulation
Garment (Mollii Suit) - Mollii Suit Feasibility Study**

In respect of the above Mollii Suit Feasibility Study being conducted on behalf of the Cerebral Palsy Education Centre Inc. (CPEC), Métier Medical Limited would like to confirm its support by way of the following provisions.

Métier Medical Limited will provide sufficient Mollii Suits to conduct the study over the multiple 6 week study periods and will ensure the availability of expertise by way of it's local therapeutic personnel to assess study participants and programme the Mollii Suit Control Units to the individual requirements of each participant.

Métier Medical Limited therapists will also be available for any follow up or technical support during and after the study as may be required.

Métier Medical Limited requests details of potential study participants as soon as possible to ensure that it can estimate and provide the range of suit sizes as will be required to complete the study.

We look forward to working with you on this important Australian study for Mollii Suit technology.

Kindest regards

Grant Howells
Director - CPEC
Métier Medical Limited

Unit 14, 10-14 North Avenue, Cessnock NSW 2325, Australia
PO Box 771, Cessnock NSW 2325
Telephone: +61 2 4909 8038 -61 7 5668 5436
Email: info@metiermedical.com
ABN 37 167 141 962

G. RESULTS

Theme 1: PRACTICALITIES COMPLYING WITH WEARING SCHEDULE AND PROTOCOL

Subtheme 1.1: Getting suit on and off

- **Ease**

(Lorraine) "And then getting it off, it was certainly - that was easy. We basically just pulled it so it came off inside out. "

(Adelaide) "it was so easy to put on compared to the [lycra body splint] which would take me a good half an hour to put on her, whereas the Mollii Suit it was just put her legs in, zip her up, she was done, she was ready to go, and the same with the arms, she would just push her arms in, zipped it up, and done."

(Jarrod) "First couple of times, maybe five times, four times, Mum gave me a hand. But after that, I got the hang of it and I could just put it on. I had it in my room. I'd just put it on at night, take it off myself."

(Layla) "It was fine. No problem. I helped her the first few times and then after that she could do it herself. So, she did it herself most of the time."

(Brie) "At the beginning, she was very cooperative and very happy to put the suit on. Probably for the first two to three weeks, either myself or Anthony had to do 100 per cent of the putting on the suit. It takes Brie a while to learn new motor patterns and she found it very challenging to get her arm and legs in with all the zips, because she would go through the wrong hole and then - so she needed us to help her completely. Then probably for the middle couple of weeks, she was doing part of it by herself but we'd still have to sort of help guide her feet in and zip it all up. But the last two times she wore it, she completely put it on independently, so she became independent putting on the suit."

(Reece) "He'd help zip it up, his arms up, and then he wanted it kept on after the hour was up."

- **Difficulty**

(John) "obviously it does take a little bit of time to put it on, particularly from John's level or motor sort of damage...a good 10 plus minutes (to put the suit on)....because he has a lot of tightness in his legs so, you know, it was kind of hard to sort of pull it on...not hugely difficult but it's not just like putting on a pair of pants or jeans or things like that. So it would be a little bit more time consuming. Some days it would take longer than 10 minute because I'd have to stretch out his arm, you know, git it on over his shoulders and zip up all the different areas..the positive outcomes can really outweigh the annoying getting the suit on and off"

(Liam) "Liam's left arm can pull in quite a lot and getting that through is tricky... so having to push through a tight garment ...was tricky...more frustration for me in trying to get him in the right position to help him get it on..."

(Lorraine) "it took us about 15-20 minutes to get it on until we got better at it..."

(Brie) “before we went into the study, I was thinking it was going to be quite easy. She just puts it on for an hour and really doesn't have to do much, you know, just lie around. But even just to get it on was such a challenge. It was never just an hour.”

Subtheme 1.2: Scheduling the wearing

- **Difficulty if sick or surgery**

(Liam) “So he had [orthopaedic surgery] and he was in a ...cast for ten days, so he didn't wear the Mollii suit during that period. “

- **Able to fit it into daily routines**

(Layla) “just follow the normal routine and then if it was a day she needed to wear the suit it would be towards the end of the day and she would usually sort of put it on either just before or just after dinner and wear it for an hour then and just, you know, chill out and either watch TV or something on the iPad or something like that. She'd just lie down and have it on.”

(John) “every second day we would just either generally put it on him when we came home from school...He would lie on his bed the majority of the time...”

(Milo) “We'd get home from school, he would take his uniform off and his shoes and socks off and his AFO, and then we'd put the suit on. He would sit and watch TV, because we called that the downtime.”

(Brie) “My husband and I both work full time so life is fairly busy...Some days, it would work that she could get the suit on at 5:30 and have it off by 6:30, have dinner, have a shower, get to bed, but a couple of nights a week she does karate, which means she gets home at about 7:00 and then we would put the suit on her at 7:00 until 8:00, so she'd go to bed a bit later.”

(Reece) “in the morning sort of after breakfast we got dressed, put it on, and then we might have been sitting for a bit doing an activity or watching a bit of TV, or going in the standing frame, so he wasn't too busy while he was wearing it...Then we just did our usual thing, whether it was going off to kinder or going somewhere or doing some other sort of activities in the day.”

(Reece) “yes you do put it on and zip it up, but you also need to be around home or a place where you can also take it off that hour later. So, some days, especially if you were at kinder and had to go somewhere it was like ,”Right, I've got to find this pocket of an hour where I can get that suit on and off,” so you know, you kind of sort of couldn't be somewhere in a difficult situation where you can't – your child can't stand up and he can't go to the toilet and just quickly whisk it off, you know, it takes a bit, I've got to lie him down an all that sort of stuff.”

(Liam) “Generally we couldn't fit it into the morning so it was an afternoon activity...finding the time was difficult, but I think it was so many things making that challenging, like kinder hours being here and there and appointments and just the time of the year so many things happening with the other boys.”

(Lorraine) "We found it was actually better for us to do it later in the afternoon when she was ready for resting time anyway...It's not just a pop the suit on at home, it fits into your life. You have to really have that time available like it's a whole another appointment time in your schedule..."

(Jarrod) "Usually I'd wear it at night. Usually, wake up, go to school, all that. I'd come home. Most of the days I'd have work, so I'd go to work first, come home, put the suit on...it's only for an hour. But there were days where I'm like, do I have to do this now? Because I've got so much homework. You just fit it in."

Subtheme 1.3: Problems with the suit

- **Skin**

(John) "one particular day where he was complaining of a tingling sensation which he did a few days, but one particular day he was pointing to his arm and when I took off the actual suit, there were red marks where some of the electrodes were."

(Milo) "I noticed that the markings, the little sensors have these little marks, they'd be on his body."

(Lorraine) "And she didn't have any other reactions, like no skin reactions or anything like that, to it."

- **Pain**

(Jarrod) "There were sort of times where you get a bit of shoulder pain"

(Brie) "Over time, I think - well, she had a couple of negative experiences in the suit where it was, for whatever reason, giving her increased pain while it was on. She described it as a stabbing pain, in particular areas on the left side of her body where apparently the suit wasn't even turned on. Then after that, she didn't want to wear the suit anymore...Brie would experience extreme stabbing pains behind her left knee and left ankle at the beginning of the trial, and then they changed the battery pack over and she then didn't experience it again."

- **Reject suit or wearing**

(Brie) "she's normally quite compliant with most of her therapy requirements, and she became very uncompliant, didn't want to wear it at all."

(Charlie) "when I put the suit, he doesn't want to put the suit, maybe because it's too fiddly because I have to stretch and all that on him. So maybe he doesn't like it"

- **Growth**

(Brie) "I think she must've had a growth spurt during it, because the suit became, particularly in the lower limbs, really difficult to zip up. She found it very uncomfortable around her waist towards the end of the study and it actually wouldn't meet around her belly by the end of the three weeks. She obviously had a big – six weeks, a big growth spurt."

(Layla) "A few times she complained that it was a bit tight." ... "in some places around the arms where you bend your arms, sort of near the elbow area, might have been a bit tight, digging in, and possibly sometimes just around the waist, the pants or the back of the knees."

Theme 2: CHILD'S EXPERIENCE WEARING THE SUIT

Subtheme 2.1: Experience during wearing

- **Pain**

(John) "He was saying "Mum, my arm hurts" or "My arm hurts up here...he would say 'I've got a bit of sore in my arm and my shoulder is sore'...I said, 'what do you mean by pain, John?' And he said 'it's like sharp, tingling'".

Jarrod "I occasionally got a bit of sharpness in my left shoulder, bit of sharp pain, as well as sort of when I sat there and - I didn't do much homework in it because I realised when you sit there and write, because they've got the electro-pads on it, when I bent my arm in a writing motion, it sort of started throbbing and then I have to straighten it and leave it for a while...It was just a bit annoying sort of pain."

(Liam) "No and he hadn't had pain."

(Lorraine) "She never had any pain with it or whatever. So she was quite happy just to wear it."

(Adelaide) "She liked the feel of it. That's about it. It never hurt her or anything, she always felt comfortable in it."

- **Relaxing**

(Layla) "She goes, "I can't move around and I can't put things away in my bedroom" and I'd say "Tidy up your bedroom while you're doing that" - "No, no, no, can't do that." And she'd come out and lie on the iPad, you know, look at the iPad."

(Liam) "He was quite relaxed with it on."

(Reece) "he seemed comfortable with it on, and like I said, pretty content that he was getting dressed in it and the feel of it, you know, against his body."

(Reece) "after a couple of weeks he was actually wanting it on. I said, "Do you like the suit on Reece? What do you like about it?" Yeah just said I think it was that hugging of his body and it gave him that feedback, that support you know that keeps him a bit together, so to speak...gave him that feedback in his body, a sense of where he was and all of that...he'd help zip it up, his arms up, and then he wanted it kept on after the hour was up...we were happy that he tolerated it really well and was happy to wear it,"

- **Tingling**

(John) "what he would say a couple of times before that "I feel tingling" or a funny sort of feeling like that."

(Milo) "He goes 'it tickles'... he was like 'it tickles, it feel good'".

(Milo) "I think he liked the sensations and the vibrations he was getting. Whatever he was getting, he wanted more of."

(Brie) "But then the next time she wore it, she felt it everywhere but had no negative experience. She actually quite liked it. She said it felt like she was wearing her vibration cushion."

(Lorraine) "Sometimes she said it felt a bit buzzy..."

(Adelaide) "She said it used to tickle her or it was tingly."

(Jarrod) "Most times when you put it on, you get some tingling in your arms and the end of your fingers."

- **Nothing**

(Layla) "She didn't have much reaction. She was quite comfortable with it."

(Reece) "He never complained of any tingling or any of those sorts of things, he was quite happy to put it on when it had to go on and helped zip it up."

(Liam) "...no complaints when he had it on."

(Lorraine) "...sometimes she couldn't feel it at all and she was quite happy just to lie and have an hour of stories or whatever."

- **Fiddling**

(Charlie) "... he just pulls on the electrode. He is very fiddly with things, so he pulls the electrodes but then I have to ... cover him up and – in the standing frame so that he doesn't move around much."

(Lorraine) "Because every time she'd sort of move, you know, she'd knock one of the leads off. And it's like hang on a minute, we've got to pop that back on."

- **Verbalizing**

(Adelaide) "...she loved it. She used to always say, "Is it Mollii Suit day?""

(Charlie) "...because he's not verbal he can't say whether he – what he's feeling...once he wears, he becomes quiet. He doesn't talk much."

Subtheme 2.2: Impact after wearing

- **Sleep**

(Adelaide) "...two times she had it on, she fell asleep with it on. Because it was so relaxing for her that she just fell asleep."

(Charlie) "He just becomes quiet for some time and a bit more relaxed and maybe a bit sleepy during the time he is wearing the Mollii suit"

(Milo) "When Milo normally goes to bed, he doesn't always put his head down and go to sleep, which is like a normal kid. But he would be up and down, up and down, up and down. When he wears the Mollii suit, he was, I put him in to bed, do the night routine, kiss goodnight, close the door,

sit down, wait for a second, third and fourth visit and I didn't get them. When you go in to check on him, he was flat out, he was dead asleep...I think he slept more soundly after the Mollii suit sessions."

- **Energised/less fatigue**

(Jarrod) "the biggest thing for me was fatigue-wise. I get fatigued much less. Used to be I could stand for ten minutes maybe holding onto something, but now I'm - at work even, I'm standing for half an hour at a time, taking breaks, standing up more."

- **Pain**

(John) "I think, in general, the first four weeks there was a decrease in the complaining of pain. You know, like when I say "complaining", he would often tell me, you know, five, six, seven, eight times a day prior to that "my legs are sore, mum", "my legs have been really, really sore today", you know. And often I'd just treat him with Panadol, stretching, massage, etc. But during the study, the first week it was pretty much still the same - often hard to gauge with his limited language ability, but he'd tell us - I noticed he wasn't complaining as much because I'd say to my husband, "Do you think he's complaining as much?" and he would say, "No, I don't think he is." But in the last two weeks it's just gone back to what it was."

(Brie) "reflecting on it and looking back at the pain diary, she actually - at the beginning of the trial, she complained about pain in her back, pain in her left leg, pain in her right leg. By the end of the study, she only complained about pain in her right foot."

(Reece) "he's never really mentioned to us that he's had any pain, so we wouldn't even know about his hips if he wasn't x-rayed. Whether that he's just used to how he feels in his body, or- but he certainly never complained of any pain to the point where he was crying or saying, "This hurts, Mummy," or whatever part of his body might hurt. He just never has. And even, before and after the suit, again, there was never any comment about whether anything hurt or whatever, it was just all good and okay."

(Lorraine) "Fortunately, she doesn't actually get a lot of pain. So she didn't have any pain prior to wearing it and that was the same afterwards as well. Like, it didn't cause her any pain."

(Jarrod) "For me, there were days where I walked quite a lot and I didn't get any pain at all, which was quite good... Normally in those situations, I'd have pain in my knees or sort of ache. But nothing."

- **Standing taller, feet flatter and improved fine motor skills**

(Lorraine) "But as it progressed, we were like yeah, she's definitely - you know, her feet are flatter, her fine motor skills have improved, her trunk ... she seemed to have more control everywhere and more stability. So we're like yeah, that foot is definitely flatter, her legs are not crossing over as much, here hands are a lot - you know, more precise with her fine motor stuff, she's sitting up straighter."

(Jarrod) "It really helped the most, getting up. Much, much easier to get up, because usually it's really stiff until you wake up, get a shower, but everything was loose. It was all good. Throughout the day, felt like you were standing much straighter, because I - I stand a little bit at school but not much. Especially at work is when I stand the most. That's when I really notice not much fatigue. That and

when I go to the gym. It wasn't even leg fatigue, it was just general fatigue. It was just getting much less of it."

- **Better motor function and daily life skills**

(John) "I would say at the start of the study it was quite substantially different in terms of – you know, you could clearly see that his legs were more relaxed; the tone was slightly more dampened; his legs were more relaxed; his toes, particularly his big toes, which curled in underneath, were easier – were just a bit more relaxed. And at school they found that his legs were also more relaxed and widened, even his ability to keep his legs open and closed together sitting in a chair."

(Milo) "He has been using his right hand a little bit more than normal. It's not a huge improvement, it's a little..."

(Reece) "at times, when I took the suit off his arms seemed a little easier or freer to get dressed after it...after the hour was up we'd go and take it off, and so that's was when we noticed that his arms were a little freer going over his head to put on his top"

(Lorraine) "...she seemed to have more control everywhere and more stability. So we're like yeah, that foot is definitely flatter, her legs are not crossing over as much, here hands are a lot - you know, more precise with her fine motor stuff, she's sitting up straighter. Like, you know, you could just see it improving all the time."

- **Nothing**

(Liam) "once I took that suit off, he was just back to him, typical Liam"

(John) "Towards the last two weeks, you know, I would say that the results of it was not as clear."

(Layla) "Unfortunately, we didn't notice really any change and so that was disappointing, I have to say. We were really hoping that we would see change. ... But in terms of any noticeable difference, not really."

(Reece) "we didn't really see anything yeah huge, I suppose, he sort of seemed the same."

- **Balance**

(Milo) "I was hoping for better balance. There was a slight improvement in my opinion, but not major."

- **Stamina**

(Jarrod) "I get fatigued much less."

- **Concentration and attention**

(John) "at school they were saying they had some great days, he's been on fire...he definitely seemed to be a little bit more alert"

(John) "he was a bit better functionally, sort of concentrating a little bit better...Now, I don't know because when we came back to fourth term of school, he seemed to be better than - like, last term he didn't have such a great term on and off. Like, he was complaining. So it's hard to know has his seizure activity, which he has in his brain, which can be simply very quickly on and off, has that subsided. It's hard to know."

(Milo) "I found that he concentrated a little bit more during dinner after the Mollii suit. You know, he was actually eating three quarters of his food without being distracted, which normally it's half."

(Jarrod) "I am doing more homework and I'm focusing a touch more"

- **Talking more**

(Milo) "I got more out of him, because I'd normally ask how was your day. Before the Mollii suit, "good". After, you know during the Mollii suit wearing, he'd go "oh it's okay, I play" and I get more out of him..."

(Charlie) "Lately his vocabulary has increased. I don't know whether it's Mollii suit or what it is. I'm not sure about that. But he has more vocab these days. He is making sentences now."

Theme 3: PARENT'S EXPERIENCE AND IMPACT OF BEING IN TRIAL

Subtheme 3.1: Appropriate to trial suit

- **Positive outcomes**

(Adelaide) "Because she's very tight in her legs she's a lot looser in her legs and her feet, she didn't have to wear her AFOs as much as I would normally have them on her."

(John) "from what I've seen initially, it really did help John. I was very, very positive and hoping that it would maintain because obviously it's better than invasive surgery or constant medications and things like that."

(Brie) "I consider that worthwhile, the reduction in pain, yeah, certainly."

- **No significant change**

(Charlie) "I haven't seen any major changes. "

Subtheme 3.2: Questioning interventions is good

- **Asking will it work**

(Layla) "And the idea of being able to potentially rent the suit and use it for a two or three month period to see if it's working or not working is quite appealing I think is the way to go."

(John) "if the child can explain the effects of the suit and whether it's really helping them."

(Reece) "we've had lots of experiences I suppose with different things and different professionals in his life with CP, and you know, some things work well for some kids, and those things don't necessarily with different kids, so it's a bit of hit and miss sometimes. I think Bob and I are sort of the

view, "Let's give it a shot. We don't know," and [Reece] doesn't really know any different, he's had CP all his life."

- **Asking why it does or doesn't work**

Milo: "If we wore it every day, I'm wondering if it would be, you know, there would be more of an improvement, if the intensity of the machine was a bit different, maybe that would make more of an improvement."

(Brie) "I would certainly give it a go again. I'd absolutely - I think you've got to try stuff. For us in particular, pain can be really bad for her sometimes. Even if it can just control pain, even if we don't see a difference in function, if we can get on top of the pain, I think it was worthwhile trying it."

- **How does it work**

(Brie) "I think that - as a health professional, I think we need to understand it a little bit better, understand the mechanisms of it a bit better, and what it's actually doing, and why there are changes occurring or not occurring, because I don't know that everyone that we have been working with has really understood it."

(Reece) "I don't really know what I expected when we got it because there wasn't sort of a lot of information about what it does or what it can do...I think I'd like to get a bit more information."

(John) "even though it doesn't functionally give him better motor functional outcomes, if it does in terms of just making his legs a little bit - you know, not as stiff, and the pain has decreased, then that would be enough of a positive for me to consider that."

- **Who will it help?**

(Lorraine) "...it's definitely worth looking into for these type of spasticity conditions... from a gross motor and fine motor skills situation, I think it would be well worth looking into as an adjunctive therapy to whatever they're doing. "

(Jarrod) "even if you didn't have that high of a physical disability, it really sort of helps with fatigue and just general things like that."

(Milo) "Maybe other kids had more of an improvement with it, maybe they are different. But it's like kids with any disability, they're all different..."

- **Future trialling**

(Layla) "...hopefully it will help some, but it just didn't have to really help Layla...Because we didn't see any sort of benefit from it, I probably wouldn't see any reason to trial it again...If they come back and tell me no, we saw a dramatic improvement in this, this and this, then perhaps it's not something that I've noticed or seen, well yeah under those circumstances could try it further."

(Liam) "Maybe in conjunction with say an individual physio appointment or OT, like rather than maybe a trial where that happens, where they wear it and you're doing something with a therapist. "

(Lorraine) "I guess it's more just working out what would be sort of an ongoing regime... would this be something that maybe you go okay let's do an intensive every second day for a month and then go back to doing your physio now that your feet are flatter or whatever."

(Jarrod) "...for me, I'd like, sort of, like I have now. I'd like a sort of, six-week block of one day on, one day off, one day on, one day off, because it does help. Then take a break for a while, and then another six-week block. Because for me, that's the most practical thing for me, because then I can balance that with my study and everything else."

(Layla) "I think it's definitely worth trialling because you don't know if you're going to get a benefit until you try it. I think the best way to go with it is to trial it...Again, it's definitely worth trying, you know. Before you embark on the surgery and what-have-you ... I think things like that are always better than surgical options...So I think it's potentially something worth considering before you embark on some of the more permanent things which have risk and side effects and what-have-you."

Subtheme 3.3: Recommending trialling to others

- **Costs versus benefit**

(Liam) "...if you've got an opportunity to try it, something that could give great benefit, I think you've got to give it a go."

(Lorraine) "I guess they would just have to look into the time constraint of it...You'd have to just look at it like another therapy. It was like okay, if you've got to get to physio once a week, you're doing speech once a fortnight, then you're doing Mollie Suit. It's just like chunking in another appointment."

(Adelaide) "If you're thinking about it just do it because, from our experience, it was the best thing for Adelaide because she is non-stop, on the go."

(Jarrod) "for the first, you know, sort of, few times you put it on, you just don't really want to go through the hassle, all the zips, sort of, buttons. It takes half an hour to put it on, take off, plus the extra hour. But after a while, it just keeps getting easier and easier to do it. You can really start seeing a difference...you always want the best for your own children. If something can help, I don't think is a harm to try."

(Reece) "to be able to access things like this, I think is hugely important for families with you know, children with disabilities because your chances of getting it on your plan is pretty minimal."

- **It might work in the future**

(John) "I think you can use it in conjunction with everything and all together, looking at it collectively, it's a good way of having to assist, particular periods."

(Lorraine) "...let's see what happens when they're not wearing it for a while. Do they build on the skills that they've got or do they slowly revert back and therefore how quickly does that happen and does it therefore mean that okay, you do an intensive for a month every three months or something."

(Reece) "I would probably say yes, I would, and just see, because he's developing, he's growing. You know, maybe – I don't know, who knows, but maybe it might yield a different result the next time round, or maybe not."

(John) "I think you just have to try it and see how it actually performs for your child and just stick to doing it exactly the way it should be done and hopefully it will work for you child."

(Reece): "I suppose just to go in with an open mind and not too many huge expectations."