

## Thesis

### **Dynamic Elastomeric Fabric Orthoses (DEFO) and physiotherapy after Botulinum toxin (BT) in adults with focal spasticity: A feasibility study using mixed methods.**

Submitted by Katharine Ann Stone to the University of Exeter  
as a thesis for the degree of  
Doctor of Clinical Research  
In September 2014

#### **Author's Declaration**

This thesis is available for Library use on the understanding that it is copyright material and that no quotation from the thesis may be published without proper acknowledgement.

I certify that all material in this thesis which is not my own work has been identified and that no material has previously been submitted and approved for the award of a degree by this or any other University.

Signature: .....

## **Acknowledgements:**

With thanks to the research participants for their co-operation, participation and patience in this feasibility study.

With thanks to the following research supervisors for their encouragement and support:

**Professor D A Richards**- Research Supervisor (Exeter University)

**Professor J Marsden**- Field Supervisor (Plymouth University)

**Vasilis Nikolaou**- Statistical Support (Exeter University)

With thanks to the following clinicians who participated in the study whose support and encouragement have made the implementation of this research possible:

**Sandra Douglas**- Physiotherapist clinician

**Ruth Osborne**- Physiotherapist clinician

**Sarah Lay**- Physiotherapist clinician (DM Orthotics Ltd<sup>©</sup>)

**Dr Abhijit Mate**- Consultant Physician in Rehabilitation Medicine

With thanks to **Mary Eason**, Research Administrative Support Worker for her excellent communication and organisational skills.

With thanks to **Karen Roach**, Therapies Manager for her encouragement and wisdom.

With thanks to **Martin Matthews**, Director of DM Orthotics Ltd<sup>©</sup> for his support of the research: by agreement to provide the supply of equipment; the clinical assessments and fitting of orthoses (DEFO's) in the study.

## **Foreword**

*“Research can be defined as the attempt to derive generalisable new knowledge by addressing clearly defined questions with systematic and rigorous methods.”* Research Governance Framework for Health and Social Care (2005)

The aim of this thesis is to clearly communicate an area of clinical research that is highly relevant to my profession and other health care providers, service users and health service commissioners. I explored the ‘black box’ of uncertainty in a defined complex clinical area. This was achieved by identifying key questions, developing and designing a methodologically appropriate and relevant clinical research study. The findings were evaluated and reported by critical commentary from the perspective of a novice in clinical research.

This thesis intends to build on previous learning in research knowledge and skills gained and accredited in the modular taught programme as part fulfilment for a Doctorate of Clinical Research. Therefore this thesis is presented on the basis of implementing critical skills for clinical research and is underpinned by an understanding of the Complex Interventions Framework (Medical Research Council, 2000, Craig *et al.*, 2008). In addition it is relevant to highlight the context of this research given the limited resources of professional part-time capacity available for this study. Consequently this thesis is explicitly for the fulfilment of the clinical research component of the Doctorate.

The purpose of this thesis is to contribute to a strategic body of evidence in support of a specific clinical area that deserves further research. This piece of work plans to build on an existing body of knowledge in the clinical area of spasticity and neurological rehabilitation to contribute in the discovery of new knowledge that can inform clinical practice. I do however acknowledge there are likely to be limitations in scope and impact of this small scale study.

The overall structure of the thesis intends to present a logical framework and contributes to the existing body of evidence. This follows the principles of Good Clinical ‘research’ Practice (Research Governance Framework for Health and Social Care, 2005). The thesis structure follows a logical template with an introduction to the key issues of spasticity, its current management and highlights the specific areas of uncertainty from critical appraisal of the literature. A research design is proposed with justification for a mixed methodology. The research process delivery is offered with subsequent findings and evaluation. The thesis then details the key findings, critical analysis and conclusions providing a unique contribution to new knowledge. The rationale for this structure is that it provides a coherent link from one chapter to another with a logical progression from concept, to delivery, to evaluation.

## Abstract

### **Title: Dynamic Elastomeric Fabric Orthoses (DEFO) And Physiotherapy After Botulinum toxin (BT) In Adults With Spasticity: A Feasibility Study Using Mixed Methods.**

**Aim:** A study to investigate the potential feasibility (including estimated effect-size), acceptability and health benefits of DEFO and physiotherapy in treatment of spasticity following intramuscular injection of BT.

**Participants:** Adults living in the community with focal spasticity of the upper or lower limb (Modified Ashworth Scale 2-3) recruited at a regional Spasticity Clinic.

**Intervention:** provision of an individually fitted DEFO (worn daily up to 8 hours) usual care and physiotherapy (as required) for 6 weeks.

**Methods: Mixed methods embedded design feasibility study: Quantitative:** Feasibility single-blind RCT: Intervention Group: DEFO intervention protocol, usual care and physiotherapy, Control Group: usual care and physiotherapy.

**Qualitative:** Topic guided interviews of the intervention group and clinicians.

**Measures:** Goal Attainment Scale (GAS) primary measure and secondary measures for function and care benefit; Arm Activity measure (ArmA), Leeds Arm Impact Score (LASIS), VAS for pain, European Quality of Life-5 Dimensions (EQ-5D), gait velocity (10MTT). Variance and fidelity was captured with: DEFO wearing record, Activity Log, clinical records and Physiotherapy modalities.

**Analysis:** ANCOVA adjusted means and statistical comparison for significance of measures (at baseline, after six weeks and twelve weeks) between groups and to inform power calculations. Thematic Analysis of clinician and participant transcribed interviews. Quantitative and qualitative findings were integrated and triangulated to inform a larger study.

**Results:** Participants (n=25) recruited over twelve months, (n=22) completed study. Statistical analysis showed improvements in both groups with greater health benefit in the intervention group with mean difference in the GAS of 12.17 (95%CI: 3.16 to 21.18;  $p = 0.014$ ) but no statistical significance in the secondary measures. Effect-size was estimated from the GAS findings for 200 per group for a larger study. Physiotherapy modalities for spasticity were linked to 'passive' and 'active' function. Feasibility and acceptability was established with Thematic Analysis providing valuable insight into patient and clinician perspectives on disability.

**Conclusions:** Findings indicated potential added health benefits including carer benefit. Feasibility, acceptability and clinical application of DEFO as a potential new intervention were established. This has implications for future spasticity management with patient benefit for passive and active function. Further research is indicated with a fully powered study (based on the GAS sample results) to evaluate DEFO efficacy in people with spasticity following BT.

**Key words:** Spasticity, Botulinum toxin, physiotherapy, dynamic orthoses.

**Acknowledgements:** DM Orthotics Ltd<sup>©</sup>

**Ethical registration and approval: Ref: 12/SC/0518** (NRES) Committee South Central-Berkshire B-ethical approval registered with local NHS R&D and Exeter University.

## Contents

	page
<b>Author's declaration</b>	<b>1</b>
<b>Acknowledgements</b>	<b>2</b>
<b>Foreword</b>	<b>3</b>
<b>Abstract</b>	<b>4</b>
<b>List of Contents</b>	<b>5</b>
<b>Chapters</b>	
<b>Chapter 1 Introduction: Opening the 'black box'</b>	<b>13</b>
1.1 Spasticity: impact and management	14
1.2 Neurological rehabilitation: outcome and efficacy of treatment	17
1.3 Physiotherapy: professional perspectives	21
1.4 Health technology: A role in rehabilitation	25
1.5 Dynamic Elastomeric Fabric Orthoses (DEFO): Health technology Industry collaboration	27
1.6 Identified research problem and uncertainties	31
1.7 Summary	32
<b>Chapter 2 Systematic Review</b>	<b>34</b>
2.1 Identified search strategy	35
2.2 Data extraction	38
2.3 Results	40
2.4 Data synthesis	50
2.5 Discussion of the findings	62
2.6 Summary	67
<b>Chapter 3 Methodology</b>	<b>68</b>
3.1 Research considerations	69
3.2 Study methodology and rationale	72
3.3 Rehabilitation and health related measures	76
3.4 Methodological approach of Thematic Analysis	82
3.5 Methodology of integration	84
3.6 Summary	87
<b>Chapter 4 Methods</b>	<b>88</b>
4.1 Background and objectives	88
4.2 Study design	90

4.3 Participants and setting, eligibility, recruitment and consent	94
4.4 Interventions and comparator groups	97
4.5 Outcome Measures	99
4.6 Randomization, concealment of allocation, and blinding	105
4.7 Sample size, statistical methods and analysis	107
4.8 Data management	109
4.9 Ethical process	110
4.10 Summary	111
<b>Chapter 5 Results I (Quantitative)</b>	<b>113</b>
5.1 Overview of data presented	113
5.2 Baseline characteristics of participants	113
5.3 Recruitment and attrition pathway	115
5.4 Quantitative pilot RCT data	118
5.4.1 Primary Measure	118
5.4.2 Secondary Measures	121
5.5 Fidelity, adherence and variance data	133
5.6 Data Summary	139
<b>Chapter 6 Results II (Qualitative)</b>	<b>142</b>
6.1 Overview of findings presented	142
6.2 Participant feedback	143
6.2.1 Global Participant theme: (GP.1) Research Experience: Acceptability	143
6.2.1.1 Organizing Participant theme (OP.1): Research expectations	146
6.2.1.2 Organizing Participant theme (OP.2): DEFO Acceptability	149
6.2.1.3 Organizing Participant theme (OP.3): Protocol feasibility	152
6.2.1.4 Organizing Participant theme (OP.4): Health benefits	154
6.2.1.5 Organizing Participant theme (OP.5): Adverse effects	158
6.2.2 Global Participant theme (GP.2): Perceptions of disability: impact on research	163
6.2.2.1 Organizing Participant theme (OP.1): Differing perceptions of disability	163
6.2.2.2 Organizing Participant theme (OP.2): Generalisability to condition	168
6.3 Clinician feedback	171
6.3.1 Global Clinician theme (GC.1): Research impact on clinical practice	171
6.3.1.1 Organizing Clinician theme (OC.1): Research expectations	174
6.3.1.2 Organizing Clinician theme (OC.2): Ethical issues	175
6.3.1.3 Organizing Clinician theme (OC.3): Clinical practice	178
6.3.1.4 Organizing Clinician theme (OC.4): Research experience	183
6.3.2 Global Clinician theme (GC.2): Feasibility and acceptability of DEFO in a clinical setting	188
6.3.2.1 Organizing Clinician theme (OC.1): Protocol feasibility	190
6.3.2.2 Organizing Clinician theme (OC.2): DEFO intervention acceptability	192
6.4 Summary	195

<b>Chapter 7 Integration</b>	<b>198</b>
7.1 Health benefits	199
7.2 Feasibility of the protocol	209
7.3 Acceptability of the DEFO intervention	218
7.4 Quality Framework for study integrated findings	227
7.5 Summary	229
<b>Chapter 8 Discussion</b>	<b>230</b>
8.1 Ethical considerations	231
8.1.1 Ethical submissions	231
8.1.2 Ethical considerations in clinical practice	232
8.1.3 Research Reference Group	234
8.2 Collaboration with health technology industry	235
8.3 Recruitment and retention	237
8.4 Strengths of the study findings and implications	238
8.5 Limitations of the study	242
8.6 Implications for practice and further research	243
8.7 Summary of key learning points	246
<b>Chapter 9 Conclusion</b>	<b>247</b>
9.1 Summary of key findings and learning points	248
9.2 Implications for further research	251
9.3 Strategy for dissemination	255
9.4 Conclusion	255
<b>Reflections from a Research Diary (for reference)</b>	<b>256-263</b>

### **List of Tables**

Table 2.1 Level of evidence (SIGN scale)	39
Table 2.2 Summary of evidence: Spasticity management with Physiotherapy	43
Table 2.3 Summary of evidence: Splinting and Dynamic Orthoses	46
Table 2.4 PICOS Summary of findings	50
Table 2.5 Summary of evidence by GRADE	53
Table 3.1 Six phases of Thematic Analysis	82
Table 4.1 Normal healthy gait velocity	104
Table 4.2 DEFO: Record of wearing	105
Table 4.3 GAS T formula	108
Table 5.1 Baseline characteristics of participants	115
Table 5.2 ANCOVA for the change (from the baseline) in GAS T score between intervention and control at six and twelve weeks	120

Table 5.3 ANCOVA for the change (from the baseline) in VAS between intervention and control at six and twelve weeks	123
Table 5.4 ANCOVA for the change (from the baseline) in EQ-5D between intervention and control at six and twelve weeks	125
Table 5.5 Summary statistics of ArmA (Active) by group over time	126
Table 5.6 ANCOVA for the change (from the baseline) in ArmA (Active) between intervention and control at six and twelve weeks	127
Table 5.7 Summary statistics of ArmA (Passive) by group over time	127
Table 5.8 ANCOVA for the change (from the baseline) in ArmA (Passive) between intervention and control at six and twelve weeks	128
Table 5.9 Summary statistics of LASIS (Participant) by group over time	129
Table 5.10 ANCOVA for the change (from the baseline) in LASIS (Participant) between intervention and control at six and twelve weeks	130
Table 5.11 Summary statistics for LASIS (Carer) by group over time	130
Table 5.12 ANCOVA for the change (from the baseline) in LASIS (Carer) between intervention and control at six and twelve weeks	131
Table 5.13 Ten Meter Timed Walk Test: Descriptive Data	132
Table 5.14 Summary of DEFO wearing record	134
Table 5.15 Summary of physiotherapy interventions and contact time (in twelve weeks)	135
Table 5.16 Research Activity log (by group)	136
Table 5.17 Summary of goals set (by group)	138
Table 5.18 Summary of findings: pilot RCT (primary and secondary measures)	140
Table 6.1 Summary of qualitative data (Thematic Analysis of participant and clinician Topic guided interview data)	196
Table 7.1 Summary table of combined qualitative and quantitative data sets for health benefit	203
Table 7.2 Summary table of combined qualitative and quantitative data findings for the feasibility of the protocol	212
Table 7.3 Summary table of combined qualitative and quantitative data findings for acceptability of the DEFO intervention	220
Table 7.4 Mixed methods quality framework for integrated findings	228
Table 9.1 Summary of the key findings and learning points	250
Table 9.2 Summary of research implications	252

### **List of Figures**

Figure 1.1 DEFO long sleeve glove	29
Figure 1.2 DEFO Sock	29
Figure 2.1 Flow diagram of selection of studies	41
Figure 3.1 Flow chart: The revised MRC Complex Interventions Framework	70
Figure 3.2 International Classification of Functioning	77
Figure 3.3 Thematic Analysis: using systematic methodology	84



Figure 4.1 Procedural diagram of mixed methods embedded study Design	91
Figure 4.2 Intervention pathway	93
Figure 5.1 CONSORT flow diagram: Recruitment and attrition pathway	117
Figure 5.2 Chart of GAS T score by group over time (SD)	119
Figure 5.3 Chart VAS by group over time (SD)	122
Figure 5.4 Chart of EQ-5D summary statistics by group over time (SD)	124
Figure 5.5 Chart for ArmA (Active) by group over time (SD)	126
Figure 5.6 Chart for ArmA (Passive) by group over time (SD)	128
Figure 5.7 Chart for LASIS (Participant) score by group over time (SD)	129
Figure 5.8 Chart for LASIS (Carer) score by group over time (SD)	131
Figure 5.9 Summary of results for ten meter timed walk test	133
Figure 6.1 Thematic Analysis of participant findings	144
Figure 6.2 'Thematic map' for Global Participants theme: (GP.1) Research Experience: Acceptability	145
Figure 6.3 'Thematic map' for Global Participants theme (GP.2): Perceptions of disability: impact on research	162
Figure 6.4 Thematic Analysis of clinician findings	172
Figure 6.5 'Thematic map' for Global Clinicians theme (GC.1) Research impact on clinical practice	173
Figure 6.6 'Thematic map' for Global Clinicians theme (GC.2): Feasibility and acceptability of DEFO in a clinical setting	189
Figure 7.1 Photograph showing DEFO fitting	224
Figure 7.2 Photograph of DEFO colour preference	225

### **List of Appendices**

<b>Appendix 1</b> Ethical approvals	264
<b>Appendix 2</b> DMO letter of agreement	266
<b>Appendix 3</b> Example of search strategy	267
<b>Appendix 4</b> Participant Information Sheet ( <b>PIS</b> )	268
<b>Appendix 5</b> Consent form	273
<b>Appendix 6</b> Research intervention protocol	275
<b>Appendix 7</b> Primary measure ( <b>GAS</b> )	276
<b>Appendix 8</b> Physiotherapy Data Capture sheet	278
<b>Appendix 9</b> DEFO Wearing protocol and Log	280
<b>Appendix 10</b> Secondary measures EQ-5D/VAS/LASIS/ArmA/10MTT	281
<b>Appendix 11</b> Topic Guided Interview (Participants)	292
<b>Appendix 12</b> Topic Guided Interview (Clinicians)	293

<b>Appendix 13</b> Activity Log	294
<b>Appendix 14</b> DM Orthotics Ltd. copyright agreement for photographs	297
<b>Appendix 15</b> Eligibility criteria definitions	298
<b>Appendix 16</b> ‘Framework’ analysis examples	301
<b>Appendix 17</b> Summary research report	307
<b>Appendix 18</b> Gantt chart	314
<b>Definitions</b>	10
<b>Abbreviations</b>	11
<b>Text (Chapters1-9 and Reflections)</b>	13-263
<b>References</b>	316-337
<b>Appendices</b>	264-314
<b>Glossary</b>	315
<b>Publications</b>	338

## Definitions

**Aphasia** ‘is an acquired language impairment following brain damage that affects some or all language modalities: expression and understanding of speech, reading and writing’. Brady, M, C *et al.*, (2012) Speech and language therapy for aphasia following stroke. *Cochrane Database of Systematic Reviews*, Issue 5. Art. No.: CD000425. DOI: 10.1002/14651858.CD000425.pub3.

**Botulinum toxin** ‘The most potent neurotoxin known and is produced by the gram negative bacterium *Clostridium botulinum*. The paralytic effect of the toxin is due to blockade of neuromuscular transmission. Injection into a muscle causes chemical denervation and local paralysis and this effect has led to the development of the toxin as a therapeutic tool’. Barnes and Davis, (2000, p143)

**Contracture** results ‘when a joint cannot be moved regularly through its full range of motion causing physiological changes in the surrounding muscles and other tissues causing them to shorten, which restricts mobility around the joint’. Farmer *et al.*, (2001, cited in NHS, QIS<sup>®</sup>, 2005)

**Mixed methods** ‘A research design with philosophical assumptions as well as methods of inquiry. As a methodology, it involves philosophical assumptions that guide the direction of the collection and analysis of data and the mixture of qualitative and quantitative approaches in many phases in the research process. As a method, it focuses on collecting, analysing and mixing both quantitative and qualitative data in a

single or series of studies. Its central premise is that the use of quantitative and qualitative approaches in combination provides a better understanding of research problems than either approach alone'. Creswell and Plano Clark, (2007, p.5)

**Orthosis or splint** A removable external device which provides a means of maintaining the specific position of a limb by providing static or dynamic support. They are which are designed to 'apply, distribute or remove forces to or from the body in a controlled manner to perform one or both basic functions of control of body motion and alteration or prevention in the shape of body tissue.' Rose, G. (1986).

**Physiotherapy** 'Physiotherapy helps restore movement and function when someone is affected by injury, illness or disability. Physiotherapists help people affected by injury, illness or disability through movement and exercise, manual therapy, education and advice. At the core is the patient's involvement in their own care, through education, awareness, empowerment and participation in their treatment' Accessed: 15 May 2014, Chartered Society of Physiotherapy (2013) <http://www.csp.org.uk/your-health/what-physiotherapy>

**Spasticity:** 'a motor disorder characterized by a velocity-dependent increase of tonic stretch-reflexes with exaggerated tendon jerks, resulting from hyperexcitability of the stretch reflex' Lance (1980, pp485-494). More recently: 'disordered sensori-motor control resulting from an Upper Motor Neuron (UMN) lesion, presenting as intermittent or sustained involuntary activation of muscles' EU-SPASM, Pandyan et al., (2005, p.2).

**Transcription** is explained as 'a process of rigorous orthographic transcript verbatim of verbal (and non-verbal where relevant) utterances' Reissman, C, K. (1993).

## Abbreviations

<b>ABI</b>	Acquired Brain Injury
<b>ANCOVA</b>	Analysis of covariance
<b>ARAT</b>	Action Research Arm Test
<b>ArmA</b>	Arm Activity measure
<b>BSRM</b>	British Society of Rehabilitation Medicine
<b>BT</b>	Botulinum toxin
<b>CASP</b>	Critical Appraisal Skills Programme
<b>CCG</b>	Clinical Commissioning Group
<b>CI</b>	Confidence Interval
<b>CNS</b>	Central Nervous System
<b>CP</b>	Cerebral Palsy
<b>DEFO</b>	Dynamic Elastomeric Fabric Orthosis
<b>DMO</b>	Dynamic Movement Orthosis

<b>EQ-5D</b>	European Quality of Life-5 Dimensions
<b>FES</b>	Functional Electrical Stimulation
<b>GAS</b>	Goal Attainment Scale
<b>ICF</b>	International Classification of Functioning
<b>LASIS</b>	Leeds Arm Spasticity Impact Score
<b>MAS</b>	Modified Ashworth Scale
<b>MMAS</b>	Modified, Modified Ashworth Scale
<b>MRC</b>	Medical Research Council
<b>MS</b>	Multiple Sclerosis
<b>MTU</b>	Muscle Tendon Unit
<b>N</b>	Number
<b>NHS</b>	National Health Service
<b>PEDro</b>	Physiotherapy Evidence Database and Resource
<b>PCI</b>	Physiological Cost Index
<b>PCT</b>	Primary Care Trust
<b>PICOS</b>	Population, Intervention, Comparators, Outcomes, Study Design
<b>PIS</b>	Participant Information Sheet
<b>PPI</b>	Patient and Public Involvement
<b>RRG</b>	Research Reference Group
<b>SCI</b>	Spinal Cord Injury
<b>SIGN</b>	Scottish Intercollegiate Guidelines Network
<b>SMART</b>	Specific Measurable Achievable Realistic Timed
<b>SPSS</b>	Statistical Package for Social Sciences
<b>TBI</b>	Traumatic Brain Injury
<b>UMNL</b>	Upper Motor Neuron Lesion
<b>UK</b>	United Kingdom
<b>VAS</b>	Visual Analogue Scale
<b>WHO</b>	World Health Organisation

## Chapter 1

### Introduction: Opening the 'black box'

#### Key points:

- **Opening and unpacking the 'black box' of rehabilitation**
- **Introduction of key topics: spasticity, rehabilitation, physiotherapy, health technology**
- **A 'window of opportunity' following Botulinum toxin (BT)**
- **Collaboration with health technology industry**
- **Defining DEFO, application and function**
- **Identified research problem and uncertainties**

#### Introduction

Clinical practice in the field of neurological rehabilitation highlights important areas of uncertainty that deserve scrutiny. Spasticity management following Botulinum toxin (BT) is identified as a specific clinical field that warrants further research. On opening the 'black box' of spasticity rehabilitation, this clinical practice is strewn with uncertainty. It is acknowledged by Khan *et al.*, (2013, p.15) '*investigating complex interventions such as MD (multidisciplinary) spasticity management is challenging in the real world*'. This study found limited evidence for practice specific guidance following BT and highlights research uncertainties; what are the optimum treatment strategy, intensity, location and specificity? Direction for research is recommended including; the evaluation of the contribution of individual components of rehabilitation, consensus of appropriate patient-centred outcomes and wider patient and caregiver perspectives (Khan *et al.*, 2013).

The significance of this clinical practice area is now discussed in light of a preliminary review of the literature which identified key topics that justified further study. This evidence provided background for the current study and was critically evaluated to find what was known and to identify the knowledge gaps. This was in order to inform relevant research questions.

This chapter provides context and rationale to explain the research approach. It includes an introduction to the area of clinical practice studied and introduces constituent themes within the thesis, including the underlying philosophical bases and methodology that are later expanded upon. An overview of the knowledge base of spasticity is presented, including its impact and management. Next neurological rehabilitation is appraised with perspectives on research and physiotherapy. Developments in health technology are acknowledged for their recent contribution to health care with the potential for translational research in the field of neurological rehabilitation. Finally the research approach for this study is introduced providing the purpose and structure of the thesis.

## **1.1 Spasticity: Impact and management**

Spasticity commonly follows damage or disease to the central nervous system (CNS). Spasticity is a phenomenon that is acknowledged to be complex in presentation and management (Sheean, 1998; Barnes, 2001; RCP *et al.*, 2009). Spasticity can present as harmful over-activity of muscles with the impact of abnormal postures and movement. Common aims for treatment are to provide symptom relief, improve function and prevent deterioration.

From an epidemiological perspective, there are no accurate figures available for the prevalence of spasticity. However it is prevalent in many neurological conditions and those with acquired brain injury. Both Sommerfeld *et al.*, (2012) and van Kuijk and colleagues, (2007) corroborated the findings of Watkins *et al.*, (2002); who identified spasticity in approximately one third of people with stroke, 75% people with severe traumatic brain injury, 60% of people with Multiple Sclerosis (MS). In addition it is prevalent in other neurological conditions such as people with Cerebral Palsy and Spinal Cord Injury.

The impact of spasticity, if left untreated, can lead to increased muscle tension and shortening of muscles and soft tissues resulting in contractures, pain and increased disability. Secondary complications such as the potential development of pressure ulcers due to reduced functional activity can be both

distressing and costly to manage. Targeted successful treatment can demonstrate measureable impact on both caregiver burden (Bhakta *et al.*, 2000) and secondary complications (Boyd *et al.*, 2000). Personal health and wellbeing are paramount in treatment planning and should be considered within a rehabilitation framework such as that in the International Classification of Functioning (ICF) Disability and Health model proposed by the World Health Organisation (WHO, 2001). This model is presented and explained in **Figure 3.2, Chapter 3.5.**

Spasticity is acknowledged to be a complex, highly variable and dynamic phenomenon (Barnes, 2001). It can lead to both reduced movement excursion and altered muscle pattern generation. Sheean (1998) observed prolonged absence of volitional movement results in biomechanical changes in the structure of the muscle and soft tissues such as reduced elasticity and compliance. Commonly spasticity produces altered timing, force generation and resistance to movement. This increases the potential for deformity of limbs with resultant disability and functional dependence (O'Dwyer *et al.*, 1996). In focal spasticity and multi-focal spasticity the impact of increased tension and shortening in the agonist muscles produces an inhibiting effect on the activation of the antagonist muscles. Consequently the antagonist muscles are impaired from prolonged overstretching and this contributes to altered length, strength ratios (Gracies, 2005) and ultimately reduced movement.

Pandyan *et al.*, (2005) suggests it is unlikely abnormal muscle activity in spasticity results exclusively from stretch reflex hyper-excitability. Other 'positive' characteristics include: increased muscle tone, exaggerated tendon reflexes, repetitive and released flexor reflexes. Both neurogenic and biomechanical components of muscle over activity contribute to changes in the muscle architecture (O'Dwyer *et al.*, 1996).

Both Sheean (2001) and Barnes (2001) agree it is important to recognise both the neural and biomechanical components of muscle stiffness as treatment options differ. The biomechanical component is unresponsive to medication but amenable to stretching and optimal positioning to maintain muscle length (Pope, 2007; Katalinic *et al.*, 2010; 2011; Sheean *et al.*, 2010; Tyson *et al.*,

2011). However, the neural component is velocity-dependent as described by Lance (1980) and responds to medical intervention; directed to the nervous system both centrally and locally. When spasticity presents globally affecting more than one limb or area of the body; it can be effectively managed by oral anti-spasmodic medication (Stevenson and Jarrett, 2006; Thompson *et al.*, 2005). It is not the purpose of this study to investigate this area of clinical practice.

On the other hand it is clear management of focal spasticity warrants further investigation. A European consensus (Wissel *et al.*, 2009) has drawn up recommendations for management of adult spasticity using Botulinum toxin (BT) as part of an integrated treatment strategy. BT is used as a therapeutic component in the management of localised spasticity by intra-muscular injection to targeted neuromuscular nerve blockade and thus temporary partial paralysis of selected muscle(s). This enables selective weakening of targeted hyperactive muscles (RCP *et al.*, 2009). BT has anti-nociceptive and muscle relaxant properties and is thus clinically indicated in the treatment of focal limb spasticity. It has become a preferred treatment option for focal spasticity due to its selectivity, reversibility and rarity of adverse reactions (Bakheit *et al.*, 2001; Moore, 2002; Pittock *et al.*, 2003; Naumann and Jankovic, 2004; Jankovic *et al.*, 2005; Simpson *et al.*, 2008).

According to Gracies *et al.*, (2007, p.1796) BT provides a '*window of opportunity*' for optimising rehabilitation for 'active' or 'passive' functional gains' (Sheean, 2001; Simpson *et al.*, 2008). This is worthy of further consideration as there is no clear guidance on what treatments are most effective during this time limited opportunity. It is however widely acknowledged BT has the potential to reduce the overall costs of long term care of people with focal and multi-focal spasticity when used in a combination of directed functional rehabilitation and 'passive' care (RCP *et al.*, 2009). Interestingly it is not yet clear what explicit components of functional rehabilitation are most effective.

Whilst the evidence is overwhelming in support of the efficacy of BT (RCP *et al.*, 2009) the impact on economic benefit is in doubt (Wallesch *et al.*, 1997; Ward *et al.*, 2005). More recently the multi-centred BoTULS trial (Shaw *et al.*, 2010)



raised further doubt regarding cost-effectiveness. The current cost of BT per average treatment is £288-£333 (for 2 vials Botox-Dysport, PCH Pharmacy, 2014) and it would appear clinically expedient to direct these costs effectively to produce cost-efficient outcomes.

Wissel and colleagues (2009) outlined the research challenges that still exist, namely muscle identification and injection guidance, cost-effectiveness, recommendations pre and post injection and trial design. In particular the European consensus (Wissel *et al.*, 2009, p.22) highlighted that more studies are required *'to ascertain the optimal, timing, duration and intensity of post botulinum toxin physical therapy'*. Furthermore the consensus recommends the use of valid and sensitive clinical scales and follows the International Classification of Functioning (ICF) model (WHO, 2001) to assess and evaluate the impact of the intervention and outcome (**Figure 3.2, Chapter 3.5**).

To date according to Thompson *et al.*, (2005) the management of spasticity is based on a 'logical and pragmatic approach' with no formally agreed evidence based model. Thompson and colleagues propose a spasticity management model according to level; mild, moderate and severe. This model simplifies a management approach linking the presentation of severity with a stepped approach. What is agreed is that education, promotion of self-management and access to supporting services with knowledge and skills in this field can help to prevent secondary complications. Furthermore methods of promoting active movement and modification in unhelpful patterns of movement when accompanied by pharmacological treatment are important factors in optimal management. This is one of the primary functions of neurological rehabilitation. Neurological rehabilitation, outcome and efficacy of treatment are considered as the underlying basis for this study.

## **1.2 Neurological rehabilitation: Outcome and efficacy of treatment**

Fundamental issues about rehabilitation can provide greater insight into its complexity. Firstly rehabilitation can be seen as a construct which is based on a model of service delivery and on the composite team members who deliver the

defined service approach by effective team-working (Wade, 1992; Khan *et al.*, 2013). Secondly the nature of rehabilitation is multi-faceted and thus requires a team approach. Each member of the multi-disciplinary team (MDT) contributes a valuable role to deliver patient centred care. Individual roles are well-defined but can often overlap and merge to produce more efficient practice and outcomes (Booth and Hewison, 2002). Accurate comprehensive assessment is required to identify the individual's clinical status, functional problems and confounding conditions or other important issues. Treatment plans involving the patient and caregivers can be formulated with the MDT to ensure realistic goal setting and expectation of outcomes (Seigert and Taylor, 2004). It is particularly important to choose measures in rehabilitation which have construct validity and that are chosen to measure what is relevant and of importance to the patient and not just the clinician (Rushton and Miller, 2002; Broetz and Birbaumer, 2013). A framework for evidence-based choice of measures is recommended for neurological physiotherapy by Tyson *et al.*, (2008). Communication between members of the MDT and the patient and family is essential to ensure efficacy of treatment (Khan *et al.*, 2013) and are fully engaged (MacDonald *et al.*, 2013).

It is claimed by Wade (1992) and yet again by Wissel *et al.*, (2009) neurological rehabilitation has made little progress to date to evidence efficacy due to the lack of consensus on what methods are used to measure progress. However, it is widely agreed that clinical assessment provides a starting point for measurement. The 'Medical' model for rehabilitation, with a diagnostic and prescriptive bias, is one that has been commonly used such as when following protocols in orthopaedic rehabilitation and in medical research. The 'Medical' model assumes a simplistic mechanical view of illness from a structural impairment or functioning basis. This model has a bias of bio-medical perception of normalcy (Seelman, 2004). Criticisms of this model include limited assumptions of quality of life, adaptation and social access. It has a limited view when considering aspects of mind, family relationships and environmental factors. In this model the authority lies with the professional with a clinician directing care from a position of knowledge and power following a biological approach in diagnostic formulations and associated treatments. In contrast an integrative 'Bio-psychosocial' model such as the ICF model of rehabilitation (WHO, 2001) is less prescriptive and more person-centred which allows for

individual variances and acknowledges the interactions between physical, psychosocial and environmental factors for optimal recovery.

It is important to evaluate the outcome of a healthcare episode holistically, taking into consideration all of the components including personal perspective, role, relationships and beliefs (WHO, 2001; Stucki *et al.*, 2007). This is the reason why the UK has adopted the ICF model of rehabilitation (**Chapter 3.5**). However the success of its implementation in clinical practice was found to be dependent on two factors according to Tempest *et al.*, (2012), firstly to adopt the ICF in ways that meet the local service needs and secondly to adapt the ICF language and format. Implications drawn from this action research suggest that the ICF, as a conceptual framework, can be used in clinical practice as a vehicle to implement local service priorities. In order for the global ICF classification to be successfully adopted into clinical practice in this study the language terminology and format was adapted to the local needs of the team.

Another consideration includes the use of predicted outcomes. The British Society of Rehabilitation Medicine (Skinner and Turner-Stokes, 2006) suggest rehabilitation warrants a '*basket*' of approved measures using well-validated measures to provide defined evidence to guide efficacy of practice. Outcomes from a co-ordinated approach should be based on the identified and defined needs of the individual which can be translated into specific goals. The current study considered this finding and used accepted methodology and clinical measures. The outcomes selected in this study included measures of improved ease of handling and care provision.

In addition it is useful to establish common predictive variables in rehabilitation. The different variables were considered that could affect the outcome. These included: age, localisation of disease or damage and extent, time since onset, co-morbidity, premorbid circumstances such as personality and intelligence and social circumstances. It was also considered important to have an understanding of what standard care consists. This was used as an ethical measure to ensure the patient had the usual care they would normally receive. It was also used as a control for variability in the delivery of care, providing a

constant for comparison. Usual care was consequently and explicitly used in this study protocol.

Whilst it is widely accepted there is a translational gap between researchers and clinicians in the health care professions, there is commonality in both striving to develop a sound evidence base for practice. This is apparent in rehabilitation medicine where the complexity of research is reported to be problematic. Medical evidence is often presented using the randomized controlled trial (RCT) as the gold standard of hierarchy. However, a number of authors in the field have challenged this with the claim that RCTs often unrepresentative of the population studied and thus it is hard to interpret results and apply them to individual patients (Goodman, 1999; Partridge, 2002; Skinner and Turner-Stokes, 2006).

Confounding factors in neurological research are commonly reported. Significantly this includes the problem of small numbers with each diagnostic group representative of a wide range of diverse conditions. Further problems that consistently confound rehabilitation research are the issues of moving baseline with spontaneous recovery or disease progression and difficulty in adherence to a uniform treatment approach. Even the goal for outcome is widely variable and dependent on the individual's personal perspective and circumstance. Whilst the RCT helps to counter these issues of systematic bias, (Shadish *et al.*, 2002) the fact remains that this approach is universally accepted as the preferred design for clinical research. The alternative is to use case reports which have their merits, but do not provide the robust statistical evidence for clinical confidence. A pragmatic approach is needed in the aim for best evidence in clinical practice with an understanding of complexity. The MRC (Craig *et al.*, 2008) recommends clinical research should use a mixed method of RCT and qualitative design. This approach is considered (in **Chapter 3.1**).

The Spasticity Guidelines (RCP *et al.*, 2009) recommend evaluation at three levels: goal attainment; impairment as in the reduction of spasticity; and functional impact. Objective markers and outcome measures should be selected as both valid and reliable (Wade, 1992).

Measures of impairment can be used to direct future management. However, Richardson and colleagues, (2000a) argue that it is often more important for the patient and caregiver to demonstrate outcome in terms of functional performance or goal attainment. The Goal Attainment Scale (GAS) can be used to measure real-life functional gains (Turner-Stokes, 2003; 2009; Ashford and Turner-Stokes, 2006; Turner-Stokes and Ashford, 2007) and was used as the primary outcome measure. Both the GAS and secondary measures selected for the study are detailed (in **Chapter 4.5**).

Next professional perspectives are presented from within a philosophical basis of neuroscience. This is underpinned by a rehabilitation philosophy and eclectic model of practice that has influenced the research approach.

### **1.3 Physiotherapy: professional perspectives**

Clinical experience in neurological physiotherapy has provided an advanced understanding of neuroscience and neuroplasticity based on the potential of the CNS to adapt, (Merzenich *et al.*, 1991; Kidd, Lawes and Musa, 1992; Taub, 1993; Nudo, 1999; 2006). It can be argued there is much untapped potential for people with spasticity to change. Human movement is complex. It involves the interaction between the individual, the task and the environment (Shumway-Cook and Woollacott, 2001).

Posture and movement are intrinsically linked. For motor recovery people require opportunities for directed patterns of movement and postures that are behaviourally acceptable; leading to more movement. Optimal postural alignment provides a starting point for comfort and confidence to progress movement. This suggests a psychosocial element by creating motivation and reward (Maclean *et al.*, 2000; Laviola, 2001; Danzl *et al.*, 2012). By providing an environment that enhances and rewards movement further functional gains can be made (Broetz and Birbaumer, 2013).

Knowledge and practice skills are established in two fundamental approaches to neurological rehabilitation. A 'hands on' approach, such as in the Neurodevelopmental 'Bobath' Approach (Bobath, 1990; Davies, 2002; Raine *et al.*, 2009) is often reported beneficial. Yet there are often limited resources to direct movement patterns with sufficient input to establish learning. Alternatively the 'Movement Science' (Carr and Shepherd, 1987; 2010) approach has been demonstrated to produce effective learning through guided, massed practice. Both of these practices have elements that can separately and collectively deliver active functional rehabilitation. However, the needs of people with spasticity commonly require care with 'passive' function. These needs are often more difficult to be met as it requires a prolonged delivery approach with sustained input. This is problematic as resources for this level of input are often limited and a compromise in postural management is made on a pragmatic rather than optimal basis.

There is no current evidence (Kwakkel *et al.*, 1999; van Vliet *et al.*, 2001; 2005) to support one approach over another. There has been a shift in emphasis of rehabilitation from management at impairment level to one of enablement in real-life situations. Indeed the two approaches are no longer poles apart and quote literature from the same evidence base to support their distinct philosophical stance. Practice in the clinical setting is more pragmatic with hybridisation of different approaches. In fact it is not uncommon for physiotherapists to be eclectic in their clinical practice as they develop experience and knowledge from different learning opportunities along their career path. This approach is supported by Stroke Guidelines '*physiotherapists should not limit their practice to one 'approach', but should select interventions according to the individual needs of the patient*' (Scottish Intercollegiate Guidelines Network (SIGN) 118, 2010, p.17). Indeed the recent evidence in the Cochrane review (Khan *et al.*, 2013) recommends therapy as most beneficial based on a mixture of different treatments tailored for the individual from a wide range of available treatment options.

Current practice demands a treatment approach that is based on the best available evidence, through critical analysis and evaluation of the evidence base (Straus and Sackett, 1998; Sackett, 2002; Akobeng, 2005). Evidence

based practice (EBP) “*means integrating individual clinical expertise with the best available external clinical evidence from systematic research*” (Sackett, 1996). It is the integration of clinical expertise, patient values, and the best research evidence into the decision making process for patient care. Clinical expertise refers to the clinician’s cumulated experience, education and clinical skills. In addition the patient contributes personal expectations and values. Accordingly clinically relevant research that has been conducted using sound methodology provides evidence for best practice (Sackett, 2002). Clinical practice in neurological rehabilitation is influenced by knowledge of theories presented from a historical perspective and how they have evolved contributing to current Motor Control Theory and its clinical applications (Shumway-Cook and Woollacott, 2001, pp. 11-25). These are tempered by discoveries in neuroscience which report that the CNS is not hierarchical, but soft wired, capable of adaptation (neuroplasticity) and has the potential for recovery through re-organization (Merzenich *et al.*, 1991; Kidd, Lawes and Musa, 1992; Taub, 1993; Nudo, 1999; 2006; Pitts and O’Brien, 2008).

These findings have provided physiotherapists with opportunities to deliver therapy and neuro-rehabilitation in new ways. By implication neuroplasticity offers the opportunity to direct recovery. This is by adapting to, or compensating for impairments through environmental and therapeutic stimulation towards purposeful activity.

As previously reported, BT is a medical component used to direct temporary partial paralysis of targeted muscle(s) in the overarching strategy for the treatment of spasticity in adults. It is recommended in the Spasticity Guidelines (RCP *et al.*, 2009) as a successful treatment option for multi-focal and focal spasticity when used in combination with physical therapy. Whilst this is the accepted case it remains unclear what physical treatments should follow and exactly when they should be applied for optimal dose-efficacy (Khan *et al.*, 2013). It is however agreed that the overarching aim of the treatment for overactive muscles is to maintain muscle length and prevent secondary shortening of soft tissues. The suggested treatments include methods of maintaining muscle length and optimal positioning by passive and active

stretching such as splints/orthotics and physiotherapy and movement (Edwards, 2001; Pope, 2007; Sheehan *et al.*, 2010; Kilbride *et al.*, 2015).

Having highlighted the recommended mainstay of treatment for focal spasticity as passive and active (dynamic) muscle stretch and movement this study aimed to explore the role of a potential new treatment that could deliver both. The emphasis being on the potential for re-educating movement patterns by directing muscle to adapt both biomechanically and neuroplasticity for optimal change during a specific time-frame.

The neuroscience behind dynamic motion orthoses (DMO) is based on neuroplasticity for learning adaptive patterns of optimal posture and movement by proprioceptive sensory stimulation (Gracies *et al.*, 2000; Matthews, 2008). This is due to the cylindrical use of elasticized and non-elasticized materials introducing a force along a weakened muscle line of activation, providing an exoskeleton. The inherent elastic properties of the material provide a localised corrective force by long term low level stretch on the neural components of tone with resultant improved levels of spasticity (Gracies *et al.*, 2000). It is proposed this effect modulates the stretch reflex. The customised fit offers slight compression with specific tension and resistive forces that offer support as required, yet afford freedom of movement. The freedom of movement benefits the non-neural biomechanical components such as viscoelastic properties, muscle fibre stiffness phenomenon of thixotropy (Goldspink and Williams 1990), muscle length–tension relationship and muscle fibre type. It is proposed the combination effect of directed, interactive movement and proprioceptive feedback provides the opportunity for muscle plasticity which in turn can influence neuroplasticity (Pitts and O'Brien, 2008).

Professional knowledge and experience in BT injection therapy for management of spasticity raised awareness of the limitations in spasticity service delivery and variance in patient experience. Some of the preliminary work informing this thesis was based on key aspects of professional learning in a small scale service project. This was in the development and testing of a new audit tool for the use of splints in adults with neurological conditions. This work was based on the findings of a national survey (Adrienne and Manigandan, 2011), which highlighted local clinical inconsistencies in theoretical underpinning for splinting



provision and practice. It was discovered that there was a significant gap in local, national and international clinical practice. The knowledge base was explored and used to develop a splinting audit tool which was then tested. The new audit tool was validated in practice and findings published (Stone, 2012) and presented by poster at Association of Chartered Physiotherapists in Neurology (ACPIN) National Conference (2012). The audit tool has since been used locally to inform splinting service development, local guidelines and monitor standards of practice.

Within the current framework of clinical guidelines for management of spasticity splinting is recommended (ACPIN, 1998; Intercollegiate Stroke Working Party, 2012; RCP *et al.*, 2009; Kilbride *et al.*, 2015). The roles of the Occupational Therapist and Physiotherapist overlap in this area of clinical practice (Booth and Hewison, 2002) based on knowledge skills experience and competency. From a practice perspective splinting remains contentious and the evidence base is conflicting with limited guidance (Lannin and Herbert, 2003; Adrienne and Manigandan, 2011). The 1998 splinting Guidelines are outdated. Consequently the new splinting Guidelines (Kilbride *et al.*, 2015) developed by collaboration between both professions were keenly received. These new splinting guidelines are informed by findings from a national cross-sectional survey of clinicians (Kilbride *et al.*, 2013).

Evidence for splinting in relation to spasticity management is reported in the systematic review (**Chapter 2.4**). A preliminary evaluation of the literature introduced the idea of research of dynamic splinting and direction to explore research possibilities in health technology products.

#### **1.4 Health technology: A role in rehabilitation**

The last twenty years has witnessed a health industry revolution with an international arena for improving health and wellbeing. More recently the Olympics and Paralympics were held in the UK in 2012, followed by the Commonwealth Games 2014 raised the researcher's awareness in the growth of health-related technology. This phenomenal development in health

technology has created a learning platform (for thinking outside the box) and provided the opportunity to investigate how new technology developed in one field can be translated in application to another.

Increasing demand for health technology in both sports and neurosciences has evolved with overlaps in design and application. Subsequently market forces have driven the development of health related technological products such as Kinesio-tape and dynamic Lycra® garments. Technological design features include the targeted use of the inherent tensile properties to enhance movement patterns. These are commonly seen on the sports field with various colours and applications including: protection against injury; or optimising movement. The tensile property is an important factor and has obvious applications in situations where in human movement there are imbalances between muscle forces around one, or more joints and resulting in altered stability, functional movement or potential injury.

Change in the political landscape has led to a new and exciting time for the health technology industry. The boundaries between statutory Health Service providers and non-statutory providers have recently become blurred with new NHS Commissioning structures in place and competitive tendering transparency. In 2013 Primary Care Trusts (PCTs) devolved their remit from combined commissioner and provider arms into new Clinical Commissioning Groups (CCGs). This has opened up the opportunity for further market competition with contract tenders from alternative providers of health care services and health technology.

Existing statutory NHS providers need to be astute to recognise how competition and working collaboratively can benefit the health of target populations. As the ageing population in the UK is set to rise, new challenges will compete for optimal efficiency and effectiveness in resource management. For example new technologies are adopted in everyday life and are moving rapidly, crossing boundaries of sports and fitness industry into the health industry. It can be proposed that patients (the public) are now driving the market forces as they become more informed.

It is worth considering why splinting is so controversial and yet dynamic support is so popular. Controversy is based on conflicting evidence of efficacy (Lannin and Herbert, 2003; Adrienne and Manigandan, 2011) and compliance (O'Brien and Bailey, 2008; Kuipers *et al.*, 2009). In addition acceptability from physical functionality and social perspective is believed to influence practical application and design popularity. Thus it can be argued that people are likely to make a pragmatic decision on splint wearing based on 'what works' and 'how it looks'. Clinical experience of poor compliance of splint wearing in the community is supported by the survey findings of Adrienne and Manigandan, (2011). Often splints are rigid and cumbersome which impact on compliance (O'Brien and Bailey, 2008). In contrast dynamic splints allow movement and are lightweight. It is evident from the popularity of Kinesio-tape and brightly coloured splints worn in public that cosmetic and social acceptability are considerations. In other words splint efficacy may not be the most important factor in wearing compliance. For this reason it was worth exploring removable dynamic splints and their application in clinical practice. The preliminary findings are outlined below together with an introduction to collaboration with the health technology industry.

### **1.5 Dynamic Elastomeric Fabric Orthoses (DEFO): Health technology industry collaboration**

Splints and orthoses are removable devices which provide a means of maintaining the specific position of a limb either providing static or dynamic support (Rose, 1983). Literature for splint efficacy is shown to be conflicting and inconclusive (Lannin and Herbert, 2003). Evidence from animal studies has informed clinical practice. Tardieu *et al.*, (1988) and O'Dwyer *et al.*, (1996) advocate optimal times for maintaining muscle length. They recommend splints should be worn for at least six hours to be effective. Compliance for rigid splints is uncertain (O'Brien and Bailey, 2008; Kuipers *et al.*, 2009); however there is descriptive evidence (Coghill and Simkiss, 2010; Elliott *et al.*, 2011a) which corroborates indicative levels of compliance and acceptability (in children) in the wearing of dynamic orthoses.

Dynamic Elastomeric Fabric Orthoses (DEFO) consist of garments with stitched sections of layered Lycra<sup>®</sup> of varying thickness to achieve specific tensions and an overall pattern of direction of force. The garments are designed to cover the body or limb of the wearer; measured to fit and customised to the individual's needs. The inherent property of the design of the garment is to enable the wearer to move rather than to restrict movement and thus it is referred to as a 'dynamic' orthosis. Most commonly the orthosis is provided for children with cerebral palsy and is used as an adjunct to other therapies for optimal benefit such as physiotherapy. It has also been used in few studies in the treatment of adults with neurological conditions (Gracies *et al.*, 2000; Bridges, 2004; Betts, 2006; Watson *et al.*, 2007).

There are a number of companies which produce DEFOs, or dynamic Lycra<sup>®</sup> garments. There are technical differences in the garments provided. The Health Technology Companies in the UK include: DM Orthotics Ltd<sup>®</sup>; Tru-Life<sup>®</sup>; Second Skin<sup>®</sup> and Jobskin<sup>®</sup>. DM Orthotics Ltd<sup>®</sup> is a manufacturer that produces a range of soft surgical goods including Lycra<sup>®</sup> based products such as Dynamic Movement Orthosis<sup>®</sup> (DMO<sup>®</sup>) and DEFO's. The DMO<sup>®</sup> product technical characteristics include a fabric made from a mix of Polyamide and Dorlastan (Lycra<sup>®</sup>) 83% and double faced with cotton 17%. In the DEFO layers of customised elastomeric material are customised to improve muscle balance, by directing muscle control during active movement and exerting postural alignment (on an individual basis).

Each DEFO is measured and customised to the individual. There are numerous measurements taken due to the need for the orthosis to be a snug fit but comfortable. This is to ensure it fits to provide stability with directive forces for optimising postural control. It also provides flexibility and allows movement. The upper limb DEFO in this study is termed a 'glove' if worn below the elbow or a 'long sleeve glove' (**Figure 1.1**) if above the elbow. The lower limb DEFO in this study is termed a 'sock' (**Figure 1.2**) Over the last few years the design of the DM Orthotics Ltd<sup>®</sup> products have developed from DMO<sup>®</sup> body suits for children with cerebral palsy and neuromuscular conditions to a range of customised orthoses to meet the wider needs of paediatric conditions (Matthews *et al.*,

2009) and more recently the adult sports (Sawle *et al.*, 2012) and neurology population.

**Figure 1.1 DEFO long sleeve glove**



**Figure 1.2 DEFO Sock**



DM Orthotics Ltd<sup>©</sup>

DM Orthotics Ltd<sup>©</sup>

From a preliminary review of the literature there was an identified gap in the existing body of evidence. Whilst there was evidence to support the use of dynamic splints and Lycra<sup>®</sup> garments in children with movement disorders (Coghill and Simkiss, 2010) there was limited evidence for use in limb spasticity (Matthews *et al.*, 2007; Elliott *et al.*, 2011a). The research gap identified limited available evidence for the use of dynamic Lycra<sup>®</sup> (DMO) worn as a splint in the treatment of adults with neurological conditions (Gracies *et al.*, 1997; 2000; Bridges, 2004; Betts, 2006; Watson *et al.*, 2007) and no evidence for specific interventions with the potential to effectively direct muscle activity following BT. In addition there was limited qualitative evidence reported on use of dynamic Lycra<sup>®</sup> in adults (Oglieve *et al.*, 2006). This provided a justification for further research.

Firstly two key studies propose further research is needed to explore the efficacy of dynamic splinting (Lannin and Herbert, 2003; Gracies *et al.*, 2000). Secondly it is acknowledged that dynamic Lycra<sup>®</sup> splints are evidenced (descriptively) as effective and acceptable in the management of children with spasticity and movement disorders (Corn *et al.*, 2003; Matthews *et al.*, 2007; Coghill and Simkiss, 2010; Elliott *et al.*, 2011a). However, the majority of studies reported focussed on whole body suits rather than specific limb orthoses. Discomfort and toileting issues were also reported on suits in the Technologies Scoping report (Calvert and Kelly, 2013). Whilst there are gains to be made on improving dynamic core stability there is less understood in terms of the effects of dynamic support in limbs. Spasticity is known to have an increased impact distally on limbs. Importantly Lycra<sup>®</sup> splint intervention has been scarcely evaluated in an adult population with few published case studies and reports (Gracies *et al.*, 1997; 2000; Bridges, 2004; Betts, 2006). These studies are indicative of acceptability and compliance in a clinical setting with predominantly descriptive findings of efficacy.

The inherent characteristics of the DEFO provide flexibility and allow movement yet affords a level of stability. This fits with the theoretical construct in support of the use of splints in the potential for prolonged stretch by addressing the non-neural components (connective tissue and muscle fibre length and number of sarcomeres) which in turn modify the neural mechanisms as in spasticity. This is seen as increased sensitivity to stretch of reflexes (Hoffman (H) and tendon reflexes). The reduction in sensitivity to stretch has been demonstrated in healthy adults by Guissard and Duchateau, (2004) however the evidence for studies with different healthy and patient populations show inconsistencies with variance in position, frequency, magnitude and duration (Mirbagheri *et al.*, 2008). Although there is potential for prolonged stretch to address changes in muscle length the exact mechanisms are not fully understood in the presence of spasticity. A further complication arises in the variance of response to different length of stretch and temporary rebound increases in spasticity (Ofori *et al.*, 2012) in different conditions such as Multiple Sclerosis. These changes and their effects on function require further investigation.

Treatment with the DEFO intervention was proposed as a potential new clinical treatment option following BT with the possibility to bridge the gap in the existing body of knowledge in the field. The opportunity to collaborate with health technology industry (**Appendix 2**), thus to bridge the technology research gap and how this was achieved is discussed in **Chapter 8.2**.

## **1.6 Identified research problem and uncertainties**

Adults with focal spasticity experience long-term management by attending clinics for cyclical treatments with Botulinum toxin (BT). Whilst providing an effective treatment option (Jankovic *et al.*, 2005; RCP *et al.*, 2009) it is of time-limited effect with the potential to create dependency on repeated cycles (Barnes and Davis, 2000). The European consensus report (Wissel *et al.*, 2009) recommends a need to research which treatments following BT offer improved health benefit.

The theoretical construct for splinting to be effective for neural and non-neural plasticity is complex and based on inconsistent and incomplete evidence. The rationale underpinning current splinting is based on early studies by Williams and Goldspink (1990) in that prolonged stretch of muscle has the potential to prevent the negative impact of remodelling muscle and connective tissue architecture (loss of sarcomeres in series, muscle fibre shortening and compliance or stiffness). The non-neural plastic changes of the muscle-tendon unit (MTU) with optimal length-tension ratios are reported by Williams and Goldspink (1978) to be affected by preservation of muscle length (by positioning). In the presence of spasticity, a positive feature of the UMNL, the neural effect is exaggeration of kinetic stretch reflexes with possible increased resistance to passive stretching of the MTU (Li *et al.*, 2006). Thus increase in sensitivity and stretch reflex gain, or reduced threshold of the stretch reflex results in maladaptive velocity dependent muscle activity. There is further potential for prolonged stretch of the MTU to modify pre and post-synaptic mechanisms. Hence it can be argued prolonged and dynamic stretch can have a beneficial effect on both neural and non-neural components.

Significantly the pathophysiology of spasticity is complex and poses a challenge to researchers when measuring intervention outcomes. Whilst Gracies *et al.*, (2007) argue there is a link between stretch and spasticity, the evidence for this remains incomplete. O'Dwyer and colleagues (1996) investigated the link between spasticity and activity post stroke and found they were not correlated with the implication that routine splinting for spasticity is incorrect. Furthermore routine splinting is not recommended by the RCP national Guidelines for stroke (Intercollegiate Stroke Working Party, 2012). Lannin and Ada (2011) recommend there is strong evidence that prolonged wearing of splints of the wrist in neutral or maximum extension does not prevent contracture after stroke. Lannin and Ada (2011, p.21) report the need; *'to re-focus on improving muscle performance in order to enable activity rather than prepare the patient for function by affecting abnormal reflex activity.'* Furthermore the authors recommend researchers should evaluate the potential benefits of dynamic and newer technology splints.

The DEFO with properties of compression providing proprioception and interactive stretch presents potential to facilitate muscle plasticity at a neural and non-neural level. The uncertainty of this intervention (DEFO) for the combined application with physiotherapy following BT was the basis for this study.

## **1.7 Summary**

On opening and unpacking the 'black box' of clinical practice for spasticity treatment following BT an opportunity was identified that required further investigation. Spasticity is known to be a significant symptom following damage to the CNS. This can lead to disability, functional disturbance and carer burden. How this is clinically managed is variable, depending on presentation and severity and whether the spasticity is global or focal. To complicate matters rehabilitation includes elements of 'active' and 'passive' care. Furthermore standard rehabilitation is multi-faceted and requires a team approach which is often anything but standardised. Neurological physiotherapy consists of varied approaches with none evidenced as most effective. Splinting guidelines (1998)



are outdated and practice remains varied and contentious (Lannin and Herbert, 2003; Lannin *et al*, 2003; Lannin and Ada, 2011; Adrienne and Manigandan, 2011). Following focal spasticity management with BT, the individual contributions of splinting and physiotherapy components are often unclear with little understood about optimal timings, duration, intensity, treatment methods and outcomes.

Recent developments in new technologies for sports, health and disability have raised their profile with associated industry actively pursuing gaps in the market. This has fuelled opportunities for translational research; by collaboration between Health Technology Industry and clinicians. The opportunity to collaborate with DM Orthotics Ltd<sup>©</sup> was used in this research study.

A preliminary review of the literature highlighted gaps in knowledge for the optimal clinical management of people with spasticity following BT. Scientific and theoretical rationale was found for spasticity management with BT. Indeed there was a substantial body of evidence for the safe and effective use of BT as a preferred treatment option for focal spasticity. Good quality research is still required to investigate the efficacy of treatment options following BT (Wissel *et al.*, 2009). A future direction of investigation proposed by Lannin and Ada (2011) is in the re-focus on improving muscle performance. It can be argued dynamic splinting should be considered for investigation on this basis. The existing evidence was explored in more depth by systematic review, (in **Chapter 2**).

## Chapter 2

### Systematic Review

#### Key points:

- **Purpose and structure of the systematic review: scope, quality and results**
- **Search strategy**
- **Data extraction**
- **Data synthesis**
- **Critical analysis of evidence: physiotherapy interventions for spasticity, splinting and dynamic orthoses**
- **Identified gaps in the evidence**
- **Research- implications and future direction**

#### Introduction

This Chapter presents the findings from an in depth systematic review of the current evidence base for clinical practice in spasticity management following BT in adults. It was guided by the findings of the preliminary literature review, (in **Chapter 1**). The purpose of the systematic review was to provide context and critical appraisal of the existing evidence base. This identified a gap in the knowledge base, thus informing direction and scope for future study in an identified area of original clinical research.

This systematic review builds on the existing evidence base for spasticity management with Botulinum toxin (BT). The review followed a specific search strategy. The data extraction results are presented in two tables and the findings are evaluated using a systematic approach.

The evidence for spasticity management in general or with BT is widely published and not within the scope of this review. Indeed there is a substantial body of evidence for the safe and effective use of BT as a preferred treatment option for focal spasticity due to its selectivity, reversibility and rarity of adverse reactions (Bakheit *et al.*, 2001; Moore, 2002; Naumann and Jankovic, 2004; Jankovic *et al.*, 2005; Simpson *et al.*, 2008; Gracies *et al.*; 2007; and RCP *et al.*, 2009).

In short, it is known that BT is effective and safe for management of focal spasticity (RCP *et al.*, 2009; Jost *et al.*, 2014), but it is not known which specific interventions can re-direct muscle recovery to maximise outcome. In clinical practice both physiotherapy and splinting are commonly recommended following treatment with BT. However, splinting in neurology is controversial in that it lacks clarity in the available evidence base and thus can be debated as clinically contentious. Physiotherapy is widely acknowledged to be clinically appropriate for management of spasticity following BT (Ramdharry, 2006; Giovannelli *et al.*, 2007, RCP *et al.*, 2009, Wissel *et al.*, 2009) but specific interventions used have been less rigorously evaluated. Significantly, dynamic Lycra<sup>®</sup> splinting/orthoses have become an accepted treatment option for children with spasticity and movement disorders, however this relatively new and potentially beneficial intervention has not been translated to the adult population. Consequently, two areas of practice (splinting and physiotherapy) were identified worthy of further investigation for their evidenced contribution to spasticity management in adults.

**The primary research question:** Following intramuscular injection with Botulinum toxin (BT) for focal spasticity in adults: What is the likelihood that there are health benefits of treatment with DEFO (dynamic splint) and physiotherapy and usual care compared to usual care alone?

The aim of the systematic review was to be as comprehensive in the search as possible yet to ensure the indexed material was equally clinically relevant to the identified research question. Therefore the scope and strategy of the review was conducted through the method of search strategy, data extraction, synthesis and critical appraisal outlined below.

## **2.1 Search strategy**

Before the search was embarked upon a clear research question was identified in the form of **PICOS**; Population, Intervention, Comparators, Outcomes, and Study Design. From this it was clear which search topic should be included and

more importantly which should be excluded. A preliminary review of the literature suggested a paucity of evidence of dynamic splinting in adults with limb spasticity which provided the rationale to widen the search to include studies of children with limb spasticity. The primary population of the study were adult therefore only the most relevant articles were reviewed on the use of dynamic Lycra<sup>®</sup> orthoses in children. This was to provide scientific and theoretical context for the research.

**Population, Intervention, Comparators, Outcomes, Study design (PICOS):**

**Population:** People with limb spasticity.

**Intervention:** Spasticity management with Botulinum toxin (BT) and physiotherapy and/or splinting/dynamic orthosis/Lycra<sup>®</sup>.

**Comparators:** Usual care for spasticity management following BT (RCP *et al.*, 2009).

**Outcomes:** Spasticity related measures of outcome for 'active' and 'passive' function, carer burden, pain, goals and quality measures.

**Study design:** All research designs.

**Inclusion criteria**

- Studies with populations of >40% people with spasticity.
- Studies that were primarily physiotherapy based rather than multidisciplinary based.
- Studies that included static and/or dynamic splints and orthotics of the upper and/or lower limbs in the presence of spasticity with or without preceding BT.

**Exclusion criteria**

- Studies with populations of <40% people with spasticity.
- Studies of general management of spasticity.
- Studies that were primarily multidisciplinary based rather than physiotherapy based.

- Studies that were primarily of electrical stimulation or robotic therapy.
- Studies that were primarily of non-removable casts.
- Studies of children that used Lycra® primarily for body stability (body suits).

The index words for the search were identified:

**Spasticity, Botulinum toxin, splint, orthosis, dynamic splint, dynamic orthosis, Lycra® and physiotherapy.**

The search strategy of this topic was supported by the local health library to be sensitive and utilise a simple preliminary search. This was repeated a number of times to look in more depth for any missed search terms and identify limitations in the strategy used.

To ensure relevant articles were reviewed, literature searches were performed using NHS Evidence Health electronic data bases: Medline and CINAHL, PsychINFO, Embase, AMED; Cochrane; Clinical Evidence in National guidelines, Map of Medicine, Database of Abstracts of Reviews of Effects (DARE); Dialog DataStar; and hand search. The search covered a period from 1990-2013. A method of both free text and subject searching was used for maximum effect. This method was useful to include new references that had not yet had thesaurus terms assigned to them. Appropriate key words and subject headings were searched using single and combination terms. Each single word or concept was initially searched and then later combined in the Medline database and mapped to thesaurus. The subject headings were then listed in a hierarchy of broader to narrower terms. Further terms were exploded to include all the narrower terms. The final collection for each concept was combined using 'AND' resulting in the key papers for this review. The search strategy included 'wildcards' to explore any truncated words such as 'splint'. This strategy is exemplified in **Appendix 3**. Each search was themed then saved, abstracts evaluated for relevance and papers requested that were identified as key to the research study.

The reference lists of these papers were also reviewed to identify other potentially relevant scientific articles or published research evidence. By definition it was important to be inclusive in the review strategy to cover both published and grey literature so as not to miss relevant papers and evidence of clinically important issues.

This search identified the benefit of utilising synopses of synthesised evidence and summaries of high quality systematic reviews, such as Clinical Evidence in National Guidelines, Map of Medicine, DARE and Cochrane. Reviews were then scrutinised further for relevant primary studies.

## **2.2 Data extraction**

This literature review used a combination of themed categorization and critical appraisal for contribution of evidence. The evidence was initially assessed for quality using the Critical Appraisal Skills Programme (CASP, 2006; 2010). This appraisal included: appropriateness of the study design; recruitment strategy; procedural rigour; appropriate method of analysis and transparency in reporting of results and interpretation of findings. The identified themes were categorised in the format of evidence hierarchy as recommended by the Cochrane Collaboration (GRADE Working Group, 2004) and presented in tables chronologically to provide historical context.

### **Levels of evidence hierarchy**

A preliminary review included a brief overview of spasticity and focal spasticity with key papers and guidelines on outcome and efficacy of treatment with BT from the perspectives of clinician, patient, health care team or carer and from health care delivery. Then papers meeting the inclusion criteria were reviewed systematically on physiotherapy interventions for spasticity management and splinting in relation to spasticity management.

This review aimed to identify gaps in knowledge with the potential to direct research for new evidence to support clinical efficacy and patient benefit. The SIGN scale (Pandyan *et al.*, 2005, pp. 2-6; RCP, 2008) was implemented due to its simplicity and clarity for adequate assessment of study outcomes in the classification of evidence (**Table 2.1**).

**Table 2.1 GRADE Levels of evidence (adapted from GRADE Working Group, 2004).**

Level of evidence GRADE	Guidance
<b>1++</b> <b>Level A</b>	-High quality meta-analysis, systematic review of RCTs or RCT's with a very low risk bias for systematic errors.
<b>1+</b>	-Well conducted meta-analysis, systematic review of RCTs or RCT's with a very low risk bias for systematic errors.
<b>1-</b>	-Meta-analysis, systematic review of RCTs or RCTs with a very low risk bias for systematic errors.
<b>2++</b> <b>Level B</b>	-High quality systematic reviews of case control or cohort studies. High quality systematic reviews of case control or cohort studies with a low risk of systematic errors, e.g. confounding with a high probability that the relationship is causal.
<b>2+</b>	-Well conducted case control or cohort studies with a low risk of systematic errors, e.g. confounding with a high probability that the relationship is causal.
<b>2-</b>	-Case control or cohort studies with a high risk of systematic errors, e.g. confounding with a high probability that the relationship is causal.
<b>3</b> <b>Level C</b>	-Non analytical studies e.g. case report, case series.
<b>4</b> <b>Level D</b>	-Expert opinions.

All titles and abstracts were screened from the searches of the electronic databases and obviously irrelevant studies were excluded. The full texts of the remaining articles were obtained and assessed for appropriateness based on the previously defined inclusion criteria for eligibility.

Each study was reviewed and data extracted according to the following data extraction criteria:

- Publication details;
- Study design, setting, inclusion and exclusion criteria, method of allocation, risk of bias;
- Population/ participant details;
- Intervention details;
- Outcome measures;
- Withdrawals, follow-up of participants.

(Higgins and Green, 2011).

### **Critical appraisal method**

After the data extraction the method used for synthesis of the studies selected was by PICOS. This provided a framework for critical analysis. Methodological quality was appraised on homogeneity of participant characteristics, interventions, outcome measures and study design.

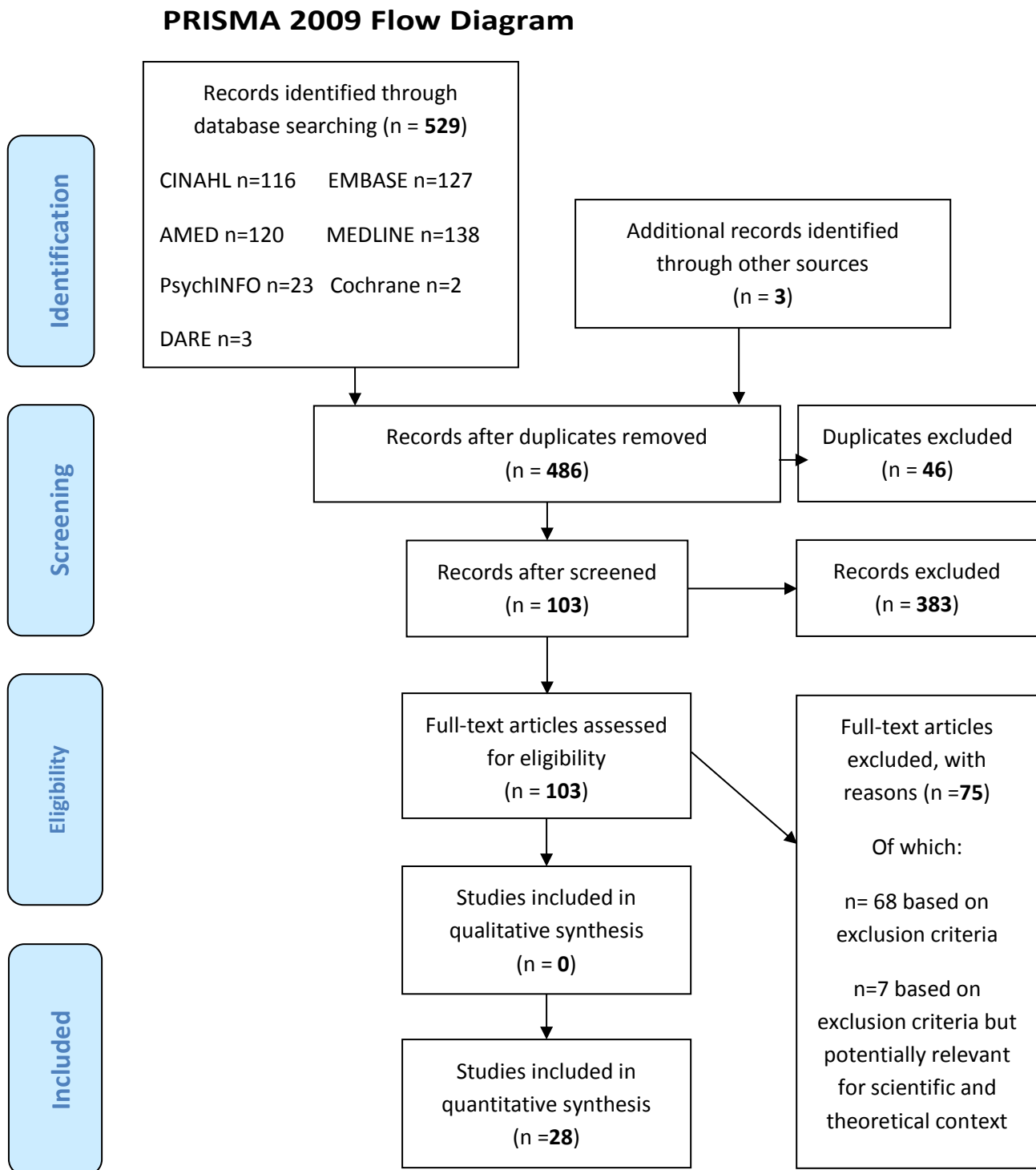
Bias was assessed on the following: random sequence generation and allocation concealment (selection bias); blinding of participants and personnel (performance bias); blinding of outcome assessors (detection bias); attrition bias; reporting bias; and other sources of bias.

### **2.3 Results**

Electronic and manual searches yielded a total of n=532 studies (titles and abstracts) with n=103 studies after initial screen and after duplicates were excluded (**Figure 2.1**). The remaining studies were scrutinised further and this resulted in n=28 studies which fully met the eligibility search criteria. The remaining studies n=75 were excluded as they did not meet the eligibility criteria. The studies included were categorized numerically for analysis (1-28). The search did not identify any exclusively qualitative or mixed method studies.



**Figure 2.1 Flow diagram of selection of studies**



The systematic review identified 28 studies in total which met the search criteria from 532 studies. These included two sub-groups: 11 studies on spasticity management with physiotherapy; 17 studies Splinting and Dynamic Orthoses.

The search also identified seven studies on best evidence for splinting practice and physiotherapy intervention. Although these studies did not meet the inclusion criteria they were used as scientific and theoretical background papers to inform the design of the study. These studies consisted of: two reviews of expert opinion and historical context (Stephenson, 1993; Richardson, 2002); three studies defining therapy content and developing intervention tools (Teasell *et al.*, 2003; De Wit *et al.*, 2007; Donaldson *et al.*, 2009); an Irish splinting survey for evidence on splinting practice consensus (Adrienne and Manigandan, 2011), and a health technologies scoping report (Calvert and Kelly, 2013). Reviews were included and assessed for further studies which met the inclusion criteria for synthesis, excluding any primary study duplicates.

Results are presented chronologically in **Table 2.2 Summary of evidence: Sub-group 1; Spasticity management with physiotherapy** and **Table 2.3 Summary of evidence: Sub-group 2; Splinting and Dynamic Orthoses** with the levels of evidence according to analysis.

**Table 2.2 Summary of evidence: Sub-group 1; Spasticity management with physiotherapy (chronological)**

Author	Title	Study Design	Participants N=	Intervention & Control	Outcome	Hierarchy of evidence*
Tolfts and Stiller <sup>1</sup> (1997)	Do patients with Traumatic brain injury benefit from Physiotherapy? A review of the evidence	Review	10 Studies investigating splinting and casting Adults with Traumatic brain injury N=123	Discussion on the effect of physiotherapy on: 1. Range of movement, abnormal muscle tone, quality of movement, balance and conscious level 2. The ability to perform functional tasks 3. Outcome in areas such as daily living, vocational and social domains	Lack of consistency in the treatment techniques used by physiotherapists makes meta-analysis difficult. There are many approaches to treatment of neurological patients. Gaining consensus for how a patient should be treated for a specific presenting problem is needed.	<b>Moderate 1-B</b> Low risk to systematic errors
Reiter <i>et al</i> <sup>2</sup> (1998)	Low dose botulinum toxin with ankle taping for the treatment of spastic equinovarus foot after stroke	Single-blind RCT	N=18 Adults with stroke	Intervention: a. Botulinum toxin into the Tibialis posterior muscle and ankle-foot taping b. Botulinum toxin into several calf muscles (control?)	Gait velocity Intervention group: $p=0.333$ Control: $p= 0.182$  There were no significant differences between groups	<b>Moderate to Low 2+ C</b>
Hyman <i>et al</i> <sup>3</sup> (2000)	Botulinum toxin (Dysport®) treatment of hip adductor spasticity in multiple sclerosis: a prospective randomised double blind, placebo controlled dose ranging	RCT double-blinded	N=74 Adults with Multiple Sclerosis	Four groups 1. 500U Dysport 2. 1000U Dysport 3. 1500U Dysport 4. Placebo Control (placebo) All had usual	Hip abduction measures (Goniometry)	<b>Moderate 2+ C</b> Risk of external validity from concurrent

	study			physiotherapy		treatment
Richardson <i>et al</i> <sup>4</sup> (2000b)	Treatment of focal spasticity with botulinum toxin: effect on the 'positive support reaction'	Case report	Adults with Acquired brain injury N=4	Intervention: botulinum toxin plus specialist rehabilitation not described No control	Gait velocity: 10 meter walk test Attention to task: VAS Ankle passive ROM All 4 cases improved functional ability to take weight through foot and walk.	<b>Low</b> <b>3</b> <b>C</b>
Stark <sup>5</sup> (2001)	Physiotherapy and botulinum toxin in spasticity management	Article 2 case studies	N=2 Adults with 1. Brain Haemorrhage 2. Brain tumour	Intervention: Botulinum toxin Physiotherapy Descriptive: Bobath and Movement Science approaches combined. In addition: serial casting, seating, splinting, taping and electrical stimulation and home programmes to include stretching. No control	Tone: MAS, Spasm scale Passive ROM Pain: VAS Upper limb: Frenchay arm test, action research arm test (ARAT) Gait: 10m walk test General function: Functional Independence Measure (FIM), Fugl Meyer scale and Barthel  Successful outcomes using goal setting in addition to the above	<b>Low</b> <b>3</b> <b>C</b>
Giovannelli <i>et al</i> <sup>6</sup> (2007)	Early physiotherapy after injection of botulinum toxin increases the beneficial effects on spasticity in patients with multiple sclerosis	Single blind RCT	N=38 Adults with Multiple Sclerosis	Intervention: Botulinum toxin and additional physiotherapy Control: BT Physiotherapy described as 40 minutes daily for 15 consecutive days of specific and regular activity through passive or active and stretching of the muscles in the injected area	MAS $P < 0.01$ VAS $P = 0.41$ (week 2) $P < 0.01$ (weeks 4 & 12)  The first RCT to attempt to evaluate the effect of physiotherapy after Botulinum toxin type-A injection	<b>Moderate to low</b> <b>2-</b> <b>C</b>  Risk to internal validity bias with concurrent treatment Risk to external validity bias as not usual treatment
Hellweg and	Physiotherapy after	Systematic Review	14 studies	Literature	Results**	<b>Moderate to</b>

Johannes <sup>7</sup> (2008)	traumatic brain injury: a systematic review of the literature		subgroups N=3,551 (excluding Lannin <i>et al</i> 2003b N=28)	systematic search of databases January 2006 to May 2007 Inclusion and exclusion criteria specified and hierarchy of evidence graded using SIGN scale (RCP, 2008)**	<ul style="list-style-type: none"> <li>Sensory stimulation- A</li> <li>Treatment intensity-A</li> <li>Serial casting-B for ROM and C for tone, splinting-A (but a more recent study suggests otherwise)</li> <li>Fitness or aerobic training-A</li> <li>Functional training-A</li> </ul>	<b>High 1-B</b> Risk of internal bias Raters not determined
Platz <i>et al</i> <sup>8</sup> (2009b)	Best conventional therapy versus modular impairment-oriented training for arm paresis after stroke: A single-blind multicentre randomized controlled trial	RCT Single blind	N=148 Adults with stroke	Intervention: a. Inflatable splint b. standardised IOT c. Control: best conventional therapy	Fugl Meyer arm motor score $P<0.001$ TEMPA $P=0.0363$	<b>Moderate 2+ C</b>
Shaw <i>et al</i> <sup>9</sup> (2010)	Botulinum toxin for the Upper Limb After Stroke (BoTULS) Trial	RCT-Multicentre Single blinded	N=333 Adults with stroke	Intervention: Botulinum toxin and 4 weeks therapy programme Control: Therapy programme alone	Primary measure: upper limb function- Action research arm test (ARAT) Secondary measures: Impairment, Activity limitation, Pain Results- no significant difference in function between groups $P=0.232$ Significant differences in favour of intervention group in measures of muscle tone, strength, basic functional upper limb tasks and pain.	<b>Moderate to High 1-B</b>
Turner-Stokes, Ashford, Nair <sup>10</sup> (2010a)	Physical Therapy and Botulinum toxin-A (BoNT-A)- The temporal relationship between spasticity reduction and functional gain	Prospective cohort study	N=58 Adults with Stroke N=30 Other brain injury N=22 Other neurological	Intervention: BT, splinting, serial casting, positioning, functional electrical stimulation and targeted task practice.	Main measures: ArmA, MAS, GAS. Results: No significant changes in active function but significant changes in passive function MAS $p<0.005$ , GAS $p<0.005$ ,	<b>Moderate 2+ C</b>

			N=6		ArmA <0.005	
Katalinic <i>et al</i> <sup>11</sup> (2011)	Effectiveness of stretch for the treatment and prevention of contractures in people with neurological conditions: A systematic review	Cochrane review	N=812 Adults with varied neurological conditions in studies: Stroke, TBI	Studies that measured stretch performance in terms of ROM (< 7 months)  (Splinting and casting included)	Primary measures: joint mobility and quality of life <b>Results</b> (Meta-analyses using a random-effects model) Immediate effect: Mean difference 3°; (95% CI 0 to 7) Short term: Mean difference 1°; (95% CI 0 to 3) Long-term: Mean difference 0°; (95% CI -2 to 2) For all conditions there is little or no effect of stretch on pain, spasticity, activity limitation, participation restriction or quality of life	<b>High to Moderate 1+ A</b> Risk of internal validity bias with confounding: combined intervention for prevention and treatment  Usual care consisted of stretches?

\* Oxford Centre for Evidence Based Medicine (2002). Available at: [www.cebm.net/index.aspx?0=1047](http://www.cebm.net/index.aspx?0=1047) , Pandyan *et al.*, (2005). RCT- randomised controlled trial, N- Number, ROM- Range of movement, CI – Confidence interval, PT=Physiotherapy, OT=Occupational Therapy, MAS – Modified Ashworth Scale, VAS- visual analogue scale, ArmA- the Arm Activity Measure, GAS- Goal Attainment Scaling.

**Table 2.3 Summary of evidence: Sub-group 2; Splinting and Dynamic Orthoses (Chronological)**

Author	Title	Study Design	Participants N=	Intervention & Control	Outcome	Hierarchy of evidence*
Gracies <sup>12</sup> (1997)	Lycra garments Designed for Patients with upper limb Spasticity: mechanical effects in Normal Subjects	RCT Double Blind	Adult N=10	Intervention: Upper limb garment (orthosis) Control-normal subjects	Paired T-test $P<0.01$ Donning technique important	<b>Moderate 2+ C</b> External validity treatment not representing current practice
Gracies <i>et</i>	Short term effects of	Cross-over design	Adults	Intervention: Upper	ROM using goniometry	<b>Moderate</b>

<i>al</i> <sup>13</sup> (2000)	Dynamic Lycra Splints on Upper Limb in Hemiplegic patients	Inclusion exclusion criteria specified	18-85 years N=16	limb garment (orthosis) No control	<i>P</i> <0.01 (Shoulder) <i>P</i> <0.05 (Fingers) Questionnaire on comfort Circumference of arm Resting posture proprioception Spasticity at shoulder	<b>2+</b> <b>C</b> Internal validity- threat of co- intervention bias External validity treatment not representing practice
Brownlee and McLeman <sup>14</sup> (2002)	Edinburgh Dynamic Lycra splinting trial-assessment of hand function	Pre-experimental design Pre/post test	Adults N=20	Intervention: 10 Suit 10 Upper limb garments (8 weeks) No control	Measures of hand function Tool non-standardised Questionnaire: quantitative and qualitative data	<b>Low</b> <b>3</b> <b>C</b>
Lannin <i>et al</i> <sup>15</sup> (2003)	Splinting of the hand in the functional position after brain impairment: A randomized, controlled trial	RCT	Adults N=28	Intervention: Static splint Control: routine training (upper limb use and stretches)	Motor Assessment Scale: Favoured control: <i>P</i> < 0.2 Pain favoured Intervention group:(95% CI -4.6 to 2.2) Results non-significant and clinically unimportant	<b>Moderate</b> <b>1+</b> <b>B</b> Internal validity- threat of co- intervention bias
Lannin and Herbert <sup>16</sup> (2003)	Is hand splinting effective for adults following stroke? A systematic review and methodological critique of published research	Systematic review	Adults N=230 19 studies 21% RCT(4) 63% reports of case series	RCT's analysed by Two independent raters	Insufficient evidence to support or refute effectiveness of splinting the hand post stroke	<b>Moderate</b> <b>1+</b> <b>B</b> Internal validity bias risk
Pizzi <i>et al</i> <sup>17</sup> (2005)	Application of a volar static splint in post-stroke spasticity of the upper limb	Pre-test post-test	Adults with stroke N=40	Intervention: static splint No control	Passive ROM: <i>P</i> =0.001 MAS: <i>P</i> =0.002 Pain: <i>P</i> =0.04 Spasms: <i>P</i> =0.08 Splint well-tolerated	<b>Low</b> <b>2-</b> <b>C</b> Internal validity bias risk
Sheehan <i>et al</i> <sup>18</sup> (2006)	A randomized controlled pilot study to obtain the best estimate of the size of effect of a thermoplastic resting	RCT	Adults with stroke N=14	Both groups received intervention of splint with differing timing of interventions	Insufficient period of contrast between splint wearing and non-wearing with clinically relevant size effect unable to be	<b>Low</b> <b>2+</b> <b>C</b> Internal validity bias

	splint on spasticity in the stroke-affected wrist and fingers				established	risk
Matthews <i>et al</i> <sup>19</sup> (2007)	A pilot study of multiple case reports to investigate the effects of dynamic Lycra orthoses on gait in children with diplegic Cerebral Palsy	Case series reports Repeated measures	Children 3-14 years N=8	Intervention: Lower limb garment (orthosis) No control	10 metre timed walk test Physiological cost index Patient specific functional score Questionnaire Daily diary	<b>Low 3 C</b> Internal validity bias risk
Lannin <i>et al</i> <sup>20</sup> (2007)	Effects of splinting on wrist contracture after stroke. A randomized controlled trial.	RCT Blinded assessor	Adult with stroke N=63	Intervention: 1. Neutral splint 2. Extended splint Control: no splint Both groups received usual treatment with exception of stretches of the wrist and long finger flexors	Extensibility of wrist using standardised torque 1. (95% CI -5.4° to 8.2°) 2. (95% CI -4.9° to 2.4°) Functional measures non-significant splinting does not prevent loss of range compared to no splinting in early stroke	<b>Moderate to High 2+ B</b>
Watson <i>et al</i> <sup>21</sup> (2007)	An evaluation of the effects of a dynamic Lycra orthosis on arm function in a late stage patient with acquired brain injury	Case study	Adult N=1	Upper limb garment (orthosis)	Patient specific functional score Writing tests Nine hole peg test	<b>Low 3 C</b>
Robinson <i>et al</i> <sup>22</sup> (2008)	No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial	Randomised Trial	Adults with stroke N=30	Intervention: 1. Tilt table 2. Ankle splint  No control Both groups received rehabilitation	Ankle passive range: (95% CI -2.8° to 9.8°) (95% CI -0.4° to 2.6°)	<b>Moderate to Low 2- C</b> Internal validity: threat of co-intervention bias
Lai <i>et al</i> <sup>23</sup> (2009)	Dynamic splinting after treatment with botulinum toxin type-A: a randomized controlled pilot study	RCT	Adults with stroke N=30	Intervention: Elbow Extension Dynasplint® Control: Manual therapy and OT	Elbow active ROM: Intervention group displayed a mean 33.5% change in active ROM compared to the control	<b>Moderate to Low 2- C</b> Internal



				Both groups received rehabilitation	group (18.7% MAS: intervention group mean 9.3% improvement versus 8.6% in control	validity: high risk of co-intervention bias
Coghill and Simkiss <sup>24</sup> (2010)	Question 1. Do Lycra garments improve function and movement in children with cerebral palsy (CP)	Systematic Review	2 RCT's Several case studies Children with CP N=76	Intervention: Wearing various Lycra <sup>®</sup> based garments Mostly case series or small numbers in studies	Results: improved proximal stability and function in some children, toileting problems and discomfort	<b>Moderate to Low 2-C</b> External validity risk of bias
Elliott, Reid, Alderson, Elliott <sup>25</sup> (2011b)	Lycra arm splints in conjunction with goal directed training can improve movement in children with CP	Randomised parallel group trial with waiting list control	Children with CP N=16	Intervention: 25 minutes of daily active task practice related to functional goals	No statistical analysis After 3 months significant improvements were seen in 20/28 measures	<b>Low 3 C</b> Internal validity bias risk
Jung <i>et al</i> <sup>26</sup> (2011)	The effect of a stretching device on hand spasticity in chronic hemiparetic stroke patients.	RCT	Adults with stroke N=21	Intervention: splint stretching device Control: content of management not reported	MAS: ANOVA $P < 0.001$ Overconfident reporting of significance by researcher	<b>Low 3 C</b> External validity bias: not current practice
Shamili, Amini, Forough <i>et al</i> <sup>27</sup> (2011)	Botulinum toxin injections or application of splints: Impact on spasticity, range of motion and function of upper extremity in chronic stroke patients.	Non-randomised Comparison study	Adults with stroke N= 28	Intervention: Volar-Dorsal Wrist/Hand Immobilization splint Control: Botulinum toxin	N=18 completed study Results: Outcome measures (MAS) improved in both groups but no significance ( $P < 0.05$ ) was found between the groups	<b>Low 3 C</b> Internal validity bias risk
Lannin and Ada <sup>28</sup> (2011)	Neurorehabilitation splinting: Theory and principles of clinical use	Review and theoretical rationale	4 RCTs Splinting in Adult stroke N=112	Intervention: Splinting post stroke	Static splinting: evidence suggests is not effective in decreasing spasticity, preventing contracture or improving activity	<b>Moderate 1+ B</b>

\* Oxford Centre for Evidence Based Medicine (2002). Available at: [www.cebm.net/index.aspx?0=1047](http://www.cebm.net/index.aspx?0=1047), Pandyan *et al.*, (2005), N= number, RCT=randomized controlled trial, CI= confidence interval, MAS= Modified Ashworth Scale, VAS= visual analogue scale, ROM= range of movement, OT= Occupational Therapy.

## 2.4 Data synthesis

The summary of evidence is presented by **PICOS** evaluation, (in **Table 2.4**)

**Table 2.4 PICOS Summary of findings**

PICOS Evaluation	Summary of Evidence
<b>Population</b>	The <b>28</b> studies provided data for analysis for a total of <b>(6,028)</b> of the population studied. These comprised total of <b>(5,928)</b> adult participants with stroke or neurological conditions. There were <b>(100)</b> children studied in a combined number of small studies (case studies or case series) with Cerebral Palsy. (one study also occurred in a review, it was not double counted).
<b>Intervention</b>	<p>The interventions studied ranged from:</p> <p><b>splinting, orthosis or casting:</b> Tolfts and Stiller<sup>1</sup> (1997), Stark<sup>5</sup> (2001), Hellweg and Johannes<sup>7</sup> (2008), Platz <i>et al</i><sup>8</sup> (2009), Turner-Stokes, Ashford, Nair<sup>10</sup> (2010a), Katalinic <i>et al</i><sup>11</sup> (2011), Gracies<sup>12</sup> (1997), Gracies <i>et al</i><sup>13</sup> (2000), Brownlee and McLeman<sup>14</sup> (2002) Lannin <i>et al</i><sup>15</sup> (2003) Lannin and Herbert<sup>16</sup> (2003), Pizzi <i>et al</i><sup>17</sup> (2005), Sheehan <i>et al</i><sup>18</sup> (2006), Matthews <i>et al</i><sup>19</sup> (2007), Lannin <i>et al</i><sup>20</sup> (2007), Watson <i>et al</i><sup>21</sup> (2007), Robinson <i>et al</i><sup>22</sup> (2008), Lai <i>et al</i><sup>23</sup> (2009), Coghill and Simkiss<sup>24</sup> (2010), Elliott <i>et al</i><sup>25</sup> (2011b), Jung <i>et al</i><sup>26</sup> (2011), Shamili, Amini, Forough <i>et al</i><sup>27</sup> (2011), Lannin and Ada<sup>28</sup> (2011)</p> <p><b>taping</b> Reiter <i>et al</i><sup>2</sup> (1998), Stark<sup>5</sup> (2001)</p> <p><b>physiotherapy</b> Tolfts and Stiller<sup>1</sup> (1997), Hyman <i>et al</i><sup>3</sup> (2000), Richardson <i>et al</i><sup>4</sup> (2000b), Stark<sup>5</sup> (2001) Giovannelli <i>et al</i><sup>6</sup> (2007), Platz <i>et al</i><sup>8</sup> (2009), Shaw <i>et al</i><sup>9</sup> (2010), Turner-Stokes, Ashford, Nair<sup>10</sup> (2010a) Katalinic <i>et al</i><sup>11</sup> (2011), Lannin <i>et al</i><sup>15</sup> (2003), Lannin <i>et al</i><sup>20</sup> (2007), Robinson <i>et al</i><sup>22</sup> (2008);</p> <p><b>muscle stretches and home programme</b> Stark<sup>5</sup> (2001), Giovannelli <i>et al</i><sup>6</sup> (2007), Katalinic <i>et al</i><sup>11</sup> (2011), Lannin <i>et al</i><sup>15</sup> (2003), Lannin <i>et al</i><sup>20</sup> (2007), Robinson <i>et al</i><sup>22</sup> (2008);</p> <p><b>functional training and task practice</b> Hellweg and Johannes<sup>7</sup> (2008), Turner-Stokes, Ashford, Nair<sup>10</sup> (2010a), Elliott <i>et al</i><sup>25</sup> (2011b);</p> <p><b>fitness training</b> Hellweg and Johannes<sup>7</sup> (2008);</p> <p><b>sensory stimulation</b> Hellweg and Johannes<sup>7</sup> (2008).</p>

<p><b>Control/ comparators</b></p>	<p>Control of interventions varied from:  <b>usual care</b> Reiter <i>et al</i><sup>2</sup> (1998), Hyman <i>et al</i><sup>3</sup> (2000), Richardson <i>et al</i><sup>4</sup> (2000b), Platz <i>et al</i><sup>8</sup> (2009), Katalinic <i>et al</i><sup>11</sup> (2011), Lannin <i>et al</i><sup>15</sup> (2003), Lannin <i>et al</i><sup>20</sup> (2007), Lai <i>et al</i><sup>21</sup> (2009) Jung <i>et al</i><sup>26</sup> (2011), Shamili, Amini, Forough <i>et al</i><sup>27</sup> (2011);  <b>timing delay or manipulation</b> Sheehan <i>et al</i><sup>18</sup> (2006);  <b>cross-over design</b> Gracies <i>et al</i><sup>13</sup> (2000);  <b>independent raters</b> Lannin and Herbert<sup>16</sup> (2003);  <b>waiting list control</b> Elliott <i>et al</i><sup>25</sup> (2011b);  <b>none</b> Tolfts and Stiller<sup>1</sup> (1997), Stark<sup>5</sup> (2001), Gracies <i>et al</i><sup>13</sup> (2000), Brownlee and McLeman<sup>14</sup> (2002), Pizzi <i>et al</i><sup>17</sup> (2005) Matthews <i>et al</i><sup>19</sup> (2007) Watson <i>et al</i><sup>21</sup> (2007), Robinson <i>et al</i><sup>22</sup> (2008).  In addition Gracies<sup>12</sup> (1997) used '<b>normal subjects</b>'.</p>
<p><b>Outcomes</b></p>	<p>Measures of outcome were assessed with a wide range of evaluation tools  <b>Standardised measures:</b>  <b>Goal Attainment Scale (GAS)</b> Stark<sup>5</sup> (2001), Turner-Stokes, Ashford, Nair<sup>10</sup> (2010a);  <b>Barthel</b> Stark<sup>5</sup> (2001);  <b>Functional Independence Measure (FIM)</b> Stark<sup>5</sup> (2001);  <b>Fugl Meyer Arm Motor Score</b> Stark<sup>5</sup> (2001), Platz <i>et al</i><sup>8</sup> (2009);  <b>Frenchay Arm Test</b> Stark<sup>5</sup> (2001);  <b>Arm Activity Measure (ArmA)</b> Turner-Stokes, Ashford, Nair<sup>10</sup> (2010a);  <b>Nine hole peg test</b> Watson <i>et al</i><sup>21</sup> (2007);  <b>Patient specific functional score</b> Matthews <i>et al</i><sup>19</sup> (2007), Watson <i>et al</i><sup>21</sup> (2007);  <b>Modified Ashworth Scale (MAS)</b> Tolfts and Stiller<sup>1</sup> (1997), Giovannelli <i>et al</i><sup>6</sup> (2007), Turner-Stokes, Ashford, Nair<sup>10</sup> (2010a), Lannin <i>et al</i><sup>15</sup> (2003), Pizzi <i>et al</i><sup>17</sup> (2005), Lannin <i>et al</i><sup>20</sup> (2007), Lai <i>et al</i><sup>23</sup> (2009), Coghill and Simkiss<sup>24</sup> (2010);  <b>Spasm scale</b> Stark<sup>5</sup> (2001), Pizzi <i>et al</i><sup>21</sup> (2005);  <b>VAS for pain</b> Richardson <i>et al</i><sup>4</sup> (2000b), Stark<sup>5</sup> (2001), Giovannelli <i>et al</i><sup>6</sup> (2007), Shaw <i>et al</i><sup>9</sup> (2010), Lannin <i>et al</i><sup>15</sup> (2003), Pizzi <i>et al</i><sup>17</sup> (2005);  <b>VAS for attention to task</b> Richardson <i>et al</i><sup>4</sup> (2000b);  <b>Action Research Arm Test (ARAT)</b> (Stark<sup>5</sup> (2001), Shaw <i>et al</i><sup>9</sup> (2010);  <b>EQ-5D</b> Katalinic <i>et al</i><sup>11</sup> (2011);  <b>Goniometry</b> Tolfts and Stiller<sup>1</sup> (1997), Hyman <i>et al</i><sup>3</sup> (2000), Richardson <i>et al</i><sup>4</sup> (2000b), Stark<sup>5</sup> (2001), Giovannelli <i>et al</i><sup>6</sup> (2007), Hellweg and Johannes<sup>7</sup> (2008), Katalinic <i>et al</i><sup>11</sup> (2011), Gracies <i>et al</i><sup>13</sup> (2000), Pizzi <i>et al</i><sup>17</sup> (2005), Robinson <i>et al</i><sup>22</sup> (2008), Lai <i>et al</i><sup>23</sup> (2009);</p>

<p><b>Outcomes (cont'd)</b></p>	<p><b>Ten metre timed walk test (10MTT)</b> Reiter <i>et al</i><sup>2</sup> (1998), Richardson <i>et al</i><sup>4</sup> (2000b), Stark<sup>5</sup> (2001), Matthews <i>et al</i><sup>19</sup> (2007);  <b>Physiological cost index (PCI)</b> Matthews <i>et al</i><sup>19</sup> (2007).</p> <p><b>Non-standardised measures:</b>  <b>General goals</b> Stark<sup>5</sup> (2001), Elliott <i>et al</i><sup>25</sup> (2011b);  <b>Hand function</b> Gracies <i>et al</i><sup>13</sup> (2000), Brownlee and McLeman<sup>15</sup> (2002) Lannin <i>et al</i><sup>20</sup> (2007);  <b>Quality questionnaires</b> Gracies <i>et al</i><sup>13</sup> (2000), Brownlee and McLeman<sup>14</sup> (2002);  <b>Daily diary</b> Matthews <i>et al</i><sup>19</sup> (2007);  <b>Donning technique</b> Gracies<sup>12</sup> (1997).</p>
<p><b>Study design</b></p>	<p>The findings of the study designs reported above included:  <b>one Cochrane review</b> Katalinic <i>et al</i><sup>11</sup> (2011);  <b>five reviews</b> Tolfts and Stiller<sup>1</sup> (1997), Hellweg and Johannes<sup>7</sup> (2008), Lannin and Herbert<sup>16</sup> (2003), Coghill and Simkiss<sup>24</sup> (2010) Lannin and Ada<sup>29</sup> (2011);  <b>twelve RCT's</b> Reiter <i>et al</i><sup>2</sup> (1998), Hyman <i>et al</i><sup>3</sup> (2000), Giovannelli <i>et al</i><sup>7</sup> (2007), Platz <i>et al</i><sup>9</sup> (2009), Shaw <i>et al</i><sup>10</sup> (2010), Gracies<sup>13</sup> (1997), Lannin <i>et al</i><sup>16</sup> (2003) Sheehan <i>et al</i><sup>19</sup> (2006), Lannin <i>et al</i><sup>21</sup> (2007), Lai <i>et al</i><sup>24</sup> (2009) Elliott <i>et al</i><sup>25</sup> (2011b) Jung <i>et al</i><sup>26</sup> (2011), which included blinding in Reiter <i>et al</i><sup>2</sup> (1998), Hyman <i>et al</i><sup>3</sup> (2000), Giovannelli <i>et al</i><sup>6</sup> (2007), Platz <i>et al</i><sup>9</sup> (2009), Shaw <i>et al</i><sup>10</sup> (2010), Gracies<sup>12</sup> (1997), Lannin <i>et al</i><sup>20</sup> (2007), Lai <i>et al</i><sup>23</sup> (2009);  <b>five experimental intervention designs without randomisation or control</b> Gracies <i>et al</i><sup>14</sup> (2000), Brownlee and McLeman<sup>14</sup> (2002), Pizzi <i>et al</i><sup>17</sup> (2005), Robinson <i>et al</i><sup>23</sup> (2008), Shamili, Amini, Forough <i>et al</i><sup>27</sup> (2011);  <b>one prospective cohort study</b> Turner-Stokes, Ashford, Nair<sup>10</sup> (2010a);  <b>two case report studies</b> Richardson <i>et al</i><sup>4</sup> (2000b), Stark<sup>5</sup> (2001);  <b>one case series</b> Matthews <i>et al</i><sup>19</sup> (2007);  <b>one case study</b> Watson <i>et al</i><sup>21</sup> (2007).</p>

## Synthesis of methodological quality

Heterogeneity of the study design, methods and interventions and outcomes meant it was not possible to pool data. Meta-analysis of this review was problematic. Firstly it was not possible due to the lack of consistency in the treatment techniques used. There were many approaches used to treat neurological patients with limited evidence of consistency or components of usual care. What was clear from the review was that splinting or casting for spasticity or contracture management was commonly practiced. Secondly the review provided evidence of a wide range of measures for outcome with limited consistency in use. Measures varied from those proven valid and reliable in the clinical setting to others which were non-standardised. This demonstrated the difficulty of evaluating or analysing outcome across studies in neurological rehabilitation. Consequently assessment of heterogeneity was not performed. Therefore, a synthesis of the best evidence based was presented on the GRADE levels of evidence.

### Evidence of search summary by GRADE

As shown in the summary **table 2.5** the majority of this evidence was assessed as low grade (grade C), followed by moderate-level evidence (grade B), only one high-level study (grade A) and no very low-level evidence (grade D):

**Table 2.5 Summary table of evidence by GRADE**

Grade of evidence	Number of studies	Percentage
Grade A	n= 1	3%
Grade B	n= 7	25%
Grade C	n= 20	72%
Grade D	n= 0	0%

The implications of the findings are now discussed specifically with reference to physiotherapy and splinting in context of the Spasticity Guidelines (RCP *et al.*, 2009). According to guidelines the need for provision of orthotics or splinting following BT should be reviewed once the clinical effect of BT has occurred (RCP *et al.*, 2009, Intercollegiate Stroke Working Party, 2012).

## **Synthesis of intervention outcomes**

Interventions in the studies are critically appraised for their contribution to evidence for splinting in relation to spasticity management and physiotherapy in relation to spasticity management.

### **Splinting, orthosis or casting and taping**

The theoretical rationale for splinting is based on neurophysiological and biomechanical approaches and the supporting scientific evidence (Lannin and Ada, 2011). Each study provides evidence on the main constructs; to decrease spasticity, decrease contracture and to improve activity. The search on splinting and orthotics found studies of casting included in the reviews. Although non-removable casts were originally excluded in the search criteria a pragmatic decision was taken to include studies only if they were within the reviews but not in primary studies.

The study by Tolfts and Stiller (1997) of the evidence for physiotherapy in people with traumatic brain injury highlighted the lack of good quality evidence on which to verify clinical practice. There was inconsistency in splint or cast provision and of duration from 2 hours to six months. In summary all ten studies evaluated for splinting or casting indicated improved passive range of movement, although often of small change, of limited duration and the validity and clinical significance was uncertain. This evidence was assessed as moderate level (Grade B) due to a low risk of bias in systematic errors. However in the study there were individual primary studies of single case studies that were likely to have been of a lower Grade.

Stark (2001) argues for the role of physiotherapy in spasticity management but that further research is indicated to establish the effectiveness of splinting in conjunction with BT. This study was assessed at low level (Grade C) however it provides useful clinical detail on outcomes. Clinical treatment options were identified following BT that included splint and orthotic provision, stretching and serial casting. Two case studies are detailed providing clinical direction. It was

identified at the time that national spasticity guidelines for were needed for equity and efficacy.

According to Lannin and Herbert (2003) despite the widespread clinical use of splints few studies have examined the effect of splinting in a rigorous manner to either refute or support its efficacy. The authors conclude that splinting the hand in a functional position post-stroke was not effective in the management of contractures in the presence of a regular stretching programme. However, there was insufficient evidence to support or refute hand splinting in the same population, not receiving a stretching programme. In a further study by Pizzi *et al.*, (2005) the theoretical basis was explored with reflex inhibitory splinting by application of a volar splint. This study was assessed for evidence and determined as low (Grade C) due to design characteristics including risk of internal validity bias and lack of a comparative control for the intervention.

In the RCT by Sheehan *et al.*, (2006) there was a predictable finding in the small sample for the estimation of the best effect-size of the effect of a thermoplastic splint on spasticity in the hand. This study was assessed at a low level of evidence (Grade C) due to methodological and design issues; with timing issues and insufficient period of contrast between splint wearing and non-wearing with clinically relevant size effect unable to be established. The internal validity of the study was also considered at risk of bias.

A study by Robinson *et al.*, (2008) explored if wearing a night splint was a viable alternative to using a tilt table as a potential treatment to prevent contracture in the ankle following stroke. The findings were inconclusive with both groups yielding similar results and both of limited clinical significance <10 degrees (mean difference 4 degrees 95%CI -3 to 10). The study was assessed at a moderate to low level of evidence (Grade C) due to the study design limitations with lack of control and co-intervention bias.

The review by Hellweg and Johannes (2008) included primary studies of orthosis and serial casting with some verifiable evidence (Grade B) for improvement in passive range of movement, but limited evidence (Grade C) for correlation between a reduction in spasticity and serial casting or provision of

orthosis. However the studies reviewed did not conduct follow-up and there were limitations in rationale for the decision making process of when to apply splints or casts. It was also reported there was only verifiable evidence (Grade A) to support the recommendation that overnight splinting does not lead to a reduction in contracture formation. This corresponds closely to clinical experience. Further discussion points raised included negative perceptions of patients towards splinting and if splinting plays a role in learned non-use of the limb. In conclusion the evidence for proof of efficacy was limited with recognition that the evidence should be integrated into clinical reasoning and practice decisions.

The RCT study presented by Platz *et al.*, (2009b) investigated the use of an inflatable splint versus best conventional motor therapy or impairment-oriented training (IOT). The evidence was assessed at a moderate level (Grade C) but provides evidence of efficacy in IOT specificity with important clinical implications for directed motor recovery rather than static splinting.

Following BT in a study by Turner-Stokes, Ashford and Nair (2010a) the physical therapy interventions based on clinical judgement including splinting or serial casting. Physical interventions also included positioning, electrical stimulation and task practice which introduced a number of variables. The study was assessed at moderate level (Grade C) as the design was at risk of bias in internal validity due to the heterogeneity of the interventions.

A splint providing a prolonged stretch to the hand in chronic stroke was evaluated in a study by Jung *et al.*, (2011). The study was based on the neurophysiological theoretical rationale for splinting to reduce hypertonicity. The potential for type I error was considered likely due to over-confident reporting of the clinical effect ( $p < 0.001$ ) in a small study ( $n=21$ ). Also the study was assessed at a low level (Grade C) due to the risk of bias for external validity with the unlikely generalization to routine practice. To date there is strong evidence that prolonged wearing a splint (all night) has no additional effect in reducing spasticity (Lannin *et al.*, 2007).



Despite the lack of consensus over the use of splinting a small number of the RCTs were found to be of quality and provided guidance for clinical practice. For example, one quality study (Lannin *et al.*, 2007) compared splinting with the wrist in neutral overnight versus splinting in an extended position overnight versus no splint in 63 stroke participants. The findings indicated no difference between groups (mean difference 1 degree, 95%CI 2 to 5) with the clinical implication; splinting alone is insignificant. This finding was reinforced by a review of splinting Lannin and Ada, (2011) which suggests is not effective in decreasing spasticity, preventing contracture or improving activity.

This finding is verified in the (Grade A) Cochrane review (Katalinic *et al.*, 2011). It was discovered there was currently no evidence to support the use of a splint in comparison to other means to prevent contracture. Of the thirty-five studies it was reported stretch over a seven month period does not have a clinically important effect on joint mobility, pain, spasticity, activity limitation, participation restriction or quality of life.

The study (n=28) by Shamili *et al.*, (2011) used a non-randomized comparison of BT and a volar-dorsal immobilization wrist splint. The findings showed improvements in both groups in the Modified Ashworth Scale (MAS) but of no significance of between group effects. The implications of this are unclear as there was a significant rate of attrition with (n=18) completing the study. A risk of bias in reporting was considered and evaluated as low level of evidence (Grade C).

Despite the paucity of high level quality evidence in the use of splinting, a pragmatic approach suggests clinical trials can be used to guide and inform future clinical decisions. Furthermore, Lannin and Ada (2011) recommended a timely re-focus on the rationale for clinical use of splints with greater emphasis to enable activity and improve muscle performance. Two small trials of moderate quality by Gracies *et al.*, (1997; 2000) investigated the short term effects of dynamic Lycra<sup>®</sup> splints in adults with upper limb spasticity and both indicated promising results. Likewise, the case study by Watson *et al.*, (2007) demonstrated patient specific benefits. However in this study there was no dynamic splint found in combination with BT. The dynamic splint evaluated by

Lai *et al.*, (2009) although classified dynamic was actually a hinged elbow splint which was set at a constant range with a constant spring loaded force. The study had a number of limitations including a high level of withdrawal and non-compliance. It was consequently assessed as moderate to low level of evidence (Grade C).

A number of studies of effects of Lycra® in children with cerebral palsy indicate both acceptability and positive functional outcomes (Matthews *et al.*, 2007; Coghill and Simkiss, 2010; Elliott *et al.*, 2011b). However there were some compliance and acceptability issues reported (around temperature related discomfort, donning and toileting access). The small study using Lycra® based garments by Brownlee and McLeman (2002) also provided useful clinical procedural detail however it was assessed as low level of evidence (Grade C) due to its limitations in lack of control and non-validated outcomes with resultant bias of internal validity. Unfortunately there were a number of methodological weaknesses in the studies reviewed such as small numbers and lack of valid and reliable measures. Indeed evaluation and synthesis of the literature was difficult due to the limitations in the evidence base, the methodological shortcomings and study inconsistencies in heterogeneity. This is a commonly reported issue in studies in rehabilitation. The absence of evidence highlighted the gap in the existing knowledge base, which was a key finding that informed the direction of the research.

Taping was used as an alternative to splinting as an intervention in two studies Reiter *et al.*, (1998) and Stark, (2001). The findings were assessed as moderate to low (Grade C) but were clinically significant with the recommendation for combination treatment of selective BT and ankle-foot taping to optimise foot position and gait.

### **Physiotherapy interventions for spasticity**

Physiotherapy is widely acknowledged to have a key role in spasticity management (RCP *et al.*, 2009). Although this is primarily anecdotal it was evaluated by Stark, (2001) who cited treatment options of: stretching and mobilizing; positioning; electrical stimulation; strapping and use of splints or

casts in combination with BT. This study also stressed the need for a multi-disciplinary approach to capitalize on the potential for successful outcome. Stark, (2001, p.391) surmised physiotherapists can '*play a lead role*' in the management of spasticity and in particular with the use of BT for focal spasticity. She explained, because of their detailed knowledge of neuro-anatomy and rehabilitation physiotherapists can ensure effective assessment, goal setting and direct, or deliver appropriate treatment. However it was detailed that further research was needed to clearly identify efficacy of timing and specific interventions.

Physiotherapy is evaluated for evidence of beneficial effect on range of movement, muscle tone, quality of movement, balance and conscious level in traumatic brain injury by Tolfts and Stiller, (1997). The study findings identify the limited evidence for efficacy in this area with the exception of splinting and casting. The study was assessed as a moderate level (Grade B) despite the author's acknowledgement that the research in this area is limited. One of the difficulties was highlighted as the heterogeneity of people with brain injury making it difficult for comparison. The paucity of RCTs in this area was reasoned to be due to the unethical use of control groups; however it was argued it should be possible to compare different treatments for relative effectiveness. The absence of evidence does not mean physiotherapy is not effective, but highlights the need for well-designed research trials.

A prospective cohort study by Turner-Stokes, Ashford and Nair, (2010a) was assessed as moderate level (Grade C). This study included a number of combined physical interventions based on clinical judgement rather than by design. The study reported no significant change in active function but claimed prolonged levels of improvement of passive function ( $p < 0.005$ ). Implications drawn included the need for evaluation of the contribution of individual physical interventions following BT.

The routine physiotherapy intervention outlined in Lannin *et al.*, (2003) comprised of upper-limb motor training and stretching of specific muscles identified at risk of developing contracture. This study was assessed as a moderate to high level (Grade B) due to its methodological internal validity. The

RCT findings showed the hand resting splint does not produce clinically significant benefits. However one of the criticisms is that the splinting intervention was only of four weeks duration with the implication that longer follow-up could provide more meaningful results.

The study by Lannin *et al.*, (2007) began because of a lack of high quality evidence to support or refute the use of hand splints to prevent the development of contracture in the clinical setting. This was assessed as moderate to high level (Grade B) evidence as the trial was well designed and although each group only consisted of twenty-one participants the results of between groups differences indicated clinically significant effects were unlikely. It can be argued splints are usually provided in combination with other therapies and in this study the stretches and active upper limb training that usually accompany BT were not included. This was considered a design limitation. Hence the study was downgraded from a high level (Grade A) to a moderate (Grade B).

A case report by Richardson *et al.*, (2000b) outlined four case studies with lower limb spasticity and 'positive support reaction' affecting foot placement and weight bearing. The evidence was assessed at low level (Grade C) with implications for clinical relevance although the specific physiotherapy intervention was not detailed. Similarly best conventional therapy was described as based on the '*therapists past experience*' and tailored to the '*individual patient characteristics*' in one arm of the RCT by Platz *et al.*, (2009, p.708). This study was assessed at a moderate level (Grade C) but it was able to demonstrate specificity of active training was more clinically significant than intensity.

Despite general consensus (RCP *et al.*, 2009) on the relevance of combined physiotherapy treatment with BT for improved efficacy; what this consisted of was not specified. Indeed the evidence for the combination of physiotherapy with BT is rather weak; primarily based on the study findings of Giovannelli *et al.*, (2007). Intervention in this study was described as stretching exercise; both passive and active for 40 minutes, for fifteen consecutive days. This study had a risk for both external and internal validity bias. It would not be typical to have

this intensive intervention in standard practice. Therefore its findings are not generalizable.

Whilst details of components of physiotherapy are underreported a number of studies in the review provided clinical direction on the use of muscle stretches and identified the benefits of a home programme (Stark, 2001; Richardson, 2002; Giovannelli *et al.*, 2007; Katalinic *et al.*, 2011; Lannin *et al.*, 2003; Lannin *et al.*, 2007; Robinson *et al.*, 2008). Specifically the study by Giovannelli and colleagues (2007) recommended treatment with stretching. The efficacy of this intervention for the prevention and management of contractures for people with neurological conditions has since been reported ineffective in the Cochrane review (Katalinic *et al.*, 2011). This review was assessed as a high to moderate level of evidence (Grade A) due to its systematic rigor yet there was a risk of internal validity bias with confounding: combined intervention for prevention and treatment.

The Botulinum Toxin for the Upper Limb after Stroke (BoTULS) trial by Shaw *et al.*, (2010) was assessed at a moderate to high evidence level (Grade B). The findings of this multi-centre RCT provided valuable insights into clinical efficacy and cost-efficiency in physiotherapy treatment of the upper limb post stroke. Despite clinical benefits the addition of BT in an upper limb therapy programme was found to be not cost-effective. Furthermore there remains considerable doubt in the relationship between spasticity and functional limitation. Again this raises the question over the efficacy of repeat cycles of BT.

Although re-learning of functional skills is one of the main tasks of physiotherapy it is underreported. Modalities of functional training and task practice were also evaluated with positive clinical outcomes (Hellweg and Johannes, 2008; Turner-Stokes, Ashford, Nair, 2010a; and Elliott, Reid, and Alderson, 2011b). There was a high level of agreement of efficacy in clinical practice. The evidence was assessed as moderate to low (Grade B and C) for these studies.

Another under reported modality of treatment is sensory stimulation. This was investigated in a combination of interventions by Hellweg and Johannes, (2008).

Both studies included in the review that addressed sensory stimulation indicated that insufficient information is available due to poor recording of clinical details. Therefore clinical evidence of efficacy cannot be verified. Fitness training was further investigated by Hellweg and Johannes, (2008). This review evaluated two studies which showed there was a moderate to high level of evidence (Grade B) to support this modality however it was unable to find evidence of transfer of cardiovascular fitness into levels of activity and participation.

Further evidence is sadly lacking as details of physical therapy modalities reported by Tolfts and Stiller, (1997); Hyman *et al.*, (2000) and Stark, (2001) demonstrate a lack of consistency in approaches to treatment of neurological patients.

## **2.5 Discussion of the findings**

From the findings there was little consensus over the directed use of physiotherapy or splinting and there was an inadequate evidence base on which to inform effective practice. The literature review is discussed on its strengths, limitations and implications of the findings.

### **Strengths of the review**

The literature was systematically reviewed and the findings have provided direction for this study. A gap in the evidence base was discovered which identified a need for further investigation of a dynamic splint intervention. The review set out specific study aims, criteria and methods for search strategy, data extraction and synthesis of the findings. Critical appraisal discovered the majority of the findings provided low grade evidence (grade C), followed by moderate-level evidence (grade B) on the use of splinting and or physiotherapy for the management of spasticity. There was only one study (Katalinic *et al.*, 2011) that was assessed at high to moderate level of evidence (Grade A). This finding provided evidence of little or no clinical effect of stretch on range of movement. The review findings indicated a wide variation in practice and measures used. There was no evidence of mixed method studies or in depth

qualitative studies on the use of dynamic movement orthoses for spasticity management.

### **Limitations of the review**

Limited availability of literature dictated the decision to be inclusive of studies with wider aetiology than spasticity alone. The decision to include reviews was taken based on the study meeting the inclusion criteria of studies with populations of >40% people with spasticity. For example the Cochrane review (Katalinic *et al.*, 2011) included people with different neurological conditions that presented with movement disorders including spasticity. Primary studies within the reviews could have been scrutinised in more depth. The strict eligibility criteria was also difficult to maintain as several studies included additional interventions or combined approaches (Tolfts and Stiller, 1997; Stark 2001; Hellwegg and Johannes, 2008; Turner-Stokes, Ashford and Nair, 2010a; Katalinic *et al.*,2011) some of which were not detailed. In addition some of the reviews included primary studies with serial-casting as well as splinting which was identified as a further limitation in this review. This demonstrated the complexity of evaluating clinical research using multi-modal approaches.

Many of the studies did not have rigorous designs including randomization or case control (Gracies *et al.*, 2000; Brownlee and McLeman, 2002; Pizzi *et al.*, 2005; Robinson *et al.*, 2008; Shamili *et al.*, 2011), or did not report what usual care consisted of (Hyman *et al.*, 2000; Richardson *et al.*,2000b; Lai *et al.*, 2009; Jung *et al.*, 2011). In addition few of the studies admitted bias, (Shadish *et al.*, 2002) from selection, blinding, assessment, or attrition.

A number of the studies were case series or case reports consisting of small numbers with limited population, or ecological generalizability. In addition, only one person graded the evidence which does not provide a high level of credibility. This review was over-inclusive and should have adhered more to the eligibility criteria; however it could be argued the findings provided valuable insight for the proposed study.

It was worth noting that even though the hierarchy of evidence was graded it used an idealised system and therefore cannot be definitive. Thus an RCT of excellent quality could be more reliable than a systematic review of average quality primary studies. It is acknowledged there was some difficulty in application of the evidence level consistency in reporting systematic reviews which included poor quality studies. Thus conclusions of systematic reviews are often limited by low methodological quality of included trials and the absence of key comparisons for clinical use. This is seen in reviews and in summaries of evidence such as in clinical (evidence based) Guidelines and Database of Abstracts of Reviews of Effects (DARE). By implication the GRADE of the evidence could be raised or lowered. There is therefore a need to design trials with more sensitive measures of treatment effect and to identify patients who will obtain most functional benefit. In addition to grading evidence the summaries should clearly identify methodological components and bias.

### **Implications of the findings**

Due to insufficient evidence and some ambiguous reporting on effectiveness of both splinting and physiotherapy practice it was identified that a pragmatic research approach was needed. The findings are now discussed in light of the identified gaps in the knowledge and implications for this study.

The gap is closing between scientific understanding of spontaneous recovery of the CNS and the extent to which it can be translated into effective rehabilitation techniques. This review aimed to bring neuroscience (**Chapter 1**. p.24) closer to everyday clinical practice for the combined benefit of patients and the delivery of healthcare. A framework for neurorehabilitation should integrate theory, scientific evidence and clinical experience tempered by patient values (Sackett, 2002). Systematic review of the available scientific evidence and critical analysis of the findings were integrated using a pragmatic clinical approach to provide direction for further investigation.

A gap in the knowledge was identified to be the lack of reported scientific evidence in the combination of BT and dynamic splinting for the management of limb spasticity. Scientific evidence proposes the rationale for prolonged stretch



(as applied by splinting) to modify spasticity (**Chapter 1.**). Further consideration is required on a clinical level for optimizing motor performance. Several studies propose further research is needed to explore the efficacy of dynamic splinting (Gracies *et al.*, 2000; 2007; and Lannin and Ada, 2011). In addition the components of physiotherapy conventional treatment that contribute to the rehabilitation of muscles following spasticity are not fully understood. Some of the concerns of splinting study limitations documented by Lannin and Herbert, (2003) include: splinting acceptability and adherence; type and position of splints used and variance in splint protocols. Acceptability and patient experience was found lacking and good qualitative studies are required (Andringa *et al.*, 2013).

The evidence base for providing splints is both conflicting and contentious causing much debate around efficacy in clinical practice (Adrienne and Manigandan, 2011). Whilst revised national splinting guidelines provide theoretical rationale and clinical guidance (Kilbride *et al.*, 2015) the evidence base remains inadequate. Studies to date have commonly investigated static (rigid) splints but there is some potential for future research in the efficacy of dynamic splints and active muscle performance. Emerging literature suggests a need to reconsider splinting rationale to a practice that embraces the potential benefit of newer technologies that deliver ways of improving muscle performance (Lannin and Ada, 2011). Dynamic orthoses have the potential to offer this benefit to the adult population with focal spasticity; by directing optimal re-alignment of functional muscle activity rather than restricting movement.

The theoretical basis of using Lycra® in the management of spasticity (as opposed to movement disorders) is that DEFO provides prolonged stretch and compression 'for stability with directive forces for optimising postural control' (Matthews, 2008). The evidence for splinting in this client group is founded on the neurophysiological and biomechanical mechanisms of deep pressure and improved proprioception leading to 'improved positional limb and body awareness, improving muscle activation and movement control' (Matthews, 2008). The DEFO provides the possibility to reduce velocity dependent hyper-reflexia in spasticity, a positive feature associated with UMNL. The theoretical basis for this is the direct modulating effect of normalisation on the neural and

non-neural components of muscle tone. The former neural components include proprioceptive reflexes (stretch reflex) and the latter non-neural components of tone include visco-elastic properties, muscle fibre type and muscle length-tension relationship. DEFO also provides flexibility and allows movement with proprioceptive sensory feedback (Gracies *et al.*, (2000) on posture and performance. This interactive characteristic is an advantage over rigid splints considering spasticity is a velocity-dependent 'sensori'-motor disorder (Pandyan *et al.*, (2005). Thus it can be argued it is worth considering the use of Lycra® in spasticity management in addition to its use in movement disorders.

Further research is required to determine the long term effects of dynamic splinting and which specific patient groups might benefit. The small study by Elliott *et al.*, (2011b) suggested upper limb Lycra® splints were of some benefit with carryover however there were limitations to the study methodology, reporting and the findings should be treated with caution. The need for further evidence based research is reiterated in a Scoping report (by Calvert and Kelly, 2013) with studies determining larger numbers, longer follow-ups and homogeneity in the type of garment design. Although this report included adults there was no published evidence available either to support or refute clinical benefit or cost-effectiveness in this population. There is a noticeable gap in the research with little evidence available for DEFO Lycra® worn as a splint in the treatment of adults with cerebral palsy and limited evidence available for neurological conditions such as stroke and multiple sclerosis.

A review of physical therapy interventions for improving motor function in adults with neurological impairments following BT is needed. The studies in this review provided direction for the proposed research design. In addition five of the studies excluded provided further direction in that they were used to inform a data capture form for the physiotherapy modalities in this study (Stephenson, 1993; Richardson; 2002; Teasell *et al.*, 2003; De Wit *et al.*, 2007 and Donaldson *et al.*, 2009). Further search of the literature discovered a recent review of rehabilitation therapies after BT by Kinnear *et al.*, (2014) which again could be used to inform future studies on best practice after BT.

## 2.6 Summary

In this review the physiotherapy and splinting topics were critically appraised and assigned into two sub-groups of summary tables: **Table 2.2** Spasticity management with Physiotherapy and **Table 2.3** Splinting and Dynamic Orthoses. The evidence presented from the systematic review confirmed the need for further research both in the management of spasticity following BT and to determine the potential role of dynamic orthoses. There was also a gap in the existing evidence to determine which physical interventions are of most benefit in achieving a clinical outcome and reducing patient burden.

Whilst it was not possible to undertake formal meta-analysis of the evidence reviewed due to heterogeneity, there were some conclusions to be drawn. There was clearly a gap in the existing body of knowledge to explore which clinically relevant treatment is best delivered following BT during this time-limited 'window of opportunity'. Whilst there is some evidence of efficacy and acceptability in the use of dynamic Lycra<sup>®</sup> orthoses with children there is limited evidence in the adult population and this is worth exploring further.

There are potential gains from transitional research in the use of dynamic orthoses in neurology and this warrants further exploration. These studies provide direction to 're-focus' on muscle performance and functional activity (Lannin and Herbert, 2003; Gracies *et al.*, 2000) rather than inhibiting abnormal reflex activity with splints. This review identified dynamic splinting as a possible adjunct to usual care and physiotherapy following BT. This review informed a pilot feasibility study to investigate the efficacy of DEFO intervention and physiotherapy following intramuscular injection of BT in the adult population. The justification for the chosen methodology for this study is presented in **Chapter 3**.

## Chapter 3

### Methodology

#### Key points:

- **Identified gaps in the knowledge**
- **Research considerations**
- **Theoretical Frameworks for research and rehabilitation**
- **Selected measures for health related benefit**
- **Justification and rationale for chosen methodology**
- **Methodology for mixed methods (quantitative and qualitative)**
- **Methodological approaches in qualitative analysis**
- **Methodology of integration and rigour**
- **Summary**

#### Introduction

This chapter presents the rationale for the chosen research methodology, with justification for the design of this study. Scientific and clinically relevant literature was reviewed systematically (in **Chapter 2**) providing context and relevance to this feasibility study. This outlined gaps in the current research evidence for the management of limb spasticity in adults with dynamic splinting.

This study has built on evidence for the need to evaluate a potential new treatment to effectively direct muscle activity in limb spasticity (Lannin and Herbert, 2003; Gracies *et al.*, 2000). The DEFO is proposed as an intervention with the potential to deliver this by dynamic prolonged stretch of muscle for both active and passive care in adults with limb spasticity. In this chapter the methodology is considered that would provide greatest rigor in evaluation of the DEFO intervention in a clinical setting.

Research deficiencies directed the need to evaluate the DEFO intervention from a qualitative perspective. The literature identified a need to gather not only quantitative data but to explore results in more depth and detail from the

participant and wider stakeholder perspectives (Hanley *et al.*, INVOLVE, 2003). The methodology was chosen to provide practical insights into the feasibility, potential efficacy and acceptability of DEFO as a likely new treatment following BT. The design for each component was guided by the research problems.

### **3.1 Research considerations**

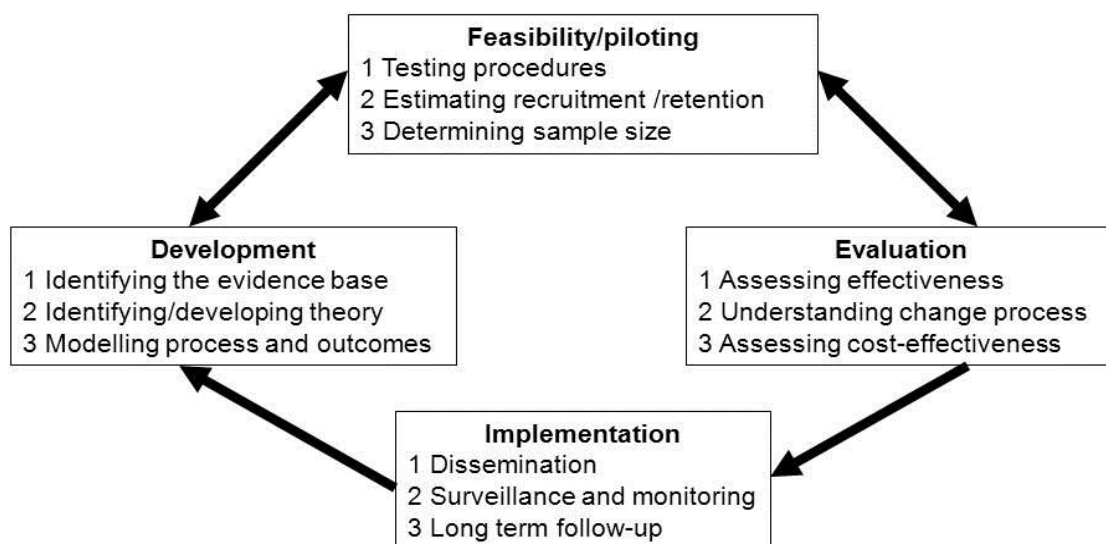
Research in healthcare is widely acknowledged to be multifaceted with complex interventions based in complex clinical environments (Medical Research Council (MRC), 2008; Richards and Borglin, 2011; Thompson and Clark, 2012; Richards *et al.*, 2014). Accordingly the research was founded on a theoretical basis of the (MRC, 2000; 2008) 'Complex Intervention Framework'. This Framework provided guidance for a phased approach by clearly defining the steps in the research process. Key elements of the MRC Framework include: 'development, feasibility/pilot work, evaluation and implementation'.

The complexity of clinical research requires an approach that can evaluate its constituent components and their inter-relationships. Accordingly adequate development and pilot work is considered important. Consequently this study is informed by the Framework (MRC, 2000; Craig *et al.*, 2008) with due consideration for the methodological and practical issues that arise in clinical research. It provides the research approach to examine methodological, clinical and procedural unknowns.

This phased model (**Figure 3.1**). tests the key elements of uncertainty, namely the practical procedures and thus enables the researcher to identify the common components that could influence outcome. The Framework is considered appropriate to examine a complex clinical area, such as neurological rehabilitation. In short, for clinical research to be useful it is important to establish clinical feasibility, compliance and acceptability.

**Figure 3.1 Flow chart: The revised MRC Complex Interventions Framework (Craig et al., 2008, p. 980)**

### Key elements for developing and evaluating complex interventions



#### Medical Research Council Research Framework

All phases are intrinsically linked but may not follow cyclical sequential steps. The MRC framework has been further refined and updated. It is summarised to include a number of key points;

- *The phased processes may not follow a linear sequence*
- *Experimental designs are preferable to observational studies but may not be practicable*
- *The understanding of processes and outcome evaluation are important*
- *Local context can influence standardisation, study reports must be sufficiently detailed for replication and add to knowledge.*

Craig et al., (2008, p. 979)

The research study presented followed the first two phases of ‘development’ and ‘feasibility testing’ in the revised MRC (Craig et al., 2008) phased process of ‘development-testing-evaluation-implementation’. This Framework was used

as a modelling process to inform feasibility for a larger study. Both a pragmatic and iterative approach was adopted to identify the main interacting components in the study and identify weaknesses of the design for further refinement. It was not within the scope of a small feasibility study to assess cost-effectiveness from a health economics perspective. Thus, this study aimed to build on the existing evidence, and follow the early developmental and feasibility testing research phases as a precursor to inform a larger study. A pilot study was proposed to test the identified complex intervention (DEFO), addressing all the unknown feasibility, acceptability, and recruitment, adherence and effect-size components.

Mixed method approaches are increasingly being used together in the context of health and health service research (Pope and Mays, 2006). Quantitative methodology involves research that is protocol driven and designed, so that it can be replicated. By contrast, qualitative methodology requires sufficient flexibility to enable the researcher to respond actively to discoveries during the research process (Holstein and Gubrium, 2011). By combining the two approaches greater depth and understanding can be ascertained with the sum of the whole greater than its constituent parts (Onwuegbuzie and Teddlie, 2003; Pope and Mays, 2006; Johnson *et al.*, 2007; O’Cathain, *et al.*, 2010; Wisdom *et al.*, 2012). This was considered an appropriate methodological approach for clinical research as in this study.

Furthermore in a modern health service it is essential to look at the perspective of different stakeholders. Patient experience provided valuable insight into how care should be delivered. Perspectives of patients and carers were used to inform clinical care and research design of this study (Hanley *et al.*, INVOLVE, 2003). The pilot study explored what could be feasibly delivered and identified whether there was any burden effect on those involved. Certainly the issues of clinical acceptability and adherence were critical to understanding the feasibility of the research study. In addition to the considerations above, the specific design was tailored to the identified research questions. The research governance followed ethical practice including Good Clinical Practice and the Research Governance Framework for Health and Social Services (2005), NHS Trust R&D approval, Data Protection Act, (1998).

## 3.2 Study methodology and rationale

### Methods considered

#### Quantitative method alone (pilot RCT)

Initially a quantitative pilot RCT was considered appropriate to answer the research questions. This was in line with MRC (Craig *et al.*, 2008) developmental methodology; using a pilot RCT with the primary objective of testing the feasibility of an intervention protocol. The RCT method is placed in the medical and science research hierarchy of the 'Rolls Royce' gold standard for rigour and construct validity. In this method the researcher, by control, has deliberately attempted to remove the effects of any variable other than the independent variable (the intervention to be tested) that might affect the outcome. However, this method alone would provide insufficient data to evaluate the intervention in a complex healthcare setting. Although it was possible to answer the primary question of likely health benefit it was unable to explain the results. The pilot RCT method alone was unlikely to fully answer important research questions of participant and clinician acceptability. It was for this reason that further qualitative methodology was selected for analyses of acceptability and identified health benefit from the participant and clinician perspectives.

#### Qualitative method alone (focus groups and interviews)

A qualitative design alone could be used to provide meaningful data (Charmaz and Bryant, 2011) on the acceptability of the DEFO intervention through focus groups and interviews. However it was likely this would have led to further developmental work as the qualitative method would have been insufficient to fully address the research problems. This iterative method could have been developed to inform a protocol based on the information gathered. It supports a phased approach based on the MRC (**Chapter 3.1.**) Framework. However, it was unlikely the findings from this method alone would have answered all of the complex intervention uncertainties that were needed to inform a larger study. Additional factors would not be identified such as likely recruitment rates,



retention rates and adherence (Thabane *et al.*, 2010). This design would not provide data for estimating effect-size for a larger study. Consequently it was unlikely evidence from a qualitative study alone would provide sufficient justification to support research funding for a larger study.

### **Single study or case-series**

Further research methods considered were single case study or case-series design. Both designs are considered applicable in the field of neurological rehabilitation research (Tolfts and Stiller, 1997; Richardson, 2000a). These methods acknowledge the likelihood of small numbers eligible for recruitment to a study in people with spasticity that would meet the eligibility criteria. A case study or single case-series design was less likely to have had impact on service demands including clinical capacity. Both were recognised as clinically feasible for that reason. This study model could have provided an alternative approach with optimal recruitment and increased potential for procedural application in the clinical area of study. However, the researcher considered both had lower construct validity from a research hierarchy stance when compared to the gold standard RCT.

This design and methodology did not acknowledge the developmental MRC, (2000; 2008) Framework approach for fully testing complex interventions in feasibility and pilot work for health evidence. Although a case study would provide valuable clinical detail of specificity it has less construct validity for generalizability to a relevant population. Neither this design, nor the case series model would test all of the procedural and unknown constituents of the intervention in a clinical setting. A defined objective for this study was to determine what effect-size is needed for this. This outcome would not have been provided from either a case study or a case-series design. Consequently this methodology and designs were not considered appropriate for this study.

## Mixed methods

A mixed methodology was chosen to evaluate the DEFO intervention in a new population (adults with focal spasticity) and address the uncertainties for a larger study. Justification for this is detailed below.

Although this methodology is not new in healthcare research (Morgan, 1998), it is considered by leading researchers in the field (Collins and O’Cathain, 2009; Johnson, Onwuegbuzie and Turner, 2007) as still in the developmental phase and accordingly open to individual interpretation. There has been an increasing popularity in the use of mixed methods since the late 20<sup>th</sup> century challenging Howe’s (1988) incompatibility thesis that quantitative and qualitative research should not be mixed. Howe argues that each methodology has its own paradigm or worldview which is based on differing philosophical assumptions. Howe (2004) challenges mixed methodology further in that it marginalizes qualitative interpretive approaches yet privileges post positivism. The basis for this mixed methodology’s recent popularity in healthcare has been supported by the MRCs interest (Craig *et al.*, 2008) and indeed recognition of the importance of qualitative research designs. There are a number of contrasting definitions for practice guidance that are informed by either philosophy and/or methodology (Teddlie and Tashakkori, 2009; Creswell and Plano Clark, 2007; 2011). This study research methodology was based on the definition by Creswell and Plano Clark, (2007, p.5) in which;

*‘mixed methods are characterised by the integration of a qualitative and quantitative approach (at any phase in the research process)’.*

The mixed methods approach is based on a worldview of pragmatism which is founded on an epistemology of knowledge that is formed by both subjective and objective human values (Creswell and Plano Clark, 2011). The pragmatic perspective for this study with a focus on ‘what works’ was based on the ideas by Tashakkori and Teddlie, (2003, p.713) who also acknowledge the role and values of the researcher in the process of interpretation. This method is justified to address the complex reality of healthcare research (MRC, 2008; Richards and Borglin, 2011; Richards *et al.*, 2014). It has been highlighted by others

(Johnson and Onwuegbuzie, 2004; O’Cathain, *et al.*, 2007; O’Cathain, 2009) that regardless of ideology, pragmatic mixed methods approaches are justified in health services research.

The rationale for choosing a quantitative pilot RCT study component is that it is widely acknowledged to be sufficiently robust for analysis of a potentially relevant and clinically practicable driven protocol. The RCT method is described as the ‘gold standard’ of evaluation. However, it is important to make clear that this study component was deliberately designed as a ‘feasibility’ pilot RCT. In essence a small scale feasibility study is not fully powered and therefore unlikely to produce a statistically significant outcome of efficacy. Accordingly this study design was deliberately chosen to address relevant research feasibility questions on the estimation of recruitment rates, refusal rates, retention rates and adherence rates (Thabane *et al*, 2010) for a larger study. A feasibility study which is not powered provides the possibility for effect-size estimates based on evidence of feasibility rather than a definitive effect-size calculation such as in a fully powered study.

The pilot RCT was purposefully designed with blinded randomization to address the four main problems of potential study systematic bias (Shadish *et al.*, 2002). The potential for selection, performance and detection bias were addressed by randomization and blinding. One of the outcomes of this study was to evaluate the rate of withdrawals (attrition bias) from the study. Quantitative quality criteria are commonly agreed to include internal validity, external validity/generalisability, reliability and objectivity (Lincoln and Guba, 1985). These criteria are reviewed in **Chapter 8.3**.

A qualitative phase was established to address uncertainties around the DEFO intervention. The quantitative method alone would provide insufficient data to answer the research questions of participant and clinician acceptability. The rationale for using a qualitative phase was to explore the research procedural, methodological and clinical issues after completion of the intervention phase of the quantitative design. This combines feasibility and acceptability detail provided a rich qualitative supplemental data strand (Creswell and Plano Clark,

2011) for analysis of the procedural, methodological and clinical issues experienced by participants and clinicians.

A mixed methodology was deliberately chosen in this study to explain and strengthen the findings of each method through integration (Onwuegbuzie and Teddlie, 2003). In this method the data sets from quantitative and qualitative results are analysed separately, then integrated (**Chapter 3.5**) by triangulation of the findings (Silvermann, 2011; Farmer *et al.*, 2006; O’Cathain *et al.*, 2010). This provides the opportunity for more depth and breadth to the analysis and interpretation (Denzin and Lincoln, 2000; Johnson *et al.*, 2007; Wisdom *et al.*, 2012). Fundamentally this was why the research methodology chosen was both quantitative and qualitative in the study design. The multiple advantages of the mixed methods approach are similarly outlined by Creswell, (2003); credibility/trustworthiness, practicality, complimentary (naturalistic and post-positivist) and incremental in terms of building a knowledge base.

A mixed method was the most appropriate approach in this study based on the rationale that ‘feasibility’ was the key objective for this study. The reason for selecting this method was determined on the basis of exploring the important feasibility issues. The underlying aim of this research was to explore implications for a larger study.

### **3.3 Rehabilitation and health related measures**

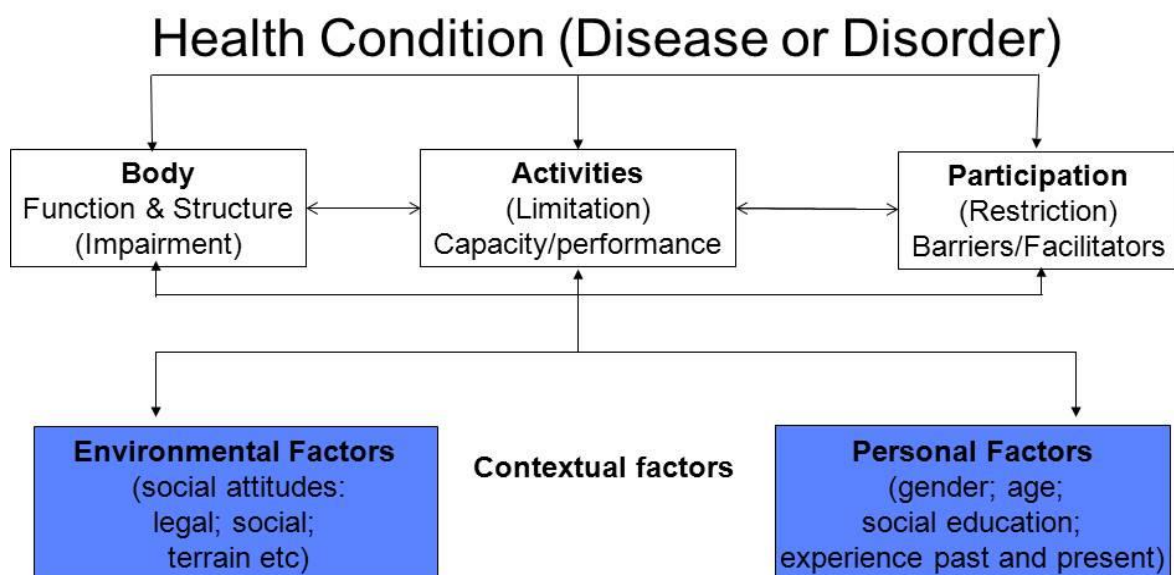
Rehabilitation involves an interdisciplinary team approach with a distinct structure and delivery (Wade, 1992) of holistic patient-centred goals based on an underlying knowledge of the International Classification of Functioning (ICF) (WHO, 2001) domains of functioning; body function, activity limitation and participation restriction. Accordingly it was planned to assess potential clinical efficacy by health-related measures in each domain. Objective markers and outcome measures should be selected as both reliable and valid (Wade, 1992).

It has been widely acknowledged that measuring effectiveness in neurological rehabilitation is problematic due to factors including changing baseline, disease progression and co-morbidity (Wade, 1992; Turner-Stokes, 1999; Tyson *et al.*,

2008; Wissel, *et al.*, 2009). The dual role of a researcher and clinician is to formulate clearly focused and relevant questions (Straus and Sackett, 1998). Outcomes were selected for measurement of potential clinical importance to identify the effect-size for a larger study and to identify specific health benefits. Hence measures were selected to find a clinical effect most likely to measure the DEFO intervention rather than for a definitively powered study. Of equal consideration was to measure the intervention from a clinical perspective for feasibility of protocol implementation in context of clinical practice in a community setting. A battery of recommended measures was chosen to assess functioning and disability outcomes in accordance with spasticity guidelines (Turner-Stokes and Ward, 2002; RCP, *et al.*, 2009). The ICF model shown below, (in **Figure 3.2**) is accompanied by a description of each level of outcome.

**Figure 3.2 Representation of the model of International Classification of Functioning (WHO, 2001; 2002, p. 9)**

## International Classification of Functioning, Disability & Health (ICF Model, 2001)



## **Impairment Level**

Symptoms that have an impact at a physical level are often reported as a common concern by clinicians and patients. This is because physical symptoms (for example pain) can have a significant impact on wider function and participation levels and overall health and well-being. The measures of spasticity and pain were assessed as levels of impairment in this study.

## **Activity Level**

The level of activity was used as a measure for specific functional activities such as walking, dressing and washing. This was reported as 'active' functional outcomes. Activity levels are commonly measured in terms of capacity and performance.

## **Participation Level**

Spasticity has a significant impact on participation level by default due to the consequential effect of limitations imposed by impairments such as pain and spasms. Participation has been explained by the societal and personal roles and interaction that the person fulfils including such activities as work, parenting, self-care and relationships. The most commonly reported difficulty was in the ability to care for a limb which has altered movement. This was often at risk of developing secondary complications such as contractures and pressure ulcers, leading to increased carer burden (Bhakta *et al.*, 2000; RCP, *et al.*, 2009). Literature evolving in this area has helped to demonstrate the importance of measuring the impact of an intervention that takes into account not only the effect on the patient but also their associated care and burden or costs (Shaw *et al.*, 2010; Ashford, Slade and Turner-Stokes, 2013). To date the exponential development of measures has also helped to categorize disability in terms of burden.

## Selecting measures for the evaluation of predicted health benefits

The selection of outcome measures was based on the predicted likely added health benefits from the DEFO intervention. These were identified by the researcher to include measures that correlated with rehabilitation aims to maximise functional potential and minimise secondary complications (RCP *et al.*, 2009). The evidence to support the relationship between reduced spasticity and functional gain is weak (Sheean, 2001; Francis, *et al.*, 2004). Although the reduction in spasticity following BT may not result in improved function, there are likely to be associated positive outcomes, which can be evaluated at levels of impairment, activity and participation. It can be argued the impact on carer burden can also be significant (Bhakta *et al.*, 1996; 1999; 2000) and should be used as a measure of benefit. Accordingly, the measures for this study were selected based on a rationale of specificity and relevance to the predicted likely health benefits associated with the DEFO intervention during the window of opportunity following BT.

The likely health benefits were identified as reduction in pain (Bergfeldt *et al.*, 2006; RCP *et al.*, 2009) and associated comfort, reduction in care burden (Bhakta *et al.*, 2000; Ashford *et al.*, 2013; 2014), improved upper and lower limb function and improved quality of life. More importantly the researcher recognised the need to evaluate potential health benefit from the patient perspective with identified goals for real-life outcomes. Measures for the study were also evaluated for reliability and sensitivity.

### Measures selected

Although this study aimed to use valid and reliable measures it is acknowledged that appropriateness (relevance to research) of the measure is also important. Measures that could demonstrate proven sensitivity of clinical effect and demonstrate patient-centred outcomes of significance were considered for this study.

The measure for 'goal attaining' that was first introduced in the 1960's by Kirusek and Sherman has since been widely adopted by clinicians to demonstrate predictive clinical outcome. The primary measure (**Appendix 7**)

Goal Attainment Scaling (GAS) score was selected on the basis of reported predictive sensitivity for real-life outcomes which are significant to the patient (Ashford and Turner-Stokes, 2006; Turner-Stokes and Ashford, 2007; Turner-Stokes, 2009). Also GAS scores were found to correlate with a reduction of spasticity and global benefit following BT (Ashford and Turner-Stokes, 2006). A further study indicated that GAS may identify functional benefits not demonstrated by other functional measures (Turner-Stokes *et al.*, 2010b). Procedural details of this measure are explained in **Chapter 4**.

Additional measures selected (**Appendix 10**) were tools previously administered: Visual Analogue Scale (VAS) for pain; Leeds Arm Spasticity Impact Scale (LASIS) (Bhakta *et al.*, 1996); Arm Activity measure (ArmA) (Ashford *et al.*, 2008) and 10 meter timed walk test (10MTT) (Watson, 2002). At the onset of this study the LASIS and ArmA were relatively new tools recommended (RCP *et al.*, 2009) for clinical outcome and were undergoing evaluation for reliability. Additional measures of European Quality of Life-5 Dimensions (EQ-5D) (EuroQol Group<sup>®</sup>, 1990) and Activity Log had not been used prior to the study.

The symptom of pain is reported to be commonly associated with spasticity (Bergfeldt *et al.*, 2006; RCP *et al.*, 2009). Pain impairment was measured using the standardised nominal Visual Analogue Scale (VAS). It is reported a reliable measure even with modification for communication or visuo-perceptual problems as those that may result in stroke (Jackson *et al.*, 2006). One such modification available was the Wong-Baker FACES<sup>®</sup> Pain Rating Scale (Hockenberry *et al.*, 2005) with six pictorial representations of faces with incremental changes of happiness or sadness across the line.

The European Quality of Life-5 Dimensions (EQ-5D) questionnaire is used to measure health benefits and this has been found both reliable and generalizable to neurological conditions (EuroQol Group<sup>®</sup>, 1990). It can also be used in the clinical and economic evaluation of health care (EQ-5D-3L UserGuide v5, 2013). However, in this small feasibility study there was no intention to use this measure for cost-analysis. This measure was selected for evaluation for use in a designated study population to inform procedural



feasibility for a larger study and for its simplicity to complete. It was registered with the EuroQol Group<sup>®</sup> for the trial.

The LASIS was originally developed by Bhakta and colleagues (1996) after findings in an earlier BT study (Hesse *et al.*, 1992) suggested the standardised measures previously used were not sensitive enough to measure change in areas such as hand hygiene. The LASIS was further evaluated (Bhakta *et al.*, 2000) and found to demonstrate increased sensitivity to change in disability when compared to the Barthel Index (Mahoney and Barthel, 1965). This new tool measured a number of items related to self-care. The LASIS was chosen to measure carer burden in this study based on its clinical relevance (RCP *et al.*, 2009).

The Arm Activity measure (ArmA) was chosen for the combined purpose of measuring arm function and care of the arm (Ashford *et al.*, 2008; RCP *et al.*, 2009). It has since been reported reliable and relevant for measuring care burden in people with upper limb spasticity (Ashford *et al.*, 2013; Ashford *et al.*, 2014).

For those with the ability to walk, the 10 meter timed walk test (10MTT) provided a measure of functional gait velocity (Watson, 2002, Foley *et al.*, 2010). For quick reference it was suggested 82m/min was the norm for a healthy adult. This was selected as a reliable and validated tool for the measure of functional impact of the DEFO intervention on gait velocity (comfortable).

The Activity Log (**Appendix 13**) was a useful measure of functional performance and provided details on participant activity level throughout the study. Further measures for testing fidelity were used such as the DEFO wearing record (**Appendix 9**) and the Physiotherapy Intervention Data Capture Sheet (**Appendix 8**). Clinical records were made available for the purpose of corroborating fidelity.

### 3.4 Methodological approaches for qualitative analysis

#### Thematic Analysis

Thematic Analysis methodological approach was developed as a useful method in comparing sets of interviews. Thematic Analysis is widely used for analysis of qualitative research, but without universal agreement for how it is accomplished (Braun and Clarke, 2006). It has been described as '*a method for identifying, analysing and reporting patterns (themes) within data*' (Braun and Clarke, 2006, p.79). It also involves interpretation of aspects within the research topic (Boyatzis, 1998). With this qualitative methodology it was reasoned appropriate to use a thematic coding method with both a theoretical deductive (Boyatzis, 1998) and interactive inductive (Frith and Gleeson, 2004) analytic approach for transparency and to go beyond just reporting emergent themes (Bazeley, 2009). In this approach the researcher is positioned actively in the process yet is able to use an analytic narrative approach to make sense of the data (Braun and Clark, 2006). This fits with the researcher's worldview as a pragmatist with orientation in real-world practice, problem focussed, pluralistic in approach and able to recognise that actions lead to consequences (Creswell and Plano-Clark, 2011). Thematic Analysis by a six phased process of analysis (**Table 3.1**) is a method for identifying, analysing and reporting patterns (themes) within data.

**Table 3.1 Six phases of Thematic Analysis** (Braun and Clarke, 2006)

1. Familiarisation of data
2. Generating initial codes
3. Search for themes
4. Refine and naming of themes
5. Integrate findings by triangulation
6. Producing a report with extracts embedded in analytic narrative

The coding of the data is an inherent part of the analysis and is thus reported on below in more detail using a Framework analytic approach (**Appendix 16**).

## Framework Analysis Methodology

A 'Framework' analysis methodology is increasingly appropriate as a coherent approach using an inclusive and systematic methodology in Health studies (Ritchie and Lewis, 2003). The Framework analytic approach (Ritchie and Spencer, 1996) is used for the data categorization in this study. In this method a process called constant comparison is used to check and compare all of the categorized data with the rest of the findings as each category is established. The data sets are coded with an analytic process: named common and distinctive categories (open coding), which involves analysis to see if they fall into common groups (axial coding) which are then analysed further (selective coding) both keeping the core and rich data detail (Ritchie and Lewis, 2003). The organisation of the groups is then further interpreted actively by creating links as the researcher makes sense of them, considering details of the context. Thus the overarching analytic methodology was Thematic Analysis with a Framework analytic approach for the categorization of the qualitative data.

### Thematic Networks

Attride-Sterling (2001, pp. 387-91) further outlined the process for 'Thematic Analysis' using a web-like systematisation of the key themes, 'thematic networks'. This process provides a method for organizing qualitative data captured as;

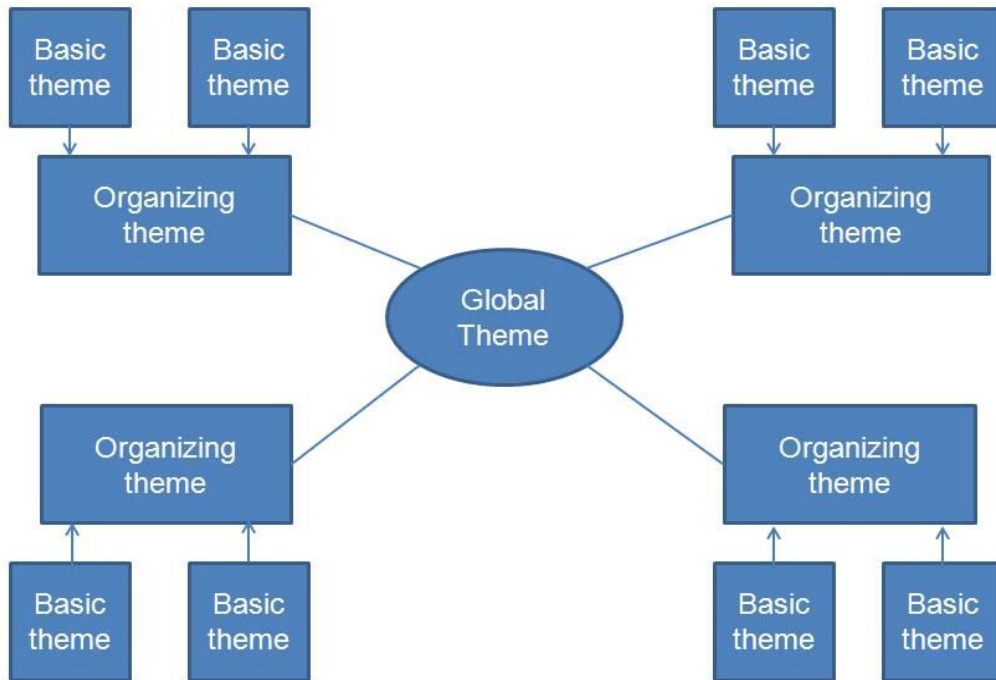
*'it simply provides a technique for breaking up text, and finding within it explicit rationalizations and their implicit signification'.*

(Attride-Sterling, 2001, p. 388)

Semantic content analysis is used to inform evaluation of findings; by defining and refining the themes as the patterns of meaning became increasingly coherent. This descriptive thematic content is then interpreted for further meaning. The thematic methodology follows good Thematic Analysis' (Attride-Sterling, 2001) using a coding system that links to the original data sets. This method is illustrated below (**Figure 3.3**) in which data was systematically and thematically organised and coded from 'basic' to 'organizing' to 'global themes'.

**Figure 3.3 Thematic Analysis (Attride-Sterling, 2001, p. 388)**

**Thematic Analysis: 'thematic networks' using systematic methodology (Attride-Sterling, 2001)**



In this study a Framework analytic approach was used to the Thematic Analysis for coding of the findings but also followed good Thematic Analysis (Attride-Sterling, 2001) with the themes displayed visually by networks and interpreted in the text.

### **3.5 Methodology of integration**

Integration is the *'interaction or conversation between the qualitative and quantitative components of a study'* (O'Cathain *et al.*, 2010). Three techniques for integrating data in mixed methods studies are described by O'Cathain and colleagues (2010): mixed methods matrix, following a thread and triangulation protocol. The former techniques are applied at the point of analysis whereas the latter is applied at the point of interpretation. Although the triangulation protocol was originally developed for multiple qualitative methods (Farmer *et al.*, 2006) it is also relevant to studies of mixed methods.

Triangulation is when data is both integrated and interpreted in a later phase. The triangulation protocol is used for example to assess the efficacy of a healthcare intervention and semi-structured interviews with participants and clinicians to provide a real-world analysis. This technique was considered to fit with the researcher's worldview as a pragmatist. Triangulation can be used to establish validity of combined quantitative data and qualitative findings. This methodology combines the multiple theories, methods and empirical materials which adds '*rigor, breadth, complexity, richness and depth*' (Denzin and Lincoln, 2000, p. 5).

The process of triangulating findings from mixed methods takes place at the interpretation stage after both data sets have been separately analysed. The methods for this process are described by O'Cathain and colleagues (2010). This depends on whether there is overall agreement, (convergence), complimentary information (complimentary) or disagreement by conflicting findings (discrepancy or dissonance). Indeed, exploration of contradictions can lead to a better understanding of the issues (O'Cathain *et al.*, 2010).

In mixed methods approach individual data analysis can be planned in parallel or sequentially then through integration of the two methods to produce meta-inference (Teddlie and Tashakkori, 2009) thus resulting in a sum greater than the individual components (Pope and Mays, 2006). The concept refers to the conclusions drawn from mixed methods study in terms of credibility of the qualitative component and internal validity of the quantitative component. The inferences drawn from the integration are legitimised and used to formulate generalisations.

Integration brings together data from quantitative and qualitative components of mixed methods studies (Bryman, 1992; 2006; Onwuegbuzie and Teddlie, 2003; Polit and Beck, 2012). It is justified on the basis of providing a more comprehensive picture of the findings in the study (O'Cathain *et al.*, 2010). By integration and triangulation (O'Cathain *et al.*, 2010; Silvermann, 2011) of the qualitative and quantitative findings it offers a strategy for greater breadth and quality of findings (Denzin and Lincoln, 2000; Johnson *et al.*, 2007; Wisdom *et*

*al.*, 2012) resulting in inference transferability (Teddlie and Tashakkori, 2009). Inference transferability is underpinned by the combined concepts of external validity (from the quantitative perspective) and transferability (from the qualitative perspective) and refers to generalisability of the integrated findings from the mixed methods study to a specified population and context. Thus a mixed method study has benefit in combining both approaches into a single study adding credibility (qualitative) and external validity (quantitative). Teddlie and Tashakkori (2009) propose integrated findings can be explained in concepts of overarching quality and transferability (generalisability to a similar population).

In mixed methods research a number of quality frameworks have emerged to address rigour. Firstly a set of four criteria was developed that includes;

- Truth value (credibility vs. Internal validity)
- Applicability (Transferability/Fittingness vs. External validity/Generalizability)
- Consistency (Dependability vs. Reliability)
- Neutrality (Confirmability vs. Objectivity)

(Sale and Brazil, 2004, pp.358-360)

Secondly the essential components developed by O’Cathain, Murphy and Nicholl, (2008, p.92) provide useful criteria for reporting mixed methods research; Good Reporting of a Mixed Methods Study (GRAMMS). This six-item framework provides a useful procedural checklist. The method of integration and inferences drawn are key components that demonstrate methodological congruence. Conflicts in findings justify further investigation (Moffat *et al.*, 2006). Further recently developed procedural checklists for mixed methods research include the ten point checklist by Collins and O’Cathain, (2009) and another by Andrew and Halcomb, (2009) which informs the design elements.

The integration of findings in this study and quality framework for rigour are presented in **Chapter 7**.

### 3.6 Summary

There was clearly an identified gap both in rigor and of clinical relevance in studies for the treatment of adults with focal spasticity following BT. Intervention of the DEFO has not been rigorously evaluated in the adult population with focal spasticity.

One data source in an exploratory study is believed to be insufficient to answer the research questions fully. The chosen methodology has informed the mixed methods study design (**Figure 4.1**). This chapter provides justification for the chosen methodological approach. How this was implemented is made explicit in the next chapter (**Chapter 4; Methods**).

## Chapter 4

### Methods

#### Key Points:

- **Background and objectives**
- **Methods and trial design**
- **Participants and setting**
- **Interventions**
- **Outcomes**
- **Recruitment, randomization, allocation, concealment and blinding**
- **Statistical methods and analysis**
- **Data management, withdrawals, adverse event recording**
- **Ethical process, Research Reference Group**

#### 4.1 Background

This chapter provides a detailed account of the research method conducted and follows the CONSORT standards of reporting (Schultz *et al.*, 2010) for a randomized trial. This study also follows 'Good Reporting of a Mixed Method Study' (GRAMMS) developed by O'Cathain *et al.*, (2008).

The scientific background for the study is presented in **Chapters 1** and **2** setting out the research problem and uncertainties. The justification and rationale for the research methodology is detailed, in **Chapter 3**, which informed the mixed methods design of this feasibility study. This chapter delivers detailed descriptions of the procedural methods and protocols used whilst investigating the multiple research feasibility questions. The results of this study are presented in **Chapters 5** and **6** with the findings integrated in **Chapter 7**. The study findings are then interpreted in light of strengths, weaknesses and generalisability by discussion in **Chapter 8** with study conclusions drawn in **Chapter 9**. The following method was submitted and gained ethical approval (12/SC/0518, **Appendix 1**) and is detailed, in **Chapter 4.9** and **Chapter 8.1.1**.



## **Study aim, objectives and research questions**

### **Study aim**

The study aimed to investigate the feasibility, potential efficacy and acceptability of DEFO and physiotherapy as a new treatment of focal spasticity following BT in an adult population.

### **Objectives**

- To identify the likely added patient health benefit in providing DEFO compared to usual care as a primary intervention as an adjunct to usual care following BT in the management of focal spasticity.
- To provide detail of clinical feasibility and acceptability in order to find the likely recruitment rate and estimated effect-size for justification of a larger study.
- To contribute to the existing knowledge base to inform clinical decisions for focal spasticity management.

The primary research question was formulated after identification of a gap in knowledge about the management of limb spasticity in adults following BT. Equally important questions were identified to provide practical insights into the feasibility, potential efficacy and acceptability of DEFO as a likely new treatment following BT.

### **Research questions**

This study identified three equally important questions to explore the uncertainty of this intervention following BT for focal spasticity in adults:

- What is the likelihood of health benefits of treatment with DEFO and physiotherapy (as required) and usual care, compared to usual care alone? (primary question)

- What is the feasibility of the protocol to inform the design of a larger study?
- How acceptable is the DEFO intervention in clinical practice?

An important consideration in the study was to identify health benefits. The likely health benefits (**Chapter 3.3**) were identified to be associated with potential reduction in limb spasticity which can impact on pain, deformity and impaired function (Bergfeldt *et al.*, 2006; RCP *et al.*, 2009). A range of valid and reliable measures (**Chapter 4.5**) were used to identify health related benefits of the intervention and examine any uncertainties.

**Alternate hypothesis-** Following BT: There is added health benefit from the intervention with DEFO with physiotherapy and usual care compared to physiotherapy and usual care alone.

**Null hypothesis-** Following BT: There is no added health benefit from the intervention with DEFO with physiotherapy and usual care compared to physiotherapy and usual care alone.

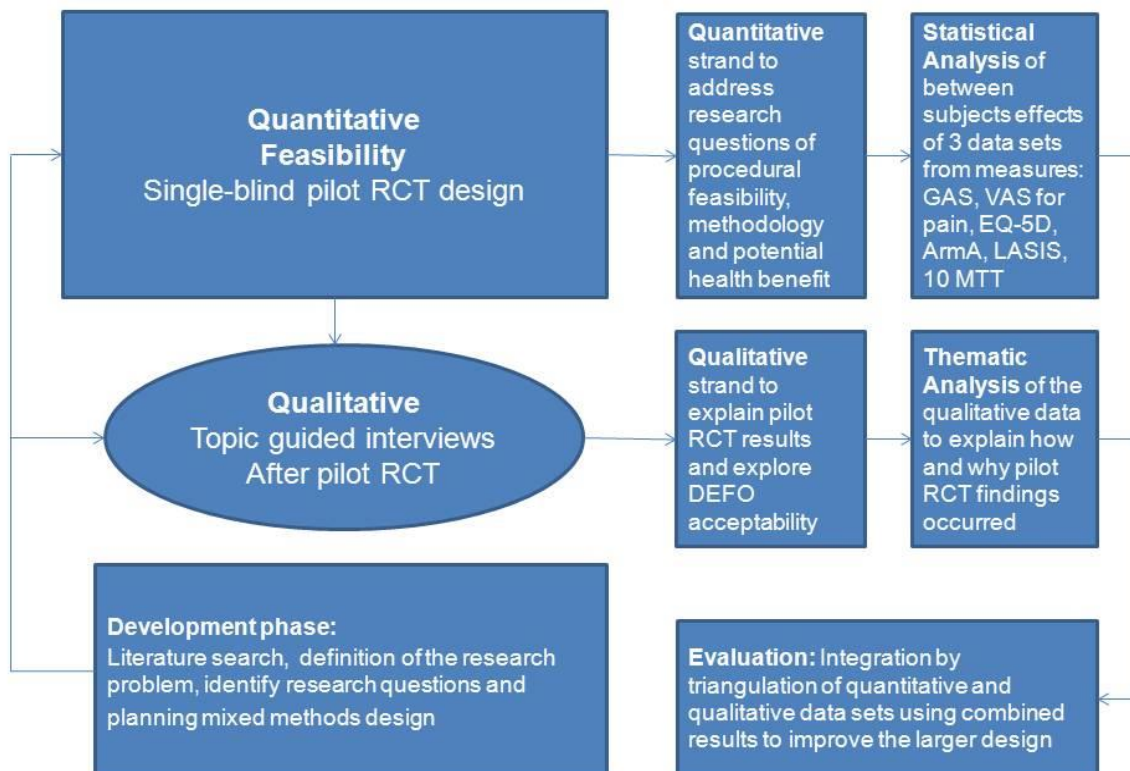
## 4.2 Study design

### **Mixed methods embedded design**

A mixed methodology with a 'mixed methods embedded design' (Creswell and Plano Clark, 2011, pp. 90-96) was used to evaluate the DEFO intervention. This embedded design integrated quantitative and qualitative methods, each informing the other. This can be exemplified by the development of the topic guided (semi-structured) interview questions, which were specifically based on the early findings of the pilot randomized controlled trial (RCT) adherence and informed by research participant experience. This qualitative design component was considered as an important modification to the research protocol (**Appendix 1**). This study design consisted of two interconnected phases;

quantitative followed by qualitative method. The quantitative component was with an experimental feasibility single-blind randomized controlled study. The qualitative component was designed with topic guided interviews for a nested sample of the participants (Campbell *et al.*, 2003; Onwuegbuzie and Collins, 2007). This nested sample was with the subgroup (intervention group) of the pilot RCT participants and clinicians who provided feedback on the intervention experience. This provided qualitative findings for external validation of the study. A procedural diagram (**Figure 4.1**) is used to describe the mixed method embedded design used in this study.

**Figure 4.1 Procedural diagram of the mixed methods embedded study design**



The research quantitative and qualitative design components are presented sequentially in a phased framework. The first phase was a quantitative comparative (pilot RCT) design followed by a second qualitative phase to describe the experience ‘what and how’ the intervention was delivered.

## **Mixed method phase I: Quantitative design**

### **Single-blind pilot RCT**

The quantitative design (phase I) of the mixed method research was designed to investigate the potential efficacy and acceptability of the DEFO intervention following BT. It was specifically designed to assess the feasibility of introducing this intervention in clinical practice.

Following development work (testing the measures and meetings with DM Orthotics Ltd<sup>®</sup> clinicians, **Chapter 8.1**) a feasible protocol was designed and replicated in the clinical setting. All participants had BT intramuscular injection of identified targeted muscle(s) following recommended guidelines (RCP *et al.*, 2009) and received usual care as required. The intervention protocol pathway is shown in **Figure 4.2**. The intervention protocol (**Appendix 6**) was devised and tested to address procedural feasibility. A DEFO wearing protocol (**Appendix 9**) was established for the intervention group and both protocols were followed for consistency. All participants were given a diary 'Activity Log' (**Appendix 13**) to record their weekly activities which was used to capture any group variance over the twelve weeks. In addition the physiotherapy clinicians were given a Physiotherapy Data Capture sheet (**Appendix 8**) to record intervention modalities for all of the participants over the twelve weeks.

#### **Intervention Group (A): DEFO (intervention) and physiotherapy and usual care.**

Delivered as: six weeks intervention, physiotherapy (as required) and usual care followed by six weeks removal of the intervention but continued physiotherapy (as required) and usual care.

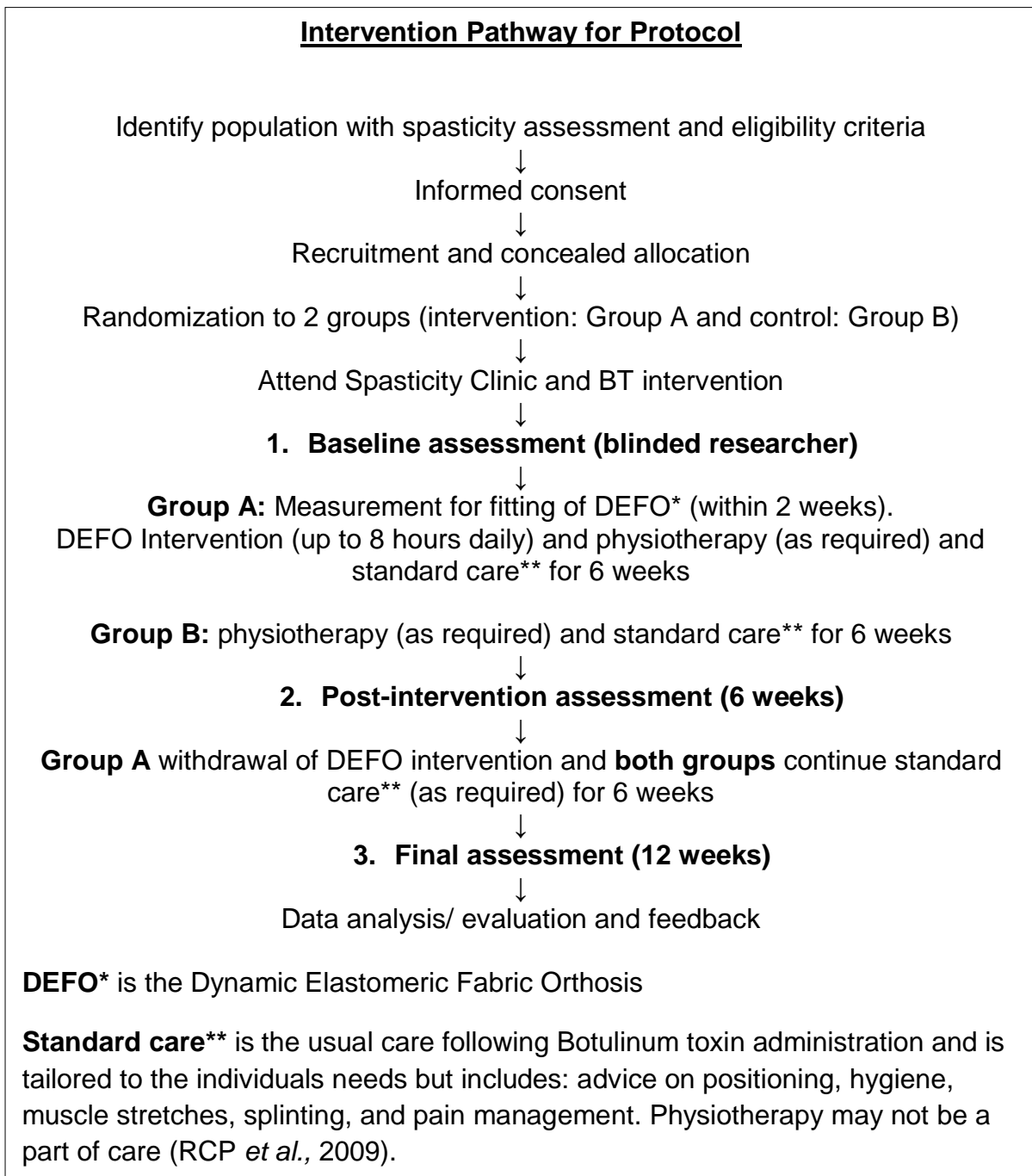
#### **Control Group (B): physiotherapy and usual care (control).**

Delivered as: twelve weeks physiotherapy (as required) and usual care.

Justification for the time of wearing for the DEFO intervention was based on the potential for efficacy within a twelve week window following BT (RCP *et al.*, 2009; Wissel *et al.*, 2009). Optimal impact of BT is from approximately two

weeks when therapy and splinting is considered to be of most benefit. The reason for removing the DEFO at six weeks was to measure the specific impact of the added intervention with a planned further six week follow up to measure for any carry-over effect.

**Figure 4.2 Intervention pathway for protocol**



## **Mixed method phase II: Qualitative design**

The qualitative design (phase II) of the mixed method research was intended to explore the experience of the DEFO intervention and provide supplementary data for analysis. Following the feasibility RCT intervention the group of participants who received the intervention and the clinicians who delivered the protocol were interviewed. Research questions on feasibility and acceptability of the intervention were used to provide critical discussion points.

This qualitative strand explores and explains the pilot RCT findings to determine the feasibility and acceptability of the DEFO intervention for further study. The scope and focus of the research questions provide a well-defined area for study. The topic guided questions were expanded following an iterative framework; using probe questions to follow further lines of interest and uncertainties (**Appendices 11 and 12**). This design strategically guided the interviewee to identify accounts of their experiences. These were later authenticated by Thematic Analysis of the data (Braun and Clarke, 2006). The analytic methodology is presented in **Chapter 3.7**. This data was collated and the findings presented (**Chapter 6**) and integrated with the quantitative data (**Chapter 7**).

### **4.3 Participants and setting, eligibility, recruitment and consent**

Potential participants were identified for recruitment on referral for spasticity management with BT at the regional Spasticity clinic. Participants possibly eligible were identified from an adult, heterogenic population with an established neurological upper motor neuron condition (including Multiple Sclerosis, Stroke, Acquired Brain Injury, and Spinal Cord Injury) presenting with symptoms of focal or multi-focal spasticity in the upper limb or calf. Details of the community setting and level of carer support was documented. The study was conducted in a community setting with physiotherapy and usual care delivered either in participant homes or therapy gyms. The inclusion and exclusion eligibility criteria were chosen to be deliberately inclusive and representative of the population studied (**Appendix 15**).

The following were integral to the research: Principal researcher, Consultant Physician in Rehabilitation Medicine, two Specialist Neuro-Physiotherapists (postgraduate M-level qualification in spasticity management and provided delivery of physiotherapy interventions) and DM Orthotics Ltd<sup>®</sup> clinician (appropriately DMO<sup>®</sup> skilled and provided DEFO intervention; assessment and fitting) and a research administrative support worker. Roles and responsibilities were established for the study and monitored (Research Reference Group, **Chapter 8.1.3**).

The Consultant Physician was responsible for the identification of potentially eligible participants in his spasticity clinic. He also administered the BT for spasticity management as a prerequisite to the study intervention.

### **Eligibility**

Potential eligibility of participants was pre-determined by an identified treatment plan with BT in place and a spasticity clinic appointment. The eligibility assessment was conducted by the principal researcher.

### **Measure of spasticity for eligibility to the study**

Measurement of biomechanical and neural components in spasticity is difficult to quantify. Both the Modified Ashworth Scale (MAS) introduced by Bohannon and Smith (1987) and the Tardieu Scale recommended by Patrick and Ada, (2006) are commonly used in practice. Despite evaluation by Mehrholz *et al.*, (2005); Haugh *et al.*, (2006); and Fleuren *et al.*, (2009) that the Tardieu Scale is more reliable for test-retest and has closer adherence to velocity-dependence in spasticity (Lance, 1980), they concede it has reduced timely application in the clinical setting. The MAS has been widely adopted by clinicians for the measurement of spasticity and was used as a guide for eligibility in this study. A predictive change in the level of spasticity is well evidenced as attributed to BT and not the purpose of this study. Accordingly; it was used as an assessment measure for eligibility and not a measure for intervention effect in the study.

The MAS consists of a five point scale where: 0= no change in muscle tone and 4= affected part is rigid. In practice it is common for BT to be most effective in MAS 2-3. It is not clinically indicated at MAS 1 or MAS 4. Hence this was a consideration for eligibility to the study.

### **Inclusion criteria**

Participants recruited were adults (over 18 years) living in the community with full capacity to provide informed consent, presenting with identified focal or multi-focal spasticity of one limb (in upper or lower limb) present for at least three months. In addition a treatment plan with BT was identified and consented for people with a spasticity score of MAS 2-3 in flexor muscles of the forearm and elbow of the upper limb or gastro-soleus muscles of the lower limb.

### **Exclusion criteria**

Those who were unable to co-operate in a rehabilitation programme (co-morbidity of dementia or mental health disorder), fixed joint contracture, pregnancy, inflammatory arthritic condition, fracture and neuromuscular diseases did not meet the criteria.

Ethical considerations included the selection and recruitment of participants from an inclusive perspective; access to information for those with aphasia; from different ethnic and cultural backgrounds.

Participants who met the above eligibility criteria were invited to be recruited for the feasibility study. Participants recruited and randomized by concealed allocation to the intervention group were automatically eligible for the qualitative topic guided interviews. The participants recruited and randomized to the control group had not experienced the intervention and so they were not interviewed for intervention acceptability. The clinicians who provided the DEFO intervention assessment and fitting and delivery of the physiotherapy interventions were also interviewed.



## **Recruitment**

Prospective potentially eligible participants were invited to participate in the study and provided with the Participant Information Sheet (PIS), (**Appendix 4**). All potentially eligible participants were given at least 24 hours for due consideration of the PIS. Alternative forms of information were available (for example large print and digital recording) and provided if needed. A further opportunity was provided to discuss any issues independently prior to consent. If interested in participating in the study they were offered an eligibility assessment. This was to provide the opportunity to discuss any research issues, informed consent and recruitment based on the eligibility criteria. Clear participant information for the potential participants to make a fully informed decision was deemed essential to ensure realistic expectations in study participation.

## **Consent**

The consent format was outlined in a two part process (**Appendix 5**). The first part of the consent form was for the main study and was completed by the participant and signed by the principal researcher. The second part was optional but was for the participant's consent to a follow-up semi-structured interview whether they participated in the study, or decided to withdraw from the study intervention. This was also completed by the participant and signed by the principal researcher. Participants were recruited with full capacity following informed consent. Participants were also able to revoke consent at any time without affecting their usual care. Copies of the signed consent forms were sent to the participant and their GP.

### **4.4 Intervention and comparator groups**

The feasibility RCT was designed with a research intervention protocol (**Appendix 6**). The intervention protocol and pathway (**Figure 4.2**) was developed by the principal researcher and informed by discussion with DM Orthotics Ltd<sup>®</sup> clinicians and Neuro-physiotherapists.

## Intervention group

After BT the intervention group participants were assessed and provided with an individually customised DEFO. Once fitted this was worn up to eight hours/day following a wearing protocol (**Appendix 9**). The wearing time protocol for the orthoses was followed to clarify implementation of the intervention and was guided by the seven day protocol for wearing dynamic Lycra<sup>®</sup> garments (Matthews, 2008).

A 'cricket sensor' was suggested by the company to be inserted into the orthoses for confirmation of wearing times. This comprised a digital pressure sensor that could be sewn into the orthosis to record pressure when worn and data transferred to an electronic database (Rahman *et al.*, 2010). It was made clear to the participants that the wearing protocol (**Appendix 9**) was flexible to their individual needs but any variance must be recorded. The participants were given an information leaflet detailing (DEFO) washing instructions and cautionary advice on when to remove it. The participants were also provided with contact numbers for the physiotherapy clinician and the research secretary.

The rationale for the chosen time of wearing the DEFO intervention was based on the potential for efficacy within a twelve week window following BT. The window of treatment opportunity was identified between two-eight weeks. This was based on the optimal weakening of the injected muscle. Optimal impact of BT is from approximately two weeks when therapy and splinting is considered to be of most benefit. The protocol was planned for the assessment for the provision of the orthoses within two weeks after the BT injection. The subsequent six weeks intervention was considered appropriate to measure the specific impact of the added DEFO intervention as the independent variable with a planned further six week follow up to measure for any carry-over effect after withdrawal of the intervention.

After administration of BT usual care was delivered according to recommended Spasticity Guidelines (RCP *et al.*, 2009) by standard optimal rehabilitation: physiotherapy as required; postural management; passive and active home exercises; splint provision and review. Usual care delivered was recorded by

the physiotherapist in the clinical field notes and interventions record. Standardised physiotherapy (as required) was delivered up to a maximum of 40 minutes contact twice weekly for six weeks with home exercises, usual care and advice. The intervention was withdrawn after six weeks but usual care was continued for a further six weeks following the intervention protocol (**Figure 4.2**). At twelve weeks the participants were reunited with their customised DEFO.

### **Comparator group**

The participants in the control group followed the study protocol for the feasibility RCT. Usual care following BT was delivered according to the recommended Spasticity Guidelines (RCP *et al.*, 2009; Sheean *et al.*, 2010) for standard rehabilitation (as described above). The usual care delivered was recorded by the physiotherapist in the clinical field notes and interventions record. Standardised physiotherapy was delivered (as required) up to a maximum of 40 minutes contact twice weekly for six weeks with home exercises, usual care and advice. A further period of usual care (including physiotherapy as required) was delivered over the next six weeks (**Figure 4.2**).

### **4.5 Outcome measures**

Blinded assessments followed the pilot RCT design; at baseline assessment, six weeks post intervention, and again at twelve weeks. The assessments coincided with the optimal time for the effect of BT to provide the 'window of opportunity' in which the intervention was tested. The measures consisted mainly of pencil and paper tests with only one clinical measure for gait velocity (lower limb participants) that required an appropriate clinical setting. The measures were conducted in community settings (participants home or therapy department in a community hospital). In practice the pen and paper tests were conducted after clinical measures and followed a set order from the researcher's measures folder. The tests took between 30 minutes to 45 minutes to complete with the consequence of minimal participant burden.

Measures for the study were evaluated for reliability and sensitivity to answer the research questions. The following measures were selected based on a clear rationale of specificity and relevance to the predicted likely health benefits (**Chapter 3.3**).

### **Primary measure: The Goal Attainment Scale**

The Goal Attainment Scale (GAS) (**Appendix 7**) was selected as the primary measure for this study (Turner-Stokes, 2009). The construct of this measure is to measure goal attainment and thus all ICF levels depending on the goal. In practice this measure was used to set and measure objectives or 'goals' which were chosen through collaboration between the clinician and the participant or their carer before the intervention commenced. Three or more goals were set for each participant. The goals were weighted by applying a factor of importance  $\times$  the difficulty of achievement:

<b>Importance</b>	<b>Difficulty</b>
1= fairly important	1= probable
2= very important	2= possible
3= extremely important	3= doubtful

Baseline scores were also attributed depending on the functional level of the participant (where -1 represented the current state unless the current state could not be any worse and in this instance the score was attributed -2). Goal attainment was measured over a set time. In this study the set time was at six weeks and again later scored at twelve weeks. The scores were attributed where:

- +2= much better than expected
- +1= somewhat better than expected
- 0= goal achieved as predicted
- 1= no change below the expected level
- 2= worsening below the target level

## **Secondary measures**

### **A measure of pain: Visual Analogue Scale (VAS)**

Pain is subjective therefore the aim of this measure was to compare the individual's perception of pain over time to assess for any change. Pain was scored using the numerically rated ten point scale: Visual Analogue Scale (VAS). This scale used a calibrated horizontal single ruled line of ten centimeters with an indication of zero being 'no pain' and ten representing 'the worst pain ever'. In practice the participant was invited to put a vertical line to cross the horizontal line at the level that most represented their pain today. All participants were assessed using this measure.

### **European Quality of Life-5 Dimensions (EQ-5D)**

This research intended to measure any additional health benefits that were not addressed by the specific outcome tools used for evaluation of rehabilitation in spasticity management. The European Quality of Life-5 Dimensions (EQ-5D) measure (EuroQol Group<sup>®</sup>, 1990) was chosen as a valid and reliable questionnaire in health-related research (**Appendix 10**). It provided a descriptive profile and a value for health status which was easily administered face to face. It was cognitively simple requiring only a few minutes to complete.

It consists of five dimensions: mobility, self-care, usual activities, pain and discomfort, anxiety and depression. The classifier had different levels for the problems (scale 1=no problem 2=some problems, 3=extreme problems and a health status rating tool the EQ VAS. The health state was determined by a five figure code (for example: 11212). The instruction for completing the EQ VAS was to; draw a line from a box to intersect a vertical, visual analogue scale where the endpoints were labelled 'best imaginable health state' and 'worst imaginable health state'. This study was registered with The EuroQol Group<sup>®</sup> and was granted permission for use. This measure was assessed in all participants.

## Upper limb measures

### The Arm Activity measure (ArmA)

The Arm Activity measure (ArmA) was used in the participants with upper limb spasticity in the study (**Appendix 10**). It is a 20 item measure for the upper limb divided into two sections for the combined purpose of measuring arm function and care of the arm (Ashford *et al.*, 2008; RCP *et al.*, 2009; Ashford *et al.*, 2014). Whilst the former section **A** (13 items) was specified for activity, the latter **B** (7 items) were classified as measures of participation. The proforma required the recording of who had completed the form: the participant alone; the carer alone or the participant and carer in combination. The participant was asked to complete all the questions based on their activity over the last seven days whether they were actual or estimated.

For each of the activities listed the participant was asked to indicate if the task was possible or not, either for them, or their carer and to measure the level of difficulty from a scale when:

0= No difficulty

1= Mild difficulty

2= Moderate difficulty

3= Severe difficulty

4= Unable to do activity

Section A was designed to measure caring for the affected arm such as 'cutting finger nails' and Section B on using the affected arm in activities such as 'brush your teeth'. Together the measures provided relevant specific detail on both care and activity levels of the upper limb. This measure was recently reported by Ashford, *et al.*, (2014) to have a low burden for completion for patients and caregivers.

## **Leeds Arm Spasticity Impact Scale (LASIS)**

A measure of care burden was used in the participants with upper limb spasticity in the study (**Appendix 10**). It is the Leeds Arm Spasticity Impact Scale (LASIS). This outcome measure follows a five point Likert scale in which:

0= No difficulty

1= A little difficulty

2= Moderate difficulty

3= A great deal of difficulty

4= Unable to do this activity

To complete the measure the subject was asked to rate eight disability items whilst the caregiver was asked to complete the four carer burden items. A summary of disability score was provided by adding together the items scored by the patient and dividing them by the number of items answered (0= no disability, 4= maximum disability). Similarly this method was used to summarize the carer burden score (0= no carer burden, 4=maximum carer burden). In practice it was recorded whether the participant was living alone, in receipt of a package of care or lived with a partner and/or an additional package of care. This influenced how this measure was administered.

## **Lower limb measure**

### **10 Meter Timed Walk Test**

For ambulant participants, the 10 meter timed walk test (10MTT) (**Appendix 10**) provided a reliable and validated tool for the measure of functional impact of the DEFO intervention on gait velocity (Watson, 2002, Foley *et al.*, 2010).

In practice it was easy to administer with a calibrated ten meter (33 feet) flat surface along a corridor or in a physiotherapy gym. To administer the test a line of tape was placed at either end of the measured ten meters. The participant was instructed to stand approximately three feet behind a taped line. They were asked to walk at a comfortable rate until they passed the end tape by

approximately three feet. This was in order to minimize the effects of acceleration and deceleration. The participant was asked not to talk when performing the test as this can slow performance from dual task interference. The measure of elapsed time was recorded in seconds and the number of steps taken over the ten meters. This measure was repeated three times and an average time taken. Velocity was calculated by dividing the average time by the ten meters and multiplying by sixty. This provided a measured speed of meters per minute which was compared to a healthy population reference table shown below, (**Table 4.1**).

**Table 4.1 Normal healthy gait velocity (comfortable m/min) (Watson, 2002)**

<b>Gender/Decade</b>	<b>Men</b>	<b>Women</b>
20s	83.6	84.4
30s	87.5	84.9
40s	88.1	83.5
50s	83.6	83.7
60s	81.5	77.8
70s	79.8	76.3

### **Measures of intervention fidelity**

Further measures of fidelity in the protocol delivery were recorded by the participants and the clinicians. For the participants this included a DEFO wearing record (intervention group participants only) and an 'Activity Log' for all participants (**Appendix 13**) to record participation activities during the six weeks intervention period. This provided a diary record of activity and participation levels variance for analysis of impact by the intervention. The physiotherapy clinicians were tasked with completing a physiotherapy intervention data capture (**Appendix 8**).

### **DEFO Intervention: Record of wearing**

The participants in the intervention group were asked to complete a DEFO wearing record whilst following the six weeks intervention phase of the protocol. The DEFO wearing record is shown below, (in **Table 4.2**).



**Table 4.2 DEFO: Record of wearing\***

<b>Week</b>	<b>Day 1</b>	<b>Day 2</b>	<b>Day 3</b>	<b>Day 4</b>	<b>Day 5</b>	<b>Day 6</b>	<b>Day 7</b>
<b>1</b>	1 hour	2 hours	4 hours	8 hours	8 hours	8 hours	8 hours
<b>2</b>							
<b>3</b>							
<b>4</b>							
<b>5</b>							
<b>6</b>							
<b>Total Hours</b>							

\*Additional comments also recorded

The Activity Log (**Appendix 13**) was a useful measure of functional performance and provided details on participant activity level throughout the study. Further measures for testing fidelity were used such as the DEFO wearing record (**Appendix 9**) and the Physiotherapy Intervention Data Capture Sheet (**Appendix 8**). Clinical records were made available for the purpose of corroborating fidelity.

#### **4.6 Randomization, concealment of allocation, and blinding**

The quantitative research design was planned as a pilot RCT. In this design there were three components delivered; randomization, concealment and allocation. The recruited participants were randomized into two groups. This was done by the following method.

The research administrative support worker (the randomizer) had 30 opaque sealed envelopes containing 15 (**intervention**) and 15 (**control**) cards. These envelopes were shuffled by a person independent to the study before recruitment. The envelopes were stored in a secure cabinet only accessible to the research administrative support worker. As each participant was recruited they were randomly allocated by the randomizer to either group as each envelope was opened in random sequence from the pile. Once recruited the participants were informed which group they were allocated to and a record of their randomization was coded and entered on a password protected database.

The participants were reminded of the importance of not discussing their allocation group with the principal researcher to maintain blinding. The treating physiotherapist and DM Orthotics Ltd<sup>®</sup> clinician were informed (by referral) of the participant's allocation. This concealed and encoded participant data was made available to the principal researcher at the end of the interventions phase in the study for evaluation. The concealed allocation of participants was anonymised to the principal researcher but in this kind of study it is not possible to blind the participants or the clinicians.

The research participants were clearly identified on their notes of their research participation in the study but not of their respective allocation. This was with a participant code sticker (provided by R&D) and placed on the front of the patient's record sheet. All assessment and outcome sheets had the participant codes for identification and this data was entered in coded format onto an electronic database. The research secretary was responsible for maintaining the password protected encoded database of allocation which was collated separately from the outcomes database.

On completion of the quantitative intervention phase of the study (after twelve weeks) and outcome data entered on the excel spread-sheet there was a sequential reveal of the participant's allocation to the principal researcher. The **intervention group** participants were followed up by the principal researcher with face to face topic guided interviews. The interviews were conducted either in the person's own home or in a community hospital setting. A paper topic guided script was used (**Appendix 11**) with the topics outlined and a digital voice recorder (Olympus DM-650) to tape the interview. The environment was prepared to minimise interruption, ensure the participant was comfortable and remind them of the purpose of the interview. Then the recorder was turned on and used for as long as the interview lasted. At the end of the interview the participant was asked if there were any further comments they wished to add and if so this was also recorded. Following the interview, the details were transcribed to an electronic encoded database for qualitative analysis.

On completion of the feasibility RCT, at twelve weeks, the participants in the **control group** were revealed to the principal researcher. They were not interviewed but additional data from the Activity log and clinical records was collated. The comparator (control) group provided a constant in standard practice. Although standard practice was seen as an appropriate practice for control, data was captured to account for variance in both groups. Participants were formally thanked and informed they had completed their part in the study and would receive a report on the study findings.

#### **4.7 Sample size and statistical methods**

The study design followed the guidance provided in the Medical Research Methodology publication by Thabane *et al.*, (2010) which suggested a pilot study can be used to assess feasibility to guide a larger study rather than merely inform sample-size calculation. Hence this feasibility pilot study was used to: inform the estimation of recruitment rates, retention rates, refusal rates, adherence rates and appropriateness of the eligibility criteria. It therefore aimed to assess the recruitment potential from an annual spasticity clinic of 180 patients; often with repeated BT. An estimated sample size of 30 participants from the clinic were considered likely to meet the eligibility criteria and consent for the feasibility study. Recruitment was planned to run over a period of twelve months with feasibility 'stopping rule' in the event of less than ten patients recruited in eight months. Similarly protocol modification was considered if feasibility was threatened. Alternately if recruitment had slowed down significantly with saturation of potential recruits, recruitment was planned to cease. This stopping rule was based on capacity in the recruitment procedure and considered as a pragmatic approach for delivering a small scale feasibility study within a specific timeframe.

The mixed methods data analysis (**Chapter 3.7**) was conducted in parallel then through integration of the two methods. Descriptive data captured was analysed for difference of demographics and standard deviation of age by group.

The pilot RCT provided three data sets from the chosen outcome measures for repeated measures analysis. The primary measure of the GAS T score was

analysed by Statistical Package for Social Sciences (SPSS) (IBMv19) analysis of co-variance (ANCOVA) using difference between-groups effects with adjusted baseline means to determine a change score analysis at six weeks and twelve weeks with a summary of significance on the effects. The GAS, EQ-5D and the VAS for pain were measures used for all of the participants. The GAS data set was used to provide an estimated effect-size for a larger study. The remaining measures (ArmA, LASIS, 10MTT) were dependent upon upper and lower limb spasticity presentation and conducted accordingly. The upper limb measures provided data sets that were analysed using the same method (ANCOVA between-groups effects). Both the ArmA and the LASIS consisted of 'active' and 'passive' components that required separate analysis due to difference in construct validity. The lower limb measure (10MTT) was analysed descriptively for gait velocity due to likely small numbers.

The GAS T score was calculated by applying the Kiresuk and Sherman formula (1968) cited in Turner-Stokes (2009, p.3), (in **Table 4.3**) to the aggregated scores for each goal using an Excel data spread-sheet:

**Table 4.3 GAS T formula, (Kiresuk and Sherman, 1968)**

<p>Overall GAS = <math>50 + \frac{10 \sum(w_i x_i)}{[(1-p) \sum w_i^2 + p(\sum(w_i)^2)]^{1/2}}</math></p> <p>Where:</p> <p><math>w_i</math> = the weight assigned to the <math>i</math>th goal (if equal weights, <math>w_i = 1</math>)</p> <p><math>x_i</math> = the numerical value achieved (between -2 and + 2)</p> <p><math>p</math> = the expected correlation of the goal scales</p> <p>For practical purposes, according to Kirusek and Sherman (Turner Stokes, 2009 p. 3), <math>p</math> most commonly approximates to 0.3, so the equation simplifies to:</p> <p>Overall GAS = <math>50 + \frac{10 \sum(w_i x_i)}{\sqrt{(0.7 \sum w_i^2 + 0.3(\sum w_i)^2)}</math></p>
---

This calculated GAS T score formula provided interval-level data with a normal distribution around a mean of 50 and standard deviation of ten. This means a change in GAS T score of  $\geq 10$  is needed to provide a measure of achievement of the combined goals set. This formula was based on the findings of Kirusek and Sherman (1968). A predictive value of  $\geq 10$  GAS T score was used for sensitivity of change in measurement of clinical efficacy (Ashford and Turner-Stokes, 2006; Turner-Stokes *et al.*, 2010b). Demonstration of a mean T score around 50 was used to provide feedback relating to the accuracy of the goal setting.

Additional data including the DEFO wearing results, physiotherapy data and Activity log was analysed for variance by group comparison. Additional data from clinical records and the DMO clinician was analysed for fidelity.

Thematic Analysis (**Chapter 3.7**) of the interview data (participant and clinician) followed a Framework analytic approach (Ritchie and Lewis, 2003) using a coding system that links to the original data sets (exampled in **Appendix 16**) and the findings are thematically represented by Thematic networks (in **Chapter 6**).

#### **4.8 Data management**

The data from both design components was collated in two databases, one that was encrypted (secure from the blinded research assessor) with data from the randomization and a second that only had the encoded databases for the research assessors data entry of the participants outcome measures. The research secretary managed the data entry in the former and the blinded research assessor managed the data entry in the latter. All demographic details and a timeline of appointments for the research protocol were managed on the securely encrypted database by the research secretary.

Following assessments data was entered onto the spread-sheet on a weekly basis or according to recruitment needs. This was to ensure the data was entered in a timely fashion. Data was double entered by the research secretary

for the pilot RCT data sets to optimise consistency reliability according to good research practice.

The participant's group allocation was revealed to the principal researcher on completion of the data entry in this database. This was to enable follow-up topic guided interviews to take place for qualitative evaluation. The digitally recorded interview data was transcribed and participant coded. Additional paper data such as the Physiotherapy Intervention Data Capture sheet, Activity Log and DEFO wearing records were also coded and filed in a secure cabinet until the allotted reveal. The Physiotherapy clinical notes were also made available for further analysis of clinical variance and other issues of each participant once the study was completed.

### **Recording withdrawals and adverse events**

Spasticity is prevalent in people with co-morbidities and thus there is a high risk that participants recruited were likely to withdraw for medical reasons. All participants were followed up with permission in the instance of withdrawal from the study or adverse event. This was outlined in part two of the participant consent form (**Appendix 3**). The proposed follow-up of the participant was by interview as outlined on the consent form, unless they were unable to cooperate and medical notes were then reviewed as ethically appropriate. By this method all reasons for withdrawal from adverse events were recorded. A CONSORT flow diagram (in **Figure 5.1**) provides details of recruitment and retention on the study (Boutron *et al.*, 2008; Schulz *et al.*, 2010).

### **4.9 Ethical process**

The study (**12/SC/0518**) was ethically approved from Berkshire-B South Central Research Committee (NRES) in September 2012 and registered with local NHS R&D and Exeter University ethics committee (PREC) in October 2012. Following approval all clinicians involved in the research were informed and the research study commenced in October 2012. Protocol amendments with the

qualitative research component were submitted and approved in July 2013 (**Chapter 8.1.1**).

The research processes followed the 'good clinical practice' (Research Governance Framework for Health and Social Care, 2005). Research ethical considerations were founded on rigor, respect and responsibility and are reflected on at the end of the thesis. All data gathered and stored followed strict NHS Data governance protocols.

Further ethical considerations are discussed in **Chapter 8.1**, including how a Research Reference Group (**Chapter 8.1.3**) was established with the aim for ethical monitoring and to establish research peer support. Essentially the purpose of the group was to keep the research on track with patient and public involvement (INVOLVE, Hanley *et al.*, 2003) and stakeholder engagement.

#### **4.10 Summary**

This chapter outlined the procedural content of process delivery through mixed methodology. The researcher identified critical elements of method for data capture and analysis, together with key ingredients and important relationships in the research process.

The pilot and developmental work covered practical and technical issues. These are explored in **Research Reflections** (p. 256) with rationale for research decisions. The overarching study protocol was clearly defined with descriptive pathways based on the rationale for delivery of each phase in the research design of mixed methods. It is explained how the measures were used in the assessments at baseline, following the DEFO intervention and after withdrawal. The procedural delivery describes the method of recruitment, retention and recording attrition. In addition procedural issues of data capture and analysis are described. Monitoring the research process delivery was not underestimated. This was supported by a Research Reference Group of key stakeholders.

This section provided transparent accounts of delivery stage by stage including pathways, roles and responsibilities. The method presented provides a detailed description of the investigation of the feasibility, potential efficacy and acceptability of the DEFO as a new treatment following BT. As an exploratory feasibility study its purpose was to test the research design and method used as a developmental phase in the research process; with potential for this study to inform further research based on the findings. Results of the two phases are presented in **Chapters 5** and **6** with the findings integrated in **Chapter 7**.



## Chapter 5

### Results I (Quantitative)

#### Key points:

- **Results overview- how data is presented and why?**
- **CONSORT (flow summary of recruitment/retention/attrition and completion of study)**
- **Baseline characteristics of participants**
- **Quantitative data: tables of results (primary measure, secondary measures)**
- **Fidelity, adherence and variance data: DEFO Wearing Log; Activity Log; Physiotherapy Interventions Data Capture; Clinical data**

#### 5.1 Overview of data presented

This is the first of two **Chapters (5 and 6)** to present results. It sets out the baseline categorical data and quantitative pilot RCT data gathered. This **Chapter (5)** includes how and why it was presented in the chosen format. The qualitative data is presented in the next **Chapter (6)**. This data was collated sequentially but was analysed in parallel to the quantitative results with both results integrated and interpreted in the discussion, (in **Chapter 7**).

Data presented in this chapter includes: baseline characteristics of the participants; summary of flow participant recruitment and attrition; quantitative data from the (pilot RCT) primary and secondary measures; fidelity; adherence and variance data.

#### 5.2 Baseline characteristics of participants

Twenty-five participants were recruited to the study with an overall age range of 29-78 years (median age of 56 years) with a mean age of 56.28 years. The age range of the intervention group was from 29-69 years (median age of 47 years) and a mean age of 50.5 years. The age range of the control group was from 30-78 years (median age of 61 years) and a mean age of 61.6 years. There were

twelve female participants and thirteen male participants. Following randomization the two groups were found to be evenly distributed with twelve participants in intervention group and thirteen in the control group. In the intervention group there were six (50%) male and six (50%) female participants, in the control group seven (53.8%) male and six (46.2%) female participants. Eighteen participants presented with diagnosis of Stroke (>3/12), three had suffered Traumatic Brain Injury (>2 years), and one participant was diagnosed with Multiple Sclerosis, one participant had a Spinal Cord Injury, one reported an Acquired Brain Injury and one with brain haemorrhage associated with Brain Tumour. All participants presented with spasticity in one or more limbs with planned management according to the study protocol; with BT and standard care. Twenty-two participants presented with upper limb spasticity for treatment with BT intramuscular injection of the forearm flexors and biceps. Three of the participants recruited had lower limb spasticity with planned treatment for BT intramuscular injection of the calf muscles.

All participants lived in the community and of those nine lived alone, with one person fully independent (one in control group) and the other eight in receipt of varying packages of care (four in control group, four intervention group). The remaining sixteen participants lived with partners (eight in control group, eight in intervention group) who provided informal care and support. Of these participants a further fourteen (seven in control group, seven in intervention group) had additional packages of care with the remaining two participants (one in control group, one in intervention group) in receipt of informal care.

Four of the participants recruited had speech difficulties following stroke with varying levels of expressive aphasia (two in control group, two in intervention group). All had capacity (Mental Capacity Act, 2005). A summary of the baseline characteristics of the participants is presented, in (**Table 5.1**).

**Table 5.1 Baseline characteristics of participants**

Characteristic	Intervention group n=12	Control group n=13	Total n=25
<b>Sex</b>			
Male	n=6	n=7	n=13
Female	n=6	n=6	n=12
<b>Age (years)</b>			
Mean (SD)	50.5 (12.60)	61.6 (14.46)	56 (14.47)
Median	47	61	65
Range	29-69	30-78	29-78 (49)
<b>Ethnic origin</b>			
White British	n=12	n=13	n=25
Other	n=0	n=0	n=0
<b>Diagnostic group</b>			
Stroke	n=8	n=10	n=18
TBI	n=2	n=1	n=2
ABI	n=0	n=1	n=1
Brain Tumour	n=1	n=0	n=1
Multiple Sclerosis	n=1	n=0	n=1
Spinal Cord Injury	n=1	n=0	n=1
<b>Affected limb</b>			
Upper limb	n=9	n=13	n=22
Lower limb	n=3	n=0	n=3
<b>Communication</b>			
Aphasia	n=2	n=2	n=4
Verbal	n=10	n=11	n=21
<b>Care support</b>			
Living alone	n=4	n=5	n=9
Married/cohabiting	n=8	n=8	n=16
Package of care	n=7	n=7	n=14

**Key:** SD=Standard Deviation, TBI=Traumatic Brain Injury, ABI= Acquired Brain Injury

### 5.3 Recruitment and attrition pathway

A CONSORT (Boutron *et al.*, 2008; Schulz *et al.*, 2010) flow diagram (**Figure 5.1**) was used to provide a summary of the participant recruitment, concealed allocation and randomization and attrition pathway. This was in order to display the number of potential participants recruited to the study, those eligible and providing consent and the rate and rationale for attrition.

## **Recruitment**

Sixty-two potential participants attending the spasticity clinic were invited to the study. Of those invited, 37 were excluded: 30 potential participants declined; six were not eligible based on the assessment criteria and one person was recruited to another study and unable to commit to the study protocol. The remaining 25 eligible participants consented to participate in the study and were recruited. Over twelve months, this was at an initial rate of more than three per month, falling to a regular rate of two per month and in the last two months (eleven and twelve) of the study there was none. This was due to saturation of recruits from the Spasticity clinic.

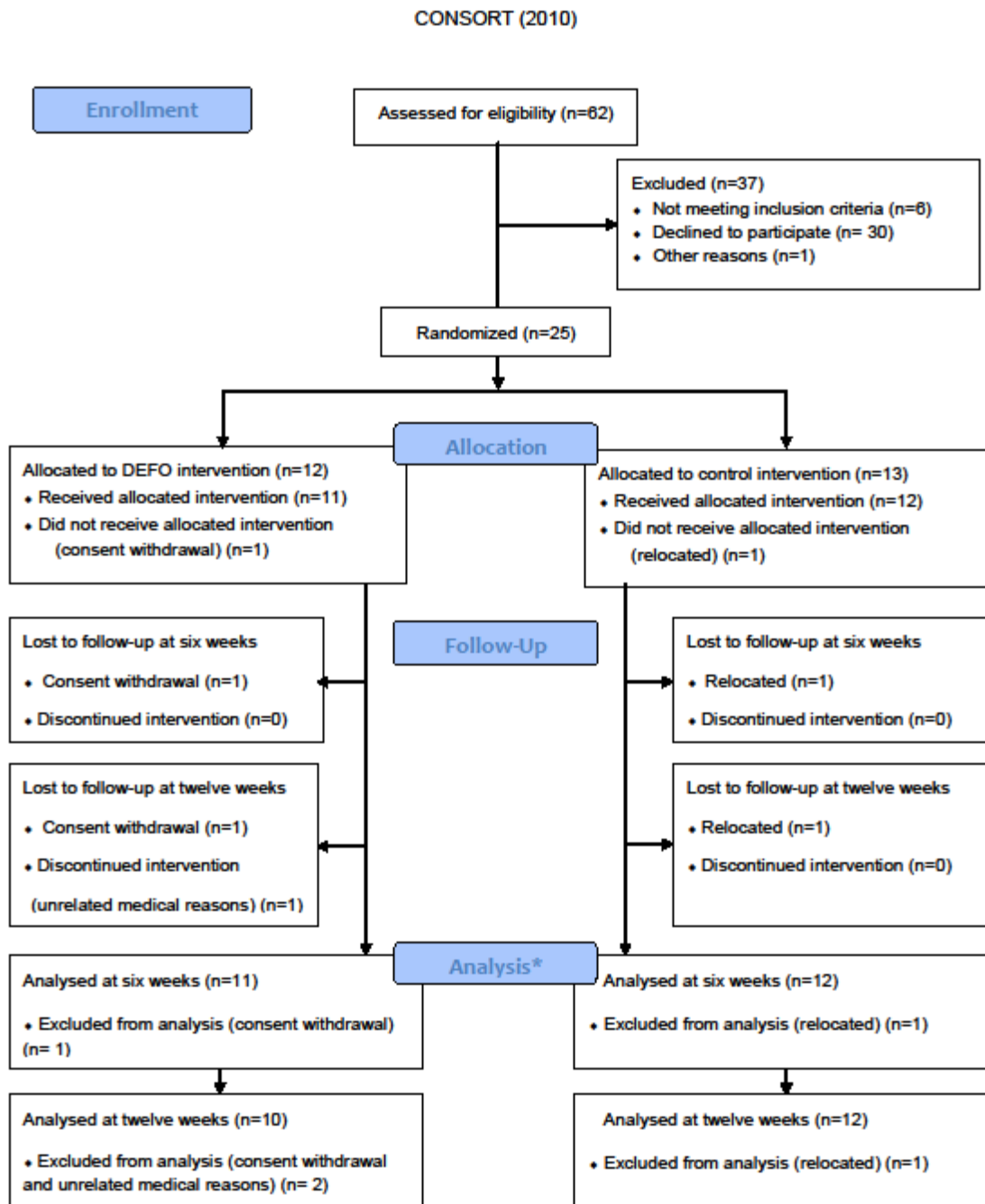
## **Delivery and receipt of the intervention**

Following concealed randomization and allocation of the 25 participants recruited who met the eligibility criteria: Twelve participants were in the DEFO intervention group; and thirteen in the control group. Of those in the intervention group; eleven received delivery of the DEFO intervention and one participant withdrew consent and consequently did not receive the intervention.

## **Attrition**

The rate of attrition was recorded including the rationale and reason for loss to the study accounted for. In the intervention group one participant dropped out of the study due to delays in recruitment following a missed appointment from ill-health, then decision to withdraw consent. In the control group one participant failed to attend a number of appointments and was lost to the study with no forwarding contact. In the intervention group one further participant did not fully complete the intervention due to unrelated medical reasons and was lost to the study. All randomized patients **n=25** had their 'observed' data analysed even if they did not receive the intervention. This was for 'intention to treat' analysis. The total number to complete the study was **n=22**.

Figure 5.1 CONSORT flow diagram (Schulz *et al.*, 2010)



\* Intention to treat (ITT) analysis (n=25) of all observed data.

## 5.4 Quantitative pilot RCT data

Data handling and statistics is now presented. Data were transferred to the Statistical Package for Social Sciences (IBM SPSS, Version19).

An adjusted mean baseline was conducted on all of the participants. The results of the measures conducted on all the participants (**n=25**) are presented first. This includes the primary measure the GAS, followed by the VAS for pain and EQ-5D. Next the upper limb measures are presented for those participants with upper limb spasticity (**n=22**). Of those there were (**n=9**) in the intervention group and (**n=13**) in the control group. Lastly the three participants with lower limb spasticity were all in the intervention group. Data was presented accordingly. Any missing data was accounted for and reported within the results.

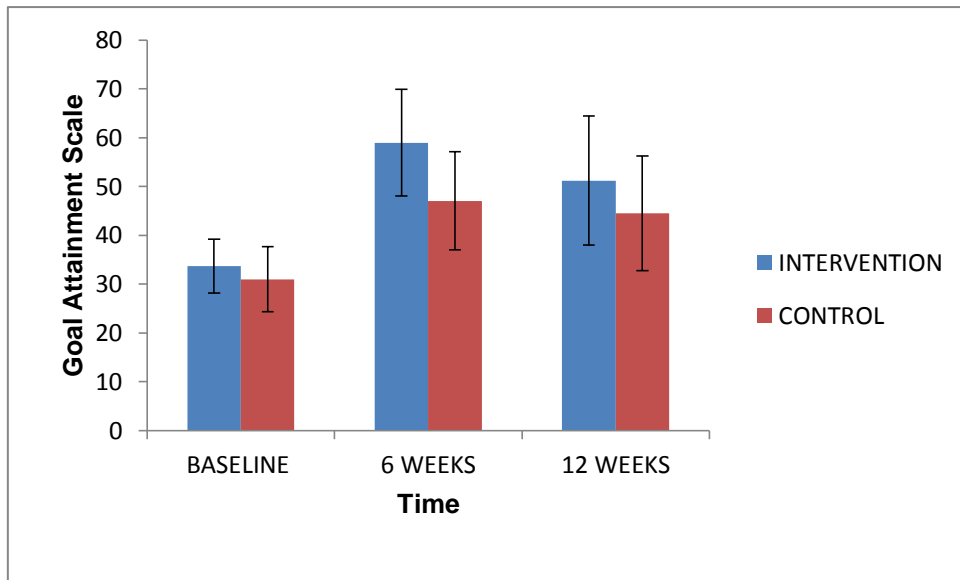
### 5.4.1 Primary Measure

The Goal Attainment Scale (GAS) T score was used as the primary measure in the pilot RCT to assess the health benefit of the DEFO intervention in the intervention group in comparison with the control group. Justification for using the GAS T score is based on the assumption of its sensitivity as a measure of patient centred meaningful outcome following BT (Turner-Stokes *et al.*, 2010b). It was also considered representative as a measure of clinical outcome for all of the participants when compared to specific limb measures. The GAS T score was measured in all participants by a baseline adjusted ANCOVA for between groups over time (at six weeks and twelve weeks).

#### Goal Attainment Scaling (GAS)

The primary outcome measure GAS T score statistics by group over time is presented in **Figure 5.2**. The predictive value of the GAS T score for a positive overall clinical outcome was set at a change  $\geq 10$ . The mean GAS for a study population around 50 is a useful quality check of GAS scoring. This is because if a clinician attempts to inflate results by scoring overcautiously the mean score is  $>50$ , whereas if they are overly ambitious the score will be  $<50$ .

**Figure 5.2 Chart of GAS T score by group over time (SD)**



SD= standard deviation

The data from the GAS T score at the six weeks primary measure presents a statistically significant difference in the score. This is presented in the chart above, (**Figure 5.2**) with a GAS T score by group over time with standard deviations shown.

**Table 5.2 ANCOVA for the change (from the baseline) in GAS T score between intervention and control at six and twelve weeks**

<b>GAS T</b>	<b>Intervention Mean(SD) N</b>	<b>Control Mean(SD) N</b>	<b>Adjusted mean difference between intervention and control* N=24</b>	<b>95% Confidence Interval</b>	<b>p-value</b>	<b>Effect size (95%CI) (standardised)</b>
<b>Baseline</b>	33.69 (5.53) <b>N= 12</b>	30.98(6.69) <b>N=13</b>				
<b>6 weeks</b>	58.92(10.93) <b>N=11</b>	47.05(10.08) <b>N=12</b>	12.17	3.16 to 21.18	0.014	1.21(0.3 to 2.1)
<b>12 weeks</b>	51.21(13.21) <b>N=10</b>	44.49(11.77) <b>N=12</b>	6.14	-4.6 to 16.97	0.28	0.52(-0.4 to 1.4)

SD= standard deviation; N=number of participants; CI=confidence interval

\*Based on 12 patients per group, i.e., 24 patients in total

As can be seen from **Table 5.2** there was a statistically significant improvement in GAS T score for the intervention group when compared to the control. The change from baseline was 12.17 units of GAS (or 1.21 standard deviations) higher in the intervention than that of the control group (95%CI: 3.16 to 21.18; p=0.014). This difference equates to a standardised effect-size of 1.21 (95% confidence interval 0.31–2.10). This effect-size of the DEFO intervention demonstrates an important clinical effect, however with a small study the large effect-size should be interpreted with caution.



It can be argued that the effect-size can be directly attributed to the DEFO intervention as the goals set were correlated with the previously identified likely health benefits associated with the DEFO (in **Chapter 3.3**). In addition the effect-size of 1.21 is likely to be representative of the intervention due to the principle of randomized control. The results are indicative that the treatment was clinically significant at the six weeks of intervention delivery, but there was no worthwhile longitudinal effect after the intervention was withdrawn after the six weeks. How meaningful this measure was as an outcome in this study is discussed in **Chapter 8.5**.

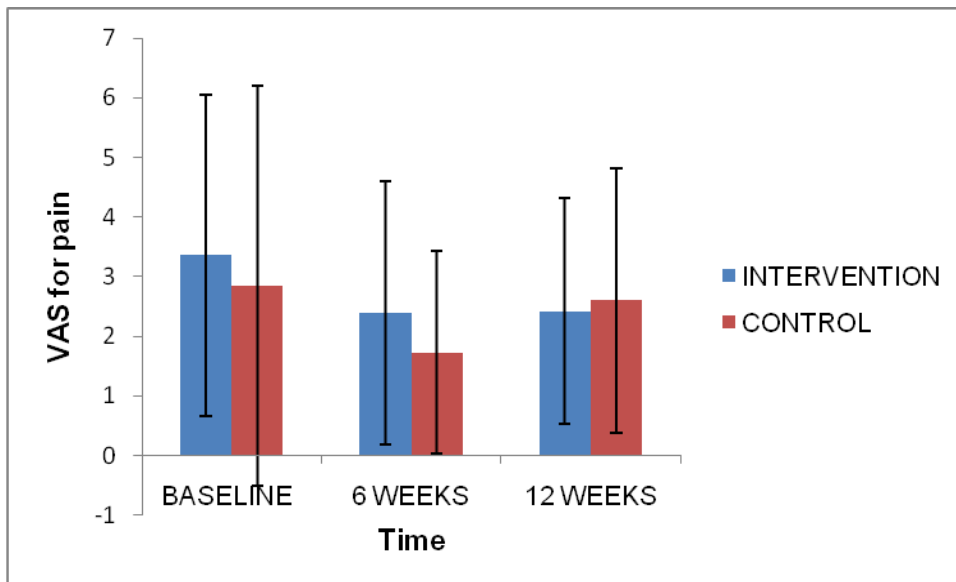
#### **5.4.2 Secondary Measures**

Additional measures were used to assess the outcomes of the DEFO intervention in the pilot RCT by comparison of the between groups. Both the VAS for pain and the EQ-5D was measured in all participants.

##### **VAS score**

The VAS score was measured in all participants by a baseline adjusted ANCOVA for between groups over time (at six weeks and twelve weeks). As is shown in **Table 5.3** there was no significant change from the baseline between the intervention and the control group at any time point. In addition the large standard deviation is presented in **Figure 5.3**. Both groups showed a reduction in pain scores at six weeks but the score change was small.

**Figure 5.3 Chart VAS by group over time (SD)**



SD= standard deviation

**Table 5.3 ANCOVA for the change (from the baseline) in VAS between intervention and control at six and twelve weeks**

<b>VAS</b>	<b>Intervention Mean(SD) N</b>	<b>Control Mean(SD) N</b>	<b>Adjusted mean difference between intervention and control* N=24</b>	<b>95% Confidence Interval</b>	<b>p-value</b>	<b>Effect size (95%CI) (standardised)</b>
<b>Baseline</b>	3.30(2.69) <b>N= 12</b>	2.85(3.36) <b>N=13</b>				
<b>6 weeks</b>	2.40(2.21) <b>N=11</b>	1.73(1.70) <b>N=12</b>	0.48	-0.66 to 1.63	0.41	1.21(0.3 to 2.1)
<b>12 weeks</b>	2.42(1.90) <b>N=10</b>	2.60(2.22) <b>N=12</b>	-0.32	-2.05 to 1.40	0.72	0.52(-0.9 to 0.6)

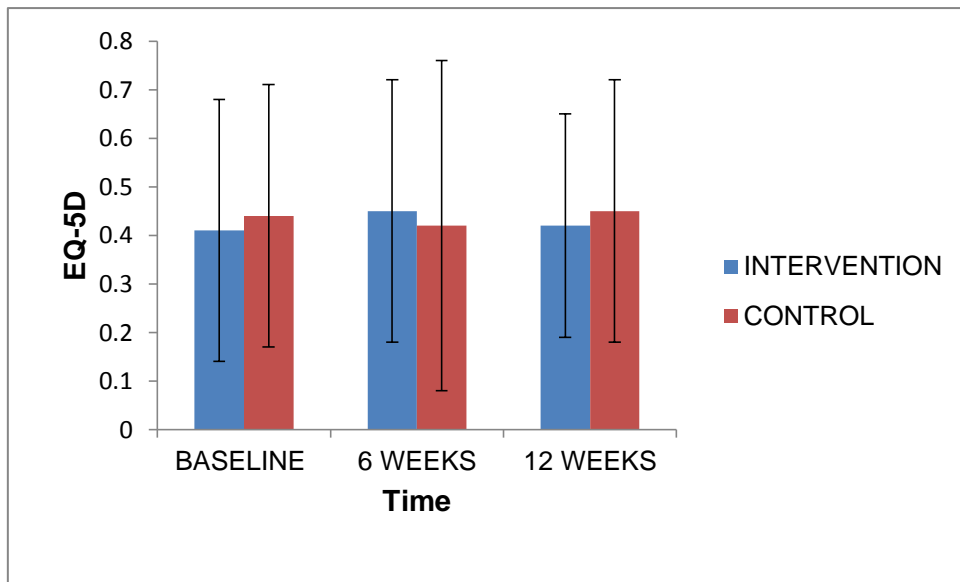
SD= standard deviation; N=number of participants; CI=confidence interval

\*Based on 12 patients per group, i.e., 24 patients in total.

## EQ-5D

The EQ-5D was measured in all participants by a baseline adjusted ANCOVA for between groups over time (at six weeks and twelve weeks). The summary of statistics of the EQ-5D by group over time is presented, in **Figure 5.4**. As is shown in **Table 5.4** there was no significant group differences from the baseline between the intervention and the control group at any time point. This is shown in the chart below, (**Figure 5.4**) illustrating the large standard deviations.

**Figure 5.4 Chart of EQ-5D summary statistics by group over time (SD)**



SD= standard deviation

**Table 5.4. ANCOVA for the change (from the baseline) in EQ-5D between intervention and control at six and twelve weeks.**

EQ-5D	Intervention Mean(SD) N	Control Mean(SD) N	Adjusted mean difference between intervention and control* N=24	95% Confidence Interval	p-value	Effect size (95%CI) (standardised)
<b>Baseline</b>	0.41(0.27) <b>N= 12</b>	0.44(0.27) <b>N=13</b>				
<b>6 weeks</b>	0.45(0.27) <b>N=11</b>	0.42(0.34) <b>N=12</b>	0.03	-0.22 to 0.28	0.79	0.08(-0.65 to 0.82)
<b>12 weeks</b>	0.42(0.23) <b>N=10</b>	0.45(0.27) <b>N=12</b>	-0.04	-0.24 to 0.16	0.73	0.15(-0.8 to 0.6)

SD= standard deviation; N=number of participants; CI=confidence interval

\*Based on 12 patients per group, i.e., 24 patients in total.

## Results for upper limb measures

The following results are presented for the participants recruited and randomised with upper limb spasticity using the appropriate outcome measures the ArmA and the LASIS. Both are reported to measure 'active' and 'passive' functional components.

### ArmA

The ArmA was measured in all upper limb participants by a baseline adjusted ANCOVA for between groups over time (at six weeks and twelve weeks). The following results for the ArmA are presented with the 'active' components score followed by the 'passive' (care) function components score. This is due to the difference in construct in each component for the purpose of analysis.

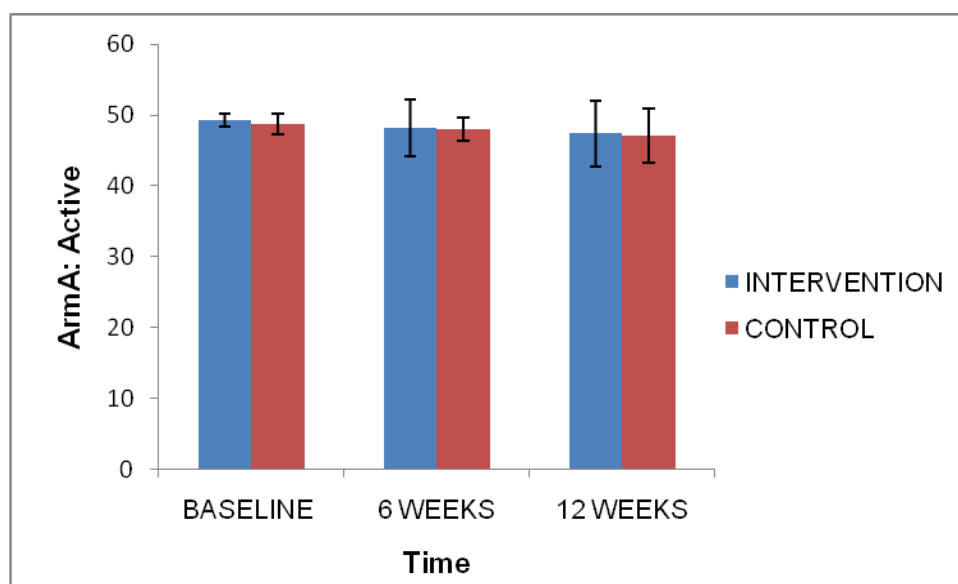
### ArmA (Active)

**Table 5.5 Summary statistics for ArmA (Active) by group over time**

Group	Baseline	6 weeks	12 weeks
<b>Intervention</b> Mean(SD) N	49.33 (0.87) 9	48.22(3.99) 9	47.38(4.63) 8
<b>Control</b> Mean(SD) N	48.69(1.44) 13	48.08(1.62) 12	47.08(3.89) 12

SD= standard deviation; N=number of participants

**Figure 5.5 Chart for ArmA (Active) by group over time (SD)**



**Table 5.6 ANCOVA for the change (from the baseline) in ArmA (Active) between intervention and control at six and twelve weeks**

Outcome	Adjusted mean difference between intervention and control	95% Confidence Interval	p-value	Effect size (standardised)
<u>ArmA-Active</u> n=22				
6 weeks	-0.46	-2.88 to 1.96	0.71	0.28 (-1.8 to 1.2)
12 weeks	-0.39	-4.08 to 3.29	0.83	0.10 (-1.0 to 0.8)

The summary of statistics for the ArmA (Active) by group over time is in **Table 5.5**. As is shown in the table above, (**Table 5.6**) there was no significant difference from the baseline between the intervention and the control group at any time point. There was a small change in both groups with reduced scores over time. As is shown in the figure above, (**Figure 5.5**) both the intervention and control groups demonstrated a small decrease in score over time (from the baseline).

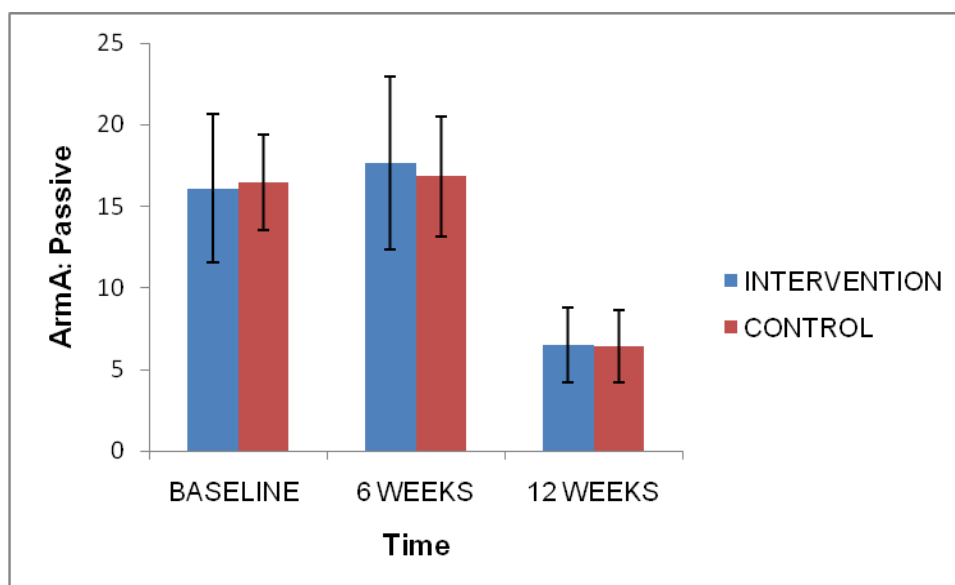
### **ArmA Passive**

**Table 5.7 Summary statistics for ArmA (Passive) by group over time**

Group	Baseline	6 weeks	12 weeks
<b>Intervention</b>			
Mean(SD)	16.11 (4.54)	17.67(5.31)	6.5(2.32)
N	9	9	8
<b>Control</b>			
Mean(SD)	16.46(2.93)	16.83(3.66)	6.42(2.19)
N	13	12	12

SD= standard deviation; N=number of participants

**Figure 5.6 Chart for ArmA (Passive) by group over time (SD)**



SD= standard deviation

**Table 5.8 ANCOVA for the change (from the baseline) in ArmA - Passive between intervention and control at six and twelve weeks**

Outcome	Adjusted mean difference between intervention and control	95% Confidence Interval	p-value	Effect size (standardised)
ArmA- Passive n=21				
6 weeks	1.53	-1.35 to 4.41	0.31	0.42 (-0.4 to 1.2)
12 weeks	-0.89	-2.56 to 0.78	0.30	0.41 (-1.2 to 0.4)

The summary of statistics for the ArmA (Passive) by group over time is in **Table 5.7**. As is shown in the table above, (**Table 5.8**) there was no significant change between the intervention and the control group at any time point as both groups provided an increased score at six weeks followed by a decreased score at twelve weeks. Both groups provided a change score (decrease) in the ArmA (Passive) between baseline and each time point as shown in the chart above, (**Figure 5.6**). There was a drop in for the ArmA (Passive) score for both groups which increased over time.



## LASIS

The LASIS was measured in all upper limb participants by a baseline adjusted ANCOVA for between groups over time (at six weeks and twelve weeks). The following results are presented for the LASIS for the participants and also for the carers. This is due to the separate constructs for analysis.

### LASIS (Participant)

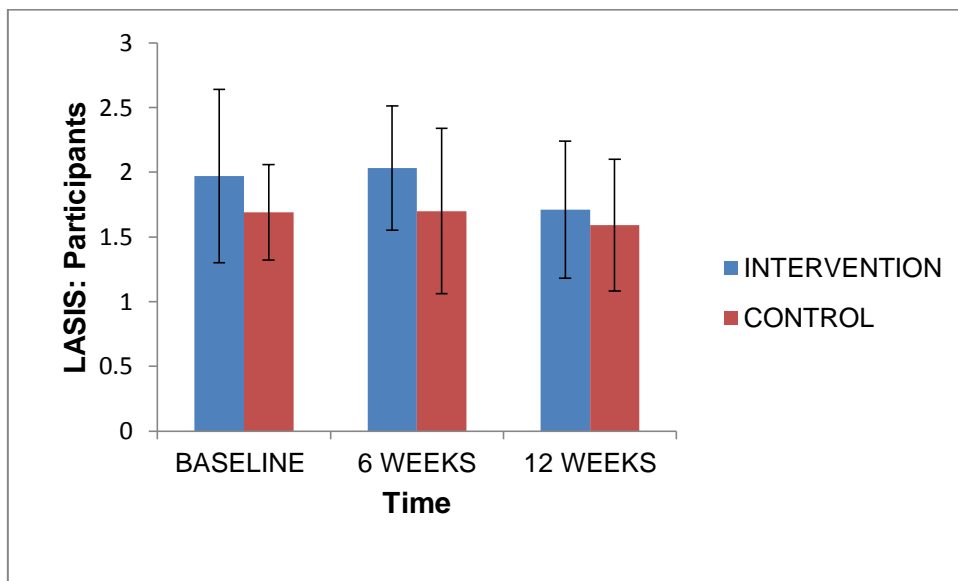
**Table 5.9 Summary statistics for the LASIS (Participant) by group over time**

Group	Baseline	6 weeks	12 weeks
<b>Intervention</b>			
Mean(SD)	1.97 (0.67)	2.03(0.48)	1.71(0.53)
N	9	8	7
<b>Control</b>			
Mean(SD)	1.69(0.37)	1.70(0.64)	1.59(0.51)
N	13	12	12

SD= standard deviation; N=number of participants

The summary of statistics for the LASIS (Participant) by group over time is in **Table 5.9**.

**Figure 5.7 Chart for LASIS (Participant) score by group over time (SD)**



SD= standard deviation

**Table 5.10 ANCOVA for the change (from the baseline) in LASIS (Participant) between intervention and control at six and twelve weeks**

Outcome	Adjusted mean difference between intervention and control	95% Confidence Interval	p-value	Effect size (standardised)
LASIS (P) n=20				
6 weeks	0.21	-0.26 to 0.68	0.39	0.33 (-0.4 to 1.06)
12 weeks	0.11	-0.34 to 0.57	0.63	0.21 (-0.7 to 1.1)

As is shown in the table above, (**Table 5.10**) there was no significant difference from the baseline between the intervention and the control group at any time point. This can be seen in **Figure 5.7** with added standard deviations.

### LASIS (Carer)

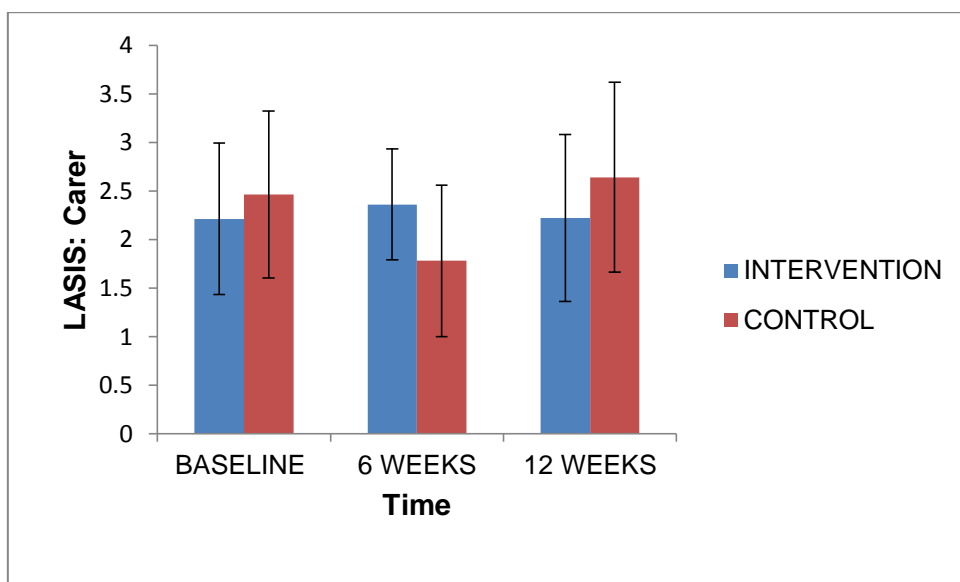
**Table 5.11 Summary statistics for LASIS (Carer) by group over time**

Group	Baseline	6 weeks	12 weeks
<b>Intervention</b>			
Mean(SD)	2.21 (0.78)	2.36(0.57)	2.22(0.86)
N	6	6	5
<b>Control</b>			
Mean(SD)	2.46(0.86)	1.78(0.78)	2.64(0.98)
N	9	8	8

SD= standard deviation; N=number of participants

The summary of statistics for the LASIS (Carer) by group over time is in **Table 5.11**. The low numbers (intervention group **n=6** and **n=9** in the control group) analysed was due to some of the participants not having a 'carer'. They were independent.

**Figure 5.8 Chart for LASIS (Carer) score by group over time (SD)**



SD= standard deviation

**Table 5.12 ANCOVA for the change (from the baseline) in LASIS (Carer) between intervention and control at six and twelve weeks**

Outcome	Adjusted mean difference between intervention and control	95% Confidence Interval	p-value	Effect size (standardised)
<u>LASIS (C)</u> n=14				
6 weeks	0.57	-0.17 to 1.31	0.14	0.73 (-0.2 to 1.7)
12 weeks	-0.73	-1.88 to 0.43	0.23	0.74 (-1.9 to 0.4)

As is shown in the table above, (**Table 5.12**) there was no significant difference from the baseline between the intervention and the control group at any time point. There was a small reduction in the LASIS score in the control group at six weeks but this returned to baseline by twelve weeks. There was no measureable difference in the LASIS score in the intervention group at any time point. This is demonstrated above, (in **Figure 5.8**).

## Results for lower limb measures

The following results are presented for the participants recruited and randomised to the study with lower limb spasticity. The outcome measure for gait velocity was used.

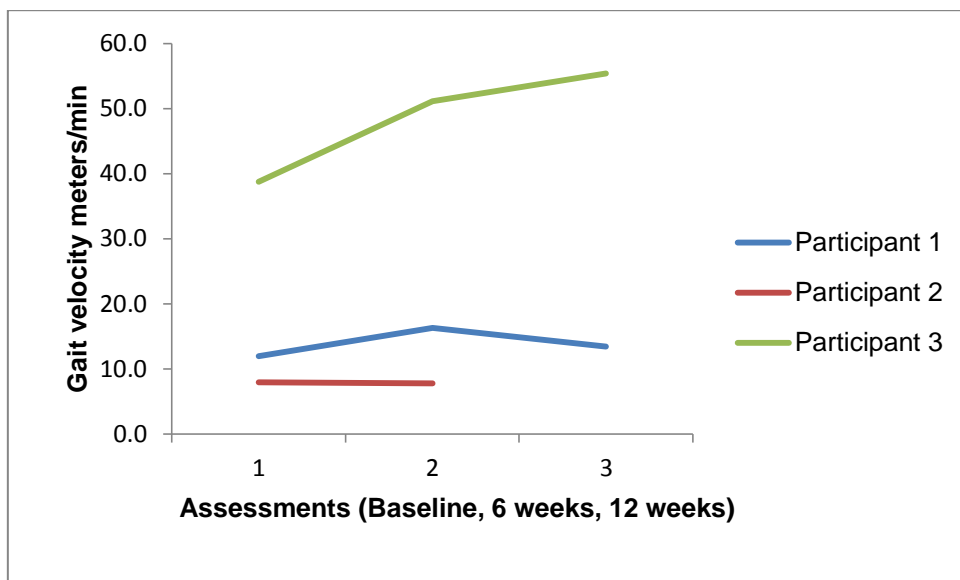
### The Ten Meter Timed Walk Test (10MTT)

Results from the 10 meter timed walk test are presented as descriptive data below, (Table 5.13). Three participants with lower limb spasticity recruited and allocated to the intervention group provided insufficient data for statistical analysis for significance. There were no participants allocated to the control group with lower limb spasticity. The participants were demographically representative of three diagnostic groups. One person had been diagnosed with stroke (P18), another presented with spasticity following traumatic head injury (P10) and the third presented with a progressive neurological disease, Multiple Sclerosis (P11). The latter participant's general medical condition deteriorated and the participant was unable to walk the necessary distances (ten meters repeated three times) for the third assessment at twelve weeks.

**Table 5.13 Ten Meter Timed Walk Test: Descriptive Data (Intervention Group)**

ID:10	1st Assessment		2nd Assessment		3rd Assessment	
Trial	Steps	Seconds	Steps	Seconds	Steps	Seconds
1	28	50.2	24	34.8	26	44
2	28	48.5	23	35.4	25	45
3	27	52.4	24	40.3	25	45
<b>Average</b>	27.66	50.36	23.66	36.83	25.33	44.66
<b>Meters/Min</b>	<b>11.45</b>		<b>14.88</b>		<b>13.33</b>	
ID:11	1st Assessment		2nd Assessment		3rd Assessment	
Trial	Steps	Seconds	Steps	Seconds	Steps	Seconds
1	37	85	42	92	-	-
2	36	70	36	71	-	-
3	36	71	38	70	-	-
<b>Average</b>	36.33	75.33	38.66	77.66	-	-
<b>Meters/Min</b>	<b>8.45</b>		<b>8.57</b>		<b>-</b>	
ID:18	1st Assessment		2nd Assessment		3rd Assessment	
Trial	Steps	Seconds	Steps	Seconds	Steps	Seconds
1	19	15.8	17	11.5	16.5	11.9
2	18	15.2	17	11.8	17	10.9
3	18	15.5	17	11.9	15	9.7
<b>Average</b>	18.33	15.5	17	11.73	16.16	10.83
<b>Meters/Min</b>	<b>38.70</b>		<b>50.42</b>		<b>61.85</b>	

**Figure 5.9 Summary of results for ten meter timed walk test**



As can be seen in the figure above, (**Figure 5.9**) **participants 1 (P10)** and **3 (P18)** made improvements in gait velocity at six weeks however this improvement was not maintained by twelve weeks following the removal of the DEFO. There was no change in the gait velocity in **participant 2 (P11)** at six weeks and retest at twelve week was not performed due to deterioration of her progressive condition.

### **5.5 Fidelity, adherence and variance data**

Data presented here is a record of procedural fidelity, adherence and variance. It includes a summary of the DEFO wearing record, a summary record by group of the physiotherapy interventions and contact time data, the Activity Log summary by group, and clinical data including goals set by group and protocol variance. Clinical data is coded for data protection.

#### **DEFO wearing record**

A summary of the DEFO wearing record (**Table 5.14**) is presented for the purpose of analysis of adherence, tolerance and fidelity of the intervention protocol.

**Table 5.14 Summary of DEFO wearing record (Total participants n=11)**

<b>Week</b>	<b>Daily wearing &lt;8 hours</b>	<b>Daily wearing &gt;8 hours</b>	<b>Preferred range daily (hours)</b>	<b>Recommended Wearing Total hours</b>	<b>Recorded mean Total hours</b>
<b>1</b>	1-4 hours	8 hours	1-13	39	35.8
<b>2</b>	0 hours*	8 hours	5-13	56	54.5
<b>3</b>	0 hours*	8 hours	6-13	56	58
<b>4</b>	0 hours*	8 hours	5-13.5	56	57.5
<b>5</b>	0 hours*	8 hours	6-13	56	60
<b>6</b>	0 hours*	8 hours	6-13	56	59.5

\* Two participants chose to not wear DEFO (1 participant refused, 1 didn't wear at the weekend)

The 'cricket sensor' for use as a wearing record was not forthcoming from DMO Ltd®. The DEFO wearing record was completed by all the participants in the intervention group who followed the protocol (n=11) and the raw data was collated by the researcher. The combined records were compared to the wearing protocol (**Chapter 4**). The combined data was then analysed to provide the preferred range of number of hours the DEFO was worn each day followed by the mean number of hours actually worn. The findings show a significant level of adherence and tolerance. The records also indicate wearing fidelity although the sensor could have further verified the written records.

As can be seen in the table above the DEFO was acceptable to wear in ten participants with one declining to wear it and a second person who chose not to wear it at weekends. This was reported in additional comments 'for washing' at weekends (worn daily at work). The DEFO protocol was closely adhered to in weeks three, four, five and six with some participants preferring to wear it longer than eight hours (13.5 hours). The wearing protocol was not fully adhered to in weeks one and two, however the recorded mean total hours did not vary greatly: week one: 35.8 hours out of 39 hours; week two: 54.5 hours out of a recommended 56 hours. It was noted that one participant was hospitalised in week six resulting in her reduced total wearing record.

### **Physiotherapy interventions**

A clinical record of physiotherapy interventions for each participant was captured over the twelve weeks study protocol. This demonstrated total contact time and individual treatment components delivered. A summary of the

interventions delivered over the protocol duration to participants in both groups together with respective contact time are presented below, (in **Table 5.15**).

From the recorded mean physiotherapy contact time it can be seen that the intervention group had less total contact (185.9 minutes) compared to the control group (237.5 minutes). It can also be seen the modalities of intervention were similarly matched for both groups. Participants from each group were evenly distributed between the clinicians. The results are analysed and discussed further in **Chapter 7**.

**Table 5.15 Summary of physiotherapy interventions and contact time (in twelve weeks)**

	<b>Intervention group n=11</b>	<b>Control group n=12</b>	<b>Total participants n=23</b>
<b>Intervention</b>			
<b>Sensory stimulation</b>	n=4	n=4	n=8
<b>Splinting or casting</b>	n=8	n=7	n=15
<b>Strength training</b>	n=7	n=7	n=14
<b>Fitness/ Aerobic training</b>	n=3	n=4	n=7
<b>Stretches</b> a)Static b)dynamic	a) n=9 b) n=9	a) n=8 b) n=9	a) n=17 b) n=18
<b>Functional training (task related)</b>	n=10	n=8	n=18
<b>Other training: FES CIMT</b>	n=4	n=6	n=10
<b>Other: Fatigue management</b>	n=4	n=4	n=8
<b>Advice and carer advice</b>	n=6	n=6	n=12
<b>Clinician</b>			
<b>C2</b>	n=5	n=6	n=11
<b>C3</b>	n=6	n=6	n=12
<b>Contact time</b>			<b>Total contact time</b>
<b>Mean (minutes)</b>	<b>185.9</b>	<b>237.5</b>	<b>212.8</b>
<b>Range (minutes)</b>	<b>45-420</b>	<b>45-500</b>	<b>45-500</b>

## Activity Log

A table summary of themes from recorded activities in the 'Activity Log' is presented in the table below, (Table 5.16). It demonstrates the variety of activities by group.

**Table 5.16 Research Activity Log (by group)**

Activity recorded	Intervention group n=11	Control group n=12	Total participants n=23
Work	n=2	n=1	n=3
Housework	n=2	n=2	n=4
Gym, practised exercises	n=3	n=2	n=5
Walking	n=3	n=3	n=6
Gardening	n=1	n=0	n=1
Swimming, Hydrotherapy	n=2	n=3	n=5
Computer	n=1	n=0	n=1
Saebo-stretch splint worn at night	n=1	n=0	n=1
Relaxation class, meditation	n=1	n=1	n=2
Clubs: Speaking club, golf club, stroke club, school reunion, dancing	n=1	n=3	n=4
Driving, school run	n=3	n=2	n=5
Shopping	n=4	n=10	n=14
Visiting bank, citizens advice	n=0	n=1	n=1
Hairdressers	n=0	n=1	n=1
Looking after pets: going to vets, walking dog, visit horses, looking after cats	n=2	n=1	n=3
Social outings: Cinema out for lunch, pub, BBQ	n=3	n=5	n=8
Appointments: GP, hospital, dentist, podiatry, wheelchair assessment	n=3	n=5	n=8
Medical events: fall, seizure, infection requiring antibiotics	n=3	n=3	n=6
Holidays, weekend trip	n=2	n=2	n=4
Moved house	n=0	n=1	n=1
Respite in care home	n=0	n=1	n=1
<b>Total activities</b>	<b>36</b>	<b>46</b>	<b>82</b>

As can be seen from the table above, (Table 5.16) there was a wide variety in activities recorded over the study period. This varied from activities of participation and roles: working (intervention group **n=2**, control group **n=1**); shopping (intervention group **n=4**, control group **n=10**); driving and school run (intervention group **n=3**, control group **n=2**), to more passive activities: attending appointments (intervention group **n=3**, control group **n=5**); relaxation



and meditation (intervention group **n=1**, control group **n=1**). From a position of variance the control group recorded more activities than the intervention group. This is descriptively analysed and discussed in **Chapter 7**. Participants also recorded physiotherapy sessions which were captured and presented elsewhere, (**Table 5.15**).

### **Clinical data**

As clinical data was embedded in both quantitative and qualitative results it is presented separately. The clinical data was sourced from the physiotherapy records and where necessary medical notes for verification of variance data.

From the clinical records two participants were hospitalised, (**n=1** control group, **n=1** intervention group). This meant one participant was lost to the study after six weeks (**P09**) with extended immobilisation for a medical condition unrelated to the study; however the other participant (**P13**) continued with the protocol and returned home. In addition there were six medical events recorded (**n=3** control group, **n=3** intervention group) including: a fall (**P06**); seizures in two participants (**P16**, **P20**) and three participants (**P02**, **P05**, **P11**) requiring antibiotics for infections. Two participants (**P11** and **P21**) received diagnostic news on disease progression. Additional issues of clinical impact included level of carer support provided and dependency. The former was reported in the participant baseline characteristics (**Table 5.1**) but the latter was only gathered from the clinical records and not quantified. Social issues which impacted on individual participants included: roles and responsibilities for dependents; financial pressures and relocation.

### **Goals identified**

The goals identified by all the participants in the study are summarised by group for variance and presented in the table below, (**Table 5.17**). There were 69 goals set (three per participant) and of these 14 common themes emerged and were categorised. There was no significant difference between the groups in the number or category of goals set.

**Table 5.17 Summary of goals set (by group)**

Goal	Intervention Group	Control Group	Total Goals (69)
ASSOCIATED REACTION (AR): e.g. To walk 50 meters outdoors on flat ground with elbow extension maintained	4	3	7
PASSIVE RANGE: e.g. To maintain passive ROM in wrist extension of 30 degrees with fingers neutral	2	0	2
EXERCISE RELATED: e.g. To be able to do strength exercises independently weekly	2	3	5
WALKING: e.g. To walk independently indoors 15 meters with a stick	4	5	9
SPLINT: e.g. To put splint on daily with ease	3	4	7
FUNCTIONAL INDEPENDENCE: e.g. Independent dressing	6	4	10
PAIN (VAS): e.g. To subjectively decrease in pain by 2 points	3	4	7
MUSCLES TENSION: e.g. To reduce feeling of tightness in leg	2	0	2
POSTURE: e.g. To rest forearm on table 15 minutes at meal times	2	2	4
BALANCE: e.g. Unsupported stand 3 minutes	1	1	2
FALLS: e.g. To fall less than 2 times in 6 weeks	0	1	1
CONFIDENCE: To increase confidence VAS score by 2 points	1	1	2
HAND FUNCTION: e.g. To hold plastic drinking cup in hand and take to mouth for a drink	2	3	5
HAND HYGEINE e.g. To allow safe nail care	3	3	6

**Key:** AR = Associated Reaction (Posture of arm when walking), VAS= Visual Analogue Scale

## Variance data

Additional data was captured from the DM Orthotics Ltd<sup>®</sup> clinician. This data was collated from the intervention group participants. There were two recorded timing delays in the protocol delivery for the assessment for fitting of the DEFO. Both of these resulted from cancelled appointments due to illness. Another delay in fitting of the DEFO of two participants was caused by unforeseen travel difficulty (from flooding). There were further delays in the fitting process with three participants as additional modifications were made in the customised DEFO. This meant the six week intervention period was considerably delayed for participants (**P16**) and (**P19**). In the former a second DEFO was provided as the first was extremely tight and difficult to put on. This participant (**P16**) took a 'dislike' to it and even when provided with another refused to wear it. In the latter case (**P19**) a second cycle of BT was awaited before the participant could be successfully recruited. Further delays due to participant illness resulted in one recruited participant rescinding his consent to the study. He was offered recruitment after his second cycle of BT, but he declined. Further variance included two incidents of revealed allocation.

## 5.6 Data Summary

In summary the baseline characteristics of the participant two groups were found to be evenly matched. This was however, with the exception of mean (SD) age difference: 50.5 (12.60) years (intervention group); 61.6 (14.46) years (control group).

Of the (**n=25**) participants recruited (**n=23**) completed the study. Two of the participants recruited (intervention group **n=1**, control group **n=1**) did not proceed with the study and their data was not analysed. One participant (intervention group, **n=1**) was lost to the study for medical reasons unrelated to the study.

A summary table of the results analysis of primary and secondary outcomes at six weeks and twelve weeks for difference between groups is presented below (in **Table 5.18**). The lower limb measures are presented descriptively for those

participants in the intervention group. There were no participants allocated to the control group with lower limb spasticity.

**Table 5.18 Summary of findings: pilot RCT (primary and secondary measures)**

Outcome	Adjusted mean difference between intervention and control	95% Confidence Interval	p-value	Size effect (95%CI) (standardised)
<b>ANCOVA</b>				
<b>Primary measure</b>				
<b><u>GAS</u></b>				
6 weeks	12.17	3.16 to 21.18	0.014	1.21 (0.3 to 2.1)
12 weeks	6.14	-4.68 to 16.97	0.28	0.52 (-0.4 to 1.4)
<b>Secondary measures</b>				
<b><u>VAS</u></b>				
6 weeks	0.48	-0.66 to 1.63	0.41	0.28 (-0.4 to 0.9)
12 weeks	-0.32	-2.05 to 1.40	0.72	0.14 (-0.9 to 0.6)
<b><u>EQ5D</u></b>				
6 weeks	0.03	-0.22 to 0.28	0.79	0.08 (-0.65 to 0.82)
12 weeks	-0.04	-0.24 to 0.16	0.73	0.15 (-0.8 to 0.6)
<b>Upper limb</b>				
<b><u>LASIS-Participant</u></b>				
6 weeks	0.21	-0.26 to 0.68	0.39	0.33 (-0.4 to 1.06)
12 weeks	0.11	-0.34 to 0.57	0.63	0.21 (-0.7 to 1.1)
<b><u>LASIS-Carer</u></b>				
6 weeks	0.57	-0.17 to 1.31	0.14	0.73 (-0.2 to 1.7)
12 weeks	-0.73	-1.88 to 0.43	0.23	0.74 (-1.9 to 0.4)
<b><u>ArmA- Active</u></b>				
6 weeks	-0.46	-2.88 to 1.96	0.71	0.28 (-1.8 to 1.2)
12 weeks	-0.39	-4.08 to 3.29	0.83	0.10 (-1.0 to 0.8)
<b><u>ArmA- Passive</u></b>				
6 weeks	1.53	-1.35 to 4.41	0.31	0.42 (-0.4 to 1.2)
12 weeks	-0.89	-2.56 to 0.78	0.30	0.41 (-1.2 to 0.4)
<b>Lower limb 10MTT</b>	<b>Trial 1 Baseline Meters/Min</b>	<b>Trial 2 6 weeks Meters/Min</b>	<b>Trial 3 12 weeks Meters/Min</b>	
Participant 1 (P10)	11.45	14.88	13.33	All participants had demonstrated improvements in gait velocity at 6 weeks.
Participant 2 (P11)	8.45	8.57	-	
Participant 3 (P18)	38.70	50.42	61.85	

The DEFO wearing record supported the tolerance and adherence of the wearing protocols. The DEFO protocol was closely adhered to in four of the six weeks with wearing preferences and tolerance of eight hours or more (13.5 hours). In addition the procedural fidelity was established with the majority of participants ten choosing to wear the DEFO and one declining to wear it.

A summary of physiotherapy intervention and contact delivery time found the modalities of intervention were similarly matched for both groups however the intervention group had less total contact (185.9 minutes) compared to the control group (237.5 minutes). Modalities most commonly used included: stretches (both active and passive); functional training; splinting; strength training and advice.

Analysis of the Activity Log provided a snapshot by group of the varied activities of the participants during the study. Shopping appointments and social outings were commonest activities recorded and both groups recorded similar levels of activity.

Goal setting and analysis by group was reported for variance in clinical practice. Of the 69 goals set there were 14 common categories. On analysis there was no significant difference either between the groups or in the number or category of goals set.

The clinical findings reported procedural variance data on timing of fitting and protocol implementation. Reasons included illness and environmental issues beyond the control of the researcher. These findings are addressed by the topic guided interviews, which were analysed and presented in **Chapter 6** and the combined findings discussed in more detail in **Chapter 7**.

## Chapter 6

### Results II (Qualitative)

#### Key points:

- **Results overview of findings presented**
- **Qualitative findings analysis of topic guided interview accounts of participants and clinicians**
- **Thematic Analysis- basic, organizing and global themes presented in 'Thematic maps', theming of quotes, and critical analysis of themes.**
- **Summary of themes**

#### 6.1 Overview of findings presented

After the quantitative phase (pilot RCT) was completed topic guided interviews were conducted and provided qualitative data to explore the results (**Chapter 5**) and address the research questions (**Chapter 3.2**).

##### Topic guided interviews

The topic guided interview questionnaires for the participants and clinicians are presented in **Appendices 11** and **12**, respectively. One (**n=1**) participant in the intervention group was not interviewed due to removal from the study for non-related medical reasons at six weeks but was followed up and contributed to the development of the interview questions). The experiences of intervention group participants (**n=10** of the **n=25** recruited to the study) and clinicians (**n=3**) were captured by digitally recorded topic guided interviews. Data was transcribed, anonymised and collated onto an NHS electronic database.

Examples of the Framework analytic approach used for coding participant and clinician data extracts are shown in **Appendix 16**. Each of the coded themes was able to be traced back to participant quotes for reference and authenticity. A colour coding system was used to explore issues and descriptives which were interpreted into sub-themes (basic themes) and further analysed into themes (organizing themes) and finally superordinate themes (global theme). The Thematic Analysis findings are presented, in a series of 'thematic maps'

(Figures; 6.2, 6.3, 6.5 and 6.6). They were generated in order to provide transparency in the method used for thematic interpretation of participant and clinician feedback, (in Chapter 3.6). Each of the data sets is presented below under the relevant headings.

## 6.2 Participant feedback

The semi-structured interviews with the participants were steered by topic guided questions (Topic Guided Interview of Participants, Appendix 11) to answer specific feasibility and acceptability issues in the research study including rationale for compliance, adherence, clinical applicability, and to identify any specific health benefits and adverse effects. A probing technique was used in the interviews. Specific topics covered: positive and negative experiences of; the research feasibility; acceptability of the DEFO intervention; and wearing preferences. For this reason the findings were likely to be deductive, however the conversations also provided interesting and inductive themes which were explored. The Thematic Analysis findings are presented, (in Figure 6.1). The figure depicts the underlying issues and descriptives which were colour coded into sub-themes, then categorized into themes and finally superordinate themes.

### 6.2.1 Global Participant theme: (GP.1) Research Experience: Acceptability

The following organizing themes that underpin the global theme (GP.1) 'Research experience: Acceptability' are presented below. These subordinate themes comprise; Organizing Participant themes: (OP.1): Research expectations; (OP.2): DEFO acceptability; (OP.3): Protocol feasibility; (OP.4): Health benefits and (OP.5): Adverse effects. Each sub-theme is analysed with evidenced references from the original textual data (quotes from the transcriptions). The findings are synthesized from the relevant and interesting themes and they are presented diagrammatically in a 'Thematic network map' (Figure 6.2). The findings are presented and interpreted with evidence theme by theme.

Figure 6.1 Thematic Analysis of participant interview findings; colour coded for categories

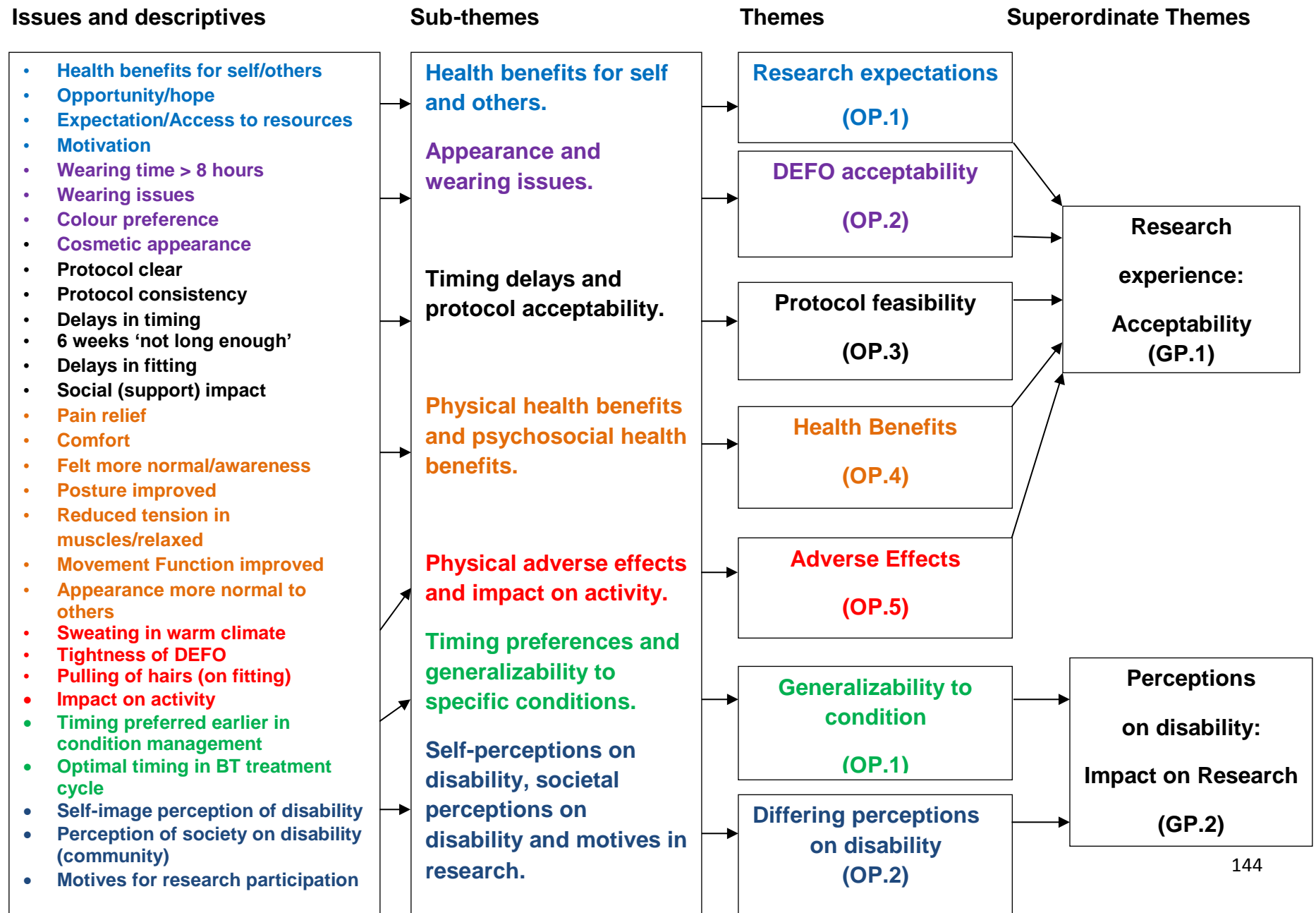
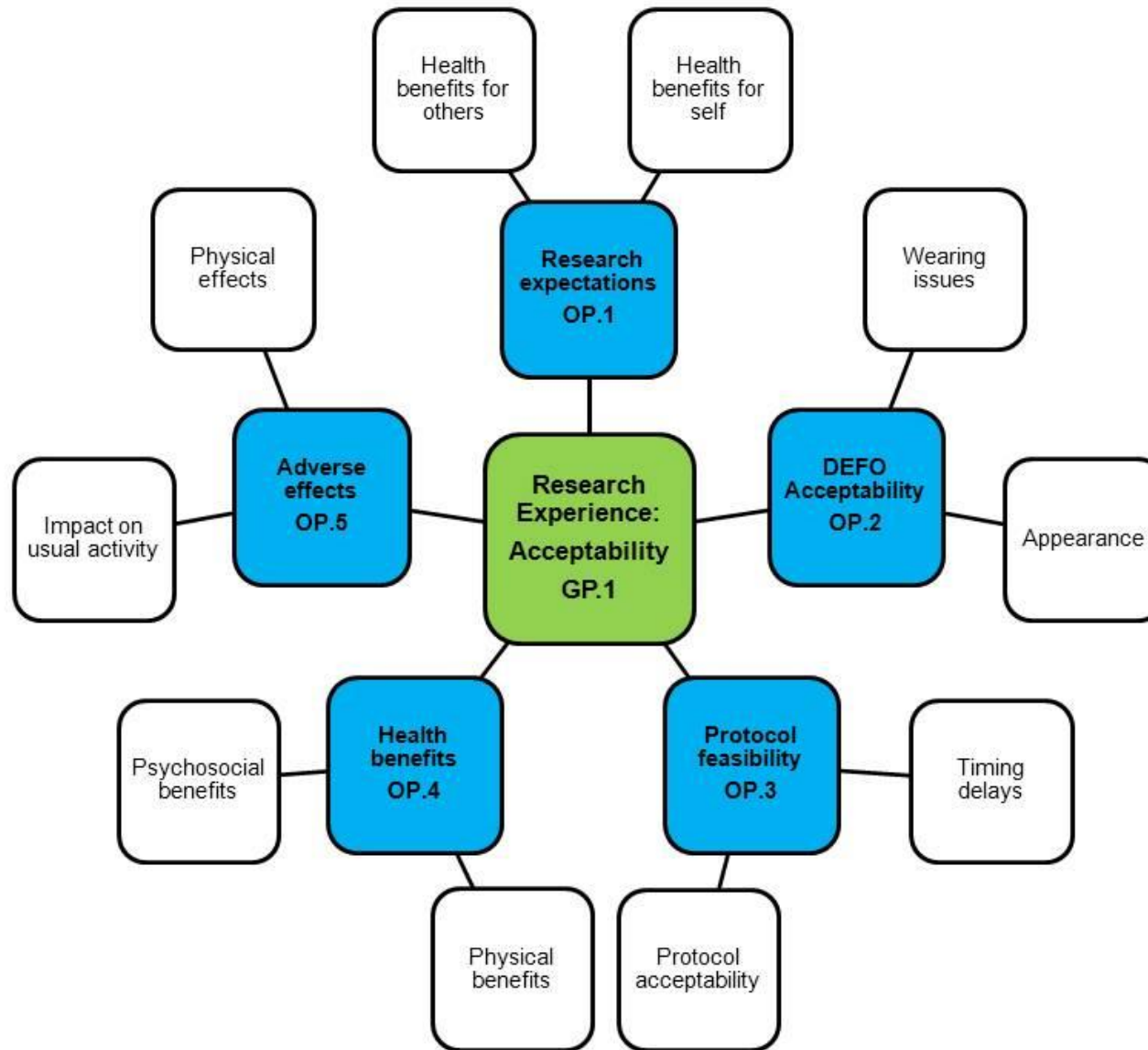




Figure 6.2 'Thematic map' for Global Participant theme: (GP.1) Research Experience: Acceptability



### 6.2.1.1 Organizing Participant theme (OP.1): Research expectations

Participants raised a number of issues around their expectations and underlying motives for participating in the research. These were categorized into two further sub-themes. Firstly participants considered their own expectations on likely benefits. Secondly a number of participants proposed likely benefits for others, for example funding opportunities and service delivery improvements.

#### **Sub-theme: Health benefits for self**

The examples from the texts below include differing perceptions of how the research or the intervention in particular could benefit them specifically as an individual. Differences in the expectations were often linked to their experiences as the interviews were after the pilot RCT.

One participant gave an interesting viewpoint in that they accepted anything offered. This could have been because he had reached the end of his rehabilitation phase, was perhaps not accepting of his level of disability and was still highly motivated to make improvements:

*‘Just because it was there it was offered ...I like to say yes to everything so... I just went for it!’ (P01)*

This raises the underlying concept of patient motivation in rehabilitation. Motivation is a term commonly used by clinicians when linked to performance and outcomes. The impact of a life-changing disability and how people adjust as individuals is likely to have an effect on attitudes and behaviours in therapy and research. There is much debate about the individual (intrinsic) and social (extrinsic) concepts of motivation (Maclean and Pound, 2000). A similar viewpoint of another participant with a progressive condition expressed a personal need to grasp every chance for potential improvement and hope at the opportunity to join the research. Understanding the concept of hope is relevant to rehabilitation clinicians (Bright *et al.*, 2011). This expression of ‘hope’ was echoed by other participants:

*'...I think in a situation like that, you would try anything really'. (P11)*

*'An opportunity to sort of try something...as part of research.' (P04)*

*'... sometimes you can go on week by week, month on month and not see anything has been done... that is a positive like a feeling of hope like something was being done... it will improve.' (P18)*

The underlying motives of individuals can be interpreted in light of their experience of a life-changing illness to which they have had to adjust both physically and emotionally. The importance of apathy and motivation for meeting the challenges of the recovery process are surprisingly undervalued (Mayo *et al.*, 2009). The problem of apathy post stroke is an issue that deserves further study. According to Mayo and colleagues it is linked to motivating factors and low mood that can impact negatively on ability to participate in promising therapies.

Another viewpoint was considered from a person-centred stance outlining the possible benefits offered by the research with access to further therapy. There is a suggestion of a link between both hope and motivation, and expectation and reward:

*'...to see if there was any long term benefit to myself'. (P18)*

*'Well...selfish... that it was going to get me better quicker- with a bit of luck. I suppose you get access to physiotherapy quicker- whether that is true or not I don't know!' (P20)*

Two further participants were clear about what they expected from the research and how these were realised. In the examples below the benefits gained were realised suggesting that the expectations for both individuals were well founded.

*'...to see if these things work. It worked for me'. (P24)*

*'...I was glad to be helping you in your research and thought it would be good for me to help me to be beneficial in my progression to my target... it was like helping my mind as well it was definitely helping me too'. (P10)*

The sentiment of helping oneself and others at the same time was commonly reported demonstrating consideration for other people in a similar predicament. This was further complemented by the suggestion of evidence influencing decisions:

*'...you do it to help yourself and other people.... and get the arm moving'.*  
(P19)

*'...it might be available if it proves successful for us to try later on because we would know a bit more about it.'* (P16)

### **Sub-theme: Health benefits for others**

Consideration for others was seen as a priority for some participants demonstrating insight into the underlying aim of the research; to find if the DEFO intervention had any added health benefit. This altruistic sentiment was expressed in a number of ways; from general, to more condition specific and for a similar younger population:

*'I decided to take part because if you do anything like that it helps other people'.* (P19)

*'Anything that can help to alleviate the suffering of stroke has got to be a good thing'.* (P20)

*'Just thought it would be helpful to other young people... to see if these things work'.* (P24)

There was a further viewpoint that considered others (people with stroke) from a perspective of the level of motivation required to comply with the research expectations. This personal insight is evidenced in the literature as 'apathy' post stroke (Mayo *et al.*, 2009).

*'High level of motivation, effort and time needed. Question whether people with stroke have the level of motivation required'.* (P21)

In addition a specific issue was raised on funding decision opportunities that could arise from the research findings. This was from a participant with previous experience in research and who had a broader perspective on potential health benefits:

*'...get me better quicker...with a bit of luck and if it helps people to make a decision about where they spend NHS funding that is good for me'.*  
**(P20)**

This was an unexpected finding from the participants and demonstrated the added value of qualitative research. The literature supports the importance of a person's motivation in determining the outcome of rehabilitation (Maclean and Pound, 2000; Nicholson *et al.*, 2012). In summary the categories of hopes, expectations and motives of participants were interpreted for significance into sub-themes of health benefits for self and others and subsequently synthesised into the theme **(OP.1): expectations in research.**

#### **6.2.1.2 Organizing Participant theme (OP.2): DEFO Acceptability**

The topic of DEFO wearing acceptability was presented overtly in the participant interviews with the intention of finding out details of importance to the participants. From the data analysis two issues were found significant for acceptability and adherence; appearance and wearing issues.

##### **Sub-theme: Appearance**

The appearance of the DEFO was considered from differing perspectives depending on the individual. It was important for some participants that it was not conspicuous as they did not wish to draw attention to their disability; to others it was an important medical emblem for others to identify a need for assistance. In contrast to the above, two participants suggested the appearance should reflect their personality with vivid statement colours.

The appearance of the DEFO was firstly considered from a self-image, 'normalising' perspective. This was considered an important aspect for reasons to wear the orthotic from a personal stance. It links with perceptions of social acceptability and wanting to fit in. Two participants were clear on their rationale for finding the DEFO acceptable:

*'...you could hardly see it ...and for the colour of it ...just blended in'.*  
**(P19)**

*'My arm felt straighter, when I was wearing it, much straighter and more normal...'* **(P24)**

Secondly, one participant viewed the DEFO appearance helpful in respect of cueing others. She raised the importance of social roles and responsibilities by openly declaring disability with a visual cue:

*'...as a physical cue for other people for if you have something wrong with your limb to be helpful for other people 'cause if you have nothing on they are not aware you have a problem. Splints in general serve as a visual aid to third parties which prompts the public to be more helpful in social situations e.g. shopping bag packing'.* **(P21)**

Lastly there was a different perspective from participants who fully embraced their DEFO as an extension of their apparel. It was suggested that in order to be acceptable to them personally the colour of the orthosis needed to be customised:

*'A choice of colours might have been nice...'* **(P21)**

*'...it was flesh coloured even with the tones... he wanted 'Orange!'* **(P04)**

*'...just part of the stroke. I would just wear it anyway...so...I dyed it purple...more me'.* **(P01)**

The issues raised were not so much about the specific colour preferences but more about the need for customising the appearance of the DEFO to optimise

the acceptability from an individual's perspective. This is presented from another viewpoint on perceptions of disability (**GP.2; OP.1: Differing perceptions of disability, self-perceptions of disability**).

### **Sub-theme: Wearing issues**

There were a number of participants who raised the important issue of acceptability from the experiences on wearing the DEFO. There were both positive and negative experiences. The positive findings identified flexibility, it was lightweight, able to be worn under clothing and was easy to remove.

*'Definite benefits are that it is more lightweight, and flexible... can put on clothing...like a coat...more easily especially in winter and prefer compared to rigid thermoplastic splints...especially coming into the winter, more accessible.'* (P21)

*'...taking it off was no trouble...'* (P19)

*'Putting it on every day it got easier and easier and easier and we could actually do it within a couple of minutes.'* (P04)

*'...splint allows movement whilst being worn so all daily exercises can still be undertaken without the need to remove and reapply. Therefore increasing the likelihood of doing physio exercises as less hassle.'* (P21)

From these findings suggest DEFO offers a real alternative to existing rigid splints with evidence of acceptability and compliance based on real-life issues. However the negative findings included: difficulty with donning, tightness or too slack, wear and tear, and uncomfortable in the summer. Adverse effects were also reported. (**GP.1; OP.5: Adverse effects**).

*'It's become a little loose in a certain area ...around the left little toe which obviously reduces the benefit of wearing it to be honest. The only slight negative I would say is that it seems to wear quite quickly.'* (P18)

*'...it did slip down a bit I remember it was loose just around the heel.'* (P10)

*'...it's a combination (name's) hand and being stiff and this thing being extremely tight and...getting one into the other was hugely difficult'. (P16)*

*'...it was tight and uncomfortable to wear, with swelling, sweating, marking and it ached'. (P21)*

*'There was a few times when I felt like giving in because the... erm sling was quite hard to get on... but I persevered and carried on'. (P24)*

From the experiences above there are some important factors raised for consideration by the orthotics company. These findings on colour, fit, function and wearing experience are similar to those reported in the literature (Kuipers *et al.*, 2009; Coghill and Simkiss, 2010; Calvert and Kelly, 2013) which have been shown to influence compliance. In summary cosmetic appearance including colour, function and optimal fit are significant findings for acceptability and adherence of the DEFO.

### **6.2.1.3 Organizing Participant theme (OP.3): Protocol feasibility**

Experiences described by the majority of participants demonstrated a high level of procedural feasibility of the research. The key issues analysed were from the procedural issues around protocol timing and its acceptability.

#### **Sub-theme: Timing issues**

The timing element was especially important in this protocol as was the coordination between the research team to assess and fit the DEFO. From a procedural perspective the majority of the participants reported positive experiences with no variance or difficulty in following the protocol:

*'... just followed what it said a few hours at first and then yeah no problems. Just did what it said'. (P01)*



*'I wore it all day... every day ....for the first six weeks. I did everything I should have done' (P11)*

*'It was good to be selected, I was more than happy to take part there was no trouble throughout. Everyone has been helpful. I appreciate being a part of the study. I think the fitting went well you know the timing'. (P18)*

The views of the above were particularly insightful in that they reported key procedural elements of the research; consent, a clear protocol, compliance and good communication between the researchers and participants. However there was an alternative perspective which resulted from a delay in the DEFO fitting and delivering the protocol for two participants:

*"... that comes back to the fitting, everything else has been OK! Just the fitting took a bit too long". (P19)*

*'By the time we got it, it was pretty much six weeks, after the event. I think the idea was to get it within a few days whilst the hand was still supple. No. It was unfortunate there was delay. The timings went haywire.' (P16)*

It was the experience of the latter participant (P16) that the first DEFO was too tight and required modifications which caused the delay in timing. The result of this was that it impacted negatively on the participant experience, so much so, that when it finally came she refused to wear it. From the literature (RCP *et al.*, 2009) the optimal time for a review of the need for splinting is suggested at two weeks post injection, once the toxin (BT) has taken effect.

### **Sub-theme: Protocol acceptability**

In the research it was important to find out about the participant's experiences of following the protocol. The protocol was analysed in terms of how it impacted on the participant's daily routine and whether this was acceptable or not.

*'...no problem just sticking to it'. (P01)*

*'It's all gone smoothly. I have an early morning start- it takes a little bit longer to get it on in the mornings to get ready'. (P18)*

*'No problem with the protocol, able to keep records to make sure I was doing it accurately'. (P21)*

*'It all went fine... just got into a routine in the morning and put it on, I took it off when I went to bed'. (P24)*

The protocol was found not to be a burden. Experiences described above were common and corroborated the results of adherence in terms of the DEFO wearing record and the clinical records. One participant worked night shifts and managed to fit his protocol around his work pattern. This participant also chose to remove the DEFO at weekends when he was not working so he could wash it. This was reported in the clinician feedback (**Chapter 5.5**). (**OC.2**): **DEFO intervention acceptability**)

As previously reported there was one participant (**P16**) who was compliant with everything in the protocol, with the exception of wearing the DEFO. She was aphasic and despite several attempts to communicate with augmentation it was difficult to ascertain the reason why she chose not to wear it:

*"I tried to explain but would not even try it on. She took one look at it and refused...Just took a dislike to it! (carer of P16) [shakes head and grimaces (P16)]*

To summarise the overall feedback from the participants indicated the protocol timing went well (**n=9**) in comparison to with those who reported delays (**n=2**) and the protocol delivery was adhered to in (**n=10**) compared to (**n=1**).

#### **6.2.1.4 Organizing Participant theme (OP.4): Health benefits**

The findings on the positive effects of wearing a DEFO were categorised into two sub-themes; physical and psychosocial. These were analysed to form the theme of (**OP.4**): **Health benefits**.

### **Sub-theme: Physical benefits**

The issues raised by the participants were vivid and demonstrate real insights into the experiences of wearing the DEFO. These included; pain relief, comfort, benefits on improved posture, muscle tension and functional activity.

Firstly two participants found the DEFO had the added benefit of specifically reducing their pain:

*'I found when I put the sleeve on that: I get pain at the top of the arm but as soon as the sleeve was on the pain went ....and it took the tightness away'. (P19)*

*'....and when walking wearing it is what gives the relief of pain. It felt very comfortable, very supportive'. (P20)*

This was reinforced by the similar findings of added comfort reported by others. The combination effect of warmth, posture and comfort were all seen as positive justifications for wearing the DEFO.

*'I felt positive yeah! Sort of ...like comfort'. (P01)*

*'No discomfort, no...very good' (P18)*

*'It was fine it was comfortable'. (P24)*

*'It kept my hand warm ... and it stopped my thumb from sticking in too much. ...will probably wear it when it gets cold- 'cause it keeps my hand, my arm warm'. (P24)*

Additional findings demonstrated a link between wearing the DEFO and improvements experienced in the positioning of joints and limbs:

*'There was definitely a difference in the first three or four weeks...The foot was in shape more... so I thought it was great'. (P11)*

*'One of the positive things is it did ...did ...did do the job to keep my thumb out' (P24)*

This was further evidenced in that the DEFO was perceived to reduce muscle tension which impacted not only on the comfort but was also a consideration

affecting posture of the limb. This is particularly important for people with spasticity that results in 'associated reaction' (AR) in the hemiplegic limb. The AR in the affected limb is an abnormal postural reaction commonly due to effort and instability (Macfarlane *et al.*, 2002). This finding was most applicable for those who set goals related to AR in the upper limb.

*'My arm felt straighter, when I was wearing it, much straighter and more normal... than being across my chest all the time'. (P24)*

*'I just found it was better for my arm it took away a lot of the tightness and that and that's all I can say'. (P19)*

In addition to reducing unwanted tension the DEFO was reported to have beneficial effects on movement in several participants:

*'More than anything else I can straighten my arm... straighten it, see. [Raises arm]...and a bit more movement in my fingers'. [wiggles fingers] (P01)*

*'...and it just felt like I was able to lift it a bit better.' (P11)*

*'I can straighten me arm more with it on'. (P19)*

*'...the stability wise...my...at the ankle tended...the foot drop...wasn't as bad as it usually is...It stabilised it so I do feel the benefit ... it hasn't cured it, don't get me wrong but it is better than it used to be'. (P18)*

A further benefit reported was joint stability provided by the DEFO which had a knock on effect on the functional activity as participants described the differences made to their confidence and participation in social activities:

*'I found in the beginning it did help with that I couldn't believe how good I was walking. I couldn't believe the difference... I would have kept it... on to use'. (P11)*

*'I wore it on nights out ... when I go bowling'. (P18)*

*'a walking frame that I walk with especially when I go food shopping ...because it is flexible (DEFO) so I can get my hand to hold on and use*

*the frame to walk, ...but with the fixed splints you can't... so I have to take it off so then I have no splints on at all'. (P21)*

The importance of participation level activity was highlighted when participants were deliberately choosing to wear the DEFO during social activities and finding the added health benefits. Participant (P21) indicated this splint (DEFO) offered something new; the added value of using her hand in a real-life situation whilst shopping. This is reflected in individual goals that are important to the person and have real-life meaning (Ashford and Turner-Stokes, 2006). This was demonstrated in the specific goals chosen in the pilot RCT for example one participants goal was to be able to walk without her arm flexing (more than 45 degrees) into an associated reaction and causing distress when she was out socially at the community centre.

### **Sub-theme: Psychosocial benefits**

There were several issues raised on the impact of wearing the DEFO that were unexpected. Firstly the feeling of 'normality' was referred to by several participants. Secondly it was hailed as providing more awareness so that the limb became a part of the person again. This is linked to the evidence for proprioception which helps with postural awareness and movement control. This was seen as a particularly important finding when compared to rigid splints that commonly restrict movement and sensory feedback (Lannin *et al.*, 2007; Lannin and Ada, 2011). Thirdly two participants were keen for the physical appearance to be acceptable from a social perspective. This is analysed further in global theme (**GP.2: OP.1: Differing perceptions of disability, societal perceptions of disability**).

*'I felt like I was missing it when I ... when I did not have it on'. (P01)*

*'More relaxed. More awareness. It was the awareness and the interaction... could do things with it. ...awareness was much... much better'. (P04)*

*'...you could hardly see it ...just blended in'. (P19)*

*'...when I was wearing it, much straighter and more normal...'. (P24)*

Again the lived experience of 'normality' is what many of the participants were keen to point out as an unexpected health benefit that is also difficult to explain or quantify. The cosmetic acceptability of the DEFO contributed to the overall high level of compliance. Continuous stretch of the spastic muscles resulted in reduced tension and improved levels of muscle tension similar to the findings of Gracies *et al.*, (2000). Although this may be considered a physiological response there is a correlation between muscle tension levels and emotional anxiety in stressful social environments.

It could be argued that the benefit of feeling more 'normal' allows the person to consciously or unconsciously adjust to their disability and relate better to the social environment. This perspective could be from the individual who wishes not to be seen as different due to their disability. There is a link between appearance and what individuals and society perceive as normal (Wa Munyi, 2014). The psychological impact of disability and perceptions of 'normality' can in turn impact on motivation in goal attainment (Seigert and Taylor, 2004). Thus the interviews provided the most relevant tool to explore this important aspect of health benefit which could easily have been missed in quantitative research methodology.

In summary the categories discussed and analysed for most significance included were pain relief, comfort, more normal, more awareness, benefit realised by improved posture, muscle tension and functional activity. These positive and tangible health benefits were interpreted to have had a significant impact on individual daily living experiences in real-life contexts which were valued by the majority of participants in the DEFO intervention group. These were themed into physical and psychosocial benefits for the sub-theme (**GP.1; OP.4: Health benefits**).

#### **6.2.1.5 Organizing Participant theme (OP.5): Adverse effects**

The sub-theme **Organizing theme (OP.5): Adverse effects** is presented comprised of the negative physical impact of the DEFO and its effect on usual activity. The findings presented here provide an interesting dissonance with the mainstay of findings but deliver a balanced approach.

### **Sub-theme: Physical effects**

The experience of one participant was that she experienced real discomfort with the DEFO which was reported with reference to the climate:

*'Unusually hot this summer there was a lot of swelling that made it tight... tight and uncomfortable to wear, swelling, sweating, marking and ache. Skin pinched and bruised during application'. (P21)*

The above findings corroborate the evidence in the literature on compliance (Coghill and Simkiss, 2010; Calvert and Kelly, 2013) in which parents of children who wore Lycra<sup>®</sup> body suits reported discomfort in warm weather. A further concern reported was the tightness of the DEFO, which for most participants was something they became accustomed to but for one participant this was unacceptable. Participant (P16) refused to wear the DEFO.

*'...this thing being extremely tight...refused...Just took a dislike to it!'*  
(P16)

There was a similar experience in another subject but this was more related to the process of donning the DEFO:

*'...this corset material pulls the hairs...not whilst it is on... but whilst putting it on.'* (P20)

*'Putting it on was a big problem- third party had to put it on...reducing independence'* (P21)

From the findings above the key physical issues were primarily based around the customised fitting of the DEFO and how it was applied. With experience the therapists, carers and participants all reported this became easier.

### **Sub-theme: Impact on usual activity**

There were a number of occasions when the DEFO impacted on usual activity. This was surprising as the inherent flexibility suggested it could be worn much like usual clothing. One of the instances that stood out is when it impacted on hand function in a negative way by loosening the grip:

*'There was only the gym side of it where I couldn't hold on...'* (P19)

On the other hand it was obvious that it was not suitable to wear for activities like swimming/ hydrotherapy, although this finding could be seen as a potential design feature modification with the orthotics company informed. Similarly it was necessary to be removed for activities and therapies involving skin contact like massage and acupuncture:

*'...do hydro quite regularly so that is another instance when I wouldn't wear it'. (P04)*

*'When was having acupuncture- had to remove it, and when having physio massaging hand'. (P20)*

One further interesting and significant personal point raised was the negative aspect that one participant liked to sunbathe and felt the DEFO was interfering with his overall appearance by blocking the sun to his skin. This was something not previously considered or observed in the literature but it does contribute to insight in the overall findings as to why splints are worn or not.

*'...likes the sun...It would detract from that...I suppose that would be a concern ...very much short sleeves exposing the skin'. (P04)*

In summary the issues discussed comprised discomfort, fitting, donning and individual preferences of wearing or not during activity. Significant findings included reducing independence and physical appearance or discomfort from tightness especially in warmer months. These were synthesised into categories of physical and impact on usual activity which were analysed into the sub-theme **(OP.5): Adverse effects.**



## Summary

From analysis of the findings there were a number of relevant and interesting themes. A summary of the key points in each **Organizing theme** is presented below:

### **Summary Global Participant theme (GP.1) Research experience: Acceptability**

#### **Organizing Participant theme (OP.1): Research expectations**

Themes of hopes, motives and expectations in regard to health benefit and improved access to resources were interpreted for significance.

#### **Organizing Participant theme (OP.2): DEFO acceptability**

Cosmetic appearance including colour and optimal fit are significant findings for DEFO wearing acceptability and adherence.

#### **Organizing Participant theme (OP.3): Protocol feasibility**

Overall the protocol timing went well (**n=9**) despite reported delays (**n=2**) and the protocol delivery was adhered to in (**n=10**) compared to (**n=1**).

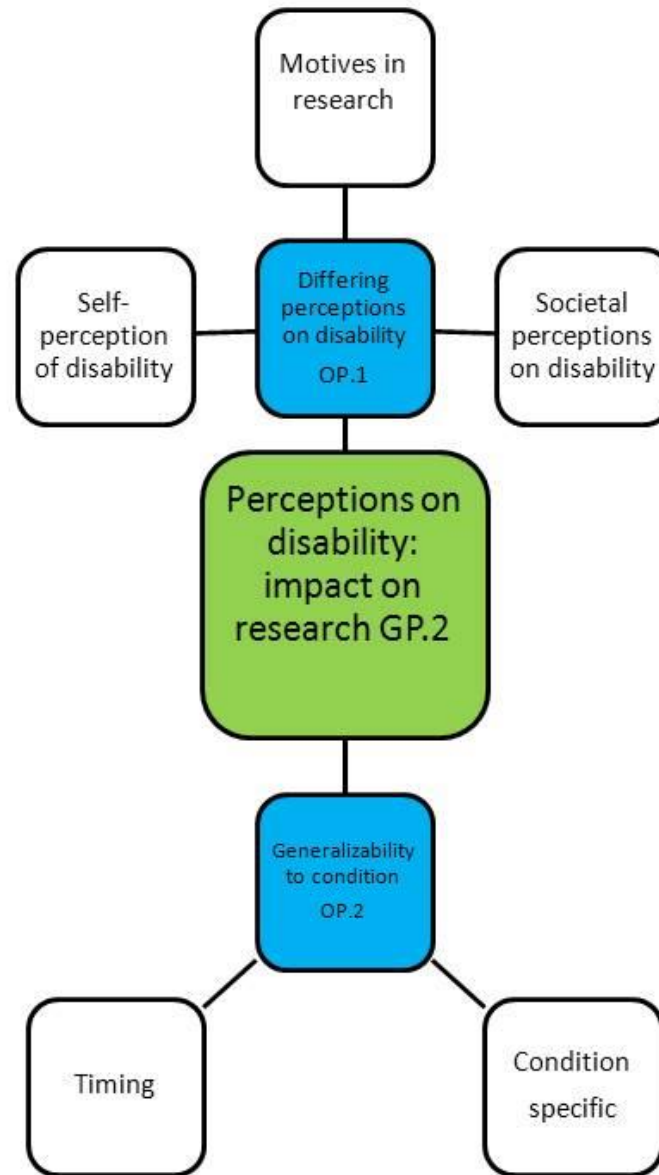
#### **Organizing Participant theme (OP.4): Health benefits**

Health benefits analysed for most significance and interpreted to have had an impact on individual daily living experiences in real-life contexts included; pain relief, comfort, more normal feeling and awareness, benefit realised by improved posture, muscle tension and functionality.

#### **Organizing Participant theme (OP.5): Adverse effects**

Significant findings included difficulty with donning thus reducing independence and physical appearance or discomfort from tightness especially in warmer months.

Figure 6.3 'Thematic map' for Global Participant theme (GP.2): Perceptions of disability: impact on research



## **6.2.2 Global Participant theme (GP.2): Perceptions of disability: impact on research**

The sub-themes (organizing themes) that underpin the superordinate (global) theme (**GP.2: Perceptions of disability: impact on research**) include two key categories. These sub-themes are presented as **Organizing themes: (OP.1) Differing perceptions of disability**; and **(OP.2) Generalizability to condition**. A 'Thematic map' for **Global Participant theme (GP.2): Perceptions of disability: impact on research** is presented (in **Figure 6.3**) for clarification of the analytic categorisation used. The themes are subsequently presented and analysed below.

### **6.2.2.1 Organizing Participant theme (OP.1): Differing perceptions of disability**

In analysis of the transcript data it was found the differing perceptions of disability had an impact on the study experience. The sub-theme **(OP.1): Differing perceptions of disability** was comprised of three distinct categories of perceptions in disability: self-perception, societal perceptions and perceptions within research itself.

#### **Sub-theme: Self-perceptions of disability**

Firstly it was found significant that people with disability viewed themselves from different perspectives. Several participants were concerned with their appearance as a means of expressing their personality and how the orthotic should complement this. This was presented earlier, (in **GP.1; OP.2: DEFO Acceptability, Appearance**) with regards to acceptability and the importance of a choice in colour of the DEFO. Another sentiment raised was of wanting to be 'accepted' for who they are, regardless of any difference. Indeed for some the personalised concept was extended in that they were happy to wear the DEFO as an emblem. It demonstrated individuality and clearly identified their needs to other people. Others indicated their frustration at being different and keen to be seen as 'normal'. Another person's perspective of her disability was one of reluctant acceptance. The findings highlighted different attitudes towards people with disability. Findings were also analysed in light of how self-perception in

disability is linked to personal motivation and how this impacts on realistic goal setting (Seigert and Taylor, 2004).

One participant was quite clear his disability was a part of him, another facet of his persona. It rankled with him that people he knew appeared to view him differently since his stroke:

*'It's more what people might say... this is just part of the stroke... But, I would just wear it anyway. I coloured it to show it is a part of me'. (P01)*

This participant was keen to embrace the DEFO as an extension of his personality in terms of choice of colour, purple (**Figure 7.2**). This participant was keen to promote his personality and was recognised by the local community for his usual flamboyant appearance. This was in direct contrast to one participant's perspective it appeared she was keen to 'fit in' with nothing drawing attention to her disability (**P19**) (p.150).

Equally it should not be underestimated how people reacted to 'feeling more normal' when wearing the DEFO. Two participants were clear that it had a beneficial effect of enhancing awareness and making their limb feel 'good':

*'...seemed to be much more aware of it. It obviously felt good...' (P04)*

*'... it was... beneficial and yeah, it was like helping my mind as well it was definitely helping me too'. (P10)*

One participant's comments can be interpreted as resignation to her acquired disability and a matter of coming to terms with this predicament. This is 'how it is', significant change is unlikely:

*'...it was not able to keep my hand straight enough to paint my nails, but then I think this will never happen'. (P24)*

This could be further explored; how individuals with different perceptions on their own disability are able to select achievable goals in the GAS. The work by Ashford and Turner-Stokes, (2006) suggests goal setting requires skill. This is explained further by Wade and Bovend'Eerdt, (2010) in that the goal is 'SMART' (**Chapter 3.6**). Clinicians who use the GAS in clinical practice report an initial

learning curve in selecting and guiding appropriate goals. This skill was reported to become easier with experience and routine use.

Self-perception in people with a long term condition is difficult, with reported need for specialist care to guide and assist in developing strategies for adjustment (Korwin-Piotrowska *et al.*, 2010). It can be argued social acceptance of disability is equally challenging.

### **Sub-theme: Societal perceptions of disability**

Findings also introduced the impact of societal perceptions on disability. This was discovered in the comments by participants on how the wearing of the DEFO had a different impact on the people around them. It was proposed an invisible line was drawn between what was socially (and culturally) acceptable and what was not. Judgments in society are often based on physical appearance and society is keen to categorise people accordingly (Wa Munyi, 2014). It also appeared to be important to the individual how others (in society) saw them. This relationship between the individual and where they fitted in society is both interesting and worth exploring further.

There were positive and negatives findings in how the DEFO was received within the local community. These perspectives are viewed through the eyes of people with disability and in one case (with aphasia) his partner. Some reported curiosity and interest, some reported blatant bias when confronted by difference and others described reactions that were more embracing with appropriate offers of help.

*'There is always this thing... people would look ...I know it was flesh coloured even with the tone...throughout summer...it would not be as acceptable if you had got short sleeves. It was OK! ...if ... at home but if ... outside in the summer without a jacket...There is always this thing... people would look'. (P04)*

The reaction to the participant wearing a DEFO by friends and others in the community was surprising in that although they knew he had a disability, they saw the new splint as something for an orthopaedic condition with potential to be fixed. It links to his previous role as a sportsman. Perhaps this was seen as more 'acceptable' in that it was something people could understand.

*'It's like people say what have you done? I've had a stroke and they know that but this is just part of the stroke and that's why I'm wearing it and they all thought I had done something to my arm like broken it or something'. (P01)*

The concept of wearing the orthosis for reasons of cueing the public was raised by one participant. This medicalisation of the DEFO was seen in a positive light in that it provided an appropriate visual aid for people to respond in an acceptable way.

*'...as a physical cue for other people for if you have something wrong with your limb to be helpful for other people 'cause if you have nothing on they are not aware you have a problem'. (P21)*

Although this was seen as a positive by the participant above there is still an invisible line. This in essence is who to help and how much help people with disability want, or need. The dialogue continues to be difficult with each situation and individual perceptions on disability. The reluctance from both parties to confront this issue openly perpetuates the societal categorisation of 'them and us'. This is entrenched in the natural order of society as it continues to categorise us all.

### **Sub-theme: Perceptions of disability and motivation in research**

From the collective comments on rationale for joining the research study a number of categories emerged. This varied from being pleased to be even considered and taking it as an opportunity that could serve of benefit personally and to others. This was interpreted to mean that the profile of disability was raised by involvement in research. The suggestion of appreciation yet accountability to represent others with disability was encountered. It was also suggested that research should mirror real life for someone with disability.

*'...life has been quite complicated so....then it has been a true indication of like life...'. (P21)*

This sentiment was interpreted to mean that it is important to participate in research as living with acquired disability is complicated; so this is worth measuring. This was in contrast to her belief that people with stroke do not have

the level of motivation required to undertake research that involved following a protocol (p. 148). This understanding is supported by the findings of stroke services Maclean and colleagues (2000) which suggest the personality trait model of motivation prevails in rehabilitation. However recent studies on stroke rehabilitation have reported the benefits of 'lived motivation' using methods of interactive technologies to tap into the underpinning theoretical models of motivation (Balaam *et al.*, 2011).

Participant motivation is worth exploring in all research studies and should be reported as it is likely to impact on compliance and bias in the findings. It was also suggested in an expectation by two participants (**P18**) and (**P20**) (p.147) in terms of access for more therapy. This was a further consideration in how the research study was perceived by participants who considered the physiotherapy research component important in the management of their disability.

*'I thought it went well, except for like I said, I didn't have no physio with it. ...but I think it would have been better to have had physio more often definitely. ...'cause I don't think it would work unless you was having physio anyway'. (P11)*

This participant had pre-conceived ideas on how much therapy the research entailed despite clear indications in the PIS (**Appendix 4**). Her findings were not corroborated with the physiotherapy intervention record and clinical records. In fact, she had regular contact with the physiotherapist (210 minutes). Again this links back to expectations in research and how experiences are reported from different perspectives.

In contrast the link identified between undertaking research now and how it helps others in the future was underlined as previously reported (**P19**) and (**P20**) in **GP.1; OP.1 Research expectations, Health benefits for others.**

*'It was good to be selected, I was more than happy to take part there was no troubles throughout. Everyone has been helpful. I appreciate being a part of the study. ...to benefit others in the future that was the main reason.'* (**P18**)

The sub-theme of differing perceptions of disability was exemplified by real-life issues of complexity in clinical research. The underlying issues of expectations, motivation, self-image, self-perception, societal perspectives and research perceptions were all explored.

#### **6.2.2.2 Organizing Participant theme (OP.2): Generalizability to condition**

Participants had strong opinions on how the intervention should be optimally delivered, to whom and when. The sub-theme **(OP.2): Generalizability to condition** was comprised of two distinct categories; diagnostic condition and timing.

##### **Sub-theme: Condition specific**

The experience of one participant with a progressive condition was significant. Despite reporting early improvements, it became apparent that her underlying progressive condition had an impact on research experience. She recognised her condition was deteriorating which contributed to the negative experience.

*'It was good, it would have been really good if I hadn't been in such a bad condition. I think I wish I had had it before it got that bad. ...If I didn't have a problem like I did at the end that would have been fine to wear it... That would have been good.'* (P11)

She says 'if it worked' with the inference that it had not. In fact it did help initially. This finding is a further example of the difficulty in undertaking research in progressive conditions like those in neurological conditions with moving baseline and pattern.

*'There was definitely a difference in the first three or four weeks...The foot was in shape more...and it just felt like I was able to lift it a bit better and shape, so I thought it was great.'* (P11)

This finding is relevant in that it points out the rationale for condition specific intervention with the idea that early intervention may be more useful in some conditions or with stratification.



### **Sub-theme: Timing**

Timing of the intervention was highlighted for relevance with optimal generalizability of the intervention. Timing for the intervention was considered firstly from the perspective of when it was likely to be of optimum benefit in the broader sense in a condition within a progressive disease trajectory. Secondly it was considered within a more specific treatment programme for those with time-limited rehabilitation potential. The above were highlighted by participants with long-term conditions:

*'I think people should have it a bit earlier ... It was a bit late for mine because if I had had it earlier I think it would have been fine'. (P11)*

*'...at six months the benefits are more obvious... there is a lot more to it. It feels like it has done some good...like I said a greater timespan would have been better'. (P01)*

As the intervention was introduced within a time-dependent window of opportunity it was not surprising the generalizability was linked to the effects of the BT. Timing of the combined intervention was deemed crucial. The long term effect of the DEFO was reported to have a positive effect. It was inferred that the orthotic effect should have been measured for a longer period. The argument could be taken further; to investigate the DEFO intervention in spasticity prior to dependency on BT.

*'Yes it worked for me but now it has umm tightened up again as Botox has worn off. It was great because my arm was nice and straight to start off with but now the Botox has been wearing off, so it is closing back down again'. (P24)*

*'By the time we got it, it was pretty much six weeks, after the event. I think the idea was to get it within a few days whilst the hand was still supple'. (P16)*

In order for the intervention to be acceptable to people with a wide range of conditions and for use in a wide variety of settings it was deliberately customised to the individual. This was supported by earlier evidence (**GP.1: (OP.2): DEFO Acceptability, (OP.4): Health benefits**) on acceptability and

health benefits for example with participant (**P21**) using her hand on a frame whilst out food shopping.

### **Summary**

From analysis of the findings there were a number of relevant and interesting themes. A summary of the key points in each **Organizing theme** is presented below:

**Summary Global Participant theme (GP.2): Perceptions of disability: impact on research**

**Organizing Participant theme (OP.1) Differing perceptions of disability**

The significant findings included underlying issues of self-perception, image and acceptability of disability. Societal and research attitudes and behaviours based on perceptions in disability were found to have an impact on the acceptability of the DEFO.

**Organizing Participant theme (OP.2) Generalizability to condition.**

From the findings; timing was preferred earlier in treatment cycle, for a longer period and earlier in condition management.

### 6.3 Clinician feedback

Data is presented from the follow-up qualitative Topic Guided interviews (**Appendix 11**) of the clinicians (**C1**), (**C2**) and (**C3**), who delivered the physiotherapy and clinical management of the intervention in the pilot RCT.

Of the clinicians two were experienced specialist stroke and neurorehabilitation physiotherapists with advanced postgraduate knowledge and skills in spasticity management with BT. They provided delivery of physiotherapy interventions as required to all participants in the pilot RCT component of the study. Both were employed by the community NHS health company provider. The third clinician had knowledge and skills in paediatric physiotherapy and was a trained assessor and fitter of DMO and provided the DEFO intervention in the study. This clinician was employed by the Health technology company (**Chapter 4.1** Participants and setting).

Framework analytic approach for Thematic Analysis is exemplified in **Appendix 15**. The topics discussed in the interviews were on the clinician experiences: motives in joining the study, their clinical experience of the protocol delivery and DEFO intervention. Feedback, both positive and negative, was asked of them. A representation of the Thematic Analysis of the clinician interview findings is presented, (in **Figure 6.4**).

#### 6.3.1 Global Clinician theme (GC.1): Research impact on clinical practice

The topic guided interviews of the clinicians revealed a depth of critical thinking and reflective practice on the impact of the research on their practice. This is presented diagrammatically as a 'Thematic map', (in **Figure 6.5**) of the key themes drawn from the analytic approach: basic to organizing to global themes. The sub-themes are comprised of the **Organizing Clinician themes (OC.1): Research expectations**, (**OC.2): Ethical issues**, (**OC.3): Clinical practice**, (**OC.4): Research experience**. The findings are presented and interpreted with evidence theme by theme.

Figure 6.4 Thematic Analysis of clinician interview findings; colour coded for categories

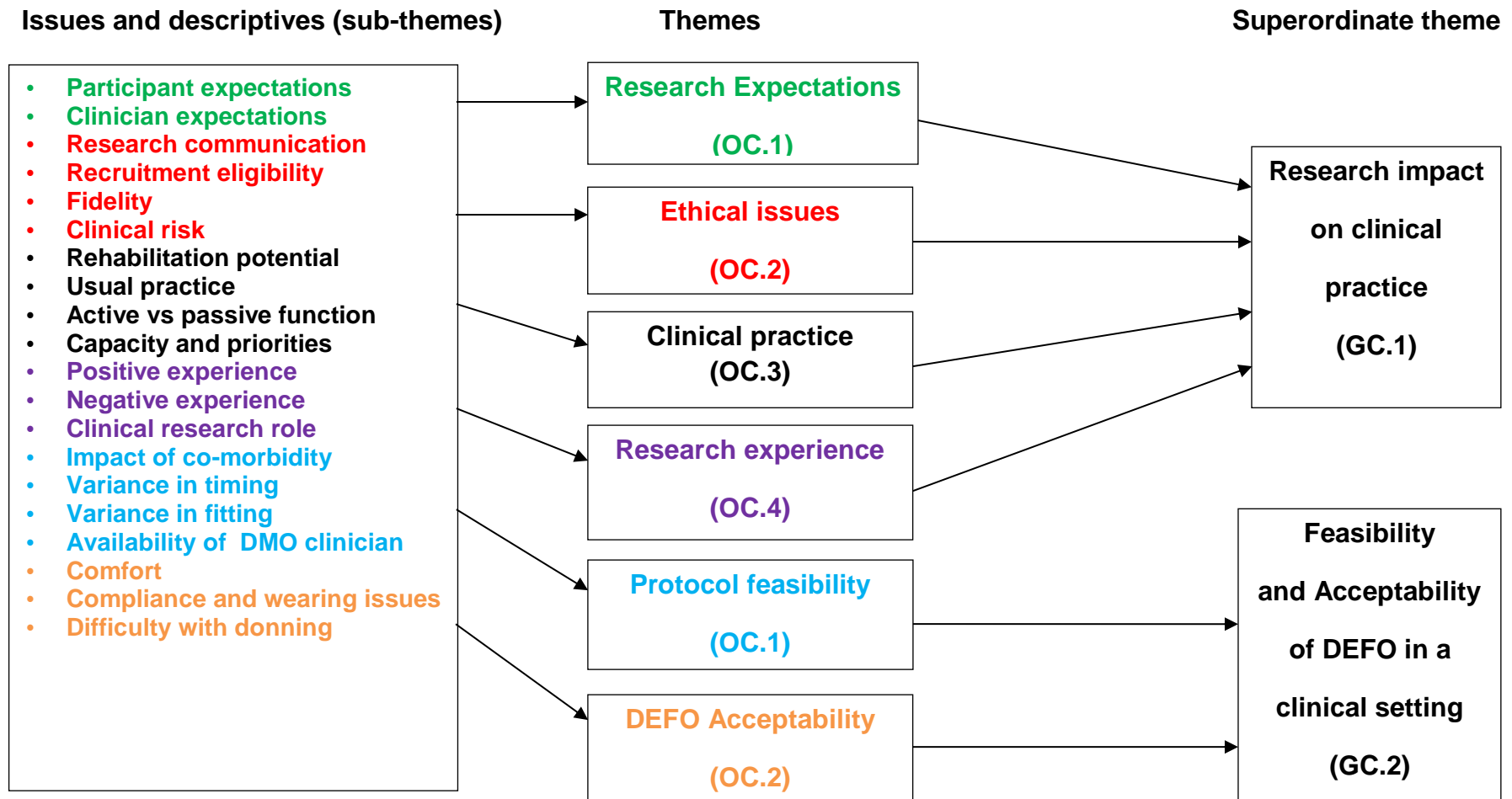
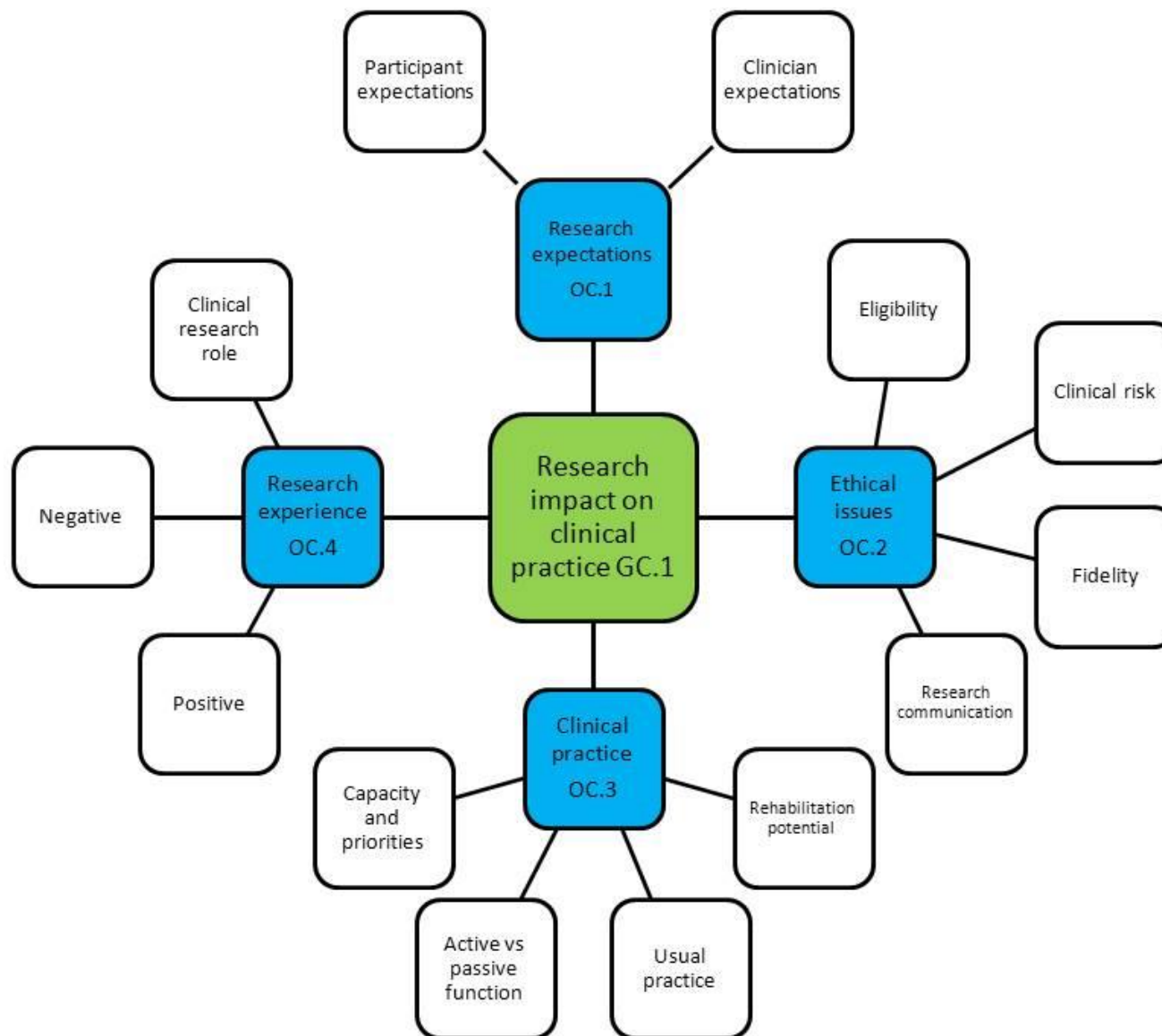


Figure 6.5 'Thematic map' for Global Clinician theme (GC.1): Research impact on clinical practice



### 6.3.1.1 Organizing Clinician theme (OC.1): Research expectations

#### Sub-theme: Clinician expectations

Expectations were raised by the clinicians from personal, professional and participant perspectives. This was a recurrent theme across all three clinicians as it was reported to impact on their 'therapeutic relationship' with the participant.

*'...discussing expectations and making it clear what it can and can't do and that is something I was unable to discuss with them'. (C1)*

It could be linked to what is taken as usual clinical practice in that expectations are part and parcel of planning therapeutic intervention. This expectation was possibly heightened due to the opportunity to try something new. This was the BT injection in some cases and in others the research:

*'...elevated expectations on what being on a research project might achieve...sometimes with passive function there is elevated expectations about what the injection might achieve... it was a matter of managing those expectations'. (C2)*

She went on to explain her role as she understood it. She described from an observed participant perspective with the understanding that her role was also to provide clarity in managing elevated expectations:

*'...people saw this new opportunity and wanted to grasp it... they... just hold on to hope, and just hold on to anything that's going'. (C2)*

This level of expectation was also observed by her colleague:

*'...they had already trawled through all the other options and this was something novel and new that could help them... they were intrigued by the actual product some of them...What's this sleeve? sort of thing and what can it do for me?' (C3)*

These concerns were tempered in that she was aware the research had a process for managing over ambitious expectations. This was done through the

participant information sheet (**Appendix 4**) and opportunities for discussion prior to commencing the study and clinical feedback throughout.

*'...which I know was done at every step of the research anyway'. (C2)*

### **Sub-theme: Participant expectations**

Although it was considered that all participants recruited were willing (by consent) and enthusiastic to undertake the research there was an undercurrent of disappointment in some of the control group following news of group allocation:

*'...those you did recruit they were all willing, certainly the ones I met and wanted to be a part of it erm...and of course some were disappointed when they were not in the intervention group'. (C3)*

From another perspective there was possibly added pressure on the participants from the carers.

*'...all the carers I worked with were quite positive, as positive as the participant and sometimes even more positive than the participant'. (C2)*

From the above it was important to acknowledge that pre-conceived expectations could influence the study experience from both the clinician and the participant perspective. It was considered particularly relevant that both could openly discuss what, if any, likely outcome could be achieved as in normal clinical practice (in a therapeutic relationship) and this was not possible in the research as it was perceived as a potential bias for the outcome.

#### **6.3.1.2 Organizing Clinician theme (OC.2): Ethical issues**

From an ethical perspective there were three issues raised by the clinicians that were categorised: eligibility, clinical risk, research communication and fidelity. These comprised the sub-theme (**OC.2): Ethical issues**. The emergent themes are analysed and presented below.

### **Sub-theme: Eligibility**

From early stage implementation of the research in clinical practice discussions around criteria for study eligibility took place. This was of particular concern for the DM Orthotics Ltd<sup>®</sup> clinician as she was applying the DEFO to a new client group.

*'...little things that we ironed out at the beginning' (C1)*

The eligibility criteria 'little things' presented a potential stumbling block to further recruitment but were sorted out by further clarification in the Research Reference Group (RRG). This was with definitions of the inclusion and exclusion criteria (**Appendix 15**). This important issue was carefully considered and is presented in a reflective diary (p.256). The role of effective communication in research was taken seriously and RRG (**Chapter 8.1.2 and 8.1.3**) meetings helped with the communication between clinicians and the principal researcher.

### **Sub-theme: Clinical risk**

A further ethical consideration was raised from a clinical perspective when the dichotomy of continuing with the research protocol or clinical need was discussed. An issue of potential clinical risk was raised when one participant highlighted a clinical need in a joint (hyperextending knee) above his DEFO. Another potential clinical issue of risk was raised in a participant with higher levels of spasticity.

*'it was unlikely the sock would help that and it was a concern' (C1)*

*'Holding her ankle I didn't feel the DEFO could achieve that'. (C1)*

*'it was one issue...knowing what was safe and what not ...so the study follows the clinical needs and that is fine. It was just that this is the first time I had done anything like this and I wasn't sure if I was upsetting the research study and that clarifies it'. (C3)*

Potential clinical safety issues were prioritised. The uncertainty of how this should be managed in clinical research was ethically clarified by supervision; clinical risk taking precedence over any research protocol (**Chapter 8.1**).



### **Sub-theme: Fidelity**

Two issues of fidelity were discussed. The first was around the delivery of usual care and physiotherapy and the second was when one participant absolutely refused to wear the DEFO.

*'I tried to just deliver just standard physiotherapy that I would normally do'. (C2)*

*'one that just did not get on with the splint and said that she was not going to wear it' (C2)*

The former example of fidelity reinforces the clinicians understanding of her role in the research delivery. This is supported by examples of her clinical practice in promoting self-efficacy and not dependency which are presented below. The latter example was a disappointing result for both the clinician and the participant. It was previously presented from the participant's perspective (**OP.5: Adverse effects (P16)**) and clinician's perspective of non-compliance. Proof of fidelity is an important reflection of how feasible the intervention was in clinical practice.

### **Sub-theme: Research communication**

All clinicians described a good level of communication between the research secretary and from the RRG (**Chapter 8.1.3**). This was essential from a feasibility perspective for the timely delivery of the protocol. The procedural impact of good communication meant things could run smoothly:

*'...the communication was good' (C1)*

*'...on the whole I think it was fine, it went well and the communication meetings helped as well. Erm... and we were in regular phone contact...'*  
(C2)

*'I think I was quite fortunate in that I have close links with the consultant clinics so I knew who was going to and coming out of the clinic and it was just knowing those patients, being ahead of the game. That helped.'* (C3)

However this was not always the experience of one clinician. From her perspective the communication was 'hit and miss' with reliance on Spasticity Clinic letter for specific details on the BT injection. In some instances she was reliant on participants or carers informing her. This was not ideal as details may have been unreliable.

*'I didn't always get the clinic letter in the most-timely fashion... I didn't always have the clinic letter telling me where the injection was so I was often reliant upon the erm... the research subject or their partner to tell me and that was sometimes a bit vague.'* (C2)

A further issue on communication was raised regarding the difficulty of communication due to the blinding. The issues of research uncertainty were directed to the supervisor for clarity and clinical issues had to be resolved by the clinicians.

### **6.3.1.3 Organizing Clinician theme (OC.3): Clinical practice**

There were a number of significant issues discussed and analysed as complexity in clinical practice. These categories included: clinical perspectives on rehabilitation, motivation, activity levels, models of delivery and practice issues of capacity and interface with private physiotherapy. These are grouped into the sub-theme **(OC.3): Clinical practice**.

#### **Sub-theme: Usual practice**

Discussion on clinical practice raised issues on the content of usual practice and individual perspectives on rehabilitation and its delivery. For instance one clinician was clear that her normal role was being extended in the research study:

*'...to learn my role which was different from my normal role and to see the use of the DEFO'S being used in a slightly different client group was still I think beneficial'. (C1)*

She was explicit in that the clients she normally saw in her role had different criteria than in the study. She was also used to seeing clients with more activity. In addition she was used to assessing and providing the orthotics in a less prescriptive way from the restrictions of the study protocol:

*'...99 percent of the time I would only prescribe the orthosis if I saw activity or a level of activity and many of the participants did not'. (C1)*

*'I was only able to go in to supply a sock or glove and not look more centrally...more centrally rather than distally'. (C1)*

This raises the possibility of conflicting expectations and tensions in research that is collaborative with industry. How this was managed is discussed in **Chapter 8.2** and reflected on at the end of the thesis.

From a perspective of usual practice the clinicians described difficulty and awkwardness in not being able to discuss the treatment intervention and expected outcome(s) with participants.

*'...not to put ideas into people's minds so it was completely neutral' (C1)*

*'promoting self-efficacy and self-management strategies, yet: ... just knowing when it is appropriate to do more hands on erm and just explaining every step of the way, and hopefully educating people as much as possible so they can understand the perspective I am coming from'. (C2)*

The clinician (C2) was clear about her usual practice role and this was unchanged in the research delivery. It is 'normal' practice for a clinician to discuss care based on the evidence about what is likely to help with a specific condition and the rationale why an intervention is done.

### **Sub-theme: Active versus passive function**

Clinical practice in common terms was repeatedly described from a reflection of usual practice and supported by evidence of efficacy in the literature. Both (C1) and (C2) explored practice issues around 'active' versus 'passive' function and respective treatment options. One clinician (C2) repeatedly emphasised her preferred practice: working more actively at function. On the other hand she was dismissive of her role in more passive care.

*'...nice to have seen more participants who were injected for active function. ...one chap that I didn't know from before the study and his goals were in fact for active function so I found that exciting and really enjoyed treating him...I felt he did really well with the combination of physiotherapy, injection and DMO (DEFO)'.(C2)*

*'...the majority of participants were being injected for passive function and there was a slightly limited role that physiotherapy could play...my input was always going to be fairly limited... someone that was injected for passive function only, rather than more active function'. (C2)*

This was not the view of another clinician (C1) who appeared more open to change in practice:

*'...if there was a perceived benefit from wearing it that opens up my practice again'. (C1)*

### **Sub-theme: Rehabilitation potential**

However in this respect the further issue of rehabilitation potential was introduced opening up the debate around 'how useful is physiotherapy in people with passive function only'?

*'...patients I have seen in the past and I knew what their rehab potential and their capacity for participating in a rehab programme was'. (C3)*

The rehabilitation potential for each individual was also considered from a wider perspective acknowledging the importance of belief systems and the ethical role and responsibility of the clinician. This was supported by the evidence that links

rehabilitation to behavioural motivation and goal setting (Seigert and Taylor, 2004; Broetz and Birbaumer, 2013). Reflections of her colleague appear to support this:

*'you are hailed as somebody who might help them get back to pre-morbid level of ability...and I have always tried to be realistic with people erm... without shattering their hopes and dreams... because there is a lot of evidence in stroke rehab in terms of the benefit of hope in maintaining peoples motivation and things like that'. (C2)*

A further theme that emerged from the interviews was on the usual practice of promoting self-efficacy rather than dependency.

*'I try to steer away from creating dependency for people I work with'. (C2)*

In addition it was problematic for the clinicians to have to discuss goals with participants who had been following a programme before and the rehabilitation phase in their care was completed. This was challenging:

*'I had to still generate goals with people that I had very recently discharged. ... sometimes that felt a little bit awkward'. (C2)*

This aspect of rehabilitation was possibly more participant focussed by one clinician she recognised therapy was not the only drive for setting goals.

*'...based on what the patients wanted to do.' (C3)*

Indeed many of the goals for people with 'passive function' or care needs were centred on opening out their hand for hygiene care and social reasons (painting nails). This is evidenced in the summary table of goals set, (**Table 5.17**, in **Chapter 5.5**).

### **Sub-theme: Interface with private physiotherapy**

In addition the issue of impact of the research was raised on the interface between usual practice roles of private physiotherapy providers and NHS physiotherapy. This provided a potential conflict in practice:

*'injection for passive function...patients were already seeing private physiotherapists and sometimes that brings a few challenges with itself...we are going down a more maintenance, passive function route and sometimes other people may have slightly different goals that are slightly more optimistic'. (C2)*

This tension was especially challenging for this clinician whose practice promoted self-efficacy. This was particularly in participants who were injected for 'passive' function only, rather than more 'active' function. A potential conflict in professional practice was raised with clinical accountability and communication of clinical reasoning.

*'I would get in touch with the private practitioner and that was standard practice anyway –if you know that somebody else is treating someone you are treating ...so I just stuck to my guns and did what I thought was the right thing to do and particularly if I had seen the patient fairly recently'. (C2)*

This raises the issue of defining the focus of the practice, from the participant/patient or from the service provider. This provides a link to treatment efficacy and professional practice issues in rehabilitation. Clarity around treatment effects and defining achievable goals are important physiotherapy roles. Interface tensions were also echoed by the participants in experiences of conflicts around access to therapy and funding for equipment. There was also an underlying theme raised around perceptions of disability and different perspectives. These issues are discussed further in **Chapter 8**.

### **Sub-theme: Capacity and priorities**

A theme that links closely with protocol feasibility includes: capacity and prioritisation. The capacity of one clinician (**C1**) was pre-set with agreement for planned clinics. However this was not the experience of another clinician:

*'...the time with the constraints of trying to shoe-horn patients in because (DMO clinician name) as you know could only visit the area on certain days...trying to meet the deadlines especially due to having to liaise with someone who was only part time and not in the area'. (C3)*

*'...the patient needed to be available for treatment to follow the protocol and it didn't always suit their diary or mine...I had other commitments elsewhere, I had leave or meetings elsewhere'. (C3)*

A similar experience highlighted the importance of research team communication:

*'I didn't always get the clinic letter in the most-timely fashion...so I was often reliant upon the erm... the research subject or their partner to tell me and that was sometimes a bit vague'. (C2)*

This added another level of pressure on the clinicians as new systems were introduced by the research and were not always found reliable. The increased pressure on capacity for one clinician resulted in her seeing participants that she was not expecting referrals for.

*'I wasn't able to attend them all so some of the recruits came from clinics I hadn't been at'. (C2)*

The research was considered to have a significant impact on the existing clinical role and capacity of the clinicians, which required careful monitoring and management.

#### **6.3.1.4 Organizing Clinician theme (OC.4): Research experience**

Next the coded data provided emerging themes from the lived research experience and these are analysed. They are primarily reported from a perspective of clinicians with limited previous experience in clinical research. They include categories of positive and negative experiences and difference in existing roles and inform the sub-theme **(OC.4): Research experience**.

##### **Sub-theme: Positive experiences: Learning experience and Clinical research role**

All three clinician's reported positive feedback in emotional terms as well as with a *'learning experience'*. This provides evidence of professional and personal development. It was reflected on by one clinician from an emotional touch-point:

*'I think it has boosted my confidence and increased my interest to get back onto my research'. (C3)*

*'I am also very proud and I do think we should be promoting it (research) in our service as clinicians'. (C3)*

She also explained her sense of belonging to an area of clinical practice as an experienced clinician:

*'It was just nice to be part of a developing world...as such... cause the field of neurology is developing all the time and it's nice to feel a part of it and it's nice to be a part of your development'. (C3)*

An alternative experience was expressed by another clinician. This 'research' was a new experience for her. However two clinicians were a little more experienced and saw research as integral to their roles:

*'...the first time I have been involved in that particular role and it was great to do it and I would like to do more'. (C1)*

*'...interesting to be actually a part of a local research project and I see it as part of my role as clinical specialist to take up these opportunities as they arise'. (C2)*

*'...as a clinical specialist I should be up there doing research whether it is data collection or analysis or clinical intervention and whatever it should be should be part of my job role... it made more sense to my working practice being involved in research' (C3)*

The latter clinician went on to explain how it made more sense of her practice. This introduces the idea of critical thinking in practice as an important component which can be used to bridge the research practice gap. She outlines her ambition:

*'I would like to build links between clinicians and researchers, 'cause I think that interface...is lacking'. (C3)*



### **Sub-theme: Different from usual role**

In one clinician's interview she described learning in a research role that was different from her current role and provided a real opportunity:

*'... a number of ways but one way was to just to learn my role which was different from my normal role... at times that was complicated for my mind so it took a bit of time to understand the reason for the research'.*

**(C1)**

*'...to see the use of the DEFO'S being used in a slightly different client group was still I think beneficial...it opens up my thoughts and my practice and that is really good'.* **(C1)**

Learning experience was valued by the clinicians in that the research was supportive with good communication in the RRG.

*'...it felt nice to be part of a team'.* **(C2)**

*'I felt it was a novel idea so it was going to be a learning experience for me about the research as well as the product and how it can be used'.*

**(C3)**

This introduces the idea of humility required as the expert clinicians are immersed in an unfamiliar learning situation and become a 'novice' in the research world along the continuum towards being an expert (research) practitioner (Benner, 2001). Certainly this experience outlines the journey for continuing professional development and learning towards enhanced skills of critical thinking (Hawkins and Shohet, 2011) and reflective practice (Schon, 1980) needed in research.

The complexity and difficulty of undertaking research in real-life; clinical practice was also highlighted in examples of maintaining blinding and non-bias.

*'I did find difficult was trying to talk about the research without un-blinding it for you'.* **(C3)**

It was apparent that each clinician held a personal perspective from which the research was experienced.

*'...very interested in research so want to promote good research in the area and DEFO's because that is the area I am involved in'. (C1)*

*'...it was also nice to be involved with a new product that I had not been familiar with so that was a positive... to think there are new things coming through all the time'. (C3)*

*'I tried to just deliver just standard physiotherapy that I would normally do'. (C2)*

There were differences in experience of the skills needed to undertake clinical research.

**Sub-theme: Negative experiences: Recruitment, eligibility and capacity issues**

There were few negative experiences reported, however these were commonly linked to recruitment pressures, clinical capacity and debate around the study eligibility criteria previously outlined.

The most significant negative experience was reported as a sudden increase in new participants following recruitment at the beginning of the study. This was subsequently monitored and managed:

*'5 new referrals came in that did feel initially quite a lot to fit in with the existing caseload... the first couple of months just felt quite busy... it seemed to even out'.. (C2)*

*'...stress came from the time constraints of the protocol and I understand the protocol has to have time constraints but there were times when I got frustrated because of my other caseload was being sacrificed for the protocol and we can't stop the research protocol because of caseload but it was difficult sometimes to fit it in'. (C3)*

This negative experience was reported with competing tensions in capacity from practice and research. The experiences were interpreted as emotive reactions to uncertainty and loss of control with conflicting priorities from caseload and the research input. This is again linked to the unfamiliar territory as a 'novice' undertaking clinical research whilst doing the day job.

*'to start with it was all a bit like oh my goodness I've got all of this to do on top of everything else, but it did settle down as I became more proficient with the paperwork and I worked out what we had to do and what we didn't have to do'. (C3)*

## Summary

From analysis of the findings there were a number of relevant and interesting themes. A summary of the key points in each **Organizing theme** is presented below:

### **Summary of key points: Global Clinician theme (GC.1): Research impact on clinical practice**

#### **Organizing Clinician theme (OC.1): Research expectations**

Personal, professional and participant expectations and motives were analysed of which the most significant finding was the elevated expectations of the participants and sometimes carers.

#### **Organizing Clinician theme (OC.2): Ethical issues**

Key findings of significance included ethical research clarification on eligibility criteria and clinical risk. The communication was effective in keeping the research on track and there was evidence of procedural fidelity reported.

#### **Organizing Clinician theme (OC.3): Clinical practice**

Clinicians showed an overall preference for clinical practice with people who have more active vs passive function and rehabilitation potential and delivery by promotion of self-efficacy. Both clinical capacity and clinical risk prioritisation were found to impact on the research delivery. Interface with private therapies suggested conflicting priorities (active vs passive).

#### **Organizing Clinician theme (OC.4): Research experience**

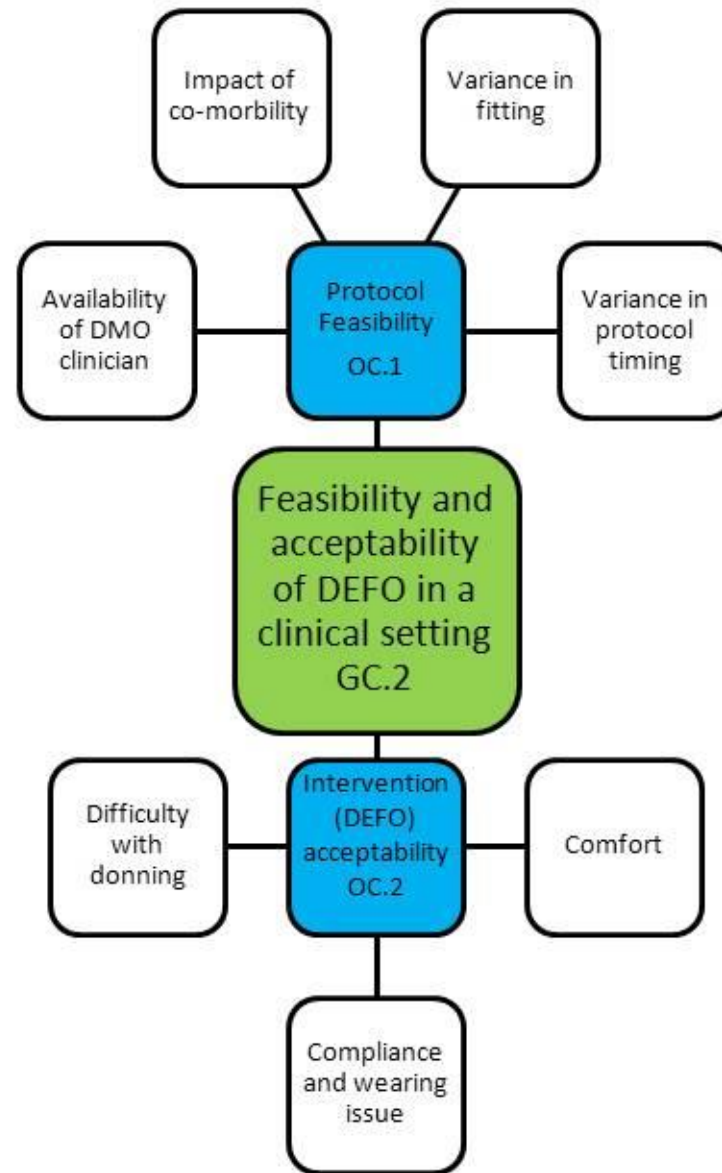
Significant findings included the learning opportunities in research, how the research provided a difference from the usual role and uncertainties around clinical priorities.

### **6.3.2 Global Clinician theme (GC.2): Feasibility and acceptability of DEFO in a clinical setting**

The themes that are outlined below address the research questions on feasibility and acceptability of the DEFO intervention. The issues discussed in the clinician interviews included topics of protocol procedural delivery and variance, and compliance, tolerance and acceptability preferences. These were grouped into two categories that naturally informed the feasibility and acceptability sub-themes. The sub-themes presented include **Organizing Clinician themes: (OC.1): Protocol feasibility and (OC.2): Intervention (DEFO) acceptability**. The presenting themes are evidenced and analysed accordingly.

A 'Thematic map' generated from the clinician interview data for **Global Clinician theme (GC.2) Feasibility and acceptability of DEFO in a clinical setting** is presented below, (in **Figure 6.6**).

Figure 6.6 'Thematic map' for Global Clinician theme (GC.2): Feasibility and acceptability of DEFO in a clinical setting



### 6.3.2.1 Organizing Clinician theme (OC.1): Protocol feasibility

#### Sub-theme: Availability of the DMO Ltd<sup>®</sup> clinician

The procedural feasibility of delivering the protocol in a timely fashion was primarily dependent on the availability of the DMO clinician. Clinics were pre-arranged on a bi-monthly basis; however there were additional environmental and personal factors that influenced this.

*'the flooding'... 'when I was ill' (C1)*

*'...constraints of trying to shoe-horn patients in because (DMO clinician) as you know could only visit the area on certain days' (C3)*

#### Sub-theme: Variance in timing

This availability subsequently had an impact on the timing of the protocol delivery:

*'...it was difficult to keep to the times in the protocol within 2 weeks post BT to have assessed the patient'. (C1)*

This sentiment of pressured timing was repeated by (C3) in that there were competing pressures as a clinician from the clinical caseload. She implied the research protocol took precedence. However this resulted in frustration that she was not in control of her own prioritisation of workload (C3) (pp.186-7). The timing posed a further challenge for (C2) in that the majority of recruits were from the Spasticity clinic in the west of the county which were more frequent. She was unable to attend all of these clinics due to caseload capacity issues:

*'I wasn't able to attend them all so some of the recruits came from clinics I hadn't been at'. (C2)*

*'...the hardest thing about the protocol was just adjusting to basically this patient needed to be seen within a fairly set time frame'. (C2)*

This clinician also received five new recruits in a short space of time which added pressure from a timely delivery perspective. This proved very challenging and raised the issue of controlling recruitment flow:

*'...it was the first couple of months just felt quite busy... it seemed to even out'. (C2)*

The important issue of protocol timing feasibility was resolved with the protocol amendment of the wording and thus the 'assessment **'for' fitting**' was within two weeks (**Chapter 8.1**).

### **Sub-theme: Variance in fitting**

A further issue raised that had an impact on the protocol feasibility was the delivery and variance in fitting of the DEFO. Although the DMO clinician was experienced in assessing and fitting the other clinicians were not. They gave clinical guidance on fitting requirements from a therapeutic perspective and reassurance around trying something new:

*'I was there for every new fitting DMO (DEFO) and without giving bias I was acknowledging it was a bit tricky to get it on. A bit tricky in the very first attempt, but that it generally gets a bit easier- so trying to reassure people that probably with a bit more practice it will get a bit easier'. (C2)*

Variance due to the modifications for customised fitting had a further impact on protocol timing delays:

*'...actual garment itself bunching up a little bit... but in that occasion I think a modification was made. Things like zips could be put in and seams could be addressed'. (C2)*

One participant who had significant issues with the fitting of the DEFO resulted in a predicament for the clinicians. The first DEFO did not fit and the second when it arrived after some delay; she refused to wear it:

*'...one that just did not get on with the splint and said that she was not going to wear it' (C2)*

*'...the participant absolutely didn't want to try it and that was quite difficult' (C1)*

It was within the participant's right to choose not to wear the DEFO. She had full capacity to make the decision.

### **Sub-theme: Impact of co-morbidity**

A further theme for consideration was the impact of co-morbidity on the protocol delivery. A number of participants had underlying health problems requiring medical intervention including antibiotics for urinary infections and seizures requiring modification of medication. This impacted at a clinical level with increased liaison with other health care professionals. This issue resulted in modifications of the physiotherapy interventions depending on the individuals' health and ability to participate.

*'...the individual health of the participant e.g. seizures and pressure sore'*  
**(C2)**

As outlined in all the previous issues above there was an impact on the protocol feasibility which was categorised as a theme **(OC.1): Protocol feasibility**.

### **6.3.2.2 Organizing Clinician theme (OC.2): DEFO intervention acceptability**

#### **Sub-theme: Comfort, compliance and wearing issues**

One of the primary concerns in the study was the question of DEFO acceptability. The findings by one of the clinicians supported that this orthosis is comfortable:

*'...most people would suggest they are comfortable.'* **(C1)**



This was considered by one clinician in more general terms in that she was interested in their experiences both positive and negative:

*'I enjoyed seeing patients experience new treatment and what they found about their experience and whether they thought it was a good idea or not'. (C3)*

Comfort is important for compliance. Poor compliance is commonly reported in wearing of splints and orthotics (Lannin *et al.*, 2007; Kuipers *et al.*, 2009). The findings of this study are positive in general terms for compliance, as was verified by the DEFO wearing log and the comments below:

*'I would have said the compliance was... with the patients I met, really good. They were very compliant with it. They were keen to be a part of it and give it a jolly good go'. (C3)*

This issue on compliance was expressed from another perspective by:

*'...in terms of compliance I think it affected them in terms of having someone around to help them put it on'. (C2)*

*'...there were some concerns about getting it on particularly when they were living alone'. (C3)*

Essentially in order to be compliant with the protocol and putting on the DEFO in some cases with increased dependency levels they were reliant on others both in fitting and wearing times:

*'...she really struggled getting the carers to help her to put it on and it was difficult for her to put it on by herself due to the severity of her tone ... and then having somebody around at the right time to take it off'. (C2)*

A further issue around wearing was raised by a clinician in that one participant worked night shifts which did not impact on wearing compliance but confused him about wearing times. The clinician clarified this. This demonstrated the importance of PPI (INVOLVE, Hanley *et al.*, 2003) for the development phase of informing protocol design to optimise compliance and acceptability.

The option for different colours was raised in the research proposal during the developmental stage. However a neutral colour DEFO was decided upon for consistency. This finding on compliance was raised as some participants were interested in other colour options:

*'...only provided the beige and there is possibility that some may not like that colour and would have preferred a different colour.'* (C1)

The option of different colours was not discussed by the other clinicians who were perhaps used to the medical appearance of splints and orthotics provided in the NHS.

### **Sub-theme: Difficulty with donning**

A specific finding was raised on difficulty with donning of the DEFO. This was either by participants as individuals or with assistance (C2) (p.193). This important issue contributed to the overall acceptability and adherence in wearing the DEFO and following the wearing protocol. It was demonstrated to be dependent on the level of disability and associated carer support.

*'A bit tricky in the very first attempt, but that it generally gets a bit easier-so trying to reassure people that probably with a bit more practice it will get a bit easier.'* (C2)

All the above issues raised were categorised and analysed thematically into the theme (OC.2): **DEFO intervention acceptability**.

### **Summary**

From analysis of the key findings there were a number of relevant and interesting themes. A summary of the key points in each **Organizing theme** is presented below:

**Summary of key points: Global Clinician theme (GC.2): Feasibility and acceptability of DEFO in a clinical setting**

**Organizing Clinician theme (OC.1): Protocol feasibility**

Overall protocol was found to be feasible in the majority of participants. However the availability of the DMO clinician had a direct impact on the protocol delivery with variances in timing and in fitting (**n=2**). Also co-morbidity had a negative impact on protocol feasibility.

**Organizing Clinician theme (OC.2): Intervention (DEFO) acceptability**

The DEFO was acceptable in the majority of participants with good compliance due to comfort and colour. Wearing issues included early difficulty with donning together with reliance on carers.

## **6.4 Summary**

From the findings of participants and clinicians reported experience there is some evidence to support the DEFO as an acceptable intervention in the clinical setting. In addition the protocol was found acceptable in a clinical setting, however the clinicians also reported constraints on capacity due to competing demands from clinical and research practice. The findings provide direction for protocol modification to improve procedural delivery and reduce burden on clinicians involved in clinical research. These are discussed in **Chapter 8**. The narratives tell a vivid account of research experiences. The qualitative analysis provides a storyline of the impact of research in real-life situations. A summary table of the themed topics from the combined interview data findings is presented below, (in **Table 6.1**). Significant findings include differing perspectives in disability that impacted on the research and the learning opportunity for research experience gained by the clinicians. Further significance was surmised from interpretation of the participant accounts of DEFO physical and social cosmetic acceptability. The findings of both participant and clinician data sets are integrated and analysed further, (in **Chapter 7**).

**Table 6.1 Summary of qualitative findings (Thematic Analysis of participant and clinician Topic guided interviews)**

<b>Topics</b>	<b>Participant themes</b>	<b>Participant findings</b>	<b>Clinician themes</b>	<b>Clinician findings</b>
<b>Health benefits</b>	<b>(GP.1) (OP.4) Health Benefits</b>	<b>Physical and Psychosocial benefits:</b> positives > negatives	No emergent theme	Not evidenced directly
<b>Feasibility</b>	<b>(GP.1) (OP.3) Protocol feasibility</b>	<b>Timing:</b> delays in <b>n=2</b> no delays in <b>n=9</b> <b>Protocol:</b> acceptable in <b>n=10</b> not acceptable <b>n=1</b>	<b>(GC.2): (OC.1) Protocol feasibility</b>	Research communication kept things on track Variances: in timing and in fitting ( <b>n=2</b> ) Availability of DMO clinician had a direct impact on protocol delivery Co-morbidity had a negative impact on protocol feasibility Overall protocol was found to be feasible in the majority of participants for both intervention and control groups ( <b>n=22</b> ) The protocol was not acceptable in ( <b>n=1</b> )
<b>Acceptability</b>	<b>(GP.1) (OP.2) DEFO acceptability</b>	<b>Appearance:</b> acceptable in <b>n=10</b> not acceptable <b>n=1</b>	<b>(GC.2):(OC.2) DEFO Acceptability</b>	The DEFO was found acceptable in the majority of participants with good compliance due to comfort and colour. Wearing issues included early difficulty with donning together with reliance on carers.
<b>Other</b>	<b>(GP.1) (OP.1) Research Expectations</b>	Hope and motives expressed for self and others. Individual expectations realised.	<b>(GC.1):(OC.1) Research Expectations</b>	Personal, professional and participant (elevated) expectations and motives expressed.

<p><b>Other (cont'd)</b></p>	<p><b>(OP.5) Adverse Effects</b></p> <p><b>(GP.2) (OP.1) Differing perceptions of disability)</b></p> <p><b>(OP.2) Generalizability to Condition</b></p>	<p>Physical discomfort (sweating, tightness and difficulty with donning. Impact on usual activities.</p> <p>Self-perception, image and acceptability of disability. Societal and research attitudes and behaviours based on perceptions in disability.</p> <p>Timing preferred earlier in treatment cycle and earlier in condition management.</p>	<p><b>(OC.3) Clinical practice</b></p> <p><b>(OC.4) Research experience</b></p> <p><b>(OC.2) Ethical issues</b></p>	<p>Practice issues were cited including usual practice, rehabilitation perspectives and delivery (promoting self-efficacy). Clinicians showed an overall preference for clinical practice with people who have more active vs passive function. Both clinical capacity and clinical risk prioritisation were found to impact on the research delivery. Interface with private therapies suggested conflicting priorities (active vs passive).</p> <p>Both positive and negative research experiences described: learning opportunities in research; difference from the usual role and clinical impact on the research with uncertainties explored.</p> <p>Ethical issues were analysed for research clarification on eligibility criteria and clinical risk. The research was found to have internal integrity with evidence of fidelity in practice reported.</p>
------------------------------	--	--	---	---

## Chapter 7

### Data Integration

#### Key points:

- **Integration of findings**
- **Health benefits**
- **Feasibility**
- **Acceptability and tolerance of the DEFO**
- **Quality framework for study integrated findings**
- **Summary of key findings**

#### Introduction

In this chapter the study findings are considered. This was by integration and interpretation of the findings from both quantitative and qualitative data sets. The former data from the pilot RCT was used to assess the potential effectiveness and feasibility of the DEFO intervention. The latter comprised of key themes gathered from participant and clinician interview feedback. This provided rich and valuable insights of the research feasibility and DEFO acceptability and tolerance. In this chapter the mixed methods approach using embedded design demonstrates how the qualitative findings provide an enhance understanding of the quantitative results.

The reporting of the mixed methods study followed the six-item guidance framework; Good Reporting of a Mixed Methods Study (GRAMMS) (O’Cathain *et al.*, 2008, p.92). The findings follow the method of triangulation protocol (O’Cathain *et al.*, (2010) for consideration of integrated findings regarding agreement or dissonance of the data components. Rigour and quality of both the data sets was established by following a procedural checklist for mixed methods research as advocated by Collins and O’Cathain, (2009, pp.2-6) and Andrew and Halcomb, (2009, p.35). Combined quantitative quality criteria and qualitative study criteria were assessed for truth value, applicability, consistency and neutrality (Sale and Brazil, 2004). In addition each data set was scrutinised by research tutors and statisticians before being presented. The findings were

reviewed for how they addressed the objectives (**Chapter 4.2**) and research questions:

- What is the likelihood of health benefits of treatment with DEFO and physiotherapy (as required) and usual care, compared to usual care alone? (primary question) *Addressed by pilot RCT data and Topic guided interview data combined.*
- What is the feasibility of the protocol (as a small feasibility pilot RCT) to inform the design of a larger study? *Addressed by pilot RCT data and Topic guided interview data combined.*
- How acceptable is the DEFO intervention in clinical practice? *Addressed by Topic guided interview data together with specific wearing data and clinical records.*

In light of the study findings, (in Chapters **5** and **6**) the integrated key issues are presented: health benefits; feasibility of the protocol; and acceptability of the DEFO intervention. Each of these sections is divided into a typology or set of categories which are analysed by combining the quantitative data and qualitative findings, data comparison and integration using a triangulation approach. These are presented in **tables 7.1, 7.2** and **7.3**.

## **7.1 Health benefits**

Uncertainty of the health benefit of DEFO intervention was addressed by findings of the pilot RCT outcome measures and qualitative data which was gathered and analysed from the participant and clinician interviews. They are discussed in terms of: person-centred goals; physical benefits and adverse effects; psychosocial benefits; quality of life and carer burden. The summary of these integrated findings for health benefit are presented, (in **Table 7.1**) and discussed.

## Person centred goals

Findings of the primary measure (**GAS**) for the pilot RCT indicated a tangible health benefit in achievement of health related goals that was significantly different in the DEFO intervention group (95%CI: 3.16 to 21.18;  $p = 0.014$ ). This difference equates to a standardised effect-size of 1.21 (95% confidence interval 0.31–2.10). In this study it cannot be reported with any precision if the effect size is small or large. Due to the wide 95% confidence intervals surrounding this effect-size this is conservatively interpreted as a statistically significant large effect to a non-significant one. In order to improve the precision of the effect-size (i.e. reduce the 95% CIs to a narrower band) there will need a larger population in a future study. As this is a small scale study there is a potential risk of a type I (false positive) error. Further, the effect, although statistically significant, may not be clinically important. An RCT should be powered to detect the smallest effect-size that is of clinical importance (p.244); for instance significant effect-size for the GAS.

Goals identified were personalised to the individual's needs reflecting importance and difficulty (Turner-Stokes, 2003; 2009). The summary table of goals by group (in **Table 5.17, Chapter 5. 5**) provides a snapshot of the goals selected by the participants. From the total of 69 goals there was a similar distribution for both groups which included 14 categories. There were a number of commonly themed goals. These included: goals for gaining functional independence; walking; and splint application; reducing associated reactions, or pain and hand hygiene. The GAS provided a useful reflection of outcome that was both critically important and found to be in context of the person's own life (Ashford and Turner-Stokes, 2006; Ashford, Slade and Turner-Stokes, 2013).

Physiotherapists as clinicians delivering the intervention were best placed in the study to discuss and agree the participant goals, rationalise difficulty and score the baseline. Recovery following brain injury becomes a continuum and needs careful monitoring and challenging to ensure the goals set are realistic and achieved. This was sometimes difficult if the participant was previously known to the physiotherapist and alignment of the goal was not functionally directed or within the clinicians perceived role (**C2**) (p.180). Issues of rehabilitation potential, activity versus passive function and motivation were all discussed as



factors that influenced goal setting (**C3**) (p.180) (**GC.1**): (**OC.3**): **Clinical practice, Active versus passive function, Rehabilitation potential**).

This is supported by evidence that links rehabilitation to motivation and goal setting (Seigert and Taylor, 2004). Equally there was difficulty with setting goals in previously unknown participants. However (**C2**) was clear in her approach with participants who demonstrated more activity (p.180).

A skill is required to implement this tool (GAS) (**Appendix 7**). Measurement was conducted and variance in goal attainment was recorded if not achieved. Considerations included: transport difficulties and financial constraints in attending a gym; even personal factors including level of motivation. This detail of variance was captured in the clinical records and presented as an important factor in the feasibility of the protocol (**Chapter 7.2**). The findings showed person-centred goals were mostly achieved, with a significant positive difference in achievement of DEFO group.

### **Physical benefits**

Health benefits reported by participants were thematically analysed as (**GP.1**); (**OP.4**): **Health benefits** and grouped into two categories: physical and psychosocial. The findings in the physical category included benefits of collective significance for instance pain relief which was linked to reducing tension in the spastic muscles (**P19**) and even further benefit in normalising posture (**P24**). The feeling of comfort and the perception of normalising awareness was also repeatedly described as an added benefit of wearing the DEFO (**P01, P04**) (p.157). This was considered important in terms of acceptability. In addition there were accounts of increased movement which was supported by increased functional use of the limb in individuals where activity was present (**P01, P11, P19**) (p.156).

There was further evidence to support positive and tangible physical health benefits in real-life contexts which were valued by the majority of participants in the DEFO intervention group. A striking example is that of one participant (**P21**) who found it provided flexibility so she could '*hold and use the frame*' with her hand whilst out shopping (p. 157).

Findings of the secondary measures of the pilot RCT data were corroborated by the clinical records. The VAS (for pain) in both groups showed a reduction in pain scores at six weeks, but the score change was small, with no significant difference between groups. The reduction in score was collectively less than two points, but in individual participants there was a change score of more than two points in three participants (**P13**, **P20** and **P23**) in the intervention group. For those participants the pain score was particularly relevant measure of health benefit. For one participant his medication for pain management was reduced resulting in health benefit.

Three participants were randomized to the intervention group with lower limb spasticity, none into the control group. This was predicted likely with few potentially eligible participants with lower limb spasticity at the clinic. The participants with lower limb spasticity were required to walk over ten meters and present with spasticity of the calf muscles. These were prerequisites for recruitment. Most of the people with lower limb spasticity at the clinic received BT injection for adductor muscle spasticity and were unable to walk. Subsequently only descriptive results were reported for the 10MTT measure.

Some improvement in gait velocity (at six weeks) was indicated in two participants (**P10** and **P18**) however this was not maintained (by twelve weeks) following the removal of the DEFO. There was minimal improved change in the gait velocity in (**P11**) at six weeks. However, retest at twelve week was not performed due to the progression of her long-term condition. She was unable to walk the necessary distances (ten meters repeated three times) at twelve weeks. The deterioration was duly noted and corroborated by the clinical records. Progression of the participant's neurological condition was considered to have had a negative impact on her participation in the study.

This is exemplified by comments made by participant (**P11**) (p.168). The inference was interpreted that she wished this intervention had been offered earlier in her own condition and also that it should be available earlier for people with similar progressive conditions. From the combined findings of the walk test and the themes gathered by interview this is a valid viewpoint.

**Table 7.1 Summary table of combined quantitative and qualitative findings: for health benefit**

Health benefits Category/typology	Quantitative data	Qualitative data	Integrated findings
<p><b>Person-centred goals (with level of difficulty and importance)</b></p>	<p><b>GAS</b> significant difference between groups with positive outcomes in the DEFO intervention group (95%CI: 3.16 to 21.18; p = 0.014).</p> <p><b>Summary of goals set (Table 5.17)</b></p>	<p><b>Global Participants theme: (GP.1); Organizing theme (OP.1): Research expectations</b>            Hopes and motivations for self and others evidenced.</p> <p><b>Global Clinician theme: (GC.1): (OC.1) Clinical practice, Active versus passive function and Clinical practice, Rehabilitation potential.</b>            Rehabilitation potential, activity versus passive function and motivation influenced goal setting  <b>Goals set and achieved</b> that were of critical importance and in context in the individuals own life.</p>	<p><b>Key findings:</b></p> <ul style="list-style-type: none"> <li>• <b>Person-centred goals achieved with significant difference in achievement in the DEFO group.</b></li> <li>• <b>Factors including rehabilitation potential and motivation influence how goals set are realistic.</b></li> </ul> <p><b>Level of agreement: The combined findings are congruent with qualitative findings supporting quantitative data.</b></p>
<p><b>Physical benefits</b></p> <p><b>Adverse effects</b></p>	<p><b>VAS</b> pain levels small reduction in both groups but of no significant difference between groups  <b>DEFO Wearing record</b> supports tolerance of comfort, appearance and functionality  <b>10 Meter timed walk</b>            All participants improved gait velocity at 6 weeks (<b>P11</b>) retest at 12 week was not performed.  <b>DEFO Wearing record (n=1)</b> non-compliance</p>	<p><b>Global Participants theme: (GP.1) Research Experience: Acceptability</b>  <b>Organizing Participants theme (OP.4): Health benefits; Physical benefits</b></p> <ul style="list-style-type: none"> <li>• Pain level reduced</li> <li>• DEFO supportive and comfortable</li> <li>• More relaxed</li> <li>• Posture more normal and improved functional activity</li> </ul> <p><b>Organizing Participants theme (OP.5): Adverse effects; Physical:</b>            tightness, sweating and swelling in hot weather, dislike, reliance on others, difficulty with donning (initially)  <b>Impact on usual activity:</b>            A block to sunbathing and therapies/ swimming.</p>	<p><b>Key findings:</b></p> <ol style="list-style-type: none"> <li>1. <b>Positive and tangible health benefits in real-life contexts which were valued by the majority of participants in the DEFO intervention group.</b></li> <li>2. <b>This negative findings were related to a few reported individual fitting and wearing issues.</b></li> </ol> <p><b>Level of agreement: The combined findings are congruent with greater depth of understanding provided by the qualitative findings.</b></p>

<p><b>Psychosocial benefits</b></p>	<p><b>Wearing record</b> compliance in (n=10) <b>Summary of goals set (Table 5.17)</b> Person-centred goals included appearance of upper limb in social settings</p>	<p><b>Global Participants theme: (GP.1) Research Experience: Acceptability; Organizing Participants theme (OP.4): Health benefits; Psychosocial health benefits:</b></p> <ul style="list-style-type: none"> <li>• Appearance acceptable from a health perspective with social cues</li> <li>• More 'normal'</li> <li>• More awareness</li> <li>• Appearance socially acceptable</li> </ul>	<p><b>Key findings:</b> Combined evidence to support psychosocial health benefit in wearing compliance and thematic analysis of health benefit.</p> <p><b>Level of agreement: The combined findings are congruent.</b></p>
<p><b>Quality of life</b></p>	<p><b>EQ-5D</b> No significant difference between groups.</p>	<p><b>Global Participants theme (GP.2); Organizing Participants theme (OP.1): Differing perceptions of disability:</b> Quality of life benefits Self-image and self-awareness issues raised by participants (links with psychosocial health benefits evidenced above and perceptions of disability).</p>	<p><b>Key findings:</b> No evidence of significant difference between groups for improved quality of life but some evidence of improved self-perception of normality and awareness.</p> <p><b>Level of agreement: The combined findings are congruent.</b></p>
<p><b>Carer burden</b></p>	<p><b>ArmA Active</b> No significant difference between groups. A small change in both groups with reduced scores over time. <b>ArmA Passive</b> Both groups demonstrated a moderate drop in the score over time with no significant difference between groups. <b>LASIS Participant</b></p>	<p><b>Positive findings:</b> <b>Global Participants theme: (GP.1); Organizing Participants theme (OP.2): DEFO Acceptability; Wearing issues:</b> Donning gets easier. <b>Organizing Participants theme (OP.3): Protocol feasibility; Protocol acceptability:</b> Fitted in with routines. <b>Global Clinicians theme (GC.1); Organizing Clinicians theme (OC.4): Research experience; Different from usual role:</b> New client group. <b>Organizing Clinicians theme (OC.3):</b></p>	<p><b>Key findings:</b></p> <ol style="list-style-type: none"> <li>1. Combined evidence of reduced carer burden in both groups but not of significant difference between groups.</li> <li>2. The findings indicated a generalizability of the DEFO to a new client group.</li> <li>3. Rehabilitation potential, motivation and compliance were factors</li> </ol>

<p><b>Carer burden (cont'd)</b></p>	<p>No significant difference between groups with a drop in score in both groups over time.</p> <p><b>LASIS Carer</b></p> <p>No significant score difference between groups at any time point. A small score reduction in the control group at 6 weeks returned to baseline by 12 weeks.</p>	<p><b>Clinical practice; Active vs passive function:</b> clinical practice issues  <b>Rehabilitation potential:</b> motivation  <b>Promote self-efficacy:</b> not dependency</p> <p><b>Negative findings:</b>  <b>Global Participants theme: (GP.1);</b>  <b>Organizing Participants theme (OP.5):</b>  <b>Adverse effects; Impact on usual activity</b> and reliance on carers  <b>Global Clinicians theme: (GC.1);</b>  <b>Organizing Clinicians theme (OC.3):</b>  <b>Clinical practice; Interface with Private Physiotherapy:</b>  Linked to realistic goals, and level of dependency  <b>Global Clinicians theme (GC.2);</b>  <b>Organizing Clinicians theme (OC.2): DEFO intervention acceptability;</b>  <b>Compliance and wearing issues; Difficulty with donning</b>  Reliance on carers and donning issues</p>	<p><b>suggested to influence likely outcome.</b></p> <p><b>4. Reliance on carers linked to level of dependency.</b>  (Level of dependency was not categorised at baseline)</p> <p><b>Level of agreement: The combined findings are congruent with greater depth of understanding provided by the qualitative findings.</b></p>
-------------------------------------	---	--	--

## 7.1 Health benefits (continued)

### Adverse effects

This is in contrast to the negative findings which were related to a few reported individual fitting and wearing issues. One participant (**P16**) refused to wear the DEFO (possibly due to tightness) but she was unable to explain her decision due to aphasia. Two other participants tolerated the DEFO and found it comfortable apart from its application (**P20**) and during hot weather (**P21**) (p.152).

### Psychosocial benefits

There was evidence to support psychosocial health benefit in wearing compliance and thematic analysis of health benefit. This was demonstrated from the perspective of cosmetic acceptability; fitting in and providing some with the feeling of 'normality' (**P04**), (**P10**), (**P19**), and (**P24**). Participants reflected on how their appearance was seen by others (**P19**) (p.150). This particular issue of health benefit was also analysed for the impact of differing perceptions and attitudes towards disability.

### Quality of life

An alternative view on cosmetic acceptability was expressed by one participant with regard to the DEFO restricting his sunbathing. There was no evidence of significant difference between groups for improved quality of life. However there was some evidence of improved self-perception of normality and '*more awareness*' (**P04**) (p.157).

The EQ-5D as a measure of quality of life did not provide any findings of significance with little change in score in either group in any time point. This was not surprising since the small numbers for a feasibility study were likely to be insufficient for prediction of significant difference. The EQ-5D was used in this small study to test clinical procedural feasibility for use in a larger study which could test economic benefit rather than for statistical benefit for calculation of sample size. From the clinical records there were a number of variances in participant's lives which impacted on their perceptions of health. This included external factors of difficulty with finances, problematic relationships and

receiving bad news of scan results. Medical complications were also recorded in the clinical records which impacted on the general health of participants in both groups equally (**Chapter 5.5**).

### **Carer burden**

Upper limb measures (ArmA and LASIS) were reported each having separate constructs for 'active' and 'passive' function/care components. The LASIS and ArmA were relatively new tools at the onset of this study recommended for clinical applicability (RCP *et al.*, 2009). Both have been recently evaluated for reliability. They were found to have relevance and specificity for the purpose of measuring care burden in people with spasticity with the ArmA most reliable (Ashford *et al.*, 2014). This measure was found to closely correlate with goals for care burden.

It was found there was reduced carer burden in both groups but this was not of any significant difference between the groups. It could be argued that the finding of reduced carer burden in both groups was the result of the rehabilitation philosophy of the physiotherapist (**C2**) in promoting self-efficacy (p.181).

Small levels of health benefit were found in the ArmA (Active) measure, but the difference was insignificant between groups with a reduction in scores in both groups over time. This finding was interpreted as a small benefit in the reduction of carer burden over time from the combined BT, usual care and physiotherapy intervention.

The ArmA passive score which represented carer burden, showed a similar pattern of reduced scores in both groups over time. This is interesting in that the carer burden appeared substantially reduced in both groups equally by the twelve week time point. This was reasoned as resulting from the combined effects of physiotherapy and BT, rather than the DEFO intervention. Alternatively it could be interpreted as a carry-over effect.

In the LASIS (Participant) measure there was no significant difference from the baseline between the intervention and the control group at any time point. There was a very small difference in both groups at week twelve indicating slight improvement in active levels of function. The findings of the LASIS (Carer) was

analysed with the proviso of small numbers due to not all participants having a 'carer'. There was no significant difference from the baseline between the intervention and the control group at any time point. There was a small reduction in the LASIS score in the control group at six weeks but this returned to baseline by twelve weeks. There was no measureable difference in the LASIS score in the intervention group at any time point. This could be interpreted in the slight difference in level of baseline age and dependency in the control group. Another factor that was considered was the level of dependency on carers for donning the DEFO (**P21**), p.159 and (**C2**), p.193. From the above findings the combined physiotherapy and BT showed a small beneficial impact of health benefit on the carer burden.

### **Summary of key points**

- Person-centred goals were achieved with significant difference in achievement in the DEFO group. Factors that influence goal setting include rehabilitation potential and motivation.
- The health benefits from the DEFO intervention were found to include both physical and psychosocial benefits (pain relief, comfort, more normal feeling and awareness, benefit realised by improved posture, muscle tension and functionality). These benefits were of varying significance to the individual depending on the critical importance and context to the person's life.
- Adverse effects were also recorded for physical discomfort (sweating, tightness and difficulty with donning and impact on usual activities), but these were analysed to be of lesser significance when compared to the generalizable health benefits realised.
- There was no evidence of significant difference between groups for improved quality of life however some evidence of improved self-perception of normality and awareness.
- There was evidence of reduced carer burden in both groups but not of significant difference between groups.
- Reliance on carers was possibly correlated to a level of dependency, though this was not formally measured.



The strategy used for interpreting the connected results of the quantitative data and qualitative findings was by distinct categories. These categories included person-centred goals, physical benefits, adverse effects, psychosocial benefits, quality of life and carer burden. Integrated findings provided a moderate level of congruence with meta-inference gained from a better understanding of the quantitative results by explaining and exploring with the qualitative findings. The findings indicated a generalizability of the DEFO to a new client group. Furthermore rehabilitation potential, motivation and compliance were factors suggested to influence likely outcome.

## **7.2 Feasibility of the protocol**

The feasibility of the protocol procedural delivery in a clinical setting was established. The integrated findings are presented, (in **Table 7.2**) in terms of protocol delivery, fidelity, variance and other factors that were found to impact on feasibility. These included baseline characteristics, expectations and ethical issues raised.

### **Protocol delivery**

The protocol feasibility was evidenced by the integrated findings of: retention, delivery and adherence (CONSORT, in **Figure 5.1**); the measures of the pilot RCT; and the combined thematic data from the participant and clinician interview feedback. The DEFO wearing record (**Table 5.14**) also supported protocol feasibility with adherence of wearing times. Wearing was adhered to in four of six weeks and with recorded tolerance of eight hours, or more (13.5 hours).

The results of recruitment show that of potential participants (**n=62**) there were (**n=30**) who declined to participate. Furthermore saturation of recruitment level was achieved two months early with **n=25** of a desired **n=30** participants. This provides indicative levels of the difficulty in recruitment to a study in a population with spasticity from a clinic setting. The CONSORT diagram (p.118) of recruitment and attrition showed the overall retention level was high with merely two participants, one from each group, who revoked consent. The study protocol was delivered in (**n=23**) of (**n=25**) participants recruited. Thus

procedural delivery and acceptability was established. The DEFO intervention was fully delivered to ten of the eleven participants in the intervention group and was partially delivered to the remaining participant. The protocol followed usual care for the twelve control group participants. In essence the adherence level was good with a high proportion of the participants following the study protocol.

From the participant interviews the protocol was found to be both feasible and acceptable (**GP.1; OP.3: Protocol feasibility; Protocol acceptability**). It was reported to fit in well with routines of everyday life (**P01, P18, P21 and P24**) (pp.153-4) and no problems in following the protocol in ten participants with one exception. This was further evidenced from the participant perspective in the acceptability of the wearing protocol with a high level of tolerance and compliance.

Specific wearing issues were found to contribute to the feasibility of the protocol. This included reliance on carers for donning the DEFO. Again this was influenced by the level of dependency of the participant and whether their care was delivered by a care agency or partner. Thus participant compliance was found to depend both on the level of dependency and subsequent reliance on carers (**C2**) (p.193).

Co-morbidity and rehabilitation potential were found to impact on clinical practice and protocol delivery. This finding was presented from the clinician's feedback and introduced the importance of motivation, and not creating dependency (**C2**) and (**C3**) (p.180-1). This finding is similar to findings of Maclean and Pound, (2000) with insights into the importance of understanding the role of motivation in rehabilitation and professionals attitudes (Maclean *et al.*, 2002). This finding highlights the potential impact of motivation in health research. Accordingly it provides direction in future studies on incorporating assessment of motivation as a baseline measure.

The protocol was reported acceptable and tolerated by both clinicians and participants with no identified burden in data capture. However, it was found for the clinicians there was a conflict in competing priorities of clinical caseload and capacity with delivery the research protocol. This finding challenged the feasibility of the protocol in a clinical setting (**C3**) (p.186-7) (**GC.1; OC.4:**

**Research experience; Negative experiences: Recruitment, eligibility and capacity issues.**

Agreement on eligibility and potential clinical risk were also identified as factors that could impact on procedural clinical research feasibility. These are considered further in relation to ethical practice (**Chapter 8.1**). The clinician was given clear instruction to follow professional guidelines on clinical accountability and ensured a risk assessment and plan was in place (as is usual practice).

**Table 7.2 Summary table of combined quantitative and qualitative findings: for feasibility of the protocol**

Feasibility Category/typology	Quantitative data	Qualitative data	Integrated finding
<p><b>Protocol delivery</b></p>	<p><b>Data capture</b>  <b>CONSORT</b> flow diagram <b>Figure 5.1</b> of recruitment and attrition shows (<b>n=25</b>) recruited from a potential (<b>n=62</b>) with (<b>n=30</b>) declined to participate. The study protocol was delivered in (<b>n=23</b>) with attrition of (<b>n=2</b>). An intention to treat (ITT) analysis was conducted.</p> <p>No added burden of data captures recorded (measures).</p> <p><b>DEFO Wearing record (Table 5.14)</b> supports protocol feasibility with adherence of wearing times: adhered to in 4 of 6 weeks and tolerance of 8 hours or more (13.5 hours).</p> <p><b>DEFO Wearing record</b>  Delays in (<b>n=2</b>)  No delays in (<b>n=9</b>)</p> <p>Compliance in (<b>n=10</b>)  Non-compliance in (<b>n=1</b>)</p>	<p><b>Global Participants theme: (GP.1); Organizing theme (OP.3): Protocol feasibility; Protocol acceptability</b>  Fitted in well with routines, no problems with following protocol (<b>n=10</b>) with (<b>n=1</b>) exception.</p> <p><b>Global Participants theme (GP.2); Organizing theme (OP.1): Differing perceptions of disability; Generalizability</b> Timing and diagnostic condition were considered factors in protocol feasibility and application to a similar population.</p> <p><b>Global Clinicians theme: (GC.1); Organizing theme (OC.2): Ethical issues; Eligibility</b> and recruitment, and potential clinical risk.</p> <p><b>Organizing theme (OC.3): Clinical practice; Rehabilitation potential</b> and practice factors affecting protocol delivery.</p> <p><b>Organizing theme (OC.3): Clinical practice; Capacity and priorities</b> Impact of research on existing caseload.</p> <p><b>Organizing theme (OC.4): Research experience; Recruitment and eligibility</b> and potential clinical risk.</p> <p><b>Global Clinicians theme (GC.2); Organizing theme (OC.2): Protocol feasibility;</b>  - <b>Research communication</b></p>	<p><b>Key findings:</b></p> <ol style="list-style-type: none"> <li>1. <b>Feasibility of the protocol delivery was established in clinical practice with a high level of adherence and tolerance with compliance in the DEFO wearing protocol.</b></li> <li>2. <b>Recruitment was saturated early from a small pool of possible participants (from a desired n=30: n=25 successfully recruited).</b></li> <li>3. <b>No added burden in data captures (measures).</b></li> <li>4. <b>Specific wearing issues contributed to feasibility of protocol including reliance on carers for donning DEFO.</b></li> <li>5. <b>Co-morbidity and rehabilitation potential were found to impact on clinical practice and protocol delivery.</b></li> <li>6. <b>The protocol was acceptable and tolerated by both clinicians and participants.</b></li> <li>7. <b>Clinical capacity, priorities, agreement on eligibility and potential clinical risk were identified as factors that could impact on procedural clinical research feasibility.</b></li> <li>8. <b>Participant compliance was found to depend on level of</b></li> </ol>

<p><b>Protocol delivery (cont'd)</b></p>		<ul style="list-style-type: none"> <li>- <b>Availability of DMO clinician</b></li> <li>- <b>Variance in protocol timing</b></li> <li>- <b>Variance in fitting</b></li> <li>- <b>Impact of co-morbidity</b></li> </ul> <p>Compliance and donning issues, reliance on carers, level of dependency, research and clinic communication.</p>	<p>dependency and reliance on carers.</p> <p><b>Level of agreement: The combined findings are congruent with greater depth of understanding provided by the qualitative findings.</b></p>
<p><b>Fidelity</b></p>	<p><b>Protocol Delivered in (n=23). DEFO Delivered (n=10) Not fully delivered (n=1). Physiotherapy data (Table 5.15)</b>          Modalities of intervention were similarly matched for both groups. Most commonly used interventions: stretches (both active and passive); functional training; splinting; strength training and advice.  <b>Intervention group time:</b>          185.9 minutes  <b>Control group time:</b>          237.5 minutes.</p>	<p><b>Global Participants theme: (GP.1); Organizing theme (OP.3): Protocol feasibility; Timing issues and Protocol acceptability</b> evidenced fidelity.</p> <p><b>Global Clinicians theme: (GC.1); Organizing theme (OC.2): Ethical issues; Fidelity and eligibility</b>          Usual practice of clinicians and clarification of eligibility criteria.</p>	<p><b>Key finding:</b>          The protocol was found to have delivered fidelity.</p> <p><b>Level of agreement: The combined findings are congruent.</b></p>
<p><b>Variance</b></p>	<p><b>Variance data:</b>  <b>Timing variance</b>          Delays in (n=2)  <b>Fitting variance</b>          Delays in (n=2)  <b>Activity log:</b> A wide variety of activities reported with similar levels of activity in both groups with exception of shopping (Intervention group n=4; control group n=10).</p>	<p><b>Global Participants theme: (GP.1); Organizing theme (OP.3): Protocol feasibility;</b>  <b>Protocol acceptability: (n=10);</b> Not acceptable (n=1)  <b>Timing variance-</b> Delays (n=2)  <b>Fitting variance-</b> Delays (n=2)  <b>Global Clinicians theme (GC.2); Protocol feasibility; Availability of DMO Ltd clinician, Variance in timing, Variance in fitting.</b></p>	<p><b>Key findings:</b></p> <ol style="list-style-type: none"> <li>1. High level of protocol compliance in (n=10) with Non-compliance (n=1).</li> <li>2. There was minimal variance reported in protocol delivery (with delays in timing and fitting n=2) and level of activity between groups.</li> </ol>



## 7.2 Feasibility of the protocol (continued)

### Fidelity

The protocol was found to have demonstrated internal validity and reliability for fidelity. The delivery of the study protocol was reported consistent with delivery to (n=23). The DEFO was delivered to ten participants but not fully delivered to one due to non-compliance. There was also reported protocol variance in two participants in delayed timing and fitting. The components of DEFO wearing record, standardised physiotherapy (**Table 5.15**) and usual care supported protocol fidelity. Modalities of intervention were similarly matched for both groups. However there was a reported difference between groups in contact time (**Intervention group time: 185.9 minutes Control group time: 237.5 minutes**). This is evidenced further in (**GC.1**); (**OC.3 Clinical practice as (C2)**) (p.186) delivered standard physiotherapy. The evidence of fidelity in the protocol delivery supports feasibility of the DEFO intervention (DEFO) in a clinical setting.

### Generalizability

Participants suggested the protocol was likely to be generalizable to a population earlier in progressive condition management and earlier and longer in a BT treatment cycle. This was from two participants: one with a progressive neurological condition (**P11**) and another who found benefit from prolonged wearing of the DEFO (**P01**), (p.169).

### Variance

There was a high level of DEFO wearing (**Table 5.14**) with compliance in ten participants and non-compliance in one. In addition there was minimal variance reported in protocol delivery (with delays in timing and fitting in two) and level of activity between groups. It should be acknowledged, however that there were time pressures reported by the clinicians involved in the protocol delivery (**GC.2**); (**OC.1: Protocol feasibility; Variance in timing, Variance in fitting (C1, C2)**), (pp.190-1).

This finding was reported by two participants from their experience of delays in the timing of the protocol. One participant had to wait for a second cycle of BT

before being successfully recruited and the other participant refused to wear her DEFO. This was following a delay in assessment and then further delays for repeat fitting of a second customised orthosis (**P16**) (p.154). The protocol was designed around the guidelines (RCP *et al.*, 2009) for spasticity management with BT in adults. The delays for this participant resulted in a less than optimal time to trial the intervention. The second participant followed the protocol without further delays, after a second cycle of BT.

### **Baseline Characteristics**

The baseline characteristics of the participants were evenly distributed as expected following randomization (with exception of age difference). The mean age difference of control group participants was of eleven years older. The impact of this was considered insignificant when compared with the group activity levels reported in the Activity Log. Indeed the control group was analysed to be more active than the intervention group.

### **Expectations**

The hopes, aspirations, motives and expectations for the research were identified by clinicians and participants. It was useful to explore how participants and clinicians saw the research as an opportunity for improvement as individuals and for others. Clarifying expectation in both was seen as integral to the research compliance. The clinicians appeared to understand their role and research responsibilities (**C3**) (p.184) but some of the participants had elevated expectations (**GC.1**); (**OC.1**): **Research expectations (C2)** (p.174); and (**GP.1**); (**OP.1**): **Research expectations; Health benefits for self (P18) (P20)**, (p.147). It was considered a positive finding that the protocol was clear and the participants understood the rationale for the pilot RCT even if they were not allocated to the intervention group (**C3**) (p.175). Good communication was analysed to be essential for the successful delivery of the protocol, contributing to feasibility.



## Ethical issues

The protocol amendment, eligibility and clinical risk are discussed separately in (Chapter 8.1 Ethical considerations) to avoid repetition.

### Summary of key findings

- Feasibility of the protocol delivery was established in clinical practice with a moderate to high level of adherence and tolerance with compliance in the DEFO wearing protocol.
- Recruitment was saturated early from a small pool of possible participants (from a desired **n=30**: **n=25** successfully recruited).
- There was a high level of protocol compliance with non-compliance of only one participant. Participant compliance was found to depend on level of dependency and reliance on carers. The protocol was found to have delivered with fidelity. There was minimal variance reported in protocol delivery (with delays in timing and fitting **n=2**) and level of activity between groups. There was no added burden in data capture (measures).
- Specific wearing issues contributed to feasibility of the protocol including reliance on carers for donning DEFO. Co-morbidity and rehabilitation potential were found to impact on clinical practice and protocol delivery. Clinical capacity, priorities, agreement on eligibility and potential clinical risk were all identified as factors that could impact on procedural clinical research feasibility.
- Baseline characteristics were evenly distributed, as expected following randomization (except age difference).
- Expectations were identified and met (in the majority). Participants suggested the protocol was likely to be generalizable to a population earlier in progressive condition management and earlier and longer in a BT treatment cycle.
- A protocol amendment was submitted to improve procedural feasibility and ethical approval was obtained.
- Potential clinical risks were highlighted and managed clinically. Importantly, no adverse events were reported.

The connected results of the quantitative data and qualitative findings were by distinct categories. These categories included protocol delivery, fidelity, variance, baseline characteristics, expectations and ethical issues that impacted on the feasibility of the study. Following integrated analysis of the above data the study protocol was found to be both clinically feasible and acceptable. The qualitative findings added value to the RCT data to provide greater understanding of the procedural feasibility. It showed that clinicians should have dedicated and funded research time to release them from competing caseload and other capacity demands. It also provided useful procedural detail on timing modifications and variance for future implementation of a larger study in a clinical setting.

### **7.3 Acceptability of the DEFO intervention**

The acceptability of the DEFO intervention in a clinical setting was established. The integrated findings are presented, in **Table 7.3**. The findings are presented in categories/typology terms of clinical practice acceptability, DEFO wearing experiences, acceptability and adverse effects and ethical issues which had an impact on acceptability.

#### **Clinical practice acceptability**

Acceptability of the DEFO in the clinical setting is presented from the participants and clinicians perspectives. There was a clear preference for the DEFO intervention in combination with physiotherapy; earlier in condition management; also in BT cycle; and to be worn for a longer period following BT **(GP.2); (OP.1): Perceptions of disability in research (P11) (p.168); (OP.2): Generalizability; Diagnostic condition and Timing (P01); (P24) (p.169).**

DEFO acceptability was considered from clinician's perspectives founded in previous knowledge and experience. This was exemplified by potential bias in predictive clinical effect and preferences for application. This included participants with more activity rather than those with passive function and care needs. This could be argued from a philosophical stance of the clinician that this was related to the rehabilitation role of the physiotherapist, rather than that of a care provider. Similarly the DMO clinician was more familiar with the use of

DEFO in people with more activity and for whom more central stability was the goal. The DEFO was used in this study in a new way, for potentially managing muscle tone (spasticity) in limbs, often with limited movement. The potential for muscle shortening in people with spasticity and reduced activity is well established (Goldspink and Williams, 1990; Katalinic *et al.*, 2011). Initially this concept was challenging but was acknowledged as a useful learning opportunity **(GC.1); (OC.4): Research experience (C1)** (p.185).

A further theme emerged from the clinician feedback was both the rehabilitation potential and the impact of co-morbidity **(GC.1); (OC.3): Clinical Practice, Rehabilitation potential (C3)** (p.180). This was corroborated with the six medical events and two participants who reported diagnostic news on disease progression. This was recorded in the clinical records previously reported, in **Chapter 5.5 (clinical data)**.

#### **Clinical practice acceptability**

The clinicians also considered DEFO acceptability dependant on caregiver's availability for donning. Both levels of dependency and reliance on carers were believed an important factor in acceptability and compliance **(GC.2); (OC.2); DEFO intervention acceptability; Comfort, Compliance and wearing issues (C2)** (p.193). Compliance was an important consideration as previous studies have indicated poor compliance in long term splint wearing (Lannin and Harvey, 2003).

**Table 7.3 Summary table of combined quantitative and qualitative findings: for acceptability of the DEFO intervention**

Acceptability Category/typology	Quantitative data	Qualitative data	Integrated finding
<p><b>Clinical practice acceptability</b></p>	<p><b>Physiotherapy data and clinical records</b></p> <p><b>DEFO Intervention</b> Delivered in (n=10) Not fully delivered in (n=1) Compliance in (n=10)</p> <p><b>DEFO Wearing record</b> supports tolerance of wearing time protocol. (Table 5.14) supports protocol feasibility with adherence of wearing times: adhered to in 4 of 6 weeks and tolerance of 8 hours or more (13.5 hours).</p>	<p><b>Global Participants theme (GP.2); Organizing Participants theme (OP.1): Differing perceptions of disability Perceptions of disability in research (P11) Physiotherapy plus DEFO</b></p> <p><b>Global Participants theme (GP.2); Organizing Participants theme (OP.1): Differing perceptions of disability; Generalizability; Diagnostic condition and Timing</b> (to conditions and timing in BT cycle (P24) Wearing DEFO for longer (P01)</p> <p><b>Global Clinicians theme (GC.1); Organizing Clinicians theme (OC.3): Clinical practice: Active vs passive function Usual practice Rehab potential and motivation Clinical practice considerations</b></p> <p><b>Global Clinicians theme (GC.2); Organizing Clinicians theme (OC.1): Protocol feasibility; Impact of co-morbidity Organizing Clinicians theme (OC.2): DEFO intervention acceptability; Comfort, Compliance and wearing issues.</b></p>	<p><b>Participant findings: Wearing compliance and tolerance evidenced; preference of DEFO in combination with physiotherapy; earlier in condition management; also in BT cycle; and to be worn for a longer period following BT.</b></p> <p><b>Clinician findings: Clinical bias over active vs passive function and central over distal application; DEFO acceptability tempered by co-morbidity and rehabilitation potential.</b></p> <p><b>Key findings: Both clinicians and participants provided evidence of DEFO acceptability in practice/setting (with caveat of stratification of participants based on the above findings).</b></p> <p><b>Level of agreement: The combined findings are congruent with greater depth of understanding provided by the qualitative findings.</b></p>
<p><b>DEFO Wearing experiences Acceptability and adverse effects</b></p>	<p><b>Clinical records DEFO Wearing record</b> supports tolerance of comfort,</p>	<p><b>Global Participants theme (GP.1) Organizing Participants theme (OP.1): Research expectations;</b></p> <ul style="list-style-type: none"> <li>Participant</li> </ul>	<p><b>Both positive and negative wearing experiences with substantive physical and psychosocial benefits reported.</b></p>

<p><b>DEFO Wearing experiences Acceptability and adverse effects (cont'd)</b></p>	<p>functionality and appearance.</p> <p><b>DEFO Wearing record</b> showed Compliance in (n=10) non-compliance in(n=1)</p>	<ul style="list-style-type: none"> <li>• Clinician</li> <li>• Research</li> </ul> <p>Hope, opportunity, expectations.</p> <p><b>Global Participants theme: (GP.1) Research Experience: Acceptability</b></p> <p><b>Organizing Participants theme (OP.4): Health benefits;</b></p> <p><b>Physical benefits</b></p> <ul style="list-style-type: none"> <li>• Pain level reduced</li> <li>• DEFO supportive and comfortable</li> <li>• More relaxed</li> <li>• Posture more normal and improved functional activity</li> </ul> <p><b>Psychosocial health benefits</b></p> <ul style="list-style-type: none"> <li>• Appearance acceptable from a health perspective with social cues</li> <li>• More 'normal'</li> <li>• More awareness</li> <li>• Appearance socially acceptable</li> </ul> <p><b>Organizing Participants theme (OP.5): Adverse effects;</b></p> <p><b>Physical:</b> tightness, sweating and swelling in hot weather, dislike, reliance on others, difficulty with donning (initially)</p> <p><b>Impact on usual activity</b></p> <p>A block to sunbathing and therapies</p> <p><b>Organizing Participants theme (OP.2): DEFO Acceptability;</b></p> <p><b>Appearance</b> and wearing preferences-colour</p>	<p><b>Key findings:</b></p> <ol style="list-style-type: none"> <li>1. Appearance was considered a significant factor in acceptability.</li> <li>2. Physical benefits were established.</li> <li>3. Psychosocial benefits were established.</li> <li>4. Functionality of the DEFO was found beneficial in comparison to rigid splints.</li> <li>5. A moderate level of compliance was established.</li> <li>6. Poor fitting was found to detract from acceptability.</li> <li>7. Negative findings included difficulty and/or reliance with donning of the DEFO.</li> </ol> <p><b>Level of agreement: Both findings agreed with the deviant outlier of non-compliance in n=1 and adverse effects. The combined findings are therefore congruent with greater depth of understanding provided by the qualitative findings.</b></p>
---	---	---	--

<p><b>DEFO Wearing experiences</b>  <b>Acceptability and adverse effects</b>  <b>(cont'd)</b></p>		<p><b>Wearing issues</b>  Flexibility, it was lightweight, able to be worn under clothing, easy to remove, or difficulty with donning, tightness / too slack, wear and tear, and uncomfortable in the summer.</p> <p><b>Global Clinicians theme (GC.1);  Organizing Clinicians theme (OC.1):  Research expectations</b></p> <ul style="list-style-type: none"> <li>• Participants</li> <li>• Clinicians</li> </ul> <p>Elevated expectations of participants and possibly carers. Research expectations and learning opportunities support practice development.</p>	
<p><b>Ethical issues</b></p>	<p><b>Pilot RCT  Recruitment and eligibility criteria</b>  Inclusive of conditions with spasticity rather than condition specific.</p>	<p><b>Global Clinicians theme: (GC.1);  Organizing Clinicians theme (OC.2):  Ethical issues;</b>  <b>Eligibility</b> - inclusion/ exclusion criteria clarification with definitions.  <b>Clinical safety</b> - potential clinical risk (n=2) reported to the Research Reference Group and risks managed clinically. No adverse events reported.</p>	<p><b>Key findings:</b>  <b>Ethical considerations included clarification of eligibility criteria and research guidance on potential clinical risks.</b></p> <p><b>Level of agreement: The combined findings are congruent.</b></p>

### 7.3 Acceptability of the DEFO intervention (continued)

#### DEFO wearing experiences

The DEFO wearing experiences are considered from situations in real-life contexts. The findings showed both positive and negative wearing experiences. These are presented in terms of acceptability of the DEFO intervention and the adverse effects (**GP.1**); (**OP.2**): **DEFO Acceptability Wearing issues**; (**OP.4**): **Health benefits and Adverse effects**. One of the most vivid accounts supporting acceptability of the DEFO intervention suggested benefits in functionality over more rigid standard splints (**P21**) (p.151). Again this was an important consideration for compliance and acceptability. There were additional considerations in support of the physical and psychosocial benefits previously presented, (in **Chapter 7. 2: Health benefits**).

#### Adverse effects

Findings of the adverse effects were centred on acceptability of fitting including issues of tightness, or too loose. The orthoses were customised to the individual needs of the participants and this sometimes resulted in additional, minor modifications for optimal fitting. This is illustrated in the complexity of a fitting a lower limb orthosis with the posterior compartment removed for comfort, (as in **Figure 7.1**).

In contrast the DEFO was often referred to as 'tight' or as the DMO clinician preferred to call it 'snug'. A fine line was drawn between acceptably tight and comfortably supportive and unacceptably tight and constrictive. This also had an impact on carer acceptability for donning the orthosis (**GP.1**; **OP.5: Adverse effects; Physical** and refusal to wear it (**P16**) (p.159).

**Figure 7.1 Photograph showing DEFO fitting (with participant consent and Trust policy)**



One further participant reported the DEFO uncomfortable to wear, but this was in the summer heat, however she was compliant in wearing the DEFO and followed the wearing protocol. It was noted from the clinical records she also gained weight over the study period which could have impacted on her experience (**P21**). However, this finding was in alignment with previous studies (Coghill and Simkiss, 2010; Calvert and Kelly, 2013).

### **Wearing preferences**

From the wearing records it can be surmised there was a high level of wearing tolerance. Although included with the tolerance, there was variability in the individual preferences for timing of when and where the DEFO was worn. These preferences took into account various factors including dependency on carer support for donning and personal choices for example: sun tanning, or weekend washing routines.



In addition to timing preferences the choice of colour was considered important (**Figure 7.2**) as a factor for cosmetic acceptability (**GP.1; OP.2: DEFO Acceptability; Appearance (P04), (P19)** (p.150). Whilst the majority preferred the neutral tones, one participant preferred the colour orange whilst another decided to dye the DEFO (purple). This was interpreted as a personal expression to reflect his personality. Both participants reported they would have preferred a choice in the colour of the DEFO. In the development of the study it was agreed by DM Orthotics Ltd<sup>®</sup> to provide neutral DEFO's to reduce bias and simplify production. The following examples provide support for the significance of appearance in the acceptability of the DEFO.

**Figure 7.2 Photograph of DEFO colour preference (with participant consent and Trust policy)**



The cosmetic appearance of the DEFO was also considered important to many of the participants from a perspective of self-image and self-perception and how they were seen and accepted by others in society. This was related to both individual and collective views on disability and the reactions of others in a social setting. Again the physical appearance of someone is the most commonly reported factor in recognising disability. Indeed judgments in society are often based on physical appearance as society is keen to categorise people accordingly (Wa Munyi, 2014).

Collectively the early categories of DEFO 'colour' and 'physical appearance' were analysed thematically to inferences on appearance, self-image and self-perceptions. A number of threads were examined from appearance and DEFO acceptability to more complex analyses of societal attitudes and behaviours. Colour was considered to impact on psychosocial acceptance for being able to blend in (P19) (p.157) (**GP.1 Research Experience: Acceptability; OP.4 Health Benefits; Psychosocial**). Appearance was also considered to impact on perceptions (**GP.2 Perceptions on disability: impact on research; OP.1 Differing perceptions of disability**).

### **Ethical issues**

Ethical considerations included clarification of eligibility criteria and research guidance on potential clinical risks. These are discussed as important considerations that impacted across the study on all levels for safe clinical practice, research communication and clarity of the protocol for recruitment and delivery. The ethical issues are discussed further in **Protocol feasibility** and **Ethical considerations** respectively (in **Chapters 7.1** and **8.1**) and reflected on at the end of the thesis.

## Summary of key findings

The integrated findings supported the acceptability of the DEFO intervention with a moderate level of agreement from the quantitative data and qualitative findings:

- Appearance was considered a highly significant factor in acceptability and a moderate level of compliance was established.
- Physical and psychosocial benefits were established with a significant finding of improved functionality of the DEFO. It was found beneficial in comparison to rigid splints.
- Poor fitting was found to detract from acceptability. Negative findings included difficulty with donning of the DEFO and reliance on carers.
- Compliance and tolerance was evidenced by participant adherence in the DEFO wearing record.
- There was a preference of the DEFO in combination with physiotherapy, earlier in condition management, also in BT cycle, and to be worn for a longer period following BT.
- There was a clinical preference in DEFO application for participants with more active vs passive function and central over distal presentation.
- Both clinicians and participants provided evidence of DEFO acceptability in a clinical setting.
- DEFO acceptability was tempered by co-morbidity and rehabilitation potential.
- Ethical considerations for acceptability included clarification of eligibility criteria and research guidance on potential clinical risks, (in **Chapter 8.1**).

## 7.4 Quality framework for study integrated findings

The credibility of this study is shown in the quality framework below (**table 7.4**). The inferences drawn from the study findings are further analysed for insights and credibility gained by the mixing of methods in **Chapter 8**.

**Table 7.4 Mixed methods quality framework for integrated findings (Sale and Brazil, 2004)**

<b>Credibility of findings</b>	<b>Quantitative</b>	<b>Qualitative</b>
<b>Truth value of</b> Health benefits Study protocol Feasibility DEFO acceptability	Internal validity of credible procedural method (blinded RCT), data and measures collected and analysis in reporting.	Thematic Analysis method was verified with a degree of confidence that the findings are credible- able to trace themes back to original coded data. Independent verification by a research tutor.
<b>Applicability of</b> Health benefits Study protocol Feasibility DEFO acceptability	RCT findings were limited due to an underpowered feasibility study. The study protocol was feasible (with modifications) for external validity with generalizable findings to inform a larger study.	Thematic Analysis of findings was able to explain and explore in depth the participants and clinicians reactions and experiences of the RCT. The findings provided credible detail for transferability to a similar population.
<b>Consistency of</b> Health benefits Study protocol Feasibility DEFO acceptability	The RCT procedural delivery was detailed sufficiently to be replicated using study and DEFO wearing protocols. Consistency was also achieved by standardised physiotherapy components and usual care.	The topic guided interviews followed a questionnaire format that was both deductive and probing to explain and explore participant and clinician experiences in the study.
<b>Neutrality of</b> Health benefits Study protocol Feasibility DEFO acceptability	RCT-recruitment, randomization, blinding, delivery of intervention by a protocol and usual care. Also reporting was unbiased with independent statistician support.	Acknowledge difficulty in maintaining un-biased accounts in data synthesis and interpretation of findings. Clinician data was verified by the clinicians, both data sets were independently verified by a research tutor, but participant findings were not verified by themselves.

## **7.5 Summary**

In summary the integrated quantitative and qualitative findings corroborate the feasibility and acceptability of the DEFO intervention in clinical practice. The combined findings provided evidence of health benefits identified further by specific examples in the qualitative findings. There was a moderate level of congruence across all categories with some inferences intended for direction for future study into the combined benefits of DEFO and BT. The qualitative findings demonstrated a coherent level of adherence and provide guidance for improving compliance based on preferences for appearance and functionality. The meta-inferences from further interpretation of this study are presented in the next two chapters. The study is discussed in light of its strengths, limitations, research implications and implications for practice from an ethical perspective.

## Chapter 8

### Discussion

#### Key points:

- **Clinical research delivery and complexity**
- **Ethical procedural considerations**
- **Collaboration with health technology industry**
- **Recruitment, attrition and retention**
- **Strengths of study findings and implications (Generalizability)**
- **Limitations of study**
- **Implications for practice**
- **Summary of key learning points**

#### Introduction

In this chapter the study findings are considered and critically analysed in light of strengths and limitations. The critical analysis followed the underpinning methodology for complex interventions in the developmental and feasibility phases. In addition the research and DEFO intervention was considered from an ethical perspective.

The systematic review (**Chapter 2**) identified a gap in the evidence for the management of people with focal spasticity following BT. This gap was the basis for the study. It highlighted the need to evaluate a potential new treatment for dynamic prolonged stretch of muscle for optimal active and passive care in adults with limb spasticity. The study aimed; *'to investigate the feasibility, potential efficacy and acceptability of DEFO and physiotherapy as a new treatment of focal spasticity following BT in an adult population'*. (**Chapter 4.2**)

Similarly the objectives for the study (**Chapter 4.2**) were set out: to identify likely added health benefit of the DEFO intervention; provide clinical feasibility and inform acceptability. These were in order to find the likely recruitment rate and estimated effect-size for justification of a larger (phase III) study and contribute to the existing knowledge base to inform clinical decisions.

The study addressed the gap by a mixed method approach of quantitative pilot RCT methodology and qualitative Thematic Analysis of interviews for integrated analysis (O’Cathain *et al.*, 2010). The findings are triangulated into a cohesive report providing direction for future clinical practice and implications for further research.

## **8.1 Ethical procedural considerations**

Ethical considerations include rigor, responsibility and respect. In this section the research procedural considerations are presented from an ethical stance. The ethical submissions and considerations for practice include: recruitment; randomization method; concealment; data governance and analysis; clinical capacity; and communication; reporting and monitoring by the Research Reference Group (RRG).

### **8.1.1 Ethical submissions**

#### **Research ethical application**

All the paperwork for the ethics application was prepared and reviewed with the assistance of the local R&D supporting officer. The study research ethics application and IRAS electronic submission on 28<sup>th</sup> August 2012 was received by NRES South Central Berkshire B Committee and approved on September 5<sup>th</sup> 2012 (**12/SC/0518**). The approval was obtained subject to simplifying and combining the two part Patient Information Sheet (**PIS**) into one. This was resubmitted and accepted prior to the study commencing. Further approval was gained and registered with the School of Psychology, University of Exeter and NHS organisations. Once all written approvals were obtained the study commenced on October 4<sup>th</sup> 2012.

#### **Ethics substantial amendment for protocol**

Firstly the need for ethical submission for a protocol amendment became apparent from monitoring the protocol delivery. After the study protocol had been running for four months it was reviewed by the RRG (**Chapter 8.1.3**) and

discussion on the process delivery resulted in the suggestion for a modification in the protocol that would have a significant impact on feasibility. The specific timing of the intervention group referral to assessment to fitting of DEFO as a two week timeframe was undeliverable. However it was more realistic to set the assessment within the two weeks target and the subsequent fitting as a no specified date as this would vary depending on availability of participant or clinician for appointments, production and even further modifications following fitting. Hence the protocol was submitted for minor amendment in the wording to allow for the feasibility of the delivery of the intervention; 'assessment **for** fitting within two weeks'.

Secondly it became apparent that further consideration should be given to the method of qualitative research to capture and provide a robust method to analyse the feedback from the participants and clinicians. The qualitative element of the research had always been considered integral in the study design however had not been given the equal procedural attention of the pilot RCT. As a consequence a series of topic related questions were piloted around the research questions for health benefit, feasibility of the protocol and acceptability of the DEFO. The piloting was done with a participant who withdrew from the intervention due to medical reasons and was unable to fully complete the study. This participant agreed to have a follow-up interview and helped with the development of the questions for the interview format. They were discussed with the research supervisor, remodelled and subsequently formed into the Topic Guided Interview format (**Appendix 11** and **12**). The proposal for the qualitative method was submitted for Thematic Analysis of the transcript interviews using Framework analytic approach (**Chapter 3.4**, p.83).

The protocol amendment was submitted together with the qualitative amendment in April 2013. The amendments were both subsequently agreed with ethical approval by the NRES committee.

### **8.1.2 Ethical considerations in clinical practice**

As a researcher situated in clinical practice it is clear that decisions can be biased by previous clinical knowledge and thus cloud decisions. Clinical bias



has the potential to incur the Hawthorn effect. There is a need to follow guidelines and keep true to method design and for measurement to be conducted in a rigorous manner. The research principle is to be transparent in conducting and reporting methodology. This is based on the rationale for doing credible research with construct validity and must follow 'good clinical (research ethical) practice' (Research Governance Framework for Health and Social Care, 2005) in methods proven for validity and reliability.

Responsibility was taken seriously for keeping all those involved with the study fully informed. By careful monitoring and putting effective reporting systems in place the potential risks and variances were captured and where necessary modified for optimal study and intervention delivery. This monitoring and reporting system was delivered by setting up the RRG (**Chapter 8.1.3**). Respect from a research perspective was also given due consideration for each participant and all those involved in the research.

Clinical practice has a responsibility not to place a patient at risk and this is also true for the research participant. Potential clinical risks were highlighted for two participants and managed clinically. Ethical discussions clarified the prioritisation of clinical safety over delivery of the research protocol. No adverse events were reported. Again, good communication monitoring and reporting systems in research were valued and integral to good clinical research ethical practice (Research Governance Framework for Health and Social Care, 2005).

Clinical risk takes precedence over any research decision. Hence when clinical risk was raised it was dealt with appropriately using a clinical risk assessment and strategies for minimising risk. Tension between research and clinical practice was explored in the clinician interviews (in **Chapter 6.3.1 (GC.1): (OC.2): Ethical issues; Eligibility (C1)** (p.176) and **Clinical risk (C3)** (p.176).

In the early phase of recruitment clarity was also sought around eligibility criteria. Definitions for the inclusion and exclusion criteria provided to ensure all clinicians and the Research Reference Group were fully informed of the recruitment eligibility criteria (**Appendix 15**). A further issue raised in the protocol delivery was the difficulty of maintaining blinding (**C3**) (p.185).

During the study delivery the RRG was informed of two incidents of revealed allocation. The first was when a participant had completed his six week measures and as he was going out the of the therapy department door he turned and asked '*when can I put my splint back on again?*' This was unintentional. He was asked to refer to his information sheet and contact his physiotherapist if further clarification was needed. The second reveal occurred as a result of a participant being seen for a six week measure at short notice prior to a physiotherapy session and he had forgotten to remove his DEFO. It was due to be taken off that week but he was still wearing it and it could be seen beneath his clothing. The participant appeared unaware of the un-blinding and it was not discussed during the assessment.

Both of the issues above were considered under the banner of ethical issues due to the impact on ethical rigor and responsibility in reporting. This was considered essential procedure for transparent reporting (GRAMMS) in mixed methods (O'Cathain *et al.*, 2008).

### **8.1.3 Research Reference Group**

A Research Reference Group (RRG) was established prior to the implementation of the research and commenced with the protocol meeting before ethical approval. Regular meetings every four to six weeks were established with alternate venues at the Researchers base and DM Orthotics Ltd<sup>®</sup> offices. Meeting agendas were circulated and notes written with key action points recorded.

The meeting dates were planned to coincide with the DMO clinician visits to optimise travel arrangements. The agenda was circulated prior to the meeting for additional issues to be raised aside of the standard agenda items. A record of the meeting was written up and disseminated to the group members. Standard agenda items included; protocol delivery, ethical issues, intervention delivery, new knowledge, and communication with a further opportunity to discuss individual cases by the clinicians in the absence of the researcher.

Fundamentally the purpose of the group was to keep the research on track, provide the opportunity for ethical monitoring and establish research peer

support. The reference group meeting notes were disseminated to the researcher's supervisor and field supervisor for monitoring of progress and to provide a steer on procedural or ethical issues raised. This was found beneficial when the discussion on eligibility criteria was raised by the DMO clinician.

The pivotal role of this clinician was acknowledged when recruitment was paused whilst clarification of the study criteria was gained. It was a significant moment in the research when the clinician questioned her role in delivering the intervention to participants that had been recruited who met the eligibility criteria but did not fit with her usual practice model (**C1**) (p.179). This was explored further in a meeting with the supervisor and resulted in clarification of the research, individual's roles and responsibilities and a full explanation of eligibility criteria was subsequently defined for the clinicians.

An additional issue was raised by a clinician regarding the potential safety of a participant with moderate to severe spasticity. The physiotherapist was advised independently by the supervisor to keep the researcher blinded. This was a clinical issue and followed safe clinical practise as discussed previously, (in **Chapter 8.1.2**).

## **8.2 Collaboration with health technology industry**

Research in dynamic Lycra<sup>®</sup> based orthotic garments for people with Multiple Sclerosis was introduced at a workshop by a colleague (Betts, 2006). This new technology was again presented at two training days which raised consideration for its potential use as a treatment option for people with spasticity.

From the literature review there was an identified gap in the research and dynamic splinting was suggested as a likely area for further research. It became apparent that collaboration with an industry that produced dynamic orthoses would be beneficial. This was considered both as a funding opportunity and to build on previous knowledge and skills within the industry. This was in alignment with National Institute of Health Research (NIHR, 2011) and UKCRC Guidelines (2009) on collaboration with industry and model agreements such as; model Industry Collaborative Agreement (mICA). It was recognised

collaboration with industry provides innovative partnering to '*speed up translation of scientific ideas and observations into therapeutics and benefits for patients*' (MRC and NIHR, 2011, p.4).

Two companies were contacted. DM Orthotics Ltd<sup>®</sup> responded first and an appointment was made with the Director to discuss my research and potential involvement. An appointment made with the company Director and a research proposal for the feasibility study was presented. The company was formally asked to collaborate in the provision of the specialist clinician assessment, fitting and supply of the customised DEFO's.

Roles and responsibilities, benefits and risks were considered including intellectual property, tax benefits, publication acknowledgement, shared data findings and so on. It was agreed by the company that the study would be in alignment with their business. A formal letter was requested stating the agreement for the assessment, fitting and supply of DEFO'S for the feasibility study and when received (**Appendix 2**) the research was able to proceed for ethical approval.

There was potential for bias in the research and it was important to explore different perspectives that might influence research decisions. From the company's perspective it was explained the research contributions in the form of time for clinical assessments and fitting and the equipment would provide tax relief. Furthermore the Director reported it was in the company's long term interest to support research towards evidencing the benefits of the DM Orthotics Ltd<sup>®</sup> products as this could influence future funding decisions. Any research findings of benefit or otherwise and recommendations would be made explicit and published with acknowledgement of the company's role (provision of the assessment, fitting and equipment). It was further discussed that as a feasibility study this could direct future larger research projects such as a multi-centre trial.

Selection bias was raised as a potential issue in that some of the participants meeting the criteria for the study were not typical of the usual patients that would benefit from the orthosis (**C1**) (p.180). This challenging perspective was from the clinician from DM Orthotics Ltd<sup>®</sup> based on a perception that all participants should have dynamic movement for the orthotic to be effective.

This bias in perspective was possibly founded in wanting the participants 'to do well'. It highlights the need for a research knowledge base and communicating effectively the aims and purpose of the intended research. Indeed the research is explicitly planned as a feasibility study to explore acceptability from the participant's perspective and the feasibility of implementing the research in a clinical setting. These considerations were explored further in the RRG meetings (**Chapter 8.1.3**). This collaborative stakeholder group was formalised to discuss and plan the protocol development and procedural feasibility for the study implementation and monitoring.

In additional issue raised in collaboration with industry was that the factory production was closed over the Christmas period for two weeks and this had an impact on the protocol timings of two participants. This together with unplanned leave of the assessor clinician due to illness demonstrated the dependency of the protocol on one person. As the weakness in delivery of the protocol was raised a contingency plan was drawn up for a further DM Orthotics Ltd<sup>®</sup> trained clinician to be involved in cover for the fitting of the orthosis. This allowed for consistency in the measurement of the DEFO but provided sufficient flexibility for pragmatic feasibility to deliver the protocol.

### **8.3 Recruitment, attrition and retention**

Recruitment was estimated at a likely 30 participants from the local spasticity clinic over a twelve month timeframe. It was initially underestimated how the flow of recruitment could impact on clinical capacity. In the first month five potential participants were assessed as eligible and recruited whilst a further three did not meet the study criteria. After the second month recruitment flow became steady, to a more manageable two recruits per month. Issues around eligibility was raised in the RRG (**8.1.3**) and resolved by defining the criteria (**Appendix 15**).

By six months, 15 participants had been recruited with the study on target. A stroke rehabilitation trial was running simultaneously and potential participants chose to participate in that instead. At nine months the numbers of recruits dropped. Awareness of the study profile was raised by local teaching and

feedback. At nine months it was clear from the clinic list that potential participants had been previously recruited, asked and declined, or was not eligible. This meant recruitment from new patients only. As only one participant was recruited in the last two months, the point of recruitment saturation was considered likely with 25 participants. The decision to stop recruitment was informed by an understanding that assessments and analysis would continue for a further six months. This pragmatic decision was considered appropriate for a small feasibility study; however, by implication it provided indicative evidence for a multi-centre phase III trial with a wider pool of potential participants for recruitment.

From the perspective of retention two participants recruited did not continue: one was unwell and the consequential delay resulted in his withdrawal of consent; a second participant moved house and left no forwarding contact. A further participant only completed part of the study as she became unwell and hospitalised. The participants all had long-term health conditions with likelihood of secondary complications. Therefore the rate of retention was considered good for this type of study.

#### **8.4 Strengths of the study findings and implications**

There is much to consider when embarking on a research study. The study was founded on a perspective of clinical relevance to further the knowledge base in which it exists. It is critical to acknowledge this stance as it has influenced the approach. This approach is to provide evidence that can be used to inform and influence clinical practice decisions. From a perspective of rigor the research provided evidence by using Complex Intervention Framework methodology (MRC, 2008). Although this provided a sound methodological framework it is unlikely that this early phased development and testing feasibility study could provide categorical evidence. The strengths of this study are now discussed on scope, methodology, design and analysis and relevance for clinical practice and patient benefit.

## **Scope**

The scope of this study was deliberately kept small, as a feasibility study. The research proposal was designed for an optimal recruitment of (**n=30**) participants over twelve months. In fact recruitment was saturated at ten months with (**n=25**) participants recruited. The inclusive scope of the eligibility criteria was based on a pragmatic consideration for generalizability to a population with limb spasticity rather than by specific conditions. This was justified on an understanding of the difficulty in recruitment in clinical research, if the eligibility criteria are too narrow. The findings of the study provided participant preferences on possible earlier timings in conditions and earlier in the BT treatment cycle. The implication of this finding supports the potential for eligibility stratification in people with spasticity in a future study.

## **Methodology, design and analysis**

To answer the research questions a mixed method approach was deliberately used; quantitative pilot RCT methodology and qualitative Thematic Analysis of interviews for integrated triangulation analysis (O’Cathain *et al.*, 2010). The pilot RCT was bound by rigour in content using single-blinded method with concealed randomization and allocation with resultant optimal reduction in systematic bias (Shadish *et al.*, 2002). In addition the RCT followed a quality standard of reporting by CONSORT (Schulz *et al.*, 2010). Furthermore there was a formal intention to treat (ITT) analysis in the quantitative analyses which included all of the randomized participants regardless of their allocation, regardless of the treatment they actually received and regardless of any subsequent withdrawal from treatment or deviation from the protocol (Fisher *et al.*, 1990). This method was used to provide a realistic outcome of clinical practice to reduce overstating the study efficacy by including non-compliers and deviation from the protocol (Gupta, 2011). This was considered an appropriate approach for generalizability to the relevant population. Further analysis by per-protocol (PP) analysis, which provides a strategy to analyse the whole study population in more depth, could have provided more confidence in the study (Gupta, 2011) and this should be a future consideration for including in the next phase of a larger study.

The Thematic Analysis was used effectively to explain the pilot RCT findings and explore the research uncertainties in depth to inform a larger trial. A Framework approach for categorization and thematic network diagrammatic representation were found appropriate methods for analysis of the qualitative data. The qualitative component provided a supplemental data strand that enhanced the overall study design by providing a more complete understanding of the intervention acceptability and the process delivery. A more complete picture was established than by single method alone (Wisdom, *et al.*, 2012). Both study components were given equal attention and significance in delivery and reporting. The component parts (quantitative data strand and qualitative data strand) when combined together added more to the sum of findings.

The mixed methodology provided a sound methodological approach in clinical research. This approach acknowledged healthcare is multi-faceted with interventions based in complex clinical environments (MRC, 2008; Richards and Borglin, 2011; Thompson and Clark, 2012; Richards *et al.*, 2014). This study followed the first two phases (development and testing) of the MRC, (2008) complex interventions Framework. The pragmatic research methodology was supported by an appropriate embedded design and integrated analysis (Creswell and Plano Clark, 2011). This method was considered appropriate as it provided procedural evidence of feasibility with a pilot RCT protocol and detail from the Thematic Analysis which demonstrated protocol feasibility and acceptability in a clinical setting with direction for modifications. Combined quantitative and qualitative analysis of the pilot RCT provided evidence of acceptability of the DEFO intervention with real-life health benefits in people with focal spasticity.

In addition the qualitative research methodology provided a rounded approach with demonstrative proof of acceptability building on proof of concept studies. The integration of the two approaches provided a holistic 360° approach with application of detail to explain the confounding variables which enabled the research to tell the clinical story as it was.

The study protocol was found feasible despite clinical challenges in a clinical setting. As outlined (in **Chapter 7.2**) the mixed methods approach enabled



detailed analysis of the feasibility of the protocol. The measures selected for the pilot RCT were justified in that they provided valid and reliable measures of clinical effect and did not add to the clinical burden of the participants or clinicians. All the participants were measured with the GAS, VAS for pain and EQ-5D. Those with upper limb spasticity were measured with the LASIS and ArmA, the latter has since been found valid and reliable (Ashford *et al.*, 2014). There were only three participants with lower limb spasticity, all in the intervention group and their gait velocity measure (10MTT) was analysed descriptively. Statistical significance in a small feasibility study was considered unlikely, however significant difference between groups was found in analysis of the primary measure (GAS). The findings provided an estimated effect-size for justification of a larger study (**Chapter 8.6**).

The chosen method of analysis of the pilot RCT measures was considered appropriate with a baseline adjusted ANCOVA for between groups over time (at six weeks and twelve weeks). The DEFO intervention was measured for clinical effect at six week and was considered worthwhile longitudinally. The longitudinal results of the GAS T score were surprising considering the usual limited effect of orthotic carry-over. The protocol timing of measures was planned to fit into the clinical cycle of BT for effect within the window of opportunity. Interestingly several of the participants (**P01**, **P11** and **P24**) reported uncertainty at the withdrawal of the DEFO after six weeks. This method of covariate analysis was for measurement of likely clinical significance with time series data. However a linear model fitted to time series data may produce a risk of auto-correction effects with under-estimated standard errors (and over-estimated t-scores).

Both clinical practice relevance and patient benefit were identified. This study evaluated the DEFO intervention in a new population (adults with focal spasticity) and addressed the uncertainties for a larger study. This was evidenced in the integrated findings of health benefits realised (**Chapter 7.1**) and acceptability of the DEFO in clinical practice (**Chapter 7.3**). The combined qualitative and quantitative findings offered greater breadth and quality of the findings (Wisdom *et al.*, 2012). This resulted in inference transferability (Teddlie and Tashakkori, 2009), meaning the study findings are generalizable to a similar clinical context and population.

## 8.5 Limitations of the study

The limitations of the study are now considered. This was a small scale feasibility study which suffered from being over-ambitious in delivery from a part-time researcher in a clinical setting with reliance on clinicians already stretched by capacity, with no research funding. Whilst deliberately planned for recruitment purposes the study was perhaps too broad in scope resulting in potentially confounding variables.

There were a number of variances recorded including incidents of systematic bias which are declared. Firstly despite randomization the age difference (eleven years older in the control group) between groups could be interpreted as a selection bias variable. Similarly all the participants with lower limb spasticity were recruited to the intervention group, providing no comparison for analysis. Secondly there were clinical philosophical differences between the clinicians which possibly led to different treatments between those with 'passive' function (care needs) and those with 'active' functional needs. This could have contributed to performance bias. Also a difference in the level of dependency was suggested by the presence of carers or a package of care in the baseline characteristics. This level of dependency was not formally analysed and is acknowledged as a limitation of this study. Next there was the potential for variance in participant compliance depending on the level of motivation. In addition there were two incidences of hospital admissions and a number of co-morbidities recorded. Two participants withdrew consent and a further participant was lost to the study at six weeks, but further attrition was not reported as a bias. Finally there were two incidents of altered timing in the protocol delivery which could have impacted on the measures. The delivery of the measures could have resulted in detection bias.

The findings of this small feasibility study are likely to present with a type I error from over stating the importance of the pilot RCT findings of the group difference in the GAS T score. It was also likely that with intention to treat analysis of the study findings cautious interpretation could have been susceptible to type II error. This is more likely in a small scale study with the potential to under report findings as their significance may be missed. However,

it was deliberate that the ANCOVA was chosen as a method of analysis to reduce potential in bias from confounding variables.

A further limitation in the study was from the limited input from PPI (INVOLVE, Hanley *et al.*, 2003) in the development of the study and in the RRG. The research pilot RCT had an unnecessary design feature with the removal of the DEFO intervention at six weeks. The original intention was to measure any carry-over of the intervention; however as an orthotic this was unlikely and previous studies have not shown this carry-over effect (Bridges, 2004; Matthews *et al.*, 2009).

Also there was a limitation in the research procedural delivery from over-reliance of another service, namely in collaboration with industry. It was reported by clinicians that the availability of a part-time clinician who was based out of county was not ideal. The availability of the DM Orthotics Ltd<sup>®</sup> clinician was reduced over school holidays and consequently assessment and fitting clinics were reduced. The DMO Ltd<sup>®</sup> factory also closed over the Christmas period for two weeks which resulted in production delays.

## **8.6 Implications for practice and further research**

From the findings in this study it is possible to draw both theoretical and clinical implications for future practice. The evaluation showed success in the procedural feasibility of the DEFO intervention. The protocol was found feasible with recruitment, randomization and delivery of the intervention as planned. Both clinicians and participants found the protocol acceptable but suggested procedural modifications. The DEFO intervention was found acceptable with positive health benefits established. This study suggests DEFO has the potential to be used to provide an acceptable strategy for the management of focal spasticity in combination with BT and usual care. Further investigation is justified to understand clinical efficacy.

## Estimated effect-size

In this study it has been possible to demonstrate a clinical effect with n=23 subjects with the GAS T score at six weeks (12.17) although this result should be interpreted with caution for clinical importance for a larger study. The primary measure GAS showed significant difference in achievement in the DEFO intervention group. From the results of the GAS sample size calculation the answer is: to be able to detect an effect-size of 0.3 standard deviations between the intervention and the control group with 80% power at 5% level of significance you would need 200 patients per group (400 in total). This takes into account an attrition rate of 20%. It is however, important to note that a potential randomized clinical trial should be powered to detect the smallest effect-size that is of clinical importance. In this case, there was enough power to detect an effect-size of 1.2 standard deviations with 80% power.

The pilot RCT provided sufficient evidence to warrant further investigation in the use of the DEFO intervention following BT and in the wider use of combined interventions for spasticity management. The findings from the GAS score provided estimated effect-size for justification of a larger study. Analysis of the pilot RCT data suggested potential stratification of participants for future evaluation. This could be taken a step further by focussing further research on participants with upper limb spasticity and stratifying participants by level of dependency.

## Physiotherapy components

Physiotherapy was evaluated to be integral to the follow-up therapy whether for 'active' or 'passive' function. This finding is in alignment with the Spasticity Guidelines (RCP *et al.*, 2009). The role was interpreted as primarily for people with rehabilitation needs but was also interpreted as having an important role to play in providing education, advice, monitoring and promoting self-efficacy. Practical issues included optimal timing, carer support and access to a trained DEFO assessor. From the physiotherapy data capture (**Chapter 5.5, Table 5.15**) it was seen the modalities were similarly matched for both groups. Most commonly delivered interventions were categorized: stretches (both active and passive); functional training; splinting; strength training and advice. This finding

can be used to inform future practice decisions. There was some variance between groups in contact time with the control group receiving 237.5 minutes and the intervention group 185.9 minutes. Additional private therapy was recorded within the contact time. In future studies physiotherapy modalities and contact time should be specifically collated after BT.

### **Measures**

The chosen measures were considered appropriate; the GAS was found to be a meaningful measure of health benefit from the patient perspective. The ArMA was found most meaningful for upper limb spasticity. However a dependency measure would have provided further validity. In addition a larger trial should incorporate cost-benefit analysis using the EQ-5D, thus following the later implementation and evaluation phases of the MRC Framework (2008). A future study should include an ITT analysis and a PP analysis to provide increased confidence in findings. Analysis of procedural feasibility provided sufficient detail to recommend protocol modification in assessment for the DEFO prior to the BT (to reduce the timing delays) and for wearing of the DEFO for a longer period (twelve weeks) with longer follow-up.

### **Clinical feasibility and DEFO intervention acceptability**

Feasibility of the protocol delivery was established in clinical practice with a high level of adherence and tolerance with compliance in the DEFO wearing protocol. The feasibility on procedural timing was enhanced by the intervention protocol amendment. The protocol was acceptable and tolerated by both clinicians and participants. There was no added burden in data captures (measures). It was found there were specific wearing issues which contributed to feasibility of protocol including reliance on carers for donning DEFO. It was also found co-morbidity and rehabilitation potential impacted on clinical practice and protocol delivery. Further factors were found to impact on the research feasibility in a clinical setting; clinical capacity, priorities, agreement on eligibility and potential clinical risk.

There was a high level of wearing compliance evidenced by the wearing record. Both clinicians and participants provided evidence of DEFO acceptability in a clinical setting (with a caveat of stratification of participants for earlier in

condition and BT treatment cycle). Most significant was the cosmetic acceptability of the appearance of the DEFO. This was acceptable in most participants with further customisation identified such as for a choice in colour. The findings also showed there were many health benefits identified in the provision of the DEFO intervention. These physical benefits were identified as; pain level reduced, supportive and comfortable, more relaxed, posture more normal and improved functional activity. Additional psychosocial benefits were found including; appearance acceptable from a health perspective with social cues, more 'normal', more awareness and appearance socially acceptable. These findings were reinforced by positive perceptions of disability (self-image and acceptability). A further finding of significance was in the functionality of the DEFO in comparison to rigid splints. Findings that detracted from acceptability included poor fitting and difficulty or reliance with donning the DEFO.

## **8.7 Summary of key learning points**

The study methodology was reviewed if it had fully addressed the research uncertainties identified (in **Chapter 4.**) The mixed methodological approach was considered appropriate and fully met the objectives. This was by identifying likely added health benefits of the DEFO intervention and further evidence of procedural clinical feasibility and acceptability. The likely recruitment rate and estimated effect-size was identified for justification of a larger study. This study has contributed to the existing knowledge base to inform future clinical decisions.

In summary the findings suggest the DEFO intervention was procedurally feasible and acceptable in a clinical setting providing evidence of added health benefit. The findings provide useful guidance on future recommendations for optimising feasibility of a larger study. Modifications of the protocol were based on the study findings. This study was a small feasibility study and the results should be interpreted with caution but provided useful insights into recruitment, refusal, retention rates, and adherence with delivery of the intervention. The next chapter concludes with a review of the key findings and learning points in relation to the research.

## Chapter 9

### Conclusion

#### Key points:

- **Summary of key findings and learning points**
- **Research evidence evaluation; to test a research design for a further larger study**
- **Thesis provides Original contribution to new knowledge; empirical, theoretical and practice**
- **Implications for further research**
- **Strategy for dissemination**

#### Introduction

This research study was planned to open and unpack the 'black box' on spasticity management following BT. It is openly acknowledged there is complexity in maintaining control of the research process in clinical research. The developmental work in this feasibility study has contributed to the successful testing of a research design, its delivery and early phase analysis providing direction for a further larger research study.

From a review of the literature there was an identified gap both in rigour and of clinical relevance in studies for interventions of adults with focal spasticity. This innovative intervention of DEFO had not been rigorously evaluated in the adult population. Neither had the explicit components of physiotherapy been evaluated in standardised practice following BT intervention. Importantly this study was a preliminary pilot RCT to allow testing for feasibility before a larger study is planned. Implications were drawn for clinical practice with patient benefit demonstrated. It is hoped this could result in access to resources previously not commissioned.

## 9.1 Summary of key findings and learning points

The key findings and learning points are reviewed by the researcher for the research study. Therefore a summary of findings are presented in answer to the specific research questions identified (**Chapter 4**) on health benefit, feasibility and acceptability.

The primary question, '*What is the likelihood that there is health benefit of treatment with DEFO and physiotherapy and usual care compared to usual care alone?*' was answered by the integrated findings of the pilot RCT measures and Thematic Analysis of the interviews. The findings showed many health benefits both physical and psychosocial in the analysis of the DEFO intervention. The most significant finding included the attainment of goals in a real-life context as the primary measure GAS showed with significant difference in achievement in the DEFO intervention group at six weeks but not at twelve weeks. This measure was considered an appropriate measure to use in a heterogenic population with limb spasticity. Although the GAS has a construct that measures attainment of goals rather than a specific outcome this measure was chosen for its construct validity, clinical application and relevance to the participants.

The most commonly identified physical benefits included pain relief, support and comfort, reduced muscle tension which improved postural alignment and enhanced functionality. The additional psychosocial benefits were found to include significant factors including the cosmetic acceptability of the DEFO. This was from its appearance and was analysed to be acceptable from a health perspective. It generated social cues and was found to be more 'normal' providing more awareness and the appearance was considered socially acceptable from different perspectives.

Next the research uncertainty '*What is the feasibility of the protocol (as a small feasibility pilot) for a larger study?*' was addressed by procedural analysis of the pilot RCT including clinician and participant feedback. There was a high level of adherence and tolerance demonstrated with compliance in the DEFO wearing protocol. Feasibility was established with tolerance and acceptability by both



clinicians and participants. The intervention protocol amendment contributed to improved procedural feasibility although delay in timing was not the only factor considered to impact on delivery in clinical practice. Other factors included comorbidity and rehabilitation potential, clinical capacity, priorities, agreement on eligibility and potential clinical risk. A further factor that contributed to the feasibility of the protocol included reliance on carers for donning the DEFO.

From the above findings a number of recommendations are proposed to improve the feasibility of the protocol for a larger study. These are addressed in **Chapter 8** and summarised in **Chapter 9.2**.

Finally the question '*How acceptable is the DEFO intervention in clinical practice?*' was addressed. This was answered by the combined DEFO wearing record data (pilot RCT), Thematic Analysis and data from clinical records. There was a high level of wearing compliance evidenced by the wearing record. Both clinicians and participants provided evidence of DEFO acceptability in practice/setting (with a caveat of stratification of participants earlier in condition and BT treatment cycle).

Most significant was the cosmetic acceptability of the appearance of the DEFO. This was acceptable in most participants with further customisation identified such as for a choice in colour. Physical and psychosocial health benefits were established as outlined earlier. Another significant finding was the benefit of functionality of the DEFO in comparison to rigid splints. Findings that detracted from acceptability included poor fitting and difficulty or reliance with donning the DEFO. A summary of the key findings and learning points is presented below, (in **Table 9.1**).

**Table 9.1 Summary of the key findings and learning points**

Topic	Key findings/Learning points
Systematic review	There was a gap in the literature with an identified need to research a potential intervention to optimise spasticity management following BT.
MRC Complex Interventions Framework	The study followed the early phases of development and testing for identifying the uncertainties and testing the study design feasibility in order to inform a larger study.
Ethical considerations	Ethical submission for approval required support (R&D) to minimise delays. Research followed good (research ethical) clinical practice: rigor, responsibility and respect. Collaboration with industry was beneficial for all those involved.
Methodology	The mixed methods approach with embedded design of quantitative (pilot RCT) and qualitative (Interviews Thematically analysed) study components was considered appropriate for clinical research. Separate analysis of data was followed by integrated analysis to strengthen the findings and explain them in more depth. This method told a more complete research story.
Procedural delivery	Research in a clinical setting is complex. Several factors and people were important in successful delivery of the research protocol; pilot work, R&D support, research supervision (access to expertise), research communication including monitoring and reporting to the Research Reference Group, Research Support (admin.), Consultant support, clinician capacity and willingness to undertake research roles and Service Manager support and last but not least the compliance of participants and their carers. Concealment of allocation was difficult with (n=2) declared exceptions. It was useful to keep a research diary and minute notes for meetings.
Data capture and results	Setting up appropriate Excel data bases for data capture and blinded data capture for participant allocation was critically important. A study flow was captured of recruitment, refusal, retention rates, and adherence with delivery of the intervention (CONSORT, <b>Figure 5.1</b> ). Pilot RCT method of statistical analysis was considered appropriate with an alternate method considered. Interview data 'Thematic Analysis' methodology with 'Framework' approach was considered appropriate. The combined results were analysed and the data provided information on design feasibility for a further larger study ( <b>Table 9.2</b> ).

## 9.2 Implications for further research

There is clearly a need to design trials with more sensitive measures of treatment effect and to identify patients who will obtain most benefit, functional or otherwise. The findings are summarised with the research implications, (in **Table 9.2**).

The impact of specific conditions of the participants who were in the study is now considered. The heterogeneity of the participant's diagnostic conditions included people with stroke, acquired and traumatic brain injury, spinal cord injury and multiple sclerosis. In light of the inclusive study findings there is sufficient evidence to support further stratification of the potential population recruited for a larger study. The stratification could focus further on participants with upper limb spasticity and a clearly identified level of dependency. In this way the measures selected would be categorized and thus more appropriate for example for those with specific issues of carer burden. Similarly the level of dependency could be used to stratify those with progressive or stable conditions.

As previously outlined in the analysis of the pilot RCT data the results of the GAS T score provided estimated effect-size for justification of a larger study. Although this study was small it showed an effect of clinical importance, however interpretation of this result should be considered with caution. For a fully powered potential randomized clinical trial it was estimated from the results of the GAS you would need 200 patients per group. For an estimated effect-size to be detected there would need to be an effect-size of 0.3 standard deviations between the intervention and the control group with 80% power at 5% (taking into account a rate of 20% attrition).

**Table 9.2 Summary of research implications**

Research findings	Implications for Research
Eligibility considerations	Stratification and generalizability need further consideration: <ul style="list-style-type: none"> <li>• Upper limb</li> <li>• Level of dependency</li> <li>• Progressive or static condition</li> </ul>
Study methodology and design	A mixed method approach is appropriate for research in a health care setting. From the pilot RCT: the results of the GAS indicated for a potential randomized clinical trial it was estimated you would need 400 patients (200 per group). From the findings of recruitment and likely attrition it is recommended a future Phase III study is designed for optimal feasibility as a fully funded multi-centre study. The Thematic Analysis of the interviews provided rich detail to identify the health benefits and explain feasibility and acceptability of the RCT. Integration of the findings provided valuable procedural detail for a future study: <ul style="list-style-type: none"> <li>• Choice of colour could improve cosmetic acceptability.</li> <li>• Improved fitting could also improve acceptability.</li> <li>• Availability of a carer for donning improved compliance.</li> </ul> Also cost-analysis should be incorporated into the design of a larger study.
Protocol delivery	Protocol modifications indicated to improve timing of assessment and delivery by: <ul style="list-style-type: none"> <li>• Earlier assessment for fitting prior to BT.</li> <li>• Longer delivery of DEFO intervention with no need for removal.</li> </ul>
Physiotherapy	Modalities of delivery and contact time should be specifically collated to identify what treatment options are of most benefit.
DEFO assessment and fitting	Clinicians could be trained as DEFO assessors to improve procedural delivery.
Patient and Public Involvement (PPI)	PPI could be used to improve a future study design and contribute to monitoring the research delivery.

## 9.2 Implications for further research (continued)

Sufficient information was shown in the results to justify further modification of the protocol. From the analysis of the protocol feasibility two areas were considered for improvement. Firstly to reduce the timing delays and promote optimal delivery in the treatment cycle, the DEFO assessment for fitting could be carried out prior to the BT. Secondly the wearing of the DEFO is recommend for a longer duration in the protocol (twelve weeks) with follow up at six weekly intervals and no need for removal as there was considered to be of no benefit from carry-over. Although BT was considered important as a prerequisite in this study a further study could evaluate another RCT comparator group of participants who did not receive this combined intervention.

A further consideration to optimise a future research protocol was for the improved access to a trained DEFO assessor. Training for assessment of the DEFO was available but not taken up by the clinicians in this study. It is recommended clinicians are trained in assessment and fitting to reduce reliance on the provider. Allocated clinical research funding could reduce conflicts between clinical and research capacity.

In future studies both physiotherapy modalities and contact time should be specifically collated to identify what treatment options are of most benefit in spasticity management after BT. The evidence gathered in this study can also be used to inform future practice decisions.

The successful implementation of the protocol demonstrated intrinsic feasibility and acceptability by clinicians and participants. This was evidenced by the high retention, delivery and adherence rates. Modifications were identified to improve protocol feasibility and reduce clinician burden in delivery. The DEFO intervention was found acceptable with many positive health benefits identified.

In summary the unique contribution to knowledge in this thesis is provided from a theoretical, empirical and practice-related stance.

**Theoretical:** Whilst clinical research is acknowledged to be complex a mixed methods approach with embedded design of quantitative (pilot RCT) and qualitative (interviews thematically analysed) study components was found to

be appropriate and feasible in a health care setting. In addition the hypothesis tested in the RCT (**Chapter 4.1**) provided evidence of added health benefits from the DEFO intervention with physiotherapy and usual care compared to physiotherapy and usual care alone, following BT. The findings support the theoretical rationale in the use of DEFO for prolonged dynamic stretch of muscle for improving muscle performance in people with limb spasticity following BT. Further investigation is warranted based on the findings in this study.

**Empirical:** This small study has demonstrated an important clinical effect in the use of DEFO intervention following BT. The results of the pilot RCT primary measure GAS T score provided estimated effect-size for justification of a larger study into the clinical efficacy of DEFO intervention for the treatment of people with limb spasticity. To be able to detect an effect-size of 0.3 standard deviations between the intervention and the control group with 80% power at 5% level of significance you would need 200 patients per group (400 in total). This finding indicates further investigation by a multi-centre fully-funded research trial.

**Practice-related:** This thesis provides procedural detail with analysis on feasibility and acceptability of the DEFO intervention. The protocol was feasible with protocol modifications identified by the findings for a future study. The DEFO intervention was found potentially acceptable and of clinical benefit for the treatment of adults with limb spasticity following BT. Findings on splint acceptability suggested compliance could be improved by choice of colour and fit and the support of a carer for donning. In future studies physiotherapy modalities and contact time should be specifically collated to identify what treatment options are of most benefit. The GAS primary measure was reported clinically acceptable and relevant as a patient-centred measure for change for people with limb spasticity.

### **9.3 Strategy for dissemination**

Dissemination is planned by timely presentation of the findings to local clinicians, stakeholders and patient support groups. Participants have received a summary report of the findings. Strategic and wider dissemination is planned with publication of the protocol and study findings in peer-reviewed journals (Clinical Rehabilitation) and by poster presentation of findings at ACPIN, Physiotherapy and Stroke National and International Conferences. Findings will be presented to commissioner stakeholders for service commissioning.

### **9.4 Conclusion**

Spasticity that is predominantly focal has been evidenced to be managed effectively with BT for many years. The effect is however reversible requiring repeated cycles of care. A long-term strategic model is worth considering for the early detection of spasticity and a stepped approach in management to reduce the potential of more severe spasticity. The role of splinting and physiotherapy in focal spasticity are yet to be proven, however this study presents the option of a new dynamic approach to splinting that was evaluated both clinically and from the perspective of the patient.

The study has met the planned objectives with a mixed methods embedded study design. This has addressed many of the uncertainties of this intervention and evaluation of the findings has informed an estimated effect-size for justification of a larger study. The findings of this developmental study indicate that it is both feasible and acceptable for replication in the clinical setting (with modifications). It has identified likely added health benefits and factors that influence cosmetic and wearing acceptability. In addition it has contributed to the existing knowledge base to inform clinical decisions. It provides the basis for a larger DEFO trial to inform clinical-effectiveness and cost-effectiveness.

The combined implications from the above suggest with further investigation DEFO is a new and promising treatment option which can be used to provide a realistic and acceptable strategy for the management of focal spasticity in combination with BT and usual care.

## Reflections on research

This reflective piece is intended to provide an account of research delivery from the perspective of a novice researcher. The reflective pieces are captured from a twelve month research diary of the planning and delivery stages of the clinical research. It covers personal perspectives on the complexity of implementing research in clinical practice and the learning mapped along the research journey.

I present my worldview as a pragmatist and with a professional and clinical lens. Research requires discipline. Physiotherapy clinical practice also requires discipline but it is a mix of science and art based on knowledge and skills and underpinned by hard won autonomy. The tensions and conflicts that these create are explored.

Clinical experience in spasticity management has led me to question the efficacy of static splinting following BT when spasticity is a complex dynamic and velocity-dependent positive feature of the UMN syndrome. The nature of spasticity is that it is a sensori-motor disorder meaning that it is influenced by sensori-motor feedback. Spasticity is associated with reduced movement and altered muscle pattern generation often leading to complications such as pain, deformity and altered function. Spasticity pathway evaluation identified repeat cycles of BT which it could be argued leads to dependency.

The systematic review clearly identified gaps in the current research evidence for management of adults with limb spasticity following BT. Leading authors in the field Lannin and Ada (2011) suggest the need to investigate the rationale for clinical use of splints and a re-focus on muscle performance. The review found evidence of splints and orthoses for spasticity management but no evidence of the use of dynamic splints or orthoses in combination with BT in adults. This study builds on theoretical evidence to evaluate a potential treatment using dynamic prolonged stretch of muscle. The focus of the research was to optimise active and passive care for patient benefit following the window of opportunity provided by BT. The DEFO intervention was identified as a potential treatment



option that had not previously been rigorously tested for limb spasticity management in an adult population.

The diary was a useful research tool to capture procedural issues and discussion points of significance that influenced research decisions. What is ethical and what is right is underpinned by doing most good and least harm. This is the moral principle of beneficence that similarly applies to professional practice (Sim, 2010). Ethical decision making follows six stages and these were adhered to in this study; describe and clarify, apply the three 'r' principles, establish boundaries including legal/governance frameworks and consult key stakeholders, make difficult decisions (weigh up), implement, reflect and review the decision. Research experience has equipped me with a better understanding of the guiding principles in research; **rigor, respect and responsibility**. I divided this chapter of reflections on the research journey into these three topics.

## **Rigor**

The rationality and rigor of research was a challenge to my intuitive practice. However I understand the need to follow guidelines and keep true to method design and for measurement to be conducted in a rigorous manner. It was important that I acknowledged the research principle; to be transparent in conducting and reporting methodology. I fully accept the rationale for doing credible research with construct validity. This must follow 'good clinical (research) practice' (Research Governance Framework for Health and Social Care, 2005) and trust in methods proven for validity and reliability.

As a small scale research study for a part-time programme competing with other work priorities I was aware of the need to prioritise my time. Planning the research study was fundamental and a Gantt chart (**Appendix 18**) was used to provide a mapped outline of necessary steps and actions to drive the research forward and deliver the thesis. This was used for the monitoring of the research delivery by the Research Reference Group (RRG) and the supervisor to ensure the study was on track.

Other strategies used for ensuring transparency included actively reporting progress to my peers. This gave the opportunity to re-focus on methods used and whether they were delivered in the way I had intended. Updates on progress provided snapshots of underlying hypotheses, methods planned, tasks achieved, numbers recruited and uncertainties identified in the delivery process. Fundamentally I was able to spend some time reflecting on progress and take stock of any flaws in my study. One such moment was in the need to revise my study approach from a pilot RCT to a mixed methods study. This resulted in a new challenge in exploring the literature on different philosophical stances, approaches and methods in qualitative design and ultimately how to integrate the two methods. It required a leap of faith followed by a number of decisions on how to implement the qualitative component and thematically analyse the findings supported by a supervisor.

The decision to use a primarily theoretical deductive analysis in my qualitative Thematic Analysis was considered appropriate to answer my research questions. I had weighed up other options of discourse analysis (DA) or content analysis (CA) and considered this theoretical deductive approach was better aligned with my researcher's interest in answering specific questions of feasibility and acceptability of the DEFO intervention and identifying likely health benefits. The topic guided probe questions in the interviews also provided the opportunity for inductive approach to analysis. It was challenging not to be overly descriptive in the thematic analysis and the interpretation of the findings was detailed in the text.

One of the key components to get right in research is setting up the spreadsheets for data collection and ensuring that there is a rigorous method to collating the data and regular entering of the data. I used the support of an administrator to ensure the data bases were encrypted and that one spreadsheet was encoded with the participants allocation concealed. This was so that I was blinded according to the concealed allocation and randomization. There were two cases of revealed allocation which I reported to the RRG and in the Results (**Chapter 5**).

Credibility of reporting research findings is important. Therefore consideration was given on use of an intention to treat analysis and reporting of the data from

the RCT. Conflicts of interest are important to declare and this was considered both when collaborating with industry and when using support for quantitative statistical analysis. Collaboration is considered under the principle of responsibility. Internal validity of the RCT data analysis was a concern to me as I had support from two statisticians who offered conflicting advice on methods of analyses. In effect both methods produced very similar results however I made a decision to work with the University statistician and this helped to clarify my understanding of the method used; ANCOVA with adjusted means at baseline and statistical comparison between groups at six weeks and twelve weeks. Justification for measures of clinical effect at six weeks was based on the procedural window of opportunity for change following BT. A double data entry method was used to ensure any errors in data entry were explored and corrected.

A further discipline in reporting was considered in authentication of the qualitative findings in that the clinicians were provided with their transcriptions and checked for truth. In addition the thematic findings of the participant transcripts were discussed with an experienced qualitative supervisor. Limitations in the study rigor have since been reflected on in that the participants could also have had copies of their transcripts for authenticated truth of the findings. They were given copies of the study findings and asked for any comments, however none were forthcoming.

### **Respect**

Respect is engendered in professional practice. It follows codes of practice and has legal implications on how participants must be treated in research. I recognised the importance of respect for people from a research perspective with due consideration of each participant and all those involved in conducting the research. This was most important from an ethical stance in my aim to be as inclusive as possible in the study which was demonstrated by including four people with aphasia. It was challenging and frustrating at times however I was able to use augmented communication skills previously learned in an aphasia workshop. Two of the participants agreed for their carers to assist in communication and one participant used scrabble letters to spell out words. The

participants were respected and they were also empowered. I reflected it was important to give them a voice where other studies may have excluded them.

The clinicians were also respected for their knowledge; skills and opinions were actively sought and valued to inform the study. Their individual contributions in the qualitative interviews offered insights into professional roles and responsibilities and conflicts between clinical practice and research. These tensions were raised with uncertainties in delivery with capacity and potential clinical risk. I addressed the capacity issue by meeting with the clinician's manager and the issue was resolved by personally taking on equivalent clinical caseloads for each research participant. Potential clinical risk was dealt with as any clinical risk and prioritised with appropriate clinical modifications to reduce the risks identified. An example included the medical deterioration of one participant, rendering the participant immobile in which the DEFO was considered unsafe and consequently removed.

When the question of defining eligibility criteria was resolved it was a great relief that the research had not been prematurely stopped. The importance of understanding the individual roles and responsibilities had been underestimated. Conflict in research practice from usual care was identified in the clinician in the industry in that the people she normally treated had more movement and DEFO was provided for more proximal management. I was aware there was a need for further clarification and discussion for agreement on the study eligibility criteria to gain trust and agreement in the recruitment process. This was achieved in a RRG meeting and the initial conflict between the clinician in the industry and the study was resolved.

### **Responsibility**

Research governance was considered essential to honest and accurate reporting of the study. I did not underestimate my responsibility as the research principal investigator and the importance of keeping all those involved with the study fully informed. Effective communication was established with pathways and roles identified for the clinicians delivering the physiotherapy in the study to address both clinical and research uncertainties.

By careful monitoring and putting effective reporting systems in place the potential risks and variances were captured and where necessary modified for optimal study and intervention delivery. Ethical responsibility is an important consideration for clinical and research practice. Clinical practice and management of clinical risk takes precedence over research. This was an important lesson learned from the delivery of a new treatment in a clinical setting.

Research is positively driven by effective communication. The exchange of ideas led to key decisions informing the research proposal, design and implementation of the study. Fundamentally this research study could not have been initiated without explicit communication of the research ideas to engage the stakeholders. The stakeholders identified were; clinicians and their managers, a supervisor and research field supervisor, the local Research and Development support staff and statistician, the DMO company manager and staff and participants. The stakeholders required different levels of communication at key stages in the delivery of the study.

The research proposal was the starting point for early discussions with my supervisor for improvements and to explore what perspective the research should take. I was challenged to look at the research differently from another perspective; not as a clinician, but as a researcher. I decided that the participant perspective was more important in that if the DEFO was to be explored as a new treatment option for limb spasticity a feasibility study must also evidence intervention acceptability from the participant. Therefore the design chosen and measures selected were based on this assumption.

It became increasingly apparent that research cannot occur in isolation and positively benefits from collaboration. A number of companies manufacturing dynamic orthoses were approached regarding potential research collaboration. This resulted in one definitive interest. Early meetings with the DM Orthotics® CEO ensured the research protocol would be deliverable and provided assurance that funding the assessment, fitting and provision of the splint would not influence intellectual property and the right to publish without interference. It was also agreed that the findings would be made available to the company.

Written agreement was sought and provided which was necessary in collaborative research with industry.

Further collaboration was established by setting up a stakeholder RRG. This was useful to discuss the protocol feasibility and procedural delivery. Initial discussion around choice of orthoses fabric colour was used to inform delivery of DEFO of neutral colour to control for bias. Further discussion was on the specific timing of the assessment for fitting of the DEFO. It was advised that changes in muscle tension following BT meant that it could impact on fit and so assessment should be after rather than before this intervention. In addition this group was able to monitor the research delivery by receiving regular reports and providing an opportunity for feedback. Important procedural decisions were made on modification of the protocol to ensure it was feasible in the timeframe and this was submitted for ethical approval as a protocol amendment.

### **Leadership in clinical research**

Knowing what you know and what you don't know is fundamental to identity and reality. I consider myself as a novice in clinical research. However as a health care professional I am used to the concept of evidence based medicine (Sackett *et al.*, 1996) and from this starting point I have developed further skills from professional practice to research specific skill sets. I have a strong ethical accountability towards professional and clinical research leadership. In truth I value transparency, honesty, loyalty, equality, respect, creativity, knowledge, fairness and generosity. These are qualities I seek personally and value in others.

The paradigm shift in the patient-clinician relationship has led to the empowerment of the patient and this has influenced my practice. The reflective diary has provided a framework for learning in a logical cycle of reflection critical to my own learning style as a constructivist (Higgs and Titchen, 2001). The diary provides evidence of a journey of transformation both in research confidence and leadership.

A critical learning point from my reflections is that research leadership provides an opportunity of power 'through' others. In order to be an effective leader I consider collaboration to be essential using a strong dynamic approach.

Working on tasks together helps to bind a group together, providing identity and common purpose as was experienced by the RRG. Even when dissonance is encountered it is an important lever for learning. This was experienced in the issues around participant eligibility and conflicting caseload and research priorities that threatened the research. Personal resilience is important as changes and challenges are common in research.

I recognise these critical challenges influencing research design and procedural delivery have led to personal transformation. The key components of resilience were identified as resistance, recovery and reconfiguration. Resistance was encountered as dissonance between managing expectations of the clinician representing industry and ensuring the research followed an ethical framework. Recovery occurred with resolution of the understanding of the research eligibility criteria. Reconfiguration occurred as the RRG was strengthened by ethical accountability.

The research study has also provided an opportunity for developing an arc of influence as a leader in clinical research and confidence in collaboration with others. This newly gained confidence in research skills has provided the opportunity for collaboration in service improvements and mentoring others. It has also led to wider experience in dissemination of research findings at a level of international impact.

### **Conclusion**

Reflections I considered of critical learning significance were; making ethical decisions and ethical practice, collaboration and developing an arc of influence. These components are not specific to research; however they are fundamental to developing leadership skills in clinical research and to influence translational research practice gaps.

## Appendix 1



### **Health Research Authority** NRES Committee South Central - Berkshire B

Bristol REC Centre  
Whitefriars  
Level 3, Block B  
Lewins Mead  
Bristol  
BS1 2NT

Telephone: 0117 342 1335  
Facsimile: 0117 342 0445

05 September 2012

Mrs Katharine Stone  
Consultant Therapist in Neurology  
Peninsula Community Health  
Therapy Office Camborne and Redruth Community Hospital  
Barncoose Terrace  
Redruth  
TR15 3ER

Dear Mrs Stone

**Study title:** Dynamic Elastomeric Fabric Orthoses (DEFO) and  
physiotherapy after Botulinum toxin type-A (BT) in  
adults with focal spasticity: A pilot randomised  
controlled study.

**REC reference:** 12/SC/0518

The Proportionate Review Sub-committee of the NRES Committee South Central -  
Berkshire B reviewed the above application on 04 September 2012.

#### **Ethical opinion**

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the  
above research on the basis described in the application form, protocol and supporting  
documentation, subject to the conditions specified below.

Members considered supplying information to participants via three separate documents  
(Participant Information Sheet Part 1, Participant Information Part 2, and Participant  
Information Intervention Protocol) could be confusing for participants. It would be  
advisable to provide a combined document, removing repetitive text and simplifying any  
technical terms used.

#### **Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to  
management permission being obtained from the NHS/HSC R&D office prior to the start of  
the study (see "Conditions of the favourable opinion" below).



## Appendix 1



### Health Research Authority

#### NRES Committee South Central - Berkshire B

Bristol REC Centre  
Whitefriars  
Level 3, Block B  
Lewins Mead  
Bristol  
BS1 2NT

Tel: 0117 342 1391

12 July 2013

Mrs Katharine Stone  
Consultant Therapist in Neurology  
Peninsula Community Health  
Therapy Office Camborne and Redruth Community Hospital  
Barncoose Terrace  
Redruth  
TR15 3ER

Dear Mrs Stone,

**Study title:** Dynamic Elastomeric Fabric Orthoses (DEFO) and physiotherapy after Botulinum toxin type-A (BT) in adults with focal spasticity: A pilot randomised controlled study.  
**REC reference:** 12/SC/0518  
**Amendment number:** 1  
**Amendment date:** 22 April 2013  
**IRAS project ID:** 114101

The above amendment was reviewed held on 11 July 2013 by the Sub-Committee in correspondence.

#### Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

#### Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Notice of Substantial Amendment (non-CTIMPs)	1	22 April 2013
Covering Letter	1	09 April 2013
Protocol Appendix 1	1	20 August 2012
Questionnaire: Qualitative Data Capture	1	09 April 2013

#### Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

A Research Ethics Committee established by the Health Research Authority

## Appendix 2



Unit 2, Cardrew Way, Cardrew Industrial Estate, Redruth, Cornwall TR15 1SH United K  
T: +44 (0) 1209 219205 F: +44 (0) 1209 211175 E: admin@dmorthotics.com  
www.dmorthotics.com

Katharine Stone  
Consultant Therapist in Neurology  
Therapy Office  
Camborne and Redruth Community Hospital  
Barncoose Terrace  
Redruth  
TR15 3ER

28<sup>TH</sup> June 2012

Dear Katherine,

**RE: Provision of Dynamic Elastomeric Fabric Orthoses (DEFO) for Randomised Control Pilot Study investigating the effects of Botulum Toxin and physiotherapy, with and without DEFO intervention.**

DM Orthotics Ltd can confirm that we will provide the orthoses free of charge for the patients involved in this study.

The company will also provide the services of a fully qualified and CRB cleared senior physiotherapist who will assess, measure and supply the correct DEFO as discussed and agreed by the clinical team.

The company are happy to be involved as proof readers for the final paper and understand that we will be acknowledged for our involvement in the trial.

Yours sincerely,

A handwritten signature in black ink, appearing to read 'M.J.A. Matthews', is written over a white background.

M.J.A. Matthews M.Phil; MBAPO; Dip.OPTEC

Managing Director / Orthotic Clinical



VAT No: 845173814 Member of BHTA No. 000354  
Company Reg. No. 5276121 Reg Office: 443 Ashley Road,  
Parkstone, Poole, Dorset, BH14 0AX



### **Appendix 3: Example of search strategy**

A literature review included: NHS Evidence Health electronic data bases: Medline and CINAHL, PsychINFO, Embase, AMED; Cochrane; Clinical Evidence in National guidelines, Map of Medicine, DARE; Dialog DataStar; and hand search. The search covered a period from 1990-2013.

**Index words: spasticity, Botulinum toxin, splint, orthosis, dynamic splint, dynamic orthosis, Lycra<sup>®</sup> and physiotherapy**

Each single word or concept was initially searched and then later combined in the Medline database and mapped to thesaurus. The subject headings were then listed in a hierarchy of broader to narrower terms. Further terms were exploded to include all the narrower terms. The final collection for each concept was combined using 'AND' resulting in the key papers for this review. It was appropriate to use the search strategy wildcards to explore any truncated words such as 'splint'. Each search was themed then saved, abstracts evaluated for relevance and papers identified as key to the research study were requested for scrutiny.

#### **Medline search terms**

1. Physiotherap\* or 'physical therap\*\*'
2. Spasticity\* AND Botulinum toxin\*
3. Splint\* or orthos\*s
4. Dynamic splint or dynamic orthos\*s
5. (splint\* or orthos\*s) OR (dynamic splint or dynamic orthos\*s)
6. Lycra<sup>®</sup> AND splint OR Lycra<sup>®</sup> AND orthos\*s
7. 1 AND 2
8. 1 AND 2 AND 3
9. 1 AND 2 AND 4
10. 1 AND 2 AND 6

## **Appendix 4: Research Study Participant Information Sheet**

**Study title: Dynamic Elastomeric Fabric Orthoses (DEFO) and physiotherapy after Botulinum toxin type-A (BT) in adults with focal spasticity: A pilot randomised controlled study.**

### **Introduction**

Spasticity or over-activity of muscle is a fairly common symptom following damage or disease of the central nervous system (CNS). It can present in people with stroke, spinal cord injury, multiple sclerosis and acquired brain injury. It is associated with reduced movement and altered muscle control, often leading to pain, deformity and altered function.

It is known that treatment of spasticity is complex and should be addressed, especially when it is causing problems such as alteration in function or care provision. The aims for treatment are to provide symptom relief, improve function and prevent deterioration.

If spasticity is fairly localised this may respond better to local treatment such as injection with Botulinum toxin. Both the National Clinical Guidelines for Stroke (2004) and the Multiple Sclerosis: National clinical guideline for diagnosis and management in primary and secondary care (NICE, 2004) recommend that Botulinum toxin is used for spasticity management in selected cases.

Evidence shows it requires a combination approach to address both the nerve-based and biomechanical (muscle and soft tissues) components. In this study the nerve-based component will be medically managed by local administration of BT type- A.

### **What is Botulinum toxin?**

Botulinum Toxin (BT) is derived from the bacterium 'Clostridium Botulinum'. When injected into muscles, BT has local and controlled effects. It blocks transmission between the nerve endings and muscle fibres around the injection site, thereby causing weakness of the nearby muscle. Injections take effect within a few days and last until new nerve endings grow back, which typically takes three to four months.

This safe and effective injection of toxin to targeted over-active muscles achieves temporary muscle weakness. BT offers a unique treatment opportunity

to inhibit specific overactive muscles whilst leaving other muscles unaffected (RCP 2009). This allows the 'window of opportunity' to direct therapy towards achieving a functional goal. The therapy is aimed at treating the biomechanical components of spasticity.

### **What is a splint?**

A splint or orthosis is a removable device which provides a means of maintaining the specific position of a limb either providing static or dynamic support. Aims for splinting commonly include: to decrease spasticity, prevent or reduce contractures, improve activity at a joint, protect joints, and to reduce pain. The splint to be used in this study is a dynamic elastomeric fabric orthosis (DEFO) which is customised (fitted) to the individual. It is made of an elastic-based material which is breathable and allows movement. It is similar to an elasticated glove or a sock. It works by providing cylindrical pressure to cause increased stability of joints, dampens down external forces to improve movement control and improves sensory feedback to provide postural awareness of the limbs. It is layered to counter-act the distorting forces of muscle spasticity to achieve better position and function.

### **What is the purpose of this study?**

The design of the study is to test the efficacy of a dynamic splint/orthosis and any added health benefits compared to standardised treatment. The therapy planned in this study is aimed at improving muscle control during this 'window of opportunity' by using a dynamic elastomeric fabric orthosis (DEFO) and standardised physiotherapy compared with standardised physiotherapy alone.

### **How will the study be conducted?**

Following consent you will be assessed for eligibility for the study by the researcher and baseline measures taken. You will be allocated to one of two treatment groups following Botulinum toxin injection. One group will have usual care and the other group will have the dynamic splint in addition to usual care. The allocation to either group will be randomised. This is necessary to make sure the study is not biased. **You will be asked NOT to discuss your treatment with the research assessor**, but if you have any concerns you will be able to discuss these with the named physiotherapist delivering your care.

The treatment protocol will encourage wearing the splint for a period of up to eight hours daily or as tolerated. This is based on evidence in previous studies. Both groups will have access to usual care and rehabilitation including postural management, provision of equipment and advice etc. Standardised physiotherapy will be provided to all participants. The study will last for 12 weeks which will include a period of 6 weeks of specific treatment followed by 6 weeks of on-going standardised care as needed. (Please see the protocol)

### **What are the identified benefits?**

The splint is designed to provide sensory awareness and joint position sense. It is also dynamic with properties that promote rather than restrict movement. There is some evidence from paediatric studies that this treatment offers improvements in movement stability and postural control with a beneficial impact on balance and walking. This study will provide evidence of added health benefits that have not been previously measured in the adult population.

### **What are the identified risks?**

The main identified risk is that of compression on the skin resulting in reduced circulation. This could be an increased risk to those with poor circulation in the extremities or those who suffer from Diabetes. However the splint will be made to measure to ensure comfort and can be easily removed. DMO can provide access to a skin surface pressure monitor to determine safety in those identified at risk.

### **How can I participate?**

If you have read and understood the information in this form and wish to proceed with participation in this study you will be asked to sign a consent form. The study has been agreed as safe and regulated by a research ethics committee. If you wish to discuss any of these issues more fully from this information sheet you are encouraged to contact the physiotherapist/clinician involved in your care who will be briefed on the purpose and plan for delivery of the research study. If you decide to participate in the study you will be given a form to sign for your consent. You will then be assessed for eligibility to the study and allocated to either group. You will have the right to withdraw your consent at any time during the study and this will not affect your provision of

usual care. If you decide not to participate you will be provided with standard care. With your consent your GP and any other health care professionals will be contacted to inform him/her that you are participating on the research study and what it involves. All personal data will be password protected, securely stored and managed according to NHS governance and data protection regulations.

### **ASSESSMENTS:**

The research assessor will conduct three assessments during the research study:

1. Baseline Initial Assessment following BT (within 2 weeks)
2. Post intervention assessment (at 6 weeks)
3. Follow-up assessment (at 12 weeks)

### **MEASURES:**

1. **Impairment:** Spasticity: Modified Ashworth Scale (MAS); pain: VAS
2. **Function:** Goal Attainment Score (GAS); 10 meter timed walk.
3. **Participation:** Activity log; Leeds Arm Spasticity Impact Scale (LASIS); EQ-5D (quality of life), participant and clinician feedback on acceptability and feasibility

### **Intervention Protocol**

**Following consent and eligibility you will be recruited to the study and randomized into 1 of 2 treatment groups:**

**The intervention (Group A) and control (Group B)**

#### **Group A**

After clinic you will be invited to attend your local physiotherapy department (or if unable to travel at home) for a baseline assessment by the researcher using validated outcome measures and a questionnaire. This should take approximately one hour. Please do **NOT** discuss your treatment with the researcher.

An appointment will be made with you for an assessment and measurement for fitting of the DEFO (within 2 weeks). This should take approximately one hour. This orthosis will be provided for you to wear daily for increasing periods of time (up to 8 hours daily within your comfort). You will be asked to keep a record of this time. You will also receive standard care\* and physiotherapy (as clinically

relevant) for up to a maximum of 40 minutes twice weekly for a period of 6 weeks. Any home exercises or activity will be recorded by you using an 'Activity log'.

After 6 weeks your progress will be assessed by the researcher using the same measures and questionnaire (approximately 1 hour). The dynamic orthosis treatment will be withdrawn but continued standard care for a further 6 weeks. After this period you will be re-assessed using the same measures and questionnaire by the researcher. Again this should take approximately one hour. You will be informed of the outcome of the study and your individual progress.

### **Group B**

After clinic you will be invited to attend your local physiotherapy department (or if unable to travel at home) for a baseline assessment by the researcher using validated outcome measures and a questionnaire. This should take approximately one hour. Please do **NOT** discuss your treatment with the researcher.

After 2 weeks you will receive standard care\* (this may or may not include a splint depending on individual clinical need and this will be recorded) and physiotherapy (as clinically relevant) for up to a maximum of 40 minutes twice weekly for a period of 6 weeks. Any home exercises or activity will be recorded by you using an 'Activity log'.

After 6 weeks your progress will be assessed by the researcher using the same measures and questionnaire (approximately 1 hour). The standard care will continue for a further 6 weeks. After this period you will be re-assessed using the same measures and questionnaire by the researcher. Again this should take approximately one hour. You will be informed of the outcome of the study and your individual progress.

### **Standard care\***

This is the usual care following Botulinum toxin (BT) administration and is tailored to the individuals needs but includes: advice on positioning, hygiene, muscle stretches, splinting, and pain management. Physiotherapy may not be a part of care.



## Appendix 5: CONSENT FORM

**Study: Dynamic Elastomeric Fabric Orthoses (DEFO) and physiotherapy after Botulinum toxin type-A (BT) in adults with focal spasticity: A pilot randomised controlled study.**

**Please see the consent form is in two parts, you do not have to sign both parts:**

**Part 1 on Page 1:** This is the main consent for your general participation in the study and if you agree to take part. **Part 2 on Page 2:** This is optional and about whether you would agree to being followed up by the researcher for the purpose of health research even if you decide to withdraw from the study.

### PART 1: MAIN STUDY CONSENT FORM

**Participant Identification No:** .....**Site Details:** .....

Consent detail	Please initial box
1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to ask questions.	
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.	
3. I agree to my GP being informed of my participation in this study and updated with information from this study relevant to my medical care.	
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from regulatory authorities or from the NHS Trust where it is relevant to my taking part in the research. I give my permission for the individuals to have access to my records.	
5. I understand that data already collected as part of the research study can be retained for up to 20 years even if I decide to withdraw from the study and that it will only be used for this study.	
6. I agree to participate in wearing the dynamic splint or other splint as required.	
7. I agree to participate in Physiotherapy treatment as required.	
8. I agree to participate in outcome measure assessments (GAS and measures identified as clinically appropriate) by the researcher.	
9. I agree to complete the EQ-5D questionnaire.	
10. I agree to complete the Activity log as required.	
11. I agree to take part in the above study.	

***When you have initialled the boxes above, please complete below including the date yourself.***

-----  
**Name of Participant (BLOCK CAPITALS) Date** **Signature**  
 -----

-----  
**Name of Researcher (BLOCK CAPITALS) Date** **Signature**  
 -----

*I have explained the study to the above patient and he/she has indicated his/her willingness to take part in the study*

**Part 2: OPTIONAL CONSENT FORM**

**Part 2: This section is optional; you can choose if you wish to take part or not and it will not affect your participation in the main part of the study.**

This consent form is about if you would agree to:

- *Being interviewed about your experiences of taking part in the study?*
- *The data from the above in the optional consent being retained?*
- *Non-identifiable data being shared for the purposes of health research only.*

Please only initial the boxes you wish to consent to, thank you.

**Participant Identification No:** .....**Site Details:** .....

<b>Consent detail</b>	<b>Please only initial the boxes that apply</b>
1. I am willing to be interviewed about my experiences of taking part in the study for research purposes only even if I decide to withdraw from the study.	
2. I agree to data being collected for this additional part of the above study being retained for up to 20 years and that it will only be used for this study.	
3. I agree to my data from this study being shared with other health researchers after my personal identifying data has been removed. I understand that it will only be used towards improving health outcomes by assessing the types of treatment that I have agreed to participate in for the main study.	
4. I agree to this additional part of the above study and consent <b>only</b> for the sections where I have clearly initialled in the boxes.	

-----  
**Name of Participant (BLOCK CAPITALS) Date** **Signature**  
 -----

-----  
**Name of Researcher (BLOCK CAPITALS) Date** **Signature**  
 -----

*I have explained the additional part of study to the above patient and he/she has indicated which parts apply*

## **Appendix 6: Research Intervention Protocol**

### **POPULATION:**

**Inclusion:** Adult (>18 years) living in the community with full capacity to undertake informed consent, with identified focal spasticity of one limb (in upper or lower limb) present for at least three months, treatment plan with Botulinum toxin identified and consented.

**Exclusion:** Unable to co-operate in a rehabilitation programme (co-morbidity of dementia or mental health disorder), fixed joint contracture, pregnancy, arthritic condition, fracture and neuromuscular diseases.

**RECRUITMENT:** Potential participants identified by clinician's independent from the researcher will be invited to take part in the study and provided with the study information for the informed consent process. After gaining consent participants will be randomized to either the Intervention group or comparison group by computer generated randomization. The participant's data will be encoded and stored in adherence with clinical and research governance for data protection. It is intended that 30 participants will be recruited with 15 participants in each group to ensure sufficient power for statistical analysis. The researcher will be blinded to the randomization and undertake baseline assessment and outcome assessment of all the participants recruited. Participants in the intervention group will be referred from the spasticity clinic to DM Orthotics Limited for assessment, supply and fitting of the orthoses. Participants in both groups will be referred to the Clinical Specialist Physiotherapist for standardized physiotherapy and have standard care\*. Heterogeneity will be evaluated for acquired and progressive disorders, upper and lower limb, age and gender.

### **PROTOCOL:**

**Intervention Group A:** Intramuscular injection with Botulinum toxin type-A. Measurement and fitting within 2 weeks of dynamic elastomeric fabric orthoses (DEFO). The orthoses should be worn 7 days a week (not at night) and in the first week: for 1 hour for the first day; 2 hours on the second day; 4 hours for the third day; and 8 hours daily from the fourth day. Wearing time for the orthoses will be recorded. Physiotherapy standardized intervention (as clinically relevant) up to a maximum of 2x 40 minutes per week for 6 weeks. A Physiotherapists intervention log will be used to record delivery of commonly used components of treatment. Treatment is to be delivered by Clinical Specialist Physiotherapists with experience in spasticity management. A standardized home exercise programme is to be provided and standard care\*. Also a Participants Activity log will be used to record activity levels.

**Control Group B:** Intramuscular injection with Botulinum toxin type-A followed by standardized Physiotherapy intervention (as clinically relevant) up to a maximum of 2x 40 minutes for 6 weeks. A Physiotherapists intervention log will be used to record delivery of commonly used components of treatment. Treatment is to be delivered by Clinical Specialist Physiotherapists with experience in spasticity management. A standardized home exercise programme is to be provided. Also a Participants Activity log will be used to record activity levels. A static splint will be provided if clinically indicated for standard care\*.

**ASSESSMENTS:** (single-blinded research assessor)

4. Baseline Initial Assessment
5. Post intervention assessment (at 6 weeks)
6. Follow-up assessment (at 12 weeks)

### **MEASURES:**

4. Impairment: Spasticity: Modified Ashworth Scale (MAS); pain: VAS
5. Function: Goal Attainment Score (GAS); 10 meter timed walk.
6. Participation: Activity log; Leeds Arm Spasticity Impact Scale (LASIS); EQ-5D, participant and clinician feedback on acceptability and feasibility.

### **Standard care\***

This is described as the usual care following Botulinum toxin administration and is tailored to the individuals needs but includes: advice on positioning, hygiene, muscle stretches, splinting, and pain management. Physiotherapy may not be a part of care.

# Appendix 7: Goal Attainment Scaling (GAS) T Record Sheet

Participant code No:.....

	Patient stated goal	SMART goal	Imp	Diff	Baseline	Achieved		Variance (Describe achievement if differs from expected and give reasons)
1.			0 1 2 3	0 1 2 3	<input type="checkbox"/> <b>Some</b> function  <input type="checkbox"/> <b>None</b> (as bad as can be)	<input type="checkbox"/> Yes  <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> <b>As expected</b>  <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse	
2.			0 1 2 3	0 1 2 3	<input type="checkbox"/> <b>Some</b> function  <input type="checkbox"/> <b>None</b> (as bad as can be)	<input type="checkbox"/> Yes  <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> <b>As expected</b>  <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse	
3.			0 1 2 3	0 1 2 3	<input type="checkbox"/> <b>Some</b> function  <input type="checkbox"/> <b>None</b> (as bad as can be)	<input type="checkbox"/> Yes  <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> <b>As expected</b>  <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse	

**Summary**

<b>Baseline GAS T-score:</b>	<b>Achieved GAS T-score</b>	<b>Change in GAS T Score</b>
------------------------------	-----------------------------	------------------------------

## Appendix 7 Goal Attainment Scaling (GAS) T Record Sheet (continued) Participant code

No:.....

	Patient stated goal	SMART goal	Imp	Diff	Baseline	Achieved		Variance (Describe achievement if differs from expected and give reasons)
4.			0 1 2 3	0 1 2 3	<input type="checkbox"/> <b>Some</b> function  <input type="checkbox"/> <b>None</b> (as bad as can be)	<input type="checkbox"/> Yes  <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> <b>As expected</b>  <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse	
5.			0 1 2 3	0 1 2 3	<input type="checkbox"/> <b>Some</b> function  <input type="checkbox"/> <b>None</b> (as bad as can be)	<input type="checkbox"/> Yes  <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> <b>As expected</b>  <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse	
6.			0 1 2 3	0 1 2 3	<input type="checkbox"/> <b>Some</b> function  <input type="checkbox"/> <b>None</b> (as bad as can be)	<input type="checkbox"/> Yes  <input type="checkbox"/> No	<input type="checkbox"/> Much better <input type="checkbox"/> A little better <input type="checkbox"/> <b>As expected</b>  <input type="checkbox"/> Partially achieved <input type="checkbox"/> Same as baseline <input type="checkbox"/> Worse	

### Summary

<b>Baseline GAS T-score:</b>	<b>Achieved GAS T-score</b>	<b>Change in GAS T Score</b>
------------------------------	-----------------------------	------------------------------

## Appendix 8: Physiotherapy Intervention Data Form

To complete: For each research participant please tick all that apply

Intervention	1	2	3	4	5	6	7	8	9	10	11	12
<b>Sensory stimulation</b>												
<b>Splinting/casting</b>												
<b>Strengthening</b>												
<b>Fitness/aerobic training</b>												
<b>Stretches (specify)</b> <b>a. Static</b> <b>b. Dynamic</b>												
<b>Functional training (specify)</b> <b>a. Sit to stand</b> <b>b. Gait training</b> <b>c. Arm ability training</b> <b>d. Other</b>												

<b>Other training</b> <b>(specify)</b> <b>a. FES</b> <b>b. CIMT</b> <b>c. Other</b>												
<b>Other comments*</b> <b>(Intensity/fatigue etc.)</b>												
<b>Total time contact</b>												

**\*Please use a separate sheet if needed to record any additional comments and include with patient data capture sheet**

Date	Other Comments

### Appendix 9: DEFO: RECORD OF WEARING LOG

WEEK	DAY 1	DAY 2	DAY 3	DAY 4	DAY 5	DAY 6	DAY 7
1	1hr	2hr	4hr	8hr	8hr	8hr	8hr
2							
3							
4							
5							
6							
TOTAL HOURS							

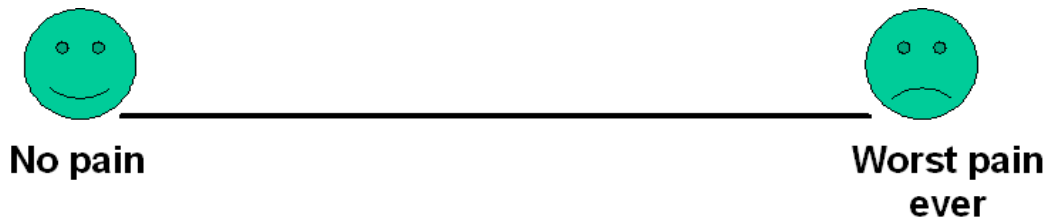
Week	Comments
1	
2	
3	
4	
5	
6	



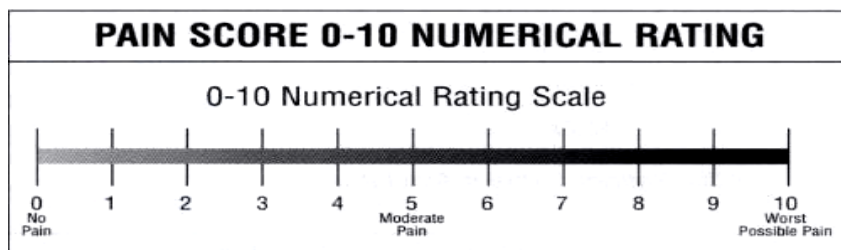
**Appendix 10: Secondary Measures: VAS/ EQ-5D, LASIS, ArMA, 10MTT**

**Pain rating scale**

**Visual analogue scale (VAS)**



Fold paper



**FACES® rating scale (FRS)**

**Wong Baker Face Scale**



## Appendix 10: The ArMA

**Patient Name:** .....

**Carer Name:**.....

**Date and time of completion:** .....

### Instructions for completion:

If the patient is unable to complete the questionnaire independently they may:

- receive assistance from a carer or professional to either act as scribe
- or facilitate understanding and completion question by question.

### **Who has completed this questionnaire?**

- Patient alone
- Carer alone
- Patient/carers in combination

### Guidance for completion:

For each of the activities listed, please indicate:

- 1 If the task is possible for you or the carer.
- 2 The amount of difficulty that you or your carer experience in doing the activity.
- 3 **Please answer every question based on your activity over the last 7 days.**

If you are unable to do the task but have not done so in the last 7 days please estimate the amount of difficulty you would have had with each task. Indicate if the score is an **estimate or actual** in every case.

<b>ArMA – Section A (caring for the affected arm)</b>							
<b>In each column, please <i>CIRCLE</i> as appropriate</b>							
<b>Care activities (affected arm)</b>	<b>Possible to do a task or not?</b>	<b>Difficulty</b> 0 = no difficulty 1 = mild 2 = moderate 3 = severe difficulty 4 = unable to do activity				<b>Estimate/Actual</b> (if the task was not actually done in the last 7 days, circle 'estimate')	
1 Cleaning palm	Yes / In part / No	0	1	2	3	4	Estimate / Actual
2 Cutting finger nails	Yes / In part / No	0	1	2	3	4	Estimate / Actual
3 Putting on a glove	Yes / In part / No	0	1	2	3	4	Estimate / Actual
4 Cleaning armpit	Yes / In part / No	0	1	2	3	4	Estimate / Actual
5 Putting arm through a sleeve	Yes / In part / No	0	1	2	3	4	Estimate / Actual
6 Put on a splint (if required)	Yes / In part / No	0	1	2	3	4	Estimate / Actual
7 Positioning arm on a cushion or support in sitting	Yes / In part / No	0	1	2	3	4	Estimate / Actual

<b>ArMA – Section B (using the affected arm)</b>							
<b>In each column, please <i>CIRCLE</i> as appropriate</b>							
<b>Care activities (affected arm)</b>	<b>Possible to do a task or not?</b>	<b>Difficulty</b> 0 = no difficulty 1 = mild 2 = moderate 3 = severe difficulty 4 = unable to do activity				<b>Estimate/Actual</b> (if the task was not actually done in the last 7 days, circle 'estimate')	
1 Do up buttons on clothing	Yes / In part / No	0	1	2	3	4	Estimate / Actual
2 Pick up a glass, bottle or can	Yes / In part / No	0	1	2	3	4	Estimate / Actual
3 Use a key to unlock the door	Yes / In part / No	0	1	2	3	4	Estimate / Actual
4 Write on paper	Yes / In part / No	0	1	2	3	4	Estimate / Actual
5 Open a previously opened jar	Yes / In part / No	0	1	2	3	4	Estimate / Actual
6 Eat with a knife and fork	Yes / In part / No	0	1	2	3	4	Estimate / Actual
7 Hold an object still while using unaffected hand	Yes / In part / No	0	1	2	3	4	Estimate / Actual
8 Effect of affected arm on balance when walking	Yes / In part / No	0	1	2	3	4	Estimate / Actual
9 Dial a number on home phone	Yes / In part / No	0	1	2	3	4	Estimate / Actual

<b>10</b> Tuck in your shirt	<b>Yes / In part / No</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>Estimate / Actual</b>
<b>11</b> Comb or brush your hair	<b>Yes / In part / No</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>Estimate / Actual</b>
<b>12</b> Brush your teeth	<b>Yes / In part / No</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>Estimate / Actual</b>
<b>13</b> Drink from a cup or mug	<b>Yes / In part / No</b>	<b>0</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>Estimate / Actual</b>

## Appendix 10: Leeds Arm Spasticity Impact Scale (LASIS)

### Instructions for LASIS

1. Investigator asks questions to the patient and carer; the responses are noted on a proforma. Each question should be qualified in terms of the usual level of difficulty when performing the task *over the preceding seven days*. The investigator may supplement the questions by demonstrating the action required for a particular activity.
2. If either the patient or carer reports difficulty then the answer to the first part of each question is yes.
3. The responses are chosen to the following question 'How difficult is this activity?' by the patient or carer from the rating chart.
4. If patients or carers have not performed a particular activity within last seven days, then leave blank.
5. A summary score for patient disability is obtained by adding together all the patient scores and dividing this total by the number of questions on which responses were made. This results in a summary score between 0 (no disability) and 4 (maximum disability). A summary score for physical carer burden can be derived in a similar way.
6. Preliminary analysis of the psychometric properties has only been performed on the patient ratings thus far. This scale has not been published yet so any data obtained should be analysed with caution.

#### How difficult is this activity?

<b>0</b>	I have <b>no</b> difficulty
<b>1</b>	I have <b>a little</b> difficulty
<b>2</b>	I have <b>moderate</b> difficulty
<b>3</b>	I have a <b>great deal</b> of difficulty
<b>4</b>	I <b>cannot do</b> this activity

**Patient Name:** .....

**Carer Name:**.....

**Date and time of completion:** .....

<b>Leeds Arm Spasticity Impact Scale</b>							
<b>1. Cleaning the palm of the hand</b>							
Do you or your carer have difficulty cleaning the palm of your affected hand?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient		Carer		
			0	1	2	3	4
		Degree of difficulty experienced by patient	0	1	2	3	4
		Degree of difficulty experienced by carer					
<b>2. Cutting fingernails</b>							
Do you or your carer have difficulty cutting the fingernails of your affected hand?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient		Carer		
			0	1	2	3	4
		Degree of difficulty experienced by patient	0	1	2	3	4
		Degree of difficulty experienced by carer					
<b>3. Cleaning around the elbow</b>							
Do you or your carer have difficulty cleaning around the elbow of your affected arm?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient		Carer		
			0	1	2	3	4
		Degree of difficulty experienced by patient	0	1	2	3	4
		Degree of difficulty experienced by carer					
<b>4. Cleaning the armpit – affected arm</b>							
Do you or your carer have difficulty cleaning the armpit of your affected arm?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient		Carer		
			0	1	2	3	4
		Degree of difficulty experienced by patient	0	1	2	3	4
		Degree of difficulty experienced by carer					
<b>5. Cleaning the armpit – unaffected arm</b>							
Do you or your carer have difficulty cleaning the armpit of your unaffected arm?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient		Carer		
			0	1	2	3	4
		Degree of difficulty experienced by patient	0	1	2	3	4
		Degree of difficulty experienced by carer					

<b>Leeds Arm Spasticity Impact Scale</b>				
<b>6. Putting arm through sleeve</b>				
Do you or your carer have difficulty putting your affected arm through the sleeve of your coat?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient	Carer
			0 1 2 3 4	
		Degree of difficulty experienced by patient	0 1 2 3 4	
		Degree of difficulty experienced by carer		
<b>7. Putting on glove</b>				
Do you have difficulty putting a glove on your affected hand?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient	Carer
			0 1 2 3 4	
		Degree of difficulty experienced by patient	0 1 2 3 4	
		Degree of difficulty experienced by carer		
<b>8. Rolling over in bed</b>				
Do you have difficulty rolling over in bed because of tightness in your arm?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient	Carer
			0 1 2 3 4	
		Degree of difficulty experienced by patient	0 1 2 3 4	
		Degree of difficulty experienced by carer		
<b>9. Doing physiotherapy exercises</b>				
Do you have difficulty doing physiotherapy exercises to your affected arm?	<i>Yes/No or Not attempted</i>	Who does this activity most of the time?	Patient	Carer
			0 1 2 3 4	
		Degree of difficulty experienced by patient	0 1 2 3 4	
		Degree of difficulty experienced by carer		
<b>10. Balance when standing alone</b>				
Does the position of your affected arm cause difficulty in balancing when you are standing by yourself?	<i>Yes/No or Cannot stand</i>	Degree of difficulty experienced by patient	0 1 2 3 4	
<b>11. Balance when walking</b>				
Does the position of your affected arm cause difficulty in balancing when you are walking by	<i>Yes/No or Cannot walk</i>	Degree of difficulty experienced by patient	0 1 2 3 4	

<b>Leeds Arm Spasticity Impact Scale</b>			
yourself (including use of a walking aid)?			
<b>12. Stabilising objects – with affected arm</b>			
Do you have difficulty using your affected arm to hold objects steady while you use your unaffected arm?	Yes/No or <i>Cannot use affected arm</i>	Degree of difficulty experienced by patient	0 1 2 3 4



## Appendix 10: Ten-Meter Walk Test

This test examines gait speed. Gait speed is important for safe community mobility (e.g. crossing a street before the light changes).

### Administering the test:

Measure a 10 meter (33 foot) course and mark its ends with tape on the floor.

Position the subject approximately 3 feet behind the tape line.

Instruct the subject to walk at a comfortable rate until s/he is approximately 3 feet past the tape line. (Distance before and after the course minimizes the effect of acceleration and deceleration).

Repeat 3 times and average the times.

Instruct the subject to walk as above, but as fast as possible.

Repeat 3 times and average the times.

Convert to m/min: divide walking distance of 10 meters by elapsed time, then multiply by 60.

Compare the times to the reference values in the table below (or for quick reference can use 82m/min norm).

Gender/Decade	Comfortable (m/min)		Maximum (m/min)	
	Men	Women	Men	Women
20s	83.6	84.4	151.9	148.0
30s	87.5	84.9	147.4	140.5
40s	88.1	83.5	147.7	127.4
50s	83.6	83.7	124.1	120.6
60s	81.5	77.8	115.9	106.4
70s	79.8	76.3	124.7	104.9

OR

1.2-1.5 m/sec healthy young adult

0.9-1.3 m/sec older adult

**Appendix 5**

**EQ-5D**

---

**Introduction:**

By placing a tick in one box in each group below, please indicate which statements best describe your own health today.

**Mobility**

- I have no problems in walking
- I have some problems in walking
- I am confined to bed

**Self-care**

- I have no problems with self-care
- I have some problems washing or dressing myself
- I am unable to wash or dress myself

**Usual activities** (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

**Pain/discomfort**

- I have no pain or discomfort
- I have moderate pain or discomfort
- I have extreme pain or discomfort

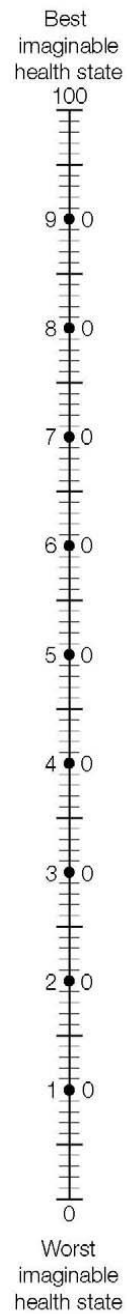
**Anxiety/depression**

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

To help people say how good or bad a health state is, we have drawn a scale (rather like a thermometer) on which the best state you can imagine is marked 100 and the worst state you can imagine is marked 0.

We would like you to indicate on this scale how good or bad your own health is today, in your opinion. Please do this by drawing a line from the box below to whichever point on the scale indicates how good or bad your health state is today.

Your own  
health state  
today



## Appendix 11

### Interview Topic Guide: Qualitative data capture (participant)

Participant Ref:

**Study: Dynamic Elastomeric Fabric Orthoses (DEFO) and physiotherapy after Botulinum toxin type-A (BT) in adults with focal spasticity: A mixed methods study.**

Recently you participated in the research study above in which you were assessed, measured and fitted with a fabric splint (DEFO) for wearing after Botulinum toxin injection(s). Please tell me about your experiences:

- **What were your experiences in joining the study (recruitment) or staying on the study (retention)?**

*Probe areas:*

*What did it feel like to take part in the study?*

*Why did you decide to take part?*

*Did you have any concerns and what were they?*

- **Were there any positive or negative experiences in the DEFO treatment?**

*Probe areas:*

*Did you feel any different?*

*Can you describe any benefits?*

*Can you describe any side-effects?*

*Did these effects interfere with your usual routines?*

- **What was the most acceptable length of time for you to wear the DEFO?**

*Probe areas:*

*What are your views on wearing the DEFO?*

*What are your reasons for when you chose to wear the DEFO?*

*Was there any time when you did not feel it acceptable to wear the DEFO?*

- **What were your experiences in following the treatment protocol?**

*Probe areas:*

*Was there anything that went well or not so well?*

*Did you think there was anything that could have been improved upon and how?*

*Can you describe any negative and positive views about your experience in the research?*

- **Was there any reason to prevent you from wearing the DEFO?**

*Probe areas:*

*How did you feel about wearing the DEFO?*

*Was there any reason why you would prefer not to wear it?*

- **Were there any additional costs?**

*Probe areas:*

*Did you incur any unexpected expenditure -for you or others?*

*What were they?*

- **Any other comments?**

*Probe areas:*

*What are your views about research?*

*As a participant, is there anything about your research experience you wish to comment on?*

*What could the research team have done differently to improve your experience?*

The above questions are asked face to face and recorded following the intervention phase.

## Appendix 12

### Interview Topic Guide: Qualitative data capture (Clinician)

Clinician Ref:

**Study: Dynamic Elastomeric Fabric Orthoses (DEFO) and physiotherapy after Botulinum toxin type-A (BT) in adults with focal spasticity: A mixed methods study.**

Recently you participated in the research study above in which you were providing clinical input. Please tell me about your experiences:

- **What were your experiences in the study?**

*Probe areas:*

*Why did you decide to take part?*

*What did it feel like to take part in the study?*

*Did you have any concerns and what were they?*

*Did you have any concerns with recruitment or retention of the participants?*

- **Can you provide feedback on the study either positive or negative?**

*Probe areas:*

*Can you describe any benefits?*

*Can you describe any difficulties?*

*Did the study interfere with your usual practice?*

- **What are your views on participant compliance?**

*Probe areas:*

*What are your views on why participants chose to wear the DEFO?*

*What are your reasons why participants chose not to wear the DEFO?*

*Was there any concern raised in wearing the DEFO?*

- **What were your experiences in following the study protocol?**

*Probe areas:*

*Was there anything that went well or not so well?*

*Did you think there was anything that could have been improved upon and how?*

*Was the protocol feasible in your clinical practice?*

*Was there any reason why the protocol was not practical to implement?*

- **Was there any reason to prevent you from delivering the intervention?**

*Probe areas:*

*How did you decide what input to deliver?*

*How did you decide how often to see the participant?*

*What are the reasons why you would not be able to treat the participant?*

- **Was there any additional impact on your service?**

*Probe areas:*

*Did you incur any unexpected work or expenditure-for you or others?*

*What were they?*

- **Any other comments?**

*Probe areas:*

*What are your views about research?*

*Can you describe any negative and positive views about your experience in the research?*

*As a clinician, is there anything about your research experience you wish to comment on?*

*What could the researcher or team have done differently to improve the study or experience?*

The above questions are asked face to face and recorded following the intervention phase.

**Appendix 13: Research Activity Log**

**Please document any activities you have participated in such as social events, shopping, hospital /clinic appointments or significant personal achievements.**

<b>Week</b>	<b>Date</b>	<b>Activity</b>
1		
2		
3		
4		
5		

<b>6</b>		
<b>7</b>		
<b>8</b>		
<b>9</b>		
<b>10</b>		

11		
12		

**Any other comments:**



## Appendix 14

### DM Orthotics Ltd<sup>®</sup> agreement for copyright to publish photographs

>>> Leanne Sawle1 <[Leanne.Sawle@dmorthotics.com](mailto:Leanne.Sawle@dmorthotics.com)> 07/24/13 12:13 PM >>>

Hi Katharine

Please find photographs of the DMO sock and glove attached.

Martin has given permission for you to use photographs of the DMO sock and glove, as long as DM Orthotics Ltd is acknowledged.

Regards,  
Leanne

Leanne Sawle MSc, PGCE (FE), MCSP

Sports Physiotherapist, and, Research and Development Lead

[www.dmactivesport.com](http://www.dmactivesport.com)

D.M.Orthotics Ltd  
2, Cardrew Way  
Cardrew Industrial Estate,  
Redruth,  
TR15 1SS  
United Kingdom  
Mobile: 07801 332355  
Tel: +44 (0)1209 219205  
Fax: +44 (0)1209 211175  
Email: [l.sawle@dmorthotics.com](mailto:l.sawle@dmorthotics.com)  
[www.dmorthotics.com](http://www.dmorthotics.com)

Member BHTA  
Company Reg No.05276121 VAT No.845173814  
Reg Office 443. Ashley Rd, Parkstone,Poole, Dorset BH14 0AX

#### Disclaimer

The contents of this communication and any attachments are for the confidential use of the named recipient(s) only. It is intended solely for the person or organisation to whom it is addressed and if you are not the intended recipient, you must not copy, distribute, disclose or take any action in reliance on it. If you have received this e-mail in error, please delete it from your computer system and notify the sender or [m.matthews@dmorthotics.com](mailto:m.matthews@dmorthotics.com) as soon as possible. Any opinions expressed in this email are those of the individual and not necessarily of the company. While this e-mail message and any attachments have been scanned for the presence of computer viruses however, D.M.Orthotics Ltd does not guarantee that either are virus-free and accepts no liability for damage sustained as a result of a virus. It is the recipient's responsibility to ensure that the onward transmission, opening or use of this message and any attachments will not adversely affect their systems or data or otherwise incur liability in law.

## Appendix 15

### Eligibility Criteria Explanations

#### Population for recruitment:

**Inclusion:** Adult (>18 years) living in the community with full capacity to undertake informed consent, with identified focal spasticity of one limb (in upper or lower limb) present for at least three months, treatment plan with Botulinum toxin identified and consented.

**Exclusion:** Unable to co-operate in a rehabilitation programme (co-morbidity of dementia or mental health disorder), fixed joint contracture, pregnancy, arthritic condition, fracture and neuromuscular diseases.

#### Inclusion criteria:

##### **Adult**

Person over 18 years old

##### **Living in the community**

Living in community accommodation (not hospital)

##### **Full capacity**

Able to retain information and weigh this up to make an informed decision (Mental Capacity Act, 2005)

##### **Focal Spasticity for a minimum period of 3/12**

Spasticity or over-activity of muscle is a fairly common symptom following damage or disease of the central nervous system (CNS). It can present in people with stroke, spinal cord injury, multiple sclerosis and acquired brain injury. It is associated with reduced movement and altered muscle control, often leading to pain, deformity and altered function. The population in this study have spasticity from different diagnostic causes and all demographic data is recorded.

Focal spasticity is identified on assessment (for the purpose of this study with a Modified Ashworth Scale (MAS) of >2) of one muscle or group of muscles over one or two joints resulting in resistance to passive movement. The majority of the patients in clinic actually have multifocal or even global spasticity. Obviously, the BT treatment targets a specific focal problem, but this could be on a background of more widespread spasticity. It is clinically appropriate to inject selected muscles out of global spasticity where functional or care improvements can be made. Typically MAS of 2 to 3 is indicative of appropriate BT intervention. (MAS of 4 is not appropriate).

## **MAS for grading spasticity:**

<b><u>Grade</u></b>	<b><u>Description</u></b>
0	No increase in muscle tone
1	Slight increase in muscle tone, manifested by a catch and release, or by minimal resistance at the end of range of motion when the affected part(s) is moved in flexion or extension.
1 <sup>1/2</sup>	Slight increase in muscle tone, manifested by catch and release, followed by minimal resistance, throughout the remainder (less than half) of the ROM.
2	More marked increase in muscle tone through most of ROM, but affected parts easily moved.
3	Considerable increase in muscle tone, passive movement difficult.
4	Affected part(s) rigid in flexion or extension.

### **Upper limb**

For the study purposes: Below the shoulder to include the elbow, wrist and hand. The muscle(s) injected (typically Biceps, Brachialis and/ or forearm wrist and finger flexors) are to be identified so the orthotic can be most appropriately targeted.

### **Lower limb**

For the study purposes: Below the hip and knee to include the foot and ankle. The muscle(s) injected (typically Gastro-soleus and/or Tibialis posterior) are to be identified so the orthotic can be most appropriately targeted. The participant needs to be able to walk > 10 meters x3 with/without a mobility aid. There also needs to be flickers of activity in the dorsi-flexor muscles (DMO Ltd).

### **Treatment plan with BT**

Botulinum Toxin (BT) is derived from the bacterium 'Clostridium Botulinum'. When injected into muscles, BT has local and controlled effects. It blocks transmission between the nerve endings and muscle fibres around the injection site, thereby causing weakness of the nearby muscle. Injections take effect within a few days and last until new nerve endings grow back, which typically takes three to four months.

This safe and effective injection of toxin to targeted over-active muscles achieves temporary muscle weakness. BT offers a unique treatment opportunity to inhibit specific overactive muscles whilst leaving other muscles unaffected (RCP *et al.*, 2009).

The potential participant has been identified by a Physiotherapist or Consultant independent from the researcher as potentially eligible for the study and has an appointment in the Spasticity Clinic with a Consultant for assessment (against specific criteria) and (following informed consent) intramuscular injection of Botulinum toxin to focal muscles with identified on-going recommended usual spasticity care plan (e.g. splint provision, postural management, physiotherapy etc.)

### **(Able to co-operate in a rehabilitation programme)**

The potential participant has demonstrated previous ability to comply with a rehabilitation programme. The participant does not have a mental health condition that will impact on their compliance of implementing the intervention.

### **Exclusion criteria:**

#### **Fixed joint contracture**

No ability to move joint (either actively or passively) due to restriction of soft tissues with no available range of movement due to loss of elasticity in muscles and soft tissues.

Note – the muscle(s) injected with BT must have the potential for improved available range and directly associated joints that can allow movement- these are pre-requisites to the BT intervention. This is sometimes difficult to clinically assess in the event of pain, distress or anxiety and in some cases assessment is only accurate under anaesthetic.

#### **Pregnancy**

Pregnant with child-Pregnancy is contra-indicated with BT management.

#### **Arthritic condition**

For the study purposes: An inflammatory arthritic condition that has a direct influence on the available joint range in the joint(s) which is controlled by the muscles injected in the affected limb. Any non-inflammatory arthritic changes will be recorded.

#### **Fracture**

A recently broken bone in the affected limb (within the last 3/12)

#### **Neuromuscular condition**

A genetic or acquired condition affecting the muscle strength e.g. Myaesthesia Gravis (Note Neuromuscular conditions are contra-indicated for treatment with BT).

**Eligibility** is assessed by the researcher with a comprehensive assessment based on the above criteria.

**Appendix 16: Example of analytic ‘Framework’ approach by coding participant data extracts** (Ritchie and Spencer (Bryman and Burgess (eds.) 1996:176-7)

Data extract (text)- (open code)	Coded for issues- (axial code)	Theme and sub-theme- (selective code)
<p><b>Topic guided question: Was there any reason to prevent you from wearing the DEFO?</b></p> <p><b>(I)</b> <i>How did you feel about wearing the DEFO?</i></p> <p><i>Was there any reason why you would prefer not to wear it?</i></p> <p><b>(P21)</b> ‘A <u>choice of colours</u> might have been nice.....because always having to wash them and they <u>always do neutral colours, or black...</u>’</p> <p><b>(I)</b> <i>Were you offered a choice of colours?</i></p> <p><b>(P21)</b> ‘No... no. It could be made obvious like a <u>medical thing</u> rather than a fashion item...( like Michael Jackson might wear)...[giggles]. I meant as a <u>physical cue for other people</u> for if you have <u>something wrong with your limb</u> to be helpful for other people ‘cause if you have nothing on they are <u>not aware you have a problem</u>’. ‘Splints in general serve as a <u>visual aid</u> to third parties which <u>prompts the public to be more helpful in social situations</u> e.g. shopping bag packing’.</p>	<p><b>Generating initial codes</b></p> <p><b>Issue: Choice of colour -</b></p> <p>Colour preference <b>(P04)</b> ‘<u>Orange!</u>’</p> <p><b>(P21)</b> ‘A <u>choice of colours...nice</u>’</p> <p><b>(P01)</b> ‘<u>I dyed it purple...</u>’</p> <p><b>Issue: Appearance importance: for self and others</b> Acceptable appearance just as important for self as others:</p> <p><b>(P04)</b> ‘...<u>people would look ... flesh coloured...</u>’</p> <p><b>(P19)</b> ‘...you could <u>hardly see it ... just blended in ...</u>’</p> <p><b>Issue: motives and perceptions of self and others:</b></p> <p><b>B.1 Self-perception of disability</b></p> <p>Acceptability appearance –individual attitudes explored about ‘difference’.</p>	<p><b>Refining and naming of themes</b></p> <p><b>Analysis:</b> Appearance and wearing acceptability with impact of differing perceptions of disability on study design, feasibility in clinical context, motives and expectations, recruitment, retention, adherence, acceptability, ethical issues etc.</p> <p><b>Sub-themes:</b></p> <p><b>B.1 Self-perception of disability</b></p> <p><b>B.2 Societal perceptions of disability</b></p> <p><b>B.3 Perceptions of disability in research</b></p> <p><b>Theme:</b></p> <p><b>Organizing Participant theme</b></p> <p><b>(OP.1): Differing perceptions of disability</b></p> <p>Impact of differing perceptions of</p>

<p>Another response:</p> <p><b>(P01)</b> <i>'It's like people say what have you done? I've had a stroke and they know that but this is <u>just part of the stroke and that's why I'm wearing it</u> and they all thought I had <u>done something</u> to my arm like broken it or something'</i></p> <p><b>(P01)</b> <i>'so ... <u>I dyed it purple</u>...more me..'</i></p> <p><b>(P01)</b> <i>'It's more <u>what people might say</u>. But I would just wear it anyway'</i></p> <p>Another response:</p> <p><b>(P04)</b> <i>'There is always this thing... <u>people would look</u> ...with short sleeves...I know it was <u>flesh coloured</u> even with the tones'</i></p> <p><b>Partner</b> <i>'You did want a different colour...didn't you?' (P04) [Laughs....]</i></p> <p><b>(I)</b> <i>'Colour?'</i></p> <p><b>(P04)</b> <i>'<u>Orange!</u>' [laughs]</i></p> <p>Another response:</p> <p><b>(P19)</b> <i>'...you could <u>hardly see it ...and for the colour of it ...just blended in'</u></i></p> <p><b>(P16) (carer)</b> <i>'Just took a <u>dislike</u> to it! That's the reaction I got!' (P16) [grimaces and shakes head] I tried to</i></p>	<p><b>(P19)</b> <i>'...<u>blended in</u>'</i></p> <p><b>(P04)</b> <i>'<u>flesh coloured</u>'</i></p> <p><b>(P01)</b> <i>'<u>just part of the stroke ...'I would just wear it anyway'</u>... '<u>dyed it purple</u>... more me'</i></p> <p><b>(P16)</b> Refused to wear DEFO- '<u>dislike</u>' of its appearance.</p> <p><b>B.2 Societal perceptions of disability</b></p> <p><b>(P21)</b> <i>'... <u>always do neutral colours</u>.'</i></p> <p><b>(P01)</b> Medicalised not seen as a fashion item <b>(P21)</b> Cueing others in society useful as '<u>a physical cue for other people</u>... '<u>prompts the public</u>'<b>(P21)</b>'<u>something wrong</u>... more <u>helpful in social situations</u> '</p> <p>Acceptable appearance for disability versus injury and disability a part of self-identity <b>(P01)</b> '<u>what people might say</u>'- Inferred sports injury ('<u>done something</u>') more acceptable in society? Relevance for orthotic appearance and adherence.</p> <p>Challenges in mainstream perceptions of disability- attitudes and 'social model of disability'.</p> <p><b>B.3 Perceptions of disability in research:</b> expectations, perspectives and motivation. Perspectives from joining research- importance of being</p>	<p>disability –self and others</p> <p>Impact of differing perceptions of</p> <p><b>Main Theme:</b></p> <p><b>Global Participant theme (GP. 2): Perceptions of disability: impact on research</b></p> <p><b>Key:</b></p> <p><b>P=</b> Participant code</p> <p><b>I=</b> Interviewer</p> <p><b>B=</b> Basic theme (sub-theme)</p> <p><b>O=</b> Organizing theme (theme)</p> <p><b>G=</b> Global theme (superordinate theme)</p>
--	--	---

explain but she would not even try it on'.

**Topic guided question: What were your experiences in the study?**

**(I)** Why did you decide to take part?

**(P04)** 'to sort of try something ...as part of research?'

**(P11)** 'I think in a situation like that, you would try anything really'.

**(P18)** '... sometimes you can go on week by week, month on month and not see anything has been done... that is a positive like a feeling of hope like something was being done.. it will improve. That was a positive. It gives you a feeling of confidence...'

**(P19)** 'I decided to take part because if you do anything like that it helps other people'.

**(P18)** '...to benefit others in the future that was the main reason'.

**(P20)** 'Anything that can help to alleviate the suffering of stroke has got to be a good thing'.

**(P10)** 'I was glad to be helping you in your research and thought it would be good for me to help me.... in my progression'.

chosen, hope, opportunity, benefit self and helping others.

**(P18)** 'something was being done... feeling of hope... feeling of confidence'  
**(P04)** 'try something' **(P11)** 'try anything really' **(P10)** '...helping me...helping you in your research...'

**(P18)** 'benefit others' **(P19)** 'it helps other people' **(P20)** '...to alleviate the suffering...'

**Appendix 16: Example of analytic ‘Framework’ approach by coding clinician data extracts** (Ritchie and Spencer (Bryman and Burgess (eds.) 1996:176-7)

Data extract (text)- (open code)	Coded for issues- (axial code)	Theme and sub-theme-(selective code)
<p><b>Topic guided question: What were your experiences in following the study protocol?</b></p> <p><b>(I) Was there anything that went well or not so well?</b></p> <p><i>Was the protocol feasible in your clinical practice?</i></p> <p><i>Was there any reason why the protocol was not practical to implement?</i></p> <p><i>‘I didn’t always get the <b>clinic letter</b> in the <b>most-timely</b> fashion’. (C2)</i></p> <p><i>‘it was <b>difficult to keep to the times in the protocol</b> within 2 weeks post BT to have assessed the patient’ (C1)</i></p> <p><i>‘...the hardest thing about the protocol was just adjusting to basically this patient <b>needed to be seen within a fairly set time frame</b>’. (C2)</i></p> <p><i>‘...<b>stress came from the time constraints of the protocol</b> and I understand the protocol has to have time constraints but there were times when I got <b>frustrated</b> because of my other caseload was</i></p>	<p><b>Generating initial codes</b></p> <p><b>Issue: Protocol issues and research procedural issues around feasibility.</b></p> <ul style="list-style-type: none"> <li>• Research communication clinic letters not <u>most-timely</u> (C2)</li> <li>• Impact of co-morbidity <u>health of the participant</u> (C2)</li> <li>• Variance in timing <u>time constraints</u> (C3)... <u>set time frame</u>. (C2)</li> <li>• Variance in fitting ‘the <u>deadlines</u> (C3)</li> <li>• Availability of DMO clinician <u>only part time and not in the area</u>. (C3)</li> </ul> <p><b>Issue: Ethical considerations: ethical discussions around protocol and clinical uncertainty.</b></p> <ul style="list-style-type: none"> <li>• Uncertainty in clinical risk <i>safety issues ... <u>not really sure</u> ...sorted out...study follows the <u>clinical needs</u></i> (C3)</li> <li>• Uncertainty and communication in research regarding eligibility</li> </ul>	<p><b>Refining and naming of themes</b></p> <p><b>Analysis:</b> Impact on study design, protocol feasibility in clinical context, uncertainty, recruitment, retention, adherence, compliance acceptability, variance, ethical issues: consent, clinical risk etc.</p> <p><b>Sub-themes:</b></p> <p><b>BC.1 Variance in fitting</b></p> <p><b>BC.2 Variance in timing</b></p> <p><b>BC.3 Availability of DMO clinician</b></p> <p><b>BC.4 Impact of co-morbidity</b></p> <p><b>Theme:</b></p> <p><b>Organizing Clinician theme (OC.1) Protocol feasibility</b></p> <p>Also linked but broader themes underpinning clinical research delivery:</p> <p><b>Sub-themes:</b></p>



<p>being sacrificed for the protocol'. (C3)</p> <p>'... trying to meet the <b>deadlines</b> especially due to having to liaise with <b>someone... who was only part time and not in the area</b>'. (C3)</p> <p><b>Topic guided question: What are your views on participant compliance?</b></p> <p>(I) <i>What are your views on why participants chose to wear the DEFO?</i></p> <p>'<b>most people</b> would suggest they are <b>comfortable</b>' (C1)</p> <p>'...the participant <b>absolutely didn't want to try it</b> and that was quite difficult' (C1)</p> <p>'They were <b>very compliant</b> with it'.(C3)</p> <p>'...in terms of compliance I think it affected them in terms of <b>having someone around to help</b> them put it on....she really <b>struggled getting the carers to help</b> her to put it on...' (C2)</p> <p>'only provided the beige and there is possibility that some may not like that colour and would have <b>preferred a different colour</b>' (C1)</p> <p>(I) <i>Was there any concern raised in wearing the DEFO?</i></p> <p>'<b>little things</b> that we <b>ironed out</b> at the</p>	<p>criteria '<b>little things that we ironed out at the beginning</b>' (C1)</p> <ul style="list-style-type: none"> <li>• Following protocol <b>standard physiotherapy</b> (C2) (fidelity).</li> </ul> <p><b>Issue: Acceptability, tolerance and compliance issues regarding:</b></p> <ul style="list-style-type: none"> <li>• Comfort '<b>most people would suggest they are comfortable</b>'(C1)</li> <li>• Colour <b>different colour</b>' (C1)</li> <li>• Safety '<b>one or two safety issues</b>' (C3)</li> <li>• Compliance and wearing issues <b>absolutely didn't want to try it</b> (C1)</li> <li>• Difficulty with donning <b>someone around to help</b> them put it on (C2)</li> </ul> <p><b>Emergent themes: feasibility, and acceptability of the DEFO intervention in a clinical setting with analysis of specific ethical issues, clinical risk and conflicts in capacity.</b></p>	<p><b>BC.1 Eligibility</b></p> <p><b>BC.2 Clinical risk</b></p> <p><b>BC.3 Fidelity</b></p> <p><b>BC.4 Research communication</b></p> <p><b>Theme:</b></p> <p><b>Organizing Clinician theme (OC.2): Ethical issues</b></p> <p><b>Main Theme:</b></p> <p><b>Global Clinician theme (GC.1): Research impact on clinical practice</b></p> <p><b>Sub-themes:</b></p> <p><b>BC.1 Comfort</b></p> <p><b>BC.2 Compliance and wearing issues</b></p> <p><b>BC.3 Difficulty with donning</b></p> <p><b>Theme:</b></p> <p><b>Organizing Clinician theme (OC.2) Intervention (DEFO) acceptability</b></p> <p><b>Main Theme:</b></p> <p><b>Global Clinician theme (GC.2): Feasibility and acceptability of DEFO in a clinical setting.</b></p>
--	--	--

<p><i>beginning'</i> (C1) (Eligibility)</p> <p><i>'...there was one or two safety issues and I was not really sure initially where to go to with. But they did get sorted out'. (C3)</i></p> <p><i>'I tried to just deliver just standard physiotherapy that I would normally do'.(C2)</i></p> <p><i>'...so the study follows the clinical needs and that is fine'. (C3)</i></p> <p><i>'the individual health of the participant e.g. seizures and pressure sore' (C2)</i></p>		<p><b>Key:</b></p> <p><b>C</b>= Clinician code</p> <p><b>I</b> = Interviewer</p> <p><b>B</b>= Basic theme (sub-theme)</p> <p><b>O</b>= Organizing theme (theme)</p> <p><b>G</b>= Global theme (superordinate theme)</p>
--	--	---

## Appendix 17

### Research Report

**Study Title: Dynamic Elastomeric Fabric Orthoses (DEFO) and physiotherapy after Botulinum toxin (BT) in adults with focal spasticity: A feasibility study using mixed methods.**

Thank you for your participation and/or involvement in the research study. The following is a summary report of the findings in the study. (Katharine Stone, Consultant Therapist in Neurology, for Doctor of Clinical Research, Exeter University).

**Ethical registration and approval: Ref: 12/SC/0518** (NRES) Committee South Central-Berkshire B-ethical approval registered with local NHS R&D and Exeter University.

#### **Acknowledgements:**

With thanks to the research participants for their co-operation, participation and patience in this feasibility study.

With thanks to the following research supervisors for their encouragement and support:

**Professor D A Richards**- Research Supervisor (Exeter University)

**Professor J Marsden**- Field Supervisor (Plymouth University)

**Vasilis Nikolaou**- Statistical Support (Exeter University)

With thanks to the following clinicians who participated in the study whose support and encouragement have made the implementation of this research possible:

**Sandra Douglas**- Physiotherapist clinician

**Ruth Osborne**- Physiotherapist clinician

**Sarah Lay**- Physiotherapist clinician (DM Orthotics Ltd<sup>©</sup>)

**Dr Abhijit Mate**- Consultant Physician in Rehabilitation Medicine

With thanks to **Mary Eason**, Research Administrative Support Worker for her excellent communication and organisational skills.

With thanks to **Karen Roach**, Therapies Manager for her encouragement and wisdom.

With thanks to **Martin Matthews**, Director of DM Orthotics Ltd<sup>©</sup> for his support of the research: by agreement to provide the supply of equipment; the clinical assessments and fitting of orthoses (DEFO's) in the study.

## The study

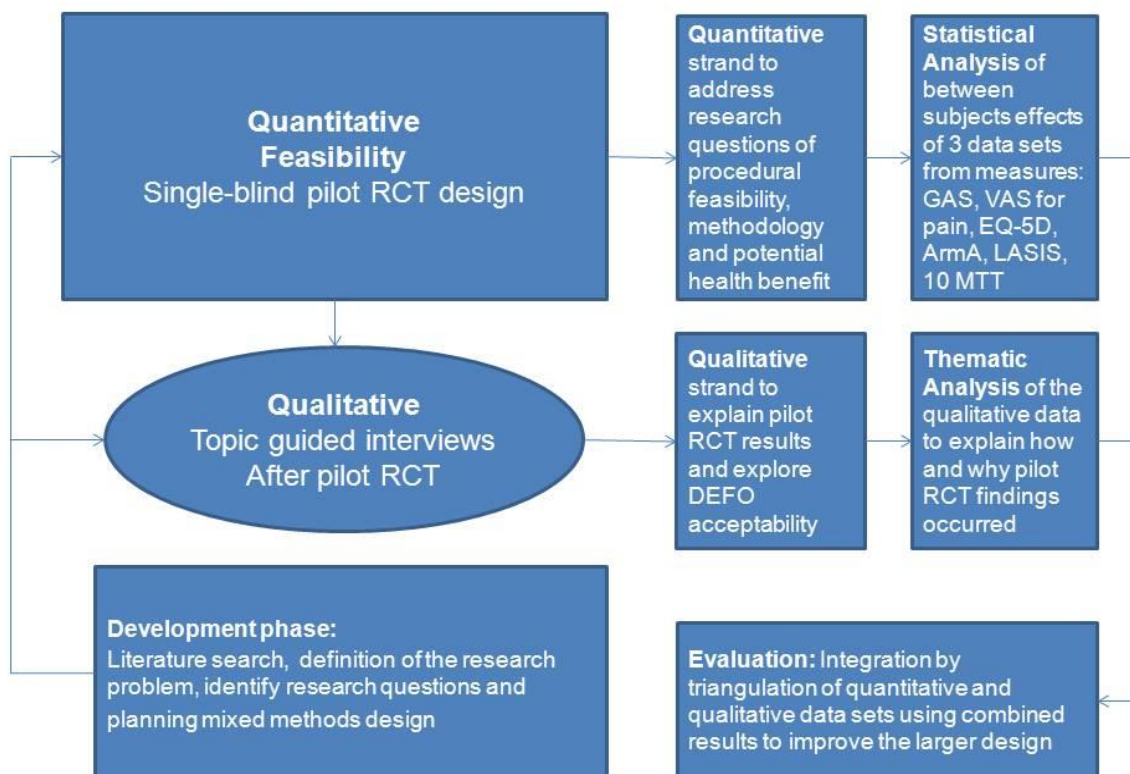
### Research questions

This study identified three equally important questions to explore the uncertainty of this intervention following BT for focal spasticity in adults:

- What is the likelihood of health benefits of treatment with DEFO and physiotherapy and usual care, compared to usual care alone? (primary question)
- What is the feasibility of the protocol to inform the design of a larger study?
- How acceptable is the DEFO intervention in clinical practice?

The research questions were explored in terms of three issues; likely benefit, feasibility of the intervention protocol and acceptability of the intervention. These were considered likely to be best addressed by a mixed methods design (Figure 1). The research questions were subsequently linked to quantitative or qualitative designs to provide data sets to address the uncertainties.

**Figure 1. Procedural diagram of the mixed methods study design**



## Key findings of the study

### 1. What were the identified health benefits?

Person-centred goals achieved with significant difference in achievement in the DEFO group.

Positive and tangible health benefits in real-life contexts which were valued by the majority of participants in the DEFO intervention group.

#### Physical benefits

- Pain level reduced
- DEFO supportive and comfortable
- More relaxed
- Posture more normal and improved functional activity

#### Psychosocial health benefits

- Appearance acceptable from a health perspective with social cues
- More 'normal'
- More awareness
- Appearance socially acceptable
- Quality of life benefits
- Self-image and self-awareness issues raised by participants

### What were the adverse effects?

Negative findings were related to a few reported individual fitting and wearing issues:

**Physical:** tightness, sweating and swelling in hot weather, dislike, reliance on others, difficulty with donning (initially)

**Impact on usual activity:** A block to sunbathing and therapies (including acupuncture and swimming).

### 2. Was the study feasible?

The study was found feasible by both participants and clinicians. The DEFO protocol was found acceptable by evidence from the DEFO wearing Log.

Findings:

- High level of protocol compliance in (n=10) with Non-compliance (n=1).
- There was minimal variance reported in protocol delivery (with delays in timing and fitting n=2) and level of activity between groups.
- Feasibility of the protocol delivery was established in clinical practice with a high level of adherence and tolerance with compliance in the DEFO wearing protocol.
- No added burden in data captures (measures).
- Specific wearing issues contributed to feasibility of protocol including reliance on carers for donning DEFO.
- Co-morbidity and rehabilitation potential were found to impact on clinical practice and protocol delivery.
- The protocol was acceptable and tolerated by both clinicians and participants.

- Clinical capacity, priorities, agreement on eligibility and potential clinical risk were identified as factors that could impact on procedural clinical research feasibility.
- Participant compliance was found to depend on level of dependency and reliance on carers.

Protocol modifications were indicated to improve timing of the assessment and delivery by:

- Earlier assessment for fitting prior to BT.
- Longer delivery of DEFO intervention with no need for removal.

### **3. Was the DEFO intervention acceptable?**

**Participant findings:** Wearing compliance and tolerance evidenced; preference of DEFO in combination with physiotherapy; earlier in condition management; also in BT cycle; and to be worn for a longer period following BT.

**Clinician findings:** Clinical bias over active vs passive function and central over distal application;

DEFO acceptability was tempered by co-morbidity and rehabilitation potential.

Both clinicians and participants provided evidence of DEFO acceptability in practice/setting (with caveat of stratification of participants based on the above findings).

Both positive and negative wearing experiences with substantive physical and psychosocial benefits reported.

- Appearance was considered a significant factor in acceptability.
- Physical benefits were established.
- Psychosocial benefits were established.
- Functionality of the DEFO was found beneficial in comparison to rigid splints.
- A high level of DEFO wearing compliance was established.
- Poor fitting was found to detract from acceptability.
- Negative findings included difficulty and/or reliance with donning of the DEFO.

#### **Ethical considerations included:**

Clarification was sought on the study eligibility criteria and research guidance was provided for this and on management of potential clinical risks. Protocol amendment was submitted to improve procedural feasibility and ethical approval was obtained.

Potential clinical risks were highlighted and managed clinically.

No adverse events were reported.

#### **Future implications**

A mixed method approach is appropriate for research in a health care setting. From the pilot RCT: the results of the GAS indicated for a potential Phase III randomised clinical trial. It was estimated you would need 400 patients (200 per

group). From this it is likely a multi-centre study would provide the optimal opportunity for recruitment to this study. A research proposal based on the findings of this feasibility study could be developed for research funding.

The Thematic Analysis of the interviews provided rich detail to identify the health benefits and explain feasibility and acceptability of the RCT. Integration of the findings provided valuable procedural detail for a future study:

- Choice of colour could improve cosmetic acceptability.
- Improved fitting could also improve acceptability.
- Availability of a carer for donning improved compliance.

Also cost-analysis should be incorporated into the design of a larger study.

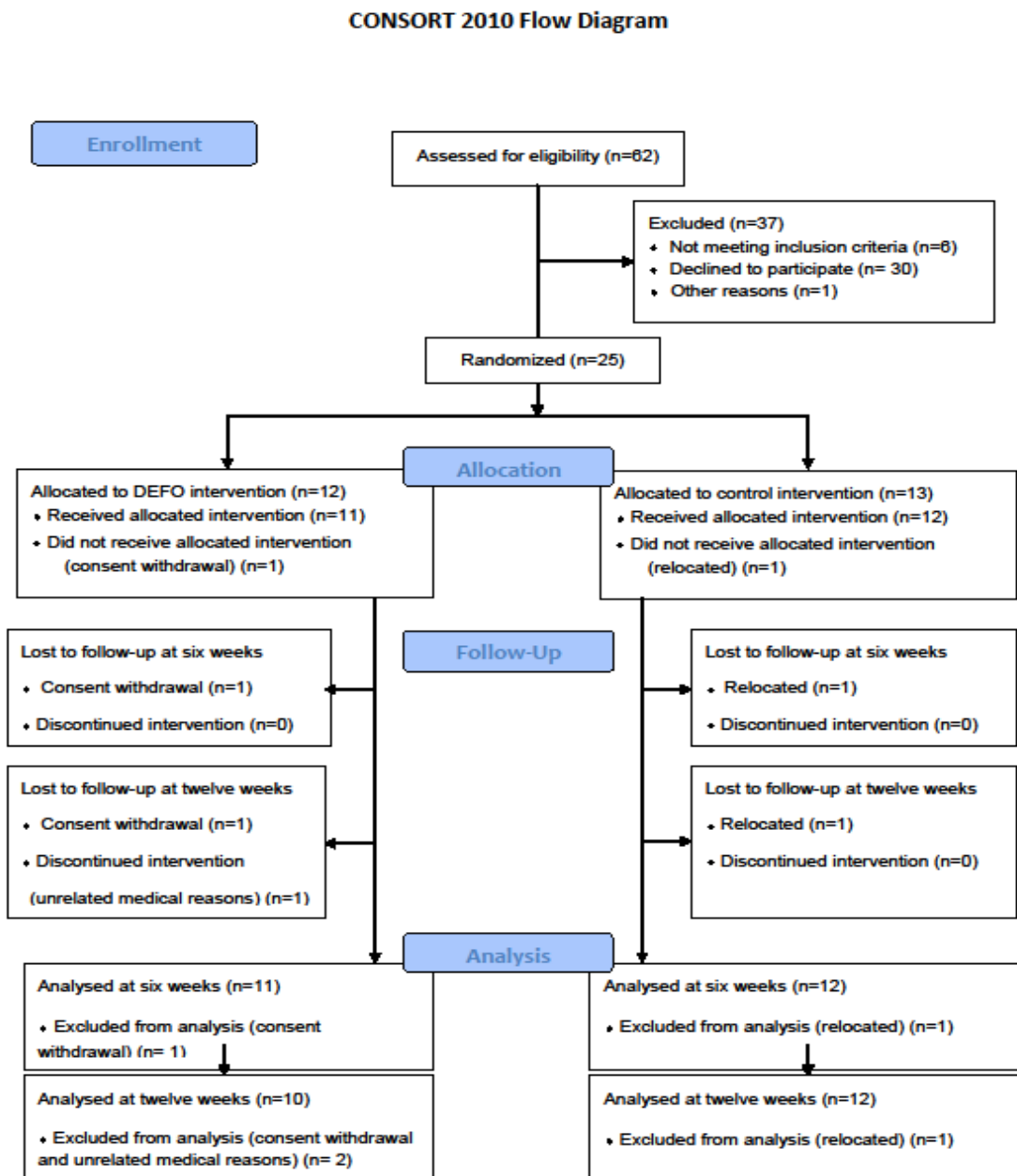
Eligibility analysis suggested the need for further consideration to stratify the research participants to specific static or progressive neurological/stroke conditions so the treatment can be applicable to conditions based on:

- Upper limb
- Level of dependency
- Progressive or static condition

Patients and public should be involved to improve a future study design and contribute to monitoring of the research delivery.

Physiotherapy modalities of delivery and contact time should be specifically collated to identify what treatment options are of most benefit. Physiotherapy clinicians could be trained as DEFO assessors to improve procedural delivery.

Figure 2 CONSORT Flow diagram of recruitment and attrition



All of the available data was analysed for intention to treat (ITT) analysis.



## Summary (Abstract)

**Aim:** A study to investigate the feasibility, acceptability and any added health benefits of a dynamic elastomeric fabric orthosis (**DEFO**) and usual care compared to treatment of usual care alone in the treatment of spasticity following intramuscular injection of Botulinum toxin (**BT**). The therapy planned in this study was aimed at improving muscle control during this '*window of opportunity*'.

**Participants:** Adults living in the community with focal spasticity of the arm or lower leg recruited from a regional Spasticity Clinic.

**Intervention:** Provision of an individually fitted DEFO (worn daily up to 8 hours) usual care and physiotherapy as required for 6 weeks.

**Measures:** A selection of reliable and validated measures were chosen together with clinical measures. **Goal Attainment Scale (GAS) primary measure** and secondary measures for function and care benefit; Arm Activity measure (ArmA), Leeds Arm Impact Score (LASIS), VAS for pain, European Quality of Life-5 Dimensions (EQ-5D), gait velocity (10MTT). Variance and fidelity was captured with: DEFO wearing record, Activity Log, clinical records and Physiotherapy modalities.

**Method: Mixed methods embedded design feasibility study (figure 1):**

**Quantitative:** Feasibility pilot single-blind Randomised Controlled Trial (RCT):

**Intervention Group:** Delivered as: six weeks DEFO intervention, physiotherapy (as required) and usual care followed by six weeks removal of the intervention but continued physiotherapy (as required) and usual care.

**Control Group:** Delivered as: twelve weeks physiotherapy (as required) and usual care.

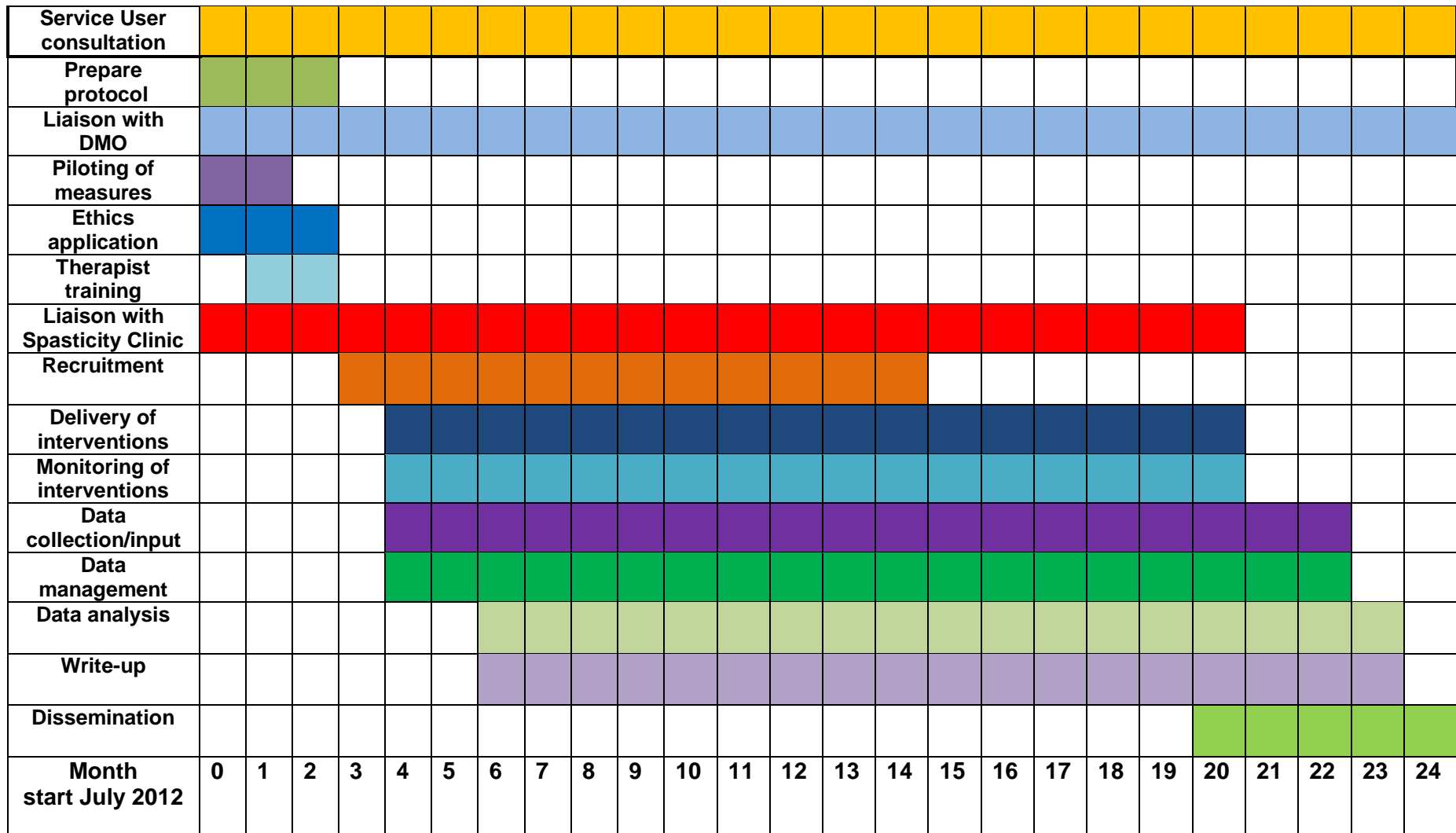
**Qualitative:** Topic guided interviews of those participants in the intervention group and the physiotherapists who delivered the physiotherapy.

**Analysis:** Statistical comparison for significance of repeated measures by ANCOVA adjusted means (at baseline, after six weeks and twelve weeks) between groups and to inform calculation for a larger study. 'Thematic Analysis' of participant and clinician transcribed interviews. Quantitative and qualitative findings were integrated and triangulated to inform a larger study.

**Results:** Participants (n=25) recruited over twelve months, (n=22) completed study. Two people (n=2) withdrawal of consent before the study commenced and one (n=1) person withdrawal due to medical complications unrelated to the study (see figure 2 CONSORT flow). Statistical analysis showed **improvement in both groups with greater health benefit in the intervention group** with mean difference between groups in the Goal Attainment Scaling (GAS) score of 12.17 (95%CI: 3.16 to 21.18;  $p = 0.014$ ) but no statistical significance in the secondary measures. Physiotherapy modalities for spasticity were linked to 'passive' and 'active' function. Feasibility and acceptability was established with Thematic Analysis providing valuable insight into patient and clinician perspectives on disability.

**Conclusions:** Findings indicated potential added health benefits including carer benefit. Feasibility, acceptability and clinical application of DEFO as a potential new intervention were established. This has implications for future spasticity management with patient benefit for 'passive' and 'active' function. Further research is indicated with a larger phase III trial (based on the GAS sample results) to evaluate DEFO efficacy in people with spasticity following BT.

## Research Activity Gantt chart (Appendix 18)



## Glossary

**Analysis of covariance (ANCOVA)** A statistical technique for equating groups on one or more variables when testing for statistical significance; it adjusts scores on a dependent variable for initial differences on other variables, such as pretest performance.

**Dependent variable** A variable affected by the independent variable; also called the “outcome variable”.

**Generalizability (population/ecological)** The degree to which results obtained from a sample can be generalized to a larger group, environments and conditions outside the research setting.

**Hawthorne effect** A positive effect of an intervention resulting from the subjects’ knowledge that they are involved in a study or their feeling that they are special in some way receiving ‘special’ attention.

**Heterogenic** The sample of research participants or constituents in which characteristics are all different with respect to one or more.

**Homogeneous** The sample of research participants or constituents in which characteristics are all similar with respect to one or more.

**External validity** The degree to which results are generalizable or applicable, to groups and environments outside the research setting.

**Independent variable** A variable that affects (or is presumed to affect) the dependent variable under study and is included in the research design so that its effect can be determined. Also called the “experimental” or “treatment” variable.

**Internal validity** The degree to which observed differences on the dependent variable are directly related to the independent variable, not to some other (uncontrollable) variable.

**Saturation** The degree of availability of potential recruits which has diminished to none.

**Standard deviation (SD)** The most stable measure of variability; it takes into account each and every score in a distribution.

**Triangulation mixed method design** A study in which quantitative and qualitative data are collated simultaneously and used to validate and clarify findings.

References accessed: 15<sup>th</sup> December 2012

[http://highered.hill.com/sites/0072532491/student\\_view0/glossary.html](http://highered.hill.com/sites/0072532491/student_view0/glossary.html)

## References

### A

Association of Physiotherapists Interested in Neurology (ACPIN). (1998) *Clinical Practice Guidelines on Splinting Adults with Neurological Dysfunction*. London: Chartered Society of Physiotherapy.

Adrienne, C and Manigandan, C. (2011) Inpatient occupational therapists hand-splinting practice for clients with stroke: A cross-sectional survey from Ireland. *Journal of Neurosciences in Rural Practice*. 2: 141-149.

Akobeng, A, K. (2005) Principles of evidence based medicine. *Archives of Disease in Childhood*; 90:837-840. Accessed: 15 April 2015 Available at: <http://adc.bmj.com/>

Andrew, S and Halcomb, E. (2009) *Mixed Methods Research for Nursing and Health Sciences*, Wiley-Blackwell, London.

Andringa, A, van de Port, I, Meijer, J, W. (2013) Long-term use of a static hand-wrist orthosis in chronic stroke patients: a pilot study. *Stroke Research and Treatment*. Accessed: 12 March 2015 Available at: <http://dx.doi.org/10.1155/2013/546093>

Ashford, S and Turner-Stokes, L. (2006) 'Goal Attainment Scaling for spasticity management using botulinum toxin'. *Physiotherapy Research International*, 11, (1): 24-34.

Ashford, S, Turner-Stokes, L, Slade, M. (2008) Preliminary evaluation of reliability and internal consistency for Arm Activity Measure (ArMA) *Clinical Rehabilitation* 22(9):856-63.

Ashford, S, Turner-Stokes, L, Slade, M. (2013) Conceptualisation and development of the arm activity measure (ArmA) for assessment of activity in the hemiparetic arm. *Disability and Rehabilitation*. 35(18):1513-1518.

Ashford, S, Slade, M, Nair, A, Turner-Stokes, L. (2014) Arm Activity measure (ArmA) application for recording functional gain following focal spasticity treatment. *International Journal of Therapy and Rehabilitation*, 21(1):10-17.

Attride-Stirling, J. (2001) Thematic networks: an analytic tool for qualitative research. *Qualitative Research*. SAGE Publications: London. vol. 1(3): 385-405.

## B

Bakheit, A, M, Pittock, S, Moore, A, P, Wurker, M, Otto, S, Erbguth, F, Coxon, L. (2001). A randomized double blind placebo-controlled study of the efficacy and safety of botulinum toxin type A in upper limb spasticity in patients with stroke. *European Journal of Neurology* 8(6):559-65.

Balaam, M, Egglestone, S, R, Fitzpatrick, G, Rodden, T, Hughes, A-M, Wilkinson, A, Nind, T, Axelrod, L, Harris, E, Ricketts, I, Mawson, S, Burrige, J. (2011) Motivating mobility: Designing for lived motivation in stroke rehabilitation. CHI , 2011, Session: Rehabilitation (May 7-12, 2011, Vancouver, B C, Canada).

Barnes, M, P and Davis, E, C. (2000) Botulinum toxin and spasticity. *Journal of Neurology and Neurosurgery and Psychiatry* (69):143-147.

Barnes, M, P. (2001) An overview of the clinical management of spasticity. In: Barnes, M, P, Johnson, G, R. (Eds.) *Upper motor neurone syndrome and spasticity. Clinical management and neurophysiology*. Cambridge: Cambridge University Press: pp.1-11.

Bazely, P. (2009) Analysing qualitative data: More than “identifying themes”. *Malaysian Journal of Qualitative Research*. (2):6-22.

Benner, P, E. (2001) *From novice to expert. Excellence and power in clinical nursing practice*. London: Prentice Hall Health International (UK) Ltd.

Bergfeldt, U, Borg, K, Kullander, K, Julin. (2006) Focal spasticity therapy with Botulinum Toxin: Effects on function, activities of daily living and pain in 100 adult patients. *Journal of Rehabilitation Medicine* 38: 166-171.

Betts, L. (2006) Lycra orthoses and their use in MS. *WayAhead*. 10(4):2.

Bhakta, B, B, Cozens, A, J, Bamford, J, M, Chamberlain, M, A. (1996) Use of botulinum toxin in stroke patients with severe upper limb spasticity. *Journal of Neurology, Neurosurgery and Psychiatry* (61): 30-35.

Bhakta, B, B, Tennant, A, Couzens J, A. (1999) ‘Application of item response theory to measure the disabling effects of severe upper limb spasticity in stroke and the consequent carer burden. *Cerebrovascular Disease*. 9 (supplement 1): 124.

Bhakta, B, B, Cozens, A, J, Chamberlain, A, M, Bamford, J, M. (2000) Impact of botulinum toxin type A on disability and carer burden due to arm spasticity after stroke: a randomised double blind placebo controlled trial. *Journal of Neurology, Neurosurgery and Psychiatry* (69):217-221.

Bobath, B. (1990) *Adult Hemiplegia: Evaluation and Treatment*, 3<sup>rd</sup> edition. Oxford: Heinemann Medical.

- Bohannon, R and Smith, M. (1987) Interrater reliability of a Modified Ashworth Scale of muscle spasticity. *Physical Therapy* (67): 206-207.
- Booth, J and Hewison, A. (2002) Role overlap between occupational therapy and physiotherapy during in-patient stroke rehabilitation: an exploratory study. *Journal of Interprofessional Care* (16):31-40.
- Boutron, I, Moher, D, Altman, D, G, Schultz, K, F, Ravaud, P. (2008) Extending the CONSORT statement to randomized trials of nonpharmacological treatment: Explanation and elaboration. *Annals of Internal Medicine* 148(4): 295-309.
- Boyd, R, N, Pliatsios, V, Starr, R, Wolfe, R, Graham, H, K. (2000) Biomechanical transformation of the gastrosoleus muscle with Botulinum toxin A in children with cerebral palsy. *Developmental Medicine and Child Neurology* 42(1):32-41.
- Boyatzis, R, E. (1998) *Transforming qualitative information: thematic analysis and code development*. London: Sage.
- Braun, V and Clarke, V. (2006) Using Thematic Analysis in Psychology. *Qualitative Research in Psychology*.3/2: 77-101 London: Edward Arnold Ltd.
- Bridges, S. (2004) The effects of dynamic lycra socks in ambulant children with cerebral palsy: A pilot study. University College London. (Unpublished MSc Research Report).
- Bright , F, A, S, Kayes, N, M, McCann, C, M, McPherson, K, M. (2011) Understanding hope after stroke: A systematic review of the literature using concept analysis. *Topics in Stroke Rehabilitation*. 18(5):490-508.
- Broetz, D and Birbaumer, N. (2013) Behavioural physiotherapy in post stroke rehabilitation. *NeuroRehabilitation* (33): 377-384.
- Brownlee, F, McLeman, A. (2002) Edinburgh Dynamic Lycra Splinting Trial-assessment of hand function. *National Association of Paediatric Occupational Therapists Journal*, 19-21.
- Bryman, A. (1992) Quantitative and qualitative research: further reflections on their integration. In: Brannen J, (Ed.) (2) *Mixing Methods: Qualitative and Quantitative Research*. Ashgate, Aldershot. pp. 57-78.
- Bryman, A. 2001: *Social research methods*. Oxford: University Press.
- Bryman, A. (2006) Integrating quantitative and qualitative research: how is it done? *Qualitative Research*. London: Sage Publications. Vol. 6(1) 97–113.

## C

Calvert, J, Kelly, J. (2013) What is the clinical and cost effectiveness of dynamic elastomeric fabric orthoses (DEFO's) for cerebral palsy? Glasgow: NHS Quality Improvement Scotland. *Technologies Scoping Report 14*.

Campbell, R, Quilty, B and Dieppe, P. (2003) Discrepancies between patients' assessments of outcome: qualitative studies nested within randomised controlled trials. *British Medical Journal*, 326, 252-253.

Carr, J, H and Shepherd, R, B. (1987) A motor learning model for rehabilitation. In: Carr, J, H, Shepherd, R, B. (Eds.) *Movement Science: Foundations for Physical Therapy in Rehabilitation*. London: Heinemann Physiotherapy, pp. 93-154.

Carr, J, H and Shepherd, R, B. (2010) *Neurological Rehabilitation: Optimizing Motor Performance*. Oxford: Butterworth and Heinemann.

Charmaz, K. and Bryant, A. (2011) Grounded theory and credibility. In D. Silverman (Ed.) *Qualitative Research*, (3rd Edition). London: Sage, pp. 291-309.

Coghill, J, E, Simkiss, D, E. (2010) Question 1 Do lycra garments improve function and movement in children with cerebral palsy? *Archives of Disease in Children* 95(5):393-5.

Collins, K and O'Cathain, A. (2009) Ten points about mixed methods research to be considered by the novice researcher. *International Journal of Multiple Research Approaches*, 3(1), 2-7.

Corn, K, Timewell, G, Imms, C, Carter, C, Collins, C. (2003) Impact of Second Skin Lycra splinting on the quality of upper limb movement in children. *British Journal of Occupational Therapy*. 66(10):9: 464-72.

Craig, P, Dieppe, P, Macintyre, S, Mitchie, S, Nazareth, I, Petticrew, M. (2008). Developing and evaluating complex interventions: the new Medical Research Council guidance. *British Medical Journal* (337):979-983.

Creswell, J, W. (2003) *Research Design: Qualitative, Quantitative, and Mixed Methods Approaches* (2<sup>nd</sup> edition). Thousand Oaks, CA: Sage.

Creswell, J, W, and Plano Clark, V, L. (2007). *Designing and conducting mixed methods research*. Thousand Oaks, CA: Sage.

Creswell, J, W, and Plano Clark, V, L. (2011). *Designing and conducting mixed methods research*. (2<sup>nd</sup> edition) Thousand Oaks, CA: Sage.

Critical Appraisal Skills Programme (CASP) © Public Health Resource Unit, England (2006) adapted from Guyatt, G, H, Sackett, D, L and Cook, D, J. Users'

guides to the medical literature. II. How to use an article about therapy or prevention. *JAMA* 1993; 270 (21): 2598-2601 and *JAMA* 1994; 271(1): 59-63.

Critical Appraisal Skills Programme (CASP©) (2010) Qualitative Research Checklist. Accessed: May 2013. Available at: <http://www.casp-uk.net>

## D

Danzl, M, M, Etter, N, M, Andreatta, R, D, Kitzman, P, H. (2012) Facilitating Neurorehabilitation Through Principles of Engagement. *Journal of Allied Health*; 41 (1): 35-40.

Data Protection Act (1998) Accessed: February 2013. Available at: <http://www.legislation.gov.uk/ukpga/1998/29/contents>

Davies, P, M. (2002) *Steps to follow. A guide to the treatment of Adult hemiplegia*. New York: Springer.

Denzin, N and Lincoln, Y. (2000) The discipline and practice of qualitative research. In Denzin, N and Lincoln, Y. (Eds.) *Handbook of Qualitative Research*, (2<sup>nd</sup> edition), Thousand Oaks, CA: Sage.

De Wit, L, Kamsteegt, H, Yadav, B, Verheyden, G, Feys, H, De Weerd, W. (2007) Defining the content of individual physiotherapy and occupational therapy sessions for stroke patients in an inpatient rehabilitation setting. Development, validation and inter-rater reliability of a scoring list. *Clinical Rehabilitation* 21(5):450–9.

Donaldson, C, Tallis, R, C, Pomeroy, V, M. (2009) A treatment schedule of conventional physical therapy provided to enhance upper limb sensorimotor recovery after stroke: expert criterion validity and intra-rater reliability. *Physiotherapy* 95(2):110–9.

## E

Edwards, S. (2001) Abnormal tone and movement as a result of neurological impairment. In Edwards S. (Ed.) *Neurological Physiotherapy: A Problem Solving Approach*. Edinburgh: Churchill Livingstone.

Elliott, C, Reid, S, Hamer P, Alderson J, Elliott, B. (2011a) Lycra arm splints improve movement fluency in children with cerebral palsy. *Gait and Posture*; 33(2):214-9. Cochrane Central Register of Controlled Trials.

Elliott, C, M, Reid, S, L, Alderson, J, A, Elliott, B. (2011b) Lycra arm splints in conjunction with goal-directed training can improve movement in children with cerebral palsy. *Neurorehabilitation* 28 (1):47-54.



EuroQol Group. EuroQol- a new facility for the measurement of health-related quality of life. *Health Policy*. 1990;(16):199-208 (EQ-5D™).

## F

Farmer, T, Robinson, K, Elliott, S, J, Eyles, J. (2006) Developing and implementing a triangulation protocol for qualitative health research. *Qualitative Health Research*; 16:377-94.

Fisher, L, D, Dixon, D, O, Herson, Frankowski, J, Hearn, M, S, Peace, K, E. (1990) Intention to treat in clinical trials. In: Peace, K, E. (Ed.). *Statistical issues in drug research and development*. New York: Marcel Dekker; pp.331-50.

Fleuren, J, F, M, Voerman, G, E, Erren-Wolters, C, V, Snoek, G, J, Reitman, J, S, Hermens, H, J, Nene, A, V. (2009) Stop using the Ashworth Scale for the assessment of spasticity. *Journal of Neurology Neurosurgery and Psychiatry* (81):46-52.

Foley, N, Murie-Fernandez, M, Speechley, M. (2010) Does the treatment of spastic equinovarus deformity following stroke with botulinum toxin increase gait velocity? A systematic review and meta-analysis. *European Journal of Neurology* (17):1419-1427.

Francis, H, P, Wade, D, T, Turner-Stokes, L. (2004) Does reducing spasticity translate into functional benefit? An exploratory meta-analysis. *Journal of Neurology Neurosurgery and Psychiatry* 75(11):1547-51.

Frith, H and Gleeson, K. (2004) Clothing and embodiment: men managing body image and using thematic analysis in psychology appearance. *Psychology of Men and Masculinity* (5): 40-48.

## G

Giovannelli, M, Borriello, G, Castri, P, Prosperini, L, Pozzilli, C. (2007) Early physiotherapy after injection of botulinum toxin increases the beneficial effects on spasticity patients with multiple sclerosis. *Clinical Rehabilitation* 21(4):331-7.

Goodman, N, W. (1999) Who will challenge evidence based medicine? *Journal of the Royal College of Physicians*. (33):249-51.

Goldspink, G, Williams, W. (1990). Muscle fibre and connective tissue changes associated with use and disuse in Ada, L. and Canning, C. (Eds.) (1990) *Key issues in Neurological Physiotherapy*. Butterworth Heineman, pp. 25-50.

Gracies, J, M. (2005) Pathophysiology of spastic paresis. II: emergence of muscle overactivity. *Muscle and Nerve*, 31 (5): 552-571.

Gracies, J, M, Fitzpatrick, R, Wilson, L, Burke, D, Gandevia, S, C. (1997) Lycra garments Designed for Patients with Upper Limb Spasticity: Mechanical Effects in Normal Subjects. *Arch Physical Medicine and Rehabilitation* (78):1066-71.

Gracies, J, M, Marosszeky, J, E, Renton, R, Sandanam, J, Gandevia, S, C, Burke, D. (2000) Short-term effects of dynamic lycra splints on upper limb in hemiplegic patients. *Archives of Physical and Medical Rehabilitation* (81):1547-55.

Gracies, J, M, Singer, B, J, Dunne, J, W. (2007) The role of botulinum toxin injections in the management of muscle overactivity of the lower limb. *Disability and Rehabilitation* 29(23): 1789-1805.

GRADE Working Group. (2004) Grading quality of evidence and strength of recommendations. London: *British Medical Journal*, 328(7454), 1490–1494.

Gupta, S, K. (2011) Intention to treat concept: A review. *Perspectives in Clinical Research*. July-September 2(3):109-112.

Guissard, N, Duchateau, J. (2004) Effect of static stretch training on neural and mechanical properties of the human plantar-flexor muscles. *Muscle and Nerve*, 29(2): 248–255.

## H

Hanley B, Bradburn, J, Barnes, M, Evans, C, Goodare, H, Kelson, M, Kent, S, Thomas, S, Wallcraft, J. (2003) Involving the public in NHS, public health, and social care research: Briefing notes for researchers. (2<sup>nd</sup> edition). INVOLVE.

Haugh, A, Pandyan, A, Johnson, G. (2006) A systematic review of the tardieu scale for the measurement of spasticity. *Disability and Rehabilitation*, 28(15): 899-907.

Hawkins, P and Shohet, R. (2011) *Supervision in the helping professions*. (3<sup>rd</sup> Edition) New York: Open University Press.

Hellweg, S and Johannes, S. (2008) Physiotherapy after traumatic brain injury: A systematic review of the literature. *Brain Injury* 22(5):365-375.

Hesse, S, Friedrich, H, Domasch, C, Mauritz, K. (1992) Botulinum toxin therapy for upper limb flexor spasticity: preliminary results. *Journal of Rehabilitation Science*. 5:98-101.

Higgins, J, P, T and Green, S. (2011) Review Manager (RevMan) 5.1 The Cochrane Collaboration. In *Cochrane Handbook for Systematic Reviews of Interventions* Accessed: June 2012 Available at: <http://handbookcochrane.org>.

Higgs, J and Titchen, A. (2001) *Practice, Knowledge and expertise in the Health Professions*. Oxford: Butterworth Heinemann.

Hockenberry, M, J, Wilson, D, Winkelstein, M, L. (2005) *Wong's Essentials of Paediatric Nursing*, Ed, 7, St Louis, p.1259.

Holstein, J, A and Gubrium, J, F. (2011) Animating Interview Narratives. In Silverman, D. (Ed.) *Qualitative Research, Issues of Theory, Method and Practice*. 3<sup>rd</sup> Edition. London: Sage. (9); pp.149-167.

Howe, K, R. (1988) Against the quantitative-qualitative incompatibility thesis or dogmas die hard. *Educational Researcher* (17):10-16.

Howe, K, R. (2004) A Critique of Experimentalism. *Qualitative Inquiry*, London: Sage Publications, Inc. 10 (4), 42-61.

Hyman, N, Barnes, M, Bhakta, B, Kreczy-Kleedorfer, B, Poewe, W, Wissel, J, Bain, P, Glickman, S, Saver, A, Richardson, A, Dott, C. (2000) Botulinum toxin (Dysport) treatment of hip adductor spasticity in multiple sclerosis: a prospective randomised double blind, placebo controlled dose ranging study. *Journal of Neurology, Neurosurgery and Psychiatry*. (68):707-12.

## I

Intercollegiate Stroke Working Party. (2012) *National clinical guideline for stroke*, 4th edition. London: Royal College of Physicians.

## J

Jackson, D, Horn, S, Kersten, P, Turner-Stokes, L. (2006) 'A pictorial scale of pain intensity (SPIN) for patients with communication impairments' *International Journal of Therapy and Rehabilitation*. 13(10):457-63.

Jankovic, J, Mejia, N, I, Dat Vuong, K. (2005) Long-term Botulinum Toxin Efficacy, Safety, and Immunogenicity. *Movement Disorders* 20(5):592-597.

Johnson, R, B and Onwuegbuzie, A, J. (2004) Mixed method research: A Research paradigm whose time has come. *Educational Research*, 33(7):14–26.

Johnson, R, B, Onwuegbuzie, A, J and Turner, L, A. (2007) Toward a definition Of mixed method research. *Journal of Mixed Method Research*, 1(2):112–133.

Jost, W, H, Hefter, H, Reissig, A, Kollewe, K, Wissel, J. (2014) Efficacy and safety of Botulinum toxin type-A (Dysport) for the treatment of post-stroke arm spasticity: Results of the German-Austrian open-label post-marketing surveillance prospective study. *Journal of the Neurological Sciences*. 337(1-2):86-90.

Jung, Y, J, Hong, J, H, Kwon, H, G. (2011) 'The effect of a stretching device on hand spasticity in chronic hemiparetic stroke patients'. *NeuroRehabilitation* (29):53-59.

## K

Katalinic, O, M, Harvey, L, A, Herbert, R, D, Moseley, A, M, Lannin, N, A, Schurr, K. (2010): Stretch for the treatment and prevention and management of contractures. *Cochrane Database of Cochrane Reviews*, Issue 9. Art. No.:CD007455.pub2.

Katalinic, O, M, Harvey, L, A, Herbert, R, D. (2011) Effectiveness of stretches for prevention of contractures in people with neurological conditions. A systematic review. *Physical Therapy*. 91(1)11-24.

Khan, D, M, Turner-Stokes, L, Brand, C, McSweeney, S. (2013) Multidisciplinary rehabilitation following botulinum toxin and other focal intramuscular treatment for post-stroke spasticity (Review). *Cochrane Database of Systematic Reviews* 2013, Issue 6. Art. No.:CD009689. DOI: 10.1002/14651858.CD009689.pub2.

Kidd, G, Lawes, N and Musa, I. (1992) *Understanding Neuromuscular Plasticity: A Basis for clinical rehabilitation*, London: Edward Arnold.

Kilbride, C, Hoffman, K, Tuckey, J, Baird, T, Marston, L, and De Souza, L. (2013) Contemporary splinting practice in the UK for adults with neurological dysfunction: A cross-sectional survey. *International Journal of Therapy and Rehabilitation*. 20(11): 559-566.

Kilbride, C. (Ed.) Ashford, S, Baird, T, Hoffman, K, Tuckey, J. (2015) *Splinting for the prevention and correction of contractures in adults with neurological dysfunction: practice guidelines for occupational therapists and physiotherapists*. College of Occupational Therapy and Association of Chartered Physiotherapists in Neurology. London: College of Occupational Therapy Ltd.

Kinnear, B, Z, Lannin, N, A, Cuisick, A, Harvey, L, A and Rawicki, B. (2014) Rehabilitation therapies after Botulinum toxin-A injection to manage limb spasticity: a systematic review. *Physical Therapy*. doi:10.2522/ptj.20130408.

Kiresuk, T and Sherman R. (1968) Goal attainment scaling: a general method of evaluating comprehensive mental health programmes. *Community Mental Health Journal* 1968; (4):443-453.

Kiresuk, T, Smith, A, Cardillo, J. (1994) Goal attainment scaling: application, theory and measurement. New York: Lawrence Erlbaum Associates in Turner-

Stokes (2003) Goal Attainment Scaling in Rehabilitation. RIMS annual meeting 23.5.03.

Korwin-Piotrowska, K, Korwin-Piotrowska, T, Samochowiec, J. (2010) Self-perception among patients with multiple sclerosis. *Archives of Psychiatry and Psychotherapy*, (3):63-68.

Kuipers, K, Rassafiani, M, Ashburner, S, Griffin, L, Worley, L, Moes, L, Fleming, J, Copley, J. (2009) Do clients with acquired brain injury use the splints prescribed by occupational therapists. A descriptive study. *Neurorehabilitation* 24(4)365-375.

Kwakkel, G, Wagenaar, R, C, Twisk, J, W, Lankhorst, G, J, Koetsier, J, C. (1999) Intensity of leg and arm training after primary middle-cerebral-artery stroke: a randomised trial. *Lancet*. 1999 Jul 17;354(9174):191-6.

## L

Lai, J, M, Francisco, G, E, Willis, F, B. (2009) Dynamic Splinting After Treatment with Botulinum Toxin Type A: A Randomized Controlled Pilot Study. *Advances in Therapy* 26(2) 241-248.

Lance, J, W. (1980). Symposium synopsis. In: Feldman, R, G, Young, R, R, Koella, W, P. (Eds.). *Spasticity: Disordered Motor Control*. Chicago: Year Book medical publishers: pp. 485- 494.

Lannin, N, A, Herbert, R, D. (2003) Is hand splinting effective for adults following stroke? A systematic review and methodological critique of published research. *Clinical Rehabilitation*; 17(8) 807-816.

Lannin, N, A, Horsley, S, A, Herbert, R, D, McCluskey, A, Cuisick, A. (2003) Splinting the hand in the functional position after brain impairment: A randomised controlled trial. *Archives of Physical Medicine and Rehabilitation*, 84 (2): 297-302.

Lannin, N, A, Cusick, A, McCluskey, A, Herbert, R, D. (2007) Effects of Splinting on Wrist Contracture After Stroke: A Randomized Controlled Trial. *Stroke* (38):111-116.

Lannin, N, A, Ada, L. (2011) Neurorehabilitation splinting: Theory and principles of clinical use. *Neurorehabilitation* 28 (1): 21-28.

Laviola, Y. (2001) Motivation: An essential component to succeed. *Rehabilitation Nursing*. 26 (1): 34-35.

Li, S, Kamper, D, G, Rymer, W, Z. (2006) Effects of changing wrist positions on finger flexor hypertonia in stroke survivors. *Muscle and Nerve*, 33(2): 183–190.

Lincoln, Y. S. and Guba, E. G. (1985) *Naturalistic inquiry*. Beverly Hills, CA: Sage publications, Inc.

## M

MacDonald, G, A, Kayes, N, M, Bright, F. (2013) Barriers and facilitators to engagement in rehabilitation for people with stroke; a review of the literature. *New Zealand Journal of Physiotherapy*. 41(3): 112-121.

Macfarlane, A, Turner-Stokes, L, De Souza, L. (2002) The associated reaction rating scale: a clinical tool to measure associated reactions in the hemiplegic upper limb. *Clinical Rehabilitation* 16(7): 726–35.

Maclean, N, Pound, P, Wolfe, C, Rudd, A. (2000) Qualitative analysis of stroke patients' motivation for rehabilitation. *British Medical Journal* (321): 1051-4.

Maclean, N, Pound P, Wolfe C, Rudd, A. (2002) The concept of patient motivation. A qualitative analysis of stroke professionals' attitudes. *Stroke*. (33): 444-448.

Mahoney, F, I, Barthel, D. (1965) Functional evaluation: The Barthel Index. *Maryland State Medical Journal* 1965;14: 56-61.

Matthews, M, Richardson, B, Watson, M. (2007) A pilot study of multiple single case reports to investigate the effects of dynamic Lycra Orthoses on gait in children with cerebral palsy. University of East Anglia.

Matthews, M. (2008) Dynamic Movement Orthoses recommended wearing regime. Dynamic Movement Orthoses Level 1 Training Manual and Prescription Guidelines. DM Orthotics Ltd. p. 23.

Matthews, M, J, Watson, M, Richardson, B. (2009) Effects of dynamic elastomeric fabric orthoses on children with cerebral palsy. *Prosthetics and Orthotics International*. 33 (4): 339-347.

Mayo, N, E, Fellows, L, K, Scott, S, C, Cameron, J and Wood-Dauphinee, S. (2009) A longitudinal view of apathy and its impact after stroke. *Stroke*. (40): 3299-3307.

Medical Research Council. (2000). *A framework for development and evaluation of RCTs for complex interventions to improve health*. London: MRC.

Medical Research Council. (2008). *Developing and evaluating complex interventions: new guidance*. London: MRC.

Medical Research Council (MRC) and National Institute of Health Research (NIHR). (2011) Academic-NHS-Industry Collaboration in Experimental Medicine. Innovative partnering. p. 4.

Mehrholz, J, Wagner, K, Meissner, D, Grundmann, K, Zange, C. (2005) Reliability of the modified Tardieu scale and the modified Ashworth scale in adult patients with severe brain injury: a comparison study. *Clinical Rehabilitation* (19): 751-9.

Mental Capacity Act (2005). Accessed: 24 August 2010. Available at: <http://www.legislation.gov.uk/ukpga/2005/9>

Merzenich, M, M, Allard, T, T and Jenkins, W, M. (1991) Neural ontogeny of higher brain function: implications of some recent neurophysiological findings. In *Information Processing in the Somatosensory System* (Eds.) Franzen, O and Westman J. London: Macmillan.

Mirbagheri, M, M, Alibiglou, L, Thajchayapong, M, Rymer, W, Z. (2008) Muscle and reflex changes with varying joint angle in hemiparetic stroke. *Journal of NeuroEngineering and Rehabilitation*. Accessed: 22 March 2014. Available at: <http://www.jneuroengrehab.com/content/5/1/6>

Moher, D, Liberati, A, Teziuff J, Altman, D, G. The PRISMA Group (2009) Preferred reporting items for systematic reviews and meta-analyses. The Prisma statement. Accessed: 13 March 2015. Available at: <http://www.prisma-statement.org>

Moffatt, S, White, M, Macintosh, J and Howel, D. (2006). Using quantitative and qualitative data in health services research – what happens when mixed method findings conflict? *BMC Health Service Research* 6:28. Accessed: 16 July 2014. Available at: <http://www.biomedcentral.com/1472-6963/6/28>

Moore, A. (2002) 'Botulinum toxin A (BoNT-A) for spasticity in adults. What is the evidence?' *European Journal of Neurology* 9(Supplement 1): 42-47.

Morgan, D, L. (1998) Practical strategies combining qualitative and quantitative methods: Applications to health research. *Qualitative Health Research*, 8(3): 362-376.

## **N**

Naumann, M, Jankovic, J. (2004) Safety of botulinum toxin type A: a systematic review and meta-analysis. *Current Medical Research and Opinion* 20(7): 981-990.

Nicholson, J, Morton, R, Attfield S, Rennie D. (2001) Assessment of upper-limb function and movement in children with cerebral palsy wearing lycra garments. *Developmental Medicine in Child Neurology* (43): 384-391.

Nicholson, S, Sniehotta, F, F, van Wijck, F, Greig, C, A, Johnston, M, McMurdo, M, E, T, Dennis, M, Mead, G. (2012) A systematic review of perceived barriers and motivators to physical activity after stroke. *International Journal of Stroke*. (8): 357-364.

National Institute for Health Research (NIHR). (2011) model Industry Collaborative Research Agreement (mICRA) Accessed: 23 April 2015 Available at: <http://www.nihr.ac.uk/industry/industry-tools.htm>

Nudo, R. (1999) Recovery after damage to motor cortical areas. *Current Opinion Neurobiology*. (9): 740-7.

Nudo, R.J. (2006) Plasticity. *Neurorehabilitation*. (3): 420-7.

## O

O'Brien, L, Bailey M. (2008) Determinants of compliance with hand splinting in acute brain injured population. *Brain Injury*, 22 (5): 411-418.

O'Cathain, A, Murphy, E and Nicholl, J. (2007) Integration and publications as indicators of "yield" from mixed methods studies. *Journal of Mixed Methods Research and Policy*, 1(2):147-163.

O'Cathain, A. (2009). Mixed methods research in the health sciences: A quiet revolution. *Journal of Mixed Methods Research*, 3(3): 3-6.

O'Cathain, A, Murphy, E and Nicholl, J. (2008) The quality of mixed method studies in health service research. *Journal of Health Service Research & Policy*, 13(2): 92 – 98.

O'Cathain, A, Murphy, E and Nicholl, J. (2010) Three techniques for integrating data in mixed methods studies. *British Medical Journal*, 341:c4587.  
doi:10.1136/bmj.c4587

O'Dwyer, N, Ada, L, Neilson, P. (1996) Spasticity and muscle contracture following stroke. *Brain* (119):1737-49.

Ofori, J, Freeman, J, Bugman, G, Gibbons, P, Zajieck, J, Hobart, J, Marsden, J. (2012) The effect of applied torque and stretch duration on range of motion, passive stiffness and spasticity in people with multiple sclerosis. *Syn'apse*. Spring/Summer. (2012) p.29.



Oglieve, K, Poland, F, Watson. (2006) An audit of satisfaction amongst people who are wearing Dynamic Lycra Orthosis for the management of Upper Limb Disorders caused by neurological disorders. University of East Anglia Norwich.

Onwuegbuzie, A, J and Collins, K. (2007) A typology of mixed methods sampling designs in social science research. *The Qualitative Report*, 12(2): 281–316.

Onwuegbuzie, A, J, and Teddlie, C. (2003). A framework for analysing data in mixed methods research. In Tashakkori, A and Teddlie, C. (Eds) *Handbook of mixed methods in social and behavioural research* (s.351-383). Thousand Oaks: Sage Publications.

Oxford Centre for Evidence Based Medicine (2002). Available at: [www.cebm.net/index.aspx?0=1047](http://www.cebm.net/index.aspx?0=1047) Accessed: 15 September 2011.

## P

Pandyan, A, D, Gregoric, M, Barnes, M, P, Wood, D, van Wijck, F, J, Burridge, J, Hermens, H, Johnson, G, R. (2005) Spasticity: Clinical perceptions, neurological realities and meaningful measurement. *Disability Rehabilitation* 21(1-2):2-6.

Partridge, C. (2002) *Neurological Physiotherapy. Bases of evidence for practice. Treatment and management of patients described by specialist clinicians.* (Ed.) Partridge, C. London: Whurr Publishers.

Patrick, E, Ada, L. (2006) The tardieu scale differentiates contracture from spasticity whereas the ashworth scale is confounded by it. *Clinical Rehabilitation*, (20): 173.

PCH Pharmacy. (2014) Pharmaceutical Advisor quoted costings of Dysport and Botox vials by: email (2nd September 2014).

Pizzi, A, Carlucci, G, Falsini, C, Verdesca, S, Grippo, A. (2005) Application of a volar static splint in poststroke spasticity of the upper limb. *Archives of Physical Medicine and Rehabilitation*. 86 (9): 1855-9.

Pittock, S, J, Moore A, P, Hardiman, O, Ehler, E, Kovac, M, Bojakowski, J, al Khawaja, I, Brozman, M, Kanovsky, P, Skorometz, A, Slawek, J, Reichel, G, Stenner, A, Timberbaeva, S, Stelmasiak, Z, Zifko, U, A, Bhakta, B, Coxon, E. (2003) A double-blind randomised placebo-controlled evaluation of three doses of botulinum toxin type-A (Dysport) in the treatment of spastic equinovarus deformity after stroke. *Cerebrovascular Diseases* 15(4): 289-300.

Pitts, D, G and O'Brien, S, P. (2008) Splinting the hand to enhance motor control and brain plasticity. *Topics in Stroke Rehabilitation*. 15 (5): 456-467.

Platz, T, van Kaick, S, Mehrholz, J, Leidner, O, Eickhof, C, Pohl, M. (2009b) Best conventional Therapy Versus Modular Impairment-Oriented Training for Arm Paresis After Stroke: A Single-Blind, Multicenter Randomized Controlled Trial. *Neurorehabilitation and Neural Repair*. 23(7):706-716.

Pope, C, and Mays, N. (Eds.) (2006) *Qualitative Research in Health Care* (3<sup>rd</sup> edition) Oxford: Blackwell Publishing Ltd.

Pope, P. (2007) *Severe and complex neurological disability- management of the physical condition*. Oxford: Butterworth-Heinemann Elsevier.

Polit, D, F and Tatano Beck, D. (2012). *Nursing Research. Generating and Assessing Evidence for Nursing Practice*. Philadelphia: Lippincott Williams & Wilkins. Chapter 25.

## R

Rahman, T, Borkhuu, B, Littleton, A,G, Sample, W, Moran, E, Campbell, S, Rogers, K, Bowen, J, R. (2010) Electronic monitoring of scoliosis brace wear compliance. *Journal of Child Orthopaedics*. (4): 343-347.

Raine, S, Meadows, L, Lynch-Ellerington, M. (Eds) (2009) *Bobath Concept: Theory and Clinical Practice in Neurological Rehabilitation*. London: Churchill Livingstone.

Ramdharry, G. (2006) Case Report: Physiotherapy cuts the dose of Botulinum toxin. *Physiotherapy Research International* 11, (2): 117-122

Reiter F, Danni, M, Lagalla, G, Ceravolo, G, Provinciali, L. (1998) Low dose botulinum toxin with ankle taping for the treatment of spastic equinovarus foot after stroke. *Archives of Physical Medicine and Rehabilitation* 79(5): 532-55.

Rennie, D, J, Attfield, S, F, Morton, R, E, Polak, F,J, Nicholson, J. (2000) An evaluation of lycra garments in lower limb using 3-D gait analysis and functional assessment (PEDI). *Gait and Posture*. (12): 1-6.

*Research Governance Framework for Health and Social Care, Second edition, (2005)* Accessed: 12 May 2013. Available at:  
[http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT\\_ID=4108962&chk=Wde1Tv](http://www.dh.gov.uk/PublicationsAndStatistics/Publications/PublicationsPolicyAndGuidance/PublicationsPolicyAndGuidanceArticle/fs/en?CONTENT_ID=4108962&chk=Wde1Tv)

Riessman, C, K. (1993) *Narrative analysis*. London: Sage.

- Richards, D, A and Borglin, G. (2011) Complex interventions and nursing: Looking through a new lens at nursing research. *International Journal of Nursing Studies* (48): 531–533.
- Richards, D, A, Coultard, V and Borglin, G. (2014) The state of European nursing research. Dead, alive or chronically diseased? A systematic literature review. *Worldviews on Evidence-Based Nursing*. Doi: 10.1111/wvn.12039.
- Richardson, D. (2002) Physical therapy in spasticity. *European Journal of Neurology*. 9(Suppl.1): 17-22.
- Richardson, D, Sheean, G, Werring, D, Desai, M, Edwards S, Greenwood, S, Thompson, A. (2000a) Evaluating the role of botulinum toxin in the management of focal hypertonia in adults. *Journal of Neurology, Neurosurgery and Psychiatry* (69):499-506.
- Richardson, D, Greenwood, R, Sheean, G, Thompson, A. (2000b) Treatment of focal spasticity with botulinum toxin: effect on the 'positive support reaction. *Physiotherapy Research International* 5(1):62-70.
- Ritchie, J and Spencer, L. (1996) Qualitative Data Analysis for Applied Policy Research, in A. Bryman and R. Burgess (Eds.) *Analyzing Qualitative Data*, pp.173-94. London: Sage.
- Ritchie, J and Lewis, J. (Eds.) (2003) *Qualitative Research Practice: A guide for social scientists and researchers*. London: Sage.
- Robinson, W, Smith, R, Aung, O, Ada, L. (2008) No difference between wearing a night splint and standing on a tilt table in preventing ankle contracture early after stroke: a randomised trial. *Australian Journal of Physiotherapy* (54):33-38.
- Rose, G. (1986) *Orthotics, Principles and Practice*. London: Heinemann.
- Royal College of Physicians (2008) in: *SIGN 50: A guideline developer's handbook*. Ed. Harbour RT. Chapter 7: forming guideline recommendations; Annex B: p.51 accessed: February 2012. Available at: [www.sign.ac.uk/guidelines/fulltext/50/index.html](http://www.sign.ac.uk/guidelines/fulltext/50/index.html)
- Royal College of Physicians (RCP), British Society of Rehabilitation Medicine, Chartered Society of Physiotherapy, Association of Chartered Physiotherapist Interested in Neurology (2009) *Spasticity in adults: management using botulinum toxin. National Guidelines*. RCP, London.
- Rushton, P, W and Miller, W, C. (2002) Goal attainment scaling in the rehabilitation of lower extremity amputations: a pilot study. *Archives of Physical Medicine and Rehabilitation* 83 (6): 771-5.

## S

Sackett, D, L. (2002) *Evidence-based Medicine: How to Practise and Teach EBM*, (2nd edition). London: Churchill Livingstone.

Sackett, D, L, Rosenberg, W, M, Muir, C. (1996) Evidence based medicine: what it is and what it isn't. *British Medical Journal* (312):71-72.

Sale, J, and Brazil, K, A. (2004). A strategy to identify critical appraisal criteria for primary mixed-method studies. *Quality & Quantity*. 38(4), 351-365.

Sawle, L, Freeman, J, Marsden, J and Matthews, M, J. (2012) Exploring the effects of pelvic configurations upon athletic lumbopelvic pain. *Prosthetics and Orthotics International*. 37(2): 124-131.

Schön, D. (1983) *The reflective practitioner*. Basic Books: New York.

Schulz, K, F, Altman, D, G, Moher, D. (2010) CONSORT Statement: updated guidelines for reporting parallel group randomised trials. *British Medical Journal*, 340:698-702.

Scottish Intercollegiate Guidelines Network (SIGN), NHS Quality Improvement Scotland (2010) 118 *Management of patients with stroke: Rehabilitation , prevention and management of complications, and discharge planning. A national clinical guideline*. Accessed July 2013: Available at: <http://www.sign.ac.uk/guidelines/fulltext/118.pdf>

Seelman, K. (2004) Trends in Rehabilitation and Disability: Transition from a Medical Model to an Integrative Model (Part 1). *Disability World* (22) January-March. Accessed: 12 March 2015. Available at: [http://www.disabilityworld.org/01-03\\_04/access/rehabtrends1.shtml](http://www.disabilityworld.org/01-03_04/access/rehabtrends1.shtml)

Seigert, R, J and Taylor, W, J. (2004) Theoretical aspects of goal-setting and motivation in rehabilitation Review. *Disability and Rehabilitation* 26(1):1-8 (doi:10.1080/09638280410001644932)

Shadish, W, J, Cook, T, D, Campbell, D, T. (2002). *Experimental and Quasi-Experimental Designs for generalized causal inference*. Boston: Houghton Mifflin.

Shamil, A, Amini, M, Forough, B, Kazemi, R, Qorbani, M. (2011) Botulinum toxin injections or application of splints: Impact on spasticity, range of motion and function of upper extremity in chronic stroke patients. *Iranian Journal of Pharmacology and Therapeutics* (10):11-16.

Shaw, L, Rodgers, H, Price, C, van Wijck, F, Shackley, P, Steen, N, Barnes, M, Ford, G, Graham, L. (2010) BoTULS: a multicentre randomised controlled trial to evaluate the clinical effectiveness and cost effectiveness of treating upper limb spasticity due to stroke with botulinum toxin type A. *NIHR Health*

*Technology Assessment*. 14(26):1-142. Accessed: 5 September 2011.

Available at: <http://www.hta.ac.uk/execsumm1426.shtml>

Sheehan, G, L. (1998) The treatment of spasticity with botulinum toxin. In: Sheehan G, (Ed.) *Spasticity Rehabilitation*. London: Churchill Communications (9) pp.109-126.

Sheehan, G, L. (2001) Botulinum treatment of spasticity: why is it so difficult to show a functional benefit? *Current opinion in Neurology* (14):771-776.

Sheehan, G, Lannin, N, A, Turner-Stokes, L, Rawicki, B, Snow, B, J. Cerebral Palsy Institute (2010) Botulinum toxin assessment, intervention and after-care for upper limb hypertonicity in adults: international consensus statement. *European Journal of Neurology* 17(supplement 2):74–93.

Sheehan, J, L, Winzeler-Mercay, U, Mudie, M, H. (2006) A randomized controlled pilot study to obtain the best estimate of the size of the effect of a thermoplastic resting splint on spasticity in the stroke-affected wrist and fingers. *Clinical Rehabilitation*. 20(12): 1032-1037.

Shumway-Cook, A and Woollacott, M, H. (2001) *Motor Control. Theory and practical applications*. (2<sup>nd</sup> edition) Philadelphia: Lippincott Williams and Wilkins.

Shumway-Cook, A and Woollacott, M, H. (2011) *Motor Control. Translating research into clinical practice*. (4<sup>th</sup> edition) Philadelphia: Lippincott Williams and Wilkins.

Silvermann, D. (2011) *Interpreting Qualitative Data, A guide to the principles of qualitative research*. (4<sup>th</sup> edition) London: Sage. pp. 369-371.

Sim, J. (2010) Addressing Conflicts in Research Ethics: Consent and Risk of Harm. *Physiotherapy Research International*. (15): 80–87. DOI: 10.1002/pri.483.

Simpson, D, M, Gracies, J, M, Graham, H, K, Miyasaki, M, Naumann, M, Russman, B, Simpson, L, So, Y. (2008) Assessment: Botulinum neurotoxin for the treatment of spasticity (an evidence-based review). *Neurology* (70): 1691-1698.

Skinner, A, Turner-Stokes, L. (2006) The use of standardised outcome measures in rehabilitation centres in the UK. *Clinical Rehabilitation* (20): 609-15.

Sommerfeld, D, K, Eec, E, U, Svensson, A, K, Holmqvist, L, W, von Arbin, M, H. (2004) 'Spasticity after Stroke: its occurrence and association with motor impairments and activity limitations'. *Stroke* (35): 134-139.

Stark, S, C. (2001) Physiotherapy and botulinum toxin in spasticity management. *British Journal of Therapy and Rehabilitation* 8 (10): 386-392.

Stephenson, R. (1993) A review of Neuroplasticity: Some Implications for Physiotherapy in the Treatment of Lesions of the Brain. *Physiotherapy* 79(10): 699-703.

Stevenson, V, L, Jarrett, L. (2006) *Spasticity management - A practical multidisciplinary guide*. London: Informa healthcare.

Straus, S, E and Sackett, D, L. (1998) Getting research findings into practice. Using research findings in clinical practice. *British Medical Journal*. (317): 339-342.

Stone, K, A. (2012) Development of a new audit tool for splinting in neurology. *Syn'apse* (Spring/Summer 2012) ACPIN pp. 27-28.

Stone, K, A. (2013) *Dynamic Elastomeric Fabric Orthosis (DEFO) A clinical protocol for focal spasticity following Botulinum toxin*. Poster presentation. International Allied Health Professionals 2<sup>nd</sup> Conference (October, 2013).

Stone, K, A. (2014) *Dynamic Elastomeric Fabric Orthosis (DEFO): A clinical protocol for focal spasticity following Botulinum toxin (BT) injection*. Poster presented at Physiotherapy UK Conference, Birmingham (October 2014).

Stone, K, A. (2015) *A feasibility study using mixed methods: Dynamic splinting and physiotherapy after Botulinum toxin (BT) in adults with focal spasticity*. Poster presented at WCPT Congress May 2015, Singapore.

Stucki, G, Cieza, A, Melvin, J. (2007) The International Classification of functioning, disability and Health: a unifying model for the conceptual description of the rehabilitation strategy. *Journal of Rehabilitation Medicine* 39 (4): 279-285.

## T

Tardieu, C, Lespargot, A, Tabary, C, Bret, M, D. (1988) How long must the soleus muscle be stretched each day to prevent a contracture? *Developmental Medicine in Child Neurology*, (30): 3-9.

Tashakkori, A and Teddlie, C. (Eds.) (2003). *Handbook of mixed methods research in social and behavioural research*. Thousand Oaks, CA: Sage.

Tashakkori, A and Creswell, J. (2007). The new era of mixed methods. *Journal of Mixed Methods Research*, 1(1): 3-7.

Taub, E. (1993) Technique to improve chronic motor deficit after stroke. *Archives of Physical Medicine and Rehabilitation*. (74): 347-354.

Teasell, R, W, Bhogal, S, K, Foley, N, C, Speechley, M, R. (2003) Gait training post stroke. *Topics in Stroke Rehabilitation* 10(2): 34-65.

Teddlie, C and Tashakkori, A. (2009). *Foundations of Mixed Method Research: Integrating Quantitative and Qualitative Approaches in the Social and Behavioral Sciences*. Thousand Oaks: Sage Publications.

Tempest, S, Harries, P, Kilbride, C, De Souza, L. (2012) To adopt is to adapt: the process of implementing the ICF with an acute stroke multidisciplinary team in England. *Disability and Rehabilitation*. 34(20): 1686-1694.

Thabane, L, Ma, J, Chu, J, Ismaila, A, Rios, L, P, Robson, R, Thabane, M, Giangregorio, L, Goldsmith, C, H. (2010) A tutorial on pilot studies: the what, why and how. *British Medical Council Medical Research Methodology* (10): 1. Accessed: 20 April 2012 Available at: <http://www.biomecentral.com/1471-2288/10/1>

Thompson, A, J, Jarrett, L, Lockley, L, Marsden, J, Stevenson, V, L. (2005) Clinical management of spasticity. *Journal of Neurology, Neurosurgery and Psychiatry*, 76:459-463. Accessed: 13 May 2013 Available at: <http://www.jnnp.bmj.com>

Thompson, D, R and Clark, A, M. (2012). Addressing the complexity conundrum in and of nursing. *International Journal of Nursing Studies*. (49): 247-248.

Tolfts, A, Stiller, K. (1997) Do patients with traumatic brain injury benefit from physiotherapy? A review of the evidence. *Physiotherapy Theory and Practice*. (13): 197-206.

Turner-Stokes, L. (Ed) (1999) The effectiveness of rehabilitation: a critical review of the evidence. *Clinical Rehabilitation BSRM (supplement)* 13(1):1-83.

Turner-Stokes, L. (2009) *Goal Attainment Scaling (GAS) in Rehabilitation. A practical guide*. Kings College London. University of London.

Turner-Stokes, L and Ward, A, B. (2002) The use of botulinum toxin in the management of adults with spasticity. *Clinical Medicine* (2): 128-130.

Turner-Stokes, L. (2003) Goal Attainment Scaling in Rehabilitation. RIMS annual meeting 23.5.03.

Turner-Stokes, L and Ashford, S. (2007) Serial injection of Botulinum toxin for muscle imbalance due to regional spasticity in the upper limb. *Disability and Rehabilitation* 29 (23): 1806-1812.

Turner-Stokes, L Ashford, S and Nair, A. (2010a) Physical Therapy and Botulinum toxin-A (BoNT-A)-The temporal relationship between spasticity reduction and functional gain. *American Academy of Physical Medicine and Rehabilitation*. 2(9) supplement: 13-14.

Turner-Stokes, L, Baguley, I and De Graaff, S. (2010b). Goal attainment scaling in the evaluation of treatment of upper limb spasticity with botulinum toxin: A secondary analysis from a double-blind, placebo-controlled randomized clinical trial. *Journal of Rehabilitation Medicine*, (42):81-89.

Tyson, S, Watson, A, Moss, S, Troop, H, Dean-Lofthouse, G, Jorritsma, S, Shannon, M. (2008) Development of a framework for the evidence-based choice of outcome measures in neurological physiotherapy. *Disability and Rehabilitation*. 30(2): 142-149.

Tyson, S, F, Kent, R, M. (2011) The effect of upper limb orthotics after stroke. A systematic review. *Neurorehabilitation*. 28(1): 29-36.

## U

UK Clinical Research Collaboration (UKCRC) (2009). *The changing regulatory and governance environment for health research across the UK: A guide for researchers*. UKCRC: London pp.10-11.

## V

van Kuijk , A, A, Hendricks, H, T, Pasman, J, W, Kremer, B, H, Geurts, A, C. (2007) Are clinical characteristics associated with upper extremity hypertonia in severe ischaemic supra-tentorial stroke? *Journal of Rehabilitation Medicine* 39(1): 33-7.

van Vliet, P, Lincoln, N, B, Robinson, E. (2001) Comparison of the content of two physiotherapy approaches for stroke. *Clinical Rehabilitation*. 15(4):398-414.

van Vliet, P, Lincoln, N, B, Foxall, A. (2005). Comparison of Bobath based and movement science based treatment for stroke: a randomised controlled trial. *Journal of Neurology, Neurosurgery and Psychiatry*. (76): 503-508.

## W

Wade, D, T. (1992) *Measurement in Neurological Rehabilitation*. Oxford: Oxford University Press pp.15-43.

Wade, D, T and Bovend'Eerd, T, J. (2010) How to set SMART goals. *Clinical Rehabilitation*. 2010; 24(4): 382.



Wallesch, C-W, Meas E, Lecomte, P, Bartels, C. (1997) Cost-effectiveness of botulinum toxin type A injection in patients with spasticity following stroke: a German perspective. *European Journal of Neurology* 4(2):s53-s57.

Wa Munyi, C. (2014) Past and present perceptions towards disability: A historical perspective. *Disability Studies Quarterly*. Kenyatta University. Accessed: 7 July 2014. Available at: <http://dsq-sds.org/article/view/3197/3068>

Ward, A, Roberts, G, Warner, J, Gillard, S. (2005) Cost-effectiveness of botulinum type A in the treatment of post stroke spasticity. *Journal of Rehabilitation Medicine*. 37(4): 252-257.

Watkins, C, L, Leathley, A, K, Gregson, J, M, (2002) Prevalence of spasticity post stroke. *Clinical Rehabilitation*. (16): 515-522.

Watson, M, J. (2002) Refining the Ten-metre Walking Test for use with Neurologically Impaired People. *Physiotherapy*. 88(7): 386-397.

Watson, M, J, Crosby, P and Matthews, M. (2007) An evaluation of the effects of a dynamic Lycra orthosis on arm function in a late stage patient with acquired brain injury. *Brain Injury*. June; 21(7): 753-761.

Williams, P, E and Goldspink, G. (1990) Muscle fibre and connective tissue changes associated with use and disuse. In: Ada, L, Canning, C. (Eds.) *Key Issues in Neurological Physiotherapy*. Oxford: Butterworth-Heinemann, pp.197-218.

Williams, P, E, Goldspink, G. (1978) Changes in sarcomere length and physiological properties in immobilized muscle. *Journal of Anatomy*, 127(Pt 3), 459-468.

Wisdom, J, P, Cavaleri, M, A, Onwuegbuzie, A, J, and Green, C, A. (2012) Methodological reporting in qualitative, quantitative and mixed methods health service research articles. *Health Service Research*, 47(2), 721-745.

Wissel, J, Ward, A, B, Erztgaard, P, Bensmail, D, Hecht, M, J, Lejeune, T, M, and Schnider, P. (2009) European consensus table on the use of Botulinum Toxin Type A in adult spasticity. Special Report. *Journal of Rehabilitation Medicine*; (41): 13-25.

World Health Organisation (WHO). (2001) International classification of function, disability and health. Geneva. Accessed: 3 March 2012. Available at: [www.3.who.int/icf/icftemplate.cfm](http://www.3.who.int/icf/icftemplate.cfm)

World Health Organisation (2002) ICF checklist. Accessed: 1 January 2014. Available at: <http://www.who.int/classifications/icf/training/icfchecklist.pdf>

## Publications

1. Stone, K, A. (2012) Development of a new audit tool for splinting in neurology. *Syn'apse* (Spring/Summer 2012) ACPIN pp. 27-28.
2. Stone, K, A. (2013) *Dynamic Elastomeric Fabric Orthosis (DEFO) A clinical protocol for focal spasticity following Botulinum toxin*. Poster presented at International Allied Health Professionals 2<sup>nd</sup> Conference October 2013, Edinburgh.
3. Stone, K, A. (2014) *Dynamic Elastomeric Fabric Orthoses (DEFO) and physiotherapy after Botulinum toxin (BT) in adults with focal spasticity: A feasibility study using mixed methods*. Poster presented at Physiotherapy UK Conference, October 2014, Birmingham.
4. Stone, K, A. (2015) *A feasibility study using mixed methods: Dynamic splinting and physiotherapy after Botulinum toxin (BT) in adults with focal spasticity*. Poster presented at the WCPT Congress, May 2015, Singapore.